

**Department of State Health Services
Council Agenda Memo for State Health Services Council
April 29, 2010**

Agenda Item Title: Amendments to rules and a new rule concerning the regulation of general hospitals

Agenda Number: 3.a.ii.

Recommended Council Action:

For Discussion Only

For Discussion and Action by the Council

Background:

The Health Facility Program is within the Regulatory Licensing Unit, Health Care Quality Section, of the Regulatory Services Division. The Health Facility Program monitors health care delivery by regulated health care facilities to ensure high quality care to the people of Texas. The Program issues licenses to general and special hospitals and conducts inspections to determine compliance with the rules. The license is valid for two years and findings of noncompliance may result in referral for escalated enforcement action. In fiscal year 2009, 362 standard and complaint surveys were conducted, with 10 facilities found in noncompliance. The final outcome of noncompliance is available to the public.

There are 618 licensed hospitals. The budget and source of funding is general revenue and program costs are offset by licensing fees.

Summary:

The purpose of the amendments and new rule is to comply with Health and Safety Code, Chapter 241, that requires hospitals be licensed by the Department of State Health Services (DSHS). The rules establish the licensing procedures and standards of operation for hospitals to protect and promote the public health and safety of individuals receiving services in these facilities.

The proposed rules implement legislation passed by the 81st Legislature, Regular Session, 2009. The proposed rule changes specifically address the following:

- Health and Safety Code, Chapter 257, Nurse Staffing, added by Senate Bill 476, relating to a hospital governing body adopting, implementing, and enforcing a written nurse staffing policy and plan; establishing a nurse staffing committee as a standing committee of the hospital; and reporting of nurse staffing information to DSHS.
- Health and Safety Code, Chapter 258, Mandatory Overtime for Nurses Prohibited, added by Senate Bill 476, relating to defining mandatory overtime, prohibiting mandatory overtime for nurses, providing exceptions for mandatory overtime, prohibiting a hospital from retaliation against a nurse who refuses to work mandatory overtime, and allowing a nurse to refuse to work mandatory overtime. The rule changes as a result of Senate Bill 476 are expected to protect patients, support greater retention of registered nurses, and promote adequate nurse staffing, as nurses and hospital management participate in a joint process regarding decisions about nurse staffing.
- Health and Safety Code, Chapter 259, added by House Bill 643, relating to employment and qualifications of surgical technologists. This rule change should increase patient safety by requiring hospitals to employ only individuals who have the appropriate education, certification, or experience in surgical technology.

- Health and Safety Code, Chapter 251, amended by Senate Bill 1932, relating to licensing requirements of hospitals temporarily providing outpatient dialysis services to a person because of a disaster. This rule change is expected to provide better access to patients needing dialysis services during a disaster.
- Health and Safety Code, Chapter 323, amended by House Bill 2626, relating to providing a forensic medical examination to a sexual assault victim who has not reported the assault to a law enforcement agency. This rule change is expected to increase access to forensic medical examinations for victims of sexual assault when those victims have not reported the assault to a law enforcement agency.
- Health and Safety Code, Chapter 98, amended by Senate Bill 203, relating to the reporting of health care-associated infections and preventable adverse events in hospitals. This rule change allows DSHS to make publicly available hospital patient safety information in Texas, including information related to health care-associated infections and preventable adverse events in a format that is easy to read and available on an Internet website. The DSHS Division of Prevention and Preparedness will implement the gathering of data related to health care-associated infections.

DSHS will collect performance measures each fiscal year, including the number of licensed or certified facilities meeting state and federal regulations at the time of their survey, the number of complaint investigations conducted, and the number of citations or facilities referred for enforcement action consideration.

Summary of Input from Stakeholder Groups:

On November 2, 2009, stakeholders were notified by email of a meeting on November 13, 2009, to discuss legislation passed in the 81st Regular Session, 2009. The following stakeholders attended the informal stakeholder meeting: Texas Hospital Association, Texas Medical Association, Texas Nurses Association, Texas Society of Anesthesiologists, Texas Association of Nurse Anesthetists, Texas Organization of Rural and Community Hospitals, Texas Physician Hospitals Advocacy Center, Texas Association Against Sexual Assault, DSHS staff, representatives from hospitals, and attorneys and representatives from law offices.

On December 23, 2009, the proposed draft rules were posted on the DSHS website and an email was sent to inform stakeholders of the proposed changes to the licensing rules that incorporate legislation and to request comments. Stakeholder input has been solicited and included throughout the development of the rules and potential issues have been addressed.

On January 21, 2010, an overview of the proposed draft rules was presented at the DSHS Council work session. Issues discussed at the Council work session include:

- The impact to TORCH (Texas Association of Rural and Community Hospitals) hospitals implementing rules related to nurse staffing restrictions. A TORCH representative stated no adverse impact has been reported.
- Whether evidence collected is kept after a forensic medical examination of a sexual assault victim who has not reported to law enforcement. The statute does not differentiate between examinations of those who report and those who do not report to law enforcement.
- The information that will be posted related to health care-associated infections and preventable adverse events reporting. The Division of Prevention and Preparedness is developing rules that define reporting.

On January 26, 2010, a meeting was held with a stakeholder group that provided written comments. The issues discussed include:

- Inserting language into the definition of “hospital,” to include “a hospital maintained or operated by this state.” Because hospitals maintained or operated by the state are exempt from DSHS licensure, no change was made to the proposed rules.

- Revising the language that prohibits scheduling nurses for procedures anticipated to last beyond the nurse’s scheduled shift as constituting mandatory overtime. The stakeholder group will submit draft language for consideration by DSHS. No change was made to the proposed rules.
- Deleting language relating to the reporting of certain events and best practices due to the “sunsetting” of House Bill 1614 in 2007. A full rule review is scheduled to begin in 2011 and this section will be reviewed with all stakeholders. No change was made to the proposed rules.
- Providing language that is more specific regarding the types of infections or adverse events that must be reported instead of adopting Chapter 98 by reference. As the DSHS Division of Prevention and Preparedness will be amending rules to implement the specific reporting requirements of infections or adverse events in 25 TAC, Chapter 200, no change was made to the proposed rules.

Proposed Motion:

Motion to recommend HHSC approval for publication of rules contained in agenda item #3.a.ii.

Approved by Assistant Commissioner/Director: Kathryn C. Perkins **Date:** 3/19/2010

Presenter: Beth Pickens **Program:** Health Care Quality Section **Phone No.:** 834-6752

Approved by CPCPI: Carolyn Bivens **Date:** 3/19/2010

Title 25. HEALTH SERVICES
Part 1. DEPARTMENT OF STATE HEALTH SERVICES
Chapter 133. Hospital Licensing
Subchapter A. General Provisions
Amendment §133.2
Subchapter C. Operational Requirements
Amendment §133.41
New §133.49
Subchapter I. Physical Plant and Construction Requirements
Amendment §133.163

Proposed Preamble

The Executive Commissioner of the Health and Human Services Commission on behalf of the Department of State Health Services (department) proposes amendments to §§133.2, 133.41, and 133.163 and proposes adding new §133.49, concerning the regulation of general hospitals.

BACKGROUND AND PURPOSE

The amendments and new section are necessary to comply with legislation passed during the 81st Legislature, 2009, Regular Session.

House Bill (HB) 643 added Health and Safety Code, Chapter 259, which requires hospitals to comply with qualification standards for employment of surgical technologists.

HB 2626 amended Health and Safety Code, Chapter 323, which requires hospitals to provide forensic medical examinations for certain sexual assault victims,

Senate Bill (SB) 1932 amended Health and Safety Code, Chapter 251, which allows hospitals to provide outpatient dialysis during declared disasters.

SB 476 added Health and Safety Code, Chapter 257, relating to nurse staffing, and Chapter 258, relating to mandatory overtime for nurses prohibited.

SB 203 amended Health and Safety Code, Chapter 98, involving the reporting of health care-associated infections and preventable adverse events in certain health care facilities to the department.

The department regulates general hospitals as required by Health and Safety Code, Chapter 241.

SECTION-BY-SECTION SUMMARY

Amendments to §133.2 add definitions for nurse and surgical technologist.

An amendment to §133.41(e) requires hospitals to provide, with documented consent, care to a sexual assault victim age 18 years or older who has not reported the assault to a law enforcement

agency, if the victim has arrived at the hospital not later than 96 hours after the time the assault occurred.

An amendment to §133.41(g) requires hospitals to, require a written, implemented, and enforced policy for reporting to the department certain health care-associated infections and preventable adverse events.

Amendments to §133.41(f) and (o) require the governing body of a hospital to adopt, implement, and enforce a written nurse staffing policy; requires hospitals to create a nurse staffing committee as a standing committee, establishes committee membership, requires the committee to meet at least quarterly, and defines responsibilities of the committee; requires a nurse services staffing plan and policies; requires annual reporting to the department on the nurse staffing policy, nurse staffing plan, nurse staffing committee, and nurse sensitive outcome measures used in the nurse staffing plan; requires the adoption, implementation and enforcement of policies on use of mandatory overtime; prohibits hospitals from requiring a nurse to work mandatory overtime or using on-call time as a substitute for mandatory overtime; prohibits scheduling nurses for procedures expected to last beyond their scheduled shift; provides exceptions to the mandatory overtime prohibition in certain situations, including disasters or emergencies, and requires the hospital to make and document a good faith effort to meet staffing needs through other measures; and requires that a hospital may not suspend, terminate, discipline, or discriminate against a nurse who refuses to work mandatory overtime.

An amendment to §133.41(t) allows hospitals to provide outpatient dialysis services when the Governor or the President of the United States declares a disaster in this state or another state.

An amendment to §133.41(w) requires hospitals to adopt, implement, and enforce policies related to the employment of surgical technologists.

The new §133.49 requires hospitals to comply with reporting certain health care-associated infections and preventable adverse events to the department in accordance with 25 TAC Chapter 200. The department will add Chapter 200 to set forth the detailed requirements for reporting. This information will allow the department to make available patient safety information in Texas, including information related to health care-associated infections and preventable adverse events in a format that is available on an Internet website.

An amendment to §133.163 establishes that outpatient renal dialysis shall not be performed in a hospital's inpatient renal dialysis suite unless authorized during a disaster declaration, as referenced in §133.41.

FISCAL NOTE

Renee Clack, Section Director, Health Care Quality Section, has determined that for each year of the first five-year period that the sections will be in effect, there will not be fiscal implications to state or local governments as a result of enforcing and administering the sections as proposed.

SMALL AND MICRO-BUSINESS IMPACT ANALYSIS

Ms. Clack has also determined that there may be an adverse economic impact on small businesses or micro-businesses required to comply with the sections as proposed. This was determined by interpretation of the rules that small businesses and micro-businesses may be required to alter their business practices in order to comply with the sections. Section 133.41(f) and (o) (SB 476), related to nurse staffing and mandatory overtime, may have an economic impact on hospitals.

Hospitals of any size, which have relied on the use of mandatory overtime, may incur costs in providing nursing coverage for nurse members of the nurse staffing committee to attend meetings. There is a potential cost to hospitals that choose to hire additional nurses or use staffing agencies if nursing services are currently provided by the use of mandatory overtime; this is a business decision of the facility. There is no historical data to determine costs or how many hospitals have used mandatory overtime of nurses to provide staffing.

Hospitals that have relied on mandatory overtime have several options for providing nursing coverage, such as requesting currently employed nurses to voluntarily work overtime, hiring additional nurses, using a float pool of nurses, working with nurse staffing agencies, or implementing potential solutions developed by the mandated nursing staffing committee. Hospitals may also consider these options to provide coverage during nurse staffing committee meetings.

ECONOMIC COSTS TO PERSONS AND IMPACT ON LOCAL EMPLOYMENT

There may be economic costs to persons who are required to comply with §133.41(f) and (o) (SB 476) as described in the small and micro-business impact analysis. There are no costs to persons who are required to comply with the proposed §133.41(e) (HB 2626), §133.41(g) and §133.49 (SB 203), §133.41(f) and §133.63 (SB 1932), or §133.41(w) (HB 643). There is no anticipated impact on local employment.

PUBLIC BENEFIT

In addition, Ms. Clack has also determined that, for each year of the first five years the sections are in effect, the public will benefit from adoption of the sections. The rules protect the health, safety, and welfare of patients receiving services in hospitals, hospital personnel, and the public. Alternative methods of compliance have been provided in these rules to allow facilities the flexibility to make business decisions based on their needs.

REGULATORY ANALYSIS

The department has determined that this proposal is not a "major environmental rule" as defined by Government Code, §2001.0225. "Major environmental rule" is defined to mean a rule the specific intent of which is to protect the environment or reduce risk to human health from environmental exposure and that may adversely affect, in a material way, the economy, a sector of the economy, productivity, competition, jobs, the environment or the public health and safety

of a state or a sector of the state. This proposal is not specifically intended to protect the environment or reduce risks to human health from environmental exposure.

TAKINGS IMPACT ASSESSMENT

The department has determined that the proposal does not restrict or limit an owner's right to his or her property that would otherwise exist in the absence of government action and, therefore, does not constitute a taking under Government Code, §2007.043.

PUBLIC COMMENT

Comments on the proposal may be submitted to Beth Pickens, Health Care Quality Section, Division of Regulatory Services, Department of State Health Services, P.O. Box 149347, Mail Code 2822, Austin, Texas 78714-9347, (512) 834-6752 or by email to beth.pickens@dshs.state.tx.us. Comments will be accepted for 30 days following publication of the proposal in the *Texas Register*.

LEGAL CERTIFICATION

The Department of State Health Services General Counsel, Lisa Hernandez, certifies that the proposed rules have been reviewed by legal counsel and found to be within the state agencies' authority to adopt.

STATUTORY AUTHORITY

The new section and amendments are authorized by Health and Safety Code, §241.026; concerning rules and minimum standards for the licensing and regulation of general hospitals; Health and Safety Code, Chapter 98, concerning the reporting the of health care-associated infections; Health and Safety Code, Chapter 257, relating to nurse staffing, and Chapter 258, relating to mandatory overtime for nurses prohibited; Health and Safety Code, Chapter 259, concerning the surgical technologists at health care facilities; Health and Safety Code, Chapter 323, which requires hospitals to provide forensic medical examinations for certain sexual assault victims; Government Code, §531.0055, and Health and Safety Code, §1001.075, which authorize the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies necessary for the operation and provision of health and human services by the department and for the administration of Health and Safety Code, Chapter 1001.

The new section and amendments affect the Health and Safety Code, Chapters 98, 241, 257, 258, 259, 323, and 1001; and Government Code, Chapter 531.

Legend: (Proposed Amendments)

Single Underline = Proposed new language

[Bold, Print, and Brackets] = Current language proposed for deletion

Regular Print = Current language

(No change.) = No changes are being considered for the designated subdivision

Subchapter A. General Provisions.

§133.2. Definitions.

The following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise.

(1) – (30) (No change.)

(31) Nurse--A registered nurse or vocational nurse licensed under Occupations Code, Chapter 301.

(32) [(31)] Outpatient--An individual who presents for diagnostic or treatment services for an intended length of stay of less than 24 hours; provided, however, that an individual who requires continued observation may be considered as an outpatient for a period of time not to exceed a total of 48 hours.

(33) [(32)] Outpatient services--Services provided to patients whose medical needs can be met in less than 24 hours and are provided within the hospital; provided, however, that services that require continued observation may be considered as outpatient services for a period of time not to exceed a total of 48 hours.

(34) [(33)] Owner--One of the following persons or governmental unit which will hold or does hold a license issued under the statute in the person's name or the person's assumed name:

(A) a corporation;

(B) a governmental unit;

(C) a limited liability company;

(D) an individual;

(E) a partnership if a partnership name is stated in a written partnership agreement or an assumed name certificate;

(F) all partners in a partnership if a partnership name is not stated in a written partnership agreement or an assumed name certificate; or

(G) all co-owners under any other business arrangement.

(35) [(34)] Patient--An individual who presents for diagnosis or treatment.

(36) [(35)] Pediatric and adolescent hospital--A general hospital that specializes in providing services to children and adolescents, including surgery and related ancillary services.

(37) [(36)] Person--An individual, firm, partnership, corporation, association, or joint stock company, and includes a receiver, trustee, assignee, or other similar representative of those entities.

(38) [(37)] Physician--A physician licensed by the Texas Medical Board.

(39) [(38)] Physician assistant--A person licensed as a physician assistant by the Texas State Board of Physician Assistant Examiners.

(40) [(39)] Podiatrist--A podiatrist licensed by the Texas State Board of Podiatric Medical Examiners.

(41) [(40)] Practitioner--A health care professional licensed in the State of Texas, other than a physician, podiatrist, or dentist. A practitioner shall practice in a manner consistent with their underlying practice act.

(42) [(41)] Premises--A premises may be any of the following:

(A) a single building where inpatients receive hospital services; or

(B) multiple buildings where inpatients receive hospital services provided that the following criteria are met:

(i) all buildings in which inpatients receive hospital services are subject to the control and direction of the same governing body;

(ii) all buildings in which inpatients receive hospital services are within a 30-mile radius of the primary hospital location;

(iii) there is integration of the organized medical staff of each of the hospital locations to be included under the single license;

(iv) there is a single chief executive officer for all of the hospital locations included under the license who reports directly to the governing body and through whom all administrative authority flows and who exercises control and surveillance over all administrative activities of the hospital;

(v) there is a single chief medical officer for all of the hospital locations under

the license who reports directly to the governing body and who is responsible for all medical staff activities of the hospital;

(vi) each hospital location to be included under the license that is geographically separate from the other hospital locations contains at least one nursing unit for inpatients which is staffed and maintains an active inpatient census, unless providing only diagnostic or laboratory services, or a combination of diagnostic or laboratory services, in the building for hospital inpatients; and

(vii) each hospital that is to be included in the license complies with the emergency services standards:

(I) for a general hospital, if the hospital provides surgery or obstetrical care or both; or

(II) for a special hospital, if the hospital does not provide surgery or obstetrical care.

(43) [(42)] Presurvey conference--A conference held with department staff and the applicant or the applicant's representative to review licensure rules and survey documents and provide consultation prior to the on-site licensure inspection.

(44) [(43)] Psychiatric disorder--A clinically significant behavioral or psychological syndrome or pattern that occurs in an individual and that is typically associated with either a painful syndrome (distress) or impairment in one or more important areas of behavioral, psychological, or biological function and is more than a disturbance in the relationship between the individual and society.

(45) [(44)] Quality improvement--A method of evaluating and improving processes of patient care which emphasizes a multidisciplinary approach to problem solving, and focuses not on individuals, but systems of patient care which might be the cause of variations.

(46) [(45)] Registered nurse (RN)--A person who is currently licensed by the Board of Nurse Examiners for the State of Texas as a registered nurse or who holds a valid registered nursing license with multi-state licensure privilege from another compact state.

(47) [(46)] Special hospital--An establishment that:

(A) offers services, facilities, and beds for use for more than 24 hours for two or more unrelated individuals who are regularly admitted, treated, and discharged and who require services more intensive than room, board, personal services, and general nursing care;

(B) has clinical laboratory facilities, diagnostic X-ray facilities, treatment facilities, or other definitive medical treatment;

(C) has a medical staff in regular attendance; and

(D) maintains records of the clinical work performed for each patient.

(48) [(47)] Stabilize--With respect to an emergency medical condition, to provide such medical treatment of the condition necessary to assure, within reasonable medical probability, that no material deterioration of the condition is likely to result from or occur during the transfer of the individual from a facility, or that the woman has delivered the child and the placenta.

(49) Surgical technologist--A person who practices surgical technology as defined in Health and Safety Code, Chapter 259.

(50) [(48)] Transfer--The movement (including the discharge) of an individual outside a hospital's facilities at the direction of any person employed by (or affiliated or associated, directly or indirectly, with) the hospital, but does not include such a movement of an individual who has been declared dead, or leaves the facility without the permission of any such person.

(51) [(49)] Universal precautions--Procedures for disinfection and sterilization of reusable medical devices and the appropriate use of infection control, including hand washing, the use of protective barriers, and the use and disposal of needles and other sharp instruments as those procedures are defined by the Centers for Disease Control and Prevention (CDC) of the Department of Health and Human Services. This term includes standard precautions as defined by CDC which are designed to reduce the risk of transmission of blood borne and other pathogens in hospitals.

(52) [(50)] Violation--Failure to comply with the licensing statute, a rule or standard, special license provision, or an order issued by the commissioner of state health services (commissioner) or the commissioner's designee, adopted or enforced under the licensing statute. Each day a violation continues or occurs is a separate violation for purposes of imposing a penalty.

Subchapter C. Operational Requirements.

§133.41. Hospital Functions and Services.

(a) – (d) (No change.)

(e) Emergency services. All licensed hospital locations, including multiple-location sites, shall have an emergency suite that complies with §133.161(a)(1)(A) of this title (relating to Requirements for Buildings in Which Existing Licensed Hospitals are Located) or §133.163(f) of this title, and the following.

(1) – (5) (No change.)

(6) Emergency services for survivors of sexual assault.

(A) The hospital shall **[must]** develop, implement and enforce policies and procedures to ensure that a sexual assault survivor who presents to the hospital following a sexual assault receives one of the following **[is]**:

(i) **[provided]** the care specified under subparagraph (B) of this paragraph; or

(ii) stabilization and transfer **[stabilized and transferred]** to a health care facility designated in a community-wide plan as the health care facility for treating sexual assault survivors, where the survivor will receive the care specified under subparagraph (B) of this paragraph.

(B) A hospital providing **[which provides]** care to a sexual assault survivor shall provide the survivor with the following:

(i) a forensic medical examination in accordance with Government Code, Chapter 420, Subchapter B;

(I) if the examination has been requested by a law enforcement agency under Code of Criminal Procedure, Article 56.06, or is conducted under Code of Criminal Procedure, Article 56.065; or

(II) for a victim age 18 or older who has not reported the assault to a law enforcement agency, if the victim has arrived at the facility not later than 96 hours after the time the assault occurred, and consents to the examination;

(ii) a private area, if available, to wait or speak with the appropriate medical, legal, or sexual assault crisis center staff or volunteer until a physician, nurse, or physician assistant is able to treat the survivor;

(iii) access to a sexual assault program advocate, if available, as provided by Code of Criminal Procedure, Article 56.045;

(iv) the information form required by Health and Safety Code, §323.005;

(v) a private treatment room, if available;

(vi) if indicated by the history of contact, access to appropriate prophylaxis for exposure to sexually transmitted infections; and

(vii) the name and telephone number of the nearest sexual assault crisis center.

[(i) a private area, if available, to wait and to speak with the appropriate medical, legal and sexual assault crisis center staff or volunteers until a physician, nurse, or other qualified medical personnel is able to treat the survivor;]

[(ii) a private treatment room, if available;]

[(iii) a forensic medical examination in accordance with Government Code, Chapter 420, Subchapter B, and Code of Criminal Procedure 56.065;]

[(iv) access to a sexual assault program advocate, if available, as provided by Code of Criminal Procedure, Article 56.045;]

[(v) the department's standard Information Form for Sexual Assault Survivors, which may be obtained through the department's website or by contacting the hospital licensing program at (512) 834-6648;]

[(vi) the name and telephone number of the nearest sexual assault crisis center; and]

[(vii) if indicated, access to appropriate prophylaxis for exposure to sexually transmitted infections.]

(C) The hospital must obtain documented consent before providing the forensic medical examination and treatment.

(D) [(C)] Upon request, the hospital shall submit to the department their plan for the provision of service to sexual assault survivors. The plan must describe how the hospital will ensure that the services required under subparagraph (B) of this paragraph will be provided.

(i) The hospital shall submit the plan by the 60th day after the department makes the request.

(ii) The department will approve or reject the plan not later than 120th day following the submission of the plan.

(iii) If the department is not able to approve the plan, the department will return the plan to the hospital and will identify the specific provisions with which the hospital's plan failed to comply.

(iv) The hospital shall correct and resubmit the plan to the department for approval not later than the 90th day after the plan is returned to the hospital.

(f) Governing body.

(1) - (7) (No change.)

(8) Nurse Staffing. The governing body shall adopt, implement and enforce a written nurse staffing policy to ensure that an adequate number and skill mix of nurses are available to meet the level of patient care needed. The governing body policy shall require that hospital administration adopt, implement and enforce a nurse staffing plan and policies that:

(A) require significant consideration be given to the nurse staffing plan recommended by the hospital's nurse staffing committee and the committee's evaluation of any existing plan;

(B) are based on the needs of each patient care unit and shift and on evidence relating to patient care needs;

(C) require use of the official nurse services staffing plan as a component in setting the nurse staffing budget;

(D) encourage nurses to provide input to the nurse staffing committee relating to nurse staffing concerns;

(E) protect from retaliation nurses who provide input to the nurse staffing committee; and

(F) comply with subsection (o) of this section.

(g) Infection control. The hospital shall provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There shall be an active program for the prevention, control, and surveillance of infections and communicable diseases.

(1) Organization and policies. A person shall be designated as infection control professional. The hospital shall ensure that policies governing prevention, control and surveillance of infections and communicable diseases are developed, implemented and enforced.

(A) – (B) (No change.)

(C) A written policy shall be adopted, implemented and enforced for reporting all reportable diseases to the local health authority and the Infectious Disease Surveillance and Epidemiology Branch, Department of State Health Services, MC 2822, P. O. Box 149347, Austin, Texas 78714-9347 [1100 West 49th Street, Austin, Texas 78756-3199], in accordance with Chapter 97 of this title (relating to Communicable Diseases), Chapter 200 of this title (relating to Healthcare-Associated Infections), and Health and Safety Code, §98.103, §98.104, and §98.1045 (relating to Reportable Infections, Alternative for Reportable Surgical Site Infections, and Reporting of Preventable Adverse Events).

(D) (No change.)

(2) – (3) (No change.)

(h) – (n) (No change.)

(o) Nursing services. The hospital shall have an organized nursing service that provides 24-hour nursing services as needed.

(1) Organization. The hospital shall have a [an organized nursing service that provides 24-hour nursing care. The nursing service shall be] well-organized service with a plan of administrative authority and delineation of responsibilities for patient care.

(A) – (E) (No change.)

(2) Staffing and delivery of care.

(A) – (E) (No change.)

[(F)] [At a minimum, the following critical factors shall be considered in the determination of staffing levels:]

[(i)] [patient characteristics and number of patients for whom care is being provided, including number of admissions, discharges and transfers on a unit;]

[(ii)] [intensity of patient care being provided and variability of patient care across a nursing unit;]

[(iii)] [scope of services provided;]

[(iv)] [context within which care is provided, including architecture and geography of the environment, and the availability of technology; and]

[(v)] [nursing staff characteristics, including staff consistency and tenure, preparation and experience, and the number and competencies of clinical and nonclinical support staff the nurse must collaborate with or supervise.]

[(G)] [The hospital shall adopt, implement and enforce a written process for setting staffing levels that takes into account the critical factors specified in subparagraph (F) of this paragraph. The process shall include:]

[(i)] [establishing presumptive or initial staffing levels that are recalculated at least annually or as necessary;]

[(ii)] [setting staffing levels on a unit by unit basis or other bases appropriate to the hospital;]

[(iii)] [adjusting of staffing levels from shift to shift based on factors, such as, the intensity of patient care; and]

[(iv)] [reporting to the advisory committee, as referenced in subparagraph (H) of this paragraph, showing variance between desired and actual staffing levels, and an explanation for the variance. The reports shall be confidential and not subject to

disclosure under Government Code, Chapter 552, and not subject to disclosure, discovery, subpoena or other means of legal compulsion for their release.]

(F) [(H)] The hospital shall establish a nurse staffing [designate an advisory] committee as a standing committee of the hospital. The committee shall be established in accordance with Health and Safety Code (HSC), §§161.031-161.033, to be responsible for soliciting and receiving input from nurses on the development, ongoing monitoring, and evaluation of the staffing plan. As provided by HSC, §161.032, the hospital's records and review relating to evaluation of these outcomes and indicators are confidential and not subject to disclosure under Government Code, Chapter 552 and not subject to disclosure, discovery, subpoena or other means of legal compulsion for their release. As used in this subsection, "committee" or "staffing committee" means a nurse staffing committee established under this subparagraph.

(i) The committee shall be composed of:

(I) [(i)] at least 60% [have, as one-half of its members,] registered nurses who are involved in direct patient care at least 50% of their work time and selected by their peers who provide direct care during at least 50% of their work time;

(II) [(ii)] [include] at least one representative from either infection control, quality assessment and performance [program] improvement or risk management; [and]

(III) [(iii)] members who are representative of the types of nursing services provided at the hospital; and [to the extent feasible, represent multiple areas of nursing practice.]

(IV) the chief nursing officer of the hospital who is a voting member.

(ii) Participation on the committee by a hospital employee as a committee member shall be part of the employee's work time and the hospital shall compensate that member for that time accordingly. The hospital shall relieve the committee member of other work duties during committee meetings.

(iii) The committee shall meet at least quarterly.

(iv) The responsibilities of the committee shall be to:

(I) develop and recommend to the hospital's governing body a nurse staffing plan that meets the requirements of subparagraph (G) of this paragraph;

(II) review, assess and respond to staffing concerns expressed to the committee;

(III) identify the nurse-sensitive outcome measures the committee will use to evaluate the effectiveness of the official nurse services staffing plan;

(IV) evaluate, at least semiannually, the effectiveness of the official nurse services staffing plan and variations between the plan and the actual staffing; and

(V) submit to the hospital's governing body, at least semiannually, a report on nurse staffing and patient care outcomes, including the committee's evaluation of the effectiveness of the official nurse services staffing plan and aggregate variations between the staffing plan and actual staffing.

(G) [(I)] The hospital shall adopt, implement and enforce a written official nurse services staffing plan. As used in this subsection, "patient care unit" means a unit or area of a hospital in which registered nurses provide patient care.

(i) The official nurse services staffing plan and policies shall:

(I) require significant consideration to be given to the nurse staffing plan recommended by the hospital's nurse staffing committee and the committee's evaluation of any existing plan;

(II) be based on the needs of each patient care unit and shift and on evidence relating to patient care needs;

(III) require use of the official nurse services staffing plan as a component in setting the nurse staffing budget;

(IV) encourage nurses to provide input to the nurse staffing committee relating to nurse staffing concerns;

(V) protect from retaliation nurses who provide input to the nurse staffing committee; and

(VI) comply with subsection (o) of this section.

(ii) The plan shall:

(I) set minimum staffing levels for patient care units that are:

(-a-) based on multiple nurse and patient considerations including:

(-1-) patient characteristics and number of patients for whom care is being provided, including number of admissions, discharges and transfers on a unit;

(-2-) intensity of patient care being provided and variability of patient care across a nursing unit;

(-3-) scope of services provided;

(-4-) context within which care is provided, including architecture and geography of the environment, and the availability of technology; and

(-5-) nursing staff characteristics, including staff consistency and tenure, preparation and experience, and the number and competencies of clinical and non-clinical support staff the nurse must collaborate with or supervise.

(-b-) determined by the nursing assessment and in accordance with evidence-based safe nursing standards; and

(-c-) recalculated at least annually, or as necessary;

(II) include a method for adjusting the staffing plan shift to shift for each patient care unit based on factors, such as, the intensity of patient care to provide staffing flexibility to meet patient needs;

(III) include a contingency plan when patient care needs unexpectedly exceed direct patient care staff resources;

(IV) [(I)] reflect current standards established by private accreditation organizations, governmental entities, national nursing professional associations, and other health professional organizations [be consistent with standards established by the Texas nurse licensing board] and should be developed based upon a review of the codes of ethics developed by the nursing profession through national nursing organizations;

(V) [(II)] include a mechanism for evaluating the effectiveness of the official nurse services staffing plan based on patient needs, nursing sensitive quality indicators, nurse satisfaction measures collected by the hospital and evidence based nurse staffing standards. [utilize outcomes and nursing-sensitive indicators as an integral role in setting and evaluating the adequacy of the staffing plan.] At least one from each of the following three types of outcomes shall be correlated to the adequacy of staffing:

(-a-) nurse-sensitive patient outcomes selected by the nurse staffing committee [that are nursing-sensitive], such as, patient falls, adverse drug events, injuries to patients, skin breakdown, pneumonia, infection rates, upper gastrointestinal bleeding, shock, cardiac arrest, length of stay, or patient readmissions;

(-b-) operational outcomes, such as, work-related injury or illness, vacancy and turnover rates, nursing care hours per patient day, on-call use, or overtime rates; and

(-c-) substantiated patient complaints related to staffing levels;

(VI) [(III)] incorporate a process that facilitates the timely and effective identification of concerns about the adequacy of the staffing plan by the nurse staffing

[**advisory**] committee established pursuant to subparagraph (F) [**H**] of this paragraph. This process shall include:

(-a-) a prohibition on retaliation for reporting concerns;

(-b-) a requirement that nurses report concerns timely through appropriate channels within the hospital;

(-c-) orientation of nurses on how to report concerns and to whom;

(-d-) encouraging nurses to provide input to the committee relating to nurse staffing concerns;

(-e-) review, assessment, and response by the committee to staffing concerns expressed to the committee;

~~(-f-) [(-d-)]~~ a process for providing feedback during the [**advisory**] committee meeting on how concerns are addressed by the [**advisory**] committee established under subparagraph (F) [**H**] of this paragraph; and

~~(-g-) [(-e-)]~~ use of the nurse safe harbor peer review process pursuant to Occupations Code, §303.005;

(VII) [(IV)] include policies and procedures that require:

(-a-) orientation of nurses and other personnel who provide nursing care to all patient care units to which they are assigned on either a temporary or permanent basis;

(-b-) that the orientation of nurses and other personnel and the competency to perform nursing services is documented in accordance with hospital policy;

(-c-) that nursing assignments be congruent with documented competency; and

(VIII) be used by the hospital as a component in setting the nurse staffing budget and guiding the hospital in assigning nurses hospital wide.

(iii) The hospital shall make readily available to nurses on each patient care unit at the beginning of each shift the official nurse services staffing plan levels and current staffing levels for that unit and that shift.

[(V)] [when utilized as a means for meeting staffing needs, include policy and procedures for mandatory overtime. The policy and procedures shall include:]

[(-a-)] [documentation of the basis and justification for mandatory overtime;]

[(-b-)] [an action plan for the reduction or elimination of the use of mandatory overtime to meet staffing needs;]

[(-c-)] [a process for monitoring and evaluating the use of mandatory overtime; and]

[(-d-)] [procedures for notifying nurses and other personnel who provide nursing care of the mandatory overtime policy. As used in this subsection, "mandatory overtime" means being required to work, other than on-call time, when not scheduled including beyond hours or days scheduled. Neither the length of the shift (whether 4, 8, 12, or 16 hours) nor the number of shifts scheduled to work (whether 4, 5, or 6 a week) is the determinative factor in defining mandatory overtime.]

(iv) [ii] There shall be a semiannual [an annual] evaluation by the staffing committee of the effectiveness of the official nurse services staffing plan and variations between the staffing plan and actual staffing. [, including an] The evaluation shall consider [of] the outcomes and nursing-sensitive indicators as set out in clause (ii)(V) [(i)(II)] of this subparagraph, patient needs, nurse satisfaction measures collected by the hospital, and evidence based nurse staffing standards. This evaluation shall be documented in the minutes of the [advisory] committee established under subparagraph (F) [(H)] of this paragraph and presented to the hospital's governing body. Hospitals may determine whether this evaluation is done on a unit or facility level basis. To assist the committee with the semiannual evaluation, the hospital shall report to the committee the variations between the staffing plan and actual staffing. This report of variations shall be confidential and not subject to disclosure under Government Code, Chapter 552 and not subject to disclosure, discovery, subpoena or other means of legal compulsion for their release.

(v) [iii] The staffing plan shall be retained for a period of two years.

(H) [(J)] Nonemployee licensed nurses who are working in the hospital shall adhere to the policies and procedures of the hospital. The CNO shall provide for the adequate orientation, supervision, and evaluation of the clinical activities of nonemployee nursing personnel which occur within the responsibility of the nursing services.

(I) The hospital shall annually report to the department on:

(i) whether the hospital's governing body has adopted a nurse staffing policy;

(ii) whether the hospital has established a nurse staffing committee that meets the membership requirements of subparagraph (F) of this paragraph;

(iii) whether the nurse staffing committee has evaluated the hospital's official nurse services staffing plan and has reported the results of the evaluation to the hospital's governing body; and

(iv) the nurse-sensitive outcome measures the committee adopted for use in evaluating the hospital's official nurse services staffing plan.

(3) Mandatory overtime. The hospital shall adopt, implement and enforce policies on use of mandatory overtime.

(A) As used in this subsection:

(i) "on-call time" means time spent by a nurse who is not working but who is compensated for availability; and

(ii) "mandatory overtime" means a requirement that a nurse work hours or days that are in addition to the hours or days scheduled, regardless of the length of a scheduled shift or the number of scheduled shifts each week. In determining whether work is mandatory overtime, prescheduled on-call time or time immediately before or after a scheduled shift necessary to document or communicate patient status to ensure patient safety is not included.

(B) A hospital may not require a nurse to work mandatory overtime, and a nurse may refuse to work mandatory overtime.

(C) This section does not prohibit a nurse from volunteering to work overtime.

(D) A hospital may not use on-call time as a substitute for mandatory overtime.

(E) The prohibitions on mandatory overtime do not apply if:

(i) a health care disaster, such as a natural or other type of disaster that increases the need for health care personnel, unexpectedly affects the county in which the nurse is employed or affects a contiguous county;

(ii) a federal, state, or county declaration of emergency is in effect in the county in which the nurse is employed or is in effect in a contiguous county;

(iii) there is an emergency or unforeseen event of a kind that:

(I) does not regularly occur;

(II) increases the need for health care personnel at the hospital to provide safe patient care; and

(III) could not prudently be anticipated by the hospital; or

(iv) the nurse is actively engaged in an ongoing medical or surgical procedure and the continued presence of the nurse through the completion of the procedure is necessary to ensure the health and safety of the patient. Scheduling nurses for procedures that could be

anticipated to require the nurse to stay beyond the end of their scheduled shift constitutes mandatory overtime and shall be prohibited.

(F) If a hospital determines that an exception exists under subparagraph (E) of this paragraph, the hospital shall, to the extent possible, make and document a good faith effort to meet the staffing need through voluntary overtime, including calling per diems and agency nurses, assigning floats, or requesting an additional day of work from off-duty employees.

(G) A hospital may not suspend, terminate, or otherwise discipline or discriminate against a nurse who refuses to work mandatory overtime.

(4) [(3)] Drugs and biologicals. Drugs and biologicals shall be prepared and administered in accordance with federal and state laws, the orders of the individuals granted privileges by the medical staff, and accepted standards of practice.

(A) All drugs and biologicals shall be administered by, or under supervision of, nursing or other personnel in accordance with federal and state laws and regulations, including applicable licensing rules, and in accordance with the approved medical staff policies and procedures.

(B) All orders for drugs and biologicals shall be in writing, dated, timed, and signed by the individual responsible for the care of the patient as specified under subsection (f)(6)(A) of this section. When telephone or verbal orders must be used, they shall be:

(i) accepted only by personnel who are authorized to do so by the medical staff policies and procedures, consistent with federal and state laws;

(ii) dated, timed, and authenticated within 48 hours by the prescriber or another practitioner who is responsible for the care of the patient and has been credentialed by the medical staff and granted privileges which are consistent with the written orders; and

(iii) used infrequently.

(C) There shall be a hospital procedure for immediately reporting transfusion reactions, adverse drug reactions, and errors in administration of drugs to the attending physician and, if appropriate, to the hospital-wide quality assessment and performance improvement program.

(5) [(4)] Blood transfusions.

(A) Transfusions shall be prescribed in accordance with hospital policy and administered in accordance with a written protocol for the administration of blood and blood components and the use of infusion devices and ancillary equipment.

(B) Personnel administering blood transfusions and intravenous medications shall have special training for this duty according to written, adopted, implemented and enforced hospital policy.

(C) Blood and blood components shall be transfused through a sterile, pyrogen-free transfusion set that has a filter designed to retain particles potentially harmful to the recipient.

(D) The patient must be observed during the transfusion and for an appropriate time thereafter for suspected adverse reactions.

(E) Pretransfusion and posttransfusion vital signs shall be recorded.

(F) When warming of blood is indicated, this shall be accomplished during its passage through the transfusion set. The warming system shall be equipped with a visible thermometer and may have an audible warning system. Blood shall not be warmed above 42 degrees Celsius.

(G) Drugs or medications, including those intended for intravenous use, shall not be added to blood or blood components. A 0.9% sodium chloride injection, United States Pharmacopeia, may be added to blood or blood components. Other solutions intended for intravenous use may be used in an administration set or added to blood or blood components under either of the following conditions:

(i) they have been approved for this use by the Federal Drug Administration; or

(ii) there is documentation available to show that addition to the component involved is safe and efficacious.

(H) There shall be a system for detection, reporting and evaluation of suspected complications of transfusion. Any adverse event experienced by a patient in association with a transfusion is to be regarded as a suspected transfusion complication. In the event of a suspected transfusion complication, the personnel attending the patient shall notify immediately a responsible physician and the transfusion service and document the complication in the patient's medical record. All suspected transfusion complications shall be evaluated promptly according to an established procedure.

(I) Following the transfusion, the blood transfusion record or a copy shall be made a part of the patient's medical record.

(6) [(5)] Reporting and peer review of a vocational or registered nurse. A hospital shall adopt, implement, and enforce a policy to ensure that the hospital complies with the Occupations Code §§301.401-301.403, 301.405 and Chapter 303 (relating to Grounds for Reporting Nurse, Duty of Nurse to Report, Duty of Peer Review Committee to Report, Duty of Person Employing Nurse to Report, and Nursing Peer Review respectively), and with the rules adopted by the Board of Nurse Examiners in 22 TAC §217.16 (relating to Minor Incidents), §217.19 (relating to

Incident-Based Nursing Peer Review), and §217.20 (relating to Safe Harbor Peer Review for Nurses).

(7) [(6)] Policies and procedures related to workplace safety.

(A) The hospital shall adopt, implement and enforce policies and procedures related to the work environment for nurses which:

(i) improve workplace safety and reduce the risk of injury, occupational illness, and violence; and

(ii) increase the use of ergonomic principles and ergonomically designed devices to reduce injury and fatigue.

(B) The policies and procedures adopted under subparagraph (A) of this paragraph, at a minimum, must include:

(i) evaluating new products and technology that incorporate ergonomic principles;

(ii) educating nurses in the application of ergonomic practices;

(iii) conducting workplace audits to identify areas of risk of injury, occupational illness, or violence and recommending ways to reduce those risks;

(iv) controlling access to those areas identified as having a high risk of violence; and

(v) promptly reporting crimes committed against nurses to appropriate law enforcement agencies.

(8) [(7)] Safe patient handling and movement practices.

(A) The hospital shall adopt, implement and enforce policies and procedures to identify, assess, and develop strategies to control risk of injury to patients and nurses associated with the lifting, transferring, repositioning, or movement of a patient.

(B) The policies and procedures shall establish a process that, at a minimum, includes the following:

(i) analysis of the risk of injury to both patients and nurses posed by the patient handling needs of the patient populations served by the hospital and the physical environment in which patient handling and movement occurs;

(ii) education of nurses in the identification, assessment, and control of risks of injury to patients and nurses during patient handling;

(iii) evaluation of alternative ways to reduce risks associated with patient handling, including evaluation of equipment and the environment;

(iv) restriction, to the extent feasible with existing equipment and aids, of manual patient handling or movement of all or most of a patient's weight to emergency, life-threatening, or otherwise exceptional circumstances;

(v) collaboration with and annual report to the nurse staffing committee;

(vi) procedures for nurses to refuse to perform or be involved in patient handling or movement that the nurse believes in good faith will expose a patient or a nurse to an unacceptable risk of injury;

(vii) submission of an annual report to the governing body on activities related to the identification, assessment, and development of strategies to control risk of injury to patients and nurses associated with the lifting, transferring, repositioning, or movement of a patient; and

(viii) development of architectural plans for constructing or remodeling a hospital or a unit of a hospital in which patient handling and movement occurs, with consideration of the feasibility of incorporating patient handling equipment or the physical space and construction design needed to incorporate that equipment at a later date.

(p) – (s) (No change.)

(t) Renal dialysis services.

(1) Hospitals may provide inpatient dialysis services without an additional license under HSC Chapter 251. Hospitals providing outpatient dialysis services shall be licensed under HSC Chapter 251.

(2) Hospitals may provide outpatient dialysis services when the governor or the president of the United States declares a disaster in this state or another state. The hospital may provide outpatient dialysis only during the term of the disaster declaration.

(3) [(1)] Equipment.

(A) Maintenance and repair. All equipment used by a facility, including backup equipment, shall be operated within manufacturer's specifications, and maintained free of defects which could be a potential hazard to patients, staff, or visitors. Maintenance and repair of all equipment shall be performed by qualified staff or contract personnel.

(i) Staff shall be able to identify malfunctioning equipment and report such equipment to the appropriate staff for immediate repair.

(ii) Medical equipment that malfunctions must be clearly labeled and immediately removed from service until the malfunction is identified and corrected.

(iii) Written evidence of all maintenance and repairs shall be maintained.

(iv) After repairs or alterations are made to any equipment or system, the equipment or system shall be thoroughly tested for proper operation before returning to service. This testing must be documented.

(v) A facility shall comply with the federal Food, Drug, and Cosmetic Act, 21 United States Code (USC), §360i(b), concerning reporting when a medical device as defined in 21 USC §321(h) has or may have caused or contributed to the injury or death of a patient of the facility.

(B) Preventive maintenance. A facility shall develop, implement and enforce a written preventive maintenance program to ensure patient care related equipment used in a facility receives electrical safety inspections, if appropriate, and maintenance at least annually or more frequently as recommended by the manufacturer. The preventive maintenance may be provided by facility staff or by contract.

(C) Backup machine. At least one complete dialysis machine shall be available on site as backup for every ten dialysis machines in use. At least one of these backup machines must be completely operational during hours of treatment. Machines not in use during a patient shift may be counted as backup except at the time of an initial or an expansion survey.

(D) Pediatric patients. If pediatric patients are treated, a facility shall use equipment and supplies, to include blood pressure cuffs, dialyzers, and blood tubing, appropriate for this special population.

(E) Emergency equipment and supplies. A facility shall have emergency equipment and supplies immediately accessible in the treatment area.

(i) At a minimum, the emergency equipment and supplies shall include the following:

(I) oxygen;

(II) mechanical ventilatory assistance equipment, to include airways, manual breathing bag, and mask;

(III) suction equipment;

(IV) supplies specified by the medical director;

(V) electrocardiograph; and

(VI) automated external defibrillator or defibrillator.

(ii) If pediatric patients are treated, the facility shall have the appropriate type and size emergency equipment and supplies listed in clause (i) of this subparagraph for this special population.

(iii) A facility shall establish, implement, and enforce a policy for the periodic testing and maintenance of the emergency equipment. Staff shall properly maintain and test the emergency equipment and supplies and document the testing and maintenance.

(F) Transducer protector. A transducer protector shall be replaced when wetted during a dialysis treatment and shall be used for one treatment only.

(4) [(2)] Water treatment and dialysate concentrates.

(A) Compliance required. A facility shall meet the requirements of this section. A facility may follow more stringent requirements than the minimum standards required by this section.

(i) The facility administrator and medical director shall each demonstrate responsibility for the water treatment and dialysate supply systems to protect hemodialysis patients from adverse effects arising from known chemical and microbial contaminants that may be found in improperly prepared dialysate, to ensure that the dialysate is correctly formulated and meets the requirements of all applicable quality standards.

(ii) The facility administrator and medical director must assure that policies and procedures related to water treatment and dialysate are understandable and accessible to the operator(s) and that the training program includes quality testing, risks and hazards of improperly prepared concentrate and bacterial issues.

(iii) The facility administrator and medical director must be informed prior to any alteration of, or any device being added to, the water system.

(B) Water treatment. These requirements apply to water intended for use in the delivery of hemodialysis, including the preparation of concentrates from powder at a dialysis facility and dialysate.

(i) The design for the water treatment system in a facility shall be based on considerations of the source water for the facility and designed by a water quality professional with education, training, or experience in dialysis system design.

(ii) When a public water system supply is not used by a facility, the source water shall be tested by the facility at monthly intervals in the same manner as a public water system as described in 30 TAC, §290.104 (relating to Summary of Maximum Contaminant Levels, Maximum Residual Disinfectant Levels, Treatment Techniques, and Action Levels), and

§290.109 (relating to Microbial Contaminants) as adopted by the Texas Commission on Environmental Quality (TCEQ).

(iii) The physical space in which the water treatment system is located must be adequate to allow for maintenance, testing, and repair of equipment. If mixing of dialysate is performed in the same area, the physical space must also be adequate to house and allow for the maintenance, testing, and repair of the mixing equipment and for performing the mixing procedure.

(iv) The water treatment system components shall be arranged and maintained so that bacterial and chemical contaminant levels in the product water do not exceed the standards for hemodialysis water quality described in §4.2.1 (concerning Water Bacteriology) and §4.2.2 (concerning Maximum Level of Chemical Contaminants) of the American National Standard, Water Treatment Equipment for Hemodialysis Applications, August 2001 Edition, published by the Association for the Advancement of Medical Instrumentation (AAMI). All documents published by the AAMI as referenced in this section may be obtained by writing the following address: 1110 North Glebe Road, Suite 220, Arlington, Virginia 22201.

(v) Written policies and procedures for the operation of the water treatment system must be developed and implemented. Parameters for the operation of each component of the water treatment system must be developed in writing and known to the operator. Each major water system component shall be labeled in a manner that identifies the device; describes its function, how performance is verified and actions to take in the event performance is not within an acceptable range.

(vi) The materials of any components of water treatment systems (including piping, storage, filters and distribution systems) that contact the purified water shall not interact chemically or physically so as to affect the purity or quality of the product water adversely. Such components shall be fabricated from unreactive materials (e.g. plastics) or appropriate stainless steel. The use of materials that are known to cause toxicity in hemodialysis, such as copper, brass, galvanized material, or aluminum, is prohibited.

(vii) Chemicals infused into the water such as iodine, acid, flocculants, and complexing agents shall be shown to be nondialyzable or shall be adequately removed from product water. Monitors or specific test procedures to verify removal of additives shall be provided and documented.

(viii) Each water treatment system shall include reverse osmosis membranes or deionization tanks and a minimum of two carbon tanks in series. If the source water is from a private supply which does not use chlorine/chloramine, the water treatment system shall include reverse osmosis membranes or deionization tanks and a minimum of one carbon tank.

(I) Reverse osmosis membranes. Reverse osmosis membranes, if used, shall meet the standards in §4.3.7 (concerning Reverse Osmosis) of the American National Standard, Water Treatment Equipment for Hemodialysis Applications, August 2001 Edition, published by the AAMI.

(II) Deionization systems.

(-a-) Deionization systems, if used, shall be monitored continuously to produce water of one megohm-centimeter (cm) or greater specific resistivity (or conductivity of one microsiemen/cm or less) at 25 degrees Celsius. An audible and visual alarm shall be activated when the product water resistivity falls below this level and the product water stream shall be prevented from reaching any point of use.

(-b-) Patients shall not be dialyzed on deionized water with a resistivity less than 1.0 megohm-cm measured at the output of the deionizer.

(-c-) A minimum of two deionization (DI) tanks in series shall be used with resistivity monitors including audible and visual alarms placed pre and post the final DI tank in the system. The alarms must be audible in the patient care area.

(-d-) Feed water for deionization systems shall be pretreated with activated carbon adsorption, or a comparable alternative, to prevent nitrosamine formation.

(-e-) If a deionization system is the last process in a water treatment system, it shall be followed by an ultrafilter or other bacteria and endotoxin reducing device.

(III) Carbon tanks.

(-a-) The carbon tanks must contain acid washed carbon, 30-mesh or smaller with a minimum iodine number of 900.

(-b-) A minimum of two carbon adsorption beds shall be installed in a series configuration.

(-c-) The total empty bed contact time (EBCT) shall be at least ten minutes, with the final tank providing at least five minutes EBCT. Carbon adsorption systems used to prepare water for portable dialysis systems are exempt from the requirement for the second carbon and a ten minute EBCT if removal of chloramines to below 0.1 milligram (mg)/1 is verified before each treatment.

(-d-) A means shall be provided to sample the product water immediately prior to the final bed(s). Water from this port(s) must be tested for chlorine/chloramine levels immediately prior to each patient shift.

(-e-) All samples for chlorine/chloramine testing must be drawn when the water treatment system has been operating for at least 15 minutes.

(-f-) Tests for total chlorine, which include both free and combined forms of chlorine, may be used as a single analysis with the maximum allowable concentration of 0.1 mg/liter (L). Test results of greater than 0.5 parts per million (ppm) for chlorine or 0.1

ppm for chloramine from the port between the initial tank(s) and final tank(s) shall require testing to be performed at the final exit and replacement of the initial tank(s).

(-g-) In a system without a holding tank, if test results at the exit of the final tank(s) are greater than the parameters for chlorine or chloramine described in this subclause, dialysis treatment shall be immediately terminated to protect patients from exposure to chlorine/chloramine and the medical director shall be notified. In systems with holding tanks, if the holding tank tests <0.1 mg/L for total chlorine, the reverse osmosis (RO) may be turned off and the product water in the holding tank may be used to finish treatments in process. The medical director shall be notified.

(-h-) If means other than granulated carbon are used to remove chlorine/chloramine, the facility's governing body must approve such use in writing after review of the safety of the intended method for use in hemodialysis applications. If such methods include the use of additives, there must be evidence the product water does not contain unsafe levels of these additives.

(ix) Water softeners, if used, shall be tested at the end of the treatment day to verify their capacity to treat a sufficient volume of water to supply the facility for the entire treatment day and shall be fitted with a mechanism to prevent water containing the high concentrations of sodium chloride used during regeneration from entering the product water line during regeneration.

(x) If used, the face(s) of timer(s) used to control any component of the water treatment or dialysate delivery system shall be visible to the operator at all times. Written evidence that timers are checked for operation and accuracy each day of operation must be maintained.

(xi) Filter housings, if used during disinfectant procedures, shall include a means to clear the lower portion of the housing of the disinfecting agents. Filter housings shall be opaque.

(xii) Ultrafilters, or other bacterial reducing filters, if used, shall be fitted with pressure gauges on the inlet and outlet water lines to monitor the pressure drop across the membrane. Ultrafilters shall be included in routine disinfection procedures.

(xiii) If used, storage tanks shall have a conical or bowl shaped base and shall drain from the lowest point of the base. Storage tanks shall have a tight-fitting lid and be vented through a hydrophobic 0.2 micron air filter. Means shall be provided to effectively disinfect any storage tank installed in a water distribution system.

(xiv) Ultraviolet (UV) lights, if used, shall be monitored at the frequency recommended by the manufacturer. A log sheet shall be used to record monitoring.

(xv) Water treatment system piping shall be labeled to indicate the contents of the pipe and direction of flow.

(xvi) The water treatment system must be continuously monitored during patient treatment and be guarded by audible and visual alarms which can be seen and heard in the dialysis treatment area should water quality drop below specific parameters. Quality monitor sensing cells shall be located as the last component of the water treatment system and at the beginning of the distribution system. No water treatment components that could affect the quality of the product water as measured by this device shall be located after the sensing cell.

(xvii) When deionization tanks do not follow a reverse osmosis system, parameters for the rejection rate of the membranes must assure that the lowest rate accepted would provide product water in compliance with §4.2.2 (concerning Maximum Level of Chemical Contaminants) of the American National Standard, Water Treatment Equipment for Hemodialysis Applications, August 2001 Edition published by the AAMI.

(xviii) A facility shall maintain written logs of the operation of the water treatment system for each treatment day. The log book shall include each component's operating parameter and the action taken when a component is not within the facility's set parameters.

(xix) Microbiological testing of product water shall be conducted.

(I) Frequency. Microbiological testing shall be conducted monthly and following any repair or change to the water treatment system. For a newly installed water distribution system, or when a change has been made to an existing system, weekly testing shall be conducted for one month to verify that bacteria and endotoxin levels are consistently within the allowed limits.

(II) Sample sites. At a minimum, sample sites chosen for the testing shall include the beginning of the distribution piping, at any site of dialysate mixing, and the end of the distribution piping.

(III) Technique. Samples shall be collected immediately before sanitization/disinfection of the water treatment system and dialysis machines. Water testing results shall be routinely trended and reviewed by the medical director in order to determine if results seem questionable or if there is an opportunity for improvement. The medical director shall determine if there is a need for retesting. Repeated results of "no growth" shall be validated via an outside laboratory. A calibrated loop may not be used in microbiological testing of water samples. Colonies shall be counted using a magnifying device.

(IV) Expected results. Product water used to prepare dialysate, concentrates from powder, or to reprocess dialyzers for multiple use, shall contain a total viable microbial count less than 200 colony forming units (CFU)/milliliter (ml) and an endotoxin concentration less than 2 endotoxin units (EU)/ml. The action level for the total viable microbial count in the product water shall be 50 CFU/ml and the action level for the endotoxin concentration shall be 1 EU/ml.

(V) Required action for unacceptable results. If the action levels described at subclause (IV) of this clause are observed in the product water, corrective measures shall be taken promptly to reduce the levels into an acceptable range.

(VI) Records. All bacteria and endotoxin results shall be recorded on a log sheet in order to identify trends that may indicate the need for corrective action.

(xx) If ozone generators are used to disinfect any portion of the water or dialysate delivery system, testing based on the manufacturer's direction shall be used to measure the ozone concentration each time disinfection is performed, to include testing for safe levels of residual ozone at the end of the disinfection cycle. Testing for ozone in the ambient air shall be conducted on a periodic basis as recommended by the manufacturer. Records of all testing must be maintained in a log.

(xxi) If used, hot water disinfection systems shall be monitored for temperature and time of exposure to hot water as specified by the manufacturer. Temperature of the water shall be recorded at a point furthest from the water heater, where the lowest water temperature is likely to occur. The water temperature shall be measured each time a disinfection cycle is performed. A record that verifies successful completion of the heat disinfection shall be maintained.

(xxii) After chemical disinfection, means shall be provided to restore the equipment and the system in which it is installed to a safe condition relative to residual disinfectant prior to the product water being used for dialysis applications.

(xxiii) Samples of product water must be submitted for chemical analysis every six months and must demonstrate that the quality of the product water used to prepare dialysate or concentrates from powder, meets §4.2.2 (concerning Maximum Level of Chemical Contaminants) of the American National Standard, Water Treatment Equipment for Hemodialysis Applications, August 2001 Edition, published by the AAMI.

(I) Samples for chemical analysis shall be collected at the end of the water treatment components and at the most distal point in each water distribution loop, if applicable. All other outlets from the distribution loops shall be inspected to ensure that the outlets are fabricated from compatible materials. Appropriate containers and pH adjustments shall be used to ensure accurate determinations. New facilities or facilities that add or change the configuration of the water distribution system must draw samples at the most distal point for each water distribution loop, if applicable, on a one time basis.

(II) Additional chemical analysis shall be submitted if substantial changes are made to the water treatment system or if the percent rejection of a reverse osmosis system decreased 5.0% or more from the percent rejection measured at the time the water sample for the preceding chemical analysis was taken.

(xxiv) Facility records must include all test results and evidence that the medical director has reviewed the results of the water quality testing and directed corrective action when indicated.

(xxv) Only persons qualified by the education or experience may operate, repair, or replace components of the water treatment system.

(C) Dialysate.

(i) Quality control procedures shall be established to ensure ongoing conformance to policies and procedures regarding dialysate quality.

(ii) Each facility shall set all hemodialysis machines to use only one family of concentrates. When new machines are put into service or the concentrate family or concentrate manufacturer is changed, samples shall be sent to a laboratory for verification.

(iii) Prior to each patient treatment, staff shall verify the dialysate conductivity and pH of each machine with an independent device.

(iv) Bacteriological testing shall be conducted.

(I) Frequency. Responsible facility staff shall develop a schedule to ensure each hemodialysis machine is tested quarterly for bacterial growth and the presence of endotoxins. Hemodialysis machines of home patients shall be cultured monthly until results not exceeding 200 CFU/ml are obtained for three consecutive months, then quarterly samples shall be cultured.

(II) Acceptable limits. Dialysate shall contain less than 200 CFU/ml and an endotoxin concentration of less than 2 EU/ml. The action level for total viable microbial count shall be 50 CFU/ml and the action level for endotoxin concentration shall be 1 EU/ml.

(III) Action to be taken. Disinfection and retesting shall be done when bacterial or endotoxin counts exceed the action levels. Additional samples shall be collected when there is a clinical indication of a pyrogenic reaction and/or septicemia.

(v) Only a licensed nurse may use an additive to increase concentrations of specific electrolytes in the acid concentrate. Mixing procedures shall be followed as specified by the additive manufacturer. When additives are prescribed for a specific patient, the container holding the prescribed acid concentrate shall be labeled with the name of the patient, the final concentration of the added electrolyte, the date the prescribed concentrate was made, and the name of the person who mixed the additive.

(vi) All components used in concentrate preparation systems (including mixing and storage tanks, pumps, valves and piping) shall be fabricated from materials (e.g., plastics or appropriate stainless steel) that do not interact chemically or physically with the concentrate so as to affect its purity, or with the germicides used to disinfect the equipment. The use of

materials that are known to cause toxicity in hemodialysis such as copper, brass, galvanized material and aluminum is prohibited.

(vii) Facility policies shall address means to protect stored acid concentrates from tampering or from degeneration due to exposure to extreme heat or cold.

(viii) Procedures to control the transfer of acid concentrates from the delivery container to the storage tank and prevent the inadvertent mixing of different concentrate formulations shall be developed, implemented and enforced. The storage tanks shall be clearly labeled.

(ix) Concentrate mixing systems shall include a purified water source, a suitable drain, and a ground fault protected electrical outlet.

(I) Operators of mixing systems shall use personal protective equipment as specified by the manufacturer during all mixing processes.

(II) The manufacturer's instructions for use of a concentrate mixing system shall be followed, including instructions for mixing the powder with the correct amount of water. The number of bags or weight of powder added shall be determined and recorded.

(III) The mixing tank shall be clearly labeled to indicate the fill and final volumes required to correctly dilute the powder.

(IV) Systems for preparing either bicarbonate or acid concentrate from powder shall be monitored according to the manufacturer's instructions.

(V) Concentrates shall not be used, or transferred to holding tanks or distribution systems, until all tests are completed.

(VI) If a facility designs its own system for mixing concentrates, procedures shall be developed and validated using an independent laboratory to ensure proper mixing.

(x) Acid concentrate mixing tanks shall be designed to allow the inside of the tank to be rinsed when changing concentrate formulas.

(I) Acid mixing systems shall be designed and maintained to prevent rust and corrosion.

(II) Acid concentrate mixing tanks shall be emptied completely and rinsed with product water before mixing another batch of concentrate to prevent cross contamination between different batches.

(III) Acid concentrate mixing equipment shall be disinfected as specified by the equipment manufacturer or in the case where no specifications are given, as defined by facility policy.

(IV) Records of disinfection and rinsing of disinfectants to safe residual levels shall be maintained.

(xi) Bicarbonate concentrate mixing tanks shall have conical or bowl shaped bottoms and shall drain from the lowest point of the base. The tank design shall allow all internal surfaces to be disinfected and rinsed.

(I) Bicarbonate concentrate mixing tanks shall not be prefilled the night before use.

(II) If disinfectant remains in the mixing tank overnight, this solution must be completely drained, the tank rinsed and tested for residual disinfectant prior to preparing the first batch of that day of bicarbonate concentrate.

(III) Unused portions of bicarbonate concentrate shall not be mixed with fresh concentrate.

(IV) At a minimum, bicarbonate distribution systems shall be disinfected weekly. More frequent disinfection shall be done if required by the manufacturer, or if dialysate culture results are above the action level.

(V) If jugs are reused to deliver bicarbonate concentrate to individual hemodialysis machines:

(-a-) jugs shall be emptied of concentrate, rinsed and inverted to drain at the end of each treatment day;

(-b-) at a minimum, jugs shall be disinfected weekly, more frequent disinfection shall be considered by the medical director if dialysate culture results are above the action level; and

(-c-) following disinfection, jugs shall be drained, rinsed free of residual disinfectant, and inverted to dry. Testing for residual disinfectant shall be done and documented.

(xii) All mixing tanks, bulk storage tanks, dispensing tanks and containers for single hemodialysis treatments shall be labeled as to the contents.

(I) Mixing tanks. Prior to batch preparation, a label shall be affixed to the mixing tank that includes the date of preparation and the chemical composition or formulation of the concentrate being prepared. This labeling shall remain on the mixing tank until the tank has been emptied.

(II) Bulk storage/dispensing tanks. These tanks shall be permanently labeled to identify the chemical composition or formulation of their contents.

(III) Single machine containers. At a minimum, single machine containers shall be labeled with sufficient information to differentiate the contents from other concentrate formulations used in the facility and permit positive identification by users of container contents.

(xiii) Permanent records of batches produced shall be maintained to include the concentrate formula produced, the volume of the batch, lot number(s) of powdered concentrate packages, the manufacturer of the powdered concentrate, date and time of mixing, test results, person performing mixing, and expiration date (if applicable).

(xiv) If dialysate concentrates are prepared in the facility, the manufacturers' recommendations shall be followed regarding any preventive maintenance. Records shall be maintained indicating the date, time, person performing the procedure, and the results (if applicable).

(5) [(3)] Prevention requirements concerning patients.

(A) Hepatitis B vaccination.

(i) With the advice and consent of a patient's attending nephrologist, facility staff shall make the hepatitis B vaccine available to a patient who is susceptible to hepatitis B, provided that the patient has coverage or is willing to pay for vaccination.

(ii) The facility shall make available to patients literature describing the risks and benefits of the hepatitis B vaccination.

(B) Serologic screening of patients.

(i) A patient new to dialysis shall have been screened for hepatitis B surface antigen (HBsAg) within one month before or at the time of admission to the facility or have a known hepatitis B surface antibody (anti-HBs) status of at least 10 milli-international units per milliliter no more than 12 months prior to admission. The facility shall document how this screening requirement is met.

(ii) Repeated serologic screening shall be based on the antigen or antibody status of the patient.

(I) Monthly screening for HBsAg is required for patients whose previous test results are negative for HBsAg.

(II) Screening of HBsAg-positive or anti-HBs-positive patients may be performed on a less frequent basis, provided that the facility's policy on this subject remains congruent with Appendices i and ii of the National Surveillance of Dialysis Associated Disease

in the United States, 2000, published by the United States Department of Health and Human Services.

(C) Isolation procedures for the HBsAg-positive patient.

(i) The facility shall treat patients positive for HBsAg in a segregated treatment area which includes a hand washing sink, a work area, patient care supplies and equipment, and sufficient space to prevent cross-contamination to other patients.

(ii) A patient who tests positive for HBsAg shall be dialyzed on equipment reserved and maintained for the HBsAg-positive patient's use only.

(iii) When a caregiver is assigned to both HBsAg-negative and HBsAg-positive patients, the HBsAg-negative patients assigned to this grouping must be Hepatitis B antibody positive. Hepatitis B antibody positive patients are to be seated at the treatment stations nearest the isolation station and be assigned to the same staff member who is caring for the HBsAg-positive patient.

(iv) If an HBsAg-positive patient is discharged, the equipment which had been reserved for that patient shall be given intermediate level disinfection prior to use for a patient testing negative for HBsAg.

(v) In the case of patients new to dialysis, if these patients are admitted for treatment before results of HBsAg or anti-HBs testing are known, these patients shall undergo treatment as if the HBsAg test results were potentially positive, except that they shall not be treated in the HBsAg isolation room, area, or machine.

(I) The facility shall treat potentially HBsAg-positive patients in a location in the treatment area which is outside of traffic patterns until the HBsAg test results are known.

(II) The dialysis machine used by this patient shall be given intermediate level disinfection prior to its use by another patient.

(III) The facility shall obtain HBsAg status results of the patient no later than three days from admission.

(u) - (v) (No change.)

(w) Surgical services. If a hospital provides surgical services, the services shall be well-organized and provided in accordance with acceptable standards of practice. If outpatient surgical services are offered, the services shall be consistent in quality with inpatient care in accordance with the complexity of services offered. A special hospital may not offer surgical services.

(1) Organization and staffing. The organization of the surgical services shall be appropriate for the scope of the services offered.

(A) - (D) (No change.)

(E) The facility shall adopt, implement, and enforce policies and procedures to comply with Health and Safety Code, Chapter 259 (relating to Surgical Technologists at Health Care Facilities).

(2) (No change.)

(x) - (y) (No change.)

§133.49. Reporting Requirements.

A hospital shall submit reports to the department in accordance with Chapter 200 of this title (relating to Healthcare-Associated Infections) and in accordance with the reporting requirements in Health and Safety Code, §98.103, §98.104, and §98.1045 (relating to Reportable Infections, Alternative for Reportable Surgical Site Infections, and Reporting of Preventable Adverse Events).

Subchapter I. Physical Plant and Construction Requirements

§133.163. Spatial Requirements for New Construction.

(a) - (aa) (No change.)

(bb) Renal dialysis suite. Outpatient renal dialysis shall not be performed in the hospital's inpatient renal dialysis suite unless authorized under §133.41(t) of this title. When outpatient renal dialysis is provided within a hospital building, the service and facilities shall be separated from the hospital with a two-hour fire rated partition. The owner of the outpatient renal dialysis facility must obtain a separate license under Texas Health and Safety Code, Chapter 251, End Stage Renal Disease Facilities. Mechanical, electrical and plumbing services may be contracted from the hospital and the hospital shall maintain all rights and controls of all systems. When inpatient renal dialysis services are provided, the following rooms or areas shall be included.

(1) – (4) (No change.)

(cc) – (ff) (No change.)