HB1370_H_HI.001

HOUSE COMMITTEE OF REFERENCE REPORT

_____ April 27, 2022
Chair of Committee Date

Committee on Health & Insurance.

After consideration on the merits, the Committee recommends the following:

HB22-1370 be amended as follows, and as so amended, be referred to the Committee on Appropriations with favorable recommendation:

Amend printed bill, page 4, line 16, strike "ADVANCE".

Page 5, line 4, strike "AN ALTERNATIVE TO THE".

Page 5, strike line 5 and substitute "A THERAPEUTIC EQUIVALENT; AND".

Page 5, strike lines 20 through 23.

Page 5, line 24, strike "(b)" and substitute "(a)".

Page 6, line 1, strike "(c)" and substitute "(b)".

Page 6, strike lines 8 through 25 and substitute:

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

Page 6, line 26, strike "(f)" and substitute "(d)".

Page 7, strike lines 2 through 6 and substitute:

"(e) "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.".

Page 7, line 8, strike "A STEP-THERAPY PROTOCOL," and substitute "STEP THERAPY,".

Page 7, line 10, after "PROTOCOL" insert "FOR STEP THERAPY".

Page 7, strike lines 11 through 14 and substitute:

"(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".

Page 7, line 17, strike " REQUESTER; AND" and substitute "REQUESTER.".

Page 7, strike lines 18 through 20.

Page 7, line 22, strike the second "A".

Page 7, strike line 23 and substitute "STEP THERAPY IF THE PRESCRIBING PROVIDER SUBMITS JUSTIFICATION AND SUPPORTING CLINICAL DOCUMENTATION, IF NEEDED, THAT STATES:".

Page 7, line 27, strike "EXPECTED TO BE".

Page 8, strike lines 11 and 12.

Renumber succeeding subparagraph accordingly.

Page 8, line 16, strike "CONSIDERATION." and substitute "CONSIDERATION AFTER UNDERGOING STEP THERAPY OR AFTER HAVING SOUGHT AND RECEIVED A STEP-THERAPY EXCEPTION.".

Page 8, strike lines 17 through 26 and substitute:

"(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.".

Page 9, line 12, strike "AN AB-RATED" and substitute "A".

Page 10, line 19, strike ""STEP-THERAPY PROTOCOL"" and substitute ""STEP THERAPY"".

Page 10, line 20, strike "10-16-145 (1)(f)" and substitute "10-16-145 (1)(e)".

Page 12, line 6, strike ""STEP-THERAPY PROTOCOL"" and substitute ""STEP THERAPY"".

Page 12, line 7, strike "10-16-145 (1)(f)" and substitute "10-16-145 (1)(e)".

Page 12, strike lines 10 through 27.

Strike pages 13 through 17.

Page 18, strike lines 1 through 21 and substitute:

"**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 OR ITS AFFILIATE, 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.".

Strike "BRAND-NAME" on: **Page 4**, lines 24 and 26; and **Page 5**, line 1.

Strike "PROTOCOL" on: **Page 8**, line 27; and **Page 9**, lines 8, 15, and 17.

Strike "A step-therapy PROTOCOL" and substitute "~~step-therapy~~ STEP THERAPY" on: **Page 10**, lines 8 and 9; and **Page 11**, lines 3 and 4, 16 and 17, and 19.

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