CHAPTER 304

PROFESSIONS AND OCCUPATIONS

HOUSE BILL 26-1262

BY REPRESENTATIVE(S) Stewart K. and Stewart R., Bacon, Brown, Clifford, Duran, Espenoza, Garcia, Hamrick, Jackson, Joseph, Lieder, Lindsay, Marshall, McCormick, Phillips, Rutinel, Sirota, Titone, Weinberg, McCluskie, Nguyen, Ricks, Smith; also SENATOR(S) Ball and Roberts.

AN ACT

CONCERNING PRESERVING PATIENT ACCESS TO COMPOUNDED MEDICAL ITEMS.

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

SECTION 1. Short title. The short title of this act is the "Colorado Patient Access and Compounding Clarity Act".

SECTION 2. Legislative declaration. (1) The general assembly finds and declares that:

(a) Sterile and nonsterile compounded medical items are used and relied upon on a daily basis in hospitals, surgical centers, behavioral health treatment facilities, and other care settings across Colorado;

(b) Federal standards for sterile and nonsterile compounding have evolved in recent years, and state law should reflect that framework to ensure clarity and continuity;

(c) Modernizing Colorado's laws regarding compounding promotes patient safety, reduces unnecessary regulatory duplication, and supports uninterrupted access to essential medications;

(d) Preserving the availability of high-quality compounded medical items is vital for Colorado patients and the providers that serve them; and

(e) Federal law recognizes 2 lawful pathways for the compounding of human drug products under sections 503a and 503b of the "Federal Food, Drug, and Cosmetic Act". These provisions establish the framework under which licensed

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Capital letters or bold & italic numbers indicate new material added to existing law; dashes through words or numbers indicate deletions from existing law and such material is not part of the act.

pharmacies and outsourcing facilities may prepare compounded medications in accordance with federal standards to meet patient needs.

SECTION 3. In Colorado Revised Statutes, 12-280-120, **add** (1.5) as follows:

12-280-120. Compounding - dispensing - sale of drugs and devices - rules - definition.

(1.5) (a) IF THE ACTION IS UNDERTAKEN IN ACCORDANCE WITH APPLICABLE FEDERAL AND STATE LAW:

(I) A LICENSED PERSON MAY COMPOUND A DRUG OR DEVICE IN THE STATE, INCLUDING THE COMPOUNDING OF A DRUG OR DEVICE IN A STERILE OR NONSTERILE ENVIRONMENT;

(II) A STATE-LICENSED RESIDENT PHARMACY, LICENSED RESIDENT 503B OUTSOURCING FACILITY, STATE-LICENSED NONRESIDENT PHARMACY, OR NONRESIDENT 503B OUTSOURCING FACILITY MAY SUPPLY A COMPOUNDED DRUG OR DEVICE TO A LICENSED HEALTH-CARE PROVIDER, PHARMACY, FACILITY, OR ORGANIZATION; AND

(III) A LICENSED HEALTH-CARE PROVIDER, PHARMACY, FACILITY, OR ORGANIZATION MAY OBTAIN, DISPENSE, OR ADMINISTER A COMPOUNDED DRUG OR DEVICE SUPPLIED BY A STATE-LICENSED RESIDENT PHARMACY, LICENSED RESIDENT 503B OUTSOURCING FACILITY, STATE-LICENSED NONRESIDENT PHARMACY, OR NONRESIDENT 503B OUTSOURCING FACILITY.

(b) IN ADOPTING RULES TO IMPLEMENT THIS SECTION OR OTHERWISE REGULATE THE COMPOUNDING OF DRUGS OR DEVICES BY LICENSED RESIDENT 503B OUTSOURCING FACILITIES OR NONRESIDENT 503B OUTSOURCING FACILITIES IN THE STATE, THE BOARD SHALL NOT ADOPT RULES THAT ARE MORE RESTRICTIVE THAN APPLICABLE FEDERAL AND STATE LAW.

(c) NOTHING IN THIS SECTION SHALL BE CONSTRUED TO CLASSIFY LAWFUL COMPOUNDING PRACTICES AS MANUFACTURING OR TO EXPAND OR ALTER THE BOARD'S ENFORCEMENT AUTHORITY AS OF THE EFFECTIVE DATE OF THIS SUBSECTION (1.5).

(d) THE FEDERAL LAW DESCRIBED IN THIS SECTION INCLUDES THE STANDARDS RECOGNIZED BY THE FDA FOR STATE-LICENSED RESIDENT PHARMACIES, LICENSED RESIDENT 503B OUTSOURCING FACILITIES, STATE-LICENSED NONRESIDENT PHARMACIES, AND NONRESIDENT 503B OUTSOURCING FACILITIES, INCLUDING INCORPORATED UNITED STATES PHARMACOPEIA STERILE OR NONSTERILE PROCESSING STANDARDS.

SECTION 4. In Colorado Revised Statutes, 12-280-131, **amend** (2) as follows:

12-280-131. New drugs - when sales permissible - exemptions.

(2) This section does not apply:

(a) To a drug THAT IS PLAINLY LABELED TO BE FOR INVESTIGATIONAL USE ONLY AND THAT IS:

(I) Intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs; ~~if the drug is plainly labeled to be for investigational use only~~ OR

(II) REVIEWED BY AN INSTITUTIONAL REVIEW BOARD;

(b) TO A COMPOUNDED DRUG OR DEVICE IF THE COMPOUNDING OF THE DRUG OR DEVICE IS UNDERTAKEN IN ACCORDANCE WITH APPLICABLE FEDERAL AND STATE LAW, INCLUDING THE STANDARDS RECOGNIZED BY THE FDA FOR STATE-LICENSED RESIDENT PHARMACIES, LICENSED RESIDENT 503B OUTSOURCING FACILITIES, STATE-LICENSED NONRESIDENT PHARMACIES, AND NONRESIDENT 503B OUTSOURCING FACILITIES, INCLUDING INCORPORATED UNITED STATES PHARMACOPEIA STERILE OR NONSTERILE PROCESSING STANDARDS.

SECTION 5. Applicability. This act applies to conduct occurring on or after the effective date of this act.

SECTION 6. Safety clause. The general assembly finds, determines, and declares that this act is necessary for the immediate preservation of the public peace, health, or safety or for appropriations for the support and maintenance of the departments of the state and state institutions.

Approved: June 2, 2026