

First Regular Session
Seventy-third General Assembly
STATE OF COLORADO

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LLS NO. 21-0497.02 Richard Sweetman x4333

SENATE BILL

SENATE SPONSORSHIP

Jaquez Lewis and Gonzales,

HOUSE SPONSORSHIP

Caraveo and Kennedy,

BILL TOPIC: "Prescription Drug Affordability Review Board"
DEADLINES: Finalize by: FEB 24, 2021 File by: MAR 2, 2021

A BILL FOR AN ACT

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

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

*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 is also required to promulgate rules as necessary for its purposes.

If the board conducts an affordability review of a prescription drug, the review must include consideration of certain factors and determine whether use of the prescription drug is unaffordable for Colorado consumers. The board may request that a manufacturer, carrier, or pharmacy benefit management firm provide pricing information for the prescription drug.

The board may establish an upper payment limit for any prescription drug for which the board performs an affordability review and determines that the use of the prescription drug is unaffordable for Colorado consumers. The board shall determine by rule the methodology for establishing a upper payment limit for a prescription drug. An upper payment limit applies to all purchases and payer reimbursements of 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 health benefit plan to reduce costs to consumers.

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

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.

The bill requires any prescription drug manufacturer that intends to withdraw from sale or distribution within the state a prescription drug for which the board has established an upper payment limit to notify 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 at least 180 days before the withdrawal to the commissioner. A manufacturer who fails to comply 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 (council) to provide stakeholder input to the board.

The bill creates the Colorado prescription drug affordability review board cash fund (fund) and authorizes the board to expend money from the

fund.

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 prescription
6 drugs, and price increases that exceed reasonable levels endanger the health and
7 safety of Coloradans;

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

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

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

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

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

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

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

7 (2) The general assembly therefore declares that in exercise of its police
8 powers and responsibility for the public health, safety and general welfare of
9 Colorado residents, it is imperative that Colorado take measures to reduce
10 excessive prescription drug costs for Coloradans who cannot afford
11 prescription drugs and create a prescription drug affordability board with the
12 authority to review prescription drug costs and protect state and local
13 governments and Colorado residents from the excessive costs of prescription
14 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 DRUG
23 AFFORDABILITY ADVISORY COUNCIL CREATED IN SECTION 10-16-1311.

24 (2) "AFFORDABILITY REVIEW" MEANS AN AFFORDABILITY REVIEW OF
25 A PRESCRIPTION DRUG PERFORMED BY THE BOARD PURSUANT TO SECTION
26 10-16-1307.

27 (3) "ALL-PAYER CLAIMS DATABASE" MEANS THE ALL-PAYER CLAIMS

1 DATABASE DESCRIBED IN SECTION 25.5-1-204.

2 (4) "AUTHORIZED GENERIC DRUG" HAS THE MEANING SET FORTH IN 42
3 C.F.R. 447.502.

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

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

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

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

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

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

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

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

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

7 (12) "GENERIC DRUG" MEANS:

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

11 (b) AN AUTHORIZED GENERIC DRUG; OR

12 (c) A PRESCRIPTION DRUG THAT WAS INTRODUCED FOR RETAIL SALE
13 BEFORE 1962 THAT WAS NOT ORIGINALLY MARKETED UNDER A NEW DRUG
14 APPLICATION.

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

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

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

24 (I) IS ACTIVELY ENGAGED IN BUSINESS;

25 (II) EMPLOYED AN AVERAGE OF MORE THAN ONE HUNDRED ELIGIBLE
26 EMPLOYEES ON BUSINESS DAYS DURING THE IMMEDIATELY PRECEDING
27 CALENDAR YEAR, EXCEPT AS PROVIDED IN SUBSECTION (15); AND

1 (III) WAS NOT FORMED PRIMARILY FOR THE PURPOSE OF PURCHASING
2 INSURANCE.

3 (b) FOR PURPOSES OF DETERMINING WHETHER AN EMPLOYER IS A
4 "LARGE EMPLOYER", THE NUMBER OF ELIGIBLE EMPLOYEES IS CALCULATED
5 USING THE METHOD SET FORTH IN 26 U.S.C. SEC. 4980h (c)(2)(E).

6 (c) IN THE CASE OF AN EMPLOYER THAT WAS NOT IN EXISTENCE
7 THROUGHOUT THE PRECEDING CALENDAR QUARTER, THE DETERMINATION OF
8 WHETHER THE EMPLOYER IS A LARGE EMPLOYER IS BASED ON THE AVERAGE
9 NUMBER OF EMPLOYEES THAT THE EMPLOYER IS REASONABLY EXPECTED TO
10 EMPLOY ON BUSINESS DAYS IN THE CURRENT CALENDAR YEAR.

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

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

14 (b) (I) ENTERS INTO A LEASE WITH A MANUFACTURER TO MARKET
15 AND DISTRIBUTE A PRESCRIPTION DRUG IN THIS STATE UNDER THE PERSON'S
16 OWN NAME; AND

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

19 (17) "OPTIONAL PARTICIPATING PLAN" MEANS A HEALTH BENEFIT
20 PLAN OFFERED IN COLORADO THAT ELECTS TO SUBJECT ITS PURCHASES OR
21 PAYER REIMBURSEMENTS OF PRESCRIPTION DRUGS FOR ITS MEMBERS IN
22 COLORADO TO THE REQUIREMENTS OF THIS PART 13, AS DESCRIBED IN TO
23 SECTION 10-16-1308 (6).

24 (18) "PRACTITIONER" HAS THE MEANING SET FORTH IN SECTION 12-
25 280-103 (40).

26 (19) "PRESCRIPTION DRUG" HAS THE MEANING SET FORTH IN SECTION
27 12-280-103 (42); EXCEPT THAT THE TERM INCLUDES ONLY PRESCRIPTION

1 DRUGS THAT ARE INTENDED FOR HUMAN USE.

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

5 (21) "SMALL EMPLOYER" HAS THE MEANING SET FORTH IN SECTION
6 10-16-102 (61)(b).

7 (22) "STATE ENTITY" MEANS ANY AGENCY OF STATE GOVERNMENT
8 THAT PURCHASES OR PROVIDES PAYER REIMBURSEMENTS FOR PRESCRIPTION
9 DRUGS ON BEHALF OF THE STATE FOR A PERSON WHOSE HEALTH CARE IS PAID
10 FOR BY THE STATE, INCLUDING ANY AGENT, VENDOR, CONTRACTOR, OR OTHER
11 PARTY ACTING ON BEHALF OF THE STATE.

12 (23) "UPPER PAYMENT LIMIT" MEANS THE MAXIMUM AMOUNT THAT
13 MAY BE PAID OR BILLED FOR A PRESCRIPTION DRUG IN ANY FINANCIAL
14 TRANSACTION CONCERNING THE PURCHASE OF, OR A PAYER REIMBURSEMENT
15 FOR, A PRESCRIPTION DRUG IN THE STATE TO BE DISPENSED OR DISTRIBUTED
16 TO A CONSUMER IN COLORADO.

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

19 **10-16-1302. Colorado prescription drug affordability review**
20 **board - created - membership - terms - conflicts of interest.** (1) THE
21 COLORADO PRESCRIPTION DRUG AFFORDABILITY REVIEW BOARD IS CREATED
22 IN THE DIVISION AS A **TYPE 1** ENTITY. THE BOARD IS A BODY POLITIC AND
23 CORPORATE AND IS AN INSTRUMENTALITY OF THE STATE. THE BOARD IS AN
24 INDEPENDENT UNIT OF STATE GOVERNMENT, AND THE EXERCISE BY THE
25 BOARD OF ITS AUTHORITY UNDER THIS PART 13 IS AN ESSENTIAL PUBLIC
26 FUNCTION.

27 (2) (a) THE BOARD CONSISTS OF FIVE MEMBERS, WHO MUST

1 COLLECTIVELY HAVE EXPERIENCE AND EXPERTISE IN HEALTH CARE ECONOMICS
2 AND CLINICAL MEDICINE.

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

6 (c) THE TERM OF OFFICE OF EACH BOARD MEMBER IS THREE YEARS;
7 EXCEPT THAT, AS TO THE INITIAL TERMS OF THE MEMBERS WHO ARE
8 INITIALLY APPOINTED TO THE BOARD, TWO SUCH MEMBERS SHALL SERVE
9 THREE-YEAR INITIAL TERMS, TWO SUCH MEMBERS SHALL SERVE TWO-YEAR
10 INITIAL TERMS, AND ONE SUCH MEMBER SHALL SERVE A ONE-YEAR INITIAL
11 TERM, TO BE DETERMINED BY THE GOVERNOR. EACH MEMBER SERVES AT THE
12 PLEASURE OF THE GOVERNOR AND MAY BE REMOVED FROM THE BOARD BY THE
13 GOVERNOR.

14 (d) THE GOVERNOR SHALL DESIGNATE ONE MEMBER OF THE BOARD TO
15 SERVE AS THE CHAIR. A MAJORITY OF THE BOARD CONSTITUTES A QUORUM.

16 (3) (a) AN INDIVIDUAL WHO IS BEING CONSIDERED FOR APPOINTMENT
17 TO THE BOARD SHALL DISCLOSE ANY CONFLICT OF INTEREST TO THE
18 GOVERNOR. WHEN APPOINTING A MEMBER OF THE BOARD, THE GOVERNOR
19 SHALL CONSIDER ANY CONFLICT OF INTEREST DISCLOSED BY THE PROSPECTIVE
20 MEMBER.

21 (b) A BOARD MEMBER MAY NOT BE AN EMPLOYEE, BOARD MEMBER,
22 OR CONSULTANT OF A MANUFACTURER OR A TRADE ASSOCIATION OF
23 MANUFACTURERS.

24 (c) A BOARD MEMBER, STAFF MEMBER, OR CONTRACTOR OF THE
25 BOARD SHALL RECUSE THEMSELVES FROM ANY BOARD ACTIVITY IN ANY CASE
26 IN WHICH THEY HAVE A CONFLICT OF INTEREST.

27 (d) ON AND AFTER JANUARY 1, 2022, THE DIVISION SHALL MAINTAIN

1 A PAGE ON ITS PUBLIC WEBSITE FOR THE BOARD TO USE FOR ITS PURPOSES.
2 THE BOARD SHALL DISCLOSE ON THE PAGE EACH CONFLICT OF INTEREST THAT
3 IS DISCLOSED TO THE BOARD PURSUANT TO SUBSECTION (3)(c) OF THIS
4 SECTION AND SECTION 10-16-1311 (5)(b).

5 (e) BOARD MEMBERS, STAFF MEMBERS, CONTRACTORS OF THE
6 BOARD, AND IMMEDIATE FAMILY MEMBERS OF SUCH PERSONS SHALL NOT
7 ACCEPT A FINANCIAL BENEFIT OR GIFTS, BEQUESTS, OR DONATIONS OF
8 SERVICES OR PROPERTY THAT SUGGEST A CONFLICT OF INTEREST OR HAVE THE
9 APPEARANCE OF CREATING BIAS IN THE WORK OF THE BOARD.

10 (4) THE BOARD MAY HIRE STAFF AS NECESSARY, INCLUDING AN
11 EXECUTIVE DIRECTOR, TO ASSIST THE BOARD IN PERFORMING ITS DUTIES
12 UNDER THIS PART 13. HIRING AND COMPENSATION OF ANY STAFF MUST
13 COMPORT WITH PART 1 OF ARTICLE 50 OF THE TITLE 24 AND ANY APPLICABLE
14 RULES OF THE STATE PERSONNEL BOARD.

15 (5) THE ATTORNEY GENERAL SHALL ASSIGN AN ASSISTANT ATTORNEY
16 GENERAL TO PROVIDE LEGAL COUNSEL TO THE BOARD. ANY ASSISTANT
17 ATTORNEY GENERAL ASSIGNED TO THE BOARD PURSUANT TO THIS
18 SUBSECTION (4) SHALL DISCLOSE ANY CONFLICT OF INTEREST TO THE BOARD.

19 **10-16-1303. Colorado prescription drug affordability review**
20 **board - powers and duties - rules.** (1) TO PROTECT COLORADO CONSUMERS
21 FROM EXCESSIVE PRESCRIPTION DRUG COSTS, THE BOARD SHALL:

22 (a) COLLECT AND EVALUATE INFORMATION CONCERNING THE COST
23 OF PRESCRIPTION DRUGS SOLD TO COLORADO CONSUMERS, AS DESCRIBED IN
24 SECTION 10-16-1307;

25 (b) PERFORM AFFORDABILITY REVIEWS OF PRESCRIPTION DRUGS, AS
26 DESCRIBED IN SECTION 10-16-1307;

27 (c) ESTABLISH UPPER PAYMENT LIMITS FOR PRESCRIPTION DRUGS, AS

1 DESCRIBED IN SECTION 10-16-1308; AND

2 (d) MAKE POLICY RECOMMENDATIONS TO THE GENERAL ASSEMBLY
3 TO IMPROVE THE AFFORDABILITY OF PRESCRIPTION DRUGS FOR COLORADO
4 CONSUMERS, AS DESCRIBED IN SECTION 10-16-1309 (1)(a).

5 (2) THE BOARD MAY ESTABLISH AD HOC WORK GROUPS TO CONSIDER
6 MATTERS RELATED TO THE WORK OF THE BOARD PURSUANT TO THIS PART 13.
7 AD HOC WORK GROUPS MAY INCLUDE MEMBERS OF THE PUBLIC.

8 (3) THE BOARD MAY ENTER INTO A CONTRACT WITH A QUALIFIED,
9 INDEPENDENT THIRD PARTY FOR ANY SERVICE NECESSARY TO CARRY OUT THE
10 POWERS AND DUTIES OF THE BOARD. A THIRD PARTY WITH WHICH THE
11 BOARD CONTRACTS PURSUANT TO THIS SUBSECTION (3) SHALL NOT RELEASE,
12 PUBLISH, OR MAKE USE OF ANY INFORMATION THAT THE THIRD PARTY
13 ACQUIRES PURSUANT TO ITS PERFORMANCE UNDER THE CONTRACT. ANY
14 THIRD PARTY WITH WHICH THE BOARD CONTRACTS PURSUANT TO THIS
15 SUBSECTION (3) SHALL DISCLOSE ANY CONFLICT OF INTEREST TO THE BOARD.

16 (4) IN CARRYING OUT ITS DUTIES PURSUANT TO THIS PART 13, THE
17 BOARD IS EXEMPT FROM THE STATE "PROCUREMENT CODE", ARTICLES 101 TO
18 112 OF TITLE 24.

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

22 **10-16-1304. Colorado prescription drug affordability review**
23 **board cash fund - created - gifts, grants, and donations.** (1) (a) THE
24 COLORADO PRESCRIPTION DRUG AFFORDABILITY REVIEW BOARD CASH FUND
25 IS CREATED IN THE STATE TREASURY. SUBJECT TO ANNUAL APPROPRIATION
26 BY THE GENERAL ASSEMBLY, THE BOARD MAY EXPEND MONEY FROM THE
27 FUND FOR THE PURPOSES DESCRIBED IN THIS PART 13.

1 (b) THE FUND CONSISTS OF ANY MONEY THAT THE GENERAL
2 ASSEMBLY MAY APPROPRIATE OR TRANSFER TO THE FUND.

3 (c) THE STATE TREASURER SHALL CREDIT ALL INTEREST AND INCOME
4 DERIVED FROM THE DEPOSIT AND INVESTMENT OF MONEY IN THE FUND TO THE
5 FUND. ANY UNEXPENDED AND UNENCUMBERED MONEY REMAINING IN THE
6 FUND AT THE END OF A FISCAL YEAR REMAINS IN THE FUND AND SHALL NOT
7 BE TRANSFERRED TO THE GENERAL FUND OR TO ANOTHER FUND.

8 (2) THE PRESCRIPTION DRUG AFFORDABILITY ACCOUNT, REFERRED TO
9 IN THIS SECTION AS THE "ACCOUNT" IS CREATED IN THE FUND. THE ACCOUNT
10 CONSISTS OF ANY GIFTS, GRANTS OR DONATIONS RECEIVED PURSUANT TO
11 SUBSECTION (2) OF THIS SECTION. MONEY IN THE ACCOUNT IS CONTINUOUSLY
12 APPROPRIATED TO THE BOARD TO USE FOR THE PURPOSES OF THIS PART 13.

13 (3) (a) THE BOARD MAY SEEK, ACCEPT, AND EXPEND GIFTS, GRANTS,
14 AND DONATIONS FROM PRIVATE OR PUBLIC SOURCES FOR THE PURPOSES OF
15 THIS PART 13; EXCEPT THAT, THE BOARD SHALL NOT ACCEPT ANY GIFT,
16 GRANT, OR DONATION THAT CREATES A CONFLICT OF INTEREST, OR THE
17 APPEARANCE OF ANY CONFLICT OF INTEREST, FOR ANY BOARD MEMBER. THE
18 BOARD SHALL TRANSFER ALL MONEY RECEIVED AS GIFTS, GRANTS OR
19 DONATIONS TO THE STATE TREASURER, WHO SHALL CREDIT THE MONEY TO
20 THE ACCOUNT.

21 (b) THE GENERAL ASSEMBLY FINDS THAT THE IMPLEMENTATION OF
22 THIS PART 13 DOES NOT RELY ENTIRELY ON THE RECEIPT OF ADEQUATE
23 FUNDING THROUGH GIFTS, GRANTS, OR DONATIONS. THEREFORE, THE BOARD
24 IS NOT SUBJECT TO THE REPORTING REQUIREMENTS DESCRIBED IN SECTION 24-
25 75-1303 (3).

26 **10-16-1305. Colorado prescription drug affordability review**
27 **board - public meetings - exceptions. (1) BEGINNING SEPTEMBER 1, 2021,**

1 THE BOARD SHALL MEET AT LEAST EVERY SIX WEEKS TO REVIEW
2 PRESCRIPTION DRUGS; EXCEPT THAT THE CHAIR MAY CANCEL OR POSTPONE
3 A MEETING IF THE BOARD HAS NO PRESCRIPTION DRUGS TO REVIEW.

4 (2) THE BOARD IS A STATE PUBLIC BODY FOR PURPOSES OF SECTION
5 24-6-402, AND THE BOARD'S MEETINGS AND THE MEETINGS OF AD HOC WORK
6 GROUPS OF THE BOARD ARE PUBLIC MEETINGS.

7 (3) THE BOARD MAY MEET IN EXECUTIVE SESSION TO DISCUSS
8 PROPRIETARY INFORMATION. THE BOARD SHALL NOT MAKE AVAILABLE TO
9 THE PUBLIC ANY MATERIALS CONTAINING TRADE SECRETS OR CONFIDENTIAL
10 OR PROPRIETARY DATA THAT IS NOT OTHERWISE AVAILABLE TO THE PUBLIC.
11 THE BOARD SHALL NOT TAKE ANY OF THE FOLLOWING ACTIONS WHILE
12 MEETING IN EXECUTIVE SESSION:

13 (a) DELIBERATIONS CONCERNING WHETHER TO SUBJECT A
14 PRESCRIPTION DRUG TO AN AFFORDABILITY REVIEW AS DESCRIBED IN SECTION
15 10-16-1307;

16 (b) VOTES CONCERNING WHETHER TO ESTABLISH AN UPPER PAYMENT
17 LIMIT ON A PRESCRIPTION DRUG; OR

18 (c) ANY FINAL DECISION OF THE BOARD.

19 **10-16-1306. Colorado prescription drug affordability review**
20 **board - reports from carriers and pharmacy benefit management firms**
21 **required - confidential materials. (1) BEGINNING IN THE 2022 CALENDAR**
22 **YEAR,** FOR ALL PRESCRIPTION DRUGS DISPENSED AT A PHARMACY AND PAID
23 FOR BY A CARRIER PURSUANT TO PART 2, 3, OR 4 OF ARTICLE 16 IN THIS
24 STATE DURING THE IMMEDIATELY PRECEDING CALENDAR YEAR, INCLUDING
25 BRAND NAME DRUGS, AUTHORIZED GENERIC DRUGS, BIOLOGICAL PRODUCTS,
26 AND BIOSIMILAR DRUGS:

27 (a) EACH CARRIER SHALL REPORT TO THE COMMISSIONER,

1 CONTEMPORANEOUS WITH AND SEPARATE FROM ITS RATE FILING PURSUANT
2 TO SECTION 10-16-107, IN A FORM AND MANNER SPECIFIED BY THE
3 COMMISSIONER, THE FOLLOWING INFORMATION:

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

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

8 (III) THE FIFTEEN PRESCRIPTION DRUGS PAID FOR BY THE CARRIER
9 THAT ACCOUNTED FOR THE HIGHEST INCREASE IN TOTAL ANNUAL PLAN
10 SPENDING WHEN COMPARED WITH THE TOTAL ANNUAL PLAN SPENDING FOR
11 THE SAME PRESCRIPTION DRUGS IN THE YEAR IMMEDIATELY PRECEDING THE
12 YEAR FOR WHICH THE INFORMATION IS REPORTED;

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

15 (V) THE FIFTEEN PRESCRIPTION DRUGS FOR WHICH THE CARRIER PAID
16 FOR THE MOST FREQUENTLY AND FOR WHICH THE HEALTH INSURER RECEIVED
17 A REBATE FROM MANUFACTURERS;

18 (VI) THE FIFTEEN PRESCRIPTION DRUGS FOR WHICH THE CARRIER
19 RECEIVED THE HIGHEST REBATES, AS DETERMINED AS PERCENTAGES OF THE
20 PRICES OF THE PRESCRIPTION DRUG; AND

21 (VII) THE FIFTEEN PRESCRIPTION DRUGS FOR WHICH THE CARRIER
22 RECEIVED THE LARGEST REBATES.

23 (b) EACH CARRIER AND EACH PHARMACY BENEFIT MANAGEMENT
24 FIRM ACTING ON BEHALF OF A CARRIER SHALL REPORT THE AVERAGE
25 WHOLESALE ACQUISITION COST PAID FOR EACH OF THE FOLLOWING
26 CATEGORIES OF PRESCRIPTION DRUGS, IN A FORM AND MANNER PRESCRIBED
27 BY THE COMMISSIONER BY RULE:

- 1 (I) BRAND NAME DRUGS PURCHASED FROM RETAIL PHARMACIES;
- 2 (II) AUTHORIZED GENERIC DRUGS PURCHASED FROM RETAIL
3 PHARMACIES;
- 4 (III) BRAND NAME DRUGS PURCHASED FROM A MAIL-ORDER
5 PHARMACIES;
- 6 (IV) AUTHORIZED GENERIC DRUGS PURCHASED FROM A MAIL-ORDER
7 PHARMACIES;
- 8 (V) PRESCRIPTION DRUGS DISPENSED BY A PRACTITIONER IN
9 ACCORDANCE WITH SECTION 12-280-120 (6);
- 10 (VI) PRESCRIPTION DRUGS ADMINISTERED IN AN INPATIENT HOSPITAL
11 SETTING; AND
- 12 (VII) PRESCRIPTION DRUGS ADMINISTERED IN AN OUTPATIENT
13 HOSPITAL SETTING; AND
- 14 (c) EACH CARRIER AND EACH PHARMACY BENEFIT MANAGEMENT
15 FIRM ACTING ON BEHALF OF A CARRIER SHALL REPORT THE WHOLESALE
16 ACQUISITION COST FOR THE PRESCRIPTION DRUGS DESCRIBED IN SUBSECTION
17 (1)(b) OF THIS SECTION PAID BY EACH OF THE FOLLOWING MARKET SECTORS
18 ENROLLED IN A HEALTH BENEFIT PLAN THAT THE CARRIER ISSUED OR THAT
19 INCLUDES PRESCRIPTION DRUG BENEFITS MANAGED OR ADMINISTERED BY THE
20 PHARMACY BENEFIT MANAGEMENT FIRM:
- 21 (I) INDIVIDUALS;
- 22 (II) SMALL EMPLOYERS; AND
- 23 (III) LARGE EMPLOYERS;
- 24 (2) (a) EXCEPT AS PROVIDED IN SUBSECTION (2)(b) OF THIS SECTION,
25 THE COMMISSIONER SHALL:
- 26 (I) POST THE INFORMATION REPORTED BY CARRIERS AND PHARMACY
27 BENEFIT MANAGEMENT FIRMS PURSUANT TO THIS SECTION ON THE DIVISION'S

1 WEBSITE; AND

2 (II) PROVIDE THE INFORMATION REPORTED BY CARRIERS AND
3 PHARMACY BENEFIT MANAGEMENT FIRM PURSUANT TO THIS SECTION TO THE
4 BOARD, IN A FORM AND MANNER PRESCRIBED BY THE BOARD.

5 (b) IF A CARRIER OR PHARMACY BENEFIT MANAGEMENT FIRM CLAIMS
6 THAT INFORMATION SUBMITTED PURSUANT TO THIS SECTION IS
7 CONFIDENTIAL OR PROPRIETARY, THE COMMISSIONER SHALL REVIEW THE
8 INFORMATION AND REDACT SPECIFIC ITEMS THAT THE CARRIER OR
9 PHARMACY BENEFIT MANAGEMENT FIRM DEMONSTRATES TO BE
10 CONFIDENTIAL OR PROPRIETARY. THE COMMISSIONER SHALL NOT DISCLOSE
11 REDACTED ITEMS TO ANY PERSON, EXCEPT THAT THE COMMISSIONER MAY
12 DISCLOSE REDACTED ITEMS:

13 (I) AS MAY BE REQUIRED PURSUANT TO PART 2 OF ARTICLE 72 OF
14 TITLE 24;

15 (II) TO EMPLOYEES OF THE DIVISION, AS NECESSARY; AND

16 (III) TO STATE AGENCIES THAT ARE PURCHASERS OF PRESCRIPTION
17 DRUGS.

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

21 (a) PROHIBIT A MANUFACTURER OF A PRESCRIPTION DRUG FROM
22 MAKING PRICING DECISIONS REGARDING ITS PRESCRIPTION DRUGS; OR

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

26 **10-16-1307. Colorado prescription drug affordability review**
27 **board - affordability reviews of prescription drugs.** (1) THE BOARD MAY

1 CONDUCT AN AFFORDABILITY REVIEW OF ANY PRESCRIPTION DRUG THAT IS:

2 (a) A BRAND NAME DRUG OR BIOLOGICAL PRODUCT THAT, AS
3 ADJUSTED ANNUALLY FOR INFLATION, HAS:

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

7 (II) AN INCREASE IN THE WHOLESALE ACQUISITION COST OF THREE
8 THOUSAND DOLLARS OR MORE FOR A TWELVE-MONTH SUPPLY OR FOR A
9 COURSE OF TREATMENT THAT IS LESS THAN TWELVE MONTHS IN DURATION;

10 (b) A BIOSIMILAR DRUG THAT HAS AN INITIAL WHOLESALE
11 ACQUISITION COST THAT IS NOT AT LEAST FIFTEEN PERCENT LOWER THAN
12 THE CORRESPONDING ORIGINATOR; OR

13 (c) A GENERIC DRUG:

14 (I) THAT, AS ADJUSTED ANNUALLY FOR INFLATION, HAS A
15 WHOLESALE ACQUISITION COST OF ONE HUNDRED DOLLARS OR MORE FOR:

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

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

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

22 (II) FOR WHICH THE WHOLESALE ACQUISITION COST INCREASED BY
23 TWO HUNDRED PERCENT OR MORE DURING THE IMMEDIATELY PRECEDING
24 TWELVE MONTHS, AS DETERMINED BY COMPARING THE CURRENT WHOLESALE
25 ACQUISITION COST TO THE AVERAGE WHOLESALE ACQUISITION COST
26 REPORTED DURING THE IMMEDIATELY PRECEDING TWELVE MONTHS.

27 (2) AFTER IDENTIFYING PRESCRIPTION DRUGS AS DESCRIBED IN

1 SUBSECTION (1) OF THIS SECTION, THE BOARD SHALL DETERMINE WHETHER
2 TO CONDUCT AN AFFORDABILITY REVIEW FOR EACH IDENTIFIED PRESCRIPTION
3 DRUG BY:

4 (a) EVALUATING THE CLASS OF THE PRESCRIPTION DRUG AND
5 WHETHER ANY THERAPEUTICALLY EQUIVALENT PRESCRIPTION DRUGS ARE
6 AVAILABLE FOR SALE;

7 (b) EVALUATING AGGREGATED DATA;

8 (c) SEEKING AND CONSIDERING INPUT FROM THE ADVISORY COUNCIL
9 ABOUT THE PRESCRIPTION DRUG; AND

10 (d) CONSIDERING THE AVERAGE PATIENT'S OUT-OF-POCKET COST FOR
11 THE PRESCRIPTION DRUG.

12 (3) IF THE BOARD CONDUCTS AN AFFORDABILITY REVIEW OF A
13 PRESCRIPTION DRUG, THE AFFORDABILITY REVIEW MUST DETERMINE
14 WHETHER USE OF THE PRESCRIPTION DRUG, WHICH USE IS CONSISTENT WITH
15 THE LABELING APPROVED FOR THE PRESCRIPTION DRUG BY THE FDA OR WITH
16 STANDARD MEDICAL PRACTICE, IS UNAFFORDABLE FOR COLORADO
17 CONSUMERS.

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

20 (a) THE WHOLESALE ACQUISITION COST OF THE PRESCRIPTION DRUG;

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

23 (c) THE EFFECT ON COLORADO CONSUMERS' ACCESS TO THE
24 PRESCRIPTION DRUG;

25 (d) THE RELATIVE FINANCIAL EFFECTS TO HEALTH, MEDICAL, OR
26 SOCIAL SERVICES COSTS, AS SUCH EFFECTS CAN BE QUANTIFIED AND
27 COMPARED TO BASELINE EFFECTS OF EXISTING THERAPEUTIC ALTERNATIVES

1 TO THE PRESCRIPTION DRUG;

2 (e) THE PATIENT COPAYMENT OR OTHER COST SHARING THAT IS
3 ASSOCIATED WITH THE PRESCRIPTION DRUG AND TYPICALLY REQUIRED BY
4 CARRIERS IN THE STATE;

5 (f) ANY OTHER INFORMATION THAT A MANUFACTURER, CARRIER,
6 PHARMACY BENEFIT MANAGEMENT FIRM, OR OTHER ENTITY CHOOSES TO
7 PROVIDE; AND

8 (g) ANY OTHER FACTORS AS DETERMINED BY RULES PROMULGATED
9 BY THE BOARD PURSUANT TO SECTION 10-16-1303 (8).

10 (5) IN PERFORMING AN AFFORDABILITY REVIEW OF A PRESCRIPTION
11 DRUG, THE BOARD MAY CONSIDER ANY DOCUMENTS AND INFORMATION
12 RELATING TO THE MANUFACTURER'S SELECTION OF THE INTRODUCTORY PRICE
13 OR PRICE INCREASE OF THE PRESCRIPTION DRUG, INCLUDING DOCUMENTS AND
14 INFORMATION RELATING TO:

15 (a) LIFE-CYCLE MANAGEMENT;

16 (b) THE AVERAGE COST OF THE PRESCRIPTION DRUG IN THE STATE;

17 (c) MARKET COMPETITION AND CONTEXT;

18 (d) PROJECTED REVENUE;

19 (e) THE ESTIMATED COST-EFFECTIVENESS OF THE PRESCRIPTION DRUG;

20 AND

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

22 (6) (a) TO THE EXTENT PRACTICABLE, THE BOARD MAY ACCESS
23 PRICING INFORMATION FOR PRESCRIPTION DRUGS BY:

24 (I) ENTERING INTO A MEMORANDUM OF UNDERSTANDING WITH
25 ANOTHER STATE TO WHICH MANUFACTURERS REPORT PRICING INFORMATION;

26 (II) ACCESSING AVAILABLE PRICING INFORMATION FROM THE
27 ALL-PAYER CLAIMS DATABASE AND FROM AGENCIES OF THE STATE

1 GOVERNMENT; AND
2 (III) ACCESSING INFORMATION THAT IS AVAILABLE FROM OTHER
3 COUNTRIES.

4 (b) TO THE EXTENT THAT THERE IS NO PUBLICLY AVAILABLE
5 INFORMATION WITH WHICH TO CONDUCT AN AFFORDABILITY REVIEW, THE
6 BOARD MAY REQUEST THAT A MANUFACTURER, CARRIER, OR PHARMACY
7 BENEFIT MANAGEMENT FIRM PROVIDE PRICING INFORMATION FOR ANY
8 PRESCRIPTION DRUG DESCRIBED IN SUBSECTION (1) OF THIS SECTION. THE
9 FAILURE OF AN ENTITY TO PROVIDE PRICING INFORMATION TO THE BOARD FOR
10 AN AFFORDABILITY REVIEW DOES NOT AFFECT THE AUTHORITY OF THE BOARD
11 TO CONDUCT THE AFFORDABILITY REVIEW, AS DESCRIBED IN THIS SECTION.

12 **10-16-1308. Colorado prescription drug affordability review**
13 **board - upper payment limits for certain prescription drugs.** (1) THE
14 BOARD MAY ESTABLISH AN UPPER PAYMENT LIMIT FOR ANY PRESCRIPTION
15 DRUG FOR WHICH THE BOARD HAS PERFORMED AN AFFORDABILITY REVIEW
16 PURSUANT TO SECTION 10-16-1307 AND DETERMINED THAT THE USE OF THE
17 PRESCRIPTION DRUG IS UNAFFORDABLE FOR COLORADO CONSUMERS. THE
18 FAILURE OF AN ENTITY TO PROVIDE INFORMATION TO THE BOARD PURSUANT
19 TO SECTION 10-16-1307 (6)(b) DOES NOT AFFECT THE AUTHORITY OF THE
20 BOARD TO ESTABLISH AN UPPER PAYMENT LIMIT FOR THE PRESCRIPTION
21 DRUG.

22 (2) THE BOARD SHALL DETERMINE BY RULE THE METHODOLOGY FOR
23 ESTABLISHING A UPPER PAYMENT LIMIT FOR A PRESCRIPTION DRUG TO
24 PROTECT CONSUMERS FROM THE EXCESSIVE COST OF PRESCRIPTION DRUGS
25 AND ENSURE THEY CAN ACCESS PRESCRIPTION DRUGS NECESSARY FOR THEIR
26 HEALTH, WHICH METHODOLOGY MUST INCLUDE CONSIDERATION OF:

27 (a) THE COST OF ADMINISTERING OR DISPENSING THE PRESCRIPTION

1 DRUG;

2 (b) THE COST OF DISTRIBUTING THE PRESCRIPTION DRUG TO
3 CONSUMERS IN THE STATE; AND

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

5 (4) AN UPPER PAYMENT LIMIT APPLIES TO ALL PURCHASES AND PAYER
6 REIMBURSEMENTS OF THE PRESCRIPTION DRUG DISPENSED OR ADMINISTERED
7 TO INDIVIDUALS IN THE STATE IN PERSON, BY MAIL, OR BY OTHER MEANS.

8 (5) ANY INFORMATION SUBMITTED TO THE BOARD IN ACCORDANCE
9 WITH THIS SECTION IS SUBJECT TO PUBLIC INSPECTION ONLY TO THE EXTENT
10 ALLOWED UNDER THE "COLORADO OPEN RECORDS ACT", PART 2 OF ARTICLE
11 72 OF TITLE 24.

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

18 (7) IF ANY PROVISION OF THIS SECTION OR ITS APPLICATION TO ANY
19 PERSON OR CIRCUMSTANCE IS HELD INVALID, THE INVALIDITY DOES NOT
20 AFFECT OTHER PROVISIONS OF APPLICATIONS OF THIS SECTION THAT CAN BE
21 GIVEN EFFECT WITHOUT THE INVALID PROVISION OR APPLICATION, AND TO
22 THIS END THE PROVISIONS OF THIS SECTION ARE SEVERABLE.

23 **10-16-1309. Reports.** (1) NOTWITHSTANDING SECTION 24-1-136
24 (11)(a), ON OR BEFORE JULY 1, 2023, AND ON OR BEFORE JULY 1 EACH YEAR
25 THEREAFTER, THE BOARD SHALL SUBMIT A REPORT TO THE GOVERNOR, THE
26 HEALTH AND INSURANCE COMMITTEE OF THE HOUSE OF REPRESENTATIVES,
27 AND THE HEALTH AND HUMAN SERVICES COMMITTEE OF THE SENATE, OR TO

1 ANY SUCCESSOR COMMITTEES, SUMMARIZING THE ACTIVITIES OF THE BOARD
2 DURING THE PRECEDING CALENDAR YEAR. AT A MINIMUM, THE REPORT MUST
3 INCLUDE:

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

9 (b) PUBLICLY AVAILABLE DATA CONCERNING PRICE TRENDS FOR
10 PRESCRIPTION DRUGS;

11 (c) THE NUMBER OF PRESCRIPTION DRUGS THAT WERE SUBJECTED TO
12 AN AFFORDABILITY REVIEW BY THE BOARD PURSUANT TO SECTION
13 10-16-1307, INCLUDING THE RESULTS OF EACH AFFORDABILITY REVIEW AND
14 THE NUMBER AND DISPOSITION OF ANY APPEALS OR JUDICIAL REVIEWS OF THE
15 BOARD'S DECISIONS; AND

16 (d) A DESCRIPTION OF EACH CONFLICT OF INTEREST THAT WAS
17 DISCLOSED TO THE BOARD DURING THE PRECEDING YEAR.

18 **10-16-1310. Colorado prescription drug affordability board -**
19 **appeals - rules - judicial review.** (1) A PERSON AGGRIEVED BY A DECISION
20 OF THE BOARD MAY APPEAL THE DECISION WITHIN SIXTY DAYS AFTER THE
21 DECISION IS MADE. THE BOARD SHALL CONSIDER THE APPEAL AND ISSUE A
22 FINAL DECISION CONCERNING THE APPEAL WITHIN SIXTY DAYS AFTER THE
23 BOARD RECEIVES THE APPEAL.

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

1 TIMELINE MUST COMPORT WITH THE "STATE ADMINISTRATIVE PROCEDURE
2 ACT", ARTICLE 4 OF TITLE 24.

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

7 **10-16-1311. Colorado prescription drug affordability advisory**
8 **council - created - membership - powers and duties.** (1) (a) THE
9 COLORADO PRESCRIPTION DRUG AFFORDABILITY ADVISORY COUNCIL IS
10 CREATED IN THE DIVISION AS A **TYPE 2** ENTITY TO PROVIDE STAKEHOLDER
11 INPUT TO THE BOARD REGARDING THE AFFORDABILITY OF PRESCRIPTION
12 DRUGS. THE ADVISORY COUNCIL INCLUDES FOURTEEN MEMBERS, TO BE
13 APPOINTED BY THE BOARD AS FOLLOWS:

14 (I) TWO MEMBERS WHO ARE HEALTH CARE CONSUMERS OR WHO
15 REPRESENTS HEALTH CONSUMERS;

16 (II) ONE MEMBER REPRESENTING A STATEWIDE HEALTH CARE
17 CONSUMER ADVOCACY ORGANIZATION;

18 (III) ONE MEMBER REPRESENTING HEALTH CARE CONSUMERS WHO
19 ARE LIVING WITH CHRONIC DISEASES;

20 (IV) ONE MEMBER REPRESENTING A LABOR UNION;

21 (V) ONE MEMBER REPRESENTING EMPLOYERS;

22 (VI) ONE MEMBER REPRESENTING CARRIERS;

23 (VII) ONE MEMBER REPRESENTING PHARMACY BENEFIT
24 MANAGEMENT FIRMS;

25 (VIII) ONE MEMBER REPRESENTING HEALTH CARE PROFESSIONALS;

26 (IX) ONE MEMBER WHO IS EMPLOYED BY AN ORGANIZATION THAT
27 PERFORMS RESEARCH CONCERNING PRESCRIPTION DRUGS, INCLUDING

1 RESEARCH CONCERNING PRICING INFORMATION;

2 (X) ONE MEMBER REPRESENTING MANUFACTURERS OF BRAND NAME
3 DRUGS;

4 (XI) ONE MEMBER REPRESENTING MANUFACTURERS OF GENERIC
5 DRUGS;

6 (XII) THE EXECUTIVE DIRECTOR OF THE DEPARTMENT OF HEALTH
7 CARE POLICY AND FINANCING, OR THE EXECUTIVE DIRECTOR'S DESIGNEE; AND

8 (XIII) ONE MEMBER REPRESENTING PHARMACISTS.

9 (b) TO THE EXTENT POSSIBLE, THE BOARD SHALL APPOINT COUNCIL
10 MEMBERS WHO REFLECT THE DIVERSITY OF THE STATE WITH REGARD TO
11 RACE, ETHNICITY, IMMIGRATION STATUS, INCOME, WEALTH, AND
12 GEOGRAPHY. IN CONSIDERING GEOGRAPHIC DIVERSITY, THE BOARD SHALL
13 ENSURE AT LEAST ONE COUNCIL MEMBER RESIDES ON THE EASTERN PLAINS
14 AND ONE MEMBER RESIDES ON THE WESTERN SLOPE, AND THE BOARD SHALL
15 ATTEMPT TO APPOINT MEMBERS FROM EACH CONGRESSIONAL DISTRICT IN
16 THE STATE.

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

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

21 (a) THE PHARMACEUTICAL BUSINESS MODEL;

22 (b) SUPPLY CHAIN BUSINESS MODELS;

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

24 (d) HEALTH CARE CONSUMER OR PATIENT PERSPECTIVES;

25 (e) HEALTH CARE COST TRENDS AND DRIVERS;

26 (f) CLINICAL AND HEALTH SERVICES RESEARCH; OR

27 (g) THE STATE'S HEALTH CARE MARKETPLACE.

1 (3) THE TERM OF EACH MEMBER OF THE ADVISORY COUNCIL IS THREE
2 YEARS; EXCEPT THAT THE MEMBERS INITIALLY APPOINTED TO THE ADVISORY
3 COUNCIL PURSUANT TO SUBSECTIONS (1)(a)(I) TO (1)(a)(V) OF THIS SECTION
4 SHALL EACH SERVE TERMS OF TWO YEARS, AND THE MEMBERS INITIALLY
5 APPOINTED TO THE ADVISORY COUNCIL PURSUANT TO SUBSECTIONS (1)(a)(VI)
6 TO (1)(a)(XIII) OF THIS SECTION SHALL EACH SERVE TERMS OF **THREE** YEARS.

7 <{?}>

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

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

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

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

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

25 (b) NOTWITHSTANDING SECTION 24-6-402, THE ADVISORY COUNCIL
26 MAY MEET IN GROUPS OF THREE OR LESS MEMBERS FOR THE FOLLOWING
27 PURPOSES, SO LONG AS NO FORMAL ACTION IS TAKEN AT THE MEETING:

- 1 (I) TO GATHER AND UNDERSTAND DATA; OR
2 (II) TO ESTABLISH, ORGANIZE, AND PLAN FOR THE BUSINESS OF THE
3 COUNCIL

4 **10-16-1312. Use of savings - report - rules.** (1) ANY SAVINGS
5 GENERATED FOR A HEALTH BENEFIT PLAN AS A RESULT OF AN UPPER
6 PAYMENT LIMIT ESTABLISHED BY THE BOARD PURSUANT TO SECTION
7 10-16-1308 MUST BE USED BY THE HEALTH BENEFIT PLAN TO REDUCE COSTS
8 TO CONSUMERS.

9 (2) NOTWITHSTANDING SECTION 24-1-136 (11)(a), ON OR BEFORE
10 MARCH 15, 2023, AND ON OR BEFORE MARCH 15 EACH YEAR THEREAFTER,
11 EACH STATE ENTITY, HEALTH BENEFIT PLAN, AND OPTIONAL PARTICIPATING
12 PLAN SHALL SUBMIT TO THE BOARD A REPORT DESCRIBING THE SAVINGS
13 ACHIEVED DURING THE PRECEDING PLAN YEAR FOR EACH PRESCRIPTION DRUG
14 FOR WHICH THE BOARD ESTABLISHED AN UPPER PAYMENT LIMIT DURING THE
15 PRECEDING YEAR AND HOW THOSE SAVINGS WERE USED TO SATISFY THE
16 REQUIREMENT DESCRIBED IN SUBSECTION (1) OF THIS SECTION.

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

20 **10-16-1313. Unlawful acts - enforcement - penalties.** (1) ON AND
21 AFTER JANUARY 1, 2022, IT IS UNLAWFUL FOR ANY PURCHASE OR PAYER
22 REIMBURSEMENTS IN THE STATE TO EXCEED AN UPPER PAYMENT LIMIT
23 ESTABLISHED BY THE BOARD PURSUANT TO SECTION 10-16-1308,
24 REGARDLESS OF WHETHER THE PRESCRIPTION DRUG IS DISPENSED OR
25 DISTRIBUTED IN PERSON, BY MAIL, OR BY OTHER MEANS.

26 (2) ON AND AFTER JANUARY 1, 2023, EACH STATE ENTITY, CARRIER,
27 AND OPTIONAL PARTICIPATING PLAN SHALL REQUIRE COMPLIANCE WITH AN

1 UPPER PAYMENT LIMIT ESTABLISHED BY THE BOARD.

2 (3) A PERSON WHO VIOLATES SUBSECTION (1) OR (2) OF THIS SECTION
3 MAY BE SUBJECT TO A FINE OF ONE THOUSAND DOLLARS FOR EACH
4 VIOLATION.

5 (4) THE ATTORNEY GENERAL IS AUTHORIZED TO ENFORCE THIS PART
6 13 ON BEHALF OF ANY STATE ENTITY OR ANY CONSUMER OF PRESCRIPTION
7 DRUGS.

8 **10-16-1314. Optional participating plans - notice.** AN OPTIONAL
9 PARTICIPATING PLAN MAY ELECT TO SUBJECT ITS PURCHASES OR PAYER
10 REIMBURESMENTS OF PRESCRIPTION DRUGS IN COLORADO TO THE
11 REQUIREMENTS OF THIS PART 13. AN OPTIONAL PARTICIPATING PLAN THAT
12 ELECTS TO DO SO SHALL NOTIFY THE COMMISSIONER IN WRITING WITHIN
13 THIRTY DAYS AFTER SUCH ELECTION.

14 **10-16-1315. Prohibition on withdrawal of prescription drugs with**
15 **upper payment limits - penalty.** (1) ANY MANUFACTURER THAT INTENDS
16 TO WITHDRAW FROM SALE OR DISTRIBUTION WITHIN THE STATE A
17 PRESCRIPTION DRUG FOR WHICH THE BOARD HAS ESTABLISHED AN UPPER
18 PAYMENT LIMIT PURSUANT TO SECTION 10-16-1308 SHALL PROVIDE A
19 NOTICE OF WITHDRAWAL IN WRITING AT LEAST ONE HUNDRED EIGHTY DAYS
20 BEFORE THE WITHDRAWAL TO THE COMMISSIONER, THE ATTORNEY GENERAL,
21 AND EACH ENTITY IN THE STATE WITH WHICH THE MANUFACTURER HAS
22 CONTRACTED FOR THE SALE OR DISTRIBUTION OF THE PRESCRIPTION DRUG.

23 (2) AFTER PROVIDING NOTICE AND A HEARING AS DESCRIBED IN
24 SECTION 24-4-105, THE COMMISSIONER MAY REQUIRE A MANUFACTURER TO
25 PAY A PENALTY NOT TO EXCEED FIVE HUNDRED THOUSAND DOLLARS IF THE
26 COMMISSIONER DETERMINES THAT THE MANUFACTURER VIOLATED
27 SUBSECTION (1) OF THIS SECTION.

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

3 **24-1-122. Department of regulatory agencies - creation.**

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

8 (b) THE COLORADO PRESCRIPTION DRUG AFFORDABILITY ADVISORY
9 COUNCIL CREATED IN SECTION 10-16-1311 IS TRANSFERRED BY A **TYPE 2**
10 TRANSFER TO THE DEPARTMENT OF REGULATORY AGENCIES AND ALLOCATED
11 TO THE DIVISION OF INSURANCE.

12 **SECTION 4.** In Colorado Revised Statutes, 24-75-402, **add** (5)(rr)
13 as follows:

14 **24-75-402. Cash funds - limit on uncommitted reserves -**
15 **reduction in the amount of fees - exclusions - repeal.** (5) Notwithstanding
16 any provision of this section to the contrary, the following cash funds are
17 excluded from the limitations specified in this section:

18 (rr) THE COLORADO PRESCRIPTION DRUG AFFORDABILITY REVIEW
19 BOARD CASH FUND CREATED IN SECTION 10-16-1303 (6).

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

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