

**Department of State Health Services
Agenda Item for State Health Services Council
January 12-13, 2006**

Agenda Item Title: 25 TAC Chapter 128 - Amendments relating to the permitting and regulation of contact lens dispensers.

Agenda Number: 3h

Recommended Council Action:

For Discussion Only

For Discussion and Action by the Council

Background:

The Contact Lens Dispensing Permit Program is a regulatory program which issues and renews permits for individuals and businesses dispensing contact lenses.

Summary:

The amendments implement House Bill (HB) 1025, 79th Legislature, Regular Session (2005), Sunset legislation, relating to the continuation and functions of the Texas Optometry Board, with conforming amendments to the Texas Contact Lens Prescription Act as required by the federal "Fairness to Contact Lens Consumers Act"(Public Law 108-164), and federal rules implementing the law, 16 CFR Part 315 (Contact Lens Rule); HB 2680, 79th Legislature, Regular Session (2005), relating to reduced fees and continuing education requirements for retired health professionals, including contact lens permit holders, engaged in the provision of voluntary charity care; and HB 164, 79th Legislature, Regular Session (2005), relating to amendments to the Health and Safety Code (HSC), including prohibiting the sale of prescription devices, including contact lenses, at a flea market. The amendments also implement HSC, §12.0111, which requires the department to charge fees for issuing or renewing a license.

Summary of Stakeholder Input to Date (including advisory committees):

n/a

Proposed Motion: Motion to recommend to HHSC approval for publication of rules contained in agenda item # 3h.

Agenda Item Approved by: Richard B. Bays /s/

Date Submitted

Presented by: Debbie Peterson **Title:** Unit Manager

11/30/05

Program/Division: PLC **Contact Name/Phone:** Debbie Peterson 834-2725

Title 25. HEALTH SERVICES
Part 1. DEPARTMENT OF STATE HEALTH SERVICES
Chapter 128. Permits for Contact Lens Dispensers
Amendments §§128.1 - 128.5, 128.9, 128.14

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 §§128.1 - 128.5, 128.9, and 128.14, concerning the permitting and regulation of contact lens dispensers.

BACKGROUND AND PURPOSE

The Texas Legislature passed House Bill (HB) 1025, 79th Legislature, Regular Session (2005), Sunset legislation, located in Occupations Code, Chapter 351, relating to the continuation and functions of the Texas Optometry Board, with conforming amendments to the Texas Contact Lens Prescription Act as required by the federal "Fairness to Contact Lens Consumers Act"(Public Law 108-164), and federal rules implementing the law, 16 CFR Part 315 (Contact Lens Rule); HB 2680, 79th Legislature, Regular Session (2005), located in Occupations Code, Chapter 112, relating to reduced fees and continuing education requirements for retired health professionals, including contact lens permit holders, engaged in the provision of voluntary charity care; and HB 164, 79th Legislature, Regular Session (2005), relating to amendments to the Health and Safety Code (HSC), Chapter 431, including prohibiting the sale of prescription devices, including contact lenses, at a flea market. The amendments also implement HSC, §12.0111, which requires the department to charge fees for issuing or renewing a license.

SECTION-BY-SECTION SUMMARY

Amendments to §128.1 reflect the new section name for §128.5, and include a prescription verification requirement. Amendments to §128.2 reflect changes required by the abolishment of the "Board of Health"; and the addition of "Executive Commissioner." The section has been renumbered to reflect deletions and insertions. Amendments to §128.3 reflect the new reduced fee for renewal for a retired contact lens dispenser providing voluntary charity care required by HB 2680 of \$50 (for a retired optician registered with the department) and \$75 (for a retired optician not registered with the department) for each two year renewal. Amendments to §128.4 remove obsolete language related to the abolished Board of Health. Amendments to §128.5 require that a record of a prescription or prescription verification be retained for a period of two years, and include the new requirement in federal and state law for prescription verification, including standards for verification. The section also authorizes the executive commissioner of HHSC and the executive director of the Texas Optometry Board to enter into interagency agreements as necessary to enforce the rules. The section also reflects the prohibition on the sale of contact lenses at a flea market. The name of the section is amended to reflect the standards for verification. Amendments to §128.9 reflect the renewal requirements for a retired contact lens dispenser providing voluntary charity care required by HB 2680. An amendment to §128.14 reflects a name change from "Division" to "Unit" necessitated by reorganization with the department.

FISCAL NOTE

Kathy Perkins, Director, Health Care Quality Section, has determined that for each year of the first five years the sections are in effect, there will be minimal fiscal implications to state or local government as a result of enforcing or administering the sections as proposed. The impact of the possible decrease in renewal fees collected due to the implementation of reduced renewal fees for retired contact lens dispensers over the age of 55 providing voluntary charity care is insignificant due to the small population of retired contact lens dispensers anticipated to provide charity care services.

SMALL AND MICRO-BUSINESS IMPACT ANALYSIS

Ms. Perkins has also determined that there will be no effect on small businesses or micro-businesses required to comply with the sections as proposed. This determination was made because the amendments implement Federal laws -which are already in effect. There is no anticipated economic cost to persons who are required to comply with the sections as proposed. There is no anticipated negative impact on local employment.

PUBLIC BENEFIT

In addition, Ms. Perkins has also determined that for each year of the first five years the sections are in effect, the public will benefit from the adoption of the sections. The public benefit anticipated as a result of enforcing or administering the sections is to continue to ensure public health and safety through the permitting and regulation of contact lens dispensers.

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 Yvonne Feinleib, Program Director, Contact Lens Dispensing Permit Program, Professional Licensing and Certification Unit, Division for

Regulatory Services, Department of State Health Services, 1100 West 49th Street, Austin, Texas 78756, 512/834-4521 or by email to Yvonne.Feinleib@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, Cathy Campbell, 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 proposed amendments to §128.4 are authorized by Health and Safety Code, §12.0111, which requires the department to charge fees for issuing or renewing a license; 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 Chapter 1001, Health and Safety Code.

The proposed amendments affect the Occupations Code, Chapter 353, Health and Safety Code, Chapters 12 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

§128.1. Introduction.

(a) (No change.)

(b) These sections cover definitions; permit fees; petition for rulemaking; sale or delivery of contact lenses and prescription verification; display of permit; permit application requirements and procedures; renewal of permits; name and address changes; filing complaints and complaint investigations; grounds for disciplinary actions; informal dispositions; formal hearings; and guidelines for issuing permits to persons with criminal convictions.

§128.2. Definitions.

The following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise. Words and terms defined in the Texas Contact Lens Prescription Act shall have the same meaning in this chapter as that assigned in the Act.

(1) - (4) (No change.)

[(5) Board--The Texas Board of Health.]

(5)[(6) Commissioner--The Commissioner of the [Texas] Department of State Health Services.

(6)[(7)] Department--The [Texas] Department of State Health Services.

(7) Executive Commissioner--The Executive Commissioner of the Health and Human Services Commission.

(8) - (9) (No change.)

§128.3. Fees.

(a) The permit fees are as follows:

(1) (No change.)

(2) \$75 for a one-year term and \$150 for a two-year term for an optician who has not registered with the department under the Opticians' Registry Act, Occupations Code, Chapter 352; **[and]**

(3) \$50 for a two-year term for a retired optician providing voluntary charity care who has registered with the department under the Opticians' Registry Act, Occupations Code, Chapter 352;

(4) \$75 for a two-year term for a retired optician who has not registered with the department under the Opticians' Registry Act, Occupations Code, Chapter 352; and

(5)[(3)] \$300 for a one-year term and \$600 for a two-year term for a business entity.

(b) - (c) (No change.)

§128.4. Petition for Rulemaking.

The Executive Commissioner's [board's] procedures for the submission, consideration, and disposition of a petition to adopt a rule are set out in 1 TAC §351.2 [§1.81 of this title] (relating to Petition for the Adoption of a Rule).

§128.5. Sale or Delivery of Contact Lenses and Prescription Verification.

(a) An individual or business holding a permit shall comply with the federal "Fairness to Contact Lens Consumers Act" Public Law 108-164, and applicable standards in Occupations Code, Chapter 353. [If federal and state laws establish conflicting standards for the dispensing of contact lenses, permit holders shall comply with federal law.]

(1) A permit holder may not deliver or dispense contact lenses to a customer unless the permit holder:

(A) receives a valid prescription directly or by facsimile; or

(B) verifies a prescription in accordance with this subsection.

(2) A permit holder shall retain an electronic or paper record of each prescription or verification for a minimum of two years from the last date lenses were dispensed based on that prescription or verification. The record shall contain all information specified by federal and state laws and rules related to requirements for a prescription or verification, including any authorized modification showing the number of lenses dispensed. If the prescription is extended by the prescriber, a record of the extension or verification of the extension shall also be maintained.

(3) A permit holder may not sell, deliver, or dispense contact lenses in a flea market.

(b) A prescription is considered verified if it meets the standards for verification set out by federal law, the "Fairness to Contact Lens Consumers Act" (Public Law 108-164), federal rules, 16 CFR Part 315 (Contact Lens Rule) and state law, Occupations Code, §353.1015.

(c) A prescription may only be verified by direct communication, which means completed communication by telephone, facsimile, or electronic mail. A prescription is verified only if one of the following occurs:

(1) the prescriber confirms the prescription is accurate by direct communication with the permit holder;

(2) the prescriber informs the permit holder through direct communication that the prescription is inaccurate and provides the accurate prescription; or

(3) the prescriber fails to communicate with the permit holder within eight business hours after receiving from the permit holder the information described in subsection (d) of this section.

(d) It is the responsibility of the permit holder to provide the prescriber with all information required by federal and state law for the verification of a prescription, including:

(1) the patient's full name and address;

(2) the contact lens power, manufacturer, base curve or appropriate designation, and diameter when appropriate;

(3) the quantity of lenses ordered;

(4) the date of patient request;

(5) the date and time of verification request; and

(6) the name of a contact person at the permit holder's company, including facsimile and telephone numbers.

(e) If the permit holder opts to include the prescriber's regular business hours on Saturdays as "business hours" as specified by subsection (c)(3) of this section, a clear statement of the prescriber's regular Saturday business hours must be included with the verification request.

(f) If a permit holder attempts to verify a prescription, and a prescriber informs a permit holder before the deadline specified by subsection (c)(3) of this section that the contact lens prescription is inaccurate, expired, or otherwise invalid, the permit holder shall not fill the prescription. The prescriber shall specify the basis for the inaccuracy or invalidity of the

prescription. If the prescription communicated by the permit holder to the prescriber is inaccurate, the prescriber shall correct it, and the prescription shall then be deemed verified.

(g) During the eight business hours specified by subsection (c)(3) of this section, the permit holder shall provide a reasonable opportunity for the prescriber to communicate with the permit holder concerning the verification request.

(h) The Executive Commissioner and the executive director of the Texas Optometry Board may enter into interagency agreements as necessary to implement and enforce this chapter.

§128.9. Renewal of Permit.

(a) - (l) (No change.)

(m) A retired individual permit holder who wishes to dispense contact lenses only in the provision of voluntary charity care may renew the permit every two years by submitting the renewal form and the retired contact lens dispenser renewal fee in accordance with the renewal procedures described in this section. Voluntary charity care means dispensing contact lenses at no cost to the consumer. A retired contact lens dispenser who renews under this subsection may not sell contact lenses or receive any remuneration for dispensing lenses.

(n) [(m)] A permit holder whose check for the renewal fee is not honored by the financial institution shall remit to the department a money order or cashier's check within 30 days of the date of the permit holder's receipt of the department's notice. If proper payment is not received, the permit shall not be renewed. If a renewed permit has already been issued, it shall be ineffective.

(o) [(n)] If a permit holder fails to timely renew his or her permit because the permit holder is or was on active duty with the armed forces of the United States of America serving outside the state of Texas, the permit holder may renew the permit pursuant to this subsection.

(1) Renewal of the permit may be requested by the permit holder, the permit holder's spouse, or an individual having power of attorney from the permit holder. The renewal form shall include a current address and telephone number for the individual requesting the renewal.

(2) Renewal may be requested before or after expiration of the permit. Permit holders who renew in accordance with this subsection shall be excused from paying late fees and penalties.

(3) A copy of the official orders or other official military documentation showing that the permit holder is or was on active duty serving outside the State of Texas shall be filed with the department along with the renewal form.

(4) A copy of the power of attorney from the permit holder shall be filed with the department along with the renewal form if the individual having the power of attorney executes any of the documents required in this subsection.

(p) ~~[(o)]~~ The department shall not renew a permit if renewal is prohibited by the Education Code, §57.491 (relating to Loan Default Ground for Nonrenewal of Professional or Occupational License).

(q) ~~[(p)]~~ The department shall not renew a permit if renewal is prohibited by a court order or attorney general's order issued pursuant to the Family Code, Chapter 232 (relating to Suspension of License), for failure to pay child support or failure to comply with a court order providing for the possession of or access to a child.

§128.14. Formal Hearings.

(a) (No change.)

(b) Copies of the formal hearing procedures are indexed and filed in the administrator's office, Professional Licensing and Certification Unit ~~[Division]~~, 1100 West 49th Street, Austin, Texas 78756-3183, and are available for public inspection during regular working hours.

Agency Unit/Section/Division Contact Lens Dispensing Permit Program, DSHS Professional Licensing and Certification Unit	Council Meeting Date January 12-13, 2006
Agency Program Contact Debbie Peterson	Telephone No. 512-834-2725
Rule Topic 25 TAC Chapter 128 Amendments relating to the permitting and regulation of contact lens dispensers	

1. Rule Summary.

(Briefly summarize the rule change and why the rule may or may not have fiscal implications.)

The amendments implement 2005 legislation.

They do not constitute the rule review required by Government Code §2001.39. There are no fiscal implications, because no changes to fees are proposed, except for the addition of a new category of renewal fees for retired contact lens dispensers providing voluntary charity care as required by HB 2680 (79th Regular Session, 2005). The impact of the possible decrease in renewal fees collected due to the implementation of reduced renewal fees for retired contact lens dispensers over the age of 55 providing voluntary charity care is insignificant due to the small population of retired contact lens dispensers anticipated to provide charity care services.

The total licensee population is 246 contact lens dispensers, which includes both individuals and businesses.

2. Fiscal Impact.

Does the rule have foreseeable fiscal implications to either costs or revenues of state government for the first five years the rule is in effect?

Yes No If yes, complete the following:

(a) If there are estimated additional costs to the department, explain (1) what new responsibilities will be required; (2) what additional staff will be needed (numbers and classifications); and (3) what other expenses, such as capital or professional services, will be required. Explain any key assumptions that will be needed to reach the figures in the chart in 2(d).

(b) If there is an estimated reduction in costs, explain how the reductions will be accomplished.

(c) If there is an estimated increase in revenue, describe the source and amount. If there is an estimated loss of revenue, describe the source and amount.

Source: Estimated Amount:

Note: Staff may provide the information in (d) on a separate spreadsheet. If spreadsheet is attached, please check here:

(d)	1. Fiscal Year <u>2006</u>	2. Fiscal Year <u>2007</u>	3. Fiscal Year <u>2008</u>	4. Fiscal Year <u>2009</u>	5. Fiscal Year <u>2010</u>
Estimated Additional/Reduction in Cost (specify reduction in parenthesis)					
STATE FUNDS					
FEDERAL FUNDS					

OTHER FUNDS					
TOTAL:					
Estimated Increase/Loss of Revenue (specify loss in parenthesis)					
STATE FUNDS					
FEDERAL FUNDS					
OTHER FUNDS					
TOTAL:					

3. Local Government Impact.

Does the rule have foreseeable positive or negative fiscal implications to either costs or revenues of local governments for the first five years the rule is in effect?

Yes No If yes, enter the amounts for each of the five years and explain key assumptions you used to reach the figures.

4. Small Businesses or Micro-Businesses Impact.

Does the rule have ANY adverse economic effect on small businesses or micro-businesses* (regardless of whether it will have an adverse effect on businesses in general)?

Yes No If yes, complete 4B-E. If no, complete 4A.

* A small business is a legal entity, including a corporation, partnership, or sole proprietorship, that is formed for the purpose of making a profit, is independently owned and operated, and has fewer than 100 employees OR less than \$1,000,000 in annual gross receipts.

A micro-business is a legal entity, including a corporation, partnership, or sole proprietorship, that is formed for the purpose of making a profit, is independently owned and operated, and has 20 or fewer employees.

A. If the rule **will not** have an adverse economic effect on either small businesses or micro-businesses, or both, explain why there will be no adverse effect on one or both.

The program does not anticipate any fiscal or non-fiscal impact on small businesses or micro-businesses because there are no fee increases being proposed. The requirements established for contact lens prescription verification are already in effect as a result of federal law.

Complete (B)-(E) if rule will have an adverse economic effect on small businesses or micro-businesses or both.

Note: You must discuss both small businesses and micro-businesses in your analysis regardless of whether the rule will have an adverse economic effect on either one or both.

B.

C. Give an analysis of the cost to small businesses or micro-businesses of complying with the rule. Explain what assumptions you used to calculate these projected costs (for example, a survey of randomly selected assisted living facilities).

D. Compare the cost to small businesses or micro-businesses of complying with the rule with the cost to the largest businesses affected by the rule, analyzing, when possible:

- cost per employee,
- cost per hour of labor, or
- cost per each \$100 of sales.

- E. Give an analysis of whether it is legal and feasible to reduce the economic effect of the rule on small businesses or micro-businesses, while still accomplishing the intent of the state or federal law being implemented with the rule.

5. Other Cost Impacts.

If there will be costs to persons who must comply with this rule change, other than costs identified in preceding sections, enter estimated costs for the first five fiscal years of implementation:

FY 1	FY 2	FY 3	FY 4	FY 5

Explain assumptions used to arrive at these costs.

6. Fiscal Impact on Local Employment:

Rule **will not** have an impact.

Rule **will** have an impact. You must complete an Economic Impact Request and submit it to TWC at least 30 days before the Council meeting.

7. Takings Impact Assessment.

Does the proposed rule create a burden on private “real property” (i.e. real estate or the buildings and other structures attached to real estate)?

Yes **No** If **yes**, contact Legal **immediately** to determine if you are required to complete a Takings Impact Assessment.

Approvals

Signature – Budget Analyst (original signature on file)	Date	Telephone No.
Signature – Budget Director (original signature on file)	Date	Telephone No.
Signature – Chief Financial Officer (original signature on file)	Date	Telephone No.
Signature – Deputy Executive Commissioner (as appropriate) (original signature on file)	Date	Telephone No.