

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

PREAMENDED

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

LLS NO. 21-0497.02 Richard Sweetman x4333

SENATE BILL 21-175

SENATE SPONSORSHIP

Jaquez Lewis and Gonzales, Buckner

HOUSE SPONSORSHIP

Caraveo and Kennedy,

Senate Committees

Health & Human Services
Appropriations

House Committees

A BILL FOR AN ACT

101 **CONCERNING THE COLORADO PRESCRIPTION DRUG AFFORDABILITY**
102 **REVIEW BOARD, AND, IN CONNECTION THEREWITH, DIRECTING**
103 **THE BOARD TO REVIEW THE AFFORDABILITY OF CERTAIN DRUGS**
104 **AND ESTABLISH UPPER PAYMENT LIMITS FOR CERTAIN DRUGS;**
105 **PROHIBITING CERTAIN ENTITIES FROM PURCHASING OR**
106 **REIMBURSING FOR ANY DRUG FOR DISTRIBUTION IN THE STATE**
107 **AT AN AMOUNT THAT EXCEEDS THE UPPER PAYMENT LIMIT**
108 **ESTABLISHED FOR THE PRESCRIPTION DRUG; ESTABLISHING**
109 **PENALTIES FOR VIOLATIONS; AND MAKING AN APPROPRIATION.**

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

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

applies to the reengrossed version of this bill will be available at <http://leg.colorado.gov>.)

The bill creates the Colorado prescription drug affordability review board (board) as an independent unit of state government and requires the board to perform affordability reviews of prescription drugs and establish upper payment limits for prescription drugs the board determines are unaffordable for Colorado consumers. The board is also required to promulgate rules as necessary for its purposes.

The board shall determine by rule the methodology for establishing an upper payment limit for a prescription drug. An upper payment limit applies to all purchases of and payer reimbursements for the prescription drug dispensed or administered to individuals in the state in person, by mail, or by other means. Any savings generated for a health benefit plan as a result of an upper payment limit established by the board must be used by the carrier that issued the health benefit plan to reduce costs to consumers.

On and after January 1, 2022, the bill prohibits any purchase or payer reimbursement for a prescription drug from exceeding an upper payment limit established by the board for that prescription drug. A person who violates the prohibition may be subject to a fine of \$1,000 for each violation. Final board decisions are subject to judicial review.

A person aggrieved by a decision of the board may appeal the decision within 60 days. The board shall consider the appeal and issue a final decision concerning the appeal within 60 days after the board receives the appeal.

Any prescription drug manufacturer (manufacturer) that intends to withdraw a prescription drug for which the board has established an upper payment limit from sale or distribution within the state must notify, at least 180 days before the withdrawal:

- The commissioner;
- The attorney general; and
- Each entity in the state with which the manufacturer has contracted for the sale or distribution of the prescription drug.

A manufacturer who fails to comply with the notice requirement may be required to pay a penalty of up to \$500,000.

For all prescription drugs dispensed at a pharmacy and paid for by a carrier during the immediately preceding calendar year, the bill requires each carrier and each pharmacy benefit management firm acting on behalf of a carrier to report certain information.

The bill creates the Colorado prescription drug affordability advisory council to provide stakeholder input to the board.

The board must submit an annual report to the governor and to subject matter committees of the general assembly summarizing the

activities of the board during the preceding calendar year.

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

2 **SECTION 1. Legislative declaration.** (1) The general assembly
3 finds that:

4 (a) Excessive costs for prescription drugs:

5 (I) Negatively impact the ability of Coloradans to obtain
6 prescription drugs, and price increases that exceed reasonable levels
7 endanger the health and safety of Coloradans;

8 (II) Threaten the economic well-being of Coloradans and
9 endanger their ability to pay for other necessary and essential goods and
10 services, including housing, food, and utilities;

11 (III) Contribute significantly to a dramatic and unsustainable rise
12 in health-care costs and health insurance premiums that threatens the
13 financial health of Coloradans and their ability to maintain their physical
14 health;

15 (IV) Pose a threat to the health and safety of all Coloradans but
16 disproportionately harm people of color and Coloradans with low
17 incomes; and

18 (V) Contribute significantly to rising costs for health care that is
19 provided to public employees, including employees of state, county, and
20 local governments, school districts, and institutions of higher education,
21 and to public retirees whose health-care costs are funded by public
22 programs, thereby threatening the ability of state and local governments
23 to adequately fund those programs and other important services, such as
24 public education and public safety;

25 (b) Lack of transparency in health insurance costs and wholesaler

1 and pharmacy benefits manager discounts and margins prevents
2 policymakers and the public from gaining a true understanding of the
3 costs of prescription drugs; and

4 (c) Information relating to the cost of prescription drugs in
5 Colorado is necessary to provide accountability to the state and to all
6 Coloradans for prescription drug pricing.

7 (2) The general assembly therefore declares that in exercise of its
8 police powers and responsibility for the public health, safety, and general
9 welfare of Colorado residents, it is imperative that Colorado take
10 measures to reduce excessive prescription drug costs for Coloradans who
11 cannot afford prescription drugs and create a prescription drug
12 affordability board with the authority to review prescription drug costs
13 and protect state and local governments and Colorado residents from the
14 excessive costs of prescription drugs.

15 **SECTION 2.** In Colorado Revised Statutes, **add** part 13 to article
16 16 of title 10 as follows:

17 PART 13

18 COLORADO PRESCRIPTION DRUG

19 AFFORDABILITY REVIEW BOARD

20 **10-16-1301. Definitions.** AS USED IN THIS PART 13, UNLESS THE
21 CONTEXT OTHERWISE REQUIRES:

22 (1) "ADVISORY COUNCIL" MEANS THE COLORADO PRESCRIPTION
23 DRUG AFFORDABILITY ADVISORY COUNCIL CREATED IN SECTION
24 10-16-1309.

25 (2) "AFFORDABILITY REVIEW" MEANS AN AFFORDABILITY REVIEW
26 OF A PRESCRIPTION DRUG PERFORMED BY THE BOARD PURSUANT TO
27 SECTION 10-16-1306.

1 (3) "ALL-PAYER HEALTH CLAIMS DATABASE" MEANS THE
2 ALL-PAYER HEALTH CLAIMS DATABASE DESCRIBED IN SECTION 25.5-1-204.

3 (4) "AUTHORIZED GENERIC DRUG" HAS THE MEANING SET FORTH
4 IN 42 CFR 447.502.

5 (5) "BIOLOGICAL PRODUCT" HAS THE MEANING SET FORTH IN 42
6 U.S.C. SEC. 262 (i)(1).

7 (6) "BIOSIMILAR DRUG" MEANS A PRESCRIPTION DRUG THAT IS
8 PRODUCED OR DISTRIBUTED IN ACCORDANCE WITH A BIOLOGICAL PRODUCT
9 LICENSE ISSUED PURSUANT TO 42 U.S.C. SEC. 262 (k)(3).

10 (7) "BOARD" MEANS THE COLORADO PRESCRIPTION DRUG
11 AFFORDABILITY REVIEW BOARD CREATED IN SECTION 10-16-1302.

12 (8) "BRAND-NAME DRUG" MEANS A PRESCRIPTION DRUG THAT IS
13 PRODUCED OR DISTRIBUTED IN ACCORDANCE WITH AN ORIGINAL NEW
14 DRUG APPLICATION APPROVED PURSUANT TO 21 U.S.C. SEC. 355.
15 "BRAND-NAME DRUG" DOES NOT INCLUDE AN AUTHORIZED GENERIC DRUG.

16 (9) "CARRIER" HAS THE MEANING SET FORTH IN SECTION
17 10-16-102 (8).

18 (10) "CONFLICT OF INTEREST" MEANS AN ASSOCIATION, INCLUDING
19 A FINANCIAL OR PERSONAL ASSOCIATION, THAT HAS THE POTENTIAL TO
20 BIAS OR APPEAR TO BIAS AN INDIVIDUAL'S DECISIONS IN MATTERS RELATED
21 TO THE BOARD OR THE ADVISORY COUNCIL OR THE CONDUCT OF THE
22 ACTIVITIES OF THE BOARD OR THE ADVISORY COUNCIL. "CONFLICT OF
23 INTEREST" INCLUDES ANY INSTANCE IN WHICH A BOARD MEMBER, AN
24 ADVISORY COUNCIL MEMBER, A STAFF MEMBER, A CONTRACTOR OF THE
25 BOARD, OR AN IMMEDIATE FAMILY MEMBER OF A BOARD MEMBER, AN
26 ADVISORY COUNCIL MEMBER, A STAFF MEMBER, OR A CONTRACTOR OF THE
27 BOARD HAS RECEIVED OR COULD RECEIVE:

1 (a) A FINANCIAL BENEFIT OF ANY AMOUNT DERIVED FROM THE
2 RESULTS OR FINDINGS OF A STUDY OR DETERMINATION THAT IS REACHED
3 BY OR FOR THE BOARD; OR

4 (b) A FINANCIAL BENEFIT FROM AN INDIVIDUAL OR COMPANY THAT
5 OWNS OR MANUFACTURES A PRESCRIPTION DRUG, SERVICE, OR ITEM THAT
6 IS BEING OR WILL BE STUDIED BY THE BOARD.

7 (11) "FINANCIAL BENEFIT" MEANS HONORARIA, FEES, STOCK, OR
8 ANY OTHER FORM OF COMPENSATION, INCLUDING INCREASES TO THE
9 VALUE OF EXISTING STOCK HOLDINGS.

10 (12) "GENERIC DRUG" MEANS:

11 (a) A PRESCRIPTION DRUG THAT IS MARKETED OR DISTRIBUTED IN
12 ACCORDANCE WITH AN ABBREVIATED NEW DRUG APPLICATION APPROVED
13 PURSUANT TO 21 U.S.C. SEC. 355 (j);

14 (b) AN AUTHORIZED GENERIC DRUG; OR

15 (c) A PRESCRIPTION DRUG THAT WAS INTRODUCED FOR RETAIL
16 SALE BEFORE 1962 THAT WAS NOT ORIGINALLY MARKETED UNDER A NEW
17 DRUG APPLICATION.

18 (13) "HEALTH BENEFIT PLAN" HAS THE MEANING SET FORTH IN
19 SECTION 10-16-102 (32).

20 (14) "INFLATION" MEANS THE ANNUAL PERCENTAGE CHANGE IN
21 THE UNITED STATES DEPARTMENT OF LABOR'S BUREAU OF LABOR
22 STATISTICS CONSUMER PRICE INDEX FOR DENVER-AURORA-LAKEWOOD
23 FOR ALL ITEMS PAID BY ALL URBAN CONSUMERS, OR ITS APPLICABLE
24 PREDECESSOR OR SUCCESSOR INDEX.

25 (15) (a) "LARGE EMPLOYER" MEANS ANY PERSON, FIRM,
26 CORPORATION, PARTNERSHIP, OR ASSOCIATION THAT:

27 (I) IS ACTIVELY ENGAGED IN BUSINESS;

1 (II) EMPLOYED AN AVERAGE OF MORE THAN ONE HUNDRED
2 ELIGIBLE EMPLOYEES ON BUSINESS DAYS DURING THE IMMEDIATELY
3 PRECEDING CALENDAR YEAR, EXCEPT AS PROVIDED IN SUBSECTION (15)(c)
4 OF THIS SECTION; AND

5 (III) WAS NOT FORMED PRIMARILY FOR THE PURPOSE OF
6 PURCHASING INSURANCE.

7 (b) FOR PURPOSES OF DETERMINING WHETHER AN EMPLOYER IS A
8 "LARGE EMPLOYER", THE NUMBER OF ELIGIBLE EMPLOYEES IS
9 CALCULATED USING THE METHOD SET FORTH IN 26 U.S.C. SEC. 4980H
10 (c)(2)(E).

11 (c) IN THE CASE OF AN EMPLOYER THAT WAS NOT IN EXISTENCE
12 THROUGHOUT THE PRECEDING CALENDAR QUARTER, THE DETERMINATION
13 OF WHETHER THE EMPLOYER IS A LARGE EMPLOYER IS BASED ON THE
14 AVERAGE NUMBER OF EMPLOYEES THAT THE EMPLOYER IS REASONABLY
15 EXPECTED TO EMPLOY ON BUSINESS DAYS IN THE CURRENT CALENDAR
16 YEAR.

17 (16) "MANUFACTURER" MEANS A PERSON THAT:

18 (a) ENGAGES IN THE MANUFACTURE OF A PRESCRIPTION DRUG
19 THAT IS SOLD TO PURCHASERS LOCATED IN THIS STATE; OR

20 (b) (I) ENTERS INTO A LEASE OR OTHER CONTRACTUAL
21 AGREEMENT WITH A MANUFACTURER TO MARKET AND DISTRIBUTE A
22 PRESCRIPTION DRUG IN THIS STATE UNDER THE PERSON'S OWN NAME; AND

23 (II) SETS OR CHANGES THE WHOLESALE ACQUISITION COST OF THE
24 PRESCRIPTION DRUG IN THIS STATE.

25 (17) "OPTIONAL PARTICIPATING PLAN" MEANS A SELF-FUNDED
26 HEALTH BENEFIT PLAN OFFERED IN COLORADO THAT ELECTS TO SUBJECT
27 ITS PURCHASES OF OR PAYER REIMBURSEMENTS FOR PRESCRIPTION DRUGS

1 FOR ITS MEMBERS IN COLORADO TO THE REQUIREMENTS OF THIS PART 13,
2 AS DESCRIBED IN SECTION 10-16-1307 (6).

3 (18) "PRACTITIONER" HAS THE MEANING SET FORTH IN SECTION
4 12-280-103 (40).

5 (19) "PRESCRIPTION DRUG" HAS THE MEANING SET FORTH IN
6 SECTION 12-280-103 (42); EXCEPT THAT THE TERM INCLUDES ONLY
7 PRESCRIPTION DRUGS THAT ARE INTENDED FOR HUMAN USE.

8 (20) "PRICING INFORMATION" MEANS INFORMATION ABOUT THE
9 PRICE OF A PRESCRIPTION DRUG, INCLUDING INFORMATION THAT EXPLAINS
10 OR HELPS EXPLAIN HOW THE PRICE WAS DETERMINED.

11 (21) "SMALL EMPLOYER" HAS THE MEANING SET FORTH IN SECTION
12 10-16-102 (61).

13 (22) "STATE ENTITY" MEANS ANY AGENCY OF STATE GOVERNMENT
14 THAT PURCHASES OR REIMBURSES PAYERS FOR PRESCRIPTION DRUGS ON
15 BEHALF OF THE STATE FOR A PERSON WHOSE HEALTH CARE IS PAID FOR BY
16 THE STATE, INCLUDING ANY AGENT, VENDOR, CONTRACTOR, OR OTHER
17 PARTY ACTING ON BEHALF OF THE STATE.

18 (23) "UPPER PAYMENT LIMIT" MEANS THE MAXIMUM AMOUNT
19 THAT MAY BE PAID OR BILLED FOR A PRESCRIPTION DRUG THAT IS
20 DISPENSED OR DISTRIBUTED IN COLORADO IN ANY FINANCIAL
21 TRANSACTION CONCERNING THE PURCHASE OF OR REIMBURSEMENT FOR
22 THE PRESCRIPTION DRUG.

23 (24) "WHOLESALE ACQUISITION COST" HAS THE MEANING SET
24 FORTH IN 42 U.S.C. 1395w-3a (c)(6)(B).

25 **10-16-1302. Colorado prescription drug affordability review**
26 **board - created - membership - terms - conflicts of interest.** (1) THE
27 COLORADO PRESCRIPTION DRUG AFFORDABILITY REVIEW BOARD IS

1 CREATED IN THE DIVISION AS A **TYPE 1** ENTITY. THE BOARD IS A BODY
2 POLITIC AND CORPORATE AND IS AN INSTRUMENTALITY OF THE STATE. THE
3 BOARD IS AN INDEPENDENT UNIT OF STATE GOVERNMENT, AND THE
4 EXERCISE BY THE BOARD OF ITS AUTHORITY UNDER THIS PART 13 IS AN
5 ESSENTIAL PUBLIC FUNCTION.

6 (2) (a) THE BOARD CONSISTS OF FIVE MEMBERS, WHO MUST EACH
7 HAVE AN ADVANCED DEGREE AND EXPERIENCE OR EXPERTISE IN
8 HEALTH-CARE ECONOMICS OR CLINICAL MEDICINE.

9 (b) THE GOVERNOR SHALL APPOINT EACH BOARD MEMBER,
10 SUBJECT TO CONFIRMATION BY THE SENATE. ALL OF THE INITIAL MEMBERS
11 OF THE BOARD MUST BE APPOINTED BY OCTOBER 1, 2021.

12 (c) THE TERM OF OFFICE OF EACH BOARD MEMBER IS THREE YEARS;
13 EXCEPT THAT, AS TO THE TERMS OF THE MEMBERS WHO ARE FIRST
14 APPOINTED TO THE BOARD, TWO SUCH MEMBERS SHALL SERVE
15 THREE-YEAR INITIAL TERMS, TWO SUCH MEMBERS SHALL SERVE TWO-YEAR
16 INITIAL TERMS, AND ONE SUCH MEMBER SHALL SERVE A ONE-YEAR INITIAL
17 TERM, TO BE DETERMINED BY THE GOVERNOR. THE GOVERNOR MAY
18 REMOVE ANY APPOINTED MEMBER OF THE BOARD FOR MALFEASANCE IN
19 OFFICE, FOR FAILURE TO REGULARLY ATTEND MEETINGS, OR FOR ANY
20 CAUSE THAT RENDERS THE MEMBER INCAPABLE OR UNFIT TO DISCHARGE
21 THE DUTIES OF THE MEMBER'S OFFICE, AND ANY SUCH REMOVAL IS NOT
22 SUBJECT TO REVIEW.

23 (d) THE GOVERNOR SHALL DESIGNATE ONE MEMBER OF THE BOARD
24 TO SERVE AS THE CHAIR. A MAJORITY OF THE BOARD CONSTITUTES A
25 QUORUM. THE CONCURRENCE OF A MAJORITY OF THE BOARD IN ANY
26 MATTER WITHIN ITS POWERS AND DUTIES IS REQUIRED FOR ANY
27 DETERMINATION MADE BY THE BOARD.

1 (3) (a) AN INDIVIDUAL WHO IS BEING CONSIDERED FOR
2 APPOINTMENT TO THE BOARD SHALL DISCLOSE ANY CONFLICT OF INTEREST
3 TO THE INDIVIDUAL'S POTENTIAL APPOINTING AUTHORITY. WHEN
4 APPOINTING A MEMBER OF THE BOARD, AN APPOINTING AUTHORITY SHALL
5 CONSIDER ANY CONFLICT OF INTEREST DISCLOSED BY THE PROSPECTIVE
6 MEMBER.

7 (b) A BOARD MEMBER MUST NOT BE AN EMPLOYEE, BOARD
8 MEMBER, OR CONSULTANT OF:

9 (I) A MANUFACTURER OR A TRADE ASSOCIATION OF
10 MANUFACTURERS;

11 (II) A CARRIER OR A TRADE ASSOCIATION OF CARRIERS; OR

12 (III) A PHARMACY BENEFIT MANAGER OR A TRADE ASSOCIATION
13 OF PHARMACY BENEFIT MANAGERS.

14 (c) BOARD MEMBERS, STAFF MEMBERS, AND CONTRACTORS OF THE
15 BOARD SHALL RECUSE THEMSELVES FROM ANY BOARD ACTIVITY IN ANY
16 CASE IN WHICH THEY HAVE A CONFLICT OF INTEREST.

17 (d) ON AND AFTER JANUARY 1, 2022, THE DIVISION SHALL
18 MAINTAIN A PAGE ON ITS PUBLIC WEBSITE FOR THE BOARD TO USE FOR ITS
19 PURPOSES. THE BOARD SHALL DISCLOSE ON THE PAGE EACH CONFLICT OF
20 INTEREST THAT IS DISCLOSED TO THE BOARD PURSUANT TO SUBSECTION
21 (3)(c) OF THIS SECTION AND SECTION 10-16-1309 (5)(b).

22 (e) BOARD MEMBERS, STAFF MEMBERS, CONTRACTORS OF THE
23 BOARD, AND IMMEDIATE FAMILY MEMBERS OF BOARD MEMBERS, STAFF
24 MEMBERS, OR CONTRACTORS OF THE BOARD SHALL NOT ACCEPT A
25 FINANCIAL BENEFIT OR GIFTS, BEQUESTS, OR DONATIONS OF SERVICES OR
26 PROPERTY THAT SUGGEST A CONFLICT OF INTEREST OR HAVE THE
27 APPEARANCE OF CREATING BIAS IN THE WORK OF THE BOARD.

1
2 (4) THE ATTORNEY GENERAL SHALL ASSIGN AN ASSISTANT
3 ATTORNEY GENERAL TO PROVIDE LEGAL COUNSEL TO THE BOARD. ANY
4 ASSISTANT ATTORNEY GENERAL ASSIGNED TO THE BOARD PURSUANT TO
5 THIS SUBSECTION (4) SHALL DISCLOSE ANY CONFLICT OF INTEREST TO THE
6 BOARD.

7 **10-16-1303. Colorado prescription drug affordability review**
8 **board - powers and duties - rules.** (1) TO PROTECT COLORADO
9 CONSUMERS FROM EXCESSIVE PRESCRIPTION DRUG COSTS, THE BOARD
10 SHALL:

11 (a) COLLECT AND EVALUATE INFORMATION CONCERNING THE COST
12 OF PRESCRIPTION DRUGS SOLD TO COLORADO CONSUMERS, AS DESCRIBED
13 IN SECTION 10-16-1305;

14 (b) PERFORM AFFORDABILITY REVIEWS OF PRESCRIPTION DRUGS,
15 AS DESCRIBED IN SECTION 10-16-1306;

16 (c) ESTABLISH UPPER PAYMENT LIMITS FOR PRESCRIPTION DRUGS,
17 AS DESCRIBED IN SECTION 10-16-1307; AND

18 (d) MAKE POLICY RECOMMENDATIONS TO THE GENERAL ASSEMBLY
19 TO IMPROVE THE AFFORDABILITY OF PRESCRIPTION DRUGS FOR COLORADO
20 CONSUMERS, AS DESCRIBED IN SECTION 10-16-1314 (1)(h).

21 (2) THE BOARD MAY ESTABLISH AD HOC WORK GROUPS TO
22 CONSIDER MATTERS RELATED TO THE WORK OF THE BOARD PURSUANT TO
23 THIS PART 13. AD HOC WORK GROUPS MAY INCLUDE MEMBERS OF THE
24 PUBLIC.

25 (3) THE BOARD MAY ENTER INTO A CONTRACT WITH A QUALIFIED,
26 INDEPENDENT THIRD PARTY FOR ANY SERVICE NECESSARY TO CARRY OUT
27 THE POWERS AND DUTIES OF THE BOARD. A THIRD PARTY WITH WHICH THE

1 BOARD CONTRACTS PURSUANT TO THIS SUBSECTION (3), INCLUDING ANY
2 OF THE THIRD PARTY'S DIRECTORS, OFFICERS, EMPLOYEES, CONTRACTORS,
3 OR AGENTS, SHALL NOT RELEASE OR PUBLISH ANY INFORMATION THAT THE
4 THIRD PARTY ACQUIRES PURSUANT TO ITS PERFORMANCE UNDER THE
5 CONTRACT. ANY THIRD PARTY WITH WHICH THE BOARD CONTRACTS
6 PURSUANT TO THIS SUBSECTION (3) SHALL DISCLOSE ANY CONFLICT OF
7 INTEREST TO THE BOARD.

8 (4) IN CARRYING OUT ITS DUTIES PURSUANT TO THIS PART 13, THE
9 BOARD IS EXEMPT FROM THE STATE "PROCUREMENT CODE", ARTICLES 101
10 TO 112 OF TITLE 24.

11 (5) THE BOARD SHALL PROMULGATE RULES AS NECESSARY,
12 PURSUANT TO ARTICLE 4 OF TITLE 24, FOR THE IMPLEMENTATION OF THIS
13 PART 13.

14 (6) (a) THE DIVISION, ON BEHALF OF THE BOARD, MAY SEEK,
15 ACCEPT, AND EXPEND GIFTS, GRANTS, AND DONATIONS FROM PRIVATE OR
16 PUBLIC SOURCES FOR THE PURPOSES OF THIS PART 13, AND ANY SUCH
17 GIFTS, GRANTS, AND DONATIONS ARE CONTINUOUSLY APPROPRIATED TO
18 THE DEPARTMENT OF REGULATORY AGENCIES; EXCEPT THAT THE DIVISION
19 SHALL NOT ACCEPT ANY GIFT, GRANT, OR DONATION THAT CREATES A
20 CONFLICT OF INTEREST OR THE APPEARANCE OF ANY CONFLICT OF
21 INTEREST FOR ANY BOARD MEMBER.

22 (b) THE GENERAL ASSEMBLY FINDS THAT THE IMPLEMENTATION OF
23 THIS PART 13 DOES NOT RELY ENTIRELY ON THE RECEIPT OF ADEQUATE
24 FUNDING THROUGH GIFTS, GRANTS, OR DONATIONS. THEREFORE, THE
25 BOARD IS NOT SUBJECT TO THE REPORTING REQUIREMENTS DESCRIBED IN
26 SECTION 24-75-1303.

27 **10-16-1304. Colorado prescription drug affordability review**

1 **board meetings - required to be public - exceptions.** (1) THE BOARD
2 SHALL HOLD ITS FIRST MEETING WITHIN SIX WEEKS AFTER ALL OF THE
3 BOARD MEMBERS ARE APPOINTED AND SHALL MEET AT LEAST EVERY SIX
4 WEEKS THEREAFTER TO REVIEW PRESCRIPTION DRUGS; EXCEPT THAT THE
5 CHAIR MAY CANCEL OR POSTPONE A MEETING IF THE BOARD HAS NO
6 PRESCRIPTION DRUGS TO REVIEW.

7 (2) THE BOARD IS A STATE PUBLIC BODY FOR PURPOSES OF SECTION
8 24-6-402, AND THE BOARD'S MEETINGS AND THE MEETINGS OF AD HOC
9 WORK GROUPS OF THE BOARD ARE PUBLIC MEETINGS.

10 (3) THE BOARD SHALL MEET IN EXECUTIVE SESSION TO DISCUSS
11 PROPRIETARY INFORMATION. THE BOARD AND ANY BOARD MEMBERS,
12 OFFICERS, DIRECTORS, EMPLOYEES, CONTRACTORS, AND AGENTS SHALL
13 NOT DISCLOSE OR OTHERWISE MAKE AVAILABLE TO THE PUBLIC ANY
14 MATERIALS OR INFORMATION CONTAINING TRADE-SECRET, CONFIDENTIAL,
15 OR PROPRIETARY DATA THAT IS NOT OTHERWISE AVAILABLE TO THE
16 PUBLIC. ELECTRONIC RECORDINGS OF SUCH EXECUTIVE SESSIONS ARE NOT
17 PERMITTED IF THEY WOULD RESULT IN THE DISCLOSURE OF ANY
18 MATERIALS OR INFORMATION CONTAINING TRADE-SECRET, CONFIDENTIAL,
19 OR PROPRIETARY DATA, AND IN NO CASE SHALL MINUTES FROM SUCH
20 EXECUTIVE SESSIONS DISCLOSE OR INCLUDE MATERIALS OR INFORMATION
21 CONTAINING TRADE-SECRET, CONFIDENTIAL, OR PROPRIETARY DATA. THE
22 BOARD SHALL NOT TAKE ANY OF THE FOLLOWING ACTIONS WHILE MEETING
23 IN EXECUTIVE SESSION:

24 (a) DELIBERATIONS CONCERNING WHETHER TO SUBJECT A
25 PRESCRIPTION DRUG TO AN AFFORDABILITY REVIEW AS DESCRIBED IN
26 SECTION 10-16-1306;

27 (b) VOTES CONCERNING WHETHER TO ESTABLISH AN UPPER

1 PAYMENT LIMIT ON A PRESCRIPTION DRUG; OR

2 (c) ANY FINAL DECISION OF THE BOARD.

3 **10-16-1305. Colorado prescription drug affordability review**
4 **board - reports from carriers and pharmacy benefit management**
5 **firms required - confidential materials. (1) BEGINNING IN THE 2022**

6 CALENDAR YEAR, FOR ALL PRESCRIPTION DRUGS DISPENSED AT A
7 PHARMACY IN THIS STATE AND PAID FOR BY A CARRIER PURSUANT TO A
8 HEALTH BENEFIT PLAN ISSUED UNDER PART 2, 3, OR 4 OF THIS ARTICLE 16
9 DURING THE IMMEDIATELY PRECEDING CALENDAR YEAR, INCLUDING
10 BRAND-NAME DRUGS, AUTHORIZED GENERIC DRUGS, BIOLOGICAL
11 PRODUCTS, AND BIOSIMILAR DRUGS:

12 (a) EACH CARRIER SHALL REPORT TO THE COMMISSIONER,
13 CONTEMPORANEOUS WITH AND SEPARATE FROM ITS RATE FILING
14 PURSUANT TO SECTION 10-16-107, IN A FORM AND MANNER SPECIFIED BY
15 THE COMMISSIONER, THE FOLLOWING INFORMATION:

16 (I) THE TOP FIFTEEN PRESCRIPTION DRUGS BY VOLUME,
17 CALCULATED BY UNIT, FOR WHICH THE CARRIER PAID;

18 (II) THE FIFTEEN COSTLIEST PRESCRIPTION DRUGS FOR WHICH THE
19 CARRIER PAID, AS DETERMINED BY TOTAL ANNUAL PLAN SPENDING;

20 (III) THE FIFTEEN PRESCRIPTION DRUGS PAID FOR BY THE CARRIER
21 THAT ACCOUNTED FOR THE HIGHEST INCREASE IN TOTAL ANNUAL PLAN
22 SPENDING WHEN COMPARED WITH THE TOTAL ANNUAL PLAN SPENDING FOR
23 THE SAME PRESCRIPTION DRUGS IN THE YEAR IMMEDIATELY PRECEDING
24 THE YEAR FOR WHICH THE INFORMATION IS REPORTED;

25 (IV) THE FIFTEEN PRESCRIPTION DRUGS THAT CAUSED THE
26 GREATEST INCREASES IN THE CARRIER'S PREMIUMS;

27 (V) THE FIFTEEN PRESCRIPTION DRUGS FOR WHICH THE CARRIER

1 PAID MOST FREQUENTLY AND FOR WHICH THE CARRIER RECEIVED A
2 REBATE FROM MANUFACTURERS;

3 (VI) THE FIFTEEN PRESCRIPTION DRUGS FOR WHICH THE CARRIER
4 RECEIVED THE HIGHEST REBATES, AS DETERMINED BY PERCENTAGES OF
5 THE PRICE OF THE PRESCRIPTION DRUG; AND

6 (VII) THE FIFTEEN PRESCRIPTION DRUGS FOR WHICH THE CARRIER
7 RECEIVED THE LARGEST REBATES.

8 (b) EACH CARRIER OR EACH PHARMACY BENEFIT MANAGEMENT
9 FIRM ACTING ON BEHALF OF A CARRIER SHALL REPORT,
10 CONTEMPORANEOUS WITH AND SEPARATE FROM THE CARRIER'S RATE
11 FILING PURSUANT TO SECTION 10-16-107, IN A FORM AND MANNER
12 SPECIFIED BY THE COMMISSIONER, THE AVERAGE WHOLESALE ACQUISITION
13 COST PAID FOR EACH OF THE FOLLOWING CATEGORIES OF PRESCRIPTION
14 DRUGS:

15 (I) BRAND-NAME DRUGS PURCHASED FROM RETAIL PHARMACIES;

16 (II) AUTHORIZED GENERIC DRUGS PURCHASED FROM RETAIL
17 PHARMACIES;

18 (III) BRAND-NAME DRUGS PURCHASED FROM MAIL-ORDER
19 PHARMACIES;

20 (IV) AUTHORIZED GENERIC DRUGS PURCHASED FROM MAIL-ORDER
21 PHARMACIES;

22 (V) PRESCRIPTION DRUGS DISPENSED BY A PRACTITIONER IN
23 ACCORDANCE WITH SECTION 12-280-120 (6);

24 (VI) PRESCRIPTION DRUGS ADMINISTERED IN AN INPATIENT
25 HOSPITAL SETTING; AND

26 (VII) PRESCRIPTION DRUGS ADMINISTERED IN AN OUTPATIENT
27 HOSPITAL SETTING.

1 (c) EACH CARRIER OR EACH PHARMACY BENEFIT MANAGEMENT
2 FIRM ACTING ON BEHALF OF A CARRIER SHALL REPORT,
3 CONTEMPORANEOUS WITH AND SEPARATE FROM THE CARRIER'S RATE
4 FILING PURSUANT TO SECTION 10-16-107, IN A FORM AND MANNER
5 SPECIFIED BY THE COMMISSIONER, THE AVERAGE WHOLESALE ACQUISITION
6 COST FOR THE PRESCRIPTION DRUGS DESCRIBED IN SUBSECTION (1)(b) OF
7 THIS SECTION PAID BY EACH OF THE FOLLOWING MARKET SECTORS
8 ENROLLED IN A HEALTH BENEFIT PLAN THAT THE CARRIER ISSUED OR THAT
9 INCLUDES PRESCRIPTION DRUG BENEFITS MANAGED OR ADMINISTERED BY
10 THE PHARMACY BENEFIT MANAGEMENT FIRM:

- 11 (I) INDIVIDUAL;
- 12 (II) SMALL EMPLOYER; AND
- 13 (III) LARGE EMPLOYER.

14 (2) (a) EXCEPT AS PROVIDED IN SUBSECTION (2)(b) OF THIS
15 SECTION, THE COMMISSIONER SHALL:

16 (I) POST THE INFORMATION REPORTED BY CARRIERS AND
17 PHARMACY BENEFIT MANAGEMENT FIRMS PURSUANT TO THIS SECTION ON
18 THE DIVISION'S WEBSITE; AND

19 (II) PROVIDE THE INFORMATION REPORTED BY CARRIERS AND
20 PHARMACY BENEFIT MANAGEMENT FIRMS PURSUANT TO THIS SECTION TO
21 THE BOARD, IN A FORM AND MANNER PRESCRIBED BY THE BOARD.

22 (b) IF A CARRIER OR PHARMACY BENEFIT MANAGEMENT FIRM
23 CLAIMS THAT INFORMATION SUBMITTED PURSUANT TO THIS SECTION IS
24 CONFIDENTIAL OR PROPRIETARY, THE COMMISSIONER SHALL REVIEW THE
25 INFORMATION AND REDACT SPECIFIC ITEMS THAT THE CARRIER OR
26 PHARMACY BENEFIT MANAGEMENT FIRM DEMONSTRATES TO BE
27 CONFIDENTIAL OR PROPRIETARY. THE COMMISSIONER SHALL NOT

1 DISCLOSE REDACTED ITEMS TO ANY PERSON; EXCEPT THAT THE
2 COMMISSIONER MAY DISCLOSE REDACTED ITEMS:

3 (I) AS MAY BE REQUIRED PURSUANT TO THE "COLORADO OPEN
4 RECORDS ACT", PART 2 OF ARTICLE 72 OF TITLE 24; AND

5 (II) TO EMPLOYEES OF THE DIVISION, AS NECESSARY.

6 (3) THE REQUIREMENT IN THIS SECTION TO REPORT INFORMATION
7 RELATING TO THE COST OF PRESCRIPTION DRUGS IS INTENDED TO CREATE
8 TRANSPARENCY IN PRESCRIPTION DRUG PRICING AND DOES NOT:

9 (a) PROHIBIT A MANUFACTURER OF A PRESCRIPTION DRUG FROM
10 MAKING PRICING DECISIONS ABOUT ITS PRESCRIPTION DRUGS; OR

11 (b) PROHIBIT PURCHASERS, BOTH PUBLIC AND PRIVATE, OR
12 PHARMACY BENEFIT MANAGEMENT FIRMS FROM NEGOTIATING DISCOUNTS
13 AND REBATES CONSISTENT WITH EXISTING STATE AND FEDERAL LAW.

14 **10-16-1306. Colorado prescription drug affordability review**
15 **board - affordability reviews of prescription drugs.** (1) THE BOARD
16 MAY CONDUCT AFFORDABILITY REVIEWS OF PRESCRIPTION DRUGS IN
17 ACCORDANCE WITH THIS SECTION. THE BOARD SHALL IDENTIFY, FOR
18 PURPOSES OF DETERMINING WHETHER TO CONDUCT AN AFFORDABILITY
19 REVIEW, ANY PRESCRIPTION DRUG THAT IS:

20 (a) A BRAND-NAME DRUG OR BIOLOGICAL PRODUCT THAT, AS
21 ADJUSTED ANNUALLY FOR INFLATION, HAS:

22 (I) AN INITIAL WHOLESALE ACQUISITION COST OF THIRTY
23 THOUSAND DOLLARS OR MORE FOR A TWELVE-MONTH SUPPLY OR FOR A
24 COURSE OF TREATMENT THAT IS LESS THAN TWELVE MONTHS IN
25 DURATION; OR

26 (II) AN INCREASE IN THE WHOLESALE ACQUISITION COST OF THREE
27 THOUSAND DOLLARS OR MORE DURING THE IMMEDIATELY PRECEDING

1 TWELVE MONTHS FOR A TWELVE-MONTH SUPPLY OR FOR A COURSE OF
2 TREATMENT THAT IS LESS THAN TWELVE MONTHS IN DURATION;

3 (b) A BIOSIMILAR DRUG THAT HAS AN INITIAL WHOLESAL
4 ACQUISITION COST THAT IS NOT AT LEAST FIFTEEN PERCENT LOWER THAN
5 THE CORRESPONDING BIOLOGICAL PRODUCT; OR

6 (c) A GENERIC DRUG:

7 (I) THAT, AS ADJUSTED ANNUALLY FOR INFLATION, HAS A
8 WHOLESAL ACQUISITION COST OF ONE HUNDRED DOLLARS OR MORE FOR:

9 (A) A THIRTY-DAY SUPPLY BASED ON THE RECOMMENDED DOSAGE
10 APPROVED FOR LABELING BY THE FDA;

11 (B) A SUPPLY THAT LASTS LESS THAN THIRTY DAYS BASED ON THE
12 RECOMMENDED DOSAGE APPROVED FOR LABELING BY THE FDA; OR

13 (C) ONE DOSE OF THE GENERIC DRUG IF THE LABELING APPROVED
14 BY THE FDA DOES NOT RECOMMEND A FINITE DOSAGE; AND

15 (II) FOR WHICH THE WHOLESAL ACQUISITION COST INCREASED BY
16 TWO HUNDRED PERCENT OR MORE DURING THE IMMEDIATELY PRECEDING
17 TWELVE MONTHS, AS DETERMINED BY COMPARING THE CURRENT
18 WHOLESAL ACQUISITION COST TO THE AVERAGE WHOLESAL
19 ACQUISITION COST REPORTED DURING THE IMMEDIATELY PRECEDING
20 TWELVE MONTHS.

21 (2) AFTER IDENTIFYING PRESCRIPTION DRUGS AS DESCRIBED IN
22 SUBSECTION (1) OF THIS SECTION, THE BOARD SHALL DETERMINE WHETHER
23 TO CONDUCT AN AFFORDABILITY REVIEW FOR EACH IDENTIFIED
24 PRESCRIPTION DRUG BY:

25 (a) EVALUATING THE CLASS OF THE PRESCRIPTION DRUG AND
26 WHETHER ANY THERAPEUTICALLY EQUIVALENT PRESCRIPTION DRUGS ARE
27 AVAILABLE FOR SALE;

- 1 (b) EVALUATING AGGREGATED DATA;
2 (c) SEEKING AND CONSIDERING INPUT FROM THE ADVISORY
3 COUNCIL ABOUT THE PRESCRIPTION DRUG; AND
4 (d) CONSIDERING THE AVERAGE PATIENT'S OUT-OF-POCKET COST
5 FOR THE PRESCRIPTION DRUG.

6 (3) IF THE BOARD CONDUCTS AN AFFORDABILITY REVIEW OF A
7 PRESCRIPTION DRUG, THE AFFORDABILITY REVIEW MUST DETERMINE
8 WHETHER USE OF THE PRESCRIPTION DRUG CONSISTENT WITH THE
9 LABELING APPROVED FOR THE PRESCRIPTION DRUG BY THE FDA OR WITH
10 STANDARD MEDICAL PRACTICE IS UNAFFORDABLE FOR COLORADO
11 CONSUMERS.

12 (4) IN PERFORMING AN AFFORDABILITY REVIEW, TO THE EXTENT
13 PRACTICABLE, THE BOARD SHALL CONSIDER:

14 (a) THE WHOLESALE ACQUISITION COST OF THE PRESCRIPTION
15 DRUG;

16 (b) THE COST AND AVAILABILITY OF THERAPEUTIC ALTERNATIVES
17 TO THE PRESCRIPTION DRUG IN THE STATE;

18 (c) THE EFFECT OF THE PRICE ON COLORADO CONSUMERS' ACCESS
19 TO THE PRESCRIPTION DRUG;

20 (d) THE RELATIVE FINANCIAL EFFECTS ON HEALTH, MEDICAL, OR
21 SOCIAL SERVICES COSTS, AS THE EFFECTS CAN BE QUANTIFIED AND
22 COMPARED TO BASELINE EFFECTS OF EXISTING THERAPEUTIC
23 ALTERNATIVES TO THE PRESCRIPTION DRUG;

24 (e) THE PATIENT COPAYMENT OR OTHER COST SHARING THAT IS
25 ASSOCIATED WITH THE PRESCRIPTION DRUG AND TYPICALLY REQUIRED
26 PURSUANT TO HEALTH BENEFIT PLANS ISSUED BY CARRIERS IN THE STATE;

27 (f) THE IMPACT ON SAFETY NET PROVIDERS IF THE PRESCRIPTION

1 DRUG IS AVAILABLE THROUGH SECTION 340B OF THE FEDERAL "PUBLIC
2 HEALTH SERVICE ACT", PUB.L. 78-410;

3 (g) ANY OTHER INFORMATION THAT A MANUFACTURER, CARRIER,
4 PHARMACY BENEFIT MANAGEMENT FIRM, OR OTHER ENTITY CHOOSES TO
5 PROVIDE; AND

6 (h) ANY OTHER FACTORS AS DETERMINED BY RULES
7 PROMULGATED BY THE BOARD PURSUANT TO SECTION 10-16-1303 (5).

8 (5) TRADE-SECRET, CONFIDENTIAL, OR PROPRIETARY
9 INFORMATION OBTAINED BY THE BOARD PURSUANT TO THIS SECTION MAY
10 BE ACCESSED ONLY BY BOARD MEMBERS AND STAFF OR BY A QUALIFIED
11 INDEPENDENT THIRD PARTY THAT HAS CONTRACTED WITH THE BOARD
12 PURSUANT TO SECTION 10-16-1303 (3) AND IS SUBJECT TO A
13 NONDISCLOSURE AGREEMENT PROHIBITING DISCLOSURE OF SUCH
14 INFORMATION. ANY PERSON WITH ACCESS TO SUCH INFORMATION SHALL
15 PROTECT THE INFORMATION FROM DIRECT OR INDIRECT PUBLICATION OR
16 RELEASE TO ANY PERSON.

17 (6) IN PERFORMING AN AFFORDABILITY REVIEW OF A PRESCRIPTION
18 DRUG, THE BOARD MAY CONSIDER ANY DOCUMENTS AND INFORMATION
19 RELATING TO THE MANUFACTURER'S SELECTION OF THE INTRODUCTORY
20 PRICE OR PRICE INCREASE OF THE PRESCRIPTION DRUG, INCLUDING
21 DOCUMENTS AND INFORMATION RELATING TO:

- 22 (a) LIFE-CYCLE MANAGEMENT;
- 23 (b) THE AVERAGE COST OF THE PRESCRIPTION DRUG IN THE STATE;
- 24 (c) MARKET COMPETITION AND CONTEXT;
- 25 (d) PROJECTED REVENUE;
- 26 (e) THE ESTIMATED COST-EFFECTIVENESS OF THE PRESCRIPTION
27 DRUG; AND

1 (f) OFF-LABEL USAGE OF THE PRESCRIPTION DRUG.

2 (7) (a) TO THE EXTENT PRACTICABLE, THE BOARD MAY ACCESS
3 PRICING INFORMATION FOR PRESCRIPTION DRUGS BY:

4 (I) ACCESSING PUBLICLY AVAILABLE PRICING INFORMATION FROM
5 A STATE TO WHICH MANUFACTURERS REPORT PRICING INFORMATION;

6 (II) ACCESSING AVAILABLE PRICING INFORMATION FROM THE
7 ALL-PAYER HEALTH CLAIMS DATABASE AND FROM STATE ENTITIES; AND

8 (III) ACCESSING INFORMATION THAT IS AVAILABLE FROM OTHER
9 COUNTRIES.

10 (b) TO THE EXTENT THAT THERE IS NO PUBLICLY AVAILABLE
11 INFORMATION WITH WHICH TO CONDUCT AN AFFORDABILITY REVIEW, THE
12 BOARD MAY REQUEST THAT A MANUFACTURER, CARRIER, OR PHARMACY
13 BENEFIT MANAGEMENT FIRM PROVIDE PRICING INFORMATION FOR ANY
14 PRESCRIPTION DRUG IDENTIFIED PURSUANT TO SUBSECTION (1) OF THIS
15 SECTION. THE FAILURE OF AN ENTITY TO PROVIDE PRICING INFORMATION
16 TO THE BOARD FOR AN AFFORDABILITY REVIEW DOES NOT AFFECT THE
17 AUTHORITY OF THE BOARD TO CONDUCT THE AFFORDABILITY REVIEW, AS
18 DESCRIBED IN THIS SECTION.

19 **10-16-1307. Colorado prescription drug affordability review**
20 **board - upper payment limits for certain prescription drugs - rules**
21 **- severability.** (1) THE BOARD MAY ESTABLISH AN UPPER PAYMENT LIMIT
22 FOR ANY PRESCRIPTION DRUG FOR WHICH THE BOARD HAS PERFORMED AN
23 AFFORDABILITY REVIEW PURSUANT TO SECTION 10-16-1306 AND
24 DETERMINED THAT THE USE OF THE PRESCRIPTION DRUG IS UNAFFORDABLE
25 FOR COLORADO CONSUMERS; EXCEPT THAT THE BOARD MAY NOT
26 ESTABLISH AN UPPER PAYMENT LIMIT FOR MORE THAN TWELVE
27 PRESCRIPTION DRUGS IN EACH CALENDAR YEAR FOR THREE YEARS

1 BEGINNING APRIL 1, 2022. THE FAILURE OF AN ENTITY TO PROVIDE
2 INFORMATION TO THE BOARD PURSUANT TO SECTION 10-16-1306 (7)(b)
3 DOES NOT AFFECT THE AUTHORITY OF THE BOARD TO ESTABLISH AN UPPER
4 PAYMENT LIMIT FOR THE PRESCRIPTION DRUG.

5 (2) THE BOARD SHALL DETERMINE BY RULE THE METHODOLOGY
6 FOR ESTABLISHING AN UPPER PAYMENT LIMIT FOR A PRESCRIPTION DRUG
7 TO PROTECT CONSUMERS FROM THE EXCESSIVE COST OF PRESCRIPTION
8 DRUGS AND ENSURE THEY CAN ACCESS PRESCRIPTION DRUGS NECESSARY
9 FOR THEIR HEALTH. THE METHODOLOGY MUST INCLUDE CONSIDERATION
10 OF:

11 (a) THE COST OF ADMINISTERING OR DISPENSING THE PRESCRIPTION
12 DRUG;

13 (b) THE COST OF DISTRIBUTING THE PRESCRIPTION DRUG TO
14 CONSUMERS IN THE STATE; AND

15 (c) OTHER RELEVANT COSTS RELATED TO THE PRESCRIPTION DRUG.

16 (3) THE METHODOLOGY DETERMINED BY THE BOARD PURSUANT TO
17 SUBSECTION (2) OF THIS SECTION SHALL NOT CONSIDER RESEARCH OR
18 METHODS THAT EMPLOY A DOLLARS-PER-QUALITY ADJUSTED LIFE YEAR,
19 OR SIMILAR MEASURE, THAT DISCOUNTS THE VALUE OF A LIFE BECAUSE OF
20 AN INDIVIDUAL'S DISABILITY OR AGE.

21 (4) AN UPPER PAYMENT LIMIT APPLIES TO ALL PURCHASES OF AND
22 PAYER REIMBURSEMENTS FOR A PRESCRIPTION DRUG THAT IS DISPENSED
23 OR ADMINISTERED TO INDIVIDUALS IN THE STATE IN PERSON, BY MAIL, OR
24 BY OTHER MEANS AND FOR WHICH AN UPPER PAYMENT LIMIT IS
25 ESTABLISHED.

26 (5) ANY INFORMATION SUBMITTED TO THE BOARD IN ACCORDANCE
27 WITH THIS SECTION OR SECTION 10-16-1305 OR 10-16-1306 IS SUBJECT TO

1 PUBLIC INSPECTION ONLY TO THE EXTENT ALLOWED UNDER THE
2 "COLORADO OPEN RECORDS ACT", PART 2 OF ARTICLE 72 OF TITLE 24,
3 AND IN NO CASE SHALL TRADE-SECRET, CONFIDENTIAL, OR PROPRIETARY
4 INFORMATION BE DISCLOSED TO ANY PERSON WHO IS NOT AUTHORIZED TO
5 ACCESS SUCH INFORMATION PURSUANT TO SECTION 10-16-1306.

6 (6) NOTWITHSTANDING ANY PROVISION OF THIS PART 13 TO THE
7 CONTRARY, WITH RESPECT TO AN ENTITY PROVIDING OR ADMINISTERING
8 A SELF-FUNDED HEALTH BENEFIT PLAN AND ITS PLAN MEMBERS, THE
9 REQUIREMENTS OF THIS PART 13 APPLY ONLY IF THE PLAN ELECTS TO BE
10 SUBJECT TO THIS PART 13 FOR ITS MEMBERS IN COLORADO. SUCH A PLAN
11 IS AN OPTIONAL PARTICIPATING PLAN FOR THE PURPOSES OF THIS PART 13.

12 (7) IF ANY PROVISION OF THIS SECTION OR ITS APPLICATION TO ANY
13 PERSON OR CIRCUMSTANCE IS HELD INVALID, THE INVALIDITY DOES NOT
14 AFFECT OTHER PROVISIONS OR APPLICATIONS OF THIS SECTION THAT CAN
15 BE GIVEN EFFECT WITHOUT THE INVALID PROVISION OR APPLICATION, AND
16 TO THIS END THE PROVISIONS OF THIS SECTION ARE SEVERABLE.

17 **10-16-1308. Colorado prescription drug affordability review**
18 **board - appeals - rules - judicial review.** (1) A PERSON AGGRIEVED BY
19 A DECISION OF THE BOARD MAY APPEAL THE DECISION WITHIN SIXTY DAYS
20 AFTER THE DECISION IS MADE. THE BOARD SHALL CONSIDER THE APPEAL
21 AND ISSUE A FINAL DECISION CONCERNING THE APPEAL WITHIN SIXTY
22 DAYS AFTER THE BOARD RECEIVES THE APPEAL.

23 (2) NOT LATER THAN DECEMBER 31, 2021, THE BOARD SHALL
24 PROMULGATE RULES ESTABLISHING A PROCESS AND TIMELINE FOR THE
25 CONSIDERATION BY THE BOARD OF ANY APPEAL THAT IS SUBMITTED TO
26 THE BOARD PURSUANT TO SUBSECTION (1) OF THIS SECTION. THE PROCESS
27 AND TIMELINE MUST COMPORT WITH THE "STATE ADMINISTRATIVE

1 PROCEDURE ACT", ARTICLE 4 OF TITLE 24.

2 (3) IN THE ABSENCE OF AN APPEAL, A DECISION OF THE BOARD
3 BECOMES FINAL AND RIPE FOR JUDICIAL REVIEW AFTER SIXTY DAYS. ANY
4 PERSON AGGRIEVED BY A FINAL DECISION OF THE BOARD MAY PETITION
5 FOR JUDICIAL REVIEW PURSUANT TO SECTION 24-4-106.

6 **10-16-1309. Colorado prescription drug affordability advisory**
7 **council - created - membership - powers and duties.** (1) (a) THE
8 COLORADO PRESCRIPTION DRUG AFFORDABILITY ADVISORY COUNCIL IS
9 CREATED IN THE DIVISION AS A **TYPE 2** ENTITY TO PROVIDE STAKEHOLDER
10 INPUT TO THE BOARD REGARDING THE AFFORDABILITY OF PRESCRIPTION
11 DRUGS. THE ADVISORY COUNCIL INCLUDES FOURTEEN MEMBERS AS
12 FOLLOWS:

13 (I) THE EXECUTIVE DIRECTOR OF THE DEPARTMENT OF HEALTH
14 CARE POLICY AND FINANCING OR THE EXECUTIVE DIRECTOR'S DESIGNEE;
15 AND

16 (II) THIRTEEN MEMBERS APPOINTED BY THE BOARD AS FOLLOWS:

17 (A) TWO MEMBERS WHO ARE HEALTH-CARE CONSUMERS OR WHO
18 REPRESENT HEALTH-CARE CONSUMERS;

19 (B) ONE MEMBER REPRESENTING A STATEWIDE HEALTH-CARE
20 CONSUMER ADVOCACY ORGANIZATION;

21 (C) ONE MEMBER REPRESENTING HEALTH-CARE CONSUMERS WHO
22 ARE LIVING WITH CHRONIC DISEASES;

23 (D) ONE MEMBER REPRESENTING A LABOR UNION;

24 (E) ONE MEMBER REPRESENTING EMPLOYERS;

25 (F) ONE MEMBER REPRESENTING CARRIERS;

26 (G) ONE MEMBER REPRESENTING PHARMACY BENEFIT
27 MANAGEMENT FIRMS;

1 (H) ONE MEMBER REPRESENTING HEALTH-CARE PROFESSIONALS
2 WITH PRESCRIBING AUTHORITY;

3 (I) ONE MEMBER WHO IS EMPLOYED BY AN ORGANIZATION THAT
4 PERFORMS RESEARCH CONCERNING PRESCRIPTION DRUGS, INCLUDING
5 RESEARCH CONCERNING PRICING INFORMATION;

6 (J) ONE MEMBER REPRESENTING MANUFACTURERS OF
7 BRAND-NAME DRUGS;

8 (K) ONE MEMBER REPRESENTING MANUFACTURERS OF GENERIC
9 DRUGS; AND

10 (L) ONE MEMBER REPRESENTING PHARMACISTS.

11 (b) TO THE EXTENT POSSIBLE, THE BOARD SHALL APPOINT COUNCIL
12 MEMBERS WHO HAVE EXPERIENCE SERVING UNDERSERVED COMMUNITIES
13 AND REFLECT THE DIVERSITY OF THE STATE WITH REGARD TO RACE,
14 ETHNICITY, IMMIGRATION STATUS, INCOME, WEALTH, DISABILITY, AGE,
15 GENDER IDENTITY, AND GEOGRAPHY. IN CONSIDERING GEOGRAPHIC
16 DIVERSITY, THE BOARD SHALL ENSURE AT LEAST ONE COUNCIL MEMBER
17 RESIDES ON THE EASTERN PLAINS AND ONE MEMBER RESIDES ON THE
18 WESTERN SLOPE, AND THE BOARD SHALL ATTEMPT TO APPOINT MEMBERS
19 FROM EACH CONGRESSIONAL DISTRICT IN THE STATE.

20 (c) ALL OF THE INITIAL MEMBERS OF THE ADVISORY COUNCIL MUST
21 BE APPOINTED BY JANUARY 1, 2022.

22 (2) EACH MEMBER OF THE ADVISORY COUNCIL MUST POSSESS
23 KNOWLEDGE OF AT LEAST ONE OF THE FOLLOWING SUBJECT MATTERS:

24 (a) THE PHARMACEUTICAL BUSINESS MODEL;

25 (b) SUPPLY CHAIN BUSINESS MODELS;

26 (c) THE PRACTICE OF MEDICINE OR CLINICAL TRAINING;

27 (d) HEALTH-CARE CONSUMER OR PATIENT PERSPECTIVES;

- 1 (e) HEALTH-CARE COST TRENDS AND DRIVERS;
- 2 (f) CLINICAL AND HEALTH SERVICES RESEARCH; OR
- 3 (g) THE STATE'S HEALTH-CARE MARKETPLACE.

4 (3) THE TERM OF EACH MEMBER OF THE ADVISORY COUNCIL IS
5 THREE YEARS; EXCEPT THAT THE MEMBERS INITIALLY APPOINTED TO THE
6 ADVISORY COUNCIL PURSUANT TO SUBSECTIONS (1)(a)(II)(A) TO
7 (1)(a)(II)(E) OF THIS SECTION SHALL EACH SERVE INITIAL TERMS OF TWO
8 YEARS.

9 (4) THE CHAIR OF THE BOARD SHALL DESIGNATE ONE MEMBER OF
10 THE ADVISORY COUNCIL TO SERVE AS CHAIR OF THE ADVISORY COUNCIL.

11 (5) (a) AN INDIVIDUAL WHO IS BEING CONSIDERED FOR
12 APPOINTMENT TO THE ADVISORY COUNCIL SHALL DISCLOSE ANY CONFLICT
13 OF INTEREST TO THE BOARD IN A FORM AND MANNER PRESCRIBED BY THE
14 BOARD. WHEN APPOINTING A MEMBER OF THE ADVISORY COUNCIL, THE
15 BOARD SHALL CONSIDER ANY CONFLICT OF INTEREST DISCLOSED BY THE
16 PROSPECTIVE MEMBER.

17 (b) THE CHAIR OF THE ADVISORY COUNCIL SHALL REPORT TO THE
18 BOARD ANY CONFLICT OF INTEREST THAT IS DISCLOSED TO THE ADVISORY
19 COUNCIL. THE BOARD SHALL INCLUDE INFORMATION CONCERNING SUCH
20 DISCLOSURES ON ITS PUBLIC WEBSITE PURSUANT TO SECTION 10-16-1302
21 (3)(d).

22 (6) THE ADVISORY COUNCIL SHALL MEET AT LEAST ONCE EVERY
23 THREE MONTHS; EXCEPT THAT THE CHAIR MAY CANCEL OR POSTPONE A
24 MEETING.

25 (7) (a) EXCEPT AS DESCRIBED IN SUBSECTION (7)(b) OF THIS
26 SECTION, THE ADVISORY COUNCIL SHALL CONDUCT ALL OF ITS MEETINGS
27 IN PUBLIC.

1 (b) NOTWITHSTANDING SECTION 24-6-402, THE ADVISORY
2 COUNCIL MAY MEET PRIVATELY IN GROUPS OF THREE OR FEWER MEMBERS
3 FOR THE FOLLOWING PURPOSES, SO LONG AS NO FORMAL ACTION IS TAKEN
4 AT THE MEETING:

5 (I) TO GATHER AND UNDERSTAND DATA; OR

6 (II) TO ESTABLISH, ORGANIZE, AND PLAN FOR THE BUSINESS OF THE
7 ADVISORY COUNCIL.

8 **10-16-1310. Use of savings - report - rules.** (1) ANY SAVINGS
9 GENERATED FOR A HEALTH BENEFIT PLAN THAT ARE ATTRIBUTABLE TO
10 THE ESTABLISHMENT OF AN UPPER PAYMENT LIMIT ESTABLISHED BY THE
11 BOARD PURSUANT TO SECTION 10-16-1307 MUST BE USED BY THE CARRIER
12 THAT ISSUES THE HEALTH BENEFIT PLAN TO REDUCE COSTS TO
13 CONSUMERS.

14 (2) ON OR BEFORE MARCH 15, 2023, AND ON OR BEFORE MARCH
15 15 EACH YEAR THEREAFTER, EACH STATE ENTITY AND EACH CARRIER THAT
16 ISSUES A HEALTH BENEFIT PLAN OR OPTIONAL PARTICIPATING PLAN SHALL
17 SUBMIT TO THE BOARD A REPORT DESCRIBING THE SAVINGS ACHIEVED
18 DURING THE PRECEDING PLAN YEAR FOR EACH PRESCRIPTION DRUG FOR
19 WHICH THE BOARD ESTABLISHED AN UPPER PAYMENT LIMIT DURING THE
20 PRECEDING YEAR AND HOW THOSE SAVINGS WERE USED TO SATISFY THE
21 REQUIREMENT DESCRIBED IN SUBSECTION (1) OF THIS SECTION.

22 (3) ON OR BEFORE NOVEMBER 1, 2022, THE BOARD SHALL
23 PROMULGATE RULES ESTABLISHING A FORMULA FOR CALCULATING
24 SAVINGS FOR THE PURPOSE OF COMPLYING WITH SUBSECTION (1) OF THIS
25 SECTION.

26 **10-16-1311. Unlawful acts - enforcement - penalties.** (1) ON
27 AND AFTER JANUARY 1, 2022, IT IS UNLAWFUL FOR ANY PERSON TO

1 PURCHASE OR REIMBURSE A PAYER FOR A PRESCRIPTION DRUG FOR WHICH
2 THE BOARD HAS ESTABLISHED AN UPPER PAYMENT LIMIT PURSUANT TO
3 SECTION 10-16-1307 AT AN AMOUNT THAT EXCEEDS THE UPPER PAYMENT
4 LIMIT ESTABLISHED BY THE BOARD FOR THAT PRESCRIPTION DRUG,
5 REGARDLESS OF WHETHER THE PRESCRIPTION DRUG IS DISPENSED OR
6 DISTRIBUTED IN PERSON, BY MAIL, OR BY OTHER MEANS.

7 (2) ON AND AFTER JANUARY 1, 2023, EACH STATE ENTITY,
8 CARRIER, AND OPTIONAL PARTICIPATING PLAN SHALL REQUIRE
9 COMPLIANCE WITH AN UPPER PAYMENT LIMIT ESTABLISHED BY THE
10 BOARD.

11
12 (3) THE ATTORNEY GENERAL IS AUTHORIZED TO ENFORCE THIS
13 PART 13 ON BEHALF OF ANY STATE ENTITY OR ANY CONSUMER OF
14 PRESCRIPTION DRUGS.

15 (4) NOTWITHSTANDING ANY PROVISION OF THIS PART 13 TO THE
16 CONTRARY, AS USED IN THIS SECTION, "PERSON" DOES NOT INCLUDE AN
17 INDIVIDUAL WHO ACQUIRES A PRESCRIPTION DRUG FOR THE INDIVIDUAL'S
18 OWN USE OR FOR A FAMILY MEMBER'S USE.

19 (5) NOTWITHSTANDING ANY PROVISION OF THIS SECTION TO THE
20 CONTRARY, A CARRIER OR STATE AGENCY THAT IS REQUIRED PURSUANT
21 TO STATE OR FEDERAL LAW TO PURCHASE OR REIMBURSE A PAYER FOR A
22 PRESCRIPTION DRUG FOR WHICH THE BOARD HAS ESTABLISHED AN UPPER
23 PAYMENT LIMIT PURSUANT TO SECTION 10-16-1307 IS NOT SUBJECT TO AN
24 ENFORCEMENT ACTION FOR A VIOLATION OF SUBSECTION (1) OR (2) OF THIS
25 SECTION FOR THAT PARTICULAR PRESCRIPTION DRUG.

26 **10-16-1312. Notice of withdrawal of prescription drugs with**
27 **upper payment limits required - rules - penalty. (1) ANY**

1 MANUFACTURER THAT INTENDS TO WITHDRAW FROM SALE OR
2 DISTRIBUTION WITHIN THE STATE A PRESCRIPTION DRUG FOR WHICH THE
3 BOARD HAS ESTABLISHED AN UPPER PAYMENT LIMIT PURSUANT TO
4 SECTION 10-16-1307 SHALL PROVIDE A NOTICE OF WITHDRAWAL IN
5 WRITING AT LEAST ONE HUNDREDEIGHTY DAYS BEFORE THE WITHDRAWAL
6 TO:

- 7 (a) THE COMMISSIONER;
- 8 (b) THE ATTORNEY GENERAL; AND
- 9 (c) EACH ENTITY IN THE STATE WITH WHICH THE MANUFACTURER
10 HAS CONTRACTED FOR THE SALE OR DISTRIBUTION OF THE PRESCRIPTION
11 DRUG.

12 (2) THE BOARD SHALL PROMULGATE RULES TO NOTIFY CONSUMERS
13 OF THE INTENT OF ANY MANUFACTURER TO WITHDRAW A PRESCRIPTION
14 DRUG FROM SALE OR DISTRIBUTION WITHIN THE STATE, AS DESCRIBED IN
15 SUBSECTION (1) OF THIS SECTION.

16 (3) AFTER PROVIDING NOTICE AND A HEARING AS DESCRIBED IN
17 SECTION 24-4-105, THE COMMISSIONER MAY REQUIRE A MANUFACTURER
18 TO PAY A PENALTY NOT TO EXCEED FIVE HUNDRED THOUSAND DOLLARS IF
19 THE COMMISSIONER DETERMINES THAT THE MANUFACTURER FAILED TO
20 PROVIDE THE NOTICE REQUIRED BY SUBSECTION (1) OF THIS SECTION
21 BEFORE WITHDRAWING FROM SALE OR DISTRIBUTION WITHIN THE STATE A
22 PRESCRIPTION DRUG FOR WHICH THE BOARD HAS ESTABLISHED AN UPPER
23 PAYMENT LIMIT PURSUANT TO SECTION 10-16-1307.

24 **10-16-1313. Optional participating plans - notice of election to**
25 **participate required.** AN OPTIONAL PARTICIPATING PLAN THAT ELECTS
26 TO SUBJECT ITS PURCHASES OF OR PAYER REIMBURSEMENTS FOR
27 PRESCRIPTION DRUGS IN COLORADO TO THE REQUIREMENTS OF THIS PART

1 13 SHALL NOTIFY THE COMMISSIONER IN WRITING WITHIN THIRTY DAYS
2 AFTER SUCH ELECTION.

3 **10-16-1314. Reports.** (1) NOTWITHSTANDING SECTION 24-1-136
4 (11)(a), ON OR BEFORE JULY 1, 2023, AND ON OR BEFORE JULY 1 EACH
5 YEAR THEREAFTER, THE BOARD SHALL SUBMIT A REPORT TO THE
6 GOVERNOR, THE HEALTH AND INSURANCE COMMITTEE OF THE HOUSE OF
7 REPRESENTATIVES, AND THE HEALTH AND HUMAN SERVICES COMMITTEE
8 OF THE SENATE, OR TO ANY SUCCESSOR COMMITTEES, SUMMARIZING THE
9 ACTIVITIES OF THE BOARD DURING THE PRECEDING CALENDAR YEAR. AT
10 A MINIMUM, THE REPORT MUST INCLUDE:

11 (a) PUBLICLY AVAILABLE DATA CONCERNING PRICE TRENDS FOR
12 PRESCRIPTION DRUGS;

13 (b) THE NUMBER OF PRESCRIPTION DRUGS THAT WERE SUBJECTED
14 TO AN AFFORDABILITY REVIEW BY THE BOARD PURSUANT TO SECTION
15 10-16-1306, INCLUDING THE RESULTS OF EACH AFFORDABILITY REVIEW
16 AND THE NUMBER AND DISPOSITION OF ANY APPEALS OR JUDICIAL REVIEWS
17 OF THE BOARD'S DECISIONS;

18 (c) A LIST OF EACH PRESCRIPTION DRUG FOR WHICH THE BOARD
19 ESTABLISHED AN UPPER PAYMENT LIMIT PURSUANT TO SECTION
20 10-16-1307, INCLUDING THE AMOUNT OF THE UPPER PAYMENT LIMIT;

21 (d) THE IMPACT OF ANY UPPER PAYMENT LIMITS ESTABLISHED BY
22 THE BOARD PURSUANT TO SECTION 10-16-1307 ON HEALTH-CARE
23 PROVIDERS AND PHARMACIES;

24 (e) A SUMMARY OF ANY APPEALS OF BOARD DECISIONS THAT WERE
25 CONSIDERED BY THE BOARD PURSUANT TO SECTION 10-16-1308,
26 INCLUDING AN INDICATION OF THE OUTCOME OF ANY SUCH APPEAL;

27 (f) A DESCRIPTION OF EACH CONFLICT OF INTEREST THAT WAS

1 DISCLOSED TO THE BOARD DURING THE PRECEDING YEAR;

2 (g) A DESCRIPTION OF ANY VIOLATIONS OF ANY OF THE PROVISIONS
3 OF THIS PART 13, INCLUDING AN INDICATION OF ANY ENFORCEMENT
4 ACTION TAKEN IN RESPONSE TO ANY SUCH VIOLATION; AND

5 (h) ANY RECOMMENDATIONS THE BOARD MAY HAVE FOR THE
6 GENERAL ASSEMBLY CONCERNING LEGISLATIVE AND REGULATORY POLICY
7 CHANGES TO INCREASE THE AFFORDABILITY OF PRESCRIPTION DRUGS AND
8 REDUCE THE EFFECTS OF EXCESS COSTS ON CONSUMERS AND COMMERCIAL
9 HEALTH INSURANCE PREMIUMS IN THE STATE.

10 (2) THE BOARD SHALL POST THE REPORT DESCRIBED IN
11 SUBSECTION (1) OF THIS SECTION ON THE PUBLIC WEB PAGE MAINTAINED
12 BY THE DIVISION FOR THE BOARD PURSUANT TO SECTION 10-16-1302
13 (3)(d).

14 **SECTION 3.** In Colorado Revised Statutes, 24-1-122, **add** (6) as
15 follows:

16 **24-1-122. Department of regulatory agencies - creation.**

17 (6) (a) THE COLORADO PRESCRIPTION DRUG AFFORDABILITY REVIEW
18 BOARD CREATED IN SECTION 10-16-1302 IS TRANSFERRED BY A **TYPE 1**
19 TRANSFER TO THE DEPARTMENT OF REGULATORY AGENCIES AND
20 ALLOCATED TO THE DIVISION OF INSURANCE.

21 (b) THE COLORADO PRESCRIPTION DRUG AFFORDABILITY
22 ADVISORY COUNCIL CREATED IN SECTION 10-16-1309 IS TRANSFERRED BY
23 A **TYPE 2** TRANSFER TO THE DEPARTMENT OF REGULATORY AGENCIES AND
24 ALLOCATED TO THE DIVISION OF INSURANCE.

25 **SECTION 4. Appropriation. (1) For the 2021-22 state fiscal**
26 **year, \$680,711 is appropriated to the department of regulatory agencies.**
27 **This appropriation is from the division of insurance cash fund created in**

1 section 10-1-103 (3), C.R.S. To implement this act, the department may
2 use this appropriation as follows:

3 (a) \$275,297 for use by the division of insurance for personal
4 services, which amount is based on an assumption that the division will
5 require an additional 3.0 FTE;

6 (b) \$22,650 for use by the division of insurance for operating
7 expenses; and

8 (c) \$382,824 for the purchase of legal services.

9 (2) For the 2021-22 state fiscal year, \$382,824 is appropriated to
10 the department of law. This appropriation is from reappropriated funds
11 received from the department of regulatory agencies under subsection
12 (1)(c) of this section and is based on an assumption that the department
13 of law will require an additional 2.0 FTE. To implement this act, the
14 department of law may use this appropriation to provide legal services for
15 the department of regulatory agencies.

16 **SECTION 5. Severability.** If any provision of this act or the
17 application thereof to any person or circumstance is held invalid, such
18 invalidity does not affect other provisions or applications of this act that
19 can be given effect without the invalid provision or application, and to
20 this end the provisions of this act are severable.

21 **SECTION 6. Safety clause.** The general assembly hereby finds,
22 determines, and declares that this act is necessary for the immediate
23 preservation of the public peace, health, or safety.