SENATE BILL 21-175

SENATE SPONSORSHIP
Jaquez Lewis and Gonzales, Buckner

HOUSE SPONSORSHIP
Caraveo and Kennedy,

A BILL FOR AN ACT
CONCERNING THE COLORADO PRESCRIPTION DRUG AFFORDABILITY

REVIEW BOARD, AND, IN CONNECTION THEREWITH, DIRECTING
THE BOARD TO REVIEW THE AFFORDABILITY OF CERTAIN DRUGS
AND ESTABLISH UPPER PAYMENT LIMITS FOR CERTAIN DRUGS;
PROHIBITING CERTAIN ENTITIES FROM PURCHASING OR
REIMBURSING FOR ANY DRUG FOR DISTRIBUTION IN THE STATE
AT AN AMOUNT THAT EXCEEDS THE UPPER PAYMENT LIMIT
ESTABLISHED FOR THE PRESCRIPTION DRUG; AND 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

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.
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.

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

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

(a) Excessive costs for prescription drugs:
   (I) Negatively impact the ability of Coloradans to obtain prescription drugs, and price increases that exceed reasonable levels endanger the health and safety of Coloradans;
   (II) Threaten the economic well-being of Coloradans and endanger their ability to pay for other necessary and essential goods and services, including housing, food, and utilities;
   (III) Contribute significantly to a dramatic and unsustainable rise in health-care costs and health insurance premiums that threatens the financial health of Coloradans and their ability to maintain their physical health;
   (IV) Pose a threat to the health and safety of all Coloradans but disproportionately harm people of color and Coloradans with low incomes; and
   (V) Contribute significantly to rising costs for health care that is provided to public employees, including employees of state, county, and local governments, school districts, and institutions of higher education, and to public retirees whose health-care costs are funded by public programs, thereby threatening the ability of state and local governments to adequately fund those programs and other important services, such as public education and public safety;

(b) Lack of transparency in health insurance costs and wholesaler
and pharmacy benefits manager discounts and margins prevents policymakers and the public from gaining a true understanding of the costs of prescription drugs; and

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

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

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

PART 13

COLORADO PRESCRIPTION DRUG AFFORDABILITY REVIEW BOARD

10-16-1301. Definitions. As used in this part 13, unless the context otherwise requires:

(1) "Advisory council" means the Colorado prescription drug affordability advisory council created in section 10-16-1309.

(2) "Affordability review" means an affordability review of a prescription drug performed by the board pursuant to section 10-16-1306.
(3) "ALL-PAYER HEALTH CLAIMS DATABASE" MEANS THE ALL-PAYER HEALTH CLAIMS DATABASE DESCRIBED IN SECTION 25.5-1-204.

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

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

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

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

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

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

(10) "CONFLICT OF INTEREST" MEANS AN ASSOCIATION, INCLUDING A FINANCIAL OR PERSONAL ASSOCIATION, THAT HAS THE POTENTIAL TO BIAS OR APPEAR TO BIAS AN INDIVIDUAL'S DECISIONS IN MATTERS RELATED TO THE BOARD OR THE ADVISORY COUNCIL OR THE CONDUCT OF THE ACTIVITIES OF THE BOARD OR THE ADVISORY COUNCIL. "CONFLICT OF INTEREST" INCLUDES ANY INSTANCE IN WHICH A BOARD MEMBER, AN ADVISORY COUNCIL MEMBER, A STAFF MEMBER, A CONTRACTOR OF THE BOARD, OR AN IMMEDIATE FAMILY MEMBER OF A BOARD MEMBER, AN ADVISORY COUNCIL MEMBER, A STAFF MEMBER, OR A CONTRACTOR OF THE BOARD HAS RECEIVED OR COULD RECEIVE:
(a) A financial benefit of any amount derived from the results or findings of a study or determination that is reached by or for the board; or

(b) A financial benefit from an individual or company that owns or manufactures a prescription drug, service, or item that is being or will be studied by the board.

(11) "Financial benefit" means honoraria, fees, stock, or any other form of compensation, including increases to the value of existing stock holdings.

(12) "Generic drug" means:

(a) A prescription drug that is marketed or distributed in accordance with an abbreviated new drug application approved pursuant to 21 U.S.C. sec. 355 (j);

(b) An authorized generic drug; or

(c) A prescription drug that was introduced for retail sale before 1962 that was not originally marketed under a new drug application.

(13) "Health benefit plan" has the meaning set forth in section 10-16-102 (32).

(14) "Inflation" means the annual percentage change in the United States Department of Labor's Bureau of Labor Statistics consumer price index for Denver-Aurora-Lakewood for all items paid by all urban consumers, or its applicable predecessor or successor index.

(15) (a) "Large employer" means any person, firm, corporation, partnership, or association that:

(I) Is actively engaged in business;
(II) Employed an average of more than one hundred eligible employees on business days during the immediately preceding calendar year, except as provided in subsection (15)(c) of this section; and

(III) Was not formed primarily for the purpose of purchasing insurance.

(b) For purposes of determining whether an employer is a "large employer", the number of eligible employees is calculated using the method set forth in 26 U.S.C. sec. 4980H (c)(2)(E).

(c) In the case of an employer that was not in existence throughout the preceding calendar quarter, the determination of whether the employer is a large employer is based on the average number of employees that the employer is reasonably expected to employ on business days in the current calendar year.

(16) "Manufacturer" means a person that:

(a) Engages in the manufacture of a prescription drug that is sold to purchasers located in this state; or

(b) (I) Enters into a lease or other contractual agreement with a manufacturer to market and distribute a prescription drug in this state under the person's own name; and

(II) Sets or changes the wholesale acquisition cost of the prescription drug in this state.

(17) "Optional participating plan" means a self-funded health benefit plan offered in Colorado that elects to subject its purchases of or payer reimbursements for prescription drugs
(18) "Practitioner" has the meaning set forth in section 12-280-103 (40).

(19) "Prescription drug" has the meaning set forth in section 12-280-103 (42); except that the term includes only prescription drugs that are intended for human use.

(20) "Pricing information" means information about the price of a prescription drug, including information that explains or helps explain how the price was determined.

(21) "Small employer" has the meaning set forth in section 10-16-102 (61).

(22) "State entity" means any agency of state government that purchases or reimburses payers for prescription drugs on behalf of the state for a person whose health care is paid for by the state, including any agent, vendor, contractor, or other party acting on behalf of the state.

(23) "Upper payment limit" means the maximum amount that may be paid or billed for a prescription drug that is dispensed or distributed in Colorado in any financial transaction concerning the purchase of or reimbursement for the prescription drug.

(24) "Wholesale acquisition cost" has the meaning set forth in 42 U.S.C. 1395w-3a (c)(6)(B).

10-16-1302. Colorado prescription drug affordability review board - created - membership - terms - conflicts of interest. (1) The Colorado prescription drug affordability review board is
created in the division as a Type 1 entity. The board is a body
politic and corporate and is an instrumentality of the state. The
board is an independent unit of state government, and the
exercise by the board of its authority under this part 13 is an
essential public function.

(2) (a) The board consists of five members, who must
collectively have experience and expertise in health-care
economics and clinical medicine.

(b) The governor shall appoint each board member,
subject to confirmation by the senate. All of the initial members
of the board must be appointed by October 1, 2021.

(c) The term of office of each board member is three years;
except that, as to the terms of the members who are first
appointed to the board, two such members shall serve
three-year initial terms, two such members shall serve two-year
initial terms, and one such member shall serve a one-year initial
term, to be determined by the governor. Each member serves at
the pleasure of the governor and may be removed from the
board by the governor.

(d) The governor shall designate one member of the board
to serve as the chair. A majority of the board constitutes a
quorum.

(3) (a) An individual who is being considered for
appointment to the board shall disclose any conflict of interest
to the individual’s potential appointing authority. When
appointing a member of the board, an appointing authority shall
consider any conflict of interest disclosed by the prospective
(b) A BOARD MEMBER MUST NOT BE AN EMPLOYEE, BOARD MEMBER, OR CONSULTANT OF:
   (I) A MANUFACTURER OR A TRADE ASSOCIATION OF MANUFACTURERS;
   (II) A CARRIER OR A TRADE ASSOCIATION OF CARRIERS; OR
   (III) A PHARMACY BENEFIT MANAGER OR A TRADE ASSOCIATION OF PHARMACY BENEFIT MANAGERS.

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

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

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

(4) THE BOARD MAY HIRE STAFF AS NECESSARY, INCLUDING AN EXECUTIVE DIRECTOR, TO ASSIST THE BOARD IN PERFORMING ITS DUTIES UNDER THIS PART 13. HIRING AND COMPENSATION OF ANY STAFF MUST COMPARE WITH PART 1 OF ARTICLE 50 OF TITLE 24 AND ANY APPLICABLE RULES OF THE STATE PERSONNEL BOARD.
(5) The attorney general shall assign an assistant attorney general to provide legal counsel to the board. Any assistant attorney general assigned to the board pursuant to this subsection (5) shall disclose any conflict of interest to the board.

10-16-1303. Colorado prescription drug affordability review board - powers and duties - rules. (1) To protect Colorado consumers from excessive prescription drug costs, the board shall:

(a) Collect and evaluate information concerning the cost of prescription drugs sold to Colorado consumers, as described in section 10-16-1305;

(b) Perform affordability reviews of prescription drugs, as described in section 10-16-1306;

(c) Establish upper payment limits for prescription drugs, as described in section 10-16-1307; and

(d) Make policy recommendations to the general assembly to improve the affordability of prescription drugs for Colorado consumers, as described in section 10-16-1314 (1)(g).

(2) The board may establish ad hoc work groups to consider matters related to the work of the board pursuant to this part 13. Ad hoc work groups may include members of the public.

(3) The board may enter into a contract with a qualified, independent third party for any service necessary to carry out the powers and duties of the board. A third party with which the board contracts pursuant to this subsection (3), including any
OF THE THIRD PARTY'S DIRECTORS, OFFICERS, EMPLOYEES, CONTRACTORS, OR AGENTS, SHALL NOT RELEASE OR PUBLISH ANY INFORMATION THAT THE THIRD PARTY ACQUIRES PURSUANT TO ITS PERFORMANCE UNDER THE CONTRACT. ANY THIRD PARTY WITH WHICH THE BOARD CONTRACTS PURSUANT TO THIS SUBSECTION (3) SHALL DISCLOSE ANY CONFLICT OF INTEREST TO THE BOARD.

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

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

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

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

10-16-1304. Colorado prescription drug affordability review board meetings - required to be public - exceptions. (1) THE BOARD
SHALL HOLD ITS FIRST MEETING WITHIN SIX WEEKS AFTER ALL OF THE BOARD MEMBERS ARE APPOINTED AND SHALL MEET AT LEAST EVERY SIX WEEKS THEREAFTER TO REVIEW PRESCRIPTION DRUGS; EXCEPT THAT THE CHAIR MAY CANCEL OR POSTPONE A MEETING IF THE BOARD HAS NO PRESCRIPTION DRUGS TO REVIEW.

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

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

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

(b) VOTES CONCERNING WHETHER TO ESTABLISH AN UPPER PAYMENT LIMIT ON A PRESCRIPTION DRUG; OR
10-16-1305. Colorado prescription drug affordability review
board - reports from carriers and pharmacy benefit management
firms required - confidential materials. (1) BEGINNING IN THE 2022
CALENDAR YEAR, FOR ALL PRESCRIPTION DRUGS DISPENSED AT A
PHARMACY IN THIS STATE AND PAID FOR BY A CARRIER PURSUANT TO A
HEALTH BENEFIT PLAN ISSUED UNDER PART 2, 3, OR 4 OF THIS ARTICLE 16
DURING THE IMMEDIATELY PRECEDING CALENDAR YEAR, INCLUDING
BRAND-NAME DRUGS, AUTHORIZED GENERIC DRUGS, BIOLOGICAL
PRODUCTS, AND BIOSIMILAR DRUGS:

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

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

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

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

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

(V) THE FIFTEEN PRESCRIPTION DRUGS FOR WHICH THE CARRIER
PAID MOST FREQUENTLY AND FOR WHICH THE CARRIER RECEIVED A
REBATE FROM MANUFACTURERS;
(VI) THE FIFTEEN PRESCRIPTION DRUGS FOR WHICH THE CARRIER RECEIVED THE HIGHEST REBATES, AS DETERMINED BY PERCENTAGES OF THE PRICE OF THE PRESCRIPTION DRUG; AND
(VII) THE FIFTEEN PRESCRIPTION DRUGS FOR WHICH THE CARRIER RECEIVED THE LARGEST REBATES.
(b) EACH CARRIER AND EACH PHARMACY BENEFIT MANAGEMENT FIRM ACTING ON BEHALF OF A CARRIER SHALL REPORT, CONTEMPORANEOUS WITH AND SEPARATE FROM THE CARRIER’S RATE FILING PURSUANT TO SECTION 10-16-107, IN A FORM AND MANNER SPECIFIED BY THE COMMISSIONER, THE AVERAGE WHOLESALE ACQUISITION COST PAID FOR EACH OF THE FOLLOWING CATEGORIES OF PRESCRIPTION DRUGS:
(I) BRAND-NAME DRUGS PURCHASED FROM RETAIL PHARMACIES;
(II) AUTHORIZED GENERIC DRUGS PURCHASED FROM RETAIL PHARMACIES;
(III) BRAND-NAME DRUGS PURCHASED FROM MAIL-ORDER PHARMACIES;
(IV) AUTHORIZED GENERIC DRUGS PURCHASED FROM MAIL-ORDER PHARMACIES;
(V) PRESCRIPTION DRUGS DISPENSED BY A PRACTITIONER IN ACCORDANCE WITH SECTION 12-280-120 (6);
(VI) PRESCRIPTION DRUGS ADMINISTERED IN AN INPATIENT HOSPITAL SETTING; AND
(VII) PRESCRIPTION DRUGS ADMINISTERED IN AN OUTPATIENT HOSPITAL SETTING.
(c) EACH CARRIER AND EACH PHARMACY BENEFIT MANAGEMENT
FIRM ACTING ON BEHALF OF A CARRIER SHALL REPORT, CONTEMPORANEOUS WITH AND SEPARATE FROM THE CARRIER'S RATE FILING PURSUANT TO SECTION 10-16-107, IN A FORM AND MANNER SPECIFIED BY THE COMMISSIONER, THE AVERAGE WHOLESALE ACQUISITION COST FOR THE PRESCRIPTION DRUGS DESCRIBED IN SUBSECTION (1)(b) OF THIS SECTION PAID BY EACH OF THE FOLLOWING MARKET SECTORS ENROLLED IN A HEALTH BENEFIT PLAN THAT THE CARRIER ISSUED OR THAT INCLUDES PRESCRIPTION DRUG BENEFITS MANAGED OR ADMINISTERED BY THE PHARMACY BENEFIT MANAGEMENT FIRM:

(I) INDIVIDUAL;

(II) SMALL EMPLOYER; AND

(III) LARGE EMPLOYER.

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

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

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

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

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

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

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

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

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

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

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

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

(II) AN INCREASE IN THE WHOLESALE ACQUISITION COST OF THREE THOUSAND DOLLARS OR MORE DURING THE IMMEDIATELY PRECEDING TWELVE MONTHS FOR A TWELVE-MONTH SUPPLY OR FOR A COURSE OF
TREATMENT THAT IS LESS THAN TWELVE MONTHS IN DURATION;
(b) A BIOSIMILAR DRUG THAT HAS AN INITIAL WHOLESALE
ACQUISITION COST THAT IS NOT AT LEAST FIFTEEN PERCENT LOWER THAN
THE CORRESPONDING BIOLOGICAL PRODUCT; OR
(c) A GENERIC DRUG:
(I) THAT, AS ADJUSTED ANNUALLY FOR INFLATION, HAS A
WHOLESALE ACQUISITION COST OF ONE HUNDRED DOLLARS OR MORE FOR:
(A) A THIRTY-DAY SUPPLY BASED ON THE RECOMMENDED DOSAGE
APPROVED FOR LABELING BY THE FDA;
(B) A SUPPLY THAT LASTS LESS THAN THIRTY DAYS BASED ON THE
RECOMMENDED DOSAGE APPROVED FOR LABELING BY THE FDA; OR
(C) ONE DOSE OF THE GENERIC DRUG IF THE LABELING APPROVED
BY THE FDA DOES NOT RECOMMEND A FINITE DOSAGE; AND
(II) FOR WHICH THE WHOLESALE ACQUISITION COST INCREASED BY
TWO HUNDRED PERCENT OR MORE DURING THE IMMEDIATELY PRECEDING
TWELVE MONTHS, AS DETERMINED BY COMPARING THE CURRENT
WHOLESALE ACQUISITION COST TO THE AVERAGE WHOLESALE
ACQUISITION COST REPORTED DURING THE IMMEDIATELY PRECEDING
TWELVE MONTHS.
(2) AFTER IDENTIFYING PRESCRIPTION DRUGS AS DESCRIBED IN
SUBSECTION (1) OF THIS SECTION, THE BOARD SHALL DETERMINE WHETHER
TO CONDUCT AN AFFORDABILITY REVIEW FOR EACH IDENTIFIED
PRESCRIPTION DRUG BY:
(a) EVALUATING THE CLASS OF THE PRESCRIPTION DRUG AND
WHETHER ANY THERAPEUTICALLY EQUIVALENT PRESCRIPTION DRUGS ARE
AVAILABLE FOR SALE;
(b) EVALUATING AGGREGATED DATA;
(c) Seeking and considering input from the advisory council about the prescription drug; and

(d) Considering the average patient’s out-of-pocket cost for the prescription drug.

(3) If the board conducts an affordability review of a prescription drug, the affordability review must determine whether use of the prescription drug consistent with the labeling approved for the prescription drug by the FDA or with standard medical practice is unaffordable for Colorado consumers.

(4) In performing an affordability review, to the extent practicable, the board shall consider:

(a) The wholesale acquisition cost of the prescription drug;

(b) The cost and availability of therapeutic alternatives to the prescription drug in the state;

(c) The effect of the price on Colorado consumers’ access to the prescription drug;

(d) The relative financial effects on health, medical, or social services costs, as the effects can be quantified and compared to baseline effects of existing therapeutic alternatives to the prescription drug;

(e) The patient copayment or other cost sharing that is associated with the prescription drug and typically required pursuant to health benefit plans issued by carriers in the state;

(f) Any other information that a manufacturer, carrier, pharmacy benefit management firm, or other entity chooses to
(g) Any other factors as determined by rules promulgated by the Board pursuant to Section 10-16-1303 (5).

(5) Trade-secret, confidential, or proprietary information obtained by the Board pursuant to this section may be accessed only by Board members and staff or by a qualified independent third party that has contracted with the Board pursuant to Section 10-16-1303 (3) and is subject to a nondisclosure agreement prohibiting disclosure of such information. Any person with access to such information shall protect the information from direct or indirect publication or release to any person.

(6) In performing an affordability review of a prescription drug, the Board may consider any documents and information relating to the manufacturer’s selection of the introductory price or price increase of the prescription drug, including documents and information relating to:

   (a) Life-cycle management;
   (b) The average cost of the prescription drug in the state;
   (c) Market competition and context;
   (d) Projected revenue;
   (e) The estimated cost-effectiveness of the prescription drug; and
   (f) Off-label usage of the prescription drug.

(7) (a) To the extent practicable, the Board may access pricing information for prescription drugs by:

   (I) Accessing publicly available pricing information from
(II) ACCESSING AVAILABLE PRICING INFORMATION FROM THE ALL-PAYER HEALTH CLAIMS DATABASE AND FROM STATE ENTITIES; AND

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

(b) To the extent that there is no publicly available information with which to conduct an affordability review, the board may request that a manufacturer, carrier, or pharmacy benefit management firm provide pricing information for any prescription drug identified pursuant to subsection (1) of this section. The failure of an entity to provide pricing information to the board for an affordability review does not affect the authority of the board to conduct the affordability review, as described in this section.


(1) The board may establish an upper payment limit for any prescription drug for which the board has performed an affordability review pursuant to section 10-16-1306 and determined that the use of the prescription drug is unaffordable for Colorado consumers. The failure of an entity to provide information to the board pursuant to section 10-16-1306 (7)(b) does not affect the authority of the board to establish an upper payment limit for the prescription drug.

(2) The board shall determine by rule the methodology for establishing an upper payment limit for a prescription drug to protect consumers from the excessive cost of prescription
DRUGS AND ENSURE THEY CAN ACCESS PRESCRIPTION DRUGS NECESSARY FOR THEIR HEALTH. THE METHODOLOGY MUST INCLUDE CONSIDERATION OF:

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

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

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

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

(4) ANY INFORMATION SUBMITTED TO THE BOARD IN ACCORDANCE WITH THIS SECTION OR SECTION 10-16-1305 OR 10-16-1306 IS SUBJECT TO PUBLIC INSPECTION ONLY TO THE EXTENT ALLOWED UNDER THE "COLORADO OPEN RECORDS ACT", PART 2 OF ARTICLE 72 OF TITLE 24, AND IN NO CASE SHALL TRADE-SECRET, CONFIDENTIAL, OR PROPRIETARY INFORMATION BE DISCLOSED TO ANY PERSON WHO IS NOT AUTHORIZED TO ACCESS SUCH INFORMATION PURSUANT TO SECTION 10-16-1306.

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

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

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

(2) NOT LATER THAN DECEMBER 31, 2021, THE BOARD SHALL
PROMULGATE RULES ESTABLISHING A PROCESS AND TIMELINE FOR THE
CONSIDERATION BY THE BOARD OF ANY APPEAL THAT IS SUBMITTED TO
THE BOARD PURSUANT TO SUBSECTION (1) OF THIS SECTION. THE PROCESS
AND TIMELINE MUST COMPORT WITH THE "STATE ADMINISTRATIVE
PROCEDURE ACT", ARTICLE 4 OF TITLE 24.

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

10-16-1309. Colorado prescription drug affordability advisory
council - created - membership - powers and duties. (1) (a) THE
COLORADO PRESCRIPTION DRUG AFFORDABILITY ADVISORY COUNCIL IS
CREATED IN THE DIVISION AS A TYPE 2 ENTITY TO PROVIDE STAKEHOLDER
INPUT TO THE BOARD REGARDING THE AFFORDABILITY OF PRESCRIPTION
DRUGS. THE ADVISORY COUNCIL INCLUDES FOURTEEN MEMBERS AS
FOLLOWS:
(I) The executive director of the department of health care policy and financing or the executive director's designee; and

(II) Thirteen members appointed by the board as follows:

(A) Two members who are health-care consumers or who represent health-care consumers;

(B) One member representing a statewide health-care consumer advocacy organization;

(C) One member representing health-care consumers who are living with chronic diseases;

(D) One member representing a labor union;

(E) One member representing employers;

(F) One member representing carriers;

(G) One member representing pharmacy benefit management firms;

(H) One member representing health-care professionals;

(I) One member who is employed by an organization that performs research concerning prescription drugs, including research concerning pricing information;

(J) One member representing manufacturers of brand-name drugs;

(K) One member representing manufacturers of generic drugs; and

(L) One member representing pharmacists.

(b) To the extent possible, the board shall appoint council members who reflect the diversity of the state with regard to race, ethnicity, immigration status, income, wealth, and...
GEOGRAPHY. IN CONSIDERING GEOGRAPHIC DIVERSITY, THE BOARD SHALL ENSURE AT LEAST ONE COUNCIL MEMBER RESIDES ON THE EASTERN PLAINS AND ONE MEMBER RESIDES ON THE WESTERN SLOPE, AND THE BOARD SHALL ATTEMPT TO APPOINT MEMBERS FROM EACH CONGRESSIONAL DISTRICT IN THE STATE.

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

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

(a) THE PHARMACEUTICAL BUSINESS MODEL;
(b) SUPPLY CHAIN BUSINESS MODELS;
(c) THE PRACTICE OF MEDICINE OR CLINICAL TRAINING;
(d) HEALTH-CARE CONSUMER OR PATIENT PERSPECTIVES;
(e) HEALTH-CARE COST TRENDS AND DRIVERS;
(f) CLINICAL AND HEALTH SERVICES RESEARCH; OR
(g) THE STATE'S HEALTH-CARE MARKETPLACE.

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

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

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

(b) The chair of the advisory council shall report to the
board any conflict of interest that is disclosed to the advisory
council. The board shall include information concerning such
disclosures on its public website pursuant to section 10-16-1302
(3)(d).

(6) The advisory council shall meet at least once every
three months; except that the chair may cancel or postpone a
meeting.

(7) (a) Except as described in subsection (7)(b) of this
section, the advisory council shall conduct all of its meetings
in public.

(b) Notwithstanding section 24-6-402, the advisory
council may meet privately in groups of three or fewer members
for the following purposes, so long as no formal action is taken
at the meeting:

(I) To gather and understand data; or

(II) To establish, organize, and plan for the business of the
advisory council.

10-16-1310. Use of savings - report - rules. (1) Any savings
generated for a health benefit plan that are attributable to
the establishment of an upper payment limit established by the
board pursuant to section 10-16-1307 must be used by the carrier
that issues the health benefit plan to reduce costs to
consumers.

(2) On or before March 15, 2023, and on or before March
15 Each year thereafter, each state entity and each carrier that
issues a health benefit plan or optional participating plan shall
submit to the board a report describing the savings achieved
during the preceding plan year for each prescription drug for
which the board established an upper payment limit during the
preceding year and how those savings were used to satisfy the
requirement described in subsection (1) of this section.

(3) On or before November 1, 2022, the board shall
promulgate rules establishing a formula for calculating
savings for the purpose of complying with subsection (1) of this
section.

10-16-1311. Unlawful acts - enforcement - penalties. (1) On
and after January 1, 2022, it is unlawful for any person to
purchase or reimburse a payer for a prescription drug for which
the board has established an upper payment limit pursuant to
section 10-16-1307 at an amount that exceeds the upper payment
limit established by the board for that prescription drug,
regardless of whether the prescription drug is dispensed or
distributed in person, by mail, or by other means.

(2) On and after January 1, 2023, each state entity,
carrier, and optional participating plan shall require
compliance with an upper payment limit established by the
board.

(3) A person who violates subsection (1) or (2) of this
section may be subject to a fine of one thousand dollars for
each violation.

(4) The attorney general is authorized to enforce this
PART 13 ON BEHALF OF ANY STATE ENTITY OR ANY CONSUMER OF PRESCRIPTION DRUGS.

10-16-1312. Notice of withdrawal of prescription drugs with upper payment limits required - penalty. (1) Any 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 pursuant to section 10-16-1307 shall provide a notice of withdrawal in writing at least one hundred eighty days before the withdrawal to:

(a) The commissioner;

(b) The attorney general; and

(c) Each entity in the state with which the manufacturer has contracted for the sale or distribution of the prescription drug.

(2) After providing notice and a hearing as described in section 24-4-105, the commissioner may require a manufacturer to pay a penalty not to exceed five hundred thousand dollars if the commissioner determines that the manufacturer failed to provide the notice required by subsection (1) of this section before withdrawing from sale or distribution within the state a prescription drug for which the board has established an upper payment limit pursuant to section 10-16-1307.

10-16-1313. Optional participating plans - notice of election to participate required. An optional participating plan that elects to subject its purchases of or payer reimbursements for prescription drugs in Colorado to the requirements of this part 13 shall notify the commissioner in writing within thirty days
AFTER SUCH ELECTION.

10-16-1314. Reports. (1) NOTWITHSTANDING SECTION 24-1-136
(11)(a), ON OR BEFORE JULY 1, 2023, AND ON OR BEFORE JULY 1 EACH
YEAR THEREAFTER, THE BOARD SHALL SUBMIT A REPORT TO THE
GOVERNOR, THE HEALTH AND INSURANCE COMMITTEE OF THE HOUSE OF
REPRESENTATIVES, AND THE HEALTH AND HUMAN SERVICES COMMITTEE
OF THE SENATE, OR TO ANY SUCCESSOR COMMITTEES, SUMMARIZING THE
ACTIVITIES OF THE BOARD DURING THE PRECEDING CALENDAR YEAR. AT
A MINIMUM, THE REPORT MUST INCLUDE:
(a) PUBLICLY AVAILABLE DATA CONCERNING PRICE TRENDS FOR
PRESCRIPTION DRUGS;
(b) THE NUMBER OF PRESCRIPTION DRUGS THAT WERE SUBJECTED
TO AN AFFORDABILITY REVIEW BY THE BOARD PURSUANT TO SECTION
10-16-1306, INCLUDING THE RESULTS OF EACH AFFORDABILITY REVIEW
AND THE NUMBER AND DISPOSITION OF ANY APPEALS OR JUDICIAL REVIEWS
OF THE BOARD'S DECISIONS;
(c) A LIST OF EACH PRESCRIPTION DRUG FOR WHICH THE BOARD
ESTABLISHED AN UPPER PAYMENT LIMIT PURSUANT TO SECTION
10-16-1307, INCLUDING THE AMOUNT OF THE UPPER PAYMENT LIMIT;
(d) A SUMMARY OF ANY APPEALS OF BOARD DECISIONS THAT WERE
CONSIDERED BY THE BOARD PURSUANT TO SECTION 10-16-1308,
INCLUDING AN INDICATION OF THE OUTCOME OF ANY SUCH APPEAL;
(e) A DESCRIPTION OF EACH CONFLICT OF INTEREST THAT WAS
DISCLOSED TO THE BOARD DURING THE PRECEDING YEAR;
(f) A DESCRIPTION OF ANY VIOLATIONS OF ANY OF THE PROVISIONS
OF THIS PART 13, INCLUDING AN INDICATION OF ANY ENFORCEMENT
ACTION TAKEN IN RESPONSE TO ANY SUCH VIOLATION; AND
(g) Any recommendations the board may have for the general assembly concerning legislative and regulatory policy changes to increase the affordability of prescription drugs and reduce the effects of excess costs on consumers and commercial health insurance premiums in the state.

(2) The board shall post the report described in subsection (1) of this section on the public web page maintained by the division for the board pursuant to section 10-16-1302 (3)(d).

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

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

(6) (a) The Colorado prescription drug affordability review board created in section 10-16-1302 is transferred by a Type 1 transfer to the department of regulatory agencies and allocated to the division of insurance.

(b) The Colorado prescription drug affordability advisory council created in section 10-16-1309 is transferred by a Type 2 transfer to the department of regulatory agencies and allocated to the division of insurance.

SECTION 4. Severability. If any provision of this act or the application thereof to any person or circumstance is held invalid, such invalidity does not affect other provisions or applications of this act that can be given effect without the invalid provision or application, and to this end the provisions of this act are severable.

SECTION 5. Safety clause. The general assembly hereby finds,
determines, and declares that this act is necessary for the immediate preservation of the public peace, health, or safety.