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Seventy-third General Assembly
STATE OF COLORADO

REREVISED
This Version Includes All Amendments
Adopted in the Second House

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

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May 9, 2022

SENATE
Amended 2nd Reading
May 6, 2022

HOUSE
3rd Reading Unamended
May 2, 2022

HOUSE
Amended 2nd Reading
April 29, 2022

A BILL FOR AN ACT

CONCERNING COVERAGE REQUIREMENTS FOR HEALTH-CARE PRODUCTS, AND, IN CONNECTION THEREWITH, MAKING AN APPROPRIATION.

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 IN THE INDIVIDUAL MARKET, 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 ON THE INDIVIDUAL MARKET 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 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;

(b) MOVE A PRESCRIPTION DRUG FROM A PRESCRIPTION DRUG COST-SHARING TIER THAT IMPOSES A LESSER COPAYMENT OR DEDUCTIBLE

FOR THE PRESCRIPTION DRUG TO A COST-SHARING TIER THAT IMPOSES A GREATER COPAYMENT OR DEDUCTIBLE FOR THE PRESCRIPTION DRUG IF THE CARRIER ADDS TO THE PRESCRIPTION DRUG FORMULARY OR LIST OF COVERED DRUGS A GENERIC PRESCRIPTION DRUG OR BIOSIMILAR DRUG THAT IS:

(I) APPROVED BY THE FDA FOR USE AS A THERAPEUTIC EQUIVALENT; AND

(II) IN A PRESCRIPTION DRUG COST-SHARING TIER THAT IMPOSES A COPAYMENT OR DEDUCTIBLE FOR THE GENERIC PRESCRIPTION DRUG OR BIOSIMILAR 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; OR

(c) REMOVE A PRESCRIPTION DRUG FROM THE PRESCRIPTION DRUG FORMULARY OR LIST OF COVERED DRUGS, OR MOVE A PRESCRIPTION DRUG TO A HIGHER COST SHARING TIER, WITH ADVANCE NOTICE TO A COVERED PERSON AND THE COVERED PERSON'S PROVIDER, IF:

(I) THE PRESCRIPTION DRUG HAS A WHOLESALE ACQUISITION COST GREATER THAN FIVE HUNDRED DOLLARS AT THE START OF THE BENEFIT YEAR AND THE CARRIER'S NET COST INCREASES BY FIFTEEN PERCENT OR MORE DURING THAT BENEFIT YEAR; AND

(II) THE PRESCRIPTION DRUG WILL BE REPLACED ON THE FORMULARY WITH A THERAPEUTICALLY EQUIVALENT GENERIC OR MULTI-SOURCE BRAND NAME DRUG, AN INTERCHANGEABLE BIOLOGIC, OR BIOSIMILAR DRUG AT A LOWER COST TO THE ENROLLEE.

(d) PRIOR TO REMOVING A DRUG FROM A FORMULARY PURSUANT TO THIS SECTION, THE CARRIER MUST ATTEST AND DEMONSTRATE TO THE

DIVISION, IN A FORM AND MANNER DETERMINED BY THE COMMISSIONER BY RULE, THAT IT HAS COMPLIED WITH THE REQUIREMENTS OF THIS SECTION AND HAS PROVIDED ADVANCED NOTICE TO ITS ENROLLEES.

(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) "BIOSIMILAR" HAS THE MEANING SET FORTH IN 42 U.S.C. SEC. 262 (i)(2).

(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) "EXIGENT CIRCUMSTANCE" MEANS A CIRCUMSTANCE IN WHICH A COVERED PERSON IS SUFFERING FROM A HEALTH CONDITION THAT MAY

SERIOUSLY JEOPARDIZE THE COVERED PERSON'S LIFE, HEALTH, OR ABILITY TO REGAIN MAXIMUM FUNCTIONS.

(e) "MEDICAL NECESSITY" HAS THE SAME MEANING AS SET FORTH IN SECTION 10-16-112.5.

(f) "PRIVATE UTILIZATION REVIEW ORGANIZATION" OR "ORGANIZATION" HAS THE SAME MEANING AS SET FORTH IN SECTION 10-16-112 (1)(a).

(g) "STEP THERAPY" MEANS A PROTOCOL THAT REQUIRES A COVERED PERSON TO USE A PRESCRIPTION DRUG OR SEQUENCE OF PRESCRIPTION DRUGS, OTHER THAN THE DRUG THAT THE COVERED PERSON'S HEALTH-CARE PROVIDER RECOMMENDS FOR THE COVERED PERSON'S TREATMENT, BEFORE THE CARRIER PROVIDES COVERAGE FOR THE RECOMMENDED PRESCRIPTION DRUG.

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

(3) A CARRIER, PRIVATE UTILIZATION REVIEW ORGANIZATION, OR PBM SHALL:

(a) MAKE THE CLINICAL REVIEW CRITERIA AND THE STEP THERAPY EXEMPTION PROCESS AVAILABLE ON THEIR WEBSITES; AND

(b) UPON WRITTEN REQUEST, 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.

(4) (a) A CARRIER, A PRIVATE UTILIZATION REVIEW ORGANIZATION, OR A PBM SHALL GRANT AN EXCEPTION TO STEP THERAPY IF THE PRESCRIBING PROVIDER SUBMITS JUSTIFICATION AND SUPPORTING CLINICAL DOCUMENTATION, IF NEEDED, THAT STATES:

(I) THE PROVIDER ATTESTS THAT 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 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 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 AFTER UNDERGOING STEP THERAPY OR AFTER HAVING SOUGHT AND RECEIVED A STEP-THERAPY EXCEPTION.

(b) (I) EXCEPT AS PROVIDED IN SUBSECTION (4)(b)(II) OF THIS SECTION, A CARRIER, ORGANIZATION, OR PBM SHALL GRANT OR DENY A STEP THERAPY EXCEPTION REQUEST OR AN APPEAL OF A DENIAL OF A

REQUEST WITHIN:

(A) THREE BUSINESS DAYS AFTER RECEIPT OF THE REQUEST; OR

(B) IN CASES WHERE EXIGENT CIRCUMSTANCES EXIST, WITHIN TWENTY-FOUR HOURS AFTER RECEIPT OF THE REQUEST.

(II) IF A REQUEST FOR A STEP THERAPY EXCEPTION OR AN APPEAL OF A DENIAL OF A REQUEST IS INCOMPLETE OR IF ADDITIONAL CLINICALLY RELEVANT INFORMATION IS REQUIRED, THE CARRIER, ORGANIZATION, OR PBM SHALL NOTIFY THE PRESCRIBING PROVIDER WITHIN SEVENTY-TWO HOURS AFTER SUBMISSION OF THE REQUEST, OR WITHIN TWENTY-FOUR HOURS AFTER THE SUBMISSION OF THE REQUEST IF EXIGENT CIRCUMSTANCES EXIST, THAT THE REQUEST OR APPEAL IS INCOMPLETE OR THAT ADDITIONAL CLINICALLY RELEVANT INFORMATION IS REQUIRED. THE CARRIER, ORGANIZATION, OR PBM MUST SPECIFY THE ADDITIONAL INFORMATION THAT IS REQUIRED IN ORDER TO CONSIDER THE STEP THERAPY EXCEPTION REQUEST OR THE APPEAL OF THE DENIAL OF THE REQUEST PURSUANT TO THE CRITERIA DESCRIBED IN SUBSECTION (4)(a) OF THIS SECTION. ONCE THE REQUESTED INFORMATION IS SUBMITTED TO THE CARRIER, ORGANIZATION, OR PBM, THE APPLICABLE PERIOD TO GRANT OR DENY A STEP THERAPY EXCEPTION REQUEST OR AN APPEAL OF A DENIAL OF A REQUEST, AS SPECIFIED IN SUBSECTION (4)(b)(I) OF THIS SECTION, APPLIES.

(III) IF A CARRIER, ORGANIZATION, OR PBM DOES NOT MAKE A DETERMINATION REGARDING THE STEP THERAPY EXCEPTION REQUEST OR THE APPEAL OF THE DENIAL OF THE REQUEST OR DOES NOT MAKE A REQUEST FOR ADDITIONAL OR CLINICALLY RELEVANT INFORMATION WITHIN THE REQUIRED TIME, THE STEP THERAPY EXCEPTION REQUEST OR THE APPEAL OF THE DENIAL OF THE REQUEST IS DEEMED GRANTED.

(c) IF THE INITIAL REQUEST FOR A STEP-THERAPY 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 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 A GENERIC EQUIVALENT DRUG, A BIOSIMILAR DRUG, 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 EXCEPTION AND THE PRESCRIBED DRUG MEETS THE CRITERIA FOR A STEP-THERAPY 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 ~~step-therapy~~ STEP THERAPY 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" HAS THE SAME MEANING AS SPECIFIED IN SECTION 10-16-145 (1)(g).

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 ~~step-therapy~~ STEP THERAPY 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 ~~step-therapy~~ STEP THERAPY or prior authorization, as defined in section 10-16-112.5 (7)(d), for that atypical opioid; and

~~(II)~~ (b) Not require ~~step-therapy~~ STEP THERAPY 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" HAS THE SAME MEANING AS SPECIFIED IN SECTION 10-16-145 (1)(g).

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

10-16-155. Prescription drugs - rebates - consumer cost reduction - point of sale - study - report - rules - definitions. (1) AS USED IN THIS SECTION, UNLESS THE CONTEXT OTHERWISE REQUIRES:

(a) "DISCOUNT" MEANS PRICE REDUCTIONS OR CONCESSIONS, INCLUDING BASE PRICE CONCESSIONS OR OTHER CONTRACTUAL AGREEMENTS MADE BY A MANUFACTURER OR ITS AFFILIATE, THAT REDUCE PAYMENT OR LIABILITY FOR PRESCRIPTION DRUGS INCLUDING A REDUCTION IN THE TOTAL AMOUNT PAID FOR PRESCRIPTION DRUGS, WITHOUT REGARD TO PERFORMANCE, VOLUME, OR UTILIZATION OF THE DRUGS AND ALL OTHER COMPENSATION THAT REDUCES PAYMENT OR LIABILITY FOR PRESCRIPTION DRUGS. "DISCOUNT" DOES NOT INCLUDE A REBATE.

(b) "HEALTH INSURER" MEANS A CARRIER:

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

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

(c) "MANUFACTURER" HAS THE SAME MEANING AS SET FORTH IN SECTION 10-16-1401 (16).

(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) "REBATE" MEANS ALL PRICE CONCESSIONS MADE BY A MANUFACTURER OR ITS AFFILIATE THAT ACCRUE TO A PBM OR ITS HEALTH INSURER CLIENT, INCLUDING CREDITS OR INCENTIVES THAT ARE BASED ON ACTUAL OR ESTIMATED UTILIZATION OF PRESCRIPTION DRUGS; THAT RESULT IN THE PLACEMENT OF A PRESCRIPTION DRUG IN A PREFERRED DRUG LIST OR FORMULARY OR PREFERRED FORMULARY POSITION; OR THAT ARE ASSOCIATED WITH CLAIMS ADMINISTERED ON BEHALF OF AN INSURER CLIENT. "REBATE" ALSO INCLUDES CREDITS, INCENTIVES, REFUNDS, AND ALL OTHER COMPENSATION THAT IS PERFORMANCE-BASED. "REBATE" DOES NOT INCLUDE A DISCOUNT.

(2) FOR EACH HEALTH BENEFIT PLAN ISSUED OR RENEWED ON OR AFTER JANUARY 1, 2024, A HEALTH INSURER SHALL ENSURE THAT ONE HUNDRED PERCENT OF DISCOUNTS RECEIVED OR TO BE RECEIVED FROM A MANUFACTURER IN CONNECTION WITH DISPENSING OR ADMINISTERING PRESCRIPTION DRUGS INCLUDED IN THE HEALTH INSURER'S FORMULARY, AS DEMONSTRATED IN THE HEALTH INSURER'S RATE FILING PURSUANT TO SECTION 10-16-107, FOR THAT PLAN YEAR ARE USED TO REDUCE COSTS.

(3) FOR EACH HEALTH BENEFIT PLAN ISSUED OR RENEWED ON OR AFTER JANUARY 1, 2024, A HEALTH INSURER SHALL ENSURE 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 POLICYHOLDER COSTS;

(b) FOR SMALL GROUP AND LARGE GROUP HEALTH BENEFIT PLANS,

ALL REBATES ARE USED TO REDUCE EMPLOYER OR INDIVIDUAL EMPLOYEE COSTS; AND

(c) FOR INDIVIDUAL HEALTH BENEFIT PLANS, ALL REBATES ARE USED TO REDUCE CONSUMER PREMIUMS AND OUT-OF-POCKET COSTS FOR PRESCRIPTION DRUGS AND THAT HEALTH INSURERS WILL MAXIMIZE THE USE OF REBATES TO REDUCE CONSUMER OUT-OF-POCKET COSTS AT THE POINT OF SALE NOT TO EXCEED THE CONSUMER'S ACTUAL OUT-OF-POCKET COSTS FOR THE PRESCRIPTION DRUG IF THE USE OF SUCH REBATES WILL NOT:

(I) INCREASE PREMIUMS;

(II) CHANGE THE ACTUARIAL VALUE OF THE PLAN INCONSISTENT WITH FEDERAL AND STATE REQUIREMENTS; OR

(III) OTHERWISE RESULT IN AN IMPACT THAT IS NOT IN THE BEST INTEREST OF CONSUMERS.

(4) (a) ON OR BEFORE JUNE 1, 2023, THE DIVISION SHALL CONDUCT AND COMPLETE A STUDY TO EVALUATE HOW REBATES MAY BE APPLIED IN THE INDIVIDUAL MARKET TO REDUCE A COVERED PERSON'S OUT-OF-POCKET COSTS AT THE POINT OF SALE OR TO REDUCE OUT-OF-POCKET COSTS IN PRESCRIPTION DRUG TIERS, TAKING INTO CONSIDERATION THE FOLLOWING FACTORS:

(I) PREMIUM IMPACTS;

(II) CHANGES IN THE PLAN'S ACTUARIAL VALUE; AND

(III) OTHER POTENTIAL IMPACTS TO CONSUMERS.

(b) REGARDLESS OF THE RESULTS OF THE STUDY, A HEALTH INSURER SHALL COMPLY WITH SUBSECTION (3) OF THIS SECTION.

(c) THE DIVISION MAY CONTRACT WITH A THIRD PARTY TO CONDUCT THE STUDY REQUIRED BY THIS SUBSECTION (4). THE

COMMISSIONER IS NOT REQUIRED TO COMPLY WITH THE "PROCUREMENT CODE", ARTICLES 101 TO 112 OF TITLE 24, FOR THE PURPOSES OF THIS SECTION, BUT SHALL ENSURE A COMPETITIVE PROCESS IS USED TO SELECT A THIRD PARTY TO CONDUCT THE STUDY.

(5) EACH HEALTH INSURER SHALL REPORT ANNUALLY:

(a) IN A FORM AND MANNER DETERMINED BY THE COMMISSIONER, DATA DEMONSTRATING THAT ALL DISCOUNTS AND REBATES RECEIVED BY HEALTH INSURERS ARE USED TO REDUCE COSTS FOR POLICYHOLDERS IN COMPLIANCE WITH THIS SECTION. THE COMMISSIONER MAY USE DISCOUNT AND REBATE DATA SUBMITTED BY HEALTH INSURERS TO THE ALL-PAYER HEALTH CLAIMS DATABASE DESCRIBED IN SECTION 25.5-1-204 TO THE EXTENT SUCH DATA ARE AVAILABLE FROM THE ALL-PAYER HEALTH CLAIMS DATABASE.

(b) AN ACTUARIAL CERTIFICATION THAT ATTESTS THAT:

(I) THE HEALTH INSURER AND PBM ARE IN COMPLIANCE WITH SUBSECTIONS (2) AND (3) OF THIS SECTION; AND

(II) THE DATA REPORTED AS REQUIRED BY THIS SECTION ARE ACCURATE.

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

(7) INFORMATION SUBMITTED BY THE HEALTH INSURERS AND PBMS TO THE DIVISION IN ACCORDANCE WITH THIS SECTION IS SUBJECT TO PUBLIC INSPECTION ONLY TO THE EXTENT ALLOWED UNDER THE "COLORADO OPEN RECORDS ACT", PART 2 OF ARTICLE 72 OF TITLE 24,

AND IN NO CASE SHALL TRADE-SECRET, CONFIDENTIAL, OR PROPRIETARY INFORMATION BE DISCLOSED TO ANY PERSON WHO IS NOT OTHERWISE AUTHORIZED TO ACCESS SUCH INFORMATION.

(8) 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 (2) OR (3) OF THIS SECTION.

(9) THE REQUIREMENTS OF SUBSECTIONS (2), (3), AND (5) 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 (2), (3), AND (5) OF THIS SECTION FOR ITS MEMBERS IN COLORADO.

(10) 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. Appropriation. (1) For the 2022-23 state fiscal year, $252,667 is appropriated to the department of regulatory agencies for use by the division of insurance. This appropriation is from the division of insurance cash fund created in section 10-1-103 (3), C.R.S. To implement this act, the division may use this appropriation as follows:

(a) $237,972 for personal services, which amount is based on an assumption that the division will require an additional 1.7 FTE; and

(b) $14,695 for operating expenses.

SECTION 9. 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.