

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

PREAMENDED

*This Unofficial Version Includes Committee
Amendments Not Yet Adopted on Second Reading*

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.

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) 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; AND

(d) ENSURE THAT CONFIDENTIALITY OF PERSONAL HEALTH INFORMATION IS MAINTAINED.

(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 WITHIN A PRESCRIPTION DRUG OUTLET, A MEDICAL FACILITY, OR THE PRACTICE LOCATION OF ONE OR MORE PRACTITIONERS.

(5) AN AUTOMATED PHARMACY DISPENSING SYSTEM MAY ONLY

1 DISPENSE PRESCRIPTION DRUGS UPON THE AUTHORIZATION OF A
2 PHARMACIST ACTING ON BEHALF OF THE PRESCRIPTION DRUG OUTLET
3 AFTER THE PHARMACIST HAS REVIEWED THE PRESCRIPTION ORDER AND
4 THE PATIENT'S PROFILE FOR POTENTIAL CONTRAINDICATIONS AND
5 ADVERSE DRUG REACTIONS.

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

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

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

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

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

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

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

27 (VII) ENSURING THAT PRESCRIPTION DRUGS ARE STORED UNDER

1 APPROPRIATE CONDITIONS AND TEMPERATURES;

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

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

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

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

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

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

27 (8) A PRESCRIPTION DRUG OUTLET THAT OPERATES INSIDE THE

1 PREMISES OF A RETAIL BUSINESS SHALL ONLY OPERATE AN AUTOMATED
2 PHARMACY DISPENSING SYSTEM DURING THE HOURS THAT THE RETAIL
3 BUSINESS IS CLOSED.

4 (9) ALL PRESCRIPTION DRUGS STORED IN AN AUTOMATED
5 PHARMACY DISPENSING SYSTEM ARE PART OF THE INVENTORY OF THE
6 PRESCRIPTION DRUG OUTLET OPERATING THE SYSTEM, AND ALL
7 PRESCRIPTION DRUGS DISPENSED FROM THE SYSTEM ARE CONSIDERED TO
8 HAVE BEEN DISPENSED BY THE PRESCRIPTION DRUG OUTLET THAT
9 OPERATES THE SYSTEM.

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

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

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