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*, 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.

[FR Doc. E6–9841 Filed 6–22–06; 8:45 am]

BILLING CODE 4120–01–P

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 ≥ 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 ≥ 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 ≥ 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*

Annual Responses: 3,674; *Total Annual Hours:* 8,816.

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,* 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 August 22, 2006.

CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development—B, Attention: William N. Parham, III, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

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

[CMS–2228–FN]

Medicare and Medicaid Programs; Denial of the TÜV Healthcare Specialists Request for Deeming Authority for Hospitals

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Final notice.

SUMMARY: This final notice announces our decision to deny TÜV Healthcare Specialists' (TÜVHS) request for deeming authority for hospitals that wish to participate in the Medicare and Medicaid programs.

EFFECTIVE DATE: This final notice is effective June 23, 2006.

FOR FURTHER INFORMATION CONTACT: Amber MacCarroll, (410) 786–6773.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services in a hospital provided certain requirements are met. The regulations specifying the Medicare conditions of participation (CoP) for hospitals are located at 42 CFR part 482. These conditions implement section 1861(e) of the Social Security Act (the Act), which specifies the conditions that a hospital program must meet in order to participate in the Medicare program. Regulations concerning provider agreements are at 42 CFR part 489, and those pertaining to activities relating to the survey and certification of facilities are at 42 CFR part 488.

Generally, in order to enter into an agreement with CMS, a hospital must first be certified by a State survey agency as complying with the conditions or requirements set forth in part 482 of our regulations. Then, the hospital is subject to regular surveys by a State survey agency to determine whether it continues to meet these requirements. There is an alternative, however, to surveys by State agencies.

Section 1865(b)(1) of the Act provides that, if a provider entity demonstrates through accreditation by an approved national accreditation organization that all applicable Medicare conditions are met or exceeded, we will ''deem'' those provider entities as having met the requirements. Accreditation by an accreditation organization is voluntary and is not required for Medicare participation.

If an accreditation organization is recognized by the Secretary as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national accrediting body's approved program would be deemed to meet the Medicare conditions. A national accreditation organization applying for approval of deeming authority under part 488, subpart A must provide us with reasonable assurance that the accreditation organization requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions.

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the American Osteopathic Association (AOA) are currently the only approved national accreditation organizations for hospitals.

II. Deeming Applications Review Process

Section 1865(b)(2) of the Act and our regulations at § 488.8(a) require that our findings concerning review and approval of a national accrediting organization's requirements consider, among other factors, the applying accreditation organization's requirements for accreditation, including health and safety standards; survey procedures; resources for conducting required surveys; capacity to furnish information for use in enforcement activities; monitoring procedures for provider entities found not in compliance with the conditions or requirements; and ability to provide us with the necessary data for validation.

Section 1865(b)(3)(A) of the Act provides a statutory timetable to ensure that our review of deeming applications is conducted in a timely manner. The Act provides us with 210 calendar days after the date of receipt of an application to complete our survey activities and application review process. At the end of the 210-day period, we must publish an approval or denial of the application.

III. Proposed Notice

On January 27, 2006, we published a proposed notice (71 FR 4584) announcing TÜV Healthcare Specialists' (TÜVHS') request for approval as a deeming organization for hospitals. In the proposed notice, we detailed our evaluation criteria as set forth in section 1865(b)(2) of the Act and our regulations at § 488.8 (Federal review of accreditation organizations). Our review and evaluation of TÜVHS was conducted in accordance with, but not necessarily limited to, the following factors:

- The equivalency of TÜVHS' standards for hospitals as compared with our Medicare hospital conditions of participation; and
- TÜVHS' survey process to determine the following:

—The composition of the survey team, surveyor qualifications, and the ability of the organization to provide continuing survey or training.

—The comparability of TÜVHS' survey procedures to those of State agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

—TÜVHS' processes and procedures for monitoring providers or suppliers found out of compliance with TÜVHS program requirements. These monitoring procedures are used only when TÜVHS identifies noncompliance. If noncompliance is identified through validation reviews, the survey agency monitors corrections as specified at § 488.7(d).

—TÜVHS' capacity to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.

—TÜVHS' capacity to provide us with electronic data in ASCII comparable code, and reports necessary for