

**First Regular Session
Seventy-fourth General Assembly
STATE OF COLORADO**

REREVISED

*This Version Includes All Amendments
Adopted in the Second House*

LLS NO. 23-0056.01 Kristen Forrestal x4217

HOUSE BILL 23-1195

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A BILL FOR AN ACT

101 **CONCERNING THE OPERATION OF AUTOMATED PHARMACY DISPENSING**
102 **SYSTEMS.**

Bill Summary

(Note: This summary applies to this bill as introduced and does not reflect any amendments that may be subsequently adopted. If this bill passes third reading in the house of introduction, a bill summary that applies to the reengrossed version of this bill will be available at <http://leg.colorado.gov>.)

The bill authorizes a prescription drug outlet to operate an automated pharmacy dispensing system for the purpose of dispensing prescription medications, other than controlled substances, to patients.

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

Shading denotes HOUSE amendment. Double underlining denotes SENATE amendment.
Capital letters or bold & italic numbers indicate new material to be added to existing law.
Dashes through the words or numbers indicate deletions from existing law.

SENATE
3rd Reading Unamended
March 29, 2023

SENATE
Amended 2nd Reading
March 28, 2023

HOUSE
3rd Reading Unamended
March 3, 2023

HOUSE
Amended 2nd Reading
March 2, 2023

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

3 **12-280-126. Unprofessional conduct - grounds for discipline.**

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

8 **(u) HAS OPERATED AN AUTOMATED PHARMACY DISPENSING**
9 **SYSTEM OR OTHERWISE DISPENSED A DRUG FROM SUCH SYSTEM UNLESS**
10 **THE SYSTEM HAS BEEN REGISTERED WITH THE BOARD BY THE OPERATING**
11 **PRESCRIPTION DRUG OUTLET.**

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

14 **12-280-141. Prescription drugs - automated pharmacy**
15 **dispensing system - rules - definition.** (1) AS USED IN THIS SECTION,
16 "AUTOMATED PHARMACY DISPENSING SYSTEM" OR "SYSTEM" MEANS A
17 MECHANICAL SYSTEM THAT DISPENSES PRESCRIPTION DRUGS TO A PERSON
18 INTERACTING WITH A REMOTE PHARMACIST AND MAINTAINS RELATED
19 TRANSACTION INFORMATION.

20 (2) A PRESCRIPTION DRUG OUTLET MAY DISPENSE PRESCRIPTION
21 DRUGS THROUGH AN AUTOMATED PHARMACY DISPENSING SYSTEM IN
22 ACCORDANCE WITH THIS SECTION AND RULES PROMULGATED BY THE
23 BOARD. A PRESCRIPTION DRUG OUTLET THAT OPERATES AN AUTOMATED
24 PRESCRIPTION DRUG DISPENSING SYSTEM IS SOLELY RESPONSIBLE FOR THE
25 SECURITY, OPERATION, AND MAINTENANCE OF THE SYSTEM AND SHALL
26 ENSURE THAT THERE IS A PHARMACIST ACTING ON BEHALF OF THE
27 PRESCRIPTION DRUG OUTLET PROVIDING SERVICES TO PATIENTS ACCESSING

1 PRESCRIPTION DRUGS THROUGH THE SYSTEM. THE PHARMACIST MAY
2 SUPERVISE THE SYSTEM THROUGH ELECTRONIC MEANS AND IS NOT
3 REQUIRED TO BE PHYSICALLY PRESENT AT THE SITE WHERE THE SYSTEM IS
4 LOCATED.

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

7 (a) REGISTER THE SYSTEM WITH THE BOARD IN ACCORDANCE WITH
8 RULES PROMULGATED BY THE BOARD.

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

12 [REDACTED]
13 (c) ENSURE THAT EACH SYSTEM CLEARLY DISPLAYS THE
14 ASSOCIATED PRESCRIPTION DRUG OUTLET REGISTRATION NUMBER AND
15 CLEAR CONTACT INFORMATION FOR PERSONS USING THE SYSTEM TO
16 CONTACT THE PRESCRIPTION DRUG OUTLET;

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

20 (e) MAINTAIN A RECORD OF EACH PRESCRIPTION DRUG DISPENSED
21 FROM THE AUTOMATED PHARMACY DISPENSING SYSTEM, INCLUDING THE
22 IDENTITY OF THE PHARMACIST RESPONSIBLE FOR VERIFYING THE
23 ACCURACY OF THE DOSAGE OF THE PRESCRIPTION DRUG DISPENSED, THE
24 DIRECTIONS FOR USE OF THE PRESCRIPTION DRUG, AND THE COUNSELING
25 SERVICES, IF ANY, PROVIDED TO THE INDIVIDUAL TO WHOM THE
26 PRESCRIPTION DRUG IS DISPENSED; [REDACTED]

27 (f) ENSURE THAT CONFIDENTIALITY OF PERSONAL HEALTH

1 INFORMATION IS MAINTAINED; AND

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

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

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

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

19 (c) LOCATED IN A SECURE LOCATION IN:

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

21 (II) THE MEDICAL FACILITY; OR

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

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

1 ADVERSE DRUG REACTIONS.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

27 (9) ALL PRESCRIPTION DRUGS STORED IN AN AUTOMATED

1 PHARMACY DISPENSING SYSTEM ARE PART OF THE INVENTORY OF THE
2 PRESCRIPTION DRUG OUTLET OPERATING THE SYSTEM, AND ALL
3 PRESCRIPTION DRUGS DISPENSED FROM THE SYSTEM ARE CONSIDERED TO
4 HAVE BEEN DISPENSED BY THE PRESCRIPTION DRUG OUTLET THAT
5 OPERATES THE SYSTEM.

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

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

14 **SECTION 3. Act subject to petition - effective date.** This act
15 takes effect at 12:01 a.m. on the day following the expiration of the
16 ninety-day period after final adjournment of the general assembly; except
17 that, if a referendum petition is filed pursuant to section 1 (3) of article V
18 of the state constitution against this act or an item, section, or part of this
19 act within such period, then the act, item, section, or part will not take
20 effect unless approved by the people at the general election to be held in
21 November 2024 and, in such case, will take effect on the date of the
22 official declaration of the vote thereon by the governor.