

NOTE: This bill has been prepared for the signatures of the appropriate legislative officers and the Governor. To determine whether the Governor has signed the bill or taken other action on it, please consult the legislative status sheet, the legislative history, or the Session Laws.

An Act

HOUSE BILL 23-1195

BY REPRESENTATIVE(S) Michaelson Jenet and Soper, Bird, Boesenecker, Daugherty, deGruy Kennedy, Duran, English, Epps, Froelich, Herod, Jodeh, Kipp, Lindsay, McCormick, McLachlan, Ricks, Sharbini, Snyder, Taggart, Titone, Velasco, Weinberg, Willford, Woodrow, Young, McCluskie, Dickson, Hamrick, Lieder, Sirota;
also SENATOR(S) Ginal and Kirkmeyer, Fenberg.

CONCERNING THE OPERATION OF AUTOMATED PHARMACY DISPENSING SYSTEMS.

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

SECTION 1. In Colorado Revised Statutes, 12-280-126, **add** (1)(u) as follows:

12-280-126. Unprofessional conduct - grounds for discipline.

(1) The board may take disciplinary or other action as authorized in section 12-20-404, after a hearing held in accordance with the provisions of sections 12-20-403 and 12-280-127, upon proof that the licensee, certificant, or registrant:

(u) HAS OPERATED AN AUTOMATED PHARMACY DISPENSING SYSTEM

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.

OR OTHERWISE DISPENSED A DRUG FROM SUCH SYSTEM UNLESS THE SYSTEM HAS BEEN REGISTERED WITH THE BOARD BY THE OPERATING PRESCRIPTION DRUG OUTLET.

SECTION 2. In Colorado Revised Statutes, **add** 12-280-141 as follows:

12-280-141. Prescription drugs - automated pharmacy dispensing system - rules - definition. (1) AS USED IN THIS SECTION, "AUTOMATED PHARMACY DISPENSING SYSTEM" OR "SYSTEM" MEANS A MECHANICAL SYSTEM THAT DISPENSES PRESCRIPTION DRUGS TO A PERSON INTERACTING WITH A REMOTE PHARMACIST AND MAINTAINS RELATED TRANSACTION INFORMATION.

(2) A PRESCRIPTION DRUG OUTLET MAY DISPENSE PRESCRIPTION DRUGS THROUGH AN AUTOMATED PHARMACY DISPENSING SYSTEM IN ACCORDANCE WITH THIS SECTION AND RULES PROMULGATED BY THE BOARD. A PRESCRIPTION DRUG OUTLET THAT OPERATES AN AUTOMATED PRESCRIPTION DRUG DISPENSING SYSTEM IS SOLELY RESPONSIBLE FOR THE SECURITY, OPERATION, AND MAINTENANCE OF THE SYSTEM AND SHALL ENSURE THAT THERE IS A PHARMACIST ACTING ON BEHALF OF THE PRESCRIPTION DRUG OUTLET PROVIDING SERVICES TO PATIENTS ACCESSING PRESCRIPTION DRUGS THROUGH THE SYSTEM. THE PHARMACIST MAY SUPERVISE THE SYSTEM THROUGH ELECTRONIC MEANS AND IS NOT REQUIRED TO BE PHYSICALLY PRESENT AT THE SITE WHERE THE SYSTEM IS LOCATED.

(3) A PRESCRIPTION DRUG OUTLET THAT DISPENSES PRESCRIPTION DRUGS THROUGH AN AUTOMATED PHARMACY DISPENSING SYSTEM SHALL:

(a) REGISTER THE SYSTEM WITH THE BOARD IN ACCORDANCE WITH RULES PROMULGATED BY THE BOARD;

(b) REQUIRE A PHARMACIST TO PERFORM ALL CLINICAL SERVICES CONDUCTED AS PART OF THE DISPENSING PROCESS, INCLUDING DRUG UTILIZATION REVIEW AND CONSULTATION SERVICES;

(c) ENSURE THAT EACH SYSTEM CLEARLY DISPLAYS THE ASSOCIATED PRESCRIPTION DRUG OUTLET REGISTRATION NUMBER AND CLEAR CONTACT INFORMATION FOR PERSONS USING THE SYSTEM TO CONTACT THE PRESCRIPTION DRUG OUTLET;

(d) LOCATE EACH SYSTEM THAT DISPENSES CONTROLLED SUBSTANCES AT THE SAME LOCATION AS A PRESCRIPTION DRUG OUTLET REGISTERED BY THE UNITED STATES DRUG ENFORCEMENT AGENCY;

(e) MAINTAIN A RECORD OF EACH PRESCRIPTION DRUG DISPENSED FROM THE AUTOMATED PHARMACY DISPENSING SYSTEM, INCLUDING THE IDENTITY OF THE PHARMACIST RESPONSIBLE FOR VERIFYING THE ACCURACY OF THE DOSAGE OF THE PRESCRIPTION DRUG DISPENSED, THE DIRECTIONS FOR USE OF THE PRESCRIPTION DRUG, AND THE COUNSELING SERVICES, IF ANY, PROVIDED TO THE INDIVIDUAL TO WHOM THE PRESCRIPTION DRUG IS DISPENSED;

(f) ENSURE THAT CONFIDENTIALITY OF PERSONAL HEALTH INFORMATION IS MAINTAINED; AND

(g) ENSURE THAT THE SYSTEM IS ACCESSIBLE TO PERSONS WITH DISABILITIES IN COMPLIANCE WITH THE REQUIREMENTS OF THE FEDERAL "AMERICANS WITH DISABILITIES ACT OF 1990", 42 U.S.C. SEC. 12101 ET SEQ., AS AMENDED.

(4) A PRESCRIPTION DRUG OUTLET MAY OPERATE AN AUTOMATED PHARMACY DISPENSING SYSTEM IN THE SAME OR IN A DIFFERENT LOCATION THAN THE PRESCRIPTION DRUG OUTLET. THE AUTOMATED PHARMACY DISPENSING SYSTEM MUST BE:

(a) UNDER THE SUPERVISION AND CONTROL OF THE PRESCRIPTION DRUG OUTLET;

(b) INSTALLED IN A PLACE AND IN A MANNER TO ENSURE THAT A PERSON IS UNABLE TO REMOVE THE SYSTEM FROM ITS LOCATION AND ANY ATTEMPTS TO OBTAIN ACCESS TO THE SYSTEM WITHOUT AUTHORIZATION ARE VISIBLE TO THE PRESCRIPTION DRUG OUTLET PHARMACIST, EITHER THROUGH THE DIRECT VIEW OF THE PHARMACIST OR BY REAL-TIME, AUDIO-VISUAL COMMUNICATION TECHNOLOGY OR AUDIO-VISUAL RECORDING TECHNOLOGY; AND

(c) LOCATED IN A SECURE LOCATION IN:

(I) THE REGISTERED ADDRESS OF THE PRESCRIPTION DRUG OUTLET;

(II) THE MEDICAL FACILITY; OR

(III) THE PRACTICE LOCATION OF ONE OR MORE PRACTITIONERS.

(5) AN AUTOMATED PHARMACY DISPENSING SYSTEM MAY ONLY DISPENSE PRESCRIPTION DRUGS UPON THE AUTHORIZATION OF A PHARMACIST ACTING ON BEHALF OF THE PRESCRIPTION DRUG OUTLET AFTER THE PHARMACIST HAS REVIEWED THE PRESCRIPTION ORDER AND THE PATIENT'S PROFILE FOR POTENTIAL CONTRAINDICATIONS AND ADVERSE DRUG REACTIONS.

(6) (a) A PRESCRIPTION DRUG OUTLET OPERATING AN AUTOMATED PHARMACY DISPENSING SYSTEM SHALL DEVELOP, IMPLEMENT, AND MAINTAIN WRITTEN POLICIES AND PROCEDURES TO ENSURE THE PROPER, SAFE, AND SECURE FUNCTIONING OF THE SYSTEM. THE POLICIES AND PROCEDURES MUST, AT A MINIMUM, ADDRESS:

(I) MAINTAINING THE SECURITY OF THE AUTOMATED PHARMACY DISPENSING SYSTEM AND ANY ACCOMPANYING ELECTRONIC VERIFICATION PROCESS AND ENSURING THE SYSTEM AND ACCOMPANYING ELECTRONIC VERIFICATION PROCESS ARE IN GOOD WORKING ORDER;

(II) ENSURING THE ACCURATE FILLING, STOCKING, RESTOCKING, AND FINAL VERIFICATION OF PRESCRIPTION DRUGS DISPENSED FROM THE SYSTEM;

(III) ENSURING THE SANITARY OPERATION OF THE SYSTEM AND THE PREVENTION OF CROSS-CONTAMINATION OF CELLS, CARTRIDGES, CONTAINERS, CASSETTES, AND PACKAGES;

(IV) TRAINING OF INDIVIDUALS AUTHORIZED TO ACCESS, STOCK, RESTOCK, AND USE THE SYSTEM;

(V) CONDUCTING ROUTINE AND PREVENTIVE MAINTENANCE OF THE SYSTEM, INCLUDING CALIBRATION OF THE SYSTEM, IF APPLICABLE;

(VI) REMOVING EXPIRED, ADULTERATED, MISBRANDED, OR RECALLED PRESCRIPTION DRUGS FROM THE SYSTEM;

(VII) ENSURING THAT PRESCRIPTION DRUGS ARE STORED UNDER APPROPRIATE CONDITIONS AND TEMPERATURES;

(VIII) PREVENTING UNAUTHORIZED INDIVIDUALS FROM ACCESSING THE SYSTEM, INCLUDING ASSIGNING, DISCONTINUING, OR MODIFYING SECURITY ACCESS TO THE SYSTEM;

(IX) IDENTIFYING AND RECORDING THE INDIVIDUALS WHO ARE RESPONSIBLE FOR FILLING, STOCKING, AND RESTOCKING THE SYSTEM; AND

(X) ENSURING COMPLIANCE WITH STATE AND FEDERAL LAWS, INCLUDING ALL APPLICABLE LABELING, STORAGE, AND SECURITY REQUIREMENTS.

(b) THE PRESCRIPTION DRUG OUTLET SHALL ANNUALLY REVIEW THE WRITTEN POLICIES AND PROCEDURES REQUIRED PURSUANT TO THIS SUBSECTION (6). THE PRESCRIPTION DRUG OUTLET SHALL DOCUMENT ITS ANNUAL REVIEW OF THE POLICIES AND PROCEDURES, MAINTAIN THE RECORD OF EACH REVIEW FOR AT LEAST TWO YEARS, AND MAKE THE REVIEW RECORDS AVAILABLE TO THE BOARD UPON REQUEST.

(c) THE PRESCRIPTION DRUG OUTLET OPERATING AN AUTOMATED PHARMACY DISPENSING SYSTEM SHALL COLLECT, CONTROL, AND MAINTAIN ALL TRANSACTION INFORMATION TO ACCURATELY TRACK THE MOVEMENT OF PRESCRIPTION DRUGS INTO AND OUT OF THE SYSTEM TO ENSURE PROPER SECURITY, ACCURACY, AND ACCOUNTABILITY.

(7) THE PRESCRIPTION DRUG OUTLET OPERATING THE AUTOMATED PHARMACY DISPENSING SYSTEM IS RESPONSIBLE FOR THE OPERATION, MAINTENANCE, AND SECURITY OF THE SYSTEM AND SHALL LABEL PRESCRIPTION DRUGS DISPENSED FROM THE SYSTEM IN ACCORDANCE WITH EXISTING LAW THAT RECORDS EACH TRANSACTION MADE THROUGH THE SYSTEM.

(8) A PRESCRIPTION DRUG OUTLET THAT OPERATES INSIDE THE PREMISES OF A RETAIL BUSINESS SHALL ONLY OPERATE AN AUTOMATED PHARMACY DISPENSING SYSTEM DURING THE HOURS THAT THE PRESCRIPTION DRUG OUTLET IS CLOSED.

(9) ALL PRESCRIPTION DRUGS STORED IN AN AUTOMATED PHARMACY DISPENSING SYSTEM ARE PART OF THE INVENTORY OF THE PRESCRIPTION DRUG OUTLET OPERATING THE SYSTEM, AND ALL PRESCRIPTION DRUGS DISPENSED FROM THE SYSTEM ARE CONSIDERED TO HAVE BEEN DISPENSED

BY THE PRESCRIPTION DRUG OUTLET THAT OPERATES THE SYSTEM.

(10) THE PRESCRIPTION DRUG OUTLET SHALL MAKE ALL TRANSACTION INFORMATION CONCERNING EACH SYSTEM UNDER ITS OPERATION READILY AVAILABLE IN A DOWNLOADABLE FORMAT FOR REVIEW AND INSPECTION BY THE BOARD. A PRESCRIPTION DRUG OUTLET SHALL MAINTAIN THE RECORDS FOR THE PERIOD OF TIME DETERMINED BY RULE OF THE BOARD.

(11) THE BOARD MAY PROMULGATE RULES AS NECESSARY TO IMPLEMENT THIS SECTION.

SECTION 3. Act subject to petition - effective date. This act takes effect at 12:01 a.m. on the day following the expiration of the ninety-day period after final adjournment of the general assembly; except that, if a referendum petition is filed pursuant to section 1 (3) of article V of the state constitution against this act or an item, section, or part of this act within such period, then the act, item, section, or part will not take effect unless approved by the people at the general election to be held in

November 2024 and, in such case, will take effect on the date of the official declaration of the vote thereon by the governor.

Julie McCluskie
SPEAKER OF THE HOUSE
OF REPRESENTATIVES

Steve Fenberg
PRESIDENT OF
THE SENATE

Robin Jones
CHIEF CLERK OF THE HOUSE
OF REPRESENTATIVES

Cindi L. Markwell
SECRETARY OF
THE SENATE

APPROVED _____
(Date and Time)

Jared S. Polis
GOVERNOR OF THE STATE OF COLORADO