

CHAPTER 209

PROFESSIONS AND OCCUPATIONS

HOUSE BILL 07-1289

BY REPRESENTATIVE(S) McFadyen, Borodkin, Butcher, Garcia, Labuda, Merrifield, Stephens, and Soper;
also SENATOR(S) Groff, Boyd, Kester, Shaffer, and Tochtrop.

AN ACT**CONCERNING AUTHORIZATION OF A QUALIFIED PHARMACY TO SELL COMPOUNDED DRUGS.**

Be it enacted by the General Assembly of the State of Colorado:

SECTION 1. 12-22-102 (30.2), Colorado Revised Statutes, is amended to read:

12-22-102. Definitions. As used in this part 1, unless the context otherwise requires:

(30.2) "Prescription drug outlet" means any pharmacy outlet registered pursuant to this article where prescriptions are compounded and dispensed. "PRESCRIPTION DRUG OUTLET" INCLUDES, WITHOUT LIMITATION, A COMPOUNDING PRESCRIPTION DRUG OUTLET REGISTERED PURSUANT TO SECTION 12-22-120 (9).

SECTION 2. 12-22-110 (3), Colorado Revised Statutes, is amended to read:

12-22-110. Powers and duties. (3) The board may:

(a) Adopt a seal to be used only in such manner as may be prescribed by the board;

(b) PROMULGATE RULES GOVERNING THE COMPOUNDING OF PHARMACEUTICAL PRODUCTS, WHICH RULES SHALL ADDRESS THE FOLLOWING:

(I) TRAINING AND QUALIFICATIONS;

(II) QUALITY CONTROL;

Capital letters indicate new material added to existing statutes; dashes through words indicate deletions from existing statutes and such material not part of act.

- (III) INTERNAL OPERATING PROCEDURES;
- (IV) PROCUREMENT OF COMPOUNDING MATERIALS;
- (V) FORMULATION, DOCUMENTATION, AND TESTING REQUIREMENTS;
- (VI) EQUIPMENT STANDARDS;
- (VII) FACILITY STANDARDS; AND
- (VIII) A RECALL SYSTEM.

SECTION 3. 12-22-120, Colorado Revised Statutes, is amended BY THE ADDITION OF A NEW SUBSECTION to read:

12-22-120. Registration of facilities. (9) (a) SUBJECT TO PARAGRAPH (b) OF THIS SUBSECTION (9), A PRESCRIPTION DRUG OUTLET MAY REGISTER AS A COMPOUNDING PRESCRIPTION DRUG OUTLET.

(b) NO FACILITY SHALL BE REGISTERED AS A COMPOUNDING PRESCRIPTION DRUG OUTLET UNLESS:

(I) THE FACILITY HAS BEEN ACCREDITED BY A BOARD-APPROVED COMPOUNDING ACCREDITATION ENTITY TO BE WITHIN ACCEPTABLE PARAMETERS TO COMPOUND MORE THAN TEN PERCENT OF THE FACILITY'S TOTAL SALES; AND

(II) OWNERSHIP OF THE FACILITY IS VESTED SOLELY IN A PHARMACIST.

(c) TO BE APPROVED BY THE BOARD TO ACCREDIT A COMPOUNDING PRESCRIPTION DRUG OUTLET, A COMPOUNDING ACCREDITATION ENTITY SHALL BE, AT A MINIMUM, A SCIENTIFIC ORGANIZATION WITH EXPERTISE IN COMPOUNDING MEDICATIONS.

SECTION 4. 12-22-121 (17), Colorado Revised Statutes, is amended, and the said 12-22-121 is further amended BY THE ADDITION OF A NEW SUBSECTION, to read:

12-22-121. Compounding - dispensing - sale of drugs and devices. (17) ~~The director of the division of registrations shall create a task force to study the compounding of drugs by pharmacists. The task force shall include equal representation from the board of pharmacy, practitioners, and pharmacists who compound drugs. By January 1, 2007, the task force shall report and make recommendations to the joint legislative oversight committee with oversight of the department of regulatory agencies pursuant to section 2-7-102, C.R.S.~~

(18) (a) A COMPOUNDING PRESCRIPTION DRUG OUTLET REGISTERED PURSUANT TO SECTION 12-22-120 (9) MAY DISPENSE AND DISTRIBUTE COMPOUNDED DRUGS WITHOUT LIMITATION TO PRACTITIONERS OR TO PRESCRIPTION DRUG OUTLETS UNDER COMMON OWNERSHIP WITH THE PHARMACIST WHO OWNS THE COMPOUNDING PRESCRIPTION DRUG OUTLET.

(b) THE FOLLOWING MAY DISTRIBUTE COMPOUNDED AND PREPACKAGED

MEDICATIONS, WITHOUT LIMITATION, TO PHARMACIES UNDER COMMON OWNERSHIP OF THE ENTITY:

(I) A PRESCRIPTION DRUG OUTLET OWNED AND OPERATED BY A HOSPITAL THAT IS ACCREDITED BY THE JOINT COMMISSION ON ACCREDITATION OF HEALTHCARE ORGANIZATIONS OR A SUCCESSOR ORGANIZATION; AND

(II) A PRESCRIPTION DRUG OUTLET OPERATED BY A HEALTH MAINTENANCE ORGANIZATION AS DEFINED IN SECTION 10-16-102, C.R.S.

(c) (I) A PRESCRIPTION DRUG OUTLET SHALL NOT COMPOUND DRUGS THAT ARE COMMERCIALY AVAILABLE EXCEPT AS PROVIDED IN SUBPARAGRAPH (II) OF THIS PARAGRAPH (c).

(II) A PHARMACIST MAY COMPOUND A COMMERCIALY AVAILABLE DRUG IF THE COMPOUNDED DRUG IS SIGNIFICANTLY DIFFERENT FROM THE COMMERCIALY AVAILABLE DRUG OR IF USE OF THE COMPOUNDED DRUG IS IN THE BEST MEDICAL INTEREST OF THE PATIENT, BASED UPON THE PRACTITIONERS'S DRUG ORDER, INCLUDING, WITHOUT LIMITATION, THE REMOVAL OF A DYE THAT CAUSES AN ALLERGIC REACTION. IF A DRUG IS COMPOUNDED IN LIEU OF A COMMERCIALY AVAILABLE PRODUCT, THE PATIENT SHALL BE NOTIFIED OF THE FACT.

SECTION 5. Effective date. This act shall take effect at 12:01 a.m. on the day following the expiration of the ninety-day period after final adjournment of the general assembly that is allowed for submitting a referendum petition pursuant to article V, section 1 (3) of the state constitution, (August 8, 2007, if adjournment sine die is on May 9, 2007); except that, if a referendum petition is filed against this act or an item, section, or part of this act within such period, then the act, item, section, or part, if approved by the people, shall take effect on the date of the official declaration of the vote thereon by proclamation of the governor.

Approved: May 14, 2007