

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

Agenda Item Title: Amendments to rules concerning the regulation of ambulatory surgical centers

Agenda Number: 3.a.iv.

Recommended Council Action:

For Discussion Only

For Discussion and Action by the Council

Background:

The Health Facility Program is located within the Regulatory Licensing Unit, Health Care Quality Section, of the Regulatory Services Division. The Health Facility Program issues licenses to ambulatory surgical centers 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, 96 standard and complaint surveys were conducted, with one facility found in noncompliance. The final outcome of noncompliance is available to the public.

There are 394 licensed ambulatory surgical centers. The program routinely monitors complaints received and resolved, numbers of new and renewed licenses, numbers of disciplinary actions taken, and violation trends. The number of complaints received, enforcement actions, inspections performed, and licensing actions are monitored on a quarterly basis.

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 243, that requires ambulatory surgical centers be licensed by the Department of State Health Services (DSHS). The rules establish the licensing procedures and standards of operation for ambulatory surgical centers to protect the health, safety, and welfare of patients receiving services in ambulatory surgical centers, personnel, and the public.

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

- 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 ambulatory surgical centers to employ only individuals who have the appropriate education, certification, or experience in surgical technology.
- 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 ambulatory surgical centers. This rule change allows DSHS to make available ambulatory surgical center 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.

Summary of Input from Stakeholder Groups:

The proposed draft rules were posted on the DSHS website on December 23, 2009. An email announcement was sent to the following stakeholders on December 23, 2009, to advise them of the proposed changes to the licensing rules that incorporate legislation and to request comments.

- Texas State Board of Pharmacy
- Texas Physician Owned Hospital Advocacy Center
- Texas Medical Association
- Texas Association of Nurse Anesthetists
- Texas Society of Anesthesiologists
- Texas Hospital Association
- Texas Organization of Rural and Community Hospitals
- Texas Board of Nursing
- Texas Medical Board
- Texas Nurses Association
- Texas Medical Foundation
- Texas Association of Healthcare Facilities Management
- United Surgical Partners
- Austin Pain Associates
- Ambulatory Surgery Center Association
- Texas Department of State Health Services staff
- Representatives from hospitals
- Individuals
- Attorneys and representatives from law offices

An overview of the proposed draft rules was presented at the DSHS Council work session meeting on January 21, 2010.

A meeting was held on January 26, 2010, with a stakeholder group who provided written comments. The stakeholder group discussed that the reporting of the types of infections or adverse events should include language that is more specific instead of adopting Health and Safety Code, Chapter 98, by reference. The DSHS Division of Prevention and Preparedness will be amending rules to implement the specific reporting of infections or adverse events in 25 TAC, Chapter 200.

Proposed Motion:

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

Approved by Assistant Commissioner/Director: Kathryn C Perkins	Date: 3/12/2010	
Presenter: Beth Pickens	Program: Health Care Quality Section	Phone No.: 834-6752
Approved by CPCPI: Carolyn Bivens	Date: 3/12/2010	

Title 25. HEALTH SERVICES
Part 1. DEPARTMENT OF STATE HEALTH SERVICES
Chapter 135. Ambulatory Surgical Centers
Subchapter A. Operating Requirements for Ambulatory Surgical Centers
Amendment §§135.2, 135.15, and 135.26

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 §135.2, §135.15, and §135.26, concerning the regulation of ambulatory surgical centers.

BACKGROUND AND PURPOSE

The amendments to §135.2 and §135.15 are necessary to comply with House Bill 643, 81st Legislature, Regular Session, 2009, which added Health and Safety Code, Chapter 259, relating to surgical technologists. House Bill 643 requires ambulatory surgical centers to comply with qualification standards for employment of surgical technologists.

The amendment to §135.26 is necessary to comply with Senate Bill (SB) 203, 81st Legislature, Regular Session, 2009, which 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 ambulatory surgical centers as required by Health and Safety Code, Chapter 243.

SECTION-BY-SECTION SUMMARY

An amendment to §135.2(21) adds the definition of “surgical technologist” as defined in Health and Safety Code, Chapter 259. An amendment to §135.15 requires ambulatory surgical centers to adopt, implement, and enforce policies related to the employment of surgical technologists.

An amendment to §135.26 requires ambulatory surgical centers to report to the department incidents of certain health care-associated infections and preventable adverse events, 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.

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 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 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 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 ambulatory surgical centers, 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 Beth Pickens, Health Care Quality Section, Division of Regulatory Services, Department of State Health Services, P.O. Box 148347, 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 amendments are authorized by Health and Safety Code, §243.009, concerning rules and minimum standards for the licensing and regulation of ambulatory surgical centers; Health and Safety Code, Chapter 259, concerning the surgical technologists at health care facilities; Health and Safety Code, Chapter 98, concerning the reporting the of health care-associated infections; 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 the Health and Safety Code, Chapters 98, 243, 259, 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. Operating Requirements for Ambulatory Surgical Centers.

§135.2. Definitions.

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

(1) – (20) (No change.)

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

(22) [(21)] Title XVIII--Title XVIII of the United States Social Security Act, 42 United States Code (USC), §§1395 et seq.

§135.15. Facility Staffing and Training.

(a) Nursing services.

(1) (No change.)

(2) There shall be a written plan of administrative authority for all nursing services with responsibilities and duties of each category of nursing personnel delineated and a written job description for each category. The scope of nursing service shall include, but is not limited to, nursing care rendered to patients preoperatively, intraoperatively, and postoperatively.

(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).

(3) - (4) (No change.)

(b) (No change.)

§135.26. Reporting Requirements.

(a) – (d) (No change.)

(e) The ASC 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).

(f) [(e)] Occurrences of fire in the ASC shall be reported as specified under §135.41(a)(2) of this title (relating to Fire Prevention and Protection) and §135.43(b)(6) of this title (relating to Handling and Storage of Gases, Anesthetics, and Flammable Liquids).