Second Regular Session
Seventy-second General Assembly
STATE OF COLORADO

PREAMENDED

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

LLS NO. 20-0046.01 Christy Chase x2008 **SENATE BILL 20-107**

SENATE SPONSORSHIP

Ginal,

HOUSE SPONSORSHIP

Mullica and Jackson,

Senate Committees
Health & Human Services
Appropriations

House Committees

A BILL FOR AN ACT

CONCERNING AN ANALYSIS OF PRESCRIPTION DRUG MANUFACTURER DATA ON HIGH-COST PRESCRIPTION DRUGS PAID FOR BY SPECIFIED STATE DEPARTMENTS TO DETERMINE THE COMPONENTS OF THE PRODUCTION PROCESS THAT DRIVE THE PRICE OF THE PRESCRIPTION DRUGS.

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.)

The bill directs the department of health care policy and financing (state department), or a third party with whom the department contracts,

to collect, analyze, and report prescription drug production cost data regarding the 20 highest-cost prescription drugs per course of therapy and the 20 highest-cost prescription drugs by volume that were purchased or paid for by the departments of corrections, human services, personnel, and health care policy and financing (departments) during the 2019-20 and future state fiscal years. Upon receipt of a list of the highest-cost prescription drugs purchased or paid for by the departments, the state department or its designated contractor, as applicable, is directed to request from the manufacturers of the drugs on the list information showing the basis for and components of the wholesale acquisition cost (WAC) of each drug on the list.

The state department or its designated contractor, as applicable, is to analyze the data received from drug manufacturers and report its findings regarding the basis for the WAC for each prescription drug on the list, specifying the percentage of the WAC that is attributable to each component driving the WAC. The state department is required to provide an annual prescription drug price transparency report by December 1, 2021, and each December 1 thereafter to specified legislative committees. The state department and its designated contractor, as applicable, are required to maintain the confidentiality of any proprietary information received from a drug manufacturer, and that information is exempt from the "Colorado Open Records Act".

The executive director of the state department is authorized to adopt rules as necessary to implement and administer the bill. A manufacturer that fails to report the required information is subject to a civil penalty of up to $10,000 per day.

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

SECTION 1. In Colorado Revised Statutes, **add** part 8 to article 1 of title 25.5 as follows:

PART 8

PRESCRIPTION DRUG PRODUCTION COSTS TRANSPARENCY

25.5-1-801. Short title. THE SHORT TITLE OF THIS PART 8 IS THE "PRESCRIPTION DRUG PRODUCTION COSTS TRANSPARENCY ACT OF 2020".

25.5-1-802. Legislative declaration. (1) THE GENERAL ASSEMBLY FINDS AND DECLARES THAT:

(a) HEALTH CARE COSTS CONTINUE TO BE ONE OF THE TOP CONCERNS OF COLORADANS, AND THE MAJORITY OF COLORADANS WANT CLEARER INFORMATION ABOUT PRESCRIPTION DRUGS, A MAIN COST DRIVER;

(b) THE PRICES FOR THE HIGHEST-COST PRESCRIPTION DRUGS HAVE BEEN AMONG THE MOST SIGNIFICANT COST DRIVERS IN THE HIGH RATE OF INFLATION OF MEDICAL COSTS;

(c) IN COLORADO, TOTAL PRESCRIPTION DRUG SPENDING FOR MEDICAID GREW BY FOUR HUNDRED THIRTY-FIVE MILLION DOLLARS FROM 2014 TO 2019 AND REACHED OVER ONE BILLION DOLLARS FOR THE 2019 CALENDAR YEAR;

(d) ACCORDING TO A MAGELLAN STRATEGIES SURVEY CONDUCTED IN 2018, NINETY-FOUR PERCENT OF COLORADANS SAY THE PUBLIC HAS A RIGHT TO KNOW THE FACTORS THAT GO INTO THE PRICE OF PRESCRIPTION DRUGS;

(e) THE STATE PURCHASES PRESCRIPTION DRUGS WITHOUT BEING PROVIDED FULL AND ADEQUATE INFORMATION FROM MANUFACTURERS THAT CAN ASSIST THE STATE IN UNDERSTANDING THE BASIS FOR PRICES;

(f) COST REPORTING ON THE PRESCRIPTION DRUGS WITH THE HIGHEST COST PER COURSE OF THERAPY WILL BE USEFUL TO POLICYMAKERS, STATE AGENCIES, AND THE GENERAL PUBLIC SEEKING TO UNDERSTAND THE PRICING AND VALUE OF HIGH-PRICED PRESCRIPTION DRUGS; AND

(g) TRANSPARENCY IN THE HEALTH CARE INDUSTRY INFORMS CONSUMERS, POLICYMAKERS, AND STATE AGENCIES ABOUT UNDERLYING COST DRIVERS, WHICH ENABLES THE FORMATION OF MORE EFFECTIVE HEALTH CARE POLICY.

25.5-1-803. Definitions. AS USED IN THIS PART 8, UNLESS THE CONTEXT OTHERWISE REQUIRES:

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

(2) "COMPREHENSIVE LIST" MEANS THE LIST OF PRESCRIPTION DRUGS COMPILED BY THE DEPARTMENTS IN ACCORDANCE WITH SECTION 25.5-1-805 (1)(a)(I) OR (1)(a)(II).

(3) "CONSOLIDATED COMPREHENSIVE LIST" MEANS A SINGLE, CONSOLIDATED LIST OF PRESCRIPTION DRUGS CONSISTING OF THE COMPREHENSIVE LISTS OF PRESCRIPTION DRUGS COMPILED BY THE DEPARTMENTS PURSUANT TO SECTION 25.5-1-805 (1)(a)(I) AND (1)(a)(II).

(4) "COURSE OF THERAPY" MEANS EITHER:

(a) THE RECOMMENDED DAILY DOSAGE UNITS OF A PRESCRIPTION DRUG FOR A THIRTY-DAY TREATMENT PURSUANT TO THE PACKAGE INSERT FOR THE PRESCRIPTION DRUG AS APPROVED BY THE FDA; OR

(b) THE RECOMMENDED DAILY DOSAGE UNITS OF A PRESCRIPTION DRUG FOR A NORMAL COURSE OF TREATMENT THAT IS LESS THAN THIRTY DAYS PURSUANT TO THE PACKAGE INSERT FOR THE PRESCRIPTION DRUG AS APPROVED BY THE FDA.

(5) "DEPARTMENTS" MEANS THE DEPARTMENT OF CORRECTIONS, THE DEPARTMENT OF HUMAN SERVICES, THE DEPARTMENT OF PERSONNEL, AND THE STATE DEPARTMENT.

(6) "DESIGNATED CONTRACTOR" MEANS AN ORGANIZATION OR ENTITY WITH WHICH THE STATE DEPARTMENT CONTRACTS UNDER SECTION 25.5-1-804 TO COLLECT, ANALYZE, AND REPORT PRESCRIPTION DRUG PRICE DATA PURSUANT TO SECTION 25.5-1-805.

(7) "FDA" MEANS THE FEDERAL FOOD AND DRUG ADMINISTRATION

IN THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES.

(8) "MANUFACTURER" MEANS:

(a) A PERSON THAT MANUFACTURES A PRESCRIPTION DRUG THAT IS MADE AVAILABLE IN COLORADO; AND

(b) A HOLDING COMPANY, PARENT COMPANY, OR OTHER AFFILIATE OF A PERSON DESCRIBED IN SUBSECTION (8)(a) OF THIS SECTION.

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

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

25.5-1-804. Establishing transparency - state department or contractor to collect and analyze production cost data - funding. (1) (a) THE STATE DEPARTMENT OR A DESIGNATED CONTRACTOR, AS APPLICABLE, SHALL COLLECT, ANALYZE, AND REPORT PRESCRIPTION DRUG PRODUCTION COST DATA PURSUANT TO SECTION 25.5-1-805. THE STATE DEPARTMENT OR DESIGNATED CONTRACTOR, AS APPLICABLE, SHALL COLLECT DATA FROM THE ALL-PAYER HEALTH CLAIMS DATABASE ESTABLISHED PURSUANT TO SECTION 25.5-1-204, THE DIVISION OF INSURANCE, THE DEPARTMENTS, AND ANY OTHER SOURCES THAT HAVE RELEVANT INFORMATION.

(b) IF THE STATE DEPARTMENT CONTRACTS WITH A THIRD-PARTY CONTRACTOR TO PERFORM ANY OF ITS DUTIES SET FORTH IN THIS SECTION:

(I) IN SELECTING AND CONTRACTING WITH A THIRD-PARTY CONTRACTOR, THE STATE DEPARTMENT IS NOT BOUND BY THE "PROCUREMENT CODE", ARTICLES 101 TO 112 OF THIS TITLE 24; AND

(II) THE STATE DEPARTMENT SHALL SELECT A THIRD-PARTY

CONTRACTOR THAT:

(A) DEMONSTRATES THAT IT IS QUALIFIED TO COLLECT AND ANALYZE DATA FROM MANUFACTURERS AND IDENTIFY COST COMPONENTS USED TO DETERMINE THE WHOLESALE ACQUISITION COST OF PRESCRIPTION DRUGS; AND

(B) HAS NO FINANCIAL INTEREST IN, IS NOT EMPLOYED BY, AND IS NOT OTHERWISE CONNECTED WITH ANY MANUFACTURER WHOSE PRESCRIPTION DRUGS WILL BE ANALYZED BY THE CONTRACTOR, ANY CARRIER, OR ANY OTHER PERSON THAT HAS A FINANCIAL INTEREST IN THE OUTCOME OF THE DRUG PRICE TRANSPARENCY ANALYSIS OR REPORT REQUIRED BY THIS PART 8.

(2) THE GENERAL ASSEMBLY SHALL APPROPRIATE MONEY FROM THE GENERAL FUND TO THE STATE DEPARTMENT TO IMPLEMENT AND ADMINISTER THIS PART 8.

25.5-1-805. Reporting requirements - departments to compile list of high-cost prescription drugs - information from manufacturers - data analysis - legislative reports. (1) (a) (I) BY DECEMBER 1, 2020, AND BY EACH DECEMBER 1 THEREAFTER, THE DEPARTMENTS SHALL JOINTLY COMPILE A COMPREHENSIVE LIST CONTAINING THE NAMES AND WHOLESALE ACQUISITION COSTS OF THE FOLLOWING PRESCRIPTION DRUGS THAT EACH DEPARTMENT PURCHASED OR PAID FOR DURING THE IMMEDIATELY PRECEDING STATE FISCAL YEAR:

(A) THE TWENTY HIGHEST-COST PRESCRIPTION DRUGS PER COURSE OF THERAPY; AND

(B) THE TWENTY HIGHEST-COST PRESCRIPTION DRUGS BASED ON THE TOTAL SPENDING BY EACH DEPARTMENT.

(II) IN ADDITION TO THE COMPREHENSIVE LIST COMPILED

PURSUANT TO SUBSECTION (1)(a)(I) OF THIS SECTION, BY DECEMBER 1, 2020, AND BY EACH DECEMBER 1 THEREAFTER, THE DEPARTMENT OF PERSONNEL SHALL COMPILE A COMPREHENSIVE LIST CONTAINING THE NAMES AND WHOLESALE ACQUISITION COSTS OF THE FOLLOWING PRESCRIPTION DRUGS THE DEPARTMENT OF PERSONNEL PURCHASED OR PAID FOR DURING THE IMMEDIATELY PRECEDING STATE FISCAL YEAR, BASED ON THE TOTAL AMOUNT SPENT BY THE DEPARTMENT OF PERSONNEL AFTER ACCOUNTING FOR ANY REBATES, DISCOUNTS, OR OTHER COST SAVINGS:

(A) THE TWENTY HIGHEST-COST PRESCRIPTION DRUGS PER COURSE OF THERAPY; AND

(B) THE TWENTY HIGHEST-COST PRESCRIPTION DRUGS BASED ON TOTAL SPENDING BY THE DEPARTMENT OF PERSONNEL.

(III) THE DEPARTMENTS SHALL DETERMINE THE PRESCRIPTION DRUGS TO INCLUDE ON THE COMPREHENSIVE LISTS COMPILED PURSUANT TO SUBSECTIONS (1)(a)(I) AND (1)(a)(II) OF THIS SECTION BASED ON THE PRICE PAID BY THE DEPARTMENTS FOR EACH PRESCRIPTION DRUG.

(b) THE DEPARTMENTS SHALL PROVIDE A CONSOLIDATED COMPREHENSIVE LIST TO THE STATE DEPARTMENT, AND, IF THE STATE DEPARTMENT HAS CONTRACTED WITH A THIRD-PARTY CONTRACTOR PURSUANT TO SECTION 25.5-1-804, THE STATE DEPARTMENT SHALL MAKE THE CONSOLIDATED COMPREHENSIVE LIST AVAILABLE TO THE DESIGNATED CONTRACTOR.

(2) (a) BY FEBRUARY 1, 2021, AND BY EACH FEBRUARY 1 THEREAFTER, THE STATE DEPARTMENT OR DESIGNATED CONTRACTOR, AS APPLICABLE, SHALL SUBMIT A WRITTEN REQUEST TO EACH MANUFACTURER FOR INFORMATION SHOWING THE BASIS FOR AND

COMPONENTS OF THE WHOLESALE ACQUISITION COST OF EACH PRESCRIPTION DRUG ON THE CONSOLIDATED COMPREHENSIVE LIST THAT THE MANUFACTURER PRODUCED, INCLUDING THE FOLLOWING:

(I) RESEARCH AND DEVELOPMENT COSTS;

(II) CLINICAL TRIAL COSTS;

(III) REGULATORY COSTS;

(IV) COSTS FOR MATERIALS, MANUFACTURING, AND ADMINISTRATION ATTRIBUTABLE TO THE PRESCRIPTION DRUG;

(V) INCOME FROM OTHER ENTITIES, INCLUDING GRANTS, SUBSIDIES, OR OTHER SUPPORT, THAT OFFSETS THE RESEARCH AND DEVELOPMENT, CLINICAL TRIAL, OR OTHER DEVELOPMENT COSTS;

(VI) THE COST TO ACQUIRE THE TECHNOLOGY ASSOCIATED WITH THE PRESCRIPTION DRUG OR THE RIGHTS OR OWNERSHIP OF THE PRESCRIPTION DRUG FROM A THIRD PARTY;

(VII) PROMOTIONAL MARKETING COSTS, INCLUDING THE COSTS OF DIRECT-TO-CONSUMER ADVERTISING; AND

(VIII) ANY OTHER INFORMATION THE MANUFACTURER DEEMS RELEVANT TO THE PRICING OF THE PRESCRIPTION DRUG.

(b) WITHIN ONE HUNDRED TWENTY DAYS AFTER RECEIPT OF A WRITTEN REQUEST UNDER SUBSECTION (2)(a) OF THIS SECTION BUT NO LATER THAN JUNE 1 OF THE SAME YEAR, A MANUFACTURER SHALL PROVIDE TO THE STATE DEPARTMENT OR DESIGNATED CONTRACTOR, AS APPLICABLE, FULL AND COMPLETE DOCUMENTATION SHOWING THE BASIS FOR THE WHOLESALE ACQUISITION COST OF EACH PRESCRIPTION DRUG ON THE CONSOLIDATED COMPREHENSIVE LIST THAT THE MANUFACTURER PRODUCED.

(c) THE STATE DEPARTMENT SHALL ESTABLISH A PROCESS FOR A MANUFACTURER TO DESIGNATE INFORMATION REPORTED PURSUANT TO THIS SUBSECTION (2) AS PROPRIETARY OR A TRADE SECRET, AS DEFINED IN SECTION 7-74-102 (4).

(3) UPON RECEIPT OF THE INFORMATION FROM MANUFACTURERS REQUESTED UNDER SUBSECTION (2) OF THIS SECTION, THE STATE DEPARTMENT OR DESIGNATED CONTRACTOR, AS APPLICABLE, SHALL ANALYZE THE DOCUMENTATION ON EACH PRESCRIPTION DRUG ON THE CONSOLIDATED COMPREHENSIVE LIST TO DETERMINE THE BASIS FOR THE WHOLESALE ACQUISITION COST OF THE DRUG. THE STATE DEPARTMENT OR DESIGNATED CONTRACTOR, AS APPLICABLE, SHALL PREPARE A REPORT DETAILING ITS FINDINGS ON THE BASIS FOR THE WHOLESALE ACQUISITION COST OF EACH PRESCRIPTION DRUG ON THE CONSOLIDATED COMPREHENSIVE LIST AND SHALL SPECIFY THE PERCENTAGE OF THE WHOLESALE ACQUISITION COST THAT IS ATTRIBUTABLE TO EACH COMPONENT SPECIFIED IN SUBSECTION (2)(a) OF THIS SECTION THAT IS DRIVING THE WHOLESALE ACQUISITION COST OF THE PRESCRIPTION DRUG.

(4) (a) BY DECEMBER 1, 2021, AND BY EACH DECEMBER 1 THEREAFTER, THE STATE DEPARTMENT OR DESIGNATED CONTRACTOR, AS APPLICABLE, SHALL PROVIDE A FINAL PRESCRIPTION DRUG PRODUCTION COST TRANSPARENCY REPORT ON THE PRESCRIPTION DRUGS CONTAINED ON THE CONSOLIDATED COMPREHENSIVE LIST COMPILED IN THE IMMEDIATELY PRECEDING CALENDAR YEAR TO THE HEALTH AND INSURANCE AND PUBLIC HEALTH CARE AND HUMAN SERVICES COMMITTEES OF THE HOUSE OF REPRESENTATIVES, THE HEALTH AND HUMAN SERVICES COMMITTEE OF THE SENATE, AND THE JOINT BUDGET COMMITTEE, OR THEIR SUCCESSOR COMMITTEES. THE REPORT MUST:

(I) CONTAIN A STATEMENT INDICATING THAT THE REPORT DOES NOT INCLUDE A MANUFACTURER'S COSTS FOR RESEARCH AND DEVELOPMENT FOR PRODUCTS THAT FAILED TO MAKE IT TO MARKET; AND

(II) INDICATE THE TOTAL AMOUNT REBATED BACK TO THE STATE DEPARTMENT IN THE IMMEDIATELY PRECEDING CALENDAR YEAR FOR PRESCRIPTION DRUGS PAID FOR UNDER THE MEDICAL ASSISTANCE PROGRAM ADMINISTERED PURSUANT TO THE "COLORADO MEDICAL ASSISTANCE ACT", ARTICLES 4 TO 6 OF THIS TITLE 25.5, AND THE PERCENTAGE OF THE STATE DEPARTMENT'S BUDGET FOR THE MEDICAL ASSISTANCE PROGRAM THAT IS SPENT ON PRESCRIPTION DRUGS, INCLUDING REBATES.

(b) NOTWITHSTANDING SECTION 24-1-136 (11)(a)(I), THE REPORTING REQUIREMENT IN THIS SUBSECTION (4) CONTINUES INDEFINITELY.

(5) THE STATE DEPARTMENT AND THE DESIGNATED CONTRACTOR, IF THE STATE DEPARTMENT CONTRACTS WITH A DESIGNATED CONTRACTOR PURSUANT TO SECTION 25.5-1-804, SHALL MAINTAIN CONFIDENTIALITY OF INFORMATION OBTAINED FROM A MANUFACTURER THAT IS DESIGNATED AS PROPRIETARY OR A TRADE SECRET IN ACCORDANCE WITH THE PROCESS ESTABLISHED BY THE STATE DEPARTMENT PURSUANT TO SUBSECTION (2)(C) OF THIS SECTION, AND ANY PROPRIETARY INFORMATION OR TRADE SECRETS ARE EXEMPT FROM THE "COLORADO OPEN RECORDS ACT", PART 2 OF ARTICLE 72 OF THIS TITLE 24.

25.5-1-806. Rules. THE EXECUTIVE DIRECTOR MAY ADOPT RULES AS NECESSARY TO IMPLEMENT AND ADMINISTER THIS PART 8.

25.5-1-807. Enforcement - civil penalties. (1) A MANUFACTURER THAT FAILS TO REPORT THE INFORMATION REQUESTED BY

THE STATE DEPARTMENT IN ACCORDANCE WITH SECTION 25.5-1-805 (2) IS SUBJECT TO A CIVIL PENALTY OF UP TO TEN THOUSAND DOLLARS PER DAY FOR EACH DAY THE MANUFACTURER FAILS TO REPORT THE INFORMATION.

(2) THE EXECUTIVE DIRECTOR SHALL REPORT MANUFACTURER VIOLATIONS OF THE REPORTING REQUIREMENTS SPECIFIED IN SECTION 25.5-1-805 (2) TO THE ATTORNEY GENERAL. THE ATTORNEY GENERAL AND THE DISTRICT ATTORNEYS OF THE JUDICIAL DISTRICTS OF THE STATE ARE AUTHORIZED TO INSTITUTE APPROPRIATE PROCEEDINGS IN THE PROPER COURTS TO PROSECUTE THE MATTER IN THE MANNER REQUIRED BY LAW.

25.5-1-808. Repeal of part - subject to review. THIS PART 8 IS REPEALED, EFFECTIVE SEPTEMBER 1, 2025. BEFORE THE REPEAL, THE FUNCTIONS OF THE STATE DEPARTMENT UNDER THIS PART 8 ARE SCHEDULED FOR REVIEW IN ACCORDANCE WITH SECTION 24-34-104.

SECTION 2. In Colorado Revised Statutes, 24-34-104, **add** (26)(a)(IX) as follows:

24-34-104. General assembly review of regulatory agencies and functions for repeal, continuation, or reestablishment - legislative declaration - repeal. (26) (a) The following agencies, functions, or both, are scheduled for repeal on September 1, 2025:

(IX) THE FUNCTIONS OF THE DEPARTMENT OF HEALTH CARE POLICY AND FINANCING WITH REGARD TO THE ANALYSIS AND REPORTING ON PRESCRIPTION DRUG PRODUCTION COSTS PURSUANT TO PART 8 OF ARTICLE 1 OF TITLE 25.5.

SECTION 3. Effective date. This act takes effect July 1, 2020.

SECTION 4. 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.