

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

REVISED

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

LLS NO. 23-0867.01 Richard Sweetman x4333

HOUSE BILL 23-1225

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A BILL FOR AN ACT

101 **CONCERNING THE PRESCRIPTION DRUG AFFORDABILITY BOARD, AND,**
102 **IN CONNECTION THEREWITH, MODIFYING THE AFFORDABILITY**
103 **REVIEW PROCESS, ALLOWING THE BOARD TO ESTABLISH UPPER**
104 **PAYMENT LIMITS FOR AN ADDITIONAL NUMBER OF**
105 **PRESCRIPTION DRUGS, CLARIFYING WHICH BOARD FUNCTIONS**
106 **ARE SUBJECT TO JUDICIAL REVIEW, AUTHORIZING AN**
107 **INDIVIDUAL TO REQUEST AN INDEPENDENT EXTERNAL REVIEW**
108 **OF A DENIAL OF A REQUEST FOR BENEFITS FOR A PRESCRIPTION**
109 **DRUG THAT HAS BEEN WITHDRAWN FROM SALE OR**
110 **DISTRIBUTION IN THE STATE, AND EXTENDING THE REPEAL DATE**
111 **OF THE BOARD.**

Bill Summary

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
Amended 2nd Reading
April 21, 2023

HOUSE
3rd Reading Unamended
March 21, 2023

HOUSE
Amended 2nd Reading
March 20, 2023

(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>.)

In 2021, the general assembly enacted SB 21-175, which created the prescription drug affordability board (board) in the division of insurance (division) and an affordability review process whereby the board may review costs associated with, and establish upper payment limits for, certain prescription drugs. The bill makes certain changes concerning the board.

Section 1 defines "board activity", and **section 2** states that only board members, and not staff members or contractors of the division, are required to recuse themselves from any board activity or vote where they have a conflict of interest.

Section 3 allows the chair of the board to cancel or postpone a board meeting for good cause.

Section 4 makes certain changes to the procedure by which the board identifies prescription drugs that may be subjected to an affordability review. **Section 4** also requires the board to report on its public web page certain information regarding its considerations.

Section 5 removes language prohibiting the board from establishing an upper payment limit for more than 12 prescription drugs within a specified period.

Section 6 establishes that an upper payment limit for a prescription drug is not a final agency action that is subject to judicial review until the board promulgates a rule establishing the upper payment limit.

Sections 6 and 7 remove certain language describing an appeals process for appealing decisions of the board.

Sections 8 and 9 extend the repeal and associated sunset review of the board from September 1, 2026, to September 1, 2031.

Section 10 establishes that a denial of a request for benefits for a prescription drug that is unavailable in the state because a manufacturer has withdrawn the prescription drug from sale or distribution within the state is an "adverse determination" for which an individual may request an independent external review.

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

2 **SECTION 1.** In Colorado Revised Statutes, 10-16-1401, **add**
3 (7.5) as follows:

4 **10-16-1401. Definitions.** As used in this part 14, unless the

1 context otherwise requires:

2 (7.5) "BOARD ACTIVITY" MEANS:

3 (a) SELECTING PRESCRIPTION DRUGS FOR AN AFFORDABILITY
4 REVIEW PURSUANT TO SECTION 10-16-1406 (2);

5 (b) DETERMINING WHETHER A PRESCRIPTION DRUG IS
6 UNAFFORDABLE PURSUANT TO SECTION 10-16-1406 (3);

7 (c) SELECTING PRESCRIPTION DRUGS FOR WHICH THE BOARD
8 ESTABLISHES AN UPPER PAYMENT LIMIT PURSUANT TO SECTION
9 10-16-1407; AND

10 (d) ESTABLISHING AN UPPER PAYMENT LIMIT FOR A PRESCRIPTION
11 DRUG PURSUANT TO SECTION 10-16-1407.

12 **SECTION 2.** In Colorado Revised Statutes, 10-16-1402, **amend**
13 (3)(c) as follows:

14 **10-16-1402. Colorado prescription drug affordability review**
15 **board - created - membership - terms - conflicts of interest.**

16 (3) (c) (I) Board members ~~staff members, and contractors of the division,~~
17 ~~on behalf of the board,~~ shall recuse themselves from any board activity OR
18 VOTE in any case in which they have a conflict of interest.

19 (II) STAFF MEMBERS AND CONTRACTORS OF THE DIVISION, ON
20 BEHALF OF THE BOARD, SHALL DISCLOSE ANY CONFLICT OF INTEREST
21 RELATED TO A PRESCRIPTION DRUG FOR WHICH THE BOARD IS CONDUCTING
22 AN AFFORDABILITY REVIEW OR ESTABLISHING AN UPPER PAYMENT LIMIT.

23 (III) NOTWITHSTANDING SUBSECTION (3)(d) OF THIS SECTION AND
24 THE REPORTING REQUIREMENTS SET FORTH IN SECTION 10-16-1414 (1)(f),
25 A CONFLICT OF INTEREST DISCLOSED BY A STAFF MEMBER OR BY A
26 CONTRACTOR OF THE DIVISION, WHICH DISCLOSURE PERTAINS TO A
27 PERSONAL ASSOCIATION, MUST REMAIN CONFIDENTIAL. THE BOARD, UPON

1 REVIEW OF SUCH A DISCLOSURE, MAY DIRECT THE STAFF MEMBER OR
2 CONTRACTOR TO RECUSE THEMSELVES BASED ON THE CONFLICT OF INTEREST.

3 **SECTION 3.** In Colorado Revised Statutes, 10-16-1404, **amend**
4 (1) as follows:

5 **10-16-1404. Colorado prescription drug affordability review**
6 **board meetings - required to be public - exceptions.** (1) The board
7 shall hold its first meeting within six weeks after all of the board
8 members are appointed and shall meet at least every six weeks thereafter
9 to review prescription drugs; except that the chair may cancel or postpone
10 a meeting if the board has no prescription drugs to review OR FOR GOOD
11 CAUSE.

12 **SECTION 4.** In Colorado Revised Statutes, 10-16-1406, **amend**
13 (1)(a), (1)(b), and (2) introductory portion; **repeal** (1)(c); and **add** (8) as
14 follows:

15 **10-16-1406. Colorado prescription drug affordability review**
16 **board - affordability reviews of prescription drugs.** (1) The board may
17 conduct affordability reviews of prescription drugs in accordance with
18 this section. The board shall identify, for purposes of determining whether
19 to conduct an affordability review: ~~any prescription drug that is:~~

20 (a) ~~A brand-name drug or biological product that, as adjusted~~
21 ~~annually for inflation, has~~ ANY PRESCRIPTION DRUG THAT HAS:

22 (I) ~~An initial~~ A wholesale acquisition cost of ~~thirty~~ THREE
23 thousand dollars or more; ~~for a twelve-month supply or for a course of~~
24 ~~treatment that is less than twelve months in duration; or~~

25 (I.5) AN INCREASE OF THREE HUNDRED DOLLARS OR MORE ABOVE
26 THE WHOLESALE ACQUISITION COST FOR THE PRESCRIPTION DRUG IN THE
27 PRECEDING TWELVE MONTHS;

1 ~~(II) An increase in the wholesale acquisition cost of ten percent~~
2 ~~or more during~~ AN INCREASE OF TWO HUNDRED PERCENT OR MORE ABOVE
3 THE WHOLESALE ACQUISITION COST FOR THE PRESCRIPTION DRUG IN the
4 ~~immediately preceding twelve months; for a twelve-month supply or for~~
5 ~~a course of treatment that is less than twelve months in duration; OR~~

6 (III) A CURRENT WHOLESALE ACQUISITION COST FOR AN AVERAGE
7 COURSE OF TREATMENT PER PERSON PER YEAR OF THIRTY THOUSAND
8 DOLLARS OR MORE; AND

9 (b) ~~A ANY biosimilar~~ drug that has an initial wholesale acquisition
10 cost that is not at least fifteen percent lower than THE WHOLESALE
11 ACQUISITION COST OF the corresponding biological ~~product. or~~

12 (c) ~~A generic drug:~~ ■ ■

13 ~~(I) That, as adjusted annually for inflation, has a wholesale~~
14 ~~acquisition cost of one hundred dollars or more for:~~

15 ~~(A) A thirty-day supply based on the recommended dosage~~
16 ~~approved for labeling by the FDA;~~

17 ~~(B) A supply that lasts less than thirty days based on the~~
18 ~~recommended dosage approved for labeling by the FDA; or~~

19 ~~(C) One dose of the generic drug if the labeling approved by the~~
20 ~~FDA does not recommend a finite dosage; and~~

21 ~~(H) For which the wholesale acquisition cost increased by two~~
22 ~~hundred percent or more during the immediately preceding twelve~~
23 ~~months, as determined by comparing the current wholesale acquisition~~
24 ~~cost to the average wholesale acquisition cost reported during the~~
25 ~~immediately preceding twelve months.~~

26 (2) After identifying prescription drugs as described in subsection
27 (1) of this section, the board shall determine whether to conduct an

1 affordability review for ~~each~~ AN identified prescription drug by:

2 (8) THE BOARD SHALL ISSUE A REPORT SUMMARIZING, TO THE
3 EXTENT PERMITTED BY SECTION 10-16-1404 (3), THE DATA THAT THE
4 BOARD CONSIDERED IN MAKING THE BOARD'S DETERMINATION AS TO
5 WHETHER A PRESCRIPTION DRUG IS UNAFFORDABLE. THE BOARD SHALL
6 MAKE THE REPORT AVAILABLE ON ITS PUBLIC WEB PAGE.

7 **SECTION 5.** In Colorado Revised Statutes, 10-16-1407, **amend**
8 (1) and (5) as follows:

9 **10-16-1407. Colorado prescription drug affordability review**
10 **board - upper payment limits for certain prescription drugs - rules**
11 **_____ - severability.** (1) (a) The board may establish an upper payment
12 limit for any prescription drug for which the board has performed an
13 affordability review pursuant to section 10-16-1406 and determined that
14 the use of the prescription drug is unaffordable for Colorado consumers;
15 except that:

16 (I) The board may not establish an upper payment limit for more
17 than twelve prescription drugs in each calendar year for three years
18 beginning April 1, 2022, UNLESS THE BOARD DETERMINES THAT THERE IS
19 A NEED TO ESTABLISH UPPER PAYMENT LIMITS FOR MORE THAN TWELVE
20 PRESCRIPTION DRUGS, IN WHICH CASE THE BOARD MAY ESTABLISH AN
21 UPPER PAYMENT LIMIT FOR UP TO EIGHTEEN PRESCRIPTION DRUGS SO LONG
22 AS THE BOARD HAS SUFFICIENT STAFF SUPPORT TO DO SO; AND

23 (II) FOR EACH PRESCRIPTION DRUG FOR WHICH THE BOARD
24 ESTABLISHES AN UPPER PAYMENT LIMIT, THE BOARD MAY INCLUDE
25 MULTIPLE NATIONAL DRUG CODES, AS DESCRIBED IN 21 CFR 207.33, THAT
26 ARE INDICATED FOR THE PRESCRIPTION DRUG.

27 (b) The failure of an entity to provide information to the board

1 pursuant to section 10-16-1406 (7)(b) does not affect the authority of the
2 board to establish an upper payment limit for the A prescription drug.

3 (5) An upper payment limit applies to all purchases of and payer
4 reimbursements for a prescription drug that is dispensed or administered
5 to individuals in the state in person, by mail, or by other means and for
6 which an upper payment limit is established. The board shall promulgate
7 rules that establish UPPER PAYMENT LIMITS AND the effective date of any
8 upper payment limit established by the board, which effective date is at
9 least six months after the adoption of the upper payment limit by the
10 board and applies only to purchases, contracts, and plans that are issued
11 on or renewed after the effective date.

12 **SECTION 6.** In Colorado Revised Statutes, 10-16-1408, **amend**
13 (1) and (2); and **repeal** (3) as follows:

14 **10-16-1408. Colorado prescription drug affordability review**
15 **board - judicial review.** (1) ~~A person aggrieved by a decision of the~~
16 ~~board may appeal the decision within sixty days after the decision is~~
17 ~~made. The board shall consider the appeal and issue a final decision~~
18 ~~concerning the appeal within sixty days after the board receives the~~
19 ~~appeal.~~ THE FOLLOWING BOARD FUNCTIONS ARE NOT FINAL AGENCY
20 ACTIONS SUBJECT TO JUDICIAL REVIEW UNDER THE "STATE
21 ADMINISTRATIVE PROCEDURE ACT", ARTICLE 4 OF TITLE 24:

22 (a) IDENTIFICATION OF ELIGIBLE PRESCRIPTION DRUGS PURSUANT
23 TO SECTION 10-16-1406 (1);

24 (b) SELECTION OF A PRESCRIPTION DRUG PURSUANT TO SECTION
25 10-16-1406 (2); AND

26 (c) DETERMINATION THAT A PRESCRIPTION DRUG IS
27 UNAFFORDABLE PURSUANT TO SECTION 10-16-1406 (3).

1 (2) ~~Not later than March 31, 2022, the board shall promulgate~~
2 ~~rules establishing a process and timeline for the consideration by the~~
3 ~~board of any appeal that is submitted to the board pursuant to subsection~~
4 ~~(1) of this section. The process and timeline must comport with the "State~~
5 ~~Administrative Procedure Act", article 4 of title 24~~ A RULE OF THE BOARD
6 ESTABLISHING AN UPPER PAYMENT LIMIT IS A FINAL AGENCY ACTION
7 SUBJECT TO JUDICIAL REVIEW UNDER THE "STATE ADMINISTRATIVE
8 PROCEDURE ACT", ARTICLE 4 OF TITLE 24. A PARTY SEEKING JUDICIAL
9 REVIEW OF A RULE ESTABLISHING AN UPPER PAYMENT LIMIT MAY SEEK
10 REVIEW OF WHETHER THE PRESCRIPTION DRUG SATISFIES THE NECESSARY
11 CRITERIA IN SECTION 10-16-1406 TO BE ELIGIBLE FOR AN UPPER PAYMENT
12 LIMIT.

13 (3) ~~In the absence of an appeal, a decision of the board becomes~~
14 ~~final and ripe for judicial review after sixty days. Any person aggrieved~~
15 ~~by a final decision of the board may petition for judicial review pursuant~~
16 ~~to section 24-4-106.~~

17 **SECTION 7.** In Colorado Revised Statutes, 10-16-1414, **amend**
18 (1) introductory portion, (1)(b), and (1)(e) as follows:

19 **10-16-1414. Reports.** (1) Notwithstanding section 24-1-136
20 (11)(a), on or before July 1, 2023, and on or before July 1 each year
21 thereafter, the board shall submit a report to the governor, the health and
22 insurance committee of the house of representatives, and the health and
23 human services committee of the senate, or to any successor committees,
24 summarizing the ~~activities~~ WORK of the board during the preceding
25 calendar year. At a minimum, the report must include:

26 (b) The number of prescription drugs that were subjected to an
27 affordability review by the board pursuant to section 10-16-1406,

1 including the results of each affordability review; ~~and the number and~~
2 ~~disposition of any appeals or judicial reviews of the board's decisions;~~

3 (e) A summary of any ~~appeals~~ JUDICIAL REVIEWS of board
4 decisions, ~~that were considered by the board pursuant to section~~
5 ~~10-16-1408~~, including an indication of the outcome of any ~~such appeal~~
6 JUDICIAL REVIEW;

7 **SECTION 8.** In Colorado Revised Statutes, **amend** 10-16-1416
8 as follows:

9 **10-16-1416. Repeal of part.** This part 14 is repealed, effective
10 ~~September 1, 2026~~ SEPTEMBER 1, 2031. Before the repeal, the functions
11 of the board are scheduled for review in accordance with section
12 24-34-104.

13 **SECTION 9.** In Colorado Revised Statutes, 24-34-104, **repeal**
14 (27)(a)(XIX); and **add** (32)(a)(X) as follows:

15 **24-34-104. General assembly review of regulatory agencies**
16 **and functions for repeal, continuation, or reestablishment - legislative**
17 **declaration - repeal.** (27) (a) The following agencies, functions, or both,
18 are scheduled for repeal on September 1, 2026:

19 (XIX) ~~The Colorado prescription drug affordability review board~~
20 ~~created in section 10-16-1402.~~

21 (32) (a) The following agencies, functions, or both, are scheduled
22 for repeal on September 1, 2031:

23 (X) THE COLORADO PRESCRIPTION DRUG AFFORDABILITY REVIEW
24 BOARD CREATED IN SECTION 10-16-1402.

25 **SECTION 10.** In Colorado Revised Statutes, 10-16-113.5,
26 **amend** (2)(a)(III) and (2)(a)(IV); and **add** (2)(a)(V) as follows:

27 **10-16-113.5. Independent external review of adverse**

1 **determinations - legislative declaration - definitions - rules.** (2) As
2 used in this section, unless the context otherwise requires:

3 (a) "Adverse determination" means a denial of:

4 (III) A request for benefits on the grounds that the treatment or
5 services are experimental or investigational; or

6 (IV) A benefit as described in section 10-16-113 (1)(c); OR

7 (V) A REQUEST FOR BENEFITS FOR A PRESCRIPTION DRUG THAT IS
8 UNAVAILABLE IN THE STATE BECAUSE A MANUFACTURER HAS WITHDRAWN
9 THE PRESCRIPTION DRUG FROM SALE OR DISTRIBUTION WITHIN THE STATE
10 UNDER SECTION 10-16-1412.

11 **SECTION 11. Act subject to petition - effective date.** Section
12 4 of this act takes effect January 1, 2025, and the remainder of this act
13 takes effect at 12:01 a.m. on the day following the expiration of the
14 ninety-day period after final adjournment of the general assembly; except
15 that, if a referendum petition is filed pursuant to section 1 (3) of article V
16 of the state constitution against this act or an item, section, or part of this
17 act within such period, then the act, item, section, or part will not take
18 effect unless approved by the people at the general election to be held in
19 November 2024 and, in such case, will take effect on the date of the
20 official declaration of the vote thereon by the governor; except that
21 section 4 of this act takes effect January 1, 2026.