

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

PREAMENDED

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

LLS NO. 19-0095.02 Christy Chase x2008

HOUSE BILL 19-1296

HOUSE SPONSORSHIP

Jackson and Jaquez Lewis, Roberts

SENATE SPONSORSHIP

Ginal and Donovan,

House Committees

Health & Insurance
Finance
Appropriations

Senate Committees

A BILL FOR AN ACT

101 **CONCERNING MEASURES TO REDUCE PRESCRIPTION DRUG COSTS, AND,**
102 **IN CONNECTION THEREWITH, CREATING THE "COLORADO**
103 **PRESCRIPTION DRUG COST REDUCTION ACT OF 2019" TO**
104 **REQUIRE HEALTH INSURERS, PRESCRIPTION DRUG**
105 **MANUFACTURERS, PHARMACY BENEFIT MANAGEMENT FIRMS,**
106 **AND NONPROFIT ORGANIZATIONS TO REPORT SPECIFIED**
107 **INFORMATION ABOUT THE COSTS OF PRESCRIPTION DRUGS TO**
108 **THE COMMISSIONER OF INSURANCE; TO DIRECT THE**
109 **COMMISSIONER TO ANALYZE THE INFORMATION AND SUBMIT A**
110 **REPORT REGARDING THE EFFECTS OF PRESCRIPTION DRUG**
111 **COSTS ON HEALTH INSURANCE PREMIUMS; TO PRECLUDE**
112 **PHARMACY BENEFIT MANAGEMENT FIRMS FROM**
113 **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.

101 **REQUIRE CARRIERS TO REDUCE CONSUMER COST SHARING FOR**
102 **PRESCRIPTION DRUGS TO REFLECT REBATES THE CARRIER OR**
103 **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.

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

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

1 16 of title 10 as follows:

2

PART 11

3

PRESCRIPTION DRUG COST REDUCTION

4

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

6

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

16

(2) THE GENERAL ASSEMBLY FURTHER DECLARES THAT THIS PART
17 11 IS INTENDED TO CREATE TRANSPARENCY IN PRESCRIPTION DRUG
18 PRICING AND DOES NOT:

19

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

22

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

26

10-16-1103. Definitions. AS USED IN THIS PART 11, UNLESS THE
27 CONTEXT OTHERWISE REQUIRES:

1 (1) "COURSE OF THERAPY" MEANS EITHER:

2 (a) THE RECOMMENDED DAILY DOSAGE UNITS OF A PRESCRIPTION
3 DRUG FOR A THIRTY-DAY TREATMENT PURSUANT TO THE PRESCRIBING
4 LABEL FOR THE PRESCRIPTION DRUG AS APPROVED BY THE FDA; OR

5 (b) THE RECOMMENDED DAILY DOSAGE UNITS OF A PRESCRIPTION
6 DRUG FOR A NORMAL COURSE OF TREATMENT THAT IS LESS THAN THIRTY
7 DAYS PURSUANT TO THE PRESCRIBING LABEL FOR THE PRESCRIPTION DRUG
8 AS APPROVED BY THE FDA.

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

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

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

23 (5) "HEALTH INSURER" MEANS:

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

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

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

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

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

8 (9) "MEDICARE PART D PROGRAM" MEANS THE "MEDICARE
9 PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF
10 2003", PUB.L. 108-173, CODIFIED IN PART D OF TITLE XVIII OF THE
11 "SOCIAL SECURITY ACT", 42 U.S.C. SEC. 1395w-101 ET SEQ.

12 (10) "PHARMACY" MEANS AN IN-STATE OR NONRESIDENT
13 PRESCRIPTION DRUG OUTLET, AS DEFINED IN SECTION 12-42.5-102 (35), AN
14 OTHER OUTLET, AS DEFINED IN SECTION 12-42.5-102 (25), A HOSPITAL
15 SATELLITE PHARMACY, AS DEFINED IN SECTION 12-42.5-102 (16), OR
16 OTHER SETTING, INCLUDING A PRACTITIONER'S OFFICE OR CLINIC, WHERE
17 A PRACTITIONER, AS DEFINED IN SECTION 12-42.5-102 (32), DISPENSES
18 PRESCRIPTION DRUGS TO PATIENTS AS AUTHORIZED BY SECTION
19 12-42.5-118 (6).

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

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

24 (13) "SPECIALTY DRUG" MEANS A PRESCRIPTION DRUG THAT
25 EXCEEDS THE THRESHOLD FOR A SPECIALTY DRUG UNDER THE MEDICARE
26 PART D PROGRAM.

27 **10-16-1104. Health insurer annual reports to commissioner -**

1 **pharmaceutical costs - penalty.** (1) STARTING IN 2020, A HEALTH
2 INSURER DESCRIBED IN SECTION 10-16-1103 (5)(a) SHALL REPORT TO THE
3 COMMISSIONER, CONTEMPORANEOUS WITH ITS RATE FILING PURSUANT TO
4 SECTION 10-16-107 AND IN THE FORM AND MANNER SPECIFIED BY THE
5 COMMISSIONER THAT ENSURES THE INFORMATION IS SEPARATED FROM THE
6 RATE FILING INFORMATION, THE INFORMATION SPECIFIED IN SUBSECTION
7 (2) OF THIS SECTION AND THE CERTIFICATION REQUIRED BY SUBSECTION
8 (3) OF THIS SECTION. A HEALTH INSURER DESCRIBED IN SECTION
9 10-16-1103 (5)(b) SHALL FILE THE INFORMATION SPECIFIED IN SUBSECTION
10 (2) OF THIS SECTION AND THE CERTIFICATION REQUIRED BY SUBSECTION
11 (3) OF THIS SECTION WITH THE COMMISSIONER BY A DATE SPECIFIED BY
12 THE COMMISSIONER THAT COINCIDES WITH RATE FILINGS FOR HEALTH
13 INSURERS DESCRIBED IN SECTION 10-16-1103 (5)(a).

14 (2) FOR ALL COVERED PRESCRIPTION DRUGS, INCLUDING GENERIC
15 PRESCRIPTION DRUGS, BRAND-NAME PRESCRIPTION DRUGS, AND SPECIALTY
16 DRUGS, DISPENSED AT A PHARMACY FOR OUTPATIENT USE AND PAID FOR
17 BY A HEALTH INSURER IN THIS STATE DURING THE IMMEDIATELY
18 PRECEDING CALENDAR YEAR, THE HEALTH INSURER SHALL REPORT THE
19 FOLLOWING INFORMATION IN A FORM AND MANNER PRESCRIBED BY THE
20 COMMISSIONER:

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

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

25 (c) THE TWENTY-FIVE PRESCRIPTION DRUGS PAID FOR BY THE
26 HEALTH INSURER THAT ACCOUNTED FOR THE HIGHEST INCREASE IN TOTAL
27 ANNUAL PLAN SPENDING WHEN COMPARED WITH THE TOTAL ANNUAL PLAN

1 SPENDING FOR THE SAME PRESCRIPTION DRUGS IN THE YEAR IMMEDIATELY
2 PRECEDING THE YEAR FOR WHICH THE INFORMATION IS REPORTED; AND

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

8 (3) EACH HEALTH INSURER SHALL SUBMIT TO THE COMMISSIONER,
9 IN A FORM AND MANNER PRESCRIBED BY THE COMMISSIONER AND IN
10 ACCORDANCE WITH SUBSECTION (1) OF THIS SECTION:

11 (a) A WRITTEN CERTIFICATION, INCLUDING SUPPORTING
12 DOCUMENTATION, FOR THE IMMEDIATELY PRECEDING CALENDAR YEAR
13 CERTIFYING THAT THE HEALTH INSURER ACCOUNTED FOR ALL REBATES
14 AND DISCOUNTS, OTHER THAN REBATES USED TO REDUCE COST SHARING
15 FOR PRESCRIPTION DRUGS IN ACCORDANCE WITH SECTION 10-16-148, THAT
16 REDUCED THE COST TO ACQUIRE A PRESCRIPTION DRUG IN CALCULATING
17 THE PREMIUM FOR HEALTH BENEFIT PLANS THAT THE HEALTH INSURER
18 ISSUED OR RENEWED DURING THAT CALENDAR YEAR; AND

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

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

7 **10-16-1105. Drug manufacturers - notice to purchasers and**
8 **commissioner - drug price increases - new drugs in the market.**

9 (1) THIS SECTION APPLIES TO A MANUFACTURER OF A PRESCRIPTION DRUG
10 THAT IS PURCHASED OR REIMBURSED BY ANY OF THE FOLLOWING:

11 (a) THE DEPARTMENT OF HEALTH CARE POLICY AND FINANCING,
12 THE DEPARTMENT OF CORRECTIONS, THE DEPARTMENT OF HUMAN
13 SERVICES, AND ANY OTHER STATE DEPARTMENT THAT PURCHASES
14 PRESCRIPTION DRUGS ON BEHALF OF THE STATE OR AN ENTITY ACTING ON
15 BEHALF OF A STATE DEPARTMENT, INCLUDING A PHARMACY BENEFIT
16 MANAGEMENT FIRM;

17 (b) A HEALTH INSURER; OR

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

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

26 (I) THE INCREASE IN THE PRICE IS TEN PERCENT OR MORE OVER THE
27 PREVIOUS TWELVE-MONTH PERIOD OR SIXTEEN PERCENT OR MORE OVER

1 THE PREVIOUS TWENTY-FOUR-MONTH PERIOD; OR

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

7 (b) THE MANUFACTURER SHALL PROVIDE THE NOTICE REQUIRED BY
8 THIS SUBSECTION (2) IN WRITING TO THE COMMISSIONER AND EACH
9 PURCHASER AT LEAST THIRTY DAYS BEFORE THE PLANNED EFFECTIVE
10 DATE OF THE INCREASE IN THE PRICE.

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

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

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

19 (3) ON OR AFTER JANUARY 1, 2020, A MANUFACTURER THAT
20 INTRODUCES A NEW SPECIALTY DRUG TO THE COMMERCIAL MARKET SHALL
21 NOTIFY THE COMMISSIONER, IN A FORM AND MANNER SPECIFIED BY THE
22 COMMISSIONER, AND EACH PURCHASER DESCRIBED IN SUBSECTION (1) OF
23 THIS SECTION IN WRITING WITHIN THREE DAYS AFTER THE RELEASE OF THE
24 SPECIALTY DRUG IN THE COMMERCIAL MARKET. A MANUFACTURER MAY
25 MAKE THIS NOTIFICATION PENDING FDA APPROVAL IF COMMERCIAL
26 AVAILABILITY OF THE SPECIALTY DRUG IS EXPECTED WITHIN THREE DAYS
27 AFTER FDA APPROVAL.

1 (4) THE COMMISSIONER SHALL MAKE AVAILABLE TO
2 MANUFACTURERS A LIST OF PURCHASERS DESCRIBED IN SUBSECTION (1) OF
3 THIS SECTION TO WHOM MANUFACTURERS ARE TO SEND THE NOTICES
4 REQUIRED BY THIS SECTION.

5 **10-16-1106. Drug manufacturer reports to commissioner -**
6 **drug price increases - new specialty drugs - rules.** (1) (a) WITHIN
7 FIFTEEN DAYS AFTER THE END OF EACH CALENDAR QUARTER THAT STARTS
8 ON OR AFTER JANUARY 1, 2020, A MANUFACTURER SHALL REPORT TO THE
9 COMMISSIONER, IN A FORM AND MANNER PRESCRIBED BY THE
10 COMMISSIONER, THE FOLLOWING INFORMATION FOR EACH PRESCRIPTION
11 DRUG FOR WHICH THE MANUFACTURER WAS REQUIRED TO NOTIFY
12 PURCHASERS OF AN INCREASE IN THE PRICE PURSUANT TO SECTION
13 10-16-1105 (2) IN THE PRIOR QUARTER:

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

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

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

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

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

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

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

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

17 (VI) THE PATENT EXPIRATION DATE OF THE PRESCRIPTION DRUG,
18 IF IT IS UNDER PATENT;

19 (VII) WHETHER THE PRESCRIPTION DRUG IS AN INNOVATOR
20 MULTIPLE SOURCE DRUG, A NONINNOVATOR MULTIPLE SOURCE DRUG, OR
21 A SINGLE SOURCE DRUG, AS DEFINED IN 42 U.S.C. SEC. 1396r-8 (k)(7), OR
22 HAS A LINE EXTENSION;

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

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

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

3 (XI) THE DIRECT COSTS INCURRED BY THE MANUFACTURER:

4 (A) TO RESEARCH AND DEVELOP THE PRESCRIPTION DRUG;

5 (B) TO MANUFACTURE THE PRESCRIPTION DRUG;

6 (C) TO MARKET THE PRESCRIPTION DRUG;

7 (D) TO DISTRIBUTE THE PRESCRIPTION DRUG; AND

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

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

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

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

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

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

24 (c) A MANUFACTURER SHALL INCLUDE WITH THE INFORMATION
25 REPORTED PURSUANT TO SUBSECTION (1)(a) OF THIS SECTION THE
26 FOLLOWING INFORMATION ABOUT EACH PATIENT ASSISTANCE PROGRAM
27 OFFERED BY THE MANUFACTURER TO CONSUMERS RESIDING IN THIS STATE

1 FOR THE PRESCRIPTION DRUGS REPORTED ON AS REQUIRED BY SUBSECTION
2 (1)(a) OF THIS SECTION:

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

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

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

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

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

15 (2) WITHIN FIFTEEN DAYS AFTER THE END OF EACH CALENDAR
16 QUARTER THAT STARTS ON OR AFTER JANUARY 1, 2020, A MANUFACTURER
17 SHALL REPORT TO THE COMMISSIONER, IN A FORM AND MANNER
18 PRESCRIBED BY THE COMMISSIONER, THE FOLLOWING INFORMATION FOR
19 EACH NEW SPECIALTY DRUG INTRODUCED TO THE MARKET IN THE PRIOR
20 QUARTER:

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

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

26 (c) WHETHER THE SPECIALTY DRUG WAS GRANTED
27 BREAKTHROUGH THERAPY DESIGNATION OR PRIORITY REVIEW BY THE

1 FDA PRIOR TO FINAL APPROVAL; AND

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

4 (3) AFTER RECEIVING A REPORT OF INFORMATION DESCRIBED IN
5 SUBSECTION (1) OR (2) OF THIS SECTION, THE COMMISSIONER MAY
6 REQUEST, IN WRITING, THAT A MANUFACTURER PROVIDE SUPPORTING
7 DOCUMENTATION OR ADDITIONAL INFORMATION CONCERNING THE
8 REPORTED INFORMATION. THE COMMISSIONER SHALL PRESCRIBE BY RULE
9 THE TIME PERIODS FOR REQUESTING ADDITIONAL DOCUMENTATION OR
10 INFORMATION AND FOR MANUFACTURERS TO RESPOND TO THE REQUEST,
11 INCLUDING EXTENSIONS FOR MANUFACTURERS TO RESPOND.

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

15 **10-16-1107. Pharmacy benefit management firms - required**

16 **reports.** (1) STARTING IN 2020, A HEALTH INSURER SHALL REPORT TO
17 THE COMMISSIONER, CONTEMPORANEOUS WITH ITS RATE FILING PURSUANT
18 TO SECTION 10-16-107 AND IN THE FORM AND MANNER SPECIFIED BY THE
19 COMMISSIONER THAT ENSURES THE INFORMATION IS SEPARATED FROM THE
20 RATE FILING INFORMATION, THE INFORMATION SPECIFIED IN SUBSECTION
21 (2) OF THIS SECTION. IF A HEALTH INSURER CONTRACTS WITH A PHARMACY
22 BENEFIT MANAGEMENT FIRM TO ADMINISTER OR MANAGE PRESCRIPTION
23 DRUG BENEFITS ON BEHALF OF THE HEALTH INSURER, THE PHARMACY
24 BENEFIT MANAGEMENT FIRM SHALL REPORT THE INFORMATION SPECIFIED
25 IN SUBSECTION (2) OF THIS SECTION BY A DATE SPECIFIED BY THE
26 COMMISSIONER THAT COINCIDES WITH HEALTH INSURER RATE FILINGS
27 PURSUANT TO SECTION 10-16-107.

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(2) FOR ALL PRESCRIPTION DRUGS PAID FOR IN THE PRIOR CALENDAR YEAR, THE HEALTH INSURER OR PHARMACY BENEFIT MANAGEMENT FIRM SHALL REPORT:

(a) THE AGGREGATE AMOUNT OF ALL REBATES AND DISCOUNTS THAT REDUCE THE COST TO ACQUIRE PRESCRIPTION DRUGS THAT THE HEALTH INSURER OR PHARMACY BENEFIT MANAGEMENT FIRM RECEIVED FROM MANUFACTURERS OF PRESCRIPTION DRUGS DURING THE IMMEDIATELY PRECEDING CALENDAR YEAR;

(b) THE AGGREGATE AMOUNT OF ALL REBATES AND DISCOUNTS THAT REDUCE THE COST TO ACQUIRE ALL PRESCRIPTION DRUGS DESCRIBED IN SUBSECTION (2)(a) OF THIS SECTION RETAINED BY THE HEALTH INSURER OR PHARMACY BENEFIT MANAGEMENT FIRM;

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

(d) THE AGGREGATE ANNUAL PAYMENTS, INCLUDING REIMBURSEMENTS AND FEES, PAID TO COLORADO PHARMACIES FOR DISPENSING PRESCRIPTION DRUGS, SEPARATELY IDENTIFYING:

(I) THE AGGREGATE AMOUNT ATTRIBUTABLE TO DISPENSING FEES; AND

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

(e) AN EXPLANATION OF ALL OTHER SERVICES OFFERED BY THE HEALTH INSURER OR PHARMACY BENEFIT MANAGEMENT FIRM, EXCLUDING

1 PROPRIETARY AND CLIENT-SPECIFIC INFORMATION.

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

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

16 **10-16-1108. Nonprofit organizations - required reports.**

17 (1) THIS SECTION APPLIES TO A NONPROFIT ORGANIZATION THAT:

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

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

22 (c) HAS RECEIVED A PAYMENT, DONATION, SUBSIDY, OR THING OF
23 VALUE THAT EXCEEDS ONE THOUSAND DOLLARS IN VALUE DURING THE
24 IMMEDIATELY PRECEDING CALENDAR YEAR FROM A MANUFACTURER,
25 PHARMACY BENEFIT MANAGEMENT FIRM, OR HEALTH INSURER THAT IS
26 SUBJECT TO THE REPORTING REQUIREMENTS OF THIS PART 11 OR A TRADE
27 ASSOCIATION REPRESENTING ANY OF THOSE INDUSTRIES.

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

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

9 (b) THE PERCENTAGE OF THE NONPROFIT ORGANIZATION'S TOTAL
10 GROSS INCOME ATTRIBUTABLE TO PAYMENTS, DONATIONS, SUBSIDIES, OR
11 OTHER THINGS OF VALUE RECEIVED FROM EACH MANUFACTURER,
12 PHARMACY BENEFIT MANAGEMENT FIRM, AND HEALTH INSURER IN THE
13 PREVIOUS CALENDAR YEAR.

14 (3) THE NONPROFIT ORGANIZATION SHALL INCLUDE IN THE REPORT
15 REQUIRED BY SUBSECTION (2) OF THIS SECTION THE INFORMATION
16 SPECIFIED IN SUBSECTIONS (2)(a) AND (2)(b) OF THIS SECTION FOR ANY
17 PAYMENT, DONATION, SUBSIDY, OR THING OF VALUE THAT EXCEEDS ONE
18 THOUSAND DOLLARS IN VALUE RECEIVED BY THE EXECUTIVE DIRECTOR OR
19 CHIEF OPERATING OFFICER OF THE ORGANIZATION OR BY THE BOARD OF
20 DIRECTORS OR ANY MEMBER OF THE BOARD OF DIRECTORS OF THE
21 ORGANIZATION.

22 (4) A NONPROFIT ORGANIZATION SUBJECT TO THE REPORTING
23 REQUIREMENTS OF THIS SECTION THAT FAILS TO COMPLY WITH THE
24 REQUIREMENTS IS SUBJECT TO A FINE OF UP TO ONE THOUSAND DOLLARS.

25 **10-16-1109. Commissioner to publish information - reporting**
26 **requirements.** (1) (a) EXCEPT AS PROVIDED IN SUBSECTION (1)(b) OF
27 THIS SECTION, THE COMMISSIONER SHALL POST ON THE DIVISION'S

1 WEBSITE:

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

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

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

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

11 (C) WRITTEN REQUESTS BY THE COMMISSIONER FOR SUPPORTING
12 DOCUMENTATION OR ADDITIONAL INFORMATION PURSUANT TO SECTION
13 10-16-1106 (3);

14 (III) THE COMBINED AGGREGATE INFORMATION REPORTED BY ALL
15 HEALTH INSURERS AND PHARMACY BENEFIT MANAGEMENT FIRMS
16 PURSUANT TO SECTION 10-16-1107; AND

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

19 (b) IF A HEALTH INSURER, MANUFACTURER, PHARMACY BENEFIT
20 MANAGEMENT FIRM, OR NONPROFIT ORGANIZATION CLAIMS THAT
21 INFORMATION CONTAINED IN A REPORT SUBMITTED TO THE COMMISSIONER
22 IS PROPRIETARY, THE COMMISSIONER SHALL REDACT SPECIFIC ITEMS OF
23 PROPRIETARY INFORMATION FROM THE INFORMATION POSTED ON THE
24 DIVISION'S WEBSITE AND SHALL NOT DISCLOSE THE INFORMATION TO THE
25 PUBLIC OR ANY PERSON OUTSIDE THE DIVISION, OTHER THAN A
26 DISINTERESTED PARTY WITH WHOM THE COMMISSIONER CONTRACTS TO
27 PERFORM THE ANALYSIS REQUIRED PURSUANT TO SUBSECTION (2) OF THIS

1 SECTION, EXCEPT AS OTHERWISE REQUIRED PURSUANT TO PART 2 OF
2 ARTICLE 72 OF TITLE 24.

3 (2) (a) (I) THE COMMISSIONER, OR A DISINTERESTED THIRD PARTY
4 WITH WHOM THE COMMISSIONER CONTRACTS, SHALL ANALYZE THE DATA
5 REPORTED BY HEALTH INSURERS PURSUANT TO SECTION 10-16-1104, THE
6 DATA REPORTED BY MANUFACTURERS PURSUANT TO SECTION 10-16-1106,
7 THE DATA REPORTED BY PHARMACY BENEFIT MANAGEMENT FIRMS
8 PURSUANT TO SECTION 10-16-1107, THE DATA REPORTED BY NONPROFIT
9 ORGANIZATIONS PURSUANT TO SECTION 10-16-1108, THE HEALTH INSURER
10 RATE INFORMATION FILED PURSUANT TO SECTION 10-16-107, AND ANY
11 OTHER RELEVANT DATA THE COMMISSIONER POSSESSES IN ORDER TO
12 DETERMINE THE OVERALL EFFECT OF PRESCRIPTION DRUG COSTS ON
13 PREMIUMS. THE COMMISSIONER SHALL ISSUE A REPORT, AS PART OF THE
14 REPORT PREPARED PURSUANT TO SECTION 10-16-111 (4)(c), ANALYZING
15 THE PRESCRIPTION DRUG COST DATA AND THE EFFECT OF PRESCRIPTION
16 DRUG COSTS ON PREMIUMS.

17 (II) THE COMMISSIONER SHALL INCLUDE IN THE REPORT REQUIRED
18 BY THIS SUBSECTION (2)(a), BASED ON INFORMATION REPORTED BY
19 HEALTH INSURERS PURSUANT TO SECTION 10-16-1104 (2)(d) AND THE
20 HEALTH INSURERS' CERTIFICATIONS SUBMITTED PURSUANT TO SECTION
21 10-16-1104 (3), A DESCRIPTION OF THE REBATE PRACTICES OF HEALTH
22 INSURERS, INCLUDING:

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

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

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

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

11 (III) IF A HEALTH INSURER, MANUFACTURER, PHARMACY BENEFIT
12 MANAGEMENT FIRM, OR NONPROFIT ORGANIZATION CLAIMS, PURSUANT TO
13 SUBSECTION (1)(b) OF THIS SECTION, THAT INFORMATION CONTAINED IN
14 A REPORT SUBMITTED TO THE COMMISSIONER IS PROPRIETARY, THE
15 COMMISSIONER SHALL EXCLUDE THE PROPRIETARY INFORMATION FROM
16 THE REPORT PREPARED PURSUANT TO THIS SUBSECTION (2). IF THE
17 COMMISSIONER CONTRACTS WITH A DISINTERESTED THIRD PARTY TO
18 CONDUCT THE ANALYSIS, THE DISINTEREST THIRD PARTY SHALL NOT
19 DISCLOSE TO THE PUBLIC OR ANY PERSON OUTSIDE THE DIVISION ANY
20 INFORMATION THAT IS PROPRIETARY PURSUANT TO SUBSECTION (1)(b) OF
21 THIS SECTION.

22 (b) AT LEAST THIRTY DAYS BEFORE THE COMMISSIONER PUBLISHES
23 AND SUBMITS THE REPORT PURSUANT TO SUBSECTIONS (2)(c) AND (2)(d)
24 OF THIS SECTION, THE COMMISSIONER SHALL PROVIDE HEALTH INSURERS,
25 MANUFACTURERS, AND PHARMACY BENEFIT MANAGEMENT FIRMS THAT
26 REPORTED DATA TO THE COMMISSIONER PURSUANT TO THIS PART 11 AN
27 EXPLANATION AND DESCRIPTION OF THE INFORMATION THAT WILL BE

1 RELEASED IN THE REPORT AND AN OPPORTUNITY TO OBJECT TO THE
2 RELEASE OF SPECIFIED INFORMATION ON THE GROUNDS THAT THE
3 INFORMATION IS PROPRIETARY. A HEALTH INSURER, MANUFACTURER, OR
4 PHARMACY BENEFIT MANAGEMENT FIRM OBJECTING TO THE RELEASE OF
5 INFORMATION MUST SUBMIT ITS OBJECTION AND INFORMATION
6 DEMONSTRATING THAT THE SPECIFIED INFORMATION IS PROPRIETARY NO
7 LATER THAN FIFTEEN DAYS AFTER RECEIPT OF THE EXPLANATION AND
8 DESCRIPTION FROM THE COMMISSIONER. THE COMMISSIONER SHALL MAKE
9 A DETERMINATION AND NOTIFY THE OBJECTING PARTY OF THE
10 DETERMINATION WITHIN FIFTEEN DAYS AFTER RECEIPT OF THE OBJECTION
11 FROM THE HEALTH INSURER, MANUFACTURER, OR PHARMACY BENEFIT
12 MANAGEMENT FIRM AND, IF THE COMMISSIONER FINDS IN FAVOR OF THE
13 OBJECTING PARTY, SHALL REMOVE THE PROPRIETARY INFORMATION FROM
14 THE REPORT BEFORE PUBLISHING AND SUBMITTING IT PURSUANT TO
15 SUBSECTIONS (2)(c) AND (2)(d) OF THIS SECTION. THE DETERMINATION OF
16 THE COMMISSIONER IS FINAL AND IS NOT SUBJECT TO REVIEW.

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

23 (d) BY DECEMBER 1, 2020, AND BY EACH DECEMBER 1
24 THEREAFTER, THE COMMISSIONER SHALL SUBMIT THE REPORT TO THE
25 GOVERNOR, THE SENATE COMMITTEE ON HEALTH AND HUMAN SERVICES,
26 AND THE HOUSE OF REPRESENTATIVES COMMITTEES ON HEALTH AND
27 INSURANCE AND PUBLIC HEALTH CARE AND HUMAN SERVICES, OR THEIR

1 SUCCESSOR COMMITTEES. ADDITIONALLY, THE COMMISSIONER SHALL
2 PRESENT THE REPORT TO THE LEGISLATIVE COMMITTEES DURING THE
3 COMMITTEES' HEARINGS HELD PRIOR TO THE 2021 LEGISLATIVE SESSION
4 AND PRIOR TO EACH LEGISLATIVE SESSION THEREAFTER UNDER THE
5 "STATE MEASUREMENT FOR ACCOUNTABLE, RESPONSIVE, AND
6 TRANSPARENT (SMART) GOVERNMENT ACT", PART 2 OF ARTICLE 7 OF
7 TITLE 2.

8 (e) THE COMMISSIONER, IN CONSULTATION WITH THE DEPARTMENT
9 OF HEALTH CARE POLICY AND FINANCING, THE DEPARTMENT OF
10 CORRECTIONS, THE DEPARTMENT OF HUMAN SERVICES, AND ANY OTHER
11 STATE DEPARTMENT THAT PURCHASES OR REIMBURSES THE COST OF
12 PRESCRIPTION DRUGS ON BEHALF OF THE STATE OR AN ENTITY ACTING ON
13 BEHALF OF A STATE DEPARTMENT, SHALL INCLUDE IN THE REPORT
14 REQUIRED BY THIS SUBSECTION (2) ANY RECOMMENDATIONS FOR
15 LEGISLATIVE CHANGES TO CONTAIN THE COSTS OF PRESCRIPTION DRUGS
16 AND REDUCE THE EFFECTS OF PRICE INCREASES ON:

17 (I) CONSUMERS;

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

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

24 AND

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

27 (f) THE REPORTING REQUIREMENT IN THIS SUBSECTION (2) IS NOT

1 SUBJECT TO EXPIRATION UNDER SECTION 24-1-136 (11)(a)(I).

2 **10-16-1110. Rules - coordination with other state entities.**

3 (1) THE COMMISSIONER MAY ADOPT RULES AS NECESSARY TO IMPLEMENT
4 THIS PART 11, INCLUDING RULES:

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

9 (b) ESTABLISHING FILING FEES TO BE PAID BY HEALTH INSURERS,
10 MANUFACTURERS, AND PHARMACY BENEFIT MANAGEMENT FIRMS, WHICH
11 FEES MUST BE USED SOLELY TO PAY THE COSTS OF THE DIVISION IN
12 IMPLEMENTING AND ADMINISTERING THIS PART 11.

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

23 **10-16-1111. Violations - enforcement.** (1) A MANUFACTURER
24 ENGAGES IN UNPROFESSIONAL CONDUCT UNDER SECTION 12-42.5-123
25 (1)(t) AND IS SUBJECT TO DISCIPLINE UNDER SECTION 12-42.5-124,
26 INCLUDING PENALTIES UNDER SECTION 12-42.5-124 (5)(a)(IV), IF THE
27 MANUFACTURER:

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

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

6 (c) FAILS TO PAY FILING FEES AS REQUIRED PURSUANT TO SECTION
7 10-16-1110 (1)(b).

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

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

12 **10-16-122.3. Pharmacy benefit management firm payments on**
13 **clean claims - retroactive reduction prohibited - exception -**
14 **enforcement - definitions.** (1) (a) A CONTRACT BETWEEN A PHARMACY
15 BENEFIT MANAGEMENT FIRM AND A PHARMACY WITH RESPECT TO
16 PRESCRIPTION DRUG BENEFITS ADMINISTERED OR MANAGED BY THE
17 PHARMACY BENEFIT MANAGEMENT FIRM MUST PROVIDE THAT AFTER THE
18 DATE THE PHARMACY BENEFIT MANAGEMENT FIRM RECEIVES A CLEAN
19 CLAIM SUBMITTED BY A PHARMACY, THE PHARMACY BENEFIT
20 MANAGEMENT FIRM SHALL NOT RETROACTIVELY REDUCE PAYMENT ON
21 THE CLAIM, EITHER DIRECTLY OR INDIRECTLY, THROUGH A NET
22 REIMBURSEMENT AMOUNT OR BY ANY OTHER MECHANISM, EXCEPT WHEN
23 THE PHARMACY BENEFIT MANAGEMENT FIRM DETERMINES, DURING THE
24 COURSE OF AN AUDIT CONDUCTED IN ACCORDANCE WITH SECTION
25 10-16-122.5, THAT THE CLAIM IS NOT A CLEAN CLAIM.

26 (b) NOTHING IN THIS SUBSECTION (1) PROHIBITS A PHARMACY
27 BENEFIT MANAGEMENT FIRM FROM RETROACTIVELY INCREASING A

1 PAYMENT TO A PHARMACY PURSUANT TO A WRITTEN AGREEMENT
2 BETWEEN THE PHARMACY BENEFIT MANAGEMENT FIRM AND THE
3 PHARMACY.

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

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

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

21 (4) AS USED IN THIS SECTION:

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

27 (b) "HEALTH INSURER" HAS THE SAME MEANING AS SET FORTH IN

1 SECTION 10-16-1103 (5).

2 (c) "PHARMACY" MEANS AN IN-STATE OR NONRESIDENT
3 PRESCRIPTION DRUG OUTLET, AS DEFINED IN SECTION 12-42.5-102 (35), AN
4 OTHER OUTLET, AS DEFINED IN SECTION 12-42.5-102 (25), A HOSPITAL
5 SATELLITE PHARMACY, AS DEFINED IN SECTION 12-42.5-102 (16), OR
6 OTHER SETTING, INCLUDING A PRACTITIONER'S OFFICE OR CLINIC, WHERE
7 A PRACTITIONER, AS DEFINED IN SECTION 12-42.5-102 (32), DISPENSES
8 PRESCRIPTION DRUGS TO PATIENTS AS AUTHORIZED BY SECTION
9 12-42.5-118 (6).

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

12 10-16-148. Cost sharing for prescription drugs - required
13 rebate reductions - definitions - rules. (1) AS USED IN THIS SECTION,
14 UNLESS THE CONTEXT OTHERWISE REQUIRES:

15 (a) "COST SHARING" MEANS A DEDUCTIBLE PAYMENT,
16 COPAYMENT, OR COINSURANCE AMOUNT IMPOSED ON A COVERED PERSON
17 FOR A COVERED PRESCRIPTION DRUG IN ACCORDANCE WITH THE TERMS
18 AND CONDITIONS OF THE COVERED PERSON'S HEALTH COVERAGE PLAN.

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

22 (c) "PRESCRIPTION DRUG" HAS THE MEANING SPECIFIED IN SECTION
23 12-42.5-102 (34).

24 (d) "REBATE" MEANS A PRICE CONCESSION GIVEN BY A
25 MANUFACTURER DIRECTLY TO A CARRIER OR PHARMACY BENEFIT
26 MANAGEMENT FIRM THAT REDUCES THE CARRIER'S PRESCRIPTION DRUG
27 COSTS FOR THE BENEFIT YEAR.

1 (2) FOR EACH OF ITS HEALTH COVERAGE PLANS ISSUED OR
2 RENEWED ON OR AFTER JANUARY 1, 2021, A CARRIER SHALL REDUCE THE
3 AMOUNT OF COST SHARING THAT IT WOULD OTHERWISE CHARGE A
4 COVERED PERSON FOR A PRESCRIPTION DRUG BY AN AMOUNT EQUAL TO
5 ONE HUNDRED PERCENT OF THE ESTIMATED REBATE PER PRESCRIPTION
6 THAT THE CARRIER RECEIVED FOR THE PRESCRIPTION DRUG, CALCULATED
7 BASED ON THE REBATES THE CARRIER RECEIVED FOR THAT PRESCRIPTION
8 DRUG IN THE PREVIOUS QUARTER; EXCEPT THAT THE REDUCTION AMOUNT
9 SHALL NOT EXCEED AN AMOUNT EQUAL TO THE COVERED PERSON'S
10 COST-SHARING AMOUNT THAT WOULD OTHERWISE BE CHARGED FOR THE
11 DISPENSED PRESCRIPTION DRUG. NEITHER THE COVERED PERSON NOR THE
12 CARRIER IS RESPONSIBLE FOR ANY DIFFERENCE BETWEEN THE ESTIMATED
13 REBATE AMOUNT AND THE ACTUAL REBATE THE CARRIER RECEIVES.

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

17 (4) THE COMMISSIONER SHALL ADOPT RULES AS NECESSARY TO
18 IMPLEMENT THIS SECTION, WHICH RULES MUST ENSURE THAT REBATES ARE
19 APPLIED IN A MANNER TO PROVIDE A PRICE REDUCTION FOR COVERED
20 PERSONS WHO HAVE NOT REACHED THEIR ANNUAL COST-SHARING LIMIT
21 AND TO LIMIT THE EFFECT ON PREMIUMS.

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

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

27 **10-3-1104. Unfair methods of competition - unfair or deceptive**

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

4 (ss) FAILING TO COMPLY WITH SECTION 10-16-122.3 (2) OR
5 10-16-1107(3) AND TO ENSURE A PHARMACY BENEFIT MANAGEMENT FIRM
6 WITH WHOM A HEALTH INSURER, AS DEFINED IN SECTION 10-16-1103 (5),
7 CONTRACTS IS COMPLYING WITH SECTIONS 10-16-122.3 (1) AND
8 10-16-1107.

9 **SECTION 5.** In Colorado Revised Statutes, 12-42.5-123, **add**
10 (1)(t) as follows:

11 **12-42.5-123. Unprofessional conduct - grounds for discipline.**

12 (1) The board may suspend, revoke, refuse to renew, or otherwise
13 discipline any license or registration issued by it, after a hearing held in
14 accordance with the provisions of this section, upon proof that the
15 licensee or registrant:

16 (t) (I) HAS FAILED TO NOTIFY PURCHASERS OF PRESCRIPTION DRUG
17 PRICE INCREASES OR OF NEW SPECIALTY DRUGS INTRODUCED TO THE
18 MARKET AS REQUIRED BY SECTION 10-16-1105;

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

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

23 **SECTION 6.** In Colorado Revised Statutes, 12-42.5-124, **amend**
24 (5)(a)(I); and **add** (5)(a)(IV) as follows:

25 **12-42.5-124. Disciplinary actions.** (5) (a) (I) Except as provided
26 in subparagraphs (II) and (III) of this paragraph (a) SUBSECTION (5)(a)(II),
27 (5)(a)(III), OR (5)(a)(IV) OF THIS SECTION, in addition to any other penalty

1 the board may impose pursuant to this section, the board may fine any
2 registrant violating this ~~article~~ ARTICLE 42.5 or any rules promulgated
3 pursuant to this ~~article~~ ARTICLE 42.5 not less than five hundred dollars and
4 not more than five thousand dollars for each violation.

5 (IV) IN ADDITION TO ANY OTHER PENALTY THE BOARD MAY
6 IMPOSE PURSUANT TO THIS SECTION, THE BOARD MAY FINE A REGISTRANT
7 FOR FAILING TO NOTIFY PURCHASERS OR REPORT INFORMATION TO THE
8 COMMISSIONER OF INSURANCE AS SPECIFIED IN SECTION 12-42.5-123 (1)(t)
9 UP TO TEN THOUSAND DOLLARS PER DAY FOR EACH DAY THE REGISTRANT
10 FAILS TO COMPLY WITH THE NOTICE OR REPORTING REQUIREMENTS.

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

13 **12-280-126. Unprofessional conduct - grounds for discipline.**

14 (1) The board may take disciplinary or other action as authorized in
15 section 12-20-404, after a hearing held in accordance with the provisions
16 of sections 12-20-403 and 12-280-127, upon proof that the licensee or
17 registrant:

18 (t) (I) HAS FAILED TO NOTIFY PURCHASERS OF PRESCRIPTION DRUG
19 PRICE INCREASES OR OF NEW SPECIALTY DRUGS INTRODUCED TO THE
20 MARKET AS REQUIRED BY SECTION 10-16-1105;

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

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

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

1 **12-280-127. Disciplinary actions.** (5) (a) Except as provided in
2 subsections (5)(b), ~~and~~ (5)(c), OR (5)(d) of this section, in addition to any
3 other penalty the board may impose pursuant to this section, the board
4 may fine any registrant violating this article 280 or any rules promulgated
5 pursuant to this article 280 not less than five hundred dollars and not
6 more than five thousand dollars for each violation.

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

13 **SECTION 9. Effective date.** This act takes effect July 1, 2019;
14 except that sections 7 and 8 of this act take effect only if House Bill
15 19-1172 becomes law, in which case sections 7 and 8 take effect October
16 1, 2019.

17 **SECTION 10. Safety clause.** The general assembly hereby finds,
18 determines, and declares that this act is necessary for the immediate
19 preservation of the public peace, health, and safety.