

**Department of State Health Services
Council Agenda Memo for State Health Services Council
February 26-27, 2014**

Agenda Item Title: Amendment to rule concerning the licensing of device distributors and manufacturers

Agenda Number: 5.f

Recommended Council Action:

For Discussion Only

For Discussion and Action by the Council

Background:

The Food and Drug programs in the Division for Regulatory Services provide a regulatory structure to protect and promote the health of citizens of Texas through licensing, inspection, and enforcement activities associated with the operation of device distributors and manufacturers. Food and Drug programs license and inspect approximately 3,199 device distributors and manufacturers in Texas.

Food and Drug programs routinely monitor complaints against device distributors and manufacturers, including the receipt, investigation, and resolution of these complaints. In addition, Food and Drug programs receive and process license applications and track disciplinary actions taken in response to findings of violation. The number of complaints received, inspections conducted, enforcement actions taken, and licenses issued are monitored on a quarterly basis.

Funding for the Food and Drug device distributor and manufacturer program is generated from fees charged for licenses issued to operate device distributor and manufacturer establishments in Texas.

Summary:

The purpose of the amendment is to implement House Bill (HB) 1395, 83rd Legislature, Regular Session, 2013, which amended Health and Safety Code, Chapter 431, Texas Food, Drug and Cosmetic Act. The rules establish licensing standards for device distributor and manufacturer establishments to ensure that safe and effective medical devices are distributed and manufactured at these establishments.

HB 1395 exempts a person from licensing as a device distributor or manufacturer if the person holds a registration certificate issued under Occupations Code, Chapter 266, Regulation of Dental Laboratories, and engages only in conduct within the scope of that registration. The proposed amendment will update and conform the rule requirements to this exemption.

Key Health Measures:

The proposed amendment is expected to result in a more effective use of DSHS resources since persons will not be unnecessarily subjected to duplicative licensing requirements.

Regulatory staff will measure compliance with the amended rule during routine inspections of device distributors and manufacturers and inform firms of the exemption when applicable. It is estimated only a small number of the 3,000+ licensees will be eligible for this exemption.

Summary of Input from Stakeholder Groups:

A draft of the proposed amendment concerning licensing of device distributors and manufacturers was posted for comment on the Drugs and Medical Devices Group website at www.dshs.state.tx.us/dmd. The proposed rules have been posted on the website for approximately 30 days and no comments have been received.

Proposed Motion:

Motion to recommend HHSC approval for publication of the rule contained in agenda item #5.f.

Approved by Assistant Commissioner/Director: Kathryn C. Perkins, R.N., M.B.A. **Date:** 2/13/2014

Presenter: Tom Brinck, Manager, **Program:** Policy, Standards and Quality **Phone No.:** (512) 834-6755
Drugs and Medical Assurance Unit / Environmental
Devices Group and Consumer Safety Section

Approved by CCEA: Carolyn Bivens **Date:** 2/12/2014

Title 25. Health Services
Part 1. Department of State Health Services
Chapter 229. Food and Drug
Subchapter X. Licensing of Device Distributors and Manufacturers
Amendments §229.434

Proposed Preamble

The Executive Commissioner of the Health and Human Services Commission, on behalf of the Department of State Health Services (department), proposes an amendment to §229.434, concerning the licensing of device distributors and manufacturers.

BACKGROUND AND PURPOSE

The amendment implements House Bill (HB) 1395, 83rd Legislature, Regular Session, 2013, which amends Health and Safety Code, §431.273, exempting persons from licensing as device distributors or manufacturers if the person holds a registration certificate issued under Occupations Code, Chapter 266, Regulation of Dental Laboratories, and engages only in conduct within the scope of that registration.

SECTION-BY-SECTION SUMMARY

The amendment to §229.434 adds subsection (b) to define new statutory licensing exemption requirements for device distributors and manufacturers. The amendment also renumbers existing subsection (b) as subsection (c) and corrects citations and grammar.

FISCAL NOTE

Jon Huss, Section Director, Environmental and Consumer Safety Section, has determined that for each year of the first five years that the section is in effect, there will be no fiscal implications to state or local government as a result of enforcing or administering the section as proposed.

SMALL AND MICRO-BUSINESS IMPACT ANALYSIS

Mr. Huss has also determined that there will be no adverse effect on small businesses or micro-businesses required to comply with the section as proposed. This is determined by interpretation of the rule that small businesses and micro-businesses will not be required to alter their business practices in order to comply with the section.

ECONOMIC COST TO PERSONS AND IMPACT ON LOCAL EMPLOYMENT

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

PUBLIC BENEFIT

In addition, Mr. Huss has also determined that for each year of the first five years the section is in effect, the public will benefit from adoption of the section. The public benefit anticipated as

the result of administering and enforcing the section is to ensure that if a person holds a registration certificate as a dental laboratory under Occupations Code, Chapter 266, and engages only in conduct within the scope of that registration, that person will not be unnecessarily subjected to duplicative licensing requirements as device distributors or manufacturers, thereby resulting in a more effective use of department resources.

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 the 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 public health and safety of a state or sector of the state.

TAKINGS IMPACT ASSESSMENT

The department has determined that the proposed amendment 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 Tom Brinck, Manager, Drugs and Medical Devices Group, Policy, Standards and Quality Assurance Unit, Environmental and Consumer Safety Section, Division for Regulatory Services, P.O. Box 149347, Mail Code 1987, Austin, Texas 78714-9347, (512) 834-6755, extension 2388, or by email to tom.brinck@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 rule has been reviewed by legal counsel and found to be within the state agencies’ authority to adopt.

STATUTORY AUTHORITY

The amendment is authorized by Health and Safety Code, §431.241, which provides the department with authority to adopt rules to enforce the Texas Food, Drug and Cosmetic Act; 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 and enforcement of the Health and Safety Code, Chapter 1001.

The amendment affects the Health and Safety Code, Chapters 431, and 1001; and Government Code, Chapter 531.

Legend: (Proposed Amendment)

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

§229.434. Exemptions.

(a) A person is exempt from licensing under §229.435 of this title (relating to Licensure Requirements) **[these sections]** if the person engages only in the following types of device distribution:

(1) - (3) (No change.)

(b) A person is exempt from licensing under §229.435 of this title if the person holds a registration certificate issued under Occupations Code, Chapter 266, and engages only in conduct within the scope of that registration.

(c) [(b)] This section **[An exemption from the licensing requirements under these sections]** does not exempt a person **[constitute an exemption]** from other applicable provisions of the Texas Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431; the Texas Dangerous Drug Act, Health and Safety Code, Chapter 483; or the rules adopted to administer and enforce those chapters **[the Acts]**.