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.

[FR Doc. E6–9842 Filed 6–22–06; 8:45 am]

BILLING CODE 4120–01–P

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

effective validation and assessment of the organization's survey process.
—The adequacy of TÜVHS' staff and other resources, and its financial viability.
—TÜVHS' capacity to adequately fund required surveys.
—TÜVHS' policies with respect to whether surveys are announced or unannounced.
—TÜVHS' agreement to provide us with a copy of the most current accreditation survey together with any other information related to the survey as we may require (including corrective action plans).

IV. Analysis of and Response to Public Comments on the Proposed Notice

We received 12 comments in response to the proposed notice published on January 27, 2006. These comments were from hospitals, professional organizations, an accrediting body and other individuals. Summaries of the public comments we received and our responses to those comments are set forth below.

Comment: The majority of commenters expressed support for increased competition in the hospital accreditation arena.

Response: We appreciate the commenters' support and agree that the accreditation process can benefit from increased competition. CMS must, however, ensure that any national accreditation organization approved for deeming authority meets our requirements and can provide us with reasonable assurance that its accredited hospitals are in compliance with accreditation standards that meet or exceed the Medicare CoPs.

Comment: A few commenters expressed support specifically for the approval of TÜVHS' request for deeming authority. Conversely, one commenter expressed concerns about the TÜVHS accreditation process and provided specific technical comments regarding the ISO 9001 certification process.

Response: Based on our findings from the review of TÜVHS' application, TÜVHS has not demonstrated that it meets our requirements for approval as a national accreditation organization. Also, TÜVHS did not provide us with reasonable assurance that its accredited hospitals are in compliance with accreditation standards that meet or exceed the Medicare CoPs.

Comment: One commenter asked us to consider the apparent conflict of interest that is posed by TÜVHS offering consultative services to prepare hospitals for JCAHO's accreditation reviews, while requesting deeming authority for Medicare participating hospitals, which would be in direct competition to JCAHO.

Response: We agree that it is an unusual situation to have an organization apply for deeming authority while continuing to offer consultative services to prepare hospitals for accreditation surveys that are conducted by another accreditation organization. Because we are not granting deeming authority to TÜVHS at this time, the suggested conflict of interest is not relevant.

V. Provisions of the Final Notice

Based on the findings from our review, using the evaluation criteria described above, we determined that the TÜVHS accreditation requirements for hospitals, including the accreditation standards, standards application and interpretation, survey procedures, and corrective action requirements, are not equivalent to the CMS requirements for hospitals. Additionally, TÜVHS has not provided reasonable assurance that the hospitals they accredit are in compliance with accreditation standards that are at least as stringent as the Medicare Hospital CoPs.

The findings from the review, as described above, preclude us from granting TÜVHS deeming authority for hospitals.

VI. Executive Order 12866 Statement

In accordance with the provisions of Executive Order 12866, this regulation was not reviewed by the Office of Management and Budget.

Authority: Section 1865 of the Social Security Act (42 U.S.C. 1395bb)

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773, Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: June 9, 2006.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E6–9907 Filed 6–22–06; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–9035–N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—January Through March 2006

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 January 2006 through March 2006, 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