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**Centers for Medicare & Medicaid Services (CMS)
Application by the TÜV Healthcare Specialists
for Deeming Authority for Hospitals**

Public Comment
Joint Commission on Accreditation of Healthcare Organizations
February 27, 2006

As the nation's oldest and largest healthcare accrediting organization, the Joint Commission knows first hand how important the accreditation process is for ensuring the delivery of high-quality and safe healthcare and welcomes competition as a mechanism to promote organizational efficiency and catalyze the development of new ideas. Having multiple accrediting organizations can broaden collective perspective, experience, and knowledge, which in turn, can improve healthcare quality. At the same time, the Joint Commission is particularly concerned that accrediting bodies are able to appropriately address the increasingly complex quality of care and patient safety issues confronting this nation. The Joint Commission has continually evolved over its lifespan to meet these challenges and such maturation requires a significant financial and operational infrastructure and the ability to draw the best survey and technical expertise from around the country.

In addition, to guarantee the integrity of the hospital accreditation process, any organization seeking Medicare deeming authority must be able to offer their services nationally and at any time. Hospital accrediting organizations must also have the appropriate systems, knowledge base and operational processes in place to ensure that the organizations they accredit meet the most current challenges surrounding healthcare delivery and safety issues. Therefore, the Joint Commission offers the following comments on TÜV Healthcare Specialists' (TÜVHS) application for Medicare hospital deeming authority.

The Joint Commission comments are intended to elucidate aspects of accreditation that are key to assessing and improving healthcare quality and safety in our nation's hospitals. We ask CMS to consider these key points during their evaluation of TÜVHS' application for Medicare hospital deeming authority. When possible, the comments are grouped around the specific items addressed in the proposed notice CMS issued on January 27, 2006 (CMS-2228-PN).

General Comments

First, an accrediting organization's financial stability is paramount to being able to provide timely and proper assessments of hospitals' compliance with health and safety requirements. As we elaborate below, an accrediting organization must have the resources to invest in a rigorous surveyor education and training program and have internal systems that bring credibility to accreditation decision making. In addition, due to increasing demands for data and information from consumers, employers and governmental entities, accreditation organizations must maintain a robust information technology system. And finally, to ensure the integrity of their processes and to test new standards and procedures, accreditation organizations must be able to conduct internal audits of accrediting reviews and decisions, as well as continually evaluate its survey methodology. Thus, CMS must ensure that TÜVHS has the financial stability and necessary resources to offer a rigorous hospital accreditation program.

Second, the Joint Commission requests that CMS consider the unusual situation and apparent conflict that is posed by TÜVHS offering consulting services to prepare hospitals for Joint Commission accreditation reviews, while asking to be competitive for deeming authority. The Joint Commission recognizes that there are numerous organizations that offer Joint Commission accreditation consulting services and welcomes additional expertise in that arena. However, none of these other organizations are conducting hospital accreditation services on behalf of Medicare. TÜVHS therefore, is in a position to use their Joint Commission consulting services as a vehicle for marketing their own accreditation services when going onsite to a hospital as a consultant.

Third, to appropriately review an application for deeming authority, CMS must ensure that the entity has sufficient experience to make sound, consistent assessments. Thus, CMS should consider whether TÜVHS has surveyed an adequate number of hospitals to demonstrate its ability to assess compliance with Medicare's health and quality requirements.

Surveyor Qualifications and Training

The quality of the surveyor cadre is of utmost importance in any accreditation system. It is the surveyor expertise and judgment that must be both accurate, insightful, and statistically reliable. Therefore, surveyor qualifications and training are critical to any successful accreditation program. Measures taken to select, screen, educate, and evaluate surveyor staff require an ongoing commitment of resources and a stable supply of surveyors. CMS must ensure that TÜVHS has a thorough training, education and mentoring program for their surveyors. Joint Commission surveyors are highly trained healthcare professionals with years of experience. Joint Commission hospital surveyors begin with a weeklong intensive educational program, followed by a rigorous preceptorship designed to provide increasing responsibility before they are allowed to survey independently.

After becoming Joint Commission surveyors, these healthcare professionals must continually update their training throughout their tenure. Joint Commission surveyors complete 40 hours of official continuing education each year through conferences and courses. They are also kept abreast of new developments through weekly updates, newsletters, and access to Joint Commission Resources publications.

In addition to training, communication and mentoring, Joint Commission surveyors are subject to annual performance evaluations. A detailed data report is kept on all surveyors' performance and is used as an indicator when mentoring, additional proctoring, or remedial training is required. All complaints regarding surveyors prompt immediate and thorough evaluation and appropriate intervention.

Survey Frequency and Complaint Surveys

As patients and their families have become better informed about the availability of grievance processes and healthcare becomes more sophisticated and fragmented, both CMS and the Joint Commission have experienced a dramatic increase in the number of complaints filed against our nation's hospitals. CMS will need to ensure that TÜVHS has an adequate number of qualified staff to immediately conduct complaint surveys focused on ever more complex and technical

services. Furthermore, TÜVHS must have a database to effectively track and manage complaint information.

Equivalency of TÜVHS' Standards with Medicare's Conditions of Participation (CoPs).

In the application process for deeming authority, TÜVHS will have to demonstrate that it has standards and survey processes that meet or exceed all of the corresponding Medicare requirements. In addition, CMS should seek evidence that TÜVHS has a system in place to continually update and improve their standards and survey processes to reflect industry trends and new technologies. This system should incorporate significant use of professional expertise external to the accrediting body, as well as a process for public input into standards changes.

Other Considerations

Deeming is a true public/private partnership. Therefore, when reviewing an application for deeming authority, the Joint Commission strongly encourages CMS to consider the additional benefits the accrediting organization brings to ensuring that Medicare and Medicaid beneficiaries, as well as the general public, receive high-quality, safe healthcare. We understand that CMS may take a literal read of current regulations and review each organization's accreditation program solely for equivalency with Medicare's requirements. However, if literal equivalency is the litmus test for approving deeming requests, the benefit to Medicare is only measured by savings to the survey and certification system. The Joint Commission believes that the government should also consider whether or not a new deeming relationship brings added value to the Medicare program.

The Joint Commission offers an assortment of additional benefits beyond compliance with hospital CoPs in our accreditation and certification programs. Every Joint Commission-accredited entity is expected to comply with patient safety standards and meet a set of National Patient Safety goals. These standards and goals are tied to problematic areas in healthcare and seek to ensure that accredited entities use evidence and expert-based solutions to resolve the problems. The Joint Commission has also developed a world renowned sentinel event taxonomy and database for collecting uniform information on patient safety events. Furthermore, the Joint Commission has incorporated the use of performance measures for facility-based healthcare providers into its accreditation requirements. And lastly, the Joint Commission has perfected the tracer methodology as a way to drill down to find any problems in hospital systems that influence poor performance. While these are only examples, CMS should expect that such benefits will accrue to the Medicare program whenever CMS enters into a deeming authority partnership with a new entity.

The Joint Commission appreciates the opportunity to submit these remarks for your consideration. If you have any questions, please contact Trisha Kurtz, Director of Federal Relations, at (202) 783-6655 or pkurtz@jcaho.org.

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Licking Memorial Hospital

February 21, 2006

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

RE: Medicare and Medicaid Programs; Application by the TUV Healthcare Specialist for Deeming Authority for Hospitals

Dear Sir or Madam:

Please accept the enclosed written comments concerning the January 27, 2006 Federal Register Notice: the Application by the TUV Healthcare Specialist for Deeming Authority for Hospitals. Below are justifications as to why the ISO 9001:2000 Standard exclusively meets the Center for Medicare and Medicaid standards for providing deemed status to an accreditation or certification entity.

Facts about ISO

The International Organization for Standardization (ISO) is a worldwide federation of national standards bodies (ISO member bodies). ISO develops standards through Technical Committees with representation from any and all ISO member bodies. The ISO 9000 series of quality management system standards were developed by Technical Committee (TC) 176 and first published in 1987. A mild revision was published in 1994, and a major revision emphasizing customer satisfaction and management control was published in 2000. The ISO 9000:2000 series of standards were approved by the American Society for Quality as American National Standards on December 13, 2000. One of the three standards in the series, ANSI/ISO/ASQ 9001-2000 Quality Management Systems Requirements, is the standard to which an organization such as a hospital can become certified by assessment and continued surveillance by third party certification bodies. The ANSI/ISO/ASQ 9001-2000 standard is identical in wording to ISO 9001:2000.

The ANSI-ASQ National Accreditation Board (ANAB) is the U.S. accreditation body for management systems. ANAB accredits certification bodies for ISO 9001 quality management systems and ISO 14001 environmental management systems, as well as a number of industry-specific requirements documents based on ISO 9001. The American National Standards Institute (ANSI) is a private, non-profit organization that administers and coordinates the U.S. voluntary standardization and conformity assessment system. ANAB is a member of the International Accreditation Forum (IAF) and a signatory of the IAF multilateral cooperative arrangements for quality management systems and environmental management systems. Through the IAF's Multilateral Cooperative Accreditation Arrangement, ANAB cooperates with other accreditation

bodies around the world to provide value to its accredited certification bodies and their clients, ensuring that accredited certificates are recognized nationally and internationally. The global conformity assessment system ensures confidence and reduces risk for customers engaging in trade worldwide.¹

What are the ISO 9001:2000 Standards?

ISO 9001:2000 is a quality management system standard that requires the organization to define its key business processes, their interaction and control, and to define and measure goals and objectives to assure continued conformity. This process management system stresses the importance of identifying patient/customer needs and expectations prior to carrying out service delivery and then delivering the agreed upon services or products. The guidance to management offered in this International Standard is based on eight quality management principles:

1. Customer (Patient) Focus
2. Leadership
3. Involvement of People
4. Process Approach
5. System Approach to Management
6. Continual Improvement
7. Factual Approach to Decision Making
8. Mutually Beneficial Supplier Relationships²

As required by the ISO Standard, the organization quality management system must address not only the ISO requirements but also any and all customer regulator requirements. In other words, the Quality Management Model must adhere to all local, state and national law, rules, regulations, ordinances or any and all accreditation standards.³

What is the Process for a Certification Body to be initially accredited by ANAB?⁴

ANAB accredits certification bodies issuing ISO 9001 quality management systems (QMS) and ISO 14001 environmental management systems (EMS) certificates, as well as a number of industry-specific requirements. Accredited QMS certification bodies are required to conform to ISO Guide 62, IAF Guidance to Guide 62, and ANAB Advisories. Accredited EMS certification bodies are required to conform to ISO Guide 66, IAF Guidance to Guide 66, and ANAB Advisories. This process requires an initial and annual audit of the certification body's office procedures and records.

An ANAB audit team will also witness the applicant certification body (CB's) audit team conducting a complete ISO 9001 or ISO 14001 registration audit. For both ISO 9001 and ISO 14001, the audit will be in a scope classification for which the registrar is seeking approval. Witness audit teams usually consist of two ANAB auditors. Registration audits are expected to be conducted in two stages, and normally both stages of the audit are witnessed. (Audit days may

¹ www.ansi.org.

² American National Standard: Quality Management Systems – Guidelines for Performance Improvement, December 13, 2000.

³ ISO 9001 International Standard, Quality Management System – Requirements, 1.1b, 5.1a, 7.2.1b&c and 7.3.2b. 7.3.2b may not apply if the organization does have product design or designing processes.

⁴ ANAB – Procedures for Accreditation of Bodies Operating Certification/Registration of Quality Management Systems R2.10, May 24, 2005.

vary depending on the depth of scope, the size of the organization, and whether it is an ANAB audit or a joint audit with another accreditation body). IAF Guidance to ISO Guide 62 spells out those requirements.

The ANAB lead auditor prepares a full accreditation report. This normally requires one auditor day. Nonconformities raised in either or both audits require corrective action responses that provide closure. The ANAB QMS Council (for ISO 9001 accreditation) or EMS Council (for ISO 14001 accreditation) evaluates the assessment information, and the Council decides if accreditation is to be granted. The applicant is notified of the Council's decision.

The applicant is awarded ANAB accreditation and is then entitled to use the ANAB accreditation mark. For ISO 9001, the scope of accreditation is documented in a schedule that accompanies the certificate of accreditation.

What is the Process for Continued Accreditation?⁵

ANAB shall monitor and evaluate the Certification Body (CB's) conformity to the accreditation criteria, referenced documents and applicable ANAB advisories and maintenance of qualification for scope categories authorized under its accreditation throughout the term of the accreditation. This activity shall include periodic monitoring through office audits of selected requirements and the periodic witnessing of a CB audit team conducting the Quality Management System audit to ISO 9001. ANAB is authorized by the QMS Council to increase surveillance activity of a certification body in circumstances where suspension or withdrawal may not be appropriate.

Can a Complaint Be Filed against the Certification Body?⁶

If a complaint is submitted to ANAB alleging nonconformance of an accredited Certifying Body (CB) with the accreditation criteria, an investigation shall be carried out by ANAB.

How ISO Can Meet CMS' Standards For a Certification Body to Achieve Deeming Authority for Hospitals⁷:

1. The composition of the survey team, surveyor qualifications, and the ability of the certification body to provide continuing surveyor training.

In order for a Certifying Body to achieve Healthcare Certification, the Certifying Body would be required to assemble an audit team including a certified lead auditor with healthcare expertise. An industry specific checklist could be utilized; such as the Medicare/Medicaid Hospital Survey Report and the Life Safety Code. The certifying body must provide training to their auditors to ensure appropriate, on-going qualifications and must provide periodic evaluation of continued competence, including on-site witnessing of auditors (per IAF Guidance to Guide 62, G 2.2.10 and 2.2.11).

⁵ Id.

⁶ Id.

⁷ CMS standard in bold, response in non-bold type.

2. The comparability of the certification body's processes to those of State agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

The certification for the ISO 9001:2000 standards is surveyed on a triennial cycle with surveillance audits occurring either every six months or every one year. This exceeds the Joint Commission for Accreditation of Healthcare Organizations, the American Osteopathic Association and the State Health Departments. These entities typically do not perform onsite mid-cycle audits. ISO Certification Bodies are equipped to process complaints and if an investigation is required, they will respond appropriately.

The certification body performs a process audit which means they audit the flow of the process and ensures the organization is in compliance with all applicable laws and regulations. The certification body traces the process to ensure it is performing as prescribed.

3. The certification body's processes and procedures for monitoring providers or suppliers found out of compliance with the program requirements.

The certification body will perform surveillance audits to ensure the organization's quality management program is functioning effectively, adequately and is suitable. Moreover, the organization performs internal audits (internally or externally) on all its written and defined business processes to ensure conformance and effectiveness. The following ISO standards assist in monitoring the organizations purchasing, supplier control and receiving processes:

- 7.4.1 Purchasing Process – The organization shall ensure that purchased products and services conform to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product. The organization shall evaluate and select suppliers based on the ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained.
- 7.4.2 Purchasing Information – Purchasing information shall describe the product/service to be purchased, including where appropriate:
 - a) requirements for approved of product, procedures, processes and equipment,
 - b) requirements for qualifications of personnel, and
 - c) quality management system requirements.

The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.

- 7.4.3 Verification of Purchased Product – The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements. Where the organization or its customer intends to perform verification at the supplier's premise, the organization shall state the intended verification arrangements and method of product release in the purchasing information.

4. The certification body's capacity to report deficiencies to the surveyed facility and response to the facility's plan of correction in a timely manner.

For any identified nonconformance found during the triennial or surveillance audits, the surveyed facility must provide a written corrective action plan submitted within 30 days or longer depending upon the magnitude and circumstances of the nonconformance. The auditors will review the plan for adequacy and review the effectiveness of the corrective action; and if needed, return to the facility to verify effectiveness of the implemented corrective action.

5. The certification body's capacity to provide CMS with electronic data in ASCII comparable code, and reports necessary for effective validation and assessment of the organization's survey process.

Certification bodies shall be prepared to provide CMS with electronic data in ASCII comparable code and via other electronic and written methods.

6. The adequacy of the certification body's staff and other resources, and its financial viability.

During the initial ANAB office audit of the Certification Body and in all subsequent annual office audits, these adequacies are audited. When the decision is favorable for accreditation as a Certification Body (CB) by ANAB, an ANAB agreement must be signed by both the applicant and ANAB. The agreement includes the requirement that the CB maintain appropriate general and professional liability insurance.

Additionally as mentioned previously, the certifying body is responsible for ensuring the ongoing qualifications and competencies of its staff.

7. The certification body's capacity to adequately fund required surveys.

When the decision is favorable for accreditation as a Certification Body (CB) by ANAB, an ANAB agreement must be signed by both the applicant and ANAB. The agreement includes the requirement that the CB have appropriate resources to adequately and effectively fund survey activities. This, too, is a subject of the annual ANAB office audit.

8. The certification body's policies with respect to whether surveys are announced or unannounced.

The certification body performs announced semi-annual or annual surveillance audits and a triennial full recertification audit. Should the certification body need to investigate conformance because it has received complaints against the organization or other evidence of potential or actual nonconformance, it has the authority to come to the organization.

9. The certification body's agreement to provide CMS with a copy of the most current accreditation/certification survey together with any other information related to the survey as we may require (including corrective action plans).

Yes, the certification body could enter into a written agreement with its client to provide CMS with a copy of the organization triennial and surveillance audits and any written corrective action plans.

Summation

The ISO 9001:2000 standard provides a quality management system model for hospitals and health systems. This quality management model assures sustained process improvements and compliance with applicable laws and rules. The ISO standards require hospitals and health systems to comply with any and all applicable local, state and federal laws and rules and with any other accreditation standards and best practices in the healthcare industry. In fact, Licking Memorial Hospital has implemented a key business process titled compliance that describes roles and responsibilities in support of the hospital's approach in complying with the Medicare Conditions of Participation, state and federal regulatory and professional laws and rules (e.g. HIPAA, Life Safety Code, Local Fire Codes, Stark I & II, and Sarbanes Oxley). In order to assure adherence to the Life Safety Codes, Licking Memorial Hospital has created two business processes titled maintenance and calibration. Furthermore, many hospitals have yearly fire inspections in which the state fire codes are more stringent than the Life Safety Code. Ohio is such a state.

In sum, ISO 9001 provides a continuous quality management model for the organization which requires the organization to adhere to all federal and state laws and rules. The hospital must perform on-going internal audits between the triennial and surveillance audits either by its own employees trained as internal auditors or contracting with external auditors. I strongly advocate having CMS recognize ISO 9001:2000 as a stand-alone standard, equivalent to JCAHO and AOA requirements for hospital accreditation.

Should you have any questions or concerns, I would be happy to personally discuss these with you.

Sincerely,

Renee Mallett
VP of Quality Improvement
Licking Memorial Health Systems
1320 West Main Street
Newark, Ohio 43055

Cc: William J. Andrews, President of Licking Memorial Health Systems
Dr. Donald Berwick, President of the Institute for Healthcare Improvement
James Castle, Executive Director of Ohio Hospital Association
Richard Davidson, Executive Director of American Hospital Association
Randy Dougherty, Director of Certification Programs at ANAB

ANSI Government Members

- Agency for Healthcare Research & Quality
- Center for Disease Control and Prevention
- Center for Medicare & Medicaid Services
- Environmental Protection Agency
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- National Archives & Records Administration
- National Cancer Institute, NIH/DHHS
- National Center for Health Statistics
- National Communications System
- National Renewable Energy Laboratory
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