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 TUV 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 TUV Healthcare
Specialists' (TUVHS) 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 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 TUV Healthcare Specialists'
(TUVHS) 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 TUVHS was
done in accordance with, but not
necessarily limited to, the following
factors:

• The equivalency of TUVHS’
standards for hospitals as compared
with our Medicare hospital conditions
of participation; and

• TUVHS’ 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 TUVHS’ survey
  procedures to those of State agencies,
  including survey frequency, and the
  ability to investigate and respond
  appropriately to complaints against
  accredited facilities.

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

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

—TUVHS’ capacity to provide us with
electronic data in ASCII comparable
code, and reports necessary for
effectiveness and assessment of the organization’s survey process.

—The adequacy of TU VH’s staff and other resources, and its financial viability.
—TU VH’s capacity to adequately fund required surveys.
—TU VH’s policies with respect to whether surveys are announced or unannounced.
—TU VH’s 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 TU VH’s request for deeming authority. Conversely, one commenter expressed concerns about the TU VH’s accreditation process and provided specific technical comments regarding the ISO 9001 certification process.
Response: Based on our findings from the review of TU VH’s application, TU VH has not demonstrated that it meets our requirements for approval as a national accreditation organization. Also, TU VH 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 TU VH 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 TU VH 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 TU VH’s 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, TU VH 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 TU VH 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.

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