A BILL FOR AN ACT

CONCERNING PRESCRIPTION DRUG PRICE TRANSPARENCY.

Bill Summary

(Note: This summary applies to this bill as introduced and does not reflect any amendments that may be subsequently adopted. If this bill passes third reading in the house of introduction, a bill summary that applies to the reengrossed version of this bill will be available at http://leg.colorado.gov.)

The bill enacts the "Colorado Prescription Drug Price Transparency Act of 2018", which requires:

- Health insurers, starting in 2019, to submit to the commissioner of insurance (commissioner), as part of the health care cost reporting requirement, information regarding prescription drugs covered under their health insurance plans that were dispensed in the preceding calendar year;
Prescription drug manufacturers, on or after July 1, 2018, to notify state purchasers, health insurers, and pharmacy benefit management firms when the manufacturer increases the price of certain prescription drugs by more than 10% or when the manufacturer introduces a new specialty drug in the commercial market; and

Prescription drug manufacturers, within 15 days after the end of each calendar quarter that starts on or after July 1, 2018, to provide specified information to the commissioner regarding the drugs about which manufacturers are required to notify purchasers of a drug price increase or new specialty drug on the market.

The commissioner is required to post the information received from prescription drug manufacturers on the division of insurance website. Additionally, the commissioner, or a disinterested third-party contractor, is to analyze the data submitted by health insurers and prescription drug manufacturers and other relevant information to determine the effect of prescription drug costs on health insurance premiums. The commissioner is to publish a report each year, submit the report to specified legislative committees, and present the report during annual "State Measurement for Accountable, Responsive, and Transparent (SMART) Government Act" hearings. The commissioner is authorized to adopt rules as necessary to implement the requirements of the act.

A prescription drug manufacturer that fails to notify purchasers or fails to report required data to the commissioner is subject to discipline by the state board of pharmacy, including a penalty of $1,000 per day for each day the manufacturer fails to comply with the notice or reporting requirements. The commissioner is to report manufacturer violations to the state board of pharmacy.

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

SECTION 1. In Colorado Revised Statutes, add part 11 to article 2 of title 10 as follows:

PART 11

PRESCRIPTION DRUG PRICE TRANSPARENCY

10-16-1101. Short title. The short title of this part 11 is the "COLORADO PRESCRIPTION DRUG PRICE TRANSPARENCY ACT OF 2018".

10-16-1102. Legislative declaration. (1) The general
ASSEMBLY FINDS AND DECLARES THAT THE STATE OF COLORADO HAS A
SUBSTANTIAL PUBLIC INTEREST IN THE PRICE AND COST OF PRESCRIPTION
DRUGS SINCE THE STATE IS A MAJOR PURCHASER OF PRESCRIPTION DRUGS
THROUGH PUBLIC HEALTH CARE PROGRAMS, STATE AGENCIES, AND STATE
EMPLOYEE GROUP BENEFIT PLANS. THEREFORE, IT IS THE INTENT OF THIS
PART 11 TO PROVIDE NOTICE AND DISCLOSURE OF INFORMATION RELATING
TO THE COST AND PRICING OF PRESCRIPTION DRUGS IN ORDER TO PROVIDE
ACCOUNTABILITY TO THE STATE FOR PRESCRIPTION DRUG PRICING.

(2) THE GENERAL ASSEMBLY FURTHER DECLARES THAT THIS PART
11 IS INTENDED TO CREATE TRANSPARENCY IN PRESCRIPTION DRUG
PRICING AND DOES NOT:

(a) PRECLUDE A MANUFACTURER OF A PRESCRIPTION DRUG FROM
MAKING PRICING DECISIONS REGARDING ITS PRESCRIPTION DRUGS,
INCLUDING PRICE INCREASES; OR

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

10-16-1103. Definitions. As used in this Part 11, unless the
context otherwise requires:

(1) "Course of therapy" means either:

(a) The recommended daily dosage units of a prescription
drug for a thirty-day treatment pursuant to the prescribing
label for the drug as approved by the FDA; or

(b) The recommended daily dosage units of a prescription
drug for a normal course of treatment that is less than thirty
days pursuant to the prescribing label for the drug as approved
BY THE FDA.

(2) "DISINTERESTED THIRD PARTY" MEANS AN ENTITY THAT HAS NO FINANCIAL INTEREST IN, IS NOT EMPLOYED BY, AND IS NOT OTHERWISE CONNECTED WITH ANY MANUFACTURER, HEALTH INSURER, OR ANY OTHER PERSON THAT HAS A FINANCIAL INTEREST IN THE OUTCOME OF THE ANALYSES OR REPORTS REQUIRED BY THIS PART 11.

(3) "FDA" MEANS THE FEDERAL FOOD AND DRUG ADMINISTRATION.

(4) "HEALTH INSURER" MEANS:

(a) A CARRIER THAT IS SUBJECT TO PART 2, 3, OR 4 OF THIS ARTICLE 16 AND THAT IS OFFERING HEALTH BENEFIT PLANS IN COLORADO; AND

(b) A CARRIER THAT PROVIDES OR ADMINISTERS A GROUP BENEFIT PLAN FOR STATE EMPLOYEES PURSUANT TO PART 6 OF ARTICLE 50 OF TITLE 24.

(5) "MANUFACTURER" MEANS THE MANUFACTURER OF A PRESCRIPTION DRUG THAT IS MADE AVAILABLE IN COLORADO.


(7) "SPECIALTY DRUG" MEANS A PRESCRIPTION DRUG THAT EXCEEDS THE THRESHOLD FOR A SPECIALTY DRUG UNDER THE MEDICARE PART D PROGRAM.

10-16-1104. Health insurer annual reports to commissioner - pharmaceutical costs - confidentiality. (1) STARTING IN 2021, A HEALTH INSURER SHALL INCLUDE, AS PART OF ITS ANNUAL HEALTH CARE COST REPORT FILED WITH THE COMMISSIONER PURSUANT TO SECTION
10-16-111 (4), THE INFORMATION SPECIFIED IN SUBSECTION (2) OF THIS
SECTION. A HEALTH INSURER DESCRIBED IN SECTION 10-16-1103 (4)(b)
SHALL FILE THE INFORMATION SPECIFIED IN SUBSECTION (2) OF THIS
SECTION WITH THE COMMISSIONER BY JUNE 1, 2021, AND BY EACH JUNE
1 THEREAFTER.

(2) FOR ALL COVERED PRESCRIPTION DRUGS, INCLUDING GENERIC
DRUGS, BRAND NAME DRUGS, AND SPECIALTY DRUGS, DISPENSED IN THIS
STATE DURING THE IMMEDIATELY PRECEDING CALENDAR YEAR AT A PLAN
PHARMACY, NETWORK PHARMACY, OR MAIL-ORDER PHARMACY FOR
OUTPATIENT USE, A HEALTH INSURER SHALL REPORT THE FOLLOWING
INFORMATION:

(a) THE TWENTY-FIVE MOST FREQUENTLY PRESCRIBED DRUGS;
(b) THE TWENTY-FIVE MOST COSTLY DRUGS BY TOTAL ANNUAL
PLAN SPENDING; AND
(c) THE TWENTY-FIVE DRUGS WITH THE HIGHEST INCREASE IN
TOTAL ANNUAL PLAN SPENDING WHEN COMPARED WITH THE TOTAL
ANNUAL PLAN SPENDING FOR THE SAME DRUGS IN THE YEAR IMMEDIATELY
PRECEDING THE YEAR FOR WHICH THE INFORMATION IS REPORTED.

(3) EXCEPT AS OTHERWISE PERMITTED UNDER SECTION 10-16-1107
(2), THE COMMISSIONER SHALL MAINTAIN CONFIDENTIALITY OF THE
INFORMATION REPORTED UNDER THIS SECTION, AND THE INFORMATION
REPORTED UNDER THIS SECTION IS NOT SUBJECT TO THE "COLORADO OPEN
RECORDS ACT", PART 2 OF ARTICLE 72 OF TITLE 24.

10-16-1105. Drug manufacturers - notice to purchasers - drug
price increases - new drugs in the market. (1) THIS SECTION APPLIES
TO A MANUFACTURER OF A PRESCRIPTION DRUG THAT IS PURCHASED OR
REIMBURSED BY ANY OF THE FOLLOWING:
(a) The Department of Health Care Policy and Financing, the Department of Corrections, and any other state department that purchases prescription drugs on behalf of the state or an entity acting on behalf of a state prescription drug purchaser;
(b) a health insurer; or
(c) a pharmacy benefit management firm.

(2) (a) The manufacturer of a prescription drug with a wholesale acquisition cost of more than forty dollars for a course of therapy shall notify each purchaser described in subsection (1) of this section of an increase in the wholesale acquisition cost of a prescription drug that will be implemented on or after July 1, 2020, if the increase is more than ten percent, including the proposed increase and the cumulative increase during the previous twenty-four-month period.

(b) The manufacturer shall provide the notice required by this subsection (2) in writing to each purchaser at least ninety days before the planned effective date of the increase in the wholesale acquisition cost.

(c) The manufacturer shall include in the notice required by this subsection (2):

(I) the date of the increase, the current wholesale acquisition cost of the prescription drug, and the dollar amount of the future increase in the wholesale acquisition cost of the prescription drug; and

(II) a statement regarding whether a change or improvement in the drug necessitates the price increase and, if so, a description of the change or improvement.
(3) On or after July 1, 2020, a manufacturer that introduces a new specialty drug to the commercial market shall notify the purchasers described in subsection (1) of this section in writing within three days after the release of the drug in the commercial market. A manufacturer may make this notification pending FDA approval if commercial availability of the specialty drug is expected within three days after FDA approval.

(4) The commissioner shall make available to manufacturers a list of purchasers described in subsection (1) of this section to whom manufacturers are to send the notices required by this section.

10-16-1106. Drug manufacturer reports to commissioner - drug price increases - new specialty drugs. (1) Within fifteen days after the end of each calendar quarter that starts on or after July 1, 2020, a manufacturer shall report to the commissioner, in a format prescribed by the commissioner, the following information for each drug for which the manufacturer was required to notify purchasers of an increase in the wholesale acquisition cost pursuant to section 10-16-1105 (2) in the prior quarter:

(a) A description of the specific financial factors and nonfinancial factors, such as shadow pricing, off-label use, changes in FDA policy that reduce requirements, the cost of current treatments, and other nonfinancial factors, used to make the decision to increase the wholesale acquisition cost of the drug and the amount of the increase, including an
EXPLANATION OF HOW THE FACTORS DRIVE THE INCREASE IN THE WHOLESALE ACQUISITION COST OF THE DRUG;

(b) A SCHEDULE OF WHOLESALE ACQUISITION COST INCREASES FOR THE DRUG FOR THE PREVIOUS FIVE YEARS, IF THE DRUG WAS MANUFACTURED BY THE MANUFACTURER;

(c) IF THE DRUG WAS ACQUIRED BY THE MANUFACTURER WITHIN THE PREVIOUS FIVE YEARS, THE FOLLOWING INFORMATION:

(I) THE WHOLESALE ACQUISITION COST OF THE DRUG AT THE TIME OF ACQUISITION AND IN THE CALENDAR YEAR PRIOR TO ACQUISITION;

(II) THE NAME OF THE COMPANY FROM WHOM THE DRUG WAS ACQUIRED, THE DATE ACQUIRED, AND THE PURCHASE PRICE; AND

(III) THE YEAR THE DRUG WAS INTRODUCED TO MARKET AND THE WHOLESALE ACQUISITION COST OF THE DRUG WHEN IT WAS INTRODUCED TO THE MARKET;

(d) FOR A BRAND NAME DRUG UNDER PATENT, THE PATENT EXPIRATION DATE OF THE DRUG AND, FOR A GENERIC DRUG, THE YEAR OF FDA APPROVAL;

(e) IF THE DRUG IS A MULTIPLE SOURCE DRUG, AN INNOVATOR MULTIPLE SOURCE DRUG, A NONINNOVATOR MULTIPLE SOURCE DRUG, OR A SINGLE SOURCE DRUG, AS DEFINED IN 42 U.S.C. SEC. 1396r-8 (k)(7);

(f) A DESCRIPTION OF THE CHANGE OR IMPROVEMENT IN THE DRUG, IF ANY, THAT NECESSITIES THE PRICE INCREASE; AND

(g) THE TOTAL GROSS REVENUES FROM SALES OF THE DRUG IN COLORADO FOR THE PREVIOUS YEAR.

(2) WITHIN FIFTEEN DAYS AFTER THE END OF EACH CALENDAR QUARTER THAT STARTS ON OR AFTER JULY 1, 2020, A MANUFACTURER SHALL REPORT TO THE COMMISSIONER, IN A FORMAT PRESCRIBED BY THE
COMMISSIONER, THE FOLLOWING INFORMATION FOR EACH NEW SPECIALTY
DRUG INTRODUCED TO THE MARKET IN THE PRIOR QUARTER:

(a) A DESCRIPTION OF THE MARKETING AND PRICING PLANS USED
IN THE LAUNCH OF THE NEW SPECIALTY DRUG IN COLORADO;

(b) THE ESTIMATED NUMBER OF PATIENTS THAT MIGHT BE
PRESCRIBED THE SPECIALTY DRUG FOR THE USE APPROVED BY THE FDA;

(c) WHETHER THE DRUG WAS GRANTED BREAKTHROUGH THERAPY
DESIGNATION OR PRIORITY REVIEW BY THE FDA PRIOR TO FINAL
APPROVAL; AND

(d) THE DATE AND PRICE OF ACQUISITION IF THE DRUG WAS NOT
DEVELOPED BY THE MANUFACTURER.

10-16-1107. Commissioner to publish information - reporting
requirements. (1) WITHIN THIRTY DAYS AFTER RECEIPT, THE
COMMISSIONER SHALL PUBLISH THE INFORMATION REPORTED BY
MANUFACTURERS PURSUANT TO SECTION 10-16-1106 ON THE DIVISION
WEBSITE. THE COMMISSIONER SHALL PUBLISH THE INFORMATION IN A
MANNER THAT ALLOWS IDENTIFICATION OF THE DRUG ABOUT WHICH THE
INFORMATION IS REPORTED AND SHALL NOT AGGREGATE THE DATA.

(2) (a) THE COMMISSIONER, OR A DISINTERESTED THIRD PARTY
WITH WHOM THE COMMISSIONER CONTRACTS, SHALL ANALYZE THE DATA
REPORTED BY HEALTH INSURERS PURSUANT TO SECTION 10-16-1104, THE
DATA REPORTED BY MANUFACTURERS PURSUANT TO SECTION 10-16-1106,
THE HEALTH INSURER RATE INFORMATION FILED PURSUANT TO SECTION
10-16-107, AND ANY OTHER RELEVANT DATA THE COMMISSIONER
POSSESSES IN ORDER TO DETERMINE THE OVERALL EFFECT OF
PRESCRIPTION DRUG COSTS ON PREMIUMS. THE COMMISSIONER SHALL
ISSUE A REPORT, AS PART OF THE REPORT PREPARED PURSUANT TO SECTION
10-16-111 (4)(c), analyzing the prescription drug cost data and
the effect of prescription drug costs on premiums. The
commissioner shall aggregate the data reported by health
insurers and shall not reveal information specific to a
particular health benefit plan in the report.

(b) By December 1, 2021, and by each December 1
thereafter, the commissioner shall publish the report required
by this subsection (2) on the division website.

(c) By December 1, 2021, and by each December 1
thereafter, the commissioner shall submit the report to the
senate committee on health and human services and the house
committees on health, insurance, and environment and public
health care and human services, or their successor committees.
Additionally, the commissioner shall present the report to
those committees during the committees' hearings held prior to
the 2022 legislative session and prior to each legislative session
thereafter under the "State Measurement for Accountable,
Responsive, and Transparent (SMART) Government Act", part 2
of article 7 of title 2.

(d) The reporting requirement in this subsection (2) is not
subject to expiration under section 24-1-136 (11)(a)(I).

10-16-1108. Rules - coordination with other state entities.

(1) The commissioner may adopt rules as necessary to implement
this part 11, including rules specifying the form and manner
health insurers and manufacturers are to report information
required by sections 10-16-1104 and 10-16-1106.

(2) The commissioner may consult with the state board of
PHARMACY, THE DEPARTMENT OF HEALTH CARE POLICY AND FINANCING, THE DEPARTMENT OF CORRECTIONS, THE DEPARTMENT OF PERSONNEL, AND ANY OTHER STATE PURCHASER OF PRESCRIPTION DRUGS OR AN ENTITY ACTING ON BEHALF OF A STATE PURCHASER, IN ADOPTING NECESSARY RULES PURSUANT TO SUBSECTION (1) OF THIS SECTION, IN POSTING INFORMATION ON THE DIVISION WEBSITE PURSUANT TO SECTION 10-16-1107 (1), AND IN TAKING ANY OTHER ACTION FOR THE PURPOSE OF IMPLEMENTING THIS PART 11.

10-16-1109. Violations - enforcement. (1) A MANUFACTURER ENGAGES IN UNPROFESSIONAL CONDUCT UNDER SECTION 12-42.5-123 (1)(t) AND IS SUBJECT TO DISCIPLINE UNDER SECTION 12-42.5-124, INCLUDING PENALTIES UNDER SECTION 12-42.5-124 (5)(a)(IV), IF THE MANUFACTURER:

(a) FAILS TO NOTIFY PURCHASERS OF A PRESCRIPTION DRUG PRICE INCREASE OR A NEW SPECIALTY DRUG INTRODUCED TO THE MARKET AS REQUIRED BY SECTION 10-16-1105; OR

(b) FAILS TO REPORT TO THE COMMISSIONER THE INFORMATION REQUIRED BY SECTION 11-16-1106.

(2) THE COMMISSIONER SHALL REPORT MANUFACTURER VIOLATIONS OF THIS PART 11 TO THE STATE BOARD OF PHARMACY.

SECTION 2. In Colorado Revised Statutes, 12-42.5-123, add (1)(t) as follows:

12-42.5-123. Unprofessional conduct - grounds for discipline.

(1) The board may suspend, revoke, refuse to renew, or otherwise discipline any license or registration issued by it, after a hearing held in accordance with the provisions of this section, upon proof that the licensee or registrant:
HAS FAILED TO NOTIFY PURCHASERS OF PRESCRIPTION DRUG PRICE INCREASES OR OF NEW SPECIALTY DRUGS INTRODUCED TO THE MARKET AS REQUIRED BY SECTION 10-16-1105; OR

(II) HAS FAILED TO REPORT THE INFORMATION REQUIRED BY SECTION 10-16-1106 TO THE COMMISSIONER OF INSURANCE.

SECTION 3. In Colorado Revised Statutes, 12-42.5-124, amend (5)(a)(I); and add (5)(a)(IV) as follows:

12-42.5-124. Disciplinary actions. (5)(a)(I) Except as provided in subparagraphs (II) and (III) of this paragraph (a) SUBSECTION (5)(a)(II), (5)(a)(III), OR (5)(a)(IV) OF THIS SECTION, in addition to any other penalty the board may impose pursuant to this section, the board may fine any registrant violating this article ARTICLE 42.5 or any rules promulgated pursuant to this article ARTICLE 42.5 not less than five hundred dollars and not more than five thousand dollars for each violation.

(IV) IN ADDITION TO ANY OTHER PENALTY THE BOARD MAY IMPOSE PURSUANT TO THIS SECTION, THE BOARD MAY FINE A REGISTRANT FOR FAILING TO NOTIFY DRUG PURCHASERS OR REPORT INFORMATION TO THE COMMISSIONER OF INSURANCE AS SPECIFIED IN SECTION 12-42.5-123 (1)(t) NOT LESS THAN ONE THOUSAND DOLLARS PER DAY FOR EACH DAY THE REGISTRANT FAILS TO COMPLY WITH THE NOTICE OR REPORTING REQUIREMENTS.

SECTION 4. Effective date. This act takes effect July 1, 2018.

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, and safety.