First Regular Session
Seventy-second General Assembly
STATE OF COLORADO

INTRODUCED

LLS NO. 19-0095.02 Christy Chase x2008 **HOUSE BILL 19-1296**

HOUSE SPONSORSHIP

Jackson and Jaquez Lewis, Roberts

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Ginal and Donovan,

House Committees
Health & Insurance
Appropriations

Senate Committees

A BILL FOR AN ACT

CONCERNING MEASURES TO REDUCE PRESCRIPTION DRUG COSTS, AND, IN CONNECTION THEREWITH, CREATING THE "COLORADO PRESCRIPTION DRUG COST REDUCTION ACT OF 2019" TO REQUIRE HEALTH INSURERS, PRESCRIPTION DRUG MANUFACTURERS, PHARMACY BENEFIT MANAGEMENT FIRMS, AND NONPROFIT ORGANIZATIONS TO REPORT SPECIFIED INFORMATION ABOUT THE COSTS OF PRESCRIPTION DRUGS TO THE COMMISSIONER OF INSURANCE; TO DIRECT THE COMMISSIONER TO ANALYZE THE INFORMATION AND SUBMIT A REPORT REGARDING THE EFFECTS OF PRESCRIPTION DRUG COSTS ON HEALTH INSURANCE PREMIUMS; TO PRECLUDE PHARMACY BENEFIT MANAGEMENT FIRMS FROM RETROACTIVELY REDUCING PAYMENTS TO PHARMACIES; AND TO

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.

REQUIRE CARRIERS TO REDUCE CONSUMER COST SHARING FOR PRESCRIPTION DRUGS TO REFLECT REBATES THE CARRIER OR PHARMACY BENEFIT MANAGEMENT FIRM RECEIVED.

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.)

Section 1 of the bill enacts the "Colorado Prescription Drug Cost Reduction Act of 2019", which requires:

- Health insurers, starting in 2020, to submit to the commissioner of insurance (commissioner) information regarding prescription drugs covered under their health insurance plans that the plan paid for in the preceding calendar year, including information about rebates received from prescription drug manufacturers, a certification regarding how rebates were accounted for in insurance premiums, and a list of all pharmacy benefit management firms (PBMs) with whom they contract;
- Prescription drug manufacturers to notify the commissioner, state purchasers, health insurers, and PBMs when the manufacturer, on or after January 1, 2020, increases the price of certain prescription drugs by more than specified amounts or introduces a new specialty drug in the commercial market;
- Prescription drug manufacturers, within 15 days after the end of each calendar quarter that starts on or after January 1, 2020, to provide specified information to the commissioner regarding the drugs about which the manufacturer notified purchasers;
- Health insurers or, if applicable, PBMs to annually report specified information to the commissioner regarding rebates and administrative fees received from manufacturers for prescription drugs for which they received the required notice from a manufacturer; and
- Certain nonprofit organizations to compile and submit to the commissioner an annual report indicating the amount of each payment, donation, subsidy, or thing of value received by the nonprofit organization or its executive director, chief operating officer, board of directors, or any member of the

board of directors from a prescription drug manufacturer, PBM, or health insurer and the percentage of the nonprofit organization's total gross income that is attributable to those payments, donations, subsidies, or things of value.

The commissioner is required to post the information received from health insurers, prescription drug manufacturers, PBMs, and nonprofit organizations on the division of insurance's website, excluding any information that is proprietary. Additionally, the commissioner, or a disinterested third-party contractor, is to analyze the data reported by health insurers, prescription drug manufacturers, PBMs, and nonprofit organizations 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 the governor and 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 bill.

Section 2 prohibits PBMs from retroactively reducing payment on a clean claim submitted by a pharmacy unless the PBM determines, through an audit conducted in accordance with state law, that the claim was not a clean claim. Health insurers that contract with PBMs must ensure that the PBMs are complying with this prohibition and the reporting requirements and are subject to penalties for failure to do so.

Section 3 requires a carrier to reduce the cost sharing a covered person is required to pay for prescription drugs by an amount equal to the greater of 51% of the average aggregate rebates received by the carrier for all prescription drugs, including price protection rebates, or an amount that ensures cost sharing will not exceed 125% of the carrier's cost for the prescription drug.

Under **sections 5 and 6**, 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 up to $10,000 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. Additionally, health insurers that fail to report the required data are subject to a fine of up to $10,000 per day.

Sections 7 and 8 of the bill make conforming amendments necessary to harmonize the bill with the title 12 recodification bill, House Bill 19-1172.

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

SECTION 1. In Colorado Revised Statutes, **add** part 11 to article

16 of title 10 as follows:

PART 11

PRESCRIPTION DRUG COST REDUCTION

10-16-1101. Short title. THE SHORT TITLE OF THIS PART 11 IS THE "COLORADO PRESCRIPTION DRUG COST REDUCTION ACT OF 2019".

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 BECAUSE 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 PRESCRIPTION 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 PRESCRIPTION DRUG AS APPROVED BY THE FDA.

(2) "DISINTERESTED THIRD PARTY" MEANS AN ENTITY THAT HAS NO FINANCIAL INTEREST IN, IS NOT EMPLOYED OR FUNDED BY, AND IS NOT OTHERWISE CONNECTED WITH ANY MANUFACTURER, HEALTH INSURER, PHARMACY BENEFIT MANAGEMENT FIRM, NONPROFIT ORGANIZATION THAT IS REQUIRED TO SUBMIT REPORTS TO THE COMMISSIONER PURSUANT TO SECTION 10-16-1108, OR OTHER PERSON THAT HAS A FINANCIAL INTEREST IN THE OUTCOME OF THE ANALYSES OR REPORTS REQUIRED BY THIS PART 11.

(3) "ESSENTIAL DRUG" MEANS A PRESCRIPTION DRUG INCLUDED ON THE MOST CURRENT VERSION OF THE "WHO MODEL LIST OF ESSENTIAL MEDICINES" OR A SUCCESSOR LIST, AS PUBLISHED BY THE WORLD HEALTH ORGANIZATION OR ITS SUCCESSOR ORGANIZATION.

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

(5) "HEALTH INSURER" MEANS:

(a) A CARRIER AS DEFINED IN SECTION 10-16-102 (8); AND

(b) A CARRIER, AS DEFINED IN SECTION 24-50-603 (2), THAT PROVIDES OR ADMINISTERS A GROUP BENEFIT PLAN FOR STATE EMPLOYEES PURSUANT TO PART 6 OF ARTICLE 50 OF TITLE 24.

(6) "LINE EXTENSION" MEANS, WITH RESPECT TO A PRESCRIPTION DRUG, A NEW OR AN ADDITIONAL FORMULATION OF THE PRESCRIPTION DRUG, SUCH AS AN EXTENDED RELEASE FORMULATION.

(7) "MANUFACTURE" HAS THE SAME MEANING AS SPECIFIED IN SECTION 12-42.5-102 (20).

(8) "MANUFACTURER" MEANS A PERSON THAT MANUFACTURES A PRESCRIPTION DRUG THAT IS MADE AVAILABLE IN COLORADO.

(9) "MEDICARE PART D PROGRAM" MEANS THE "MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003", PUB.L. 108-173, CODIFIED IN PART D OF TITLE XVIII OF THE "SOCIAL SECURITY ACT", 42 U.S.C. SEC. 1395w-101 ET SEQ.

(10) "PRESCRIPTION DRUG" HAS THE SAME MEANING AS SPECIFIED IN SECTION 12-42.5-102 (34).

(11) "PRICE" MEANS THE WHOLESALE ACQUISITION COST AS DEFINED IN 42 U.S.C. SEC. 1395w-3a (c)(6)(B).

(12) "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 - penalty. (1) STARTING IN 2020, A HEALTH INSURER DESCRIBED IN SECTION 10-16-1103 (5)(a) SHALL REPORT TO THE COMMISSIONER, CONTEMPORANEOUS WITH ITS RATE FILING PURSUANT TO SECTION 10-16-107 AND IN THE FORM AND MANNER SPECIFIED BY THE COMMISSIONER THAT ENSURES THE INFORMATION IS SEPARATED FROM THE RATE FILING INFORMATION, THE INFORMATION SPECIFIED IN SUBSECTION (2) OF THIS SECTION AND THE CERTIFICATION REQUIRED BY SUBSECTION (3) OF THIS SECTION. A HEALTH INSURER DESCRIBED IN SECTION

10-16-1103 (5)(b) SHALL FILE THE INFORMATION SPECIFIED IN SUBSECTION (2) OF THIS SECTION AND THE CERTIFICATION REQUIRED BY SUBSECTION (3) OF THIS SECTION WITH THE COMMISSIONER BY A DATE SPECIFIED BY THE COMMISSIONER THAT COINCIDES WITH RATE FILINGS FOR HEALTH INSURERS DESCRIBED IN SECTION 10-16-1103 (5)(a).

(2) FOR ALL COVERED PRESCRIPTION DRUGS, INCLUDING GENERIC PRESCRIPTION DRUGS, BRAND-NAME PRESCRIPTION DRUGS, AND SPECIALTY DRUGS, PAID FOR BY THE HEALTH INSURER 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 IN A FORM AND MANNER PRESCRIBED BY THE COMMISSIONER:

(a) THE TWENTY-FIVE PRESCRIPTION DRUGS THAT THE HEALTH INSURER PAID FOR THE MOST FREQUENTLY;

(b) THE TWENTY-FIVE MOST COSTLY PRESCRIPTION DRUGS BY TOTAL ANNUAL DRUG SPEND;

(c) THE TWENTY-FIVE PRESCRIPTION DRUGS PAID FOR BY THE HEALTH INSURER 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; AND

(d) THE TWENTY-FIVE OUTPATIENT PRESCRIPTION DRUGS THAT THE HEALTH INSURER PAID FOR THE MOST FREQUENTLY AND FOR WHICH THE HEALTH INSURER RECEIVED FROM MANUFACTURERS A REBATE, DISCOUNT, OR OTHER SOURCE OF REVENUE THAT REDUCED THE COST TO ACQUIRE THE PRESCRIPTION DRUG.

(3) EACH HEALTH INSURER SHALL SUBMIT TO THE COMMISSIONER,

IN A FORM AND MANNER PRESCRIBED BY THE COMMISSIONER AND IN ACCORDANCE WITH SUBSECTION (1) OF THIS SECTION:

(a) A WRITTEN CERTIFICATION, INCLUDING SUPPORTING DOCUMENTATION, FOR THE IMMEDIATELY PRECEDING CALENDAR YEAR CERTIFYING THAT THE HEALTH INSURER ACCOUNTED FOR ALL REBATES, DISCOUNTS, OR OTHER SOURCES OF REVENUE THAT REDUCED THE COST TO ACQUIRE A PRESCRIPTION DRUG IN CALCULATING THE PREMIUM FOR HEALTH BENEFIT PLANS THAT THE HEALTH INSURER ISSUED OR RENEWED DURING THAT CALENDAR YEAR; AND

(b) A LIST OF ALL PHARMACY BENEFIT MANAGEMENT FIRMS WITH WHOM THE HEALTH INSURER CONTRACTS TO ADMINISTER OR MANAGE PRESCRIPTION DRUG BENEFITS THAT THE HEALTH INSURER PROVIDES. A HEALTH INSURER SHALL PROVIDE THE COMMISSIONER, WITHIN TEN BUSINESS DAYS AFTER A CHANGE, WITH UPDATED INFORMATION ABOUT ANY CHANGE IN THE PHARMACY BENEFIT MANAGEMENT FIRMS WITH WHOM THE HEALTH INSURER CONTRACTS, INCLUDING A CHANGE IN THE NAME OR CONTACT INFORMATION OF THE PHARMACY BENEFIT MANAGEMENT FIRM.

(4) A HEALTH INSURER THAT FAILS TO COMPLY WITH THE REQUIREMENTS OF THIS SECTION IS SUBJECT TO A FINE OF UP TO TEN THOUSAND DOLLARS PER DAY FOR EACH DAY THE HEALTH INSURER FAILS TO COMPLY WITH THIS SECTION. THE COMMISSIONER SHALL TRANSMIT ANY MONEY COLLECTED UNDER THIS SUBSECTION (4) TO THE STATE TREASURER FOR DEPOSIT IN THE GENERAL FUND.

10-16-1105. Drug manufacturers - notice to purchasers and commissioner - 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, THE DEPARTMENT OF HUMAN SERVICES, AND ANY OTHER STATE DEPARTMENT THAT PURCHASES PRESCRIPTION DRUGS ON BEHALF OF THE STATE OR AN ENTITY ACTING ON BEHALF OF A STATE DEPARTMENT, INCLUDING A PHARMACY BENEFIT MANAGEMENT FIRM;

(b) A HEALTH INSURER; OR

(c) A PHARMACY BENEFIT MANAGEMENT FIRM THAT HAS CONTRACTED WITH A HEALTH INSURER.

(2) (a) THE MANUFACTURER OF A PRESCRIPTION DRUG WITH A PRICE OF MORE THAN ONE HUNDRED DOLLARS FOR A COURSE OF THERAPY SHALL NOTIFY THE COMMISSIONER, IN A FORM AND MANNER SPECIFIED BY THE COMMISSIONER, AND EACH PURCHASER DESCRIBED IN SUBSECTION (1) OF THIS SECTION OF AN INCREASE IN THE PRICE OF THE PRESCRIPTION DRUG THAT WILL BE IMPLEMENTED ON OR AFTER JANUARY 1, 2020, IF:

(I) THE INCREASE IN THE PRICE IS TEN PERCENT OR MORE OVER THE PREVIOUS TWELVE-MONTH PERIOD OR SIXTEEN PERCENT OR MORE OVER THE PREVIOUS TWENTY-FOUR-MONTH PERIOD; OR

(II) THE PRESCRIPTION DRUG IS AN ESSENTIAL DRUG AND THE INCREASE IN THE PRICE OF THE PRESCRIPTION DRUG IS TEN PERCENT OR MORE OVER THE PREVIOUS TWELVE-MONTH PERIOD, SIXTEEN PERCENT OR MORE OVER THE PREVIOUS TWENTY-FOUR-MONTH PERIOD, OR TWENTY PERCENT OR MORE OVER THE PREVIOUS THIRTY-SIX-MONTH PERIOD.

(b) THE MANUFACTURER SHALL PROVIDE THE NOTICE REQUIRED BY THIS SUBSECTION (2) IN WRITING TO THE COMMISSIONER AND EACH PURCHASER AT LEAST THIRTY DAYS BEFORE THE PLANNED EFFECTIVE

DATE OF THE INCREASE IN THE PRICE.

(c) THE MANUFACTURER SHALL INCLUDE IN THE NOTICE REQUIRED BY THIS SUBSECTION (2):

(I) THE DATE OF THE INCREASE, THE CURRENT PRICE OF THE PRESCRIPTION DRUG, AND THE DOLLAR AMOUNT OF THE FUTURE INCREASE IN THE PRICE OF THE PRESCRIPTION DRUG; AND

(II) A STATEMENT REGARDING WHETHER A CHANGE OR IMPROVEMENT IN THE PRESCRIPTION DRUG NECESSITATES THE PRICE INCREASE AND, IF SO, A DESCRIPTION OF THE CHANGE OR IMPROVEMENT.

(3) ON OR AFTER JANUARY 1, 2020, A MANUFACTURER THAT INTRODUCES A NEW SPECIALTY DRUG TO THE COMMERCIAL MARKET SHALL NOTIFY THE COMMISSIONER, IN A FORM AND MANNER SPECIFIED BY THE COMMISSIONER, AND EACH PURCHASER DESCRIBED IN SUBSECTION (1) OF THIS SECTION IN WRITING WITHIN THREE DAYS AFTER THE RELEASE OF THE SPECIALTY 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 - rules. (1) (a) WITHIN FIFTEEN DAYS AFTER THE END OF EACH CALENDAR QUARTER THAT STARTS ON OR AFTER JANUARY 1, 2020, A MANUFACTURER SHALL REPORT TO THE COMMISSIONER, IN A FORM AND MANNER PRESCRIBED BY THE

COMMISSIONER, THE FOLLOWING INFORMATION FOR EACH PRESCRIPTION DRUG FOR WHICH THE MANUFACTURER WAS REQUIRED TO NOTIFY PURCHASERS OF AN INCREASE IN THE PRICE PURSUANT TO SECTION 10-16-1105 (2) IN THE PRIOR QUARTER:

(I) THE NAME AND PRICE OF THE PRESCRIPTION DRUG AND THE INCREASE, EXPRESSED AS A PERCENTAGE, IN THE PRICE OF THE PRESCRIPTION DRUG OVER THE COURSE OF THE IMMEDIATELY PRECEDING CALENDAR YEAR;

(II) THE LENGTH OF TIME THE PRESCRIPTION DRUG HAS BEEN ON THE MARKET;

(III) A DESCRIPTION OF THE SPECIFIC FINANCIAL FACTORS AND NONFINANCIAL FACTORS, SUCH AS SHADOW PRICING, OFF-LABEL USE, CHANGES IN FDA POLICY THAT AFFECT REQUIREMENTS, THE COST OF CURRENT TREATMENTS, AND OTHER NONFINANCIAL FACTORS, USED TO MAKE THE DECISION TO INCREASE THE PRICE OF THE PRESCRIPTION DRUG AND THE AMOUNT OF THE INCREASE, INCLUDING AN EXPLANATION OF HOW THE FACTORS DRIVE THE INCREASE IN THE PRICE OF THE PRESCRIPTION DRUG;

(IV) THE INTRODUCTORY PRICE OF THE PRESCRIPTION DRUG WHEN IT WAS APPROVED FOR MARKETING BY THE FDA AND THE NET YEARLY INCREASE, LISTED BY CALENDAR YEAR, IN THE PRICE OF THE PRESCRIPTION DRUG DURING THE FIVE IMMEDIATELY PRECEDING CALENDAR YEARS;

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

(A) THE PRICE OF THE PRESCRIPTION DRUG AT THE TIME OF ACQUISITION AND IN THE CALENDAR YEAR IMMEDIATELY PRECEDING THE

ACQUISITION;

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

(C) THE YEAR THE PRESCRIPTION DRUG WAS INTRODUCED TO THE MARKET AND THE PRICE OF THE PRESCRIPTION DRUG WHEN IT WAS INTRODUCED TO THE MARKET;

(VI) FOR A BRAND-NAME PRESCRIPTION DRUG UNDER PATENT, ALL RELEVANT APPROVED AND PENDING PATENTS, THE STATUS OF THE PATENTS, AND THE EXPIRATION DATES OF THE PATENTS AND, FOR A GENERIC PRESCRIPTION DRUG, THE YEAR OF FDA APPROVAL;

(VII) WHETHER THE PRESCRIPTION DRUG IS 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), OR HAS A LINE EXTENSION;

(VIII) A DESCRIPTION OF THE CHANGE OR IMPROVEMENT IN THE PRESCRIPTION DRUG, IF ANY, THAT NECESSITATES THE PRICE INCREASE;

(IX) THE TOTAL GROSS REVENUES FROM SALES OF THE PRESCRIPTION DRUG IN COLORADO FOR THE IMMEDIATELY PRECEDING CALENDAR YEAR;

(X) THE NAME OF ANY GENERIC VERSION OF THE PRESCRIPTION DRUG THAT IS AVAILABLE ON THE MARKET;

(XI) THE DIRECT COSTS INCURRED BY THE MANUFACTURER:

(A) TO RESEARCH AND DEVELOP THE PRESCRIPTION DRUG;

(B) TO MANUFACTURE THE PRESCRIPTION DRUG;

(C) TO MARKET THE PRESCRIPTION DRUG;

(D) TO DISTRIBUTE THE PRESCRIPTION DRUG; AND

(E) FOR ONGOING SAFETY AND EFFECTIVENESS RESEARCH ASSOCIATED WITH THE PRESCRIPTION DRUG;

(XII) THE MANUFACTURER'S PROFIT ATTRIBUTABLE TO THE PRESCRIPTION DRUG DURING THE IMMEDIATELY PRECEDING CALENDAR YEAR;

(XIII) THE TEN HIGHEST PRICES PAID FOR THE PRESCRIPTION DRUG DURING THE IMMEDIATELY PRECEDING CALENDAR YEAR IN ANY COUNTRY OTHER THAN THE UNITED STATES;

(XIV) ANY OTHER INFORMATION THAT THE MANUFACTURER DEEMS RELEVANT TO THE PRICE INCREASE; AND

(XV) THE DOCUMENTATION NECESSARY TO SUPPORT THE INFORMATION REPORTED PURSUANT TO THIS SUBSECTION (1)(a).

(b) THE COMMISSIONER MAY USE ANY PRESCRIPTION DRUG PRICE INFORMATION THE COMMISSIONER DEEMS APPROPRIATE TO VERIFY THAT MANUFACTURERS HAVE PROPERLY REPORTED PRICE INCREASES AS REQUIRED BY THIS SUBSECTION (1).

(c) A MANUFACTURER SHALL INCLUDE WITH THE INFORMATION REPORTED PURSUANT TO SUBSECTION (1)(a) OF THIS SECTION THE FOLLOWING INFORMATION ABOUT EACH PATIENT ASSISTANCE PROGRAM OFFERED BY THE MANUFACTURER TO CONSUMERS RESIDING IN THIS STATE FOR THE PRESCRIPTION DRUGS REPORTED ON AS REQUIRED BY SUBSECTION (1)(a) OF THIS SECTION:

(I) THE NUMBER OF CONSUMERS WHO PARTICIPATED IN THE PROGRAM;

(II) THE TOTAL VALUE OF THE COUPONS, DISCOUNTS, COPAYMENT ASSISTANCE, OR OTHER REDUCTIONS IN COSTS PROVIDED TO CONSUMERS IN THIS STATE WHO PARTICIPATED IN THE PROGRAM;

(III) FOR EACH PRESCRIPTION DRUG, THE NUMBER OF REFILLS THAT QUALIFY FOR THE PROGRAM, IF APPLICABLE;

(IV) IF THE PROGRAM EXPIRES AFTER A SPECIFIED PERIOD OF TIME, THE PERIOD OF TIME THAT THE PROGRAM IS AVAILABLE TO EACH CONSUMER; AND

(V) THE ELIGIBILITY CRITERIA FOR THE PROGRAM AND HOW ELIGIBILITY IS VERIFIED FOR ACCURACY.

(2) WITHIN FIFTEEN DAYS AFTER THE END OF EACH CALENDAR QUARTER THAT STARTS ON OR AFTER JANUARY 1, 2020, A MANUFACTURER SHALL REPORT TO THE COMMISSIONER, IN A FORM AND MANNER 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 SPECIALTY DRUG IN COLORADO;

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

(c) WHETHER THE SPECIALTY 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 SPECIALTY DRUG WAS NOT DEVELOPED BY THE MANUFACTURER.

(3) AFTER RECEIVING A REPORT OF INFORMATION DESCRIBED IN SUBSECTION (1) OR (2) OF THIS SECTION, THE COMMISSIONER MAY REQUEST, IN WRITING, THAT A MANUFACTURER PROVIDE SUPPORTING DOCUMENTATION OR ADDITIONAL INFORMATION CONCERNING THE

REPORTED INFORMATION. THE COMMISSIONER SHALL PRESCRIBE BY RULE THE TIME PERIODS FOR REQUESTING ADDITIONAL DOCUMENTATION OR INFORMATION AND FOR MANUFACTURERS TO RESPOND TO THE REQUEST, INCLUDING EXTENSIONS FOR MANUFACTURERS TO RESPOND.

(4) THE DIVISION SHALL MAKE AVAILABLE TO CONSUMERS, ONLINE AND BY TELEPHONE, A PROCESS FOR CONSUMERS TO NOTIFY THE DIVISION ABOUT AN INCREASE IN THE PRICE OF A PRESCRIPTION DRUG.

10-16-1107. Pharmacy benefit management firms - required reports. (1) (a) STARTING IN 2020, EXCEPT AS SPECIFIED IN SUBSECTION (1)(b) OF THIS SECTION, A HEALTH INSURER SHALL REPORT TO THE COMMISSIONER, CONTEMPORANEOUS WITH ITS RATE FILING PURSUANT TO SECTION 10-16-107 AND IN THE FORM AND MANNER SPECIFIED BY THE COMMISSIONER THAT ENSURES THE INFORMATION IS SEPARATED FROM THE RATE FILING INFORMATION, THE INFORMATION SPECIFIED IN SUBSECTION (2) OF THIS SECTION. IF A HEALTH INSURER CONTRACTS WITH A PHARMACY BENEFIT MANAGEMENT FIRM TO ADMINISTER OR MANAGE PRESCRIPTION DRUG BENEFITS ON BEHALF OF THE HEALTH INSURER, THE PHARMACY BENEFIT MANAGEMENT FIRM SHALL REPORT THE INFORMATION SPECIFIED IN SUBSECTION (2) OF THIS SECTION BY A DATE SPECIFIED BY THE COMMISSIONER THAT COINCIDES WITH HEALTH INSURER RATE FILINGS PURSUANT TO SECTION 10-16-107.

(b) FOR PURPOSES OF THE REPORT REQUIRED TO BE SUBMITTED IN THE 2020 CALENDAR YEAR, THE HEALTH INSURER OR PHARMACY BENEFIT MANAGEMENT FIRM SHALL REPORT INFORMATION ON ANY PRESCRIPTION DRUG FOR WHICH THE HEALTH INSURER OR PHARMACY BENEFIT MANAGEMENT FIRM RECEIVED A NOTICE FROM A MANUFACTURER PURSUANT TO SECTION 10-16-1105 DURING THE FIRST QUARTER OF THE

CALENDAR YEAR. FOR THE 2021 CALENDAR YEAR AND EACH CALENDAR YEAR THEREAFTER, THE REPORT MUST CONTAIN INFORMATION ON ALL PRESCRIPTION DRUGS FOR WHICH A NOTICE WAS RECEIVED FROM A MANUFACTURER DURING THE IMMEDIATELY PRECEDING CALENDAR YEAR.

(2) FOR EACH PRESCRIPTION DRUG INCLUDED IN A MANUFACTURER'S NOTICE TO A HEALTH INSURER OR PHARMACY BENEFIT MANAGEMENT FIRM PURSUANT TO SECTION 10-16-1105, THE HEALTH INSURER OR PHARMACY BENEFIT MANAGEMENT FIRM SHALL REPORT:

(a) THE TOTAL AMOUNT OF ALL REBATES, DISCOUNTS, OR OTHER SOURCES OF REVENUE THAT REDUCE THE COST TO ACQUIRE THE PRESCRIPTION DRUG THAT THE HEALTH INSURER OR PHARMACY BENEFIT MANAGEMENT FIRM RECEIVED FROM MANUFACTURERS OF THE PRESCRIPTION DRUG DURING THE IMMEDIATELY PRECEDING CALENDAR QUARTER;

(b) THE TOTAL AMOUNT OF ALL REBATES, DISCOUNTS, OR OTHER SOURCES OF REVENUE THAT REDUCE THE COST TO ACQUIRE THE PRESCRIPTION DRUG DESCRIBED IN SUBSECTION (2)(a) OF THIS SECTION RETAINED BY THE HEALTH INSURER OR PHARMACY BENEFIT MANAGEMENT FIRM;

(c) THE TOTAL AMOUNT OF ADMINISTRATIVE FEES THE PHARMACY BENEFIT MANAGEMENT FIRM RECEIVED FROM MANUFACTURERS AND HEALTH INSURERS FOR THE PRESCRIPTION DRUG;

(d) THE TOTAL AMOUNT OF ALL REBATES, DISCOUNTS, OR OTHER SOURCES OF REVENUE THAT REDUCE THE COST TO ACQUIRE THE PRESCRIPTION DRUG DESCRIBED IN SUBSECTION (2)(a) OF THIS SECTION NEGOTIATED FOR PURCHASES OF THE PRESCRIPTION DRUG FOR USE BY:

(I) COLORADO MEDICARE RECIPIENTS IN ACCORDANCE WITH 42

U.S.C. SEC. 1395 ET SEQ.;

(II) COLORADO MEDICAID RECIPIENTS IN ACCORDANCE WITH 42 U.S.C. SEC. 1396 ET SEQ.;

(III) ENROLLEES, AS DEFINED IN SECTION 25.5-8-103 (5), IN THE CHILDREN'S BASIC HEALTH PLAN, AS DEFINED IN SECTION 25.5-8-103 (2); AND

(IV) COLORADO RESIDENTS ENROLLED IN PRIVATE HEALTH INSURANCE PLANS OTHER THAN PLANS INCLUDED IN SUBSECTION (2)(d)(III) OF THIS SECTION;

(e) THE TOTAL ANNUAL PAYMENTS, INCLUDING REIMBURSEMENTS AND FEES, PAID TO COLORADO PHARMACIES FOR DISPENSING THE PRESCRIPTION DRUG, SEPARATELY IDENTIFYING:

(I) THE AMOUNT ATTRIBUTABLE TO DISPENSING FEES; AND

(II) THE AMOUNT ATTRIBUTABLE TO SERVICE OR ADMINISTRATIVE FEES; AND

(f) THE TOTAL ANNUAL PAYMENTS THE PHARMACY BENEFIT MANAGEMENT FIRM RECEIVED FROM HEALTH INSURERS AND EMPLOYERS FOR THE PRESCRIPTION DRUG.

(3) (a) EACH HEALTH INSURER THAT CONTRACTS WITH A PHARMACY BENEFIT MANAGEMENT FIRM TO MANAGE OR ADMINISTER PRESCRIPTION DRUG BENEFITS ON BEHALF OF THE HEALTH INSURER SHALL INCLUDE IN A NEW OR RENEWED CONTRACT WITH THE PHARMACY BENEFIT MANAGEMENT FIRM A REQUIREMENT THAT THE PHARMACY BENEFIT MANAGEMENT FIRM COMPLY WITH THIS SECTION. THE HEALTH INSURER SHALL PERIODICALLY AUDIT THE PHARMACY BENEFIT MANAGEMENT FIRM TO MONITOR AND ENSURE COMPLIANCE WITH THIS SECTION.

(b) FAILURE OF A HEALTH INSURER TO COMPLY WITH THIS

SUBSECTION (3) OR TO ENSURE THAT A PHARMACY BENEFIT MANAGEMENT FIRM WITH WHOM THE HEALTH INSURER CONTRACTS IS COMPLYING WITH THIS SECTION IS AN UNFAIR METHOD OF COMPETITION AND AN UNFAIR OR DECEPTIVE ACT OR PRACTICE IN THE BUSINESS OF INSURANCE PURSUANT TO SECTION 10-3-1104 (1)(ss).

10-16-1108. Nonprofit organizations - required reports. (1) THIS SECTION APPLIES TO A NONPROFIT ORGANIZATION THAT:

(a) HAS AN ANNUAL BUDGET OF MORE THAN FIFTY THOUSAND DOLLARS;

(b) ADVOCATES ON BEHALF OF PATIENTS ON ISSUES REGARDING PHARMACEUTICAL TREATMENT; AND

(c) HAS RECEIVED A PAYMENT, DONATION, SUBSIDY, OR THING OF VALUE DURING THE IMMEDIATELY PRECEDING CALENDAR YEAR FROM A MANUFACTURER, PHARMACY BENEFIT MANAGEMENT FIRM, OR HEALTH INSURER THAT IS SUBJECT TO THE REPORTING REQUIREMENTS OF THIS PART 11.

(2) BY APRIL 1, 2020, AND BY EACH APRIL 1 THEREAFTER, A NONPROFIT ORGANIZATION DESCRIBED IN SUBSECTION (1) OF THIS SECTION SHALL COMPILE AND SUBMIT TO THE COMMISSIONER A REPORT THAT INCLUDES:

(a) THE AMOUNT OF EACH PAYMENT, DONATION, SUBSIDY, OR THING OF VALUE RECEIVED DIRECTLY OR INDIRECTLY FROM EACH MANUFACTURER, PHARMACY BENEFIT MANAGEMENT FIRM, AND HEALTH INSURER; AND

(b) THE PERCENTAGE OF THE NONPROFIT ORGANIZATION'S TOTAL GROSS INCOME ATTRIBUTABLE TO PAYMENTS, DONATIONS, SUBSIDIES, OR OTHER THINGS OF VALUE RECEIVED FROM EACH MANUFACTURER,

PHARMACY BENEFIT MANAGEMENT FIRM, AND HEALTH INSURER IN THE PREVIOUS CALENDAR YEAR.

(3) THE NONPROFIT ORGANIZATION SHALL INCLUDE IN THE REPORT REQUIRED BY SUBSECTION (2) OF THIS SECTION THE INFORMATION SPECIFIED IN SUBSECTIONS (2)(a) AND (2)(b) OF THIS SECTION FOR ANY PAYMENT, DONATION, SUBSIDY, OR THING OF VALUE RECEIVED BY THE EXECUTIVE DIRECTOR OR CHIEF OPERATING OFFICER OF THE ORGANIZATION OR BY THE BOARD OF DIRECTORS OR ANY MEMBER OF THE BOARD OF DIRECTORS OF THE ORGANIZATION.

10-16-1109. Commissioner to publish information - reporting requirements. (1) (a) EXCEPT AS PROVIDED IN SUBSECTION (1)(b) OF THIS SECTION, THE COMMISSIONER SHALL POST ON THE DIVISION'S WEBSITE:

(I) THE INFORMATION REPORTED BY HEALTH INSURERS PURSUANT TO SECTION 10-16-1104;

(II) THE FOLLOWING INFORMATION REPORTED BY MANUFACTURERS PURSUANT TO SECTION 10-16-1106:

(A) A LIST OF THE PRESCRIPTION DRUGS REPORTED PURSUANT TO SECTION 10-16-1106 AND THE MANUFACTURERS OF THOSE PRESCRIPTION DRUGS;

(B) INFORMATION REPORTED TO THE COMMISSIONER PURSUANT TO SECTION 10-16-1106 (1) AND (2); AND

(C) WRITTEN REQUESTS BY THE COMMISSIONER FOR SUPPORTING DOCUMENTATION OR ADDITIONAL INFORMATION PURSUANT TO SECTION 10-16-1106 (3);

(III) THE INFORMATION REPORTED BY PHARMACY BENEFIT MANAGEMENT FIRMS PURSUANT TO SECTION 10-16-1107; AND

(IV) THE INFORMATION REPORTED BY NONPROFIT ORGANIZATIONS PURSUANT TO SECTION 10-16-1108.

(b) IF A HEALTH INSURER, MANUFACTURER, PHARMACY BENEFIT MANAGEMENT FIRM, OR NONPROFIT ORGANIZATION CLAIMS THAT INFORMATION CONTAINED IN A REPORT SUBMITTED TO THE COMMISSIONER IS PROPRIETARY, THE COMMISSIONER SHALL REDACT SPECIFIC ITEMS OF PROPRIETARY INFORMATION FROM THE INFORMATION POSTED ON THE DIVISION'S WEBSITE AND SHALL NOT DISCLOSE THE INFORMATION TO THE PUBLIC OR ANY PERSON OUTSIDE THE DIVISION, OTHER THAN A DISINTERESTED PARTY WITH WHOM THE COMMISSIONER CONTRACTS TO PERFORM THE ANALYSIS REQUIRED PURSUANT TO SUBSECTION (2) OF THIS SECTION, EXCEPT AS OTHERWISE REQUIRED PURSUANT TO PART 2 OF ARTICLE 72 OF TITLE 24.

(2) (a) (I) 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 DATA REPORTED BY PHARMACY BENEFIT MANAGEMENT FIRMS PURSUANT TO SECTION 10-16-1107, THE DATA REPORTED BY NONPROFIT ORGANIZATIONS PURSUANT TO SECTION 10-16-1108, 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.

(II) THE COMMISSIONER SHALL INCLUDE IN THE REPORT REQUIRED BY THIS SUBSECTION (2)(a), BASED ON INFORMATION REPORTED BY HEALTH INSURERS PURSUANT TO SECTION 10-16-1104 (2)(d) AND THE HEALTH INSURERS' CERTIFICATIONS SUBMITTED PURSUANT TO SECTION 10-16-1104 (3), A DESCRIPTION OF THE REBATE PRACTICES OF HEALTH INSURERS, INCLUDING:

(A) AN EXPLANATION OF THE MANNER IN WHICH HEALTH INSURERS ACCOUNTED FOR REBATES, DISCOUNTS, OR OTHER SOURCES OF REVENUE THAT REDUCE THE COST TO ACQUIRE A PRESCRIPTION DRUG IN CALCULATING PREMIUMS FOR HEALTH BENEFIT PLANS ISSUED OR RENEWED DURING THE YEAR;

(B) A STATEMENT DISCLOSING WHETHER, AND DESCRIBING THE MANNER IN WHICH, HEALTH INSURERS MADE REBATES, DISCOUNTS, OR OTHER SOURCES OF REVENUE THAT REDUCE THE COST TO ACQUIRE A PRESCRIPTION DRUG AVAILABLE TO COVERED PERSONS AT THE POINT OF PURCHASE DURING THE YEAR;

(C) ANY OTHER MANNER IN WHICH HEALTH INSURERS APPLIED REBATES, DISCOUNTS, OR OTHER SOURCES OF REVENUE THAT REDUCE THE COST TO ACQUIRE A PRESCRIPTION DRUG DURING THE YEAR; AND

(D) OTHER INFORMATION THE COMMISSIONER DEEMS RELEVANT FOR PURPOSES OF THE REPORT REQUIRED BY THIS SUBSECTION (2).

(III) IF A HEALTH INSURER, MANUFACTURER, PHARMACY BENEFIT MANAGEMENT FIRM, OR NONPROFIT ORGANIZATION CLAIMS, PURSUANT TO SUBSECTION (1)(b) OF THIS SECTION, THAT INFORMATION CONTAINED IN A REPORT SUBMITTED TO THE COMMISSIONER IS PROPRIETARY, THE COMMISSIONER SHALL EXCLUDE THE PROPRIETARY INFORMATION FROM THE REPORT PREPARED PURSUANT TO THIS SUBSECTION (2). IF THE

COMMISSIONER CONTRACTS WITH A DISINTERESTED THIRD PARTY TO CONDUCT THE ANALYSIS, THE DISINTEREST THIRD PARTY SHALL NOT DISCLOSE TO THE PUBLIC OR ANY PERSON OUTSIDE THE DIVISION ANY INFORMATION THAT IS PROPRIETARY PURSUANT TO SUBSECTION (1)(b) OF THIS SECTION.

(b) BY DECEMBER 1, 2020, AND BY EACH DECEMBER 1 THEREAFTER, THE COMMISSIONER SHALL PUBLISH THE REPORT REQUIRED BY THIS SUBSECTION (2) ON THE DIVISION'S WEBSITE, WHICH REPORT MUST ANALYZE THE DATA SPECIFIED IN SUBSECTION (2)(a)(I) OF THIS SECTION THAT THE COMMISSIONER RECEIVED THROUGH JULY OF THE CALENDAR YEAR IN WHICH THE REPORT IS PUBLISHED.

(c) BY DECEMBER 1, 2020, AND BY EACH DECEMBER 1 THEREAFTER, THE COMMISSIONER SHALL SUBMIT THE REPORT TO THE GOVERNOR, THE SENATE COMMITTEE ON HEALTH AND HUMAN SERVICES, AND THE HOUSE OF REPRESENTATIVES COMMITTEES ON HEALTH AND INSURANCE AND PUBLIC HEALTH CARE AND HUMAN SERVICES, OR THEIR SUCCESSOR COMMITTEES. ADDITIONALLY, THE COMMISSIONER SHALL PRESENT THE REPORT TO THE LEGISLATIVE COMMITTEES DURING THE COMMITTEES' HEARINGS HELD PRIOR TO THE 2021 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 COMMISSIONER, IN CONSULTATION WITH THE DEPARTMENT OF HEALTH CARE POLICY AND FINANCING, THE DEPARTMENT OF CORRECTIONS, THE DEPARTMENT OF HUMAN SERVICES, AND ANY OTHER STATE DEPARTMENT THAT PURCHASES OR REIMBURSES THE COST OF

PRESCRIPTION DRUGS ON BEHALF OF THE STATE OR AN ENTITY ACTING ON BEHALF OF A STATE DEPARTMENT, SHALL INCLUDE IN THE REPORT REQUIRED BY THIS SUBSECTION (2) ANY RECOMMENDATIONS FOR LEGISLATIVE CHANGES TO CONTAIN THE COSTS OF PRESCRIPTION DRUGS AND REDUCE THE EFFECTS OF PRICE INCREASES ON:

(I) CONSUMERS;

(II) THE DEPARTMENT OF HEALTH CARE POLICY AND FINANCING, THE DEPARTMENT OF CORRECTIONS, THE DEPARTMENT OF HUMAN SERVICES, AND ANY OTHER STATE DEPARTMENT THAT PURCHASES OR REIMBURSES THE COST OF PRESCRIPTION DRUGS ON BEHALF OF THE STATE OR AN ENTITY ACTING ON BEHALF OF A STATE DEPARTMENT;

(III) HEALTH INSURANCE PREMIUMS IN THE COMMERCIAL MARKET; AND

(IV) HEALTH INSURANCE PREMIUMS FOR STATE GROUP BENEFIT PLANS.

(e) THE REPORTING REQUIREMENT IN THIS SUBSECTION (2) IS NOT SUBJECT TO EXPIRATION UNDER SECTION 24-1-136 (11)(a)(I).

10-16-1110. Rules - coordination with other state entities. (1) THE COMMISSIONER MAY ADOPT RULES AS NECESSARY TO IMPLEMENT THIS PART 11, INCLUDING RULES:

(a) SPECIFYING THE FORM AND MANNER IN WHICH HEALTH INSURERS, MANUFACTURERS, PHARMACY BENEFIT MANAGEMENT FIRMS, AND NONPROFIT ORGANIZATIONS ARE TO REPORT INFORMATION REQUIRED BY SECTIONS 10-16-1104, 10-16-1106, 10-16-1107, AND 10-16-1108; AND

(b) ESTABLISHING FILING FEES TO BE PAID BY HEALTH INSURERS, MANUFACTURERS, AND PHARMACY BENEFIT MANAGEMENT FIRMS, WHICH FEES MUST BE USED SOLELY TO PAY THE COSTS OF THE DIVISION IN

IMPLEMENTING AND ADMINISTERING THIS PART 11.

(2) THE COMMISSIONER MAY CONSULT WITH THE STATE BOARD OF PHARMACY, THE SECRETARY OF STATE, THE DEPARTMENT OF HEALTH CARE POLICY AND FINANCING, THE DEPARTMENT OF CORRECTIONS, THE DEPARTMENT OF HUMAN SERVICES, THE DEPARTMENT OF PERSONNEL, AND ANY OTHER STATE PURCHASER OF PRESCRIPTION DRUGS OR AN ENTITY ACTING ON BEHALF OF A STATE PRESCRIPTION DRUG PURCHASER, IN ADOPTING NECESSARY RULES PURSUANT TO SUBSECTION (1) OF THIS SECTION, IN POSTING INFORMATION ON THE DIVISION'S WEBSITE PURSUANT TO SECTION 10-16-1109 (1), AND IN TAKING ANY OTHER ACTION FOR THE PURPOSE OF IMPLEMENTING THIS PART 11.

10-16-1111. 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;

(b) FAILS TO REPORT TO THE COMMISSIONER THE INFORMATION REQUIRED BY SECTION 10-16-1106; OR

(c) FAILS TO PAY FILING FEES AS REQUIRED PURSUANT TO SECTION 10-16-1110 (1)(b).

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

SECTION 2. In Colorado Revised Statutes, **add** 10-16-122.3 as follows:

10-16-122.3. Pharmacy benefit management firm payments on clean claims - retroactive reduction prohibited - exception - enforcement - definitions. (1) (a) A CONTRACT BETWEEN A PHARMACY BENEFIT MANAGEMENT FIRM AND A PHARMACY WITH RESPECT TO PRESCRIPTION DRUG BENEFITS ADMINISTERED OR MANAGED BY THE PHARMACY BENEFIT MANAGEMENT FIRM MUST PROVIDE THAT AFTER THE DATE THE PHARMACY BENEFIT MANAGEMENT FIRM RECEIVES A CLEAN CLAIM SUBMITTED BY A PHARMACY, THE PHARMACY BENEFIT MANAGEMENT FIRM SHALL NOT RETROACTIVELY REDUCE PAYMENT ON THE CLAIM, EITHER DIRECTLY OR INDIRECTLY, THROUGH A NET REIMBURSEMENT AMOUNT OR BY ANY OTHER MECHANISM, EXCEPT WHEN THE PHARMACY BENEFIT MANAGEMENT FIRM DETERMINES, DURING THE COURSE OF AN AUDIT CONDUCTED IN ACCORDANCE WITH SECTION 10-16-122.5, THAT THE CLAIM IS NOT A CLEAN CLAIM.

(b) NOTHING IN THIS SUBSECTION (1) PROHIBITS A PHARMACY BENEFIT MANAGEMENT FIRM FROM RETROACTIVELY INCREASING A PAYMENT TO A PHARMACY PURSUANT TO A WRITTEN AGREEMENT BETWEEN THE PHARMACY BENEFIT MANAGEMENT FIRM AND THE PHARMACY.

(2) (a) EACH HEALTH INSURER THAT CONTRACTS WITH A PHARMACY BENEFIT MANAGEMENT FIRM TO MANAGE OR ADMINISTER PRESCRIPTION DRUG BENEFITS ON THE HEALTH INSURER'S BEHALF SHALL INCLUDE IN A NEW, AMENDED, OR RENEWED CONTRACT WITH THE PHARMACY BENEFIT MANAGEMENT FIRM A REQUIREMENT THAT THE PHARMACY BENEFIT MANAGEMENT FIRM COMPLY WITH THIS SECTION. THE HEALTH INSURER SHALL PERIODICALLY AUDIT THE PHARMACY BENEFIT MANAGEMENT FIRM TO MONITOR AND ENSURE COMPLIANCE WITH THIS

SECTION.

(b) FAILURE OF A HEALTH INSURER TO COMPLY WITH THIS SUBSECTION (2) OR TO ENSURE THAT A PHARMACY BENEFIT MANAGEMENT FIRM WITH WHOM THE HEALTH INSURER CONTRACTS IS COMPLYING WITH THIS SECTION IS AN UNFAIR METHOD OF COMPETITION AND AN UNFAIR OR DECEPTIVE ACT OR PRACTICE IN THE BUSINESS OF INSURANCE PURSUANT TO SECTION 10-3-1104 (1)(ss).

(3) THIS SECTION APPLIES TO CONTRACTS ENTERED INTO, RENEWED, OR AMENDED ON OR AFTER JULY 1, 2019.

(4) AS USED IN THIS SECTION:

(a) "CLEAN CLAIM" MEANS A CLAIM THAT HAS NO DEFECT OR IMPROPRIETY, INCLUDING ANY LACK OF REQUIRED SUBSTANTIATING DOCUMENTATION, OR PARTICULAR CIRCUMSTANCE REQUIRING SPECIAL TREATMENT THAT PREVENTS TIMELY PAYMENT FROM BEING MADE ON THE CLAIM.

(b) "HEALTH INSURER" HAS THE SAME MEANING AS SET FORTH IN SECTION 10-16-1103 (5).

(c) "PHARMACY" MEANS AN ENTITY LICENSED UNDER ARTICLE 42.5 OF TITLE 12 TO DISPENSE PRESCRIPTION DRUGS.

SECTION 3. In Colorado Revised Statutes, **add** 10-16-148 as follows:

10-16-148. Cost sharing in prescription drugs - limits - definitions - confidentiality of rebate information - rules. (1) AS USED IN THIS SECTION, UNLESS THE CONTEXT OTHERWISE REQUIRES:

(a) "COST SHARING" MEANS A DEDUCTIBLE PAYMENT, COPAYMENT, OR COINSURANCE AMOUNT IMPOSED ON A COVERED PERSON FOR A COVERED PRESCRIPTION DRUG IN ACCORDANCE WITH THE TERMS

AND CONDITIONS OF THE COVERED PERSON'S HEALTH COVERAGE PLAN.

(b) "DRUG MANUFACTURER" OR "MANUFACTURER" MEANS A MANUFACTURER OF PRESCRIPTION DRUGS THAT ARE MADE AVAILABLE IN COLORADO.

(c) "PRESCRIPTION DRUG" HAS THE MEANING SPECIFIED IN SECTION 12-42.5-102 (34).

(d) "PRICE PROTECTION REBATE" MEANS A NEGOTIATED PRICE CONCESSION THAT ACCRUES, DIRECTLY OR INDIRECTLY, TO A CARRIER OR OTHER PARTY ON BEHALF OF THE CARRIER IN THE EVENT OF AN INCREASE IN THE WHOLESALE ACQUISITION COST OF A PRESCRIPTION DRUG ABOVE A SPECIFIED THRESHOLD.

(e) "REBATE" MEANS:

(I) A NEGOTIATED PRICE CONCESSION, INCLUDING A BASE REBATE AND A PERFORMANCE-BASED REBATE BUT EXCLUDING A PRICE PROTECTION REBATE, THAT MAY ACCRUE, DIRECTLY OR INDIRECTLY, TO A CARRIER DURING THE COVERAGE YEAR FROM A MANUFACTURER, DISPENSING PHARMACY, OR OTHER PARTY TO THE TRANSACTION; OR

(II) A PRICE CONCESSION GIVEN TO A CARRIER THAT SERVES TO REDUCE THE CARRIER'S PRESCRIPTION DRUG LIABILITIES FOR THE COVERAGE YEAR.

(2) FOR EACH OF ITS HEALTH COVERAGE PLANS ISSUED OR RENEWED ON OR AFTER JANUARY 1, 2021, A CARRIER SHALL REDUCE THE LEVEL OF COST SHARING THAT IT WOULD OTHERWISE CHARGE A COVERED PERSON FOR A PRESCRIPTION DRUG BY AN AMOUNT EQUAL TO THE GREATER OF:

(a) FIFTY-ONE PERCENT OF THE AVERAGE AGGREGATE AMOUNT OF REBATES RECEIVED BY THE CARRIER FOR ALL PRESCRIPTION DRUGS,

INCLUDING PRICE PROTECTION REBATES; OR

(b) AN AMOUNT THAT ENSURES THAT THE COVERED PERSON'S COST SHARING WILL NOT EXCEED ONE HUNDRED TWENTY-FIVE PERCENT OF THE CARRIER'S COST FOR THE PRESCRIPTION DRUG.

(3) NOTHING IN THIS SECTION PREVENTS A CARRIER FROM REDUCING A COVERED PERSON'S COST SHARING BY AN AMOUNT GREATER THAN THE AMOUNT SPECIFIED IN SUBSECTION (2) OF THIS SECTION.

(4) THE COMMISSIONER SHALL ADOPT RULES AS NECESSARY TO IMPLEMENT THIS SECTION.

(5) THE COMMISSIONER MAY USE ANY OF THE COMMISSIONER'S ENFORCEMENT POWERS TO OBTAIN A CARRIER'S COMPLIANCE WITH THIS SECTION.

SECTION 4. In Colorado Revised Statutes, 10-3-1104, **add** (1)(ss) as follows:

10-3-1104. Unfair methods of competition - unfair or deceptive acts or practices. (1) The following are defined as unfair methods of competition and unfair or deceptive acts or practices in the business of insurance:

(ss) FAILING TO COMPLY WITH SECTION 10-16-122.3 (2) OR 10-16-1107 (3) AND TO ENSURE A PHARMACY BENEFIT MANAGEMENT FIRM WITH WHOM A HEALTH INSURER, AS DEFINED IN SECTION 10-16-1103 (5), CONTRACTS IS COMPLYING WITH SECTIONS 10-16-122.3 (1) AND 10-16-1107.

SECTION 5. 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:

(t) (I) 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;

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

(III) HAS FAILED TO PAY FILING FEES AS REQUIRED PURSUANT TO SECTION 10-16-1110 (1)(b).

SECTION 6. 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 PURCHASERS OR REPORT INFORMATION TO THE COMMISSIONER OF INSURANCE AS SPECIFIED IN SECTION 12-42.5-123 (1)(t) UP TO TEN THOUSAND DOLLARS PER DAY FOR EACH DAY THE REGISTRANT FAILS TO COMPLY WITH THE NOTICE OR REPORTING REQUIREMENTS.

SECTION 7. In Colorado Revised Statutes, 12-280-126, **add as relocated by House Bill 19-1172** (1)(t) as follows:

12-280-126. Unprofessional conduct - grounds for discipline. (1) The board may take disciplinary or other action as authorized in section 12-20-404, after a hearing held in accordance with the provisions of sections 12-20-403 and 12-280-127, upon proof that the licensee or registrant:

(t) (I) 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;

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

(III) HAS FAILED TO PAY FILING FEES AS REQUIRED PURSUANT TO SECTION 10-16-1110 (1)(b).

SECTION 8. In Colorado Revised Statutes, 12-280-127, **amend as relocated by House Bill 19-1172** (5)(a); and **add as relocated by House Bill 19-1172** (5)(d) as follows:

12-280-127. Disciplinary actions. (5) (a) Except as provided in subsections (5)(b), ~~and~~ (5)(c), OR (5)(d) 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 280 or any rules promulgated pursuant to this article 280 not less than five hundred dollars and not more than five thousand dollars for each violation.

(d) IN ADDITION TO ANY OTHER PENALTY THE BOARD MAY IMPOSE PURSUANT TO THIS SECTION, THE BOARD MAY FINE A REGISTRANT FOR FAILING TO NOTIFY PURCHASERS OR REPORT INFORMATION TO THE COMMISSIONER OF INSURANCE AS SPECIFIED IN SECTION 12-280-126 (1)(t) UP TO TEN THOUSAND DOLLARS PER DAY FOR EACH DAY THE REGISTRANT FAILS TO COMPLY WITH THE NOTICE OR REPORTING REQUIREMENTS.

SECTION 9. Effective date. This act takes effect July 1, 2019; except that sections 7 and 8 of this act take effect only if House Bill 19-1172 becomes law, in which case sections 7 and 8 take effect October 1, 2019.

SECTION 10. 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.