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Who Sets the Standards? Medicare? JCAHO? The Texas Department of Health?

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I. INTRODUCTION

The accelerating pace of regulatory activity creates new compliance challenges for providers. The Texas Department of Health's recently adopted hospital licensing rules, the Health Care Financing Administration's new Medicare conditions of participation affecting organ and tissue donation and transplantation, and the latest recommendations of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) concerning the reporting of sentinel events are a few of the regulatory changes that providers are required to address.

II. MEDICARE (HEALTH CARE FINANCING ADMINISTRATION)

A. Background.

Section 1861(e)(9) of the Social Security Act (the "Act") provides that a hospital participating in the Medicare program must meet certain requirements designated by the Secretary of the Department of Health and Human Services (the "Secretary"). 42 U.S.C.A. ' 1395x(e)(9). In addition, Section 1138 of the Act requires that a hospital participating in Medicare must establish written protocols for the identification of potential organ donors that: (1) ensure that families of potential organ donors are made aware of the option of organ or tissue donation and their option to decline donation, (2) encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of those families, and (3) require that an organ procurement agency designated by the Secretary be notified of potential organ donors. 42 U.S.C.A. ' 1320b-8(a)(1)(A).

The Health Care Financing Administration (HCFA) originally published for comment a complete overhaul of the existing Conditions of Participation (COPs) for Hospitals in December, 1997. See, 62 FedReg 66726 (December 19, 1997). The publication of these rules was the beginning of a shift from a process-fixed method of regulation to a more outcome-oriented means of ensuring the provision of quality medical care to Medicare beneficiaries. In June, 1998, HCFA adopted as final rules that portion of the Conditions of Participation on the identification of potential organ, tissue, and eye donors and transplantation. 63 FedReg 33856 (June 22, 1998). These regulations became effective August 21, 1998.

The HCFA final rule on organ donor identification and transplantation imposes several requirements that a hospital must meet that are designed to increase organ donation. One of these requirements is that a hospital must have an agreement with the Organ Procurement Organization (OPO) designated by the Secretary, under which the hospital will contact the OPO in a timely manner about individuals who die or whose death is imminent in the hospital. The OPO will then determine the individual's medical suitability for donation. As well, the hospital must have an agreement with at least one tissue bank and at least one eye bank to cooperate in the retrieval, processing, preservation, storage, and distribution of tissues and

eyes, as long as the agreement does not interfere with organ donation. The final rule requires a hospital to ensure, in collaboration with the OPO with which it has a final an agreement, that the family of every potential donor is informed of its option to donate organs or tissues or not to donate. Under the final rule, hospitals must work with the OPO and at least on tissue bank in educating staff on donation issues, reviewing death records to improve identification of potential donors, and maintaining potential donors while necessary testing and placement of organs and tissues take place. In addition, transplant hospitals must provide organ-transplant-related data, as requested by the Organ Transplant Procurement Network (OPTN), the Scientific Registry, and the OPOs. The hospital must also provide, if requested, such data directly to the Department of Health and Human Services. 63 FedReg 33856.

A new National Organ and Tissue Donation Initiative was launched by Vice President Al Gore and DHHS Secretary Shalala on December 15, 1997, and the new COPs on organ/tissue donation and transplantation are one part of that initiative.

B. Challenges.

Primarily, hospitals will need to review their existing policies and procedures to ensure compliance with the COPs' three areas of focus:

1. Hospital-OPO collaboration to increase the identification of potential donors.
 - a. Negotiate, draft and execute (or revise) an agreement with the Secretary-designated OPO. Ensure that protocols are developed and implemented that will function efficiently for both the hospital and OPO. Hospital protocols must incorporate the hospital-OPO agreement.
 - b. Negotiate, draft and execute (or revise) agreement with at least one tissue bank. Hospital protocols must incorporate the hospital-tissue bank agreement
 - c. Negotiate, draft and execute (or revise) agreement with at least one eye bank. Hospital protocols must incorporate the hospital-eye bank agreement
 - d. These agreement can be used to spell out whether the OPO will determine medical suitability for tissue and eye donation and handle the referral process for tissue and eye donors or whether an alternative referral process will be used. If the OPO determines medical suitability and refers tissue and eye donors, it must do so using the definition of potential tissue and eye donor and a notification protocol developed in consultation with the tissue bank and eye bank designated by the hospital. An alternative arrangement might, for example, specify that the hospital will refer potential tissue and eye donors directly to the tissue bank and eye bank.
2. Hospital-OPO collaboration for approaching families to ask consent for organ donation.
 - a. Review and redraft hospital structure polices for approaching families to ask consent for organ/tissue/eye donation. This may involve a collaborative effort from the institution's transplant committee and clinical ethics committee. Hospital departments responsible for notification of and working with families in the event of a patient death should be included. Most likely this will involve a joint effort between the Medical Staff, Pastoral Care and Social Work.
 - b. Each facility is required to have "designated requestors" for organ procurement. Hospitals should implement and provide proper training to hospital employees who initiate a request for donation to the family of a potential donor.
3. Transplant hospitals's collection and reporting of transplant data.
 - a. The Transplant and Health Information Management Department of hospitals should make arrangements to collect and provide transplant data as requested to the OPTN, the Scientific Registry, or the hospital's OPO.
 - b. The same hospital departments should be prepared to data directly to DHHS "when requested". HCFA has not yet determined the type of organ transplant data that may be requested by the DHHS. 63 FedReg 33868.

Other issues raised concern the extent of the application of the HCFA regulations. The COPs state that "all deaths" must be reported to the OPO. 42 C.F.R. ' 482.45; 63 FedReg 33859. However, the HCFA regulations are conditions of participation for Medicare-participating hospitals. 42 U.S.C.A. 1395x(e). Does the obligation to report "all deaths" extend to deaths occurring in other, non-hospital-based areas of

a health care system's service line (i.e., home health, hospice, outpatient departments, senior care centers, etc.)? Note the definition of "hospital" provided at 42 U.S.C.A. ' 1395x(e), the portion of the Social Security Act granting the Secretary authority to issue requirements for participating institutions.

Thirdly, a question arises concerning conflicting Federal and state laws. The Texas Anatomical Gift Act, Tex. Health & Safety Code ' 692.001 *et seq.* (Vernon Supp. 1998), requires each hospital to develop a protocol for identifying potential organ and tissue donors from among those persons who die in the hospital. That hospital protocol requires:

- (1) the use of trained requestors;
- (2) sensitivity toward families' beliefs and circumstances;
- (3) the establishment of guidelines based on accepted medical standards for determining medical suitability for donation;
- (4) an exception to making a donation inquiry if the patient is not medically suitable or if there is notice of an objection to donation. *Id.*

HCFA does not believe the final rule is in conflict with the "spirit" of state legislation requiring hospitals to develop their own protocols for organ donation. 63 FedReg 33866. HCFA points out that the Federal regulations supersede both state law and regulations to the extent that the COPs present otherwise "irreconcilable conflicts" with the state statute or rules. *Id.* Accordingly, hospitals should ensure that their organ/tissue donation policies and procedures are based on the superseding federal regulations, rather than the conflicting state law.

III. THE TEXAS DEPARTMENT OF HEALTH HOSPITAL LICENSING RULES

A. Background.

The Texas Health and Safety Code provides the Texas Board of Health with the authority to adopt rules for hospitals concerning procedures for the investigation of patient abuse and neglect, patient complaints, hospital staff, patient services, fire prevention, safety and sanitation, patient care, patient bill of rights, patient transfers, hospital construction, and other areas. Texas Health and Safety Code " 161.132, 222.026, 241.026, 241.027, 241.104, 241.123, 321.002. Accordingly, the Texas Board of Health approved final Hospital Licensing Rules on July 17, 1998. These new rules replaced the existing Hospital Licensing Rules and the Hospital Licensing Standards and were published by TDH in early August. 23 TexReg 8042 (August 7, 1998). The rules became effective August 18, 1998.

B. Challenges.

Providers licensed under the newly adopted rules should be aware of the following changes:

1. CRNA Anesthesia Services.

a. One of the issues TDH received numerous comments about concerned the administration of anesthesia by a certified registered nurse anesthetist (CRNA) who is under the supervision of the operation physician or of an anesthesiologist who is immediately available if needed. This issues centers on the question of whether CRNAs are independent practitioners and, if not, the level and method of supervision required for their practice. Many hospitals have recently reexamined their policies concerning the practice and supervision of CRNAs in light of the questions raised in the 1997 Forth Worth Court of Appeals case, *Denton Regional Medical Center v. LaCroix*, 947 S.W.2d 941 (Tex. App.--Fort Worth 1997, writ dismissed).

b. New 25 TAC ' 133.41 provides that if the hospital furnishes anesthesia services, these services shall be provided in a well-organized manner under the direction of a qualified physician. The anesthesia service is responsible for all anesthesia administered in the hospital. Anesthesia shall be administered only by:

- (A) a qualified anesthesiologist;
- (B) a physician (other than an anesthesiologist);
- (C) a dentists, oral surgeon, or podiatrist who is qualified to administer anesthesia under state law; or

(D) a certified registered nurse anesthetist who is under the supervision, as defined by the Medical Practice Act, Texas Civil Statutes, Article 4495b, and the Nurse Practice Act, Texas Civil Statutes, Article 4513-4528, of the operating physician or of an anesthesiologist who is immediately available if needed.

c. Hospital counsel should review their anesthesia coverage agreements and hospital structure policies on supervision of CRNAs for compliance with 25 TAC ' 133.41. Policies and coverage agreements should conform in the delegation of responsibility for CRNA supervision. This will reduce the likelihood of *LaCroix*-type direct hospital liability.

2. Infectious Disease Control.

a. Another change in the licensing rules concerns the safety of hospital employees who are exposed to infectious diseases. New 25 TAC ' 133.41(g) requires hospitals to adopt, implement and enforce a written policy to monitor compliance of the hospital and its personnel and medical staff with universal precautions, in accordance with Texas Health & Safety Code Chapter 85 (relating to the prevention of transmission of Human Immunodeficiency Virus and Hepatitis B Virus).

b. 25 TAC ' 133.41(g) also requires an active program for the prevention, control, and investigation of infections and communicable disease; requires the hospital to develop, implement and enforce policies governing prevention, control and surveillance of infections and communicable diseases; and other requirements.

c. Hospital counsel, administration, and the health care facility infection control officer should coordinate with the drafting, revision and/or implementation of policies and procedures to ensure compliance with the rules concerning infectious disease control.

IV. ACCREDITATION STANDARDS OF THE JCAHO

A. Background.

The JCAHO Sentinel Event Policy is designed to encourage the self-reporting of medical errors in order to learn about the relative frequencies and underlying causes of sentinel events, share "lessons learned" with other health care organizations, and reduce the risk of future sentinel event occurrences.

A sentinel event is any unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Under the Sentinel Event Policy, a defined subset of sentinel events are *reportable* to the JCAHO on a *voluntary* basis. Only those sentinel events that affect recipients of care (patients, clients, residents) and that meet the following criteria fall into this category:

1. The event has resulted in an unanticipated death or major permanent loss of function, not related to the natural course of the patient's illness or underlying condition; or

2. The event is one of the following (even if the outcome was not death or major permanent loss of function):

a. Suicide of a patient in a setting where the patient received around-the-clock care (e.g., hospital, residential treatment center, crisis stabilization center);

b. Infant abduction or discharge to the wrong family;

c. Rape;

d. Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities; or

e. Surgery on the wrong patient or wrong body part.

Under the JCAHO policy, an accredited health care organization that experiences a voluntarily reportable sentinel event and notifies JCAHO within five business days of its occurrence (or within five days of learning its occurrence) will not be placed on Accreditation Watch if it subsequently submits to JCAHO an acceptable root cause analysis within 30 days. In addition, such organizations usually will not be subject to an immediate on-site review unless it is determined that there is a potential ongoing threat to patient safety.

The reporting of sentinel events is voluntary under the policy. However, accredited organizations are required to conduct root cause analyses any time a sentinel event occurs. If JCAHO learns of an

organization that has not reported a sentinel event within five business days of its occurrence (or within five business days of learning of its occurrence) and has not completed an adequate root cause analysis within 30 days of its occurrence or learning of its occurrence, the organization is at immediate risk of being placed on Accreditation Watch. Accreditation Watch is a publicly disclosable attribute of an organization's existing accreditation status. Accreditation Watch signifies that an organization is under close monitoring by JCAHO. The Accreditation Watch status is removed once an organization completes and submits an acceptable root cause analysis.

B. Challenges.

1. Development of sentinel event policy.

- a. JCAHO sentinel event process flow chart.
- b. Baylor Health Care System sentinel event process flow chart.
- c. Include participation of institution's quality assurance, medical staff, administration, and outside legal counsel during development process.

2. Decision of whether to voluntarily report.

- a. Arguments in favor of reporting.
- b. Arguments against reporting.

3. Confidentiality.

- a. JCAHO states it will not disclose legally protected sentinel event-related information to any third party and will defend the legal confidentiality of this information, if necessary, through the legal process. If subpoenaed for sentinel event-related information, JCAHO will not release the information, defend its position in the courts, and will notify the health care organization of the request.
- b. The medical peer review privilege allows disclosure of written or oral communications to another medical peer review committee, appropriate state and federal agencies and national accreditation bodies. Texas Revised Civil Statutes, Art. 4495b Sec. 5.06(h) (Vernon Supp. 1998).
- c. As a strategy to protect the confidentiality of sentinel event-related information at the health care organization, JCAHO will include language in future contracts between JCAHO and accredited organization that will formally recognize JCAHO as a participating entity in the organization's quality monitoring and improvement activities. Until an organization's contract is revised, counsel should request that JCAHO provide written documentation which articulates the JCAHO role in quality improvement and peer review activities.