Second Regular Session
Seventy-third General Assembly
STATE OF COLORADO

INTRODUCED

LLS NO. 22-0251.01 Kristen Forrestal x4217 **HOUSE BILL 22-1370**

HOUSE SPONSORSHIP

Jodeh and Sirota, Amabile, Bacon, Bernett, Boesenecker, Caraveo, Cutter, Duran, Froelich, Gonzales-Gutierrez, Gray, Hooton, Kennedy, Kipp, Lindsay, Michaelson Jenet, Ortiz, Sullivan, Weissman, Will, Woodrow, Young

SENATE SPONSORSHIP

Winter and Buckner,

House Committees
Health & Insurance

Senate Committees

A BILL FOR AN ACT

CONCERNING COVERAGE REQUIREMENTS FOR HEALTH-CARE PRODUCTS.

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.)

Beginning in 2023, the bill requires each health insurance carrier (carrier) that offers an individual or small group health benefit plan in this state to offer at least 25% of its health benefit plans on the Colorado health benefit exchange (exchange) and at least 25% of its plans not on the exchange in each bronze, silver, gold, and platinum benefit level in each service area as copayment-only payment structures for all

prescription drug cost tiers.

Starting in 2024, a carrier or, if a carrier uses a pharmacy benefit manager (PBM) for claims processing services or other prescription drug or device services under a health benefit plan offered by the carrier, the PBM, or a representative of the carrier or the PBM, is prohibited from modifying or applying a modification to the current prescription drug formulary during the current plan year.

The bill repeals and reenacts the current requirements for step therapy and requires a carrier to use clinical review criteria to establish the step-therapy protocol.

For each health benefit plan issued or renewed on or after January 1, 2024, the bill requires each carrier or PBM to demonstrate to the division of insurance that:

- 100% of the estimated rebates received or to be received in connection with dispensing or administering prescription drugs included in the carrier's prescription drug formulary are used to reduce costs for the employer or individual purchasing the plan;
- For small group and large employer health benefit plans, all rebates are used to reduce employer and individual employee costs; and
- For individual health benefit plans, all rebates are used to reduce consumers' premiums and out-of-pocket costs for prescription drugs to the extent practicable.

The bill requires the commissioner of insurance (commissioner) to promulgate rules to implement prescription drug pass-through requirements for carriers. Each carrier or PBM is required to report annually specified prescription drug rebate information to the commissioner.

Beginning in 2023, the bill requires the department of health care policy and financing, in collaboration with the administrator of the all-payer claims database, to conduct an annual analysis of the prescription drug rebates received in the previous calendar year, by carrier and prescription drug tier, and make the analysis available to the public.

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

SECTION 1. In Colorado Revised Statutes, **add** 10-16-103.6 as follows:

10-16-103.6. Copayment-only prescription payment structures - required inclusion in health benefit plans - rules. (1) (a) (I) IN

ADDITION TO THE REQUIREMENTS IN SECTION 10-16-103.4 (2), FOR HEALTH BENEFIT PLANS ISSUED OR RENEWED ON OR AFTER JANUARY 1, 2023, EACH CARRIER THAT OFFERS AN INDIVIDUAL OR SMALL GROUP HEALTH BENEFIT PLAN SHALL OFFER AT LEAST TWENTY-FIVE PERCENT OF ITS HEALTH BENEFIT PLANS ON THE EXCHANGE AND AT LEAST TWENTY-FIVE PERCENT OF ITS PLANS NOT ON THE EXCHANGE IN EACH BRONZE, SILVER, GOLD, AND PLATINUM BENEFIT LEVEL IN EACH SERVICE AREA AS COPAYMENT-ONLY PAYMENT STRUCTURES FOR ALL PRESCRIPTION DRUG COST TIERS.

(b) FOR EACH COPAYMENT-ONLY PAYMENT STRUCTURE FOR PRESCRIPTIONS DRUGS:

(I) THE COPAYMENT AMOUNT FOR THE HIGHEST PRESCRIPTION DRUG COST TIER MUST NOT BE GREATER THAN ONE-TWELFTH OF THE HEALTH BENEFIT PLAN'S OUT-OF-POCKET MAXIMUM AMOUNT;

(II) THE COPAYMENT AMOUNTS BETWEEN THE TWO HIGHEST PRESCRIPTION DRUG COST TIERS MUST HAVE A COST DIFFERENCE OF AT LEAST TEN PERCENT;

(III) NO MORE THAN FIFTY PERCENT OF THE DRUGS ON THE PRESCRIPTION DRUG FORMULARY USED TO TREAT A SPECIFIC CONDITION MAY BE PLACED ON THE HIGHEST PRESCRIPTION DRUG COST TIER; AND

(IV) EACH CARRIER SHALL USE "RX COPAY" AT THE END OF THE MARKETING NAMES FOR EACH COPAYMENT-ONLY PAYMENT STRUCTURE.

(2) THE COMMISSIONER MAY PROMULGATE RULES TO IMPLEMENT AND ENFORCE THIS SECTION.

SECTION 2. In Colorado Revised Statutes, **add** 10-16-122.4 as follows:

10-16-122.4. Pharmacy benefits - formulary change prohibition - exceptions - definition - rules. (1) (a) STARTING IN 2024,

EXCEPT AS PROVIDED IN SUBSECTION (2) OF THIS SECTION, A CARRIER OR, IF A CARRIER USES A PBM FOR CLAIMS PROCESSING SERVICES OR OTHER PRESCRIPTION DRUG OR DEVICE SERVICES, AS THOSE TERMS ARE DEFINED IN SECTION 10-16-122.1, UNDER A HEALTH BENEFIT PLAN OFFERED BY THE CARRIER, THE PBM, OR A REPRESENTATIVE OF THE CARRIER OR THE PBM, SHALL NOT MODIFY OR APPLY A MODIFICATION TO THE CURRENT PRESCRIPTION DRUG FORMULARY DURING THE CURRENT PLAN YEAR.

(b) AS USED IN THIS SUBSECTION (1), "MODIFY" OR "MODIFICATION" INCLUDES ELIMINATING A PARTICULAR PRESCRIPTION DRUG FROM THE FORMULARY OR MOVING A PRESCRIPTION DRUG TO A HIGHER COST-SHARING TIER.

(2) A CARRIER OFFERING A HEALTH BENEFIT PLAN IN THIS STATE THAT INCLUDES A PRESCRIPTION DRUG BENEFIT AND USES A PRESCRIPTION DRUG FORMULARY OR LIST OF COVERED DRUGS MAY:

(a) REMOVE A PRESCRIPTION DRUG FROM THE PRESCRIPTION DRUG FORMULARY OR LIST OF COVERED DRUGS, WITH ADVANCE NOTICE TO A COVERED PERSON AND THE COVERED PERSON'S PROVIDER, IF:

(I) THE FDA ISSUES AN ANNOUNCEMENT, GUIDANCE, NOTICE, WARNING, OR STATEMENT CONCERNING THE PRESCRIPTION DRUG THAT CALLS INTO QUESTION THE CLINICAL SAFETY OF THE PRESCRIPTION DRUG; OR

(II) THE PRESCRIPTION DRUG IS APPROVED BY THE FDA FOR USE WITHOUT A PRESCRIPTION; OR

(b) MOVE A BRAND-NAME PRESCRIPTION DRUG FROM A PRESCRIPTION DRUG COST-SHARING TIER THAT IMPOSES A LESSER COPAYMENT OR DEDUCTIBLE FOR THE BRAND-NAME PRESCRIPTION DRUG TO A COST-SHARING TIER THAT IMPOSES A GREATER COPAYMENT OR

DEDUCTIBLE FOR THE BRAND-NAME PRESCRIPTION DRUG IF THE CARRIER ADDS TO THE PRESCRIPTION DRUG FORMULARY OR LIST OF COVERED DRUGS A GENERIC PRESCRIPTION DRUG THAT IS:

(I) APPROVED BY THE FDA FOR USE AS AN ALTERNATIVE TO THE BRAND-NAME PRESCRIPTION DRUG; AND

(II) IN A PRESCRIPTION DRUG COST-SHARING TIER THAT IMPOSES A COPAYMENT OR DEDUCTIBLE FOR THE GENERIC PRESCRIPTION DRUG THAT IS LESS THAN THE COPAYMENT OR DEDUCTIBLE THAT IS IMPOSED FOR THE BRAND-NAME PRESCRIPTION DRUG IN THE COST-SHARING TIER TO WHICH THE BRAND-NAME PRESCRIPTION DRUG IS MOVED.

(3) THIS SECTION DOES NOT PROHIBIT A CARRIER FROM ADDING A PRESCRIPTION DRUG TO A PRESCRIPTION DRUG FORMULARY OR LIST OF COVERED DRUGS AT ANY TIME.

(4) THE COMMISSIONER MAY PROMULGATE RULES TO IMPLEMENT AND ENFORCE THIS SECTION.

SECTION 3. In Colorado Revised Statutes, **repeal and reenact, with amendments,** 10-16-145 as follows:

10-16-145. Step-therapy protocol - limitations - exceptions - definitions - rules. (1) AS USED IN THIS SECTION:

(a) "AB-RATED" MEANS THERAPEUTICALLY EQUIVALENT AS EVALUATED BY THE FDA IN THE MOST CURRENT EDITION OF THE FDA PUBLICATION "APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS" OR ITS SUCCESSOR PUBLICATION.

(b) "CLINICAL PRACTICE GUIDELINES" MEANS A SYSTEMATICALLY DEVELOPED STATEMENT TO ASSIST PROVIDERS AND COVERED PERSONS IN MAKING DECISIONS ABOUT APPROPRIATE HEALTH CARE FOR SPECIFIC CLINICAL CIRCUMSTANCES AND CONDITIONS.

(c) "CLINICAL REVIEW CRITERIA" MEANS THE WRITTEN SCREENING PROCEDURES, DECISION ABSTRACTS, CLINICAL PROTOCOLS, AND CLINICAL PRACTICE GUIDELINES USED BY A CARRIER OR PRIVATE UTILIZATION REVIEW ORGANIZATION TO DETERMINE THE MEDICAL NECESSITY AND APPROPRIATENESS OF THE PROVISION OF HEALTH-CARE SERVICES. CLINICAL REVIEW CRITERIA MUST NOT BE MORE RESTRICTIVE THAN THE FDA'S INDICATION FOR A SPECIFIC DRUG OR HEALTH- CARE SERVICE.

(d) "MEDICAL NECESSITY" MEANS A DETERMINATION BY A CARRIER THAT A PRUDENT PROVIDER WOULD PROVIDE A PARTICULAR COVERED HEALTH-CARE SERVICE TO A PATIENT FOR THE PURPOSE OF PREVENTING, DIAGNOSING, OR TREATING AN ILLNESS, AN INJURY, A DISEASE, OR A SYMPTOM IN A MANNER THAT IS:

(I) IN ACCORDANCE WITH GENERALLY ACCEPTED STANDARDS OF MEDICAL PRACTICE AND APPROVED BY THE FDA OR OTHER REQUIRED AGENCY;

(II) CLINICALLY APPROPRIATE IN TERMS OF TYPE, FREQUENCY, EXTENT, SERVICE SITE, AND LEVEL AND DURATION OF SERVICE;

(III) KNOWN TO BE EFFECTIVE IN IMPROVING HEALTH, AS PROVEN BY SCIENTIFIC EVIDENCE;

(IV) THE MOST APPROPRIATE SUPPLY, SETTING, OR LEVEL OF SERVICE THAT CAN BE SAFELY PROVIDED GIVEN THE PATIENT'S CONDITION AND THAT CANNOT BE OMITTED FROM THE PATIENT'S TREATMENT; AND

(V) NOT PRIMARILY FOR THE ECONOMIC BENEFIT OF A CARRIER OR PURCHASER OR FOR THE CONVENIENCE OF THE PATIENT, THE TREATING PROVIDER, OR OTHER PROVIDER.

(f) "PRIVATE UTILIZATION REVIEW ORGANIZATION" OR "ORGANIZATION" HAS THE SAME MEANING AS SET FORTH IN SECTION

10-16-112 (1)(a).

(g) "STEP-THERAPY PROTOCOL" MEANS A PROTOCOL, POLICY, OR PROGRAM THAT ESTABLISHES THE SPECIFIC SEQUENCE IN WHICH PRESCRIPTION DRUGS THAT ARE MEDICALLY APPROPRIATE FOR A PARTICULAR COVERED PERSON ARE COVERED BY A HEALTH BENEFIT PLAN FOR A SPECIFIED MEDICAL CONDITION.

(2) IF A CARRIER, A PRIVATE UTILIZATION REVIEW ORGANIZATION, OR A PBM REQUIRES A STEP-THERAPY PROTOCOL, THE CARRIER, ORGANIZATION, OR PBM SHALL USE CLINICAL REVIEW CRITERIA TO ESTABLISH THE PROTOCOL BASED ON CLINICAL PRACTICE GUIDELINES.

(3) UPON WRITTEN REQUEST OF A COVERED PERSON OR COVERED PERSON'S PRESCRIBING PROVIDER, A CARRIER, PRIVATE UTILIZATION REVIEW ORGANIZATION, OR PBM SHALL:

(a) PROVIDE ALL SPECIFIC CLINICAL REVIEW CRITERIA AND OTHER CLINICAL INFORMATION RELATING TO A COVERED PERSON'S PARTICULAR CONDITION OR DISEASE, INCLUDING CLINICAL REVIEW CRITERIA RELATING TO A STEP-THERAPY EXCEPTION, TO THE REQUESTER; AND

(b) MAKE THE CLINICAL REVIEW CRITERIA AND OTHER CLINICAL INFORMATION AVAILABLE ON THE CARRIER'S, ORGANIZATION'S, OR PBM'S WEBSITE.

(4) (a) A CARRIER, A PRIVATE UTILIZATION REVIEW ORGANIZATION, OR A PBM SHALL GRANT AN EXCEPTION TO A STEP-THERAPY PROTOCOL IF:

(I) THE REQUIRED PRESCRIPTION DRUG IS CONTRAINDICATED OR WILL LIKELY CAUSE AN ADVERSE REACTION OR HARM TO THE COVERED PERSON;

(II) THE REQUIRED PRESCRIPTION DRUG IS EXPECTED TO BE

INEFFECTIVE BASED ON THE KNOWN CLINICAL CHARACTERISTICS OF THE COVERED PERSON AND THE KNOWN CHARACTERISTICS OF THE PRESCRIPTION DRUG REGIMEN;

(III) THE COVERED PERSON HAS TRIED, WHILE UNDER THE COVERED PERSON'S CURRENT OR PREVIOUS HEALTH BENEFIT PLAN, THE REQUIRED PRESCRIPTION DRUG OR ANOTHER PRESCRIPTION DRUG IN THE SAME PHARMACOLOGIC CLASS OR WITH THE SAME MECHANISM OF ACTION, AND THE USE OF THE PRESCRIPTION DRUG BY THE COVERED PERSON WAS DISCONTINUED DUE TO LACK OF EFFICACY OR EFFECTIVENESS, DIMINISHED EFFECT, OR AN ADVERSE EVENT;

(IV) THE REQUIRED PRESCRIPTION DRUG IS NOT IN THE BEST INTEREST OF THE COVERED PERSON, BASED ON MEDICAL NECESSITY; OR

(V) THE COVERED PERSON, WHILE ON THE COVERED PERSON'S CURRENT OR PREVIOUS HEALTH BENEFIT PLAN, IS STABLE ON A PRESCRIPTION DRUG SELECTED BY THE PRESCRIBING PROVIDER FOR THE MEDICAL CONDITION UNDER CONSIDERATION.

(b) THE COMMISSIONER SHALL PROMULGATE RULES TO ESTABLISH:

(I) A PROCESS, AND THE NECESSARY DOCUMENTS, FOR PROVIDERS TO SUBMIT STEP-THERAPY EXCEPTION REQUESTS; AND

(II) TIME FRAMES FOR:

(A) CARRIERS, ORGANIZATIONS, AND PBMS TO GRANT OR DENY STEP-THERAPY EXCEPTION REQUESTS;

(B) CARRIERS, ORGANIZATIONS, AND PBMS TO REQUEST ADDITIONAL INFORMATION FROM PRESCRIBING PROVIDERS; AND

(C) PROVIDERS TO RESPOND TO REQUESTS FROM CARRIERS, ORGANIZATIONS, AND PBMS FOR ADDITIONAL INFORMATION.

(c) IF THE INITIAL REQUEST FOR A STEP-THERAPY PROTOCOL

EXCEPTION IS DENIED, THE CARRIER, ORGANIZATION, OR PBM SHALL INFORM THE COVERED PERSON IN WRITING THAT THE COVERED PERSON HAS THE RIGHT TO AN INTERNAL OR EXTERNAL REVIEW OR AN APPEAL OF THE ADVERSE DETERMINATION PURSUANT TO SECTIONS 10-16-113 AND 10-16-113.5.

(d) A CARRIER, AN ORGANIZATION, OR A PBM SHALL AUTHORIZE COVERAGE FOR THE PRESCRIPTION DRUG PRESCRIBED BY THE COVERED PERSON'S PRESCRIBING PROVIDER WHEN THE STEP-THERAPY PROTOCOL EXCEPTION REQUEST IS GRANTED.

(5) THIS SECTION DOES NOT PROHIBIT:

(a) A CARRIER, AN ORGANIZATION, OR A PBM FROM REQUIRING A COVERED PERSON TO TRY AN AB-RATED GENERIC EQUIVALENT OR AN INTERCHANGEABLE BIOLOGICAL PRODUCT AS DEFINED BY 42 U.S.C. SEC. 262 (i)(3), UNLESS THE COVERED PERSON OR COVERED PERSON'S PRESCRIBING PROVIDER HAS REQUESTED A STEP-THERAPY PROTOCOL EXCEPTION AND THE PRESCRIBED DRUG MEETS THE CRITERIA FOR A STEP-THERAPY PROTOCOL EXCEPTION SPECIFIED IN SUBSECTION (4)(a) OF THIS SECTION;

(b) A CARRIER, AN ORGANIZATION, OR A PBM FROM REQUIRING A PHARMACIST TO MAKE SUBSTITUTIONS OF PRESCRIPTION DRUGS CONSISTENT WITH PART 5 OF ARTICLE 280 OF TITLE 12; OR

(c) A PROVIDER FROM PRESCRIBING A DRUG THAT IS DETERMINED TO BE MEDICALLY APPROPRIATE.

(6) THE COMMISSIONER MAY PROMULGATE RULES TO IMPLEMENT AND ENFORCE THIS SECTION.

SECTION 4. In Colorado Revised Statutes, **amend as it exists until January 1, 2023,** 10-16-145.5 as follows:

10-16-145.5. Step therapy prohibited - stage four advanced metastatic cancer - definitions. (1) Notwithstanding section 10-16-145, a carrier that provides coverage under a health benefit plan for the treatment of stage four advanced metastatic cancer shall not limit or exclude coverage under the health benefit plan for a drug approved by the ~~United States food and drug administration~~ FDA and that is on the carrier's prescription drug formulary by mandating that a covered person with stage four advanced metastatic cancer undergo A step-therapy PROTOCOL if the use of the approved drug is consistent with:

(a) The ~~United States food and drug administration-approved~~ FDA-APPROVED indication or the National Comprehensive Cancer Network drugs and biologics compendium indication for the treatment of stage four advanced metastatic cancer; or

(b) Peer-reviewed medical literature.

(2) ~~For the purposes of~~ AS USED IN this section:

(a) "Stage four advanced metastatic cancer" means cancer that has spread from the primary or original site of the cancer to nearby tissues, lymph nodes, or other parts of the body.

(b) "STEP-THERAPY PROTOCOL" HAS THE SAME MEANING AS SPECIFIED IN SECTION 10-16-145 (1)(f).

SECTION 5. In Colorado Revised Statutes, **amend as it will become effective January 1, 2023,** 10-16-145.5 as follows:

10-16-145.5. Step therapy - prior authorization - prohibited - stage four advanced metastatic cancer - opioid prescription - definitions. (1) ~~(a)~~ Notwithstanding section 10-16-145, a carrier that provides coverage under a health benefit plan for the treatment of stage four advanced metastatic cancer shall not limit or exclude coverage under

the health benefit plan for a drug that is approved by the FDA and that is on the carrier's prescription drug formulary by mandating that a covered person with stage four advanced metastatic cancer undergo A step-therapy PROTOCOL if the use of the approved drug is consistent with:

~~(I)~~ (a) The FDA-approved indication or the National Comprehensive Cancer Network drugs and biologics compendium indication for the treatment of stage four advanced metastatic cancer; or

~~(II)~~ (b) Peer-reviewed medical literature.

~~(b) As used in this subsection (1), "stage four advanced metastatic cancer" means cancer that has spread from the primary or original site of the cancer to nearby tissues, lymph nodes, or other parts of the body.~~

(2) ~~(a)~~ Notwithstanding section 10-16-145, a carrier that provides prescription drug benefits shall:

~~(I)~~ (a) Provide coverage for at least one atypical opioid that has been approved by the FDA for the treatment of acute or chronic pain at the lowest tier of the carrier's drug formulary and not require A step-therapy PROTOCOL or prior authorization, as defined in section 10-16-112.5 (7)(d), for that atypical opioid; and

~~(II)~~ (b) Not require A step-therapy PROTOCOL for the prescription and use of any additional atypical opioid medications that have been approved by the FDA for the treatment of acute or chronic pain.

~~(b) As used in this subsection (2), "atypical opioid" means an opioid agonist with a documented safer side-effect profile and less risk of addiction than older opium-based medications.~~

(3) AS USED IN THIS SECTION:

(a) "ATYPICAL OPIOID" MEANS AN OPIOID AGONIST WITH A DOCUMENTED SAFER SIDE-EFFECT PROFILE AND LESS RISK OF ADDICTION

THAN OLDER OPIUM-BASED MEDICATIONS.

(b) "STAGE FOUR ADVANCED METASTATIC CANCER" MEANS CANCER THAT HAS SPREAD FROM THE PRIMARY OR ORIGINAL SITE OF THE CANCER TO NEARBY TISSUES, LYMPH NODES, OR OTHER PARTS OF THE BODY.

(c) "STEP-THERAPY PROTOCOL" HAS THE SAME MEANING AS SPECIFIED IN SECTION 10-16-145 (1)(f).

SECTION 6. In Colorado Revised Statutes, **add** 10-16-155 as follows:

10-16-155. Prescription drugs - cost sharing - point-of-sale calculation - rebates - confidentiality - rules - legislative declaration - definitions. (1) THE GENERAL ASSEMBLY HEREBY FINDS AND DECLARES THAT:

(a) WITH APPROXIMATELY ONE HUNDRED FIFTY BILLION DOLLARS IN PRESCRIPTION DRUG REBATES IN THE HEALTH-CARE SYSTEM EACH YEAR, IT IS UNCLEAR IF THESE REBATES ARE BEING USED TO BENEFIT CONSUMERS BY PROVIDING THEM MAXIMIZED COST SAVINGS;

(b) MOST COLORADANS EXPERIENCE INCREASES IN PRESCRIPTION DRUG COSTS AND DO NOT BENEFIT FROM INCREASING REBATES WITH CORRESPONDING OFFSETS IN THEIR COSTS; AND

(c) REQUIRING HEALTH INSURERS TO PASS REBATE SAVINGS ON TO CONSUMERS BASED ON THE REBATES THEY RECEIVE FROM MANUFACTURERS FOR PRESCRIPTION DRUGS COVERED UNDER THEIR HEALTH BENEFIT PLANS WILL PROVIDE IMMEDIATE FINANCIAL RELIEF FOR COLORADANS AND ENABLE THEM TO OFFSET RISING PRESCRIPTION DRUG COSTS.

(2) AS USED IN THIS SECTION, UNLESS THE CONTEXT OTHERWISE

REQUIRES:

(a) "HEALTH INSURER" MEANS:

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

(II) A CARRIER AS DEFINED IN SECTION 24-50-603 (2).

(b) "DEFINED COST SHARING" MEANS A DEDUCTIBLE PAYMENT, COPAYMENT AMOUNT, OR COINSURANCE AMOUNT IMPOSED ON A COVERED PERSON FOR A COVERED PRESCRIPTION DRUG UNDER THE COVERED PERSON'S HEALTH BENEFIT PLAN.

(c) "MANUFACTURER" MEANS:

(I) A PERSON THAT:

(A) MANUFACTURES A PRESCRIPTION DRUG THAT IS SOLD TO PURCHASERS IN THIS STATE; OR

(B) ENTERS INTO A LEASE OR OTHER CONTRACTUAL AGREEMENT WITH ANOTHER MANUFACTURER TO MARKET AND DISTRIBUTE A PRESCRIPTION DRUG IN THIS STATE UNDER THE PERSON'S OWN NAME AND SETS OR CHANGES THE WHOLESALE ACQUISITION COST OF THE PRESCRIPTION DRUG IN THIS STATE; OR

(II) A REBATE AGGREGATOR, A SUBSIDIARY, ANY AFFILIATED HOLDING OR PARENT COMPANY, OR ANY OTHER ORGANIZATIONAL AFFILIATE OF A PERSON THAT MANUFACTURES A PRESCRIPTION DRUG THAT IS SOLD IN THIS STATE.

(d) "PRESCRIPTION DRUG" HAS THE SAME MEANING AS SET FORTH IN SECTION 12-280-103 (42); EXCEPT THAT THE TERM INCLUDES ONLY PRESCRIPTION DRUGS THAT ARE INTENDED FOR HUMAN USE.

(e) (I) "REBATE" MEANS A PRICE CONCESSION, A PRICE DISCOUNT, OR A DISCOUNT OF ANY SORT MADE BY A MANUFACTURER THAT REDUCES PAYMENTS FOR A PRESCRIPTION DRUG, INCLUDING:

(A) A PARTIAL REFUND OF PAYMENTS;

(B) A REDUCTION IN THE TOTAL AMOUNT PAID FOR A PRESCRIPTION DRUG;

(C) A PERFORMANCE-BASED FINANCIAL REWARD;

(D) A FINANCIAL REWARD FOR INCLUDING A PRESCRIPTION DRUG IN A PREFERRED DRUG LIST OR FORMULARY OR PREFERRED FORMULARY POSITION;

(E) A MARKET SHARE INCENTIVE PAYMENT OR REWARD;

(F) A COMMISSION; OR

(G) ANY OTHER COMPENSATION PAID BY A SUBSIDIARY, ANY AFFILIATED HOLDING OR PARENT COMPANY, OR ANY OTHER ORGANIZATIONAL AFFILIATE OF A PERSON THAT MANUFACTURES A PRESCRIPTION DRUG THAT IS SOLD IN THIS STATE.

(II) THE COMMISSIONER MAY PROMULGATE RULES TO FURTHER DEFINE "REBATE" FOR PURPOSES OF THIS SECTION.

(3) FOR EACH HEALTH BENEFIT PLAN ISSUED OR RENEWED ON OR AFTER JANUARY 1, 2024, A HEALTH INSURER OR PBM SHALL DEMONSTRATE TO THE DIVISION THAT:

(a) ONE HUNDRED PERCENT OF THE ESTIMATED REBATES RECEIVED OR TO BE RECEIVED IN CONNECTION WITH DISPENSING OR ADMINISTERING PRESCRIPTION DRUGS INCLUDED IN THE HEALTH INSURER'S FORMULARY FOR THAT PLAN YEAR ARE USED TO REDUCE COSTS;

(b) FOR SMALL GROUP AND LARGE EMPLOYER PLANS, ALL REBATES ARE USED TO REDUCE EMPLOYER AND INDIVIDUAL EMPLOYEE COSTS; AND

(c) FOR INDIVIDUAL HEALTH BENEFIT PLANS, ALL REBATES ARE USED TO REDUCE CONSUMERS' PREMIUMS AND DEFINED COST SHARING FOR PRESCRIPTION DRUGS AND THAT THE MAJORITY OF REBATES WILL BE USED

TO MAXIMIZE THE REDUCTION OF DEFINED COST SHARING FOR CONSUMERS AT THE POINT OF SALE.

(4) A HEALTH INSURER OR PBM SHALL NOT REDUCE A DISPENSING PHARMACY'S PAYMENT OR REIMBURSEMENT BASED ON A COVERED PERSON'S COST-SHARING PRICE REDUCTION. A HEALTH INSURER OR PBM SHALL NOT INCLUDE IN A CONTRACT WITH A DISPENSING PHARMACY A PROVISION THAT WOULD LOWER THE PHARMACY REIMBURSEMENT BASED ON A COVERED PERSON'S COST-SHARING PRICE REDUCTION.

(5) THE DIVISION SHALL EVALUATE HOW REBATES MAY BE APPLIED TO REDUCE A COVERED PERSON'S DEFINED COST SHARING FOR EACH PRESCRIPTION DRUG AT THE POINT OF SALE AND HOW REBATES MAY BE APPLIED TO REDUCE DEFINED COST SHARING, TAKING INTO CONSIDERATION THE AVERAGE PREMIUM IMPACTS. REGARDLESS OF THE RESULTS OF THE EVALUATION IN THIS SUBSECTION (5), A HEALTH INSURER OR PBM SHALL COMPLY WITH SUBSECTION (4) OF THIS SECTION.

(6) EACH HEALTH INSURER AND PBM SHALL REPORT ANNUALLY, IN A MANNER DETERMINED BY THE COMMISSIONER, THE FOLLOWING INFORMATION:

(a) PROSPECTIVE, ACTUARIALLY SOUND ESTIMATES OF ALL REBATES TO BE RECEIVED DURING THE UPCOMING PLAN YEAR, SEGREGATED BY TIERS THAT ARE IDENTIFIED IN THE HEALTH INSURER'S FORMULARY FOR HEALTH BENEFIT PLANS. THE ESTIMATES SHALL INCLUDE:

(I) FOR INDIVIDUAL, SMALL GROUP, AND LARGE EMPLOYER PLANS, THE ESTIMATED AGGREGATE AMOUNT OF REBATES THE HEALTH INSURER EXPECTS TO RECEIVE, IN DOLLARS AND AS A PERCENTAGE OF EXPECTED TOTAL PRESCRIPTION DRUG CLAIM EXPENDITURES;

(II) FOR SMALL GROUP AND LARGE EMPLOYER PLANS, THE

ESTIMATED AGGREGATE AMOUNT OF REBATES THE HEALTH INSURER EXPECTS TO PASS ON TO EMPLOYERS FOR EMPLOYERS TO REDUCE COSTS FOR COVERED PERSONS, IN DOLLARS AND AS A PERCENTAGE OF TOTAL REBATES RECEIVED;

(III) FOR INDIVIDUAL PLANS, THE ESTIMATED AGGREGATE AMOUNT OF REBATES THAT WILL BE USED TO REDUCE DEFINED COST SHARING FOR COVERED PERSONS;

(IV) FOR INDIVIDUAL, SMALL GROUP, AND LARGE EMPLOYER PLANS, THE ESTIMATED AGGREGATE AMOUNT OF REBATES THE HEALTH INSURER EXPECTS TO USE TO REDUCE PREMIUMS FOR EMPLOYERS AND COVERED PERSONS; AND

(V) ANY OTHER DATA, AS SPECIFIED BY RULE OF THE COMMISSIONER, THAT IS NECESSARY TO DETERMINE A HEALTH INSURER'S OR PBM'S COMPLIANCE WITH SUBSECTION (3) OF THIS SECTION.

(b) ACTUAL AMOUNTS OF REBATES FOR ALL REBATES RECEIVED DURING THE PAST PLAN YEAR, SEGREGATED BY TIERS THAT ARE IDENTIFIED IN THE HEALTH INSURER'S FORMULARY FOR HEALTH BENEFIT PLANS. THESE ACTUAL AMOUNTS SHALL INCLUDE:

(I) FOR INDIVIDUAL, SMALL GROUP, AND LARGE EMPLOYER PLANS, THE AGGREGATE AMOUNT OF REBATES RECEIVED BY THE HEALTH INSURER, IN DOLLARS AND AS A PERCENTAGE OF TOTAL PRESCRIPTION DRUG CLAIM EXPENDITURES;

(II) FOR SMALL GROUP AND LARGE EMPLOYER PLANS, THE AGGREGATE AMOUNT OF REBATES PASSED ON TO EMPLOYERS FOR EMPLOYERS TO REDUCE COSTS FOR COVERED PERSONS, IN DOLLARS AND AS A PERCENTAGE OF TOTAL REBATES RECEIVED;

(III) FOR INDIVIDUAL PLANS, THE AGGREGATE AMOUNT OF

REBATES USED TO REDUCE DEFINED COST SHARING FOR COVERED PERSONS;

(IV) FOR INDIVIDUAL, SMALL GROUP, AND LARGE EMPLOYER PLANS, THE AGGREGATE AMOUNT OF REBATES USED TO REDUCE PREMIUMS FOR EMPLOYERS AND COVERED PERSONS; AND

(V) ANY OTHER DATA, AS SPECIFIED BY RULE OF THE COMMISSIONER, THAT IS NECESSARY TO DETERMINE A HEALTH INSURER'S OR PBM'S COMPLIANCE WITH SUBSECTION (3) OF THIS SECTION.

(c) AN EXPLANATION AND DEMONSTRATION OF HOW DIFFERENCES IN ACTUARIALLY SOUND ESTIMATES OF PRESCRIPTION DRUG REBATES TO BE RECEIVED DURING A PLAN YEAR AND ACTUAL PRESCRIPTION DRUG REBATES RECEIVED DURING THAT PLAN YEAR ARE ACCOUNTED FOR IN MEDICAL-LOSS RATIO REFUND CALCULATIONS FOR THAT PLAN YEAR;

(d) FOR SMALL GROUP AND LARGE EMPLOYER PLANS, ADMINISTRATIVE FEES, DISPENSING FEES, DRUG UTILIZATION REVIEW FEES, AND THE AVERAGE REIMBURSEMENT FOR NONSPECIALTY, BRAND-NAME PRESCRIPTION DRUGS; AND

(e) AN ACTUARIAL CERTIFICATION THAT ATTESTS THAT:

(I) THE HEALTH INSURER OR PBM IS IN COMPLIANCE WITH SUBSECTION (3) OF THIS SECTION; AND

(II) THE DATA REPORTED AS REQUIRED BY THIS SUBSECTION (5) IS ACCURATE.

(7) THE DIVISION MAY USE DATA FROM THE DEPARTMENT OF HEALTH CARE POLICY AND FINANCING, THE ALL-PAYER CLAIM DATABASE DESCRIBED IN SECTION 25.5-1-204, AND OTHER SOURCES TO VERIFY THAT A HEALTH INSURER OR PBM IS IN COMPLIANCE WITH THIS SECTION.

(8) THE DIVISION SHALL NOT DISCLOSE OR OTHERWISE MAKE

AVAILABLE TO THE PUBLIC ANY MATERIALS OR INFORMATION RECEIVED PURSUANT TO THIS SECTION THAT CONTAINS TRADE SECRETS OR CONFIDENTIAL OR PROPRIETARY DATA THAT IS NOT OTHERWISE AVAILABLE TO THE PUBLIC.

(9) THIS SECTION DOES NOT PROHIBIT A HEALTH INSURER FROM DECREASING COST-SHARING AMOUNTS OR PREMIUMS BY AN AMOUNT GREATER THAN THE AMOUNT REQUIRED IN SUBSECTION (3) OF THIS SECTION.

(10) THE REQUIREMENTS OF SUBSECTIONS (3) AND (6) OF THIS SECTION APPLY TO A SELF-FUNDED HEALTH BENEFIT PLAN AND ITS PLAN MEMBERS ONLY IF THE ENTITY THAT PROVIDES THE PLAN ELECTS TO BE SUBJECT TO SUBSECTIONS (3) AND (6) OF THIS SECTION FOR ITS MEMBERS IN COLORADO.

(11) FOR EACH HEALTH BENEFIT PLAN ISSUED OR RENEWED ON OR AFTER JANUARY 1, 2024, THE CONTRACTED REIMBURSEMENT AMOUNT PAID BY THE HEALTH INSURER OR THE PBM TO THE CONTRACTED PHARMACY FOR A PRESCRIPTION DRUG MUST BE THE SAME AS THE CHARGE BY THE HEALTH INSURER OR THE PBM TO THE RESPECTIVE INDIVIDUAL HEALTH BENEFIT PLAN OR EMPLOYER-SPONSORED PLAN FOR THAT DRUG.

(12) THE COMMISSIONER SHALL PROMULGATE RULES TO IMPLEMENT AND ENFORCE THIS SECTION.

SECTION 7. In Colorado Revised Statutes, **add** 25.5-5-513 as follows:

25.5-5-513. Pharmacy benefits - prescription drugs - rebates - analysis. (1) BEGINNING IN 2023, THE STATE DEPARTMENT SHALL, IN COLLABORATION WITH THE ADMINISTRATOR OF THE ALL-PAYER CLAIMS DATABASE DESCRIBED IN SECTION 25.5-1-204, CONDUCT AN ANNUAL

ANALYSIS OF THE PRESCRIPTION DRUG REBATES RECEIVED IN THE PREVIOUS CALENDAR YEAR, BY HEALTH INSURANCE CARRIER AND PRESCRIPTION DRUG TIER. THE ANALYSIS, USING DATA FROM THE ALL-PAYERS CLAIM DATABASE AND OTHER SOURCES, MUST BE COMPLETED ON OR BEFORE MAY 1 OF EACH YEAR.

(2) THE STATE DEPARTMENT SHALL MAKE THE ANALYSIS CONDUCTED IN SUBSECTION (1) OF THIS SECTION AVAILABLE TO THE PUBLIC ON AN ANNUAL BASIS.

SECTION 8. Act subject to petition - effective date - applicability. (1) This act takes effect at 12:01 a.m. on the day following the expiration of the ninety-day period after final adjournment of the general assembly; except that, if a referendum petition is filed pursuant to section 1 (3) of article V of the state constitution against this act or an item, section, or part of this act within such period, then the act, item, section, or part will not take effect unless approved by the people at the general election to be held in November 2022 and, in such case, will take effect on the date of the official declaration of the vote thereon by the governor.

(2) Section 1 of this act applies to health benefit plans issued or renewed on or after January 1, 2023.

(3) Sections 2 through 6 of this act apply to health benefit plans issued or renewed on or after January 1, 2024.