

applicable, the cost of potentially non-covered services when Medicare denial of payment is expected by the HHA. *Form Number:* CMS-R-296 (OMB#: 0938-0781); *Frequency:* Recordkeeping, Third party disclosure and Reporting: On occasion, Other: As needed; *Affected Public:* Individuals or households, Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 7,612; *Total Annual Responses:* 10,351,703; *Total Annual Hours:* 780,918.

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 or faxed 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. Fax Number: (202) 395-6974.

Dated: June 20, 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-1957, CMS-R-72, CMS-10175 and CMS-R-05]

#### 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:* SSO Report of State Buy-in Problem and Supporting Regulations in 42 CFR 407.40; *Use:* Under the State Buy-In program, States enroll certain groups of needy people under the Part B Supplementary Medical Insurance (SMI) Program and pay their premiums. The purpose of the "buy-in" is to allow the States to provide SMI protection to certain groups of needy individuals as part of its total assistance plan. Generally, States "buy-in" for individuals who are categorically needy under Medicaid and meet the eligibility requirements for Medicare Part B. States can also include in their buy-in agreement those eligible for medical assistance only. The CMS-1957 is used in the resolution of beneficiary complaints regarding State buy-in. This form facilitates the coordination of efforts between the SSO, State Medicaid Agencies, and CMS in the resolution of a beneficiary's State buy-in problem; *Form Number:* CMS-1957 (OMB#: 0938-0035); *Frequency:* Reporting—On occasion; *Affected Public:* Federal government, Individuals or Households, and State, Local, and Tribal governments; *Number of Respondents:* 6,600; *Total Annual Responses:* 6,600; *Total Annual Hours:* 2,366.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Information Collection Requirements in 42 CFR 478.18, 478.34, 478.36, 478.42, QIO Reconsiderations and Appeals; *Use:* In the event that a beneficiary, provider, physician, or other practitioner does not agree with the initial determination of a Quality Improvement Organization (QIO) or a QIO subcontractor, it is within that party's rights to request reconsideration. The information collection requirements 42 CFR 478.18, 478.34, 478.36, and 478.42, contain procedures for QIOs to use in reconsideration of initial determinations. The information requirements contained in these

regulations are on QIOs to provide information to parties requesting the reconsideration. These parties will use the information as guidelines for appeal rights in instances where issues are actively being disputed; *Form Number:* CMS-R-72 (OMB#: 0938-0443); *Frequency:* Reporting—On occasion; *Affected Public:* Individuals or Households and Business or other for-profit institutions; *Number of Respondents:* 2,590; *Total Annual Responses:* 5,228; *Total Annual Hours:* 2,822.

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Certification Statement for Electronic File Interchange Organizations (EFIOS) that Submit National Provider Identifier (NPI) Data to the National Plan and Enumeration System; *Use:* The EFI process is designed to allow organizations to submit NPI application information for large numbers of providers in a single file. Once it has obtained and formatted the necessary provider data, the EFIO will electronically submit the file to NPPES for processing. As each file can contain up to approximately 100,000 records, or provider applications, the EFI process greatly reduces the paperwork and overall administrative burden associated with enumerating providers; *Form Number:* CMS-10175 (OMB#: 0938-0984); *Frequency:* Other—One-time; *Affected Public:* Business or other for-profit, and Not-for-profit institutions; *Number of Respondents:* 1000; *Total Annual Responses:* 1000; *Total Annual Hours:* 3000.

4. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Physician Certifications/Recertifications in Skilled Nursing Facilities (SNFs) Manual Instructions and Supporting Regulations in 42 CFR 424.20; *Use:* Regulations at 42 CFR 424.20 require SNFs to keep record of physician certifications and recertifications of information such as the need for care and services, estimated duration of the SNF stay, and plan for home care. As a condition for Medicare Part A payment for post-hospital skilled nursing facility (SNF) services, the Medicare program requires that a physician certify and periodically recertify that a beneficiary requires an SNF level of care. The physician certification and recertification is intended to ensure that the beneficiary's need for services has been established and then reviewed and updated at appropriate intervals; *Form Number:* CMS-R-05 (OMB#: 0938-0454);

*Frequency:* Recordkeeping and Reporting—On occasion; *Affected Public:* State, Local or Tribal governments, Individuals or Households, Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 2,458,549; *Total Annual Responses:* 981,642; *Total Annual Hours:* 547,578.

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 or faxed by July 24, 2006 directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Carolyn Lovett, New Executive Office Building, Room 10235, Washington, DC 20503. Fax Number: (202) 395-6974.

Dated: June 14, 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-10199, CMS-R-247, and CMS-R-38]

#### 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:* New collection; *Title of Information Collection:* Data Collection for Medicare Facilities Performing Carotid Artery Stenting with Embolic Protection in Patients at High Risk for Carotid Endarterectomy; *Use:* CMS provides coverage for carotid artery stenting (CAS) with embolic protection for patients at high risk for carotid endarterectomy and who also have symptomatic carotid artery stenosis between 50% and 70% or have asymptomatic carotid artery stenosis  $\geq 80\%$  in accordance with the Category B IDE clinical trials regulation (42 CFR 405.201), a trial under the CMS Clinical Trial Policy (NCD Manual § 310.1, or in accordance with the National Coverage Determination on CAS post approval studies (Medicare NCD Manual 20.7). Accordingly, CMS considers coverage for CAS reasonable and necessary {section 1862 (A)(1)(a) of the Social Security Act}. However, evidence for use of CAS with embolic protection for patients at high risk for carotid endarterectomy and who also have symptomatic carotid artery stenosis  $\geq 70\%$  who are not enrolled in a study or trial is less compelling. To encourage responsible and appropriate use of CAS with embolic protection, CMS issued a *Decision Memo for Carotid Artery Stenting* on March 17, 2005, indicating that CAS with embolic protection for patients at high risk for carotid endarterectomy and who also have symptomatic carotid artery stenosis  $\geq 70\%$  will be covered only if performed in facilities that have been determined to be competent. In accordance with this criteria CMS considers coverage for CAS reasonable and necessary {section 1862(A)(1)(a) of the Social Security Act}. *Form Number:* CMS-10199 (OMB#: 0938-NEW); *Frequency:* Reporting—On occasion; *Affected Public:* Business or other for-profit, Not-for-profit institutions; *Number of Respondents:* 1,000; *Total Annual Responses:* 1,000; *Total Annual Hours:* 500.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Expanded Coverage for Diabetes Outpatient Self-Management Training Services and Supporting Regulations Contained in 42 CFR 410.141, 410.142, 410.143, 410.144,

410.145, 410.146, 414.63; *Use:* According to the National Health and Nutrition Examination Survey (NHANES), as many as 18.7 percent of Americans over age 65 are at risk for developing diabetes. The goals in the management of diabetes are to achieve normal metabolic control and reduce the risk of micro- and macro-vascular complications. Numerous epidemiologic and interventional studies point to the necessity of maintaining good glycemic control to reduce the risk of the complications of diabetes. In expanding the Medicare program to include diabetes outpatient self-management training services, the Congress intended to empower Medicare beneficiaries with diabetes to better manage and control their conditions. The Conference Report indicates that the conferees believed that "this provision will provide significant Medicare savings over time due to reduced hospitalizations and complications arising from diabetes." (H.R. Conf. Rep. No. 105-217, at 701 (1997)). *Form Number:* CMS-R-247 (OMB#: 0938-0818); *Frequency:* Recordkeeping and Reporting—On occasion; *Affected Public:* Business or other for-profit institutions; *Number of Respondents:* 2,008; *Total Annual Responses:* 8,032; *Total Annual Hours:* 88,519.

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Conditions of Certification for Rural Health Clinics and Supporting Regulations in 42 CFR 491.9, 491.10, 491.11; *Use:* The Rural Health Clinic (RHC) conditions of participation are based on criteria prescribed in law and are designed to ensure that each facility has a properly trained staff to provide appropriate care and to assure a safe physical environment for patients. The Centers for Medicare and Medicaid Services (CMS) uses these conditions of participation to certify RHCs wishing to participate in the Medicare program. These requirements are similar in intent to standards developed by industry organizations such as the Joint Commission on Accreditation of Hospitals, and the National League of Nursing/American Public Association and merely reflect accepted standards of management and care to which rural health clinics must adhere. *Form Number:* CMS-R-38 (OMB#: 0938-0334); *Frequency:* Recordkeeping and Reporting—Annually and upon initial application for Medicare approval; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 3,674; *Total*