

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

ENGROSSED

*This Version Includes All Amendments Adopted
on Second Reading in the House of Introduction*

LLS NO. 23-0056.01 Kristen Forrestal x4217

HOUSE BILL 23-1195

HOUSE SPONSORSHIP

Michaelson Jenet,

SENATE SPONSORSHIP

(None),

House Committees
Health & Insurance

Senate Committees

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.

HOUSE
Amended 2nd Reading
March 2, 2023

1 **SECTION 1.** In Colorado Revised Statutes, **add** 12-280-141 as
2 follows:

3 **12-280-141. Prescription drugs - automated pharmacy**
4 **dispensing system - rules - definition.** (1) AS USED IN THIS SECTION,
5 "AUTOMATED PHARMACY DISPENSING SYSTEM" OR "SYSTEM" MEANS A
6 MECHANICAL SYSTEM THAT DISPENSES PRESCRIPTION DRUGS TO A PERSON
7 INTERACTING WITH A REMOTE PHARMACIST AND MAINTAINS RELATED
8 TRANSACTION INFORMATION.

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

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

23 (a) NOTIFY THE BOARD OF THE LOCATION OF THE SYSTEM AND ANY
24 SUBSEQUENT CHANGES IN THE LOCATION OF THE SYSTEM;

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

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(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) ENSURE THAT EACH SYSTEM THAT DISPENSES CONTROLLED SUBSTANCES IS IN COMPLIANCE WITH THE REQUIREMENTS OF THE FEDERAL 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;

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

- 8 (c) LOCATED IN A SECURE LOCATION IN:
9 (I) THE REGISTERED ADDRESS OF THE PRESCRIPTION DRUG OUTLET;
10 (II) THE MEDICAL FACILITY; OR
11 (III) THE PRACTICE LOCATION OF ONE OR MORE PRACTITIONERS.

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

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

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

- 27 (II) ENSURING THE ACCURATE FILLING, STOCKING, RESTOCKING,

1 AND FINAL VERIFICATION OF PRESCRIPTION DRUGS DISPENSED FROM THE
2 SYSTEM;

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

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

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

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

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

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

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

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

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

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

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

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

16 (9) ALL PRESCRIPTION DRUGS STORED IN AN AUTOMATED
17 PHARMACY DISPENSING SYSTEM ARE PART OF THE INVENTORY OF THE
18 PRESCRIPTION DRUG OUTLET OPERATING THE SYSTEM, AND ALL
19 PRESCRIPTION DRUGS DISPENSED FROM THE SYSTEM ARE CONSIDERED TO
20 HAVE BEEN DISPENSED BY THE PRESCRIPTION DRUG OUTLET THAT
21 OPERATES THE SYSTEM.

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

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

3 **SECTION 2. Act subject to petition - effective date.** This act
4 takes effect at 12:01 a.m. on the day following the expiration of the
5 ninety-day period after final adjournment of the general assembly; except
6 that, if a referendum petition is filed pursuant to section 1 (3) of article V
7 of the state constitution against this act or an item, section, or part of this
8 act within such period, then the act, item, section, or part will not take
9 effect unless approved by the people at the general election to be held in
10 November 2024 and, in such case, will take effect on the date of the
11 official declaration of the vote thereon by the governor.