

An Act

SENATE BILL 21-175

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CONCERNING THE COLORADO PRESCRIPTION DRUG AFFORDABILITY REVIEW BOARD, AND, IN CONNECTION THEREWITH, DIRECTING THE BOARD TO REVIEW THE AFFORDABILITY OF CERTAIN DRUGS AND ESTABLISH UPPER PAYMENT LIMITS FOR CERTAIN DRUGS; PROHIBITING CERTAIN ENTITIES FROM PURCHASING OR REIMBURSING FOR ANY DRUG FOR DISTRIBUTION IN THE STATE AT AN AMOUNT THAT EXCEEDS THE UPPER PAYMENT LIMIT ESTABLISHED FOR THE PRESCRIPTION DRUG; ESTABLISHING PENALTIES FOR VIOLATIONS; AND MAKING AN APPROPRIATION.

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

SECTION 1. Legislative declaration. (1) The general assembly finds that:

Capital letters or bold & italic numbers indicate new material added to existing law; dashes through words or numbers indicate deletions from existing law and such material is not part of the act.

(a) Excessive costs for prescription drugs:

(I) Negatively impact the ability of Coloradans to obtain prescription drugs, and price increases that exceed reasonable levels endanger the health and safety of Coloradans;

(II) Threaten the economic well-being of Coloradans and endanger their ability to pay for other necessary and essential goods and services, including housing, food, and utilities;

(III) Contribute significantly to a dramatic and unsustainable rise in health-care costs and health insurance premiums that threatens the financial health of Coloradans and their ability to maintain their physical health;

(IV) Pose a threat to the health and safety of all Coloradans but disproportionately harm people of color and Coloradans with low incomes; and

(V) Contribute significantly to rising costs for health care that is provided to public employees, including employees of state, county, and local governments, school districts, and institutions of higher education, and to public retirees whose health-care costs are funded by public programs, thereby threatening the ability of state and local governments to adequately fund those programs and other important services, such as public education and public safety;

(b) Lack of transparency in health insurance costs and wholesaler and pharmacy benefits manager discounts and margins prevents policymakers and the public from gaining a true understanding of the costs of prescription drugs; and

(c) Information relating to the cost of prescription drugs in Colorado is necessary to provide accountability to the state and to all Coloradans for prescription drug pricing.

(2) The general assembly therefore declares that in exercise of its police powers and responsibility for the public health, safety, and general welfare of Colorado residents, it is imperative that Colorado take measures to reduce excessive prescription drug costs for Coloradans who cannot afford prescription drugs and create a prescription drug affordability board

with the authority to review prescription drug costs and protect Colorado residents and entities who purchase or reimburse for prescription drugs from the excessive costs of prescription drugs, including but not limited to state and local governments, contractors and vendors, commercial health plans, providers, and pharmacies.

SECTION 2. In Colorado Revised Statutes, **add** part 14 to article 16 of title 10 as follows:

PART 14
COLORADO PRESCRIPTION DRUG
AFFORDABILITY REVIEW BOARD

10-16-1401. Definitions. AS USED IN THIS PART 14, UNLESS THE CONTEXT OTHERWISE REQUIRES:

(1) "ADVISORY COUNCIL" MEANS THE COLORADO PRESCRIPTION DRUG AFFORDABILITY ADVISORY COUNCIL CREATED IN SECTION 10-16-1409.

(2) "AFFORDABILITY REVIEW" MEANS AN AFFORDABILITY REVIEW OF A PRESCRIPTION DRUG PERFORMED BY THE BOARD PURSUANT TO SECTION 10-16-1406.

(3) "ALL-PAYER HEALTH CLAIMS DATABASE" MEANS THE ALL-PAYER HEALTH CLAIMS DATABASE DESCRIBED IN SECTION 25.5-1-204.

(4) "AUTHORIZED GENERIC DRUG" HAS THE MEANING SET FORTH IN 42 CFR 447.502.

(5) "BIOLOGICAL PRODUCT" HAS THE MEANING SET FORTH IN 42 U.S.C. SEC. 262 (i)(1).

(6) "BIOSIMILAR DRUG" MEANS A PRESCRIPTION DRUG THAT IS PRODUCED OR DISTRIBUTED IN ACCORDANCE WITH A BIOLOGICAL PRODUCT LICENSE ISSUED PURSUANT TO 42 U.S.C. SEC. 262 (k)(3).

(7) "BOARD" MEANS THE COLORADO PRESCRIPTION DRUG AFFORDABILITY REVIEW BOARD CREATED IN SECTION 10-16-1402.

(8) "BRAND-NAME DRUG" MEANS A PRESCRIPTION DRUG THAT IS

PRODUCED OR DISTRIBUTED IN ACCORDANCE WITH AN ORIGINAL NEW DRUG APPLICATION APPROVED PURSUANT TO 21 U.S.C. SEC. 355. "BRAND-NAME DRUG" DOES NOT INCLUDE AN AUTHORIZED GENERIC DRUG.

(9) "CARRIER" HAS THE MEANING SET FORTH IN SECTION 10-16-102 (8).

(10) "CONFLICT OF INTEREST" MEANS AN ASSOCIATION, INCLUDING A FINANCIAL OR PERSONAL ASSOCIATION, THAT HAS THE POTENTIAL TO BIAS OR APPEAR TO BIAS AN INDIVIDUAL'S DECISIONS IN MATTERS RELATED TO THE BOARD OR THE ADVISORY COUNCIL OR THE CONDUCT OF THE ACTIVITIES OF THE BOARD OR THE ADVISORY COUNCIL. "CONFLICT OF INTEREST" INCLUDES ANY INSTANCE IN WHICH A BOARD MEMBER; AN ADVISORY COUNCIL MEMBER; A STAFF MEMBER; A CONTRACTOR OF THE DIVISION, ON BEHALF OF THE BOARD; OR AN IMMEDIATE FAMILY MEMBER OF A BOARD MEMBER, AN ADVISORY COUNCIL MEMBER, A STAFF MEMBER, OR A CONTRACTOR OF THE DIVISION, ON BEHALF OF THE BOARD, HAS RECEIVED OR COULD RECEIVE:

(a) A FINANCIAL BENEFIT OF ANY AMOUNT DERIVED FROM THE RESULTS OR FINDINGS OF A STUDY OR DETERMINATION THAT IS REACHED BY OR FOR THE BOARD; OR

(b) A FINANCIAL BENEFIT FROM AN INDIVIDUAL OR COMPANY THAT OWNS OR MANUFACTURES A PRESCRIPTION DRUG, SERVICE, OR ITEM THAT IS BEING OR WILL BE STUDIED BY THE BOARD.

(11) "FINANCIAL BENEFIT" MEANS HONORARIA, FEES, STOCK, OR ANY OTHER FORM OF COMPENSATION, INCLUDING INCREASES TO THE VALUE OF EXISTING STOCK HOLDINGS.

(12) "GENERIC DRUG" MEANS:

(a) A PRESCRIPTION DRUG THAT IS MARKETED OR DISTRIBUTED IN ACCORDANCE WITH AN ABBREVIATED NEW DRUG APPLICATION APPROVED PURSUANT TO 21 U.S.C. SEC. 355 (j);

(b) AN AUTHORIZED GENERIC DRUG; OR

(c) A PRESCRIPTION DRUG THAT WAS INTRODUCED FOR RETAIL SALE

BEFORE 1962 THAT WAS NOT ORIGINALLY MARKETED UNDER A NEW DRUG APPLICATION.

(13) "HEALTH BENEFIT PLAN" HAS THE MEANING SET FORTH IN SECTION 10-16-102 (32).

(14) "INFLATION" MEANS THE ANNUAL PERCENTAGE CHANGE IN THE UNITED STATES DEPARTMENT OF LABOR'S BUREAU OF LABOR STATISTICS CONSUMER PRICE INDEX FOR DENVER-AURORA-LAKEWOOD FOR ALL ITEMS PAID BY ALL URBAN CONSUMERS, OR ITS APPLICABLE PREDECESSOR OR SUCCESSOR INDEX.

(15) (a) "LARGE EMPLOYER" MEANS ANY PERSON, FIRM, CORPORATION, PARTNERSHIP, OR ASSOCIATION THAT:

(I) IS ACTIVELY ENGAGED IN BUSINESS;

(II) EMPLOYED AN AVERAGE OF MORE THAN ONE HUNDRED ELIGIBLE EMPLOYEES ON BUSINESS DAYS DURING THE IMMEDIATELY PRECEDING CALENDAR YEAR, EXCEPT AS PROVIDED IN SUBSECTION (15)(c) OF THIS SECTION; AND

(III) WAS NOT FORMED PRIMARILY FOR THE PURPOSE OF PURCHASING INSURANCE.

(b) FOR PURPOSES OF DETERMINING WHETHER AN EMPLOYER IS A "LARGE EMPLOYER", THE NUMBER OF ELIGIBLE EMPLOYEES IS CALCULATED USING THE METHOD SET FORTH IN 26 U.S.C. SEC. 4980H (c)(2)(E).

(c) IN THE CASE OF AN EMPLOYER THAT WAS NOT IN EXISTENCE THROUGHOUT THE PRECEDING CALENDAR QUARTER, THE DETERMINATION OF WHETHER THE EMPLOYER IS A LARGE EMPLOYER IS BASED ON THE AVERAGE NUMBER OF EMPLOYEES THAT THE EMPLOYER IS REASONABLY EXPECTED TO EMPLOY ON BUSINESS DAYS IN THE CURRENT CALENDAR YEAR.

(16) "MANUFACTURER" MEANS A PERSON THAT:

(a) ENGAGES IN THE MANUFACTURE OF A PRESCRIPTION DRUG THAT IS SOLD TO PURCHASERS LOCATED IN THIS STATE; OR

(b) (I) ENTERS INTO A LEASE OR OTHER CONTRACTUAL AGREEMENT WITH A MANUFACTURER TO MARKET AND DISTRIBUTE A PRESCRIPTION DRUG IN THIS STATE UNDER THE PERSON'S OWN NAME; AND

(II) SETS OR CHANGES THE WHOLESALE ACQUISITION COST OF THE PRESCRIPTION DRUG IN THIS STATE.

(17) "OPTIONAL PARTICIPATING PLAN" MEANS A SELF-FUNDED HEALTH BENEFIT PLAN OFFERED IN COLORADO THAT ELECTS TO SUBJECT ITS PURCHASES OF OR PAYER REIMBURSEMENTS FOR PRESCRIPTION DRUGS FOR ITS MEMBERS IN COLORADO TO THE REQUIREMENTS OF THIS PART 14, AS DESCRIBED IN SECTION 10-16-1407 (8).

(18) "PRACTITIONER" HAS THE MEANING SET FORTH IN SECTION 12-280-103 (40).

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

(20) "PRICING INFORMATION" MEANS INFORMATION ABOUT THE PRICE OF A PRESCRIPTION DRUG, INCLUDING INFORMATION THAT EXPLAINS OR HELPS EXPLAIN HOW THE PRICE WAS DETERMINED.

(21) "SMALL EMPLOYER" HAS THE MEANING SET FORTH IN SECTION 10-16-102 (61).

(22) "STATE ENTITY" MEANS ANY AGENCY OF STATE GOVERNMENT THAT PURCHASES OR REIMBURSES PAYERS FOR PRESCRIPTION DRUGS ON BEHALF OF THE STATE FOR A PERSON WHOSE HEALTH CARE IS PAID FOR BY THE STATE, INCLUDING ANY AGENT, VENDOR, CONTRACTOR, OR OTHER PARTY ACTING ON BEHALF OF THE STATE.

(23) "UPPER PAYMENT LIMIT" MEANS THE MAXIMUM AMOUNT THAT MAY BE PAID OR BILLED FOR A PRESCRIPTION DRUG THAT IS DISPENSED OR DISTRIBUTED IN COLORADO IN ANY FINANCIAL TRANSACTION CONCERNING THE PURCHASE OF OR REIMBURSEMENT FOR THE PRESCRIPTION DRUG.

(24) "WHOLESALE ACQUISITION COST" HAS THE MEANING SET FORTH IN 42 U.S.C. SEC. 1395w-3a (c)(6)(B).

(25) "WHOLESALE" HAS THE MEANING SET FORTH IN SECTION 12-280-103 (55).

10-16-1402. Colorado prescription drug affordability review board - created - membership - terms - conflicts of interest. (1) THE COLORADO PRESCRIPTION DRUG AFFORDABILITY REVIEW BOARD IS CREATED IN THE DIVISION. THE BOARD IS A BODY POLITIC AND CORPORATE AND IS AN INSTRUMENTALITY OF THE STATE. THE BOARD IS AN INDEPENDENT UNIT OF STATE GOVERNMENT, AND THE EXERCISE BY THE BOARD OF ITS AUTHORITY UNDER THIS PART 14 IS AN ESSENTIAL PUBLIC FUNCTION.

(2) (a) THE BOARD CONSISTS OF FIVE MEMBERS, WHO MUST EACH HAVE AN ADVANCED DEGREE AND EXPERIENCE OR EXPERTISE IN HEALTH-CARE ECONOMICS OR CLINICAL MEDICINE.

(b) THE GOVERNOR SHALL APPOINT EACH BOARD MEMBER, SUBJECT TO CONFIRMATION BY THE SENATE. ALL OF THE INITIAL MEMBERS OF THE BOARD MUST BE APPOINTED BY OCTOBER 1, 2021.

(c) THE TERM OF OFFICE OF EACH BOARD MEMBER IS THREE YEARS; EXCEPT THAT, AS TO THE TERMS OF THE MEMBERS WHO ARE FIRST APPOINTED TO THE BOARD, TWO SUCH MEMBERS SHALL SERVE THREE-YEAR INITIAL TERMS, TWO SUCH MEMBERS SHALL SERVE TWO-YEAR INITIAL TERMS, AND ONE SUCH MEMBER SHALL SERVE A ONE-YEAR INITIAL TERM, TO BE DETERMINED BY THE GOVERNOR. THE GOVERNOR MAY REMOVE ANY APPOINTED MEMBER OF THE BOARD FOR MALFEASANCE IN OFFICE, FOR FAILURE TO REGULARLY ATTEND MEETINGS, OR FOR ANY CAUSE THAT RENDERS THE MEMBER INCAPABLE OR UNFIT TO DISCHARGE THE DUTIES OF THE MEMBER'S OFFICE, AND ANY SUCH REMOVAL IS NOT SUBJECT TO REVIEW.

(d) THE GOVERNOR SHALL DESIGNATE ONE MEMBER OF THE BOARD TO SERVE AS THE CHAIR. A MAJORITY OF THE BOARD CONSTITUTES A QUORUM. THE CONCURRENCE OF A MAJORITY OF THE BOARD IN ANY MATTER WITHIN ITS POWERS AND DUTIES IS REQUIRED FOR ANY DETERMINATION MADE BY THE BOARD.

(3) (a) AN INDIVIDUAL WHO IS BEING CONSIDERED FOR APPOINTMENT TO THE BOARD SHALL DISCLOSE ANY CONFLICT OF INTEREST TO THE INDIVIDUAL'S POTENTIAL APPOINTING AUTHORITY. WHEN APPOINTING A MEMBER OF THE BOARD, AN APPOINTING AUTHORITY SHALL CONSIDER ANY

CONFLICT OF INTEREST DISCLOSED BY THE PROSPECTIVE MEMBER.

(b) A BOARD MEMBER MUST NOT BE AN EMPLOYEE, BOARD MEMBER, OR CONSULTANT OF:

(I) A MANUFACTURER OR A TRADE ASSOCIATION OF MANUFACTURERS;

(II) A CARRIER OR A TRADE ASSOCIATION OF CARRIERS; OR

(III) A PHARMACY BENEFIT MANAGER OR A TRADE ASSOCIATION OF PHARMACY BENEFIT MANAGERS.

(c) BOARD MEMBERS, STAFF MEMBERS, AND CONTRACTORS OF THE DIVISION, ON BEHALF OF THE BOARD, SHALL RECUSE THEMSELVES FROM ANY BOARD ACTIVITY IN ANY CASE IN WHICH THEY HAVE A CONFLICT OF INTEREST.

(d) ON AND AFTER JANUARY 1, 2022, THE DIVISION SHALL MAINTAIN A PAGE ON ITS PUBLIC WEBSITE FOR THE BOARD TO USE FOR ITS PURPOSES. THE BOARD SHALL DISCLOSE ON THE PAGE EACH CONFLICT OF INTEREST THAT IS DISCLOSED TO THE BOARD PURSUANT TO SUBSECTION (3)(c) OF THIS SECTION AND SECTION 10-16-1409 (5)(b).

(e) BOARD MEMBERS, STAFF MEMBERS, CONTRACTORS OF THE DIVISION, ON BEHALF OF THE BOARD, AND IMMEDIATE FAMILY MEMBERS OF BOARD MEMBERS, STAFF MEMBERS, OR CONTRACTORS SHALL NOT ACCEPT A FINANCIAL BENEFIT OR GIFTS, BEQUESTS, OR DONATIONS OF SERVICES OR PROPERTY THAT SUGGEST A CONFLICT OF INTEREST OR HAVE THE APPEARANCE OF CREATING BIAS IN THE WORK OF THE BOARD.

(4) THE ATTORNEY GENERAL SHALL ASSIGN AN ASSISTANT ATTORNEY GENERAL TO PROVIDE LEGAL COUNSEL TO THE BOARD. ANY ASSISTANT ATTORNEY GENERAL ASSIGNED TO THE BOARD PURSUANT TO THIS SUBSECTION (4) SHALL DISCLOSE ANY CONFLICT OF INTEREST TO THE BOARD.

10-16-1403. Colorado prescription drug affordability review board - powers and duties - rules. (1) TO PROTECT COLORADO CONSUMERS FROM EXCESSIVE PRESCRIPTION DRUG COSTS, THE BOARD SHALL:

(a) COLLECT AND EVALUATE INFORMATION CONCERNING THE COST OF PRESCRIPTION DRUGS SOLD TO COLORADO CONSUMERS, AS DESCRIBED IN SECTION 10-16-1405;

(b) PERFORM AFFORDABILITY REVIEWS OF PRESCRIPTION DRUGS, AS DESCRIBED IN SECTION 10-16-1406;

(c) ESTABLISH UPPER PAYMENT LIMITS FOR PRESCRIPTION DRUGS, AS DESCRIBED IN SECTION 10-16-1407; AND

(d) MAKE POLICY RECOMMENDATIONS TO THE GENERAL ASSEMBLY TO IMPROVE THE AFFORDABILITY OF PRESCRIPTION DRUGS FOR COLORADO CONSUMERS, AS DESCRIBED IN SECTION 10-16-1414 (1)(h).

(2) THE BOARD MAY ESTABLISH AD HOC WORK GROUPS TO CONSIDER MATTERS RELATED TO THE WORK OF THE BOARD PURSUANT TO THIS PART 14. AD HOC WORK GROUPS MAY INCLUDE MEMBERS OF THE PUBLIC.

(3) THE DIVISION, ON BEHALF OF THE BOARD, MAY ENTER INTO A CONTRACT WITH A QUALIFIED, INDEPENDENT THIRD PARTY FOR ANY SERVICE NECESSARY TO CARRY OUT THE POWERS AND DUTIES OF THE BOARD. A THIRD PARTY WITH WHICH THE DIVISION CONTRACTS PURSUANT TO THIS SUBSECTION (3), INCLUDING ANY OF THE THIRD PARTY'S DIRECTORS, OFFICERS, EMPLOYEES, CONTRACTORS, OR AGENTS, SHALL NOT RELEASE OR PUBLISH ANY INFORMATION THAT THE THIRD PARTY ACQUIRES PURSUANT TO ITS PERFORMANCE UNDER THE CONTRACT. ANY THIRD PARTY WITH WHICH THE DIVISION CONTRACTS PURSUANT TO THIS SUBSECTION (3) SHALL DISCLOSE ANY CONFLICT OF INTEREST TO THE BOARD.

(4) IN CARRYING OUT ITS DUTIES PURSUANT TO THIS PART 14, THE DIVISION, WHEN PERFORMING ITS DUTIES ON BEHALF OF THE BOARD, IS EXEMPT FROM THE STATE "PROCUREMENT CODE", ARTICLES 101 TO 112 OF TITLE 24.

(5) THE BOARD SHALL PROMULGATE RULES AS NECESSARY, PURSUANT TO ARTICLE 4 OF TITLE 24, FOR THE IMPLEMENTATION OF THIS PART 14.

(6)(a) THE DIVISION, ON BEHALF OF THE BOARD, MAY SEEK, ACCEPT, AND EXPEND GIFTS, GRANTS, AND DONATIONS FROM PRIVATE OR PUBLIC

SOURCES FOR THE PURPOSES OF THIS PART 14, AND ANY SUCH GIFTS, GRANTS, AND DONATIONS ARE CONTINUOUSLY APPROPRIATED TO THE DEPARTMENT OF REGULATORY AGENCIES; EXCEPT THAT THE DIVISION SHALL NOT ACCEPT ANY GIFT, GRANT, OR DONATION THAT CREATES A CONFLICT OF INTEREST OR THE APPEARANCE OF ANY CONFLICT OF INTEREST FOR ANY BOARD MEMBER.

(b) THE GENERAL ASSEMBLY FINDS THAT THE IMPLEMENTATION OF THIS PART 14 DOES NOT RELY ENTIRELY ON THE RECEIPT OF ADEQUATE FUNDING THROUGH GIFTS, GRANTS, OR DONATIONS. THEREFORE, THE BOARD IS NOT SUBJECT TO THE REPORTING REQUIREMENTS DESCRIBED IN SECTION 24-75-1303.

10-16-1404. Colorado prescription drug affordability review board meetings - required to be public - exceptions. (1) THE BOARD SHALL HOLD ITS FIRST MEETING WITHIN SIX WEEKS AFTER ALL OF THE BOARD MEMBERS ARE APPOINTED AND SHALL MEET AT LEAST EVERY SIX WEEKS THEREAFTER TO REVIEW PRESCRIPTION DRUGS; EXCEPT THAT THE CHAIR MAY CANCEL OR POSTPONE A MEETING IF THE BOARD HAS NO PRESCRIPTION DRUGS TO REVIEW.

(2) THE BOARD IS A STATE PUBLIC BODY FOR PURPOSES OF SECTION 24-6-402, AND THE BOARD'S MEETINGS AND THE MEETINGS OF AD HOC WORK GROUPS OF THE BOARD ARE PUBLIC MEETINGS.

(3) THE BOARD SHALL MEET IN EXECUTIVE SESSION TO DISCUSS PROPRIETARY INFORMATION. THE BOARD AND ANY BOARD MEMBERS, OFFICERS, DIRECTORS, EMPLOYEES, CONTRACTORS, AND AGENTS SHALL NOT DISCLOSE OR OTHERWISE MAKE AVAILABLE TO THE PUBLIC ANY MATERIALS OR INFORMATION CONTAINING TRADE-SECRET, CONFIDENTIAL, OR PROPRIETARY DATA THAT IS NOT OTHERWISE AVAILABLE TO THE PUBLIC. ELECTRONIC RECORDINGS OF SUCH EXECUTIVE SESSIONS ARE NOT PERMITTED IF THEY WOULD RESULT IN THE DISCLOSURE OF ANY MATERIALS OR INFORMATION CONTAINING TRADE-SECRET, CONFIDENTIAL, OR PROPRIETARY DATA, AND IN NO CASE SHALL MINUTES FROM SUCH EXECUTIVE SESSIONS DISCLOSE OR INCLUDE MATERIALS OR INFORMATION CONTAINING TRADE-SECRET, CONFIDENTIAL, OR PROPRIETARY DATA. THE BOARD SHALL NOT TAKE ANY OF THE FOLLOWING ACTIONS WHILE MEETING IN EXECUTIVE SESSION:

(a) DELIBERATIONS CONCERNING WHETHER TO SUBJECT A

PRESCRIPTION DRUG TO AN AFFORDABILITY REVIEW AS DESCRIBED IN SECTION 10-16-1406;

(b) VOTES CONCERNING WHETHER TO ESTABLISH AN UPPER PAYMENT LIMIT ON A PRESCRIPTION DRUG; OR

(c) ANY FINAL DECISION OF THE BOARD.

10-16-1405. Colorado prescription drug affordability review board - reports from carriers and pharmacy benefit management firms required - confidential materials. (1) BEGINNING IN THE 2022 CALENDAR YEAR, FOR ALL PRESCRIPTION DRUGS DISPENSED AT A PHARMACY IN THIS STATE AND PAID FOR BY A CARRIER PURSUANT TO A HEALTH BENEFIT PLAN ISSUED UNDER PART 2, 3, OR 4 OF THIS ARTICLE 16 DURING THE IMMEDIATELY PRECEDING CALENDAR YEAR, INCLUDING BRAND-NAME DRUGS, AUTHORIZED GENERIC DRUGS, BIOLOGICAL PRODUCTS, AND BIOSIMILAR DRUGS:

(a) EACH CARRIER AND EACH PHARMACY BENEFIT MANAGEMENT FIRM ACTING ON BEHALF OF A CARRIER SHALL REPORT TO THE ALL-PAYER HEALTH CLAIMS DATABASE THE FOLLOWING INFORMATION:

(I) THE TOP FIFTEEN PRESCRIPTION DRUGS BY VOLUME, CALCULATED BY UNIT, FOR WHICH THE CARRIER PAID;

(II) THE FIFTEEN COSTLIEST PRESCRIPTION DRUGS FOR WHICH THE CARRIER PAID, AS DETERMINED BY TOTAL ANNUAL PLAN SPENDING;

(III) THE FIFTEEN PRESCRIPTION DRUGS PAID FOR BY THE CARRIER THAT ACCOUNTED FOR THE HIGHEST INCREASE IN TOTAL ANNUAL PLAN SPENDING WHEN COMPARED WITH THE TOTAL ANNUAL PLAN SPENDING FOR THE SAME PRESCRIPTION DRUGS IN THE YEAR IMMEDIATELY PRECEDING THE YEAR FOR WHICH THE INFORMATION IS REPORTED;

(IV) THE FIFTEEN PRESCRIPTION DRUGS THAT CAUSED THE GREATEST INCREASES IN THE CARRIER'S PREMIUMS;

(V) THE FIFTEEN PRESCRIPTION DRUGS FOR WHICH THE CARRIER PAID MOST FREQUENTLY AND FOR WHICH THE CARRIER RECEIVED A REBATE FROM MANUFACTURERS;

(VI) THE FIFTEEN PRESCRIPTION DRUGS FOR WHICH THE CARRIER RECEIVED THE HIGHEST REBATES, AS DETERMINED BY PERCENTAGES OF THE PRICE OF THE PRESCRIPTION DRUG;

(VII) THE FIFTEEN PRESCRIPTION DRUGS FOR WHICH THE CARRIER RECEIVED THE LARGEST REBATES;

(VIII) THE TOTAL SPENDING FOR EACH OF THE FOLLOWING CATEGORIES OF PRESCRIPTION DRUGS:

(A) BRAND-NAME DRUGS PURCHASED FROM RETAIL PHARMACIES;

(B) AUTHORIZED GENERIC DRUGS PURCHASED FROM RETAIL PHARMACIES;

(C) BRAND-NAME DRUGS PURCHASED FROM MAIL-ORDER PHARMACIES;

(D) AUTHORIZED GENERIC DRUGS PURCHASED FROM MAIL-ORDER PHARMACIES;

(E) PRESCRIPTION DRUGS DISPENSED BY A PRACTITIONER IN ACCORDANCE WITH SECTION 12-280-120 (6);

(F) PRESCRIPTION DRUGS ADMINISTERED IN AN INPATIENT HOSPITAL SETTING; AND

(G) PRESCRIPTION DRUGS ADMINISTERED IN AN OUTPATIENT HOSPITAL SETTING; AND

(IX) THE TOTAL SPENDING FOR THE PRESCRIPTION DRUGS DESCRIBED IN SUBSECTION (1)(a)(VIII) OF THIS SECTION PAID FOR BY A CARRIER PURSUANT TO A HEALTH BENEFIT PLAN ISSUED UNDER PART 2, 3, OR 4 OF THIS ARTICLE 16 DURING THE IMMEDIATELY PRECEDING CALENDAR YEAR FOR EACH OF THE FOLLOWING MARKET SECTORS:

(A) INDIVIDUAL;

(B) SMALL EMPLOYER; AND

(C) LARGE EMPLOYER.

(b) IF THE ALL-PAYER HEALTH CLAIMS DATABASE DOES NOT COLLECT AND MAINTAIN THE DATA THAT IS REQUIRED TO BE REPORTED TO THE DATABASE PURSUANT TO SUBSECTION (1)(a) OF THIS SECTION, THE ADMINISTRATOR OF THE ALL-PAYER HEALTH CLAIMS DATABASE SHALL AMEND THE REQUIREMENTS REGARDING THE DATA TO BE SUBMITTED TO THE DATABASE PURSUANT TO SECTION 25.5-1-204 (5) TO INCLUDE THE DATA REQUIRED BY SUBSECTION (1)(a) OF THIS SECTION DURING THE NEXT UPDATE OF SUCH REQUIREMENTS, BUT NO LATER THAN JUNE 1, 2022.

(2) THE ADMINISTRATOR OF THE ALL-PAYER HEALTH CLAIMS DATABASE SHALL PROVIDE TO THE COMMISSIONER, IN A FORM AND MANNER DETERMINED BY THE COMMISSIONER, THE INFORMATION THAT IS REPORTED TO THE DATABASE BY CARRIERS AND PHARMACY BENEFIT MANAGEMENT FIRMS PURSUANT TO SUBSECTION (1)(a) OF THIS SECTION.

(3) (a) EXCEPT AS PROVIDED IN SUBSECTION (3)(b) OF THIS SECTION, THE COMMISSIONER SHALL:

(I) POST THE INFORMATION REPORTED BY CARRIERS AND PHARMACY BENEFIT MANAGEMENT FIRMS PURSUANT TO THIS SECTION ON THE DIVISION'S WEBSITE; AND

(II) PROVIDE THE INFORMATION REPORTED BY CARRIERS AND PHARMACY BENEFIT MANAGEMENT FIRMS PURSUANT TO THIS SECTION TO THE BOARD, IN A FORM AND MANNER PRESCRIBED BY THE BOARD.

(b) IF A CARRIER OR PHARMACY BENEFIT MANAGEMENT FIRM CLAIMS THAT INFORMATION SUBMITTED PURSUANT TO THIS SECTION IS CONFIDENTIAL OR PROPRIETARY, THE COMMISSIONER SHALL REVIEW THE INFORMATION AND REDACT SPECIFIC ITEMS THAT THE CARRIER OR PHARMACY BENEFIT MANAGEMENT FIRM DEMONSTRATES TO BE CONFIDENTIAL OR PROPRIETARY. THE COMMISSIONER SHALL NOT DISCLOSE REDACTED ITEMS TO ANY PERSON; EXCEPT THAT THE COMMISSIONER MAY DISCLOSE REDACTED ITEMS:

(I) AS MAY BE REQUIRED PURSUANT TO THE "COLORADO OPEN RECORDS ACT", PART 2 OF ARTICLE 72 OF TITLE 24; AND

(II) TO EMPLOYEES OF THE DIVISION, AS NECESSARY.

(4) THE REQUIREMENT IN THIS SECTION TO REPORT INFORMATION RELATING TO THE COST OF PRESCRIPTION DRUGS IS INTENDED TO CREATE TRANSPARENCY IN PRESCRIPTION DRUG PRICING AND DOES NOT:

(a) PROHIBIT A MANUFACTURER OF A PRESCRIPTION DRUG FROM MAKING PRICING DECISIONS ABOUT ITS PRESCRIPTION DRUGS; OR

(b) PROHIBIT PURCHASERS, BOTH PUBLIC AND PRIVATE, OR PHARMACY BENEFIT MANAGEMENT FIRMS FROM NEGOTIATING DISCOUNTS AND REBATES CONSISTENT WITH EXISTING STATE AND FEDERAL LAW.

10-16-1406. Colorado prescription drug affordability review board - affordability reviews of prescription drugs. (1) THE BOARD MAY CONDUCT AFFORDABILITY REVIEWS OF PRESCRIPTION DRUGS IN ACCORDANCE WITH THIS SECTION. THE BOARD SHALL IDENTIFY, FOR PURPOSES OF DETERMINING WHETHER TO CONDUCT AN AFFORDABILITY REVIEW, ANY PRESCRIPTION DRUG THAT IS:

(a) A BRAND-NAME DRUG OR BIOLOGICAL PRODUCT THAT, AS ADJUSTED ANNUALLY FOR INFLATION, HAS:

(I) AN INITIAL WHOLESALE ACQUISITION COST OF THIRTY THOUSAND DOLLARS OR MORE FOR A TWELVE-MONTH SUPPLY OR FOR A COURSE OF TREATMENT THAT IS LESS THAN TWELVE MONTHS IN DURATION; OR

(II) AN INCREASE IN THE WHOLESALE ACQUISITION COST OF TEN PERCENT OR MORE DURING THE IMMEDIATELY PRECEDING TWELVE MONTHS FOR A TWELVE-MONTH SUPPLY OR FOR A COURSE OF TREATMENT THAT IS LESS THAN TWELVE MONTHS IN DURATION;

(b) A BIOSIMILAR DRUG THAT HAS AN INITIAL WHOLESALE ACQUISITION COST THAT IS NOT AT LEAST FIFTEEN PERCENT LOWER THAN THE CORRESPONDING BIOLOGICAL PRODUCT; OR

(c) A GENERIC DRUG:

(I) THAT, AS ADJUSTED ANNUALLY FOR INFLATION, HAS A WHOLESALE ACQUISITION COST OF ONE HUNDRED DOLLARS OR MORE FOR:

(A) A THIRTY-DAY SUPPLY BASED ON THE RECOMMENDED DOSAGE APPROVED FOR LABELING BY THE FDA;

(B) A SUPPLY THAT LASTS LESS THAN THIRTY DAYS BASED ON THE RECOMMENDED DOSAGE APPROVED FOR LABELING BY THE FDA; OR

(C) ONE DOSE OF THE GENERIC DRUG IF THE LABELING APPROVED BY THE FDA DOES NOT RECOMMEND A FINITE DOSAGE; AND

(II) FOR WHICH THE WHOLESALE ACQUISITION COST INCREASED BY TWO HUNDRED PERCENT OR MORE DURING THE IMMEDIATELY PRECEDING TWELVE MONTHS, AS DETERMINED BY COMPARING THE CURRENT WHOLESALE ACQUISITION COST TO THE AVERAGE WHOLESALE ACQUISITION COST REPORTED DURING THE IMMEDIATELY PRECEDING TWELVE MONTHS.

(2) AFTER IDENTIFYING PRESCRIPTION DRUGS AS DESCRIBED IN SUBSECTION (1) OF THIS SECTION, THE BOARD SHALL DETERMINE WHETHER TO CONDUCT AN AFFORDABILITY REVIEW FOR EACH IDENTIFIED PRESCRIPTION DRUG BY:

(a) EVALUATING THE CLASS OF THE PRESCRIPTION DRUG AND WHETHER ANY THERAPEUTICALLY EQUIVALENT PRESCRIPTION DRUGS ARE AVAILABLE FOR SALE;

(b) EVALUATING AGGREGATED DATA;

(c) SEEKING AND CONSIDERING INPUT FROM THE ADVISORY COUNCIL ABOUT THE PRESCRIPTION DRUG; AND

(d) CONSIDERING THE AVERAGE PATIENT'S OUT-OF-POCKET COST FOR THE PRESCRIPTION DRUG.

(3) IF THE BOARD CONDUCTS AN AFFORDABILITY REVIEW OF A PRESCRIPTION DRUG, THE AFFORDABILITY REVIEW MUST DETERMINE WHETHER USE OF THE PRESCRIPTION DRUG CONSISTENT WITH THE LABELING APPROVED FOR THE PRESCRIPTION DRUG BY THE FDA OR WITH STANDARD MEDICAL PRACTICE IS UNAFFORDABLE FOR COLORADO CONSUMERS.

(4) IN PERFORMING AN AFFORDABILITY REVIEW, TO THE EXTENT PRACTICABLE, THE BOARD SHALL CONSIDER:

- (a) THE WHOLESALE ACQUISITION COST OF THE PRESCRIPTION DRUG;
- (b) THE COST AND AVAILABILITY OF THERAPEUTIC ALTERNATIVES TO THE PRESCRIPTION DRUG IN THE STATE;
- (c) THE EFFECT OF THE PRICE ON COLORADO CONSUMERS' ACCESS TO THE PRESCRIPTION DRUG;
- (d) THE RELATIVE FINANCIAL EFFECTS ON HEALTH, MEDICAL, OR SOCIAL SERVICES COSTS, AS THE EFFECTS CAN BE QUANTIFIED AND COMPARED TO BASELINE EFFECTS OF EXISTING THERAPEUTIC ALTERNATIVES TO THE PRESCRIPTION DRUG;
- (e) THE PATIENT COPAYMENT OR OTHER COST SHARING THAT IS ASSOCIATED WITH THE PRESCRIPTION DRUG AND TYPICALLY REQUIRED PURSUANT TO HEALTH BENEFIT PLANS ISSUED BY CARRIERS IN THE STATE;
- (f) THE IMPACT ON SAFETY NET PROVIDERS IF THE PRESCRIPTION DRUG IS AVAILABLE THROUGH SECTION 340B OF THE FEDERAL "PUBLIC HEALTH SERVICE ACT", PUB.L. 78-410;
- (g) ORPHAN DRUG STATUS;
- (h) INPUT FROM:
- (I) PATIENTS AND CAREGIVERS AFFECTED BY THE CONDITION OR DISEASE THAT IS TREATED BY THE PRESCRIPTION DRUG THAT IS UNDER REVIEW BY THE BOARD; AND
- (II) INDIVIDUALS WHO POSSESS SCIENTIFIC OR MEDICAL TRAINING WITH RESPECT TO A CONDITION OR DISEASE TREATED BY THE PRESCRIPTION DRUG THAT IS UNDER REVIEW BY THE BOARD;
- (i) ANY OTHER INFORMATION THAT A MANUFACTURER, CARRIER, PHARMACY BENEFIT MANAGEMENT FIRM, OR OTHER ENTITY CHOOSES TO PROVIDE; AND
- (j) ANY OTHER FACTORS AS DETERMINED BY RULES PROMULGATED BY THE BOARD PURSUANT TO SECTION 10-16-1403 (5).

(5) TRADE-SECRET, CONFIDENTIAL, OR PROPRIETARY INFORMATION OBTAINED BY THE BOARD PURSUANT TO THIS SECTION MAY BE ACCESSED ONLY BY BOARD MEMBERS AND STAFF OR BY A QUALIFIED INDEPENDENT THIRD PARTY THAT HAS CONTRACTED WITH THE DIVISION PURSUANT TO SECTION 10-16-1403 (3) AND IS SUBJECT TO A NONDISCLOSURE AGREEMENT PROHIBITING DISCLOSURE OF SUCH INFORMATION. ANY PERSON WITH ACCESS TO SUCH INFORMATION SHALL PROTECT THE INFORMATION FROM DIRECT OR INDIRECT PUBLICATION OR RELEASE TO ANY PERSON.

(6) IN PERFORMING AN AFFORDABILITY REVIEW OF A PRESCRIPTION DRUG, THE BOARD MAY CONSIDER ANY DOCUMENTS AND INFORMATION RELATING TO THE MANUFACTURER'S SELECTION OF THE INTRODUCTORY PRICE OR PRICE INCREASE OF THE PRESCRIPTION DRUG, INCLUDING DOCUMENTS AND INFORMATION RELATING TO:

- (a) LIFE-CYCLE MANAGEMENT;
- (b) THE AVERAGE COST OF THE PRESCRIPTION DRUG IN THE STATE;
- (c) MARKET COMPETITION AND CONTEXT;
- (d) PROJECTED REVENUE;
- (e) THE ESTIMATED COST-EFFECTIVENESS OF THE PRESCRIPTION DRUG; AND
- (f) OFF-LABEL USAGE OF THE PRESCRIPTION DRUG.

(7) (a) TO THE EXTENT PRACTICABLE, THE BOARD MAY ACCESS PRICING INFORMATION FOR PRESCRIPTION DRUGS BY:

(I) ACCESSING PUBLICLY AVAILABLE PRICING INFORMATION FROM A STATE TO WHICH MANUFACTURERS REPORT PRICING INFORMATION;

(II) ACCESSING AVAILABLE PRICING INFORMATION FROM THE ALL-PAYER HEALTH CLAIMS DATABASE AND FROM STATE ENTITIES; AND

(III) ACCESSING INFORMATION THAT IS AVAILABLE FROM OTHER COUNTRIES.

(b) TO THE EXTENT THAT THERE IS NO PUBLICLY AVAILABLE INFORMATION WITH WHICH TO CONDUCT AN AFFORDABILITY REVIEW, THE BOARD MAY REQUEST THAT A MANUFACTURER, CARRIER, OR PHARMACY BENEFIT MANAGEMENT FIRM PROVIDE PRICING INFORMATION FOR ANY PRESCRIPTION DRUG IDENTIFIED PURSUANT TO SUBSECTION (1) OF THIS SECTION. THE FAILURE OF AN ENTITY TO PROVIDE PRICING INFORMATION TO THE BOARD FOR AN AFFORDABILITY REVIEW DOES NOT AFFECT THE AUTHORITY OF THE BOARD TO CONDUCT THE AFFORDABILITY REVIEW, AS DESCRIBED IN THIS SECTION.

10-16-1407. Colorado prescription drug affordability review board - upper payment limits for certain prescription drugs - rules - severability. (1) THE BOARD MAY ESTABLISH AN UPPER PAYMENT LIMIT FOR ANY PRESCRIPTION DRUG FOR WHICH THE BOARD HAS PERFORMED AN AFFORDABILITY REVIEW PURSUANT TO SECTION 10-16-1406 AND DETERMINED THAT THE USE OF THE PRESCRIPTION DRUG IS UNAFFORDABLE FOR COLORADO CONSUMERS; EXCEPT THAT THE BOARD MAY NOT ESTABLISH AN UPPER PAYMENT LIMIT FOR MORE THAN TWELVE PRESCRIPTION DRUGS IN EACH CALENDAR YEAR FOR THREE YEARS BEGINNING APRIL 1, 2022. THE FAILURE OF AN ENTITY TO PROVIDE INFORMATION TO THE BOARD PURSUANT TO SECTION 10-16-1406 (7)(b) DOES NOT AFFECT THE AUTHORITY OF THE BOARD TO ESTABLISH AN UPPER PAYMENT LIMIT FOR THE PRESCRIPTION DRUG.

(2) THE BOARD SHALL DETERMINE BY RULE THE METHODOLOGY FOR ESTABLISHING AN UPPER PAYMENT LIMIT FOR A PRESCRIPTION DRUG TO PROTECT CONSUMERS FROM THE EXCESSIVE COST OF PRESCRIPTION DRUGS AND ENSURE THEY CAN ACCESS PRESCRIPTION DRUGS NECESSARY FOR THEIR HEALTH. THE METHODOLOGY MUST INCLUDE CONSIDERATION OF:

(a) THE COST OF ADMINISTERING OR DISPENSING THE PRESCRIPTION DRUG;

(b) THE COST OF DISTRIBUTING THE PRESCRIPTION DRUG TO CONSUMERS IN THE STATE;

(c) THE STATUS OF THE PRESCRIPTION DRUG ON THE DRUG SHORTAGE LIST PUBLISHED BY THE DRUG SHORTAGE PROGRAM WITHIN THE FDA; AND

(d) OTHER RELEVANT COSTS RELATED TO THE PRESCRIPTION DRUG.

(3) THE METHODOLOGY DETERMINED BY THE BOARD PURSUANT TO SUBSECTION (2) OF THIS SECTION MUST CONSIDER THE IMPACT TO OLDER ADULTS AND PERSONS WITH DISABILITIES AND SHALL NOT PLACE A LOWER VALUE ON THEIR LIVES.

(4) THE METHODOLOGY DETERMINED BY THE BOARD PURSUANT TO SUBSECTION (2) OF THIS SECTION:

(a) SHALL NOT CONSIDER RESEARCH OR METHODS THAT EMPLOY A DOLLARS-PER-QUALITY ADJUSTED LIFE YEAR, OR SIMILAR MEASURE, THAT DISCOUNTS THE VALUE OF A LIFE BECAUSE OF AN INDIVIDUAL'S DISABILITY OR AGE; AND

(b) MUST AUTHORIZE A PHARMACY LICENSED BY THE STATE BOARD OF PHARMACY TO CHARGE REASONABLE FEES, TO BE PAID BY THE PROVIDING HEALTH BENEFIT PLAN OF THE CONSUMER, FOR DISPENSING OR DELIVERING A PRESCRIPTION DRUG FOR WHICH THE BOARD HAS ESTABLISHED AN UPPER PAYMENT LIMIT.

(5) AN UPPER PAYMENT LIMIT APPLIES TO ALL PURCHASES OF AND PAYER REIMBURSEMENTS FOR A PRESCRIPTION DRUG THAT IS DISPENSED OR ADMINISTERED TO INDIVIDUALS IN THE STATE IN PERSON, BY MAIL, OR BY OTHER MEANS AND FOR WHICH AN UPPER PAYMENT LIMIT IS ESTABLISHED. THE BOARD SHALL PROMULGATE RULES THAT ESTABLISH THE EFFECTIVE DATE OF ANY UPPER PAYMENT LIMIT ESTABLISHED BY THE BOARD, WHICH EFFECTIVE DATE IS AT LEAST SIX MONTHS AFTER THE ADOPTION OF THE UPPER PAYMENT LIMIT BY THE BOARD AND APPLIES ONLY TO PURCHASES, CONTRACTS, AND PLANS THAT ARE ISSUED ON OR RENEWED AFTER THE EFFECTIVE DATE.

(6) THE BOARD SHALL PROMULGATE RULES TO NOTIFY CONSUMERS OF ANY DECISION TO ESTABLISH AN UPPER PAYMENT LIMIT PURSUANT TO THIS SECTION.

(7) ANY INFORMATION SUBMITTED TO THE BOARD IN ACCORDANCE WITH THIS SECTION OR SECTION 10-16-1405 OR 10-16-1406 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 AUTHORIZED TO ACCESS SUCH

INFORMATION PURSUANT TO SECTION 10-16-1406.

(8) NOTWITHSTANDING ANY PROVISION OF THIS PART 14 TO THE CONTRARY, WITH RESPECT TO AN ENTITY PROVIDING OR ADMINISTERING A SELF-FUNDED HEALTH BENEFIT PLAN AND ITS PLAN MEMBERS, THE REQUIREMENTS OF THIS PART 14 APPLY ONLY IF THE PLAN ELECTS TO BE SUBJECT TO THIS PART 14 FOR ITS MEMBERS IN COLORADO. SUCH A PLAN IS AN OPTIONAL PARTICIPATING PLAN FOR THE PURPOSES OF THIS PART 14.

(9) IF ANY PROVISION OF THIS SECTION OR ITS APPLICATION TO ANY PERSON OR CIRCUMSTANCE IS HELD INVALID, THE INVALIDITY DOES NOT AFFECT OTHER PROVISIONS OR APPLICATIONS OF THIS SECTION THAT CAN BE GIVEN EFFECT WITHOUT THE INVALID PROVISION OR APPLICATION, AND TO THIS END THE PROVISIONS OF THIS SECTION ARE SEVERABLE.

(10) FOR ANY UPPER PAYMENT LIMIT ESTABLISHED BY THE BOARD PURSUANT TO THIS SECTION, THE BOARD SHALL:

(a) INQUIRE OF MANUFACTURERS OF THE PRESCRIPTION DRUG AS TO WHETHER EACH SUCH MANUFACTURER IS ABLE TO MAKE THE PRESCRIPTION DRUG AVAILABLE FOR SALE IN THE STATE AND REQUEST THE RATIONALE FOR THE MANUFACTURER'S RESPONSE; AND

(b) SUBMIT ANNUALLY TO THE HEALTH AND HUMAN SERVICES COMMITTEE OF THE SENATE AND THE HEALTH AND INSURANCE COMMITTEE OF THE HOUSE OF REPRESENTATIVES, OR TO ANY SUCCESSOR COMMITTEES, THE RESPONSE OF EACH MANUFACTURER TO THE INQUIRY DESCRIBED IN SUBSECTION (10)(a) OF THIS SECTION.

10-16-1408. Colorado prescription drug affordability review board - appeals - rules - judicial review. (1) A PERSON AGGRIEVED BY A DECISION OF THE BOARD MAY APPEAL THE DECISION WITHIN SIXTY DAYS AFTER THE DECISION IS MADE. THE BOARD SHALL CONSIDER THE APPEAL AND ISSUE A FINAL DECISION CONCERNING THE APPEAL WITHIN SIXTY DAYS AFTER THE BOARD RECEIVES THE APPEAL.

(2) NOT LATER THAN MARCH 31, 2022, THE BOARD SHALL PROMULGATE RULES ESTABLISHING A PROCESS AND TIMELINE FOR THE CONSIDERATION BY THE BOARD OF ANY APPEAL THAT IS SUBMITTED TO THE BOARD PURSUANT TO SUBSECTION (1) OF THIS SECTION. THE PROCESS AND

TIMELINE MUST COMPORT WITH THE "STATE ADMINISTRATIVE PROCEDURE ACT", ARTICLE 4 OF TITLE 24.

(3) IN THE ABSENCE OF AN APPEAL, A DECISION OF THE BOARD BECOMES FINAL AND RIPE FOR JUDICIAL REVIEW AFTER SIXTY DAYS. ANY PERSON AGGRIEVED BY A FINAL DECISION OF THE BOARD MAY PETITION FOR JUDICIAL REVIEW PURSUANT TO SECTION 24-4-106.

(4) NOTWITHSTANDING ANY PROVISION OF LAW TO THE CONTRARY:

(a) AN INDIVIDUAL MAY REQUEST AN EXPEDITED REVIEW, AS DESCRIBED IN SECTION 10-16-113.5, OF ACCESS TO A PRESCRIPTION DRUG THAT IS UNAVAILABLE TO THE INDIVIDUAL BECAUSE A MANUFACTURER REFUSES TO MAKE THE DRUG AVAILABLE AS A RESULT OF AN UPPER PAYMENT LIMIT ESTABLISHED FOR THE PRESCRIPTION DRUG BY THE BOARD; AND

(b) A CARRIER MAY DISREGARD THE UPPER PAYMENT LIMIT IF THE INDEPENDENT EXTERNAL REVIEW ENTITY THAT PERFORMS THE EXPEDITED REVIEW DETERMINES PURSUANT TO SUCH REVIEW THAT THE PRESCRIPTION DRUG SHOULD BE COVERED FOR AND AVAILABLE TO THAT INDIVIDUAL.

10-16-1409. Colorado prescription drug affordability advisory council - created - membership - powers and duties. (1) (a) THE COLORADO PRESCRIPTION DRUG AFFORDABILITY ADVISORY COUNCIL IS CREATED IN THE DIVISION TO PROVIDE STAKEHOLDER INPUT TO THE BOARD REGARDING THE AFFORDABILITY OF PRESCRIPTION DRUGS. THE ADVISORY COUNCIL INCLUDES FIFTEEN MEMBERS AS FOLLOWS:

(I) THE EXECUTIVE DIRECTOR OF THE DEPARTMENT OF HEALTH CARE POLICY AND FINANCING OR THE EXECUTIVE DIRECTOR'S DESIGNEE; AND

(II) FOURTEEN MEMBERS APPOINTED BY THE BOARD AS FOLLOWS:

(A) TWO MEMBERS WHO ARE HEALTH-CARE CONSUMERS OR WHO REPRESENT HEALTH-CARE CONSUMERS;

(B) ONE MEMBER REPRESENTING A STATEWIDE HEALTH-CARE CONSUMER ADVOCACY ORGANIZATION;

(C) ONE MEMBER REPRESENTING HEALTH-CARE CONSUMERS WHO ARE LIVING WITH CHRONIC DISEASES;

(D) ONE MEMBER REPRESENTING A LABOR UNION;

(E) ONE MEMBER REPRESENTING EMPLOYERS;

(F) ONE MEMBER REPRESENTING CARRIERS;

(G) ONE MEMBER REPRESENTING PHARMACY BENEFIT MANAGEMENT FIRMS;

(H) ONE MEMBER REPRESENTING HEALTH-CARE PROFESSIONALS WITH PRESCRIBING AUTHORITY;

(I) ONE MEMBER WHO IS EMPLOYED BY AN ORGANIZATION THAT PERFORMS RESEARCH CONCERNING PRESCRIPTION DRUGS, INCLUDING RESEARCH CONCERNING PRICING INFORMATION;

(J) ONE MEMBER REPRESENTING MANUFACTURERS OF BRAND-NAME DRUGS;

(K) ONE MEMBER REPRESENTING MANUFACTURERS OF GENERIC DRUGS;

(L) ONE MEMBER REPRESENTING PHARMACISTS; AND

(M) ONE MEMBER REPRESENTING WHOLESALERS.

(b) TO THE EXTENT POSSIBLE, THE BOARD SHALL APPOINT COUNCIL MEMBERS WHO HAVE EXPERIENCE SERVING UNDERSERVED COMMUNITIES AND REFLECT THE DIVERSITY OF THE STATE WITH REGARD TO RACE, ETHNICITY, IMMIGRATION STATUS, INCOME, WEALTH, DISABILITY, AGE, GENDER IDENTITY, AND GEOGRAPHY. IN CONSIDERING GEOGRAPHIC DIVERSITY, THE BOARD SHALL ENSURE AT LEAST ONE COUNCIL MEMBER RESIDES ON THE EASTERN PLAINS AND ONE MEMBER RESIDES ON THE WESTERN SLOPE, AND THE BOARD SHALL ATTEMPT TO APPOINT MEMBERS FROM EACH CONGRESSIONAL DISTRICT IN THE STATE.

(c) ALL OF THE INITIAL MEMBERS OF THE ADVISORY COUNCIL MUST

BE APPOINTED BY JANUARY 1, 2022.

(2) EACH MEMBER OF THE ADVISORY COUNCIL MUST POSSESS KNOWLEDGE OF AT LEAST ONE OF THE FOLLOWING SUBJECT MATTERS:

- (a) THE PHARMACEUTICAL BUSINESS MODEL;
- (b) SUPPLY CHAIN BUSINESS MODELS;
- (c) THE PRACTICE OF MEDICINE OR CLINICAL TRAINING;
- (d) HEALTH-CARE CONSUMER OR PATIENT PERSPECTIVES;
- (e) HEALTH-CARE COST TRENDS AND DRIVERS;
- (f) CLINICAL AND HEALTH SERVICES RESEARCH; OR
- (g) THE STATE'S HEALTH-CARE MARKETPLACE.

(3) THE TERM OF EACH MEMBER OF THE ADVISORY COUNCIL IS THREE YEARS; EXCEPT THAT THE MEMBERS INITIALLY APPOINTED TO THE ADVISORY COUNCIL PURSUANT TO SUBSECTIONS (1)(a)(II)(A) TO (1)(a)(II)(E) OF THIS SECTION SHALL EACH SERVE INITIAL TERMS OF TWO YEARS.

(4) THE CHAIR OF THE BOARD SHALL DESIGNATE ONE MEMBER OF THE ADVISORY COUNCIL TO SERVE AS CHAIR OF THE ADVISORY COUNCIL.

(5)(a) AN INDIVIDUAL WHO IS BEING CONSIDERED FOR APPOINTMENT TO THE ADVISORY COUNCIL SHALL DISCLOSE ANY CONFLICT OF INTEREST TO THE BOARD IN A FORM AND MANNER PRESCRIBED BY THE BOARD. WHEN APPOINTING A MEMBER OF THE ADVISORY COUNCIL, THE BOARD SHALL CONSIDER ANY CONFLICT OF INTEREST DISCLOSED BY THE PROSPECTIVE MEMBER.

(b) THE CHAIR OF THE ADVISORY COUNCIL SHALL REPORT TO THE BOARD ANY CONFLICT OF INTEREST THAT IS DISCLOSED TO THE ADVISORY COUNCIL. THE BOARD SHALL INCLUDE INFORMATION CONCERNING SUCH DISCLOSURES ON ITS PUBLIC WEBSITE PURSUANT TO SECTION 10-16-1402 (3)(d).

(6) THE ADVISORY COUNCIL SHALL MEET AT LEAST ONCE EVERY THREE MONTHS; EXCEPT THAT THE CHAIR MAY CANCEL OR POSTPONE A MEETING.

(7) (a) EXCEPT AS DESCRIBED IN SUBSECTION (7)(b) OF THIS SECTION, THE ADVISORY COUNCIL SHALL CONDUCT ALL OF ITS MEETINGS IN PUBLIC.

(b) NOTWITHSTANDING SECTION 24-6-402, THE ADVISORY COUNCIL MAY MEET PRIVATELY IN GROUPS OF THREE OR FEWER MEMBERS FOR THE FOLLOWING PURPOSES, SO LONG AS NO FORMAL ACTION IS TAKEN AT THE MEETING:

(I) TO GATHER AND UNDERSTAND DATA; OR

(II) TO ESTABLISH, ORGANIZE, AND PLAN FOR THE BUSINESS OF THE ADVISORY COUNCIL.

10-16-1410. Use of savings - report - rules. (1) ANY SAVINGS GENERATED FOR A HEALTH BENEFIT PLAN THAT ARE ATTRIBUTABLE TO THE ESTABLISHMENT OF AN UPPER PAYMENT LIMIT ESTABLISHED BY THE BOARD PURSUANT TO SECTION 10-16-1407 MUST BE USED BY THE CARRIER THAT ISSUES THE HEALTH BENEFIT PLAN TO REDUCE COSTS TO CONSUMERS, PRIORITIZING THE REDUCTION OF OUT-OF-POCKET COSTS FOR PRESCRIPTION DRUGS.

(2) ON OR BEFORE MARCH 15, 2023, AND ON OR BEFORE MARCH 15 EACH YEAR THEREAFTER, EACH STATE ENTITY AND EACH CARRIER THAT ISSUES A HEALTH BENEFIT PLAN OR OPTIONAL PARTICIPATING PLAN SHALL SUBMIT TO THE BOARD A REPORT DESCRIBING THE SAVINGS ACHIEVED DURING THE PRECEDING PLAN YEAR FOR EACH PRESCRIPTION DRUG FOR WHICH THE BOARD ESTABLISHED AN UPPER PAYMENT LIMIT DURING THE PRECEDING YEAR AND HOW THOSE SAVINGS WERE USED TO SATISFY THE REQUIREMENT DESCRIBED IN SUBSECTION (1) OF THIS SECTION.

(3) ON OR BEFORE NOVEMBER 1, 2022, THE BOARD SHALL PROMULGATE RULES ESTABLISHING A FORMULA FOR CALCULATING SAVINGS FOR THE PURPOSE OF COMPLYING WITH SUBSECTION (1) OF THIS SECTION.

10-16-1411. Unlawful acts - enforcement - penalties. (1) ON AND AFTER JANUARY 1, 2022, IT IS UNLAWFUL FOR ANY PERSON TO PURCHASE OR

REIMBURSE A PAYER FOR A PRESCRIPTION DRUG FOR WHICH THE BOARD HAS ESTABLISHED AN UPPER PAYMENT LIMIT PURSUANT TO SECTION 10-16-1407 AT AN AMOUNT THAT EXCEEDS THE UPPER PAYMENT LIMIT ESTABLISHED BY THE BOARD FOR THAT PRESCRIPTION DRUG, REGARDLESS OF WHETHER THE PRESCRIPTION DRUG IS DISPENSED OR DISTRIBUTED IN PERSON, BY MAIL, OR BY OTHER MEANS.

(2) ON AND AFTER JANUARY 1, 2023, EACH STATE ENTITY, CARRIER, AND OPTIONAL PARTICIPATING PLAN SHALL REQUIRE COMPLIANCE WITH AN UPPER PAYMENT LIMIT ESTABLISHED BY THE BOARD.

(3) THE ATTORNEY GENERAL IS AUTHORIZED TO ENFORCE THIS PART 14 ON BEHALF OF ANY STATE ENTITY OR ANY CONSUMER OF PRESCRIPTION DRUGS.

(4) NOTWITHSTANDING ANY PROVISION OF THIS PART 14 TO THE CONTRARY, AS USED IN THIS SECTION, "PERSON" DOES NOT INCLUDE AN INDIVIDUAL WHO ACQUIRES A PRESCRIPTION DRUG FOR THE INDIVIDUAL'S OWN USE OR FOR A FAMILY MEMBER'S USE.

(5) NOTWITHSTANDING ANY PROVISION OF THIS SECTION TO THE CONTRARY, A CARRIER OR STATE AGENCY THAT IS REQUIRED PURSUANT TO STATE OR FEDERAL LAW TO PURCHASE OR REIMBURSE A PAYER FOR A PRESCRIPTION DRUG FOR WHICH THE BOARD HAS ESTABLISHED AN UPPER PAYMENT LIMIT PURSUANT TO SECTION 10-16-1407 IS NOT SUBJECT TO AN ENFORCEMENT ACTION FOR A VIOLATION OF SUBSECTION (1) OR (2) OF THIS SECTION FOR THAT PARTICULAR PRESCRIPTION DRUG.

10-16-1412. Notice of withdrawal of prescription drugs with upper payment limits required - rules - penalty. (1) ANY MANUFACTURER THAT INTENDS TO WITHDRAW FROM SALE OR DISTRIBUTION WITHIN THE STATE A PRESCRIPTION DRUG FOR WHICH THE BOARD HAS ESTABLISHED AN UPPER PAYMENT LIMIT PURSUANT TO SECTION 10-16-1407 SHALL PROVIDE A NOTICE OF WITHDRAWAL IN WRITING AT LEAST ONE HUNDRED EIGHTY DAYS BEFORE THE WITHDRAWAL TO:

- (a) THE COMMISSIONER;
- (b) THE ATTORNEY GENERAL; AND

(c) EACH ENTITY IN THE STATE WITH WHICH THE MANUFACTURER HAS CONTRACTED FOR THE SALE OR DISTRIBUTION OF THE PRESCRIPTION DRUG.

(2) THE BOARD SHALL PROMULGATE RULES TO NOTIFY CONSUMERS OF THE INTENT OF ANY MANUFACTURER TO WITHDRAW A PRESCRIPTION DRUG FROM SALE OR DISTRIBUTION WITHIN THE STATE, AS DESCRIBED IN SUBSECTION (1) OF THIS SECTION.

(3) AFTER PROVIDING NOTICE AND A HEARING AS DESCRIBED IN SECTION 24-4-105, THE COMMISSIONER MAY REQUIRE A MANUFACTURER TO PAY A PENALTY NOT TO EXCEED FIVE HUNDRED THOUSAND DOLLARS IF THE COMMISSIONER DETERMINES THAT THE MANUFACTURER FAILED TO PROVIDE THE NOTICE REQUIRED BY SUBSECTION (1) OF THIS SECTION BEFORE WITHDRAWING FROM SALE OR DISTRIBUTION WITHIN THE STATE A PRESCRIPTION DRUG FOR WHICH THE BOARD HAS ESTABLISHED AN UPPER PAYMENT LIMIT PURSUANT TO SECTION 10-16-1407.

10-16-1413. Optional participating plans - notice of election to participate required. AN OPTIONAL PARTICIPATING PLAN THAT ELECTS TO SUBJECT ITS PURCHASES OF OR PAYER REIMBURSEMENTS FOR PRESCRIPTION DRUGS IN COLORADO TO THE REQUIREMENTS OF THIS PART 14 SHALL NOTIFY THE COMMISSIONER IN WRITING WITHIN THIRTY DAYS AFTER SUCH ELECTION.

10-16-1414. Reports. (1) NOTWITHSTANDING SECTION 24-1-136 (11)(a), ON OR BEFORE JULY 1, 2023, AND ON OR BEFORE JULY 1 EACH YEAR THEREAFTER, THE BOARD SHALL SUBMIT A REPORT TO THE GOVERNOR, THE HEALTH AND INSURANCE COMMITTEE OF THE HOUSE OF REPRESENTATIVES, AND THE HEALTH AND HUMAN SERVICES COMMITTEE OF THE SENATE, OR TO ANY SUCCESSOR COMMITTEES, SUMMARIZING THE ACTIVITIES OF THE BOARD DURING THE PRECEDING CALENDAR YEAR. AT A MINIMUM, THE REPORT MUST INCLUDE:

(a) PUBLICLY AVAILABLE DATA CONCERNING PRICE TRENDS FOR PRESCRIPTION DRUGS;

(b) THE NUMBER OF PRESCRIPTION DRUGS THAT WERE SUBJECTED TO AN AFFORDABILITY REVIEW BY THE BOARD PURSUANT TO SECTION 10-16-1406, INCLUDING THE RESULTS OF EACH AFFORDABILITY REVIEW AND THE NUMBER AND DISPOSITION OF ANY APPEALS OR JUDICIAL REVIEWS OF

THE BOARD'S DECISIONS;

(c) A LIST OF EACH PRESCRIPTION DRUG FOR WHICH THE BOARD ESTABLISHED AN UPPER PAYMENT LIMIT PURSUANT TO SECTION 10-16-1407, INCLUDING THE AMOUNT OF THE UPPER PAYMENT LIMIT;

(d) THE IMPACT OF ANY UPPER PAYMENT LIMITS ESTABLISHED BY THE BOARD PURSUANT TO SECTION 10-16-1407 ON HEALTH-CARE PROVIDERS, PHARMACIES, AND PATIENTS' ABILITY TO ACCESS ANY PRESCRIPTION DRUGS FOR WHICH THE BOARD HAS ESTABLISHED UPPER PAYMENT LIMITS;

(e) A SUMMARY OF ANY APPEALS OF BOARD DECISIONS THAT WERE CONSIDERED BY THE BOARD PURSUANT TO SECTION 10-16-1408, INCLUDING AN INDICATION OF THE OUTCOME OF ANY SUCH APPEAL;

(f) A DESCRIPTION OF EACH CONFLICT OF INTEREST THAT WAS DISCLOSED TO THE BOARD DURING THE PRECEDING YEAR;

(g) A DESCRIPTION OF ANY VIOLATIONS OF ANY OF THE PROVISIONS OF THIS PART 14, INCLUDING AN INDICATION OF ANY ENFORCEMENT ACTION TAKEN IN RESPONSE TO ANY SUCH VIOLATION; AND

(h) ANY RECOMMENDATIONS THE BOARD MAY HAVE FOR THE GENERAL ASSEMBLY CONCERNING LEGISLATIVE AND REGULATORY POLICY CHANGES TO INCREASE THE AFFORDABILITY OF PRESCRIPTION DRUGS AND REDUCE THE EFFECTS OF EXCESS COSTS ON CONSUMERS AND COMMERCIAL HEALTH INSURANCE PREMIUMS IN THE STATE.

(2) THE BOARD SHALL POST THE REPORT DESCRIBED IN SUBSECTION (1) OF THIS SECTION ON THE PUBLIC WEB PAGE MAINTAINED BY THE DIVISION FOR THE BOARD PURSUANT TO SECTION 10-16-1402 (3)(d).

(3) (a) THE CHAIR OF THE BOARD SHALL PRESENT TO THE JOINT HEALTH AND INSURANCE COMMITTEE OF THE HOUSE OF REPRESENTATIVES AND HEALTH AND HUMAN SERVICES COMMITTEE OF THE SENATE, OR ANY SUCCESSOR COMMITTEES, WHICH PRESENTATION OCCURS PURSUANT TO THE "STATE MEASUREMENT FOR ACCOUNTABLE, RESPONSIVE, AND TRANSPARENT (SMART) GOVERNMENT ACT", PART 2 OF ARTICLE 7 OF TITLE 2, INFORMATION CONCERNING ANY PRESCRIPTION DRUG FOR WHICH

THE BOARD ESTABLISHED AN UPPER PAYMENT LIMIT DURING THE PRECEDING CALENDAR YEAR. THE CHAIR SHALL SUMMARIZE FOR THE COMMITTEE MEMBERS:

(I) THE AFFORDABILITY REVIEW OF THE PRESCRIPTION DRUG, INCLUDING THE RESULTS OF THE BOARD'S CONSIDERATIONS AS DESCRIBED IN SECTION 10-16-1406 (4) AND, IF APPLICABLE, SECTION 10-16-1406 (6); AND

(II) THE ESTABLISHMENT OF THE UPPER PAYMENT LIMIT, INCLUDING A SUMMARY OF THE METHODOLOGY USED TO ESTABLISH THE UPPER PAYMENT LIMIT.

(b) BASED ON THE INFORMATION PRESENTED IN SUBSECTION (3)(a) OF THIS SECTION, MEMBERS OF THE JOINT HEALTH AND INSURANCE COMMITTEE OF THE HOUSE OF REPRESENTATIVES AND HEALTH AND HUMAN SERVICES COMMITTEE OF THE SENATE, OR ANY SUCCESSOR COMMITTEES, MAY PURSUE LEGISLATION, IF THE MAJORITY OF COMMITTEE MEMBERS VOTE TO PURSUE SUCH LEGISLATION, TO DISCONTINUE THE UPPER PAYMENT LIMIT FOR ANY PRESCRIPTION DRUG FOR WHICH THE BOARD ESTABLISHED AN UPPER PAYMENT LIMIT. ANY SUCH LEGISLATION SHALL NOT COUNT AGAINST ANY LIMITATION UPON THE NUMBER OF BILLS THAT A MEMBER OF THE GENERAL ASSEMBLY MAY INTRODUCE EACH REGULAR LEGISLATIVE SESSION, WHICH LIMITATION MAY EXIST PURSUANT TO RULES ADOPTED BY THE GENERAL ASSEMBLY.

10-16-1415. Exemption - prescription drugs derived from cannabis. NOTWITHSTANDING ANY PROVISION OF THIS PART 14 TO THE CONTRARY, THE BOARD HAS NO AUTHORITY TO PERFORM AN AFFORDABILITY REVIEW OF, OR TO ESTABLISH AN UPPER PAYMENT LIMIT FOR, ANY PRESCRIPTION DRUG THAT IS DERIVED IN WHOLE OR IN PART FROM CANNABIS.

10-16-1416. Repeal of part. THIS PART 14 IS REPEALED, EFFECTIVE SEPTEMBER 1, 2026. BEFORE THE REPEAL, THE FUNCTIONS OF THE BOARD ARE SCHEDULED FOR REVIEW IN ACCORDANCE WITH SECTION 24-34-104.

SECTION 3. In Colorado Revised Statutes, 24-1-122, add (6) as follows:

24-1-122. Department of regulatory agencies - creation.

(6) (a) THE COLORADO PRESCRIPTION DRUG AFFORDABILITY REVIEW BOARD CREATED IN SECTION 10-16-1402 IS TRANSFERRED BY A TYPE 1 TRANSFER TO THE DEPARTMENT OF REGULATORY AGENCIES AND ALLOCATED TO THE DIVISION OF INSURANCE.

(b) THE COLORADO PRESCRIPTION DRUG AFFORDABILITY ADVISORY COUNCIL CREATED IN SECTION 10-16-1409 IS TRANSFERRED BY A TYPE 2 TRANSFER TO THE DEPARTMENT OF REGULATORY AGENCIES AND ALLOCATED TO THE DIVISION OF INSURANCE.

SECTION 4. In Colorado Revised Statutes, 24-34-104, add (27)(a)(XIX) as follows:

24-34-104. General assembly review of regulatory agencies and functions for repeal, continuation, or reestablishment - legislative declaration - repeal. (27) (a) The following agencies, functions, or both, are scheduled for repeal on September 1, 2026:

(XIX) THE COLORADO PRESCRIPTION DRUG AFFORDABILITY REVIEW BOARD CREATED IN SECTION 10-16-1402.

SECTION 5. Appropriation. (1) For the 2021-22 state fiscal year, \$730,711 is appropriated to the department of regulatory agencies. 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 department may use this appropriation as follows:

(a) \$325,297 for use by the division of insurance for personal services, which amount is based on an assumption that the division will require an additional 3.0 FTE;

(b) \$22,650 for use by the division of insurance for operating expenses; and

(c) \$382,824 for the purchase of legal services.

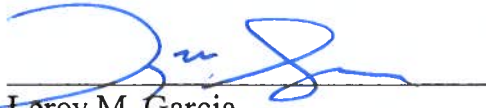
(2) For the 2021-22 state fiscal year, \$382,824 is appropriated to the department of law. This appropriation is from reappropriated funds received from the department of regulatory agencies under subsection (1)(c) of this section and is based on an assumption that the department of law will

require an additional 2.0 FTE. To implement this act, the department of law may use this appropriation to provide legal services for the department of regulatory agencies.

SECTION 6. Severability. If any provision of this act or the application thereof to any person or circumstance is held invalid, such invalidity does not affect other provisions or applications of this act that can be given effect without the invalid provision or application, and to this end the provisions of this act are severable.

SECTION 7. Safety clause. The general assembly hereby finds,

determines, and declares that this act is necessary for the immediate preservation of the public peace, health, or safety.



Leroy M. Garcia
PRESIDENT OF
THE SENATE



Alec Garnett
SPEAKER OF THE HOUSE
OF REPRESENTATIVES

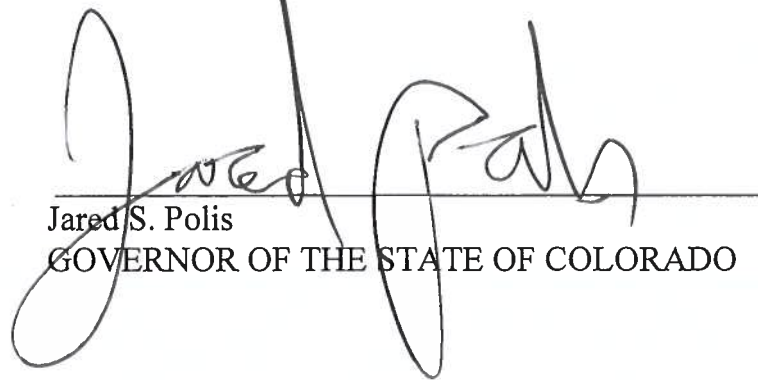


Cindi L. Markwell
SECRETARY OF
THE SENATE



Robin Jones
CHIEF CLERK OF THE HOUSE
OF REPRESENTATIVES

APPROVED June 16, 2021 at 9:36am
(Date and Time)



Jared S. Polis
GOVERNOR OF THE STATE OF COLORADO