H.B. NO. 3109

A BILL FOR AN ACT

RELATING TO DISPENSING OPTICIANS.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF HAWAII:

SECTION 1. Section 458-1, Hawaii Revised Statutes, is amended to read as follows:

"**§458-1 Dispensing optician defined.** An individual is deemed to be engaged in the occupation of dispensing optician when the individual prepares and dispenses lenses, spectacles, eyeglasses, or appurtenances thereto to the intended wearer thereof on written prescription from physicians or optometrists duly licensed to practice their professions, and in accordance with the prescriptions interprets, measures, adapts, fits, and adjusts the lenses, spectacles, eyeglasses, or appurtenances thereto to the human face <u>based on the prescription or</u> for the aid or correction of visual or ocular anomalies of the human eyes[~~.~~]<u>, or when the individual offers to sell or sells non-corrective contact lenses.</u>"

SECTION 2. Section 458-14, Hawaii Revised Statutes, is amended by amending subsection (a) to read as follows:

"(a) Nothing in this chapter applies to any physician, optometrist, or ophthalmologist licensed under the laws of the

State, nor shall anything in this chapter [~~contained~~] prohibit the sale of glasses, sun glasses, colored glasses, or [~~occupational~~] eye devices if they do not have refractive values[~~.~~] and are not contact lenses."

SECTION 3. Statutory material to be repealed is bracketed and stricken. New statutory material is underscored.

SECTION 4. This Act shall take effect on July 1, 2008.

INTRODUCED BY: Calvin K.Y. Say

BY REQUEST

JAN 22 2008

Report Title:
Dispensing Opticians; Licensure; Non-corrective Contact Lenses

Description:
Specifies that a dispensing optician's license is required for the dispensing and fitting, upon written prescription, of non-corrective contact lenses and for the sale of or offer to sell non-corrective contact lenses.

HB 3109

JUSTIFICATION SHEET

DEPARTMENT: Commerce and Consumer Affairs.

TITLE: A BILL FOR AN ACT RELATING TO DISPENSING OPTICIANS.

PURPOSE: To clarify the Department's ability to investigate and prosecute cases involving the sale of non-corrective contact lenses.

MEANS: Amend sections 458-1 and 458-14(a), Hawaii Revised Statutes (HRS).

JUSTIFICATION: All contact lenses, including decorative, non-corrective lenses, are now regulated as medical devices through Public Law 109-06, which amended the Federal Food, Drug, and Cosmetic Act (Act) in November 2005. In Report No. 109-110, the U. S. Senate Committee on Health, Education, Labor, and Pensions, concluded that an amendment was necessary because the sale of non-corrective contact lenses without approval by the Food and Drug Administration (FDA) and without a prescription posed a threat to public health of national import. As a result of Public Law 109-06, contact lenses, as medical devices, are subject to premarket notification and approval application requirements prior to marketing.

As the Act's enforcing agency, the FDA considers decorative contact lenses distributed without a prescription and fitting by a qualified eye care professional adulterated and misbranded devices in violation of the Act. The FDA recommends that consumers purchase decorative, non-corrective lenses only upon a valid prescription and fitting by a licensed eye care professional. Without these protections, decorative contact lenses can cause serious injuries or conditions, such as corneal ulcer, internal ocular infection,

HB 3109

conjunctivitis, or permanent vision problems.

Chapter 458, HRS, which regulates the practice of dispensing opticians, does not specify that a dispensing optician license is required for the fitting or sale of decorative, non-corrective contact lenses. This proposal seeks to implement the FDA's recommendations by amending chapter 458, HRS, to specify that a dispensing optician's license is required for the dispensing and fitting, upon written prescription, of non-corrective contact lenses and for the sale of or offer to sell non-corrective contact lenses.

Impact on the public: The proposal will protect consumers by requiring that non-corrective contact lenses are dispensed, fitted, sold or offered for sale by licensed dispensing opticians or by other licensed healthcare professionals.

Impact on the department and other agencies: This proposal will clarify the Department's ability to investigate and prosecute cases involving the sale of non-corrective contact lenses.

GENERAL FUND:	None.
OTHER FUNDS:	None.
PPBS PROGRAM DESIGNATION:	None.
OTHER AFFECTED AGENCIES:	None.
EFFECTIVE DATE:	July 1, 2008.