

**Department of State Health Services
Council Agenda Memo for State Health Services Council
September 5-6, 2012**

Agenda Item Title: Amendments to rules concerning emergency department staffing and colored alert wrist bands for hospitals

Agenda Number: 5.a

Recommended Council Action:

For Discussion Only

For Discussion and Action by the Council

Background: The Health Facility Licensing Group is located within the Regulatory Licensing Unit, Health Care Quality Section, of the Regulatory Services Division. The Health Facility Licensing Group monitors health care delivery by regulated health care facilities to ensure high quality care is provided to the people of Texas. This Group issues licenses to general and special hospitals and conducts inspections to determine compliance with state and federal rules and regulations. Findings of non-compliance may result in referral for escalated enforcement action.

There are 426 licensed general hospitals and 212 licensed special hospitals in Texas. The budget and source of funding is general revenue and program costs are offset by licensing fees.

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

Amendments to Sections 133.41(e)(2)(C)(i) and 133.81(a) require that general hospitals, except for hospitals designated as critical access hospitals by the Centers for Medicare & Medicaid Services, located in counties with a population of 100,000 or more to have a physician qualified to provide emergency medical care on duty in the hospital at all times and available to initiate appropriate lifesaving care or able to respond by telephone immediately and in person within 20 minutes. The proposed amendments remove the waiver provisions that are currently in the rules.

An amendment to Section 133.41(f)(6) complies with the requirement of Senate Bill (S.B.) 7, Article 5, 82nd Legislature, First Called Session, 2011, which requires the development of a statewide standardized patient risk identification system. The system will enable hospital staff to identify patients with specific medical risks, such as drug allergies, using standardized, colored wrist bands. This system is consistent with, and based upon, the American Hospital Association's recommendations. The American Hospital Association has been advocating for all hospitals to consider using three standardized colors for alert wristbands: red for patient allergies; yellow for a fall risk; and purple for do-not-resuscitate.

Key Health Measures: The rules changes are expected to allow greater flexibility within the hospital to a physician while assigned primary responsibility to the emergency treatment area. In addition, by allowing a physician to be available immediately by telephone and to respond within 20 minutes, other models of health care will be able to comply with licensing standards and maximize the utilization of resources while still protecting patient outcomes. Expected outcomes for hospitals are significantly reducing costs associated with having a physician on duty at all times in a hospital and maximizing resource utilization by allowing a physician when on duty to work in other areas of the hospital in addition to the emergency treatment area.

The rule change for a standardized patient risk identification system is to enable hospital staff to readily identify patients with specific medical risks. It is expected that this practice will result in fewer errors in treatment and improved safety for patients.

DSHS will evaluate compliance with these new rules through onsite initial surveys, resurveys, complaint investigations, and follow-up visits to verify corrective action has been completed for any and all rule violations that have been identified. Resurveys are conducted every three years. Performance measures include the number of facility surveys conducted, the number of complaint investigations conducted, and the percentage of health facilities found to be in compliance.

Summary of Input from Stakeholder Groups: Proposed amendments to Sections 133.41(e)(2)(C)(i) and 133.81(a) are the culmination of extensive stakeholder input that has been obtained from various stakeholders, in writing and via multiple workgroup sessions. DSHS amended the rule related to emergency department requirements on June 21, 2007, and the current rule requires physicians to be present at all times in the emergency treatment areas (for hospitals in counties with populations of 100,000 or more); it also included waiver provisions. Since that time, this rule has been under continual review due to stakeholder feedback.

The proposed language was presented at a stakeholder meeting in October 2011 that included representatives from urban and rural hospitals, the Texas Hospital Association, other trade and professional organizations, and state agencies. The proposed amendments were subsequently presented during the November 2011 and February 2012 State Health Services Council Work Sessions. As a result of input received from stakeholders at that time, the draft language has been modified to include a provision that allows an emergency physician to be able to respond by telephone immediately and within 20 minutes to present, in person, to the emergency department. Waiver provisions for emergency services personnel will not be allowed.

An appointment of an ad hoc committee to assist DSHS in developing a statewide standardized patient risk identification system was required by S.B. 7 and DSHS solicited nominations from hospital stakeholder organizations. Seven nominations were received and all nominees were appointed to the Patient Risk Identification ad hoc committee.

The ad hoc committee by consensus made recommendations to: 1) adopt the American Hospital Association's three standard conditional alert colors; 2) allow hospitals six months to implement use of the standard alert colors following adoption of the DSHS rule; 3) add two "optional" condition alert colors – green for patients with a latex allergy and pink for patients with restricted extremity, and if hospitals adopt the use of the optional colors that the hospitals must use the colors as recommended; 4) allow hospitals an additional six months to implement use of the optional colors; 5) allow hospitals to determine their own policies and procedures regarding removal of personal wristbands, as well as the patients right to refuse a conditional alert wrist band.

Proposed Motion:

Motion to recommend HHSC approval for publication of rules contained in agenda item #5.a.

Approved by Assistant Commissioner/Director: Kathryn C. Perkins, R.N., M.B.A **Date:** 8/23/2012

Presenter: Ellen Cooper, Health Facilities Group Manager **Program:** Regulatory Licensing Unit **Phone No.:** 512/834-6639

Approved by CCEA: Carolyn Bivens **Date:** 8/23/2012

Title 25. Health Services
Part 1. Department of State Health Services
Chapter 133. Hospital Licensing
Subchapter C. Operational Requirements.
Amendment §133.41
Subchapter E. Waiver Provisions.
Amendment §133.81

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 §133.41(e) (Emergency Services); §133.41(f)(Governing Body) and §133.81(a)(Request for a Waiver) concerning the regulation of hospitals.

BACKGROUND AND PURPOSE

The proposed amendments to §133.41(e)(2)(C)(i) and §133.81(a) require that general hospitals, except for hospitals designated as critical access hospitals (CAHs) by the Centers for Medicare & Medicaid Services (CMS), located in counties with a population of 100,000 or more to have a physician qualified to provide emergency medical care on duty in the hospital at all times and available to initiate appropriate lifesaving care; or able to respond immediately by telephone, and in person within 20 minutes to initiate appropriate lifesaving care. The current rule requires the physician on duty to be limited to and exclusively available in the emergency treatment area. Current waiver provisions for this rule are being removed.

The proposed amendment to §133.41(f)(6) is required for the implementation of Senate Bill 7, Article 5, 82nd Legislature, First Called Session, 2011, which added Health and Safety Code, §311.004, and requires the development of a statewide standardized patient risk identification system. The purpose of this system is to better enable hospital staff to readily identify patients with specific medical risks, such as drug allergies, using standardized, colored wrist bands. This system is consistent with, and based upon, the American Hospital Association's recommendations.

SECTION-BY-SECTION SUMMARY

The proposed rule amendments to §133.41(e)(2)(C)(i) concerning emergency services eliminates the requirement that a physician qualified to provide emergency medical care be on duty in the emergency department treatment area at all times. The amended rule requires that General hospitals, except for hospitals designated as CAHs by CMS, located in counties with a population of 100,000 or more to have a physician qualified to provide emergency medical care on duty in the hospital at all times and available to initiate appropriate lifesaving care; or able to respond immediately by telephone, and in person within 20 minutes to initiate appropriate lifesaving care.

The proposed rule amendment to §133.81(a) regarding waiver provisions removes emergency services personnel from being eligible to be waived by the department.

The proposed rule amendment to §133.41(f)(6) concerning the governing body will be revised by adding subparagraphs (D), (E) and (F). The new language requires the governing body to ensure that specific colored alert wrist bands are utilized in hospitals as follows: red wrist bands for allergies; yellow wrist bands for fall risks; and purple wrist bands for do-not-resuscitate status. New language also allows the governing body to consider use of optional condition alert wrist bands as follows: green wrist bands for latex allergies and pink wrist bands for restricted extremity. In addition, new language requires the

governing body to implement and enforce a policy and procedure regarding removal of personal wrist bands and bracelets as well as a patient's right to refuse to wear condition alert wrist bands. Section 133.41(f)(6)(B) and (C) were amended for punctuation clarification.

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 also has determined that there will not be an adverse economic impact on small businesses or micro-businesses required to comply with the sections as proposed because this was determined by interpretation of the rules that small business and micro-businesses will not be required to alter their business practices in order to comply with the sections.

ECONOMIC COSTS TO PERSONS AND IMPACT ON LOCAL EMPLOYMENT

There are no economic costs anticipated to persons who are required to comply with the sections as proposed. There is no anticipated impact on local employment.

PUBLIC BENEFIT

In addition, Ms. Clack also has 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, personnel, and the public.

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 Ellen Cooper, Manager, Facility Licensing Group, Regulatory Licensing Unit, Division of Regulatory Services, Department of State Health Services, P.O. Box 149347, Mail Code 2835, Austin, Texas 78714-9347, (512) 834-6639 or by email to ellen.cooper@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 amendments are authorized by Health and Safety Code, §241.026, concerning rules and minimum standards for the licensing and regulation of hospitals required to obtain a license under this chapter; Health and Safety Code, §311.004, which requires the development of a statewide standardized patient risk identification system; and 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 amendments affect Health and Safety Code, Chapters 241, 311, and 1001; and Government Code, Chapter 531.

Legend: (Proposed Amendment(s))

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 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) (No change.)

(2) Personnel.

(A) - (B) (No change.)

(C) Except for comprehensive medical rehabilitation hospitals and pediatric and adolescent hospitals that generally provide care that is not administered for or in expectation of compensation, the hospital shall provide that one or more physicians shall be available at all times for emergencies, as follows.

(i) General hospitals, except for hospitals designated as critical access hospitals (CAHs) by the Centers for Medicare & Medicaid Services (CMS), located in counties with a population of 100,000 or more shall have a physician qualified to provide emergency medical care on duty in the hospital [emergency treatment area] at all times and available to initiate appropriate lifesaving care; or able to respond immediately by telephone, and in person within 20 minutes to initiate appropriate lifesaving care.

(ii) (No change.)

(D) (No change.)

(3) - (6) (No change.)

(f) Governing body.

(1) - (5) (No change.)

(6) Patient care. In accordance with hospital policy adopted, implemented and enforced, the governing body shall ensure that:

(A) (No change.)

(B) patients are admitted to the hospital only by members of the medical staff who have been granted admitting privileges; **[and]**

(C) a physician is on duty or on-call at all times; **[.]**

(D) specific colored condition alert wrist bands that have been standardized for all hospitals licensed under Health and Safety Code, Chapter 241, are used as follows:

(i) red wrist bands for allergies;

(ii) yellow wrist bands for fall risks; and

(iii) purple wrist bands for do not resuscitate status.

(E) the governing body shall consider the addition of the following optional condition alert wrist bands. This consideration must be documented in the minutes of the meeting of the governing body in which the discussion was held:

(i) green wrist bands for latex allergy; and

(ii) pink wrist bands for restricted extremity; and

(F) the governing body shall adopt, implement, and enforce a policy and procedure regarding the removal of personal wrist bands and bracelets as well as a patient's right to refuse to wear condition alert wrist bands.

(7) - (8) (No change.)

(g) - (y) (No change.)

Subchapter E. Waiver Provisions.

§133.81. Waiver Provisions.

(a) Request for a waiver. A hospital may submit a written request to the director for a waiver or modification of a particular provision of the Texas Hospital Licensing Act (Act) or a minimum standard in this chapter, except fire safety requirements and emergency services personnel. The written request shall specify the section(s) of the Act or this chapter for which a waiver is requested.

(b) - (g) (No change.)