By Sen. Romer and Rep. Riesberg

Background to SB 251

- Researchers have developed the ability to embed some drugs into contact lenses.
- One such contact lens is very close to final approval by the FDA, and there are indications that several other companies have begun the regulatory process for a similar product.
- The FDA will regulate this new technology as a drug that must be prescribed.

What does SB09-251 do?

SB 09-251 makes clear that this specific FDA approved contact lens may be dispensed by a licensed physician or a licensed optometrist for a professional fee.

Why is SB 251 necessary?

- 1. Currently Colorado law expressly prohibits a licensed optometrist from dispensing any drug for a fee. This prohibition is contained in the Optometric Practice Act and classifies such an action as being unprofessional conduct making the optometrist subject to disciplinary action by the Optometric Board.
 - The prohibition is a very old prohibition that could not have anticipated the newly developed technology that combines contact lenses and certain therapeutic drugs.
- 2. Ophthalmologists are physicians who have a medical specialty in ophthalmology and are licensed under the Medical Practice Act. The Medical Practice Act is silent with respect to the issue of charging a fee for dispensing a drug. The statutory prohibition appears to apply solely to licensed optometrists.
- 3. It is expected that these FDA approved drug-emitting contact lenses will be a great benefit to individuals who need the embedded drug and also need a simple means of self administering the drug. This delivery mechanism would be particularly beneficial to patients who work in agriculture, are active in sports, or otherwise have pronounced allergy related difficulties

Specific SB 251 Language

- SB09-251 is specifically and narrowly drawn to identify FDA approved ophthalmic devices that are classified by the FDA as being a drug.
- Page 2, lines 25-27, and page 3, lines 1-13, remove a provision in law that prohibits a licensed optometrist from being able to charge a fee for dispensing a certain type of new drug that is embedded in a contact lens.
- Page 2, lines 2-11, would amend the pharmacy act to make clear that with respect to this specific FDA approved
 therapeutic contact lens that a licensed optometrist or a licensed physician who charges a professional fee for
 dispensing the lenses would not be in violation of either the pharmacy act or his or her professional licensing act.

Effective Dates: Two Triggers

- The law would go into effect on July 1, 2009.
- · However, the second date is really the controlling date, and that is the date when the FDA approves the drug.

Patient Education

Whenever a drug is prescribed for a patient, the patient needs to be educated about the drug and proper handling of it. Optometrists and ophthalmologists also educate their patients about the proper wearing, storing and use of contact lenses. These patient education protocols provide the necessary foundation for successful and satisfactory use of contact lenses and medications.

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