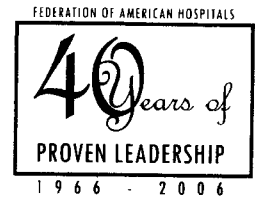




FEB 13 2006



February 7, 2006

Dr. Mark McClellan, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-2228-PN
Mail Stop C4-26-05, 7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS Proposed Notice with Comment Period, Medicare and Medicaid Programs;
Application by the TUV Healthcare Specialists for Deeming Authority for Hospitals, Federal
Register, Vol. 71, No. 18, January 27, 2006, pp. 4584-4586.

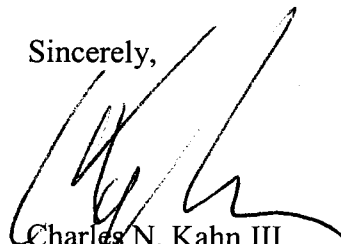
Dear Administrator McClellan:

The Federation of American Hospitals (FAH) is the national representative of the investor-owned or managed community hospitals and health systems throughout the United States. Our members are full-service community hospitals, teaching and non-teaching, urban and rural, who provide critical health care services across the ambulatory, acute, and post-acute continuum of care. We appreciate the opportunity to comment on the proposed notice regarding the application by TUV Healthcare Specialists for Medicare deeming authority.

Federation members believe in market-oriented health care, and that competition plays a valuable role in the provision of high quality health care. Because of our market-oriented philosophy, we believe the same principle applies to other organizations including hospital accrediting bodies.

The TUV Healthcare Specialist application for Medicare hospital deeming authority is the first such application that the Medicare program has considered since the American Osteopathic Association was approved almost 40 years ago. The Federation supports the improvement of the accreditation process through increasing competition that should occur if hospitals have more choices in selecting their accreditation agency.

Sincerely,



Charles N. Kahn III
President



Northern Arizona Healthcare .com

2

1200 North Beaver Street
Flagstaff, Arizona 86001
928-779-3366
www.nahealth.com

FEB 23 2006

February 9, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-2228-PN
P.O. Box 8018, Baltimore, MD 21244-8018

Dear Sir or Madam:

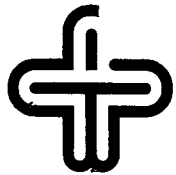
On behalf of Northern Arizona Healthcare and its affiliated hospitals, Flagstaff Medical Center and Verde Valley Medical Center, (collectively "NAH") this letter is offered in support of TUV Healthcare Specialists application for Deeming Authority for Hospitals.

NAH recognizes the need for healthcare organizations to provide comprehensive healthcare services of the highest quality and safety.

NAH has determined that its own commitment and approach to clinical quality and safety was not compatible with the approach and methods demonstrated by the Joint Commission on Accreditation of Healthcare Organizations. It supports, therefore, other organizations being designated to hold Deeming Authority to assist hospitals and CMS in their common goal of advancing quality of care.

Sincerely,


James A. Puffenberger
President/CEO



WRH
Health System

FEB 23 2006

195 Wadsworth Road, Wadsworth, Ohio 44281
Phone: 330-334-1504 or 800-828-1789 www.wrhhs.org

WRH Health System

Wadsworth-Rittman
Hospital

Wadsworth-Rittman
Hospital Home Care

Wadsworth-Rittman
Hospital Foundation

Healthy Benefits
Occupational Health
Services

Wadsworth-Rittman
Hospital Professional
Services Corporation

February 16, 2006

Center for Medicare & Medicaid Services
Department of Health and Human Services
ATTN: CMS-2228-PN
P O Box 8018
Baltimore, MD 21244-8018

RE: File Code CMS-2228-PN
Application By TUV Healthcare Specialists
for Deeming Authority for Hospitals

To Whom It May Concern:

On behalf of my organization, and myself I am submitting these comments for consideration in the review of the application of TUV Healthcare Specialists for deeming authority for hospitals. In making my comments I have considered the factors that CMS will consider, including the following: the equivalency of standards, the adequacy of the survey team training and qualifications, survey frequency, complaint response, monitoring of non-compliant organizations, reporting, validation, timeliness and capabilities.

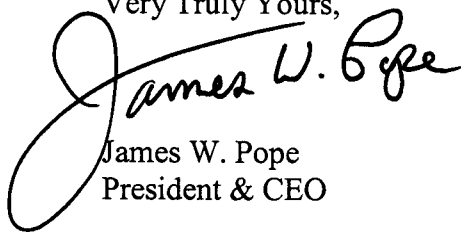
Our organization has taken the time and committed the resources to investigate TUV and its training and survey procedures. We have reviewed TUV Healthcare Specialists ' proposed NIAHO Accrediting Program, Accreditation Process, Auditor Training Program and a crosswalk of the accreditation requirements and the CMS Conditions of Participation. On the basis of our review, we believe that the TUVHC process is well suited to the needs and complexity of hospitals.

We find the TUVHC accreditation requirements and the CMS Conditions of Participation to be equivalent. We are aware that the size and complexity of the audit teams will be adequate to carry out the process. We have seen that the education and experience requirement for auditors (surveyors) is extensive and includes field experience as well as certification. We believe that TUVHC's process for monitoring, follow-up, validation and response is very consistent and effective. TUVHC is able to provide accurate and timely reporting and to work efficiently with the administrative and regulatory process.

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Center for Medicare & Medicaid Services
Department of Health and Human Services
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TUVHC provides high quality competition in the very important area of hospital accreditation. We support the application of TUV Healthcare Specialists and recommend that the organization be granted Deeming Authority for Hospitals.

Very Truly Yours,

A handwritten signature in black ink that reads "James W. Pope". The signature is written in a cursive style with a large, looping initial "J".

James W. Pope
President & CEO

FEB 23 2006
FEB 3 2006



4
MANAGEMENT
SYSTEM
REGISTRATION

Smithers Quality Assessments, Inc.

425 WEST MARKET STREET • AKRON, OH 44303-2099
PH: 330/762-4231 • FAX: 330/762-7447

WORLD HEADQUARTERS
Web: www.smithersregistrar.com
E-mail: SQA@smithersmail.com

February 16, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-2228-PN
P.O. Box 8018
Baltimore, MD 21244-8018

Dear Sirs:

Reference: File Code CMS-2228-PN

The following are comments regarding the TUV Healthcare Services (TUVHS) application for Medicare deeming status based on two documents: 1) National Integrated Accreditation for Healthcare Organizations (NIAHO) – Accreditation Requirements, Issue 307-4, and 2) TUV Healthcare Specialists NIAHO Accreditation Program Accreditation Process. My comments are limited to the second document, the Accreditation Process.

Reference: Section 3, SR.2b, NIAHO Accreditation Process document:

In the United States, the organization that accredits registrars (also known as certification bodies) to grant certification to ISO 9001 is ANSI-ASQ National Accreditation Board, ANAB. According to ANAB requirements, only one successful witness audit is required of a registrar seeking accreditation to International Accreditation Forum (IAF) sectors 38, Health and Social Work. Upon accreditation to IAF 38, a registrar is deemed qualified to grant ISO 9001 certification to healthcare organizations.

Any requirement beyond accreditation to IAF 38, such as the NIAHO requirement for a registrar to have certified 12 hospitals (reference Section 3, SR.2b of the NIAHO Accreditation Process document), is clearly intended to impede other registrars accredited for IAF 38 from entry into the ISO 9001 certification part of the NIAHO process. This is a definite example of restraint of trade, and, at least in the short term, has the potential of establishing TUVHS as a monopoly for accreditation to NIAHO. If the Department of Health and Human Service grants deeming authority to TUVHS with this requirement, it would have the definite effect of restraint of trade for other, non-TUV registrars accredited by ANAB.

Very few hospitals in the United States have achieved accredited certification to ISO 9001. Therefore, any registrar that had 12 hospitals certified most likely achieved this by certifying hospitals outside of the United State, and this should not be recognized by CMS, since CMS is a sub-section of the Department of Health and Human Services – a purely United States entity.

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-2228-PN
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Reference ISO/IEC Guide 62:1996, paragraph 2.1.1.2: *“The certification/registration body shall make its services accessible to all applicants. There shall not be undue financial or other conditions. Access shall not be conditional upon the size of the supplier or membership of any association or group, nor shall certification/registration be conditional upon the number of suppliers already certified/registered.”* Comment: This would seem to preclude placing a requirement such as “12 hospitals certified.”

General comments:

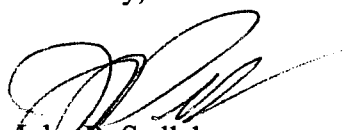
1. There is no stated requirement for number of audit days required for an NIAHO accreditation audit. Nor is it clear that these days are distinctly separate from the audit days executed by the registrar for ISO 9001 certification. Accredited registrars are required by IAF Guidance on the Application of ISO/IEC Guide 62, Annex 2, to execute a defined number of audit days solely dedicated to the ISO 9001 certification process. Any additional auditing for other reasons, e.g., accreditation to NIAHO, would need to be in addition to those required for ISO 9001.
2. There is insufficient separation of audit activities between NIAHO audit team members and ISO 9001 audit team members. There may be an inherent conflict of interest in TUVHS offering both accreditation and certification. Reference ISO/IEC Guide 62:1996, paragraph 2.1.2 m: *“In particular, the certification/registration body shall...together with its senior executive and staff, be free from any commercial, financial and other pressures which might influence the results of the certification/registration process.”* When two audit teams, working for the same organization, uncover findings that may have an effect on either the certification or accreditation, it can create the perception of conflict of interest. This is best avoided by having one team from an accreditation organization deal with accreditation issues and one team from a completely different organization deal with certification issues. In this manner, potential conflicts of interest will be avoided. In other words, there should be two separate teams executing the audits – one for accreditation to NIAHO and one for certification to ISO 9001.
3. There is a definite error in SR.2b: On one hand it states that the registrar “Shall have certified/registered a minimum of twelve (12) hospitals;” It then goes on to say “...six of these required audits may be pre-assessments with documented organization reports.” Pre-assessments are not part of any certification audit – period! Therefore, it is impossible for this requirement to be met by pre-assessment activity – only certification audits can count. This sounds like TUVHS is “stacking the deck” in favor of itself, which is viewed as a restraint of trade. (See comments on this matter above.)
4. The verbiage in the Accreditation Process document, section SR.2b is distinctly different from that contained in the Accreditation Requirements documents, section SR.2b.

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-2228-PN
February 16, 2006
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5. The entire topic of "Jeopardy Status" is vague. Of special concern is the effect on ISO 9001 certification.

Thank you for your time and consideration. I trust that you will give my concerns your attention. I will value any feedback that you can provide.

Sincerely,



John R. Sedlak
Vice President, COO

JRS/ghb