

**Second Regular Session
Seventy-second General Assembly
STATE OF COLORADO**

INTRODUCED

LLS NO. 20-0046.01 Christy Chase x2008

SENATE BILL 20-107

SENATE SPONSORSHIP

Ginal,

HOUSE SPONSORSHIP

(None),

Senate Committees
Health & Human Services

House Committees

A BILL FOR AN ACT

101 **CONCERNING AN ANALYSIS OF PRESCRIPTION DRUG MANUFACTURER**
102 **DATA ON HIGH-COST PRESCRIPTION DRUGS PAID FOR BY**
103 **SPECIFIED STATE DEPARTMENTS TO DETERMINE THE**
104 **COMPONENTS OF THE PRODUCTION PROCESS THAT DRIVE THE**
105 **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,

Shading denotes HOUSE amendment. Double underlining denotes SENATE amendment.
Capital letters or bold & italic numbers indicate new material to be added to existing statute.
Dashes through the words indicate deletions from existing statute.

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.

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

2 **SECTION 1.** In Colorado Revised Statutes, **add** part 8 to article
3 1 of title 25.5 as follows:

4 **PART 8**

5 **PRESCRIPTION DRUG PRODUCTION**

6 **COSTS TRANSPARENCY**

7 **25.5-1-801. Short title.** THE SHORT TITLE OF THIS PART 8 IS THE
8 "PRESCRIPTION DRUG PRODUCTION COSTS TRANSPARENCY ACT OF 2020".

9 **25.5-1-802. Legislative declaration.** (1) THE GENERAL
10 ASSEMBLY FINDS AND DECLARES THAT:

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

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

8 (c) IN COLORADO, TOTAL PRESCRIPTION DRUG SPENDING FOR
9 MEDICAID GREW BY FOUR HUNDRED THIRTY-FIVE MILLION DOLLARS FROM
10 2014 TO 2019 AND REACHED OVER ONE BILLION DOLLARS FOR THE 2019
11 CALENDAR YEAR;

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

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

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

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

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

3 (1) "CARRIER" HAS THE SAME MEANING AS SET FORTH IN SECTION
4 10-16-102 (8).

5 (2) "COMPREHENSIVE LIST" MEANS THE LIST OF PRESCRIPTION
6 DRUGS COMPILED BY THE DEPARTMENTS IN ACCORDANCE WITH SECTION
7 25.5-1-805.

8 (3) "COURSE OF THERAPY" MEANS EITHER:

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

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

16 (4) "DEPARTMENTS" MEANS THE DEPARTMENT OF CORRECTIONS,
17 THE DEPARTMENT OF HUMAN SERVICES, THE DEPARTMENT OF PERSONNEL,
18 AND THE STATE DEPARTMENT.

19 (5) "DESIGNATED CONTRACTOR" MEANS AN ORGANIZATION OR
20 ENTITY WITH WHICH THE STATE DEPARTMENT CONTRACTS UNDER SECTION
21 25.5-1-804 TO COLLECT, ANALYZE, AND REPORT PRESCRIPTION DRUG
22 PRICE DATA PURSUANT TO SECTION 25.5-1-805.

23 (6) "FDA" MEANS THE FEDERAL FOOD AND DRUG ADMINISTRATION
24 IN THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES.

25 (7) "MANUFACTURER" MEANS:

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

1 (b) A HOLDING COMPANY, PARENT COMPANY, OR OTHER AFFILIATE
2 OF A PERSON DESCRIBED IN SUBSECTION (7)(a) OF THIS SECTION.

3 (8) "PRESCRIPTION DRUG" HAS THE SAME MEANING AS SET FORTH
4 IN SECTION 12-280-103 (42).

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

7 **25.5-1-804. Establishing transparency - state department or**
8 **contractor to collect and analyze production cost data - funding.**

9 (1) (a) THE STATE DEPARTMENT OR A DESIGNATED CONTRACTOR, AS
10 APPLICABLE, SHALL COLLECT, ANALYZE, AND REPORT PRESCRIPTION DRUG
11 PRODUCTION COST DATA PURSUANT TO SECTION 25.5-1-805. THE STATE
12 DEPARTMENT OR DESIGNATED CONTRACTOR, AS APPLICABLE, SHALL
13 COLLECT DATA FROM THE ALL-PAYER HEALTH CLAIMS DATABASE
14 ESTABLISHED PURSUANT TO SECTION 25.5-1-204, THE DIVISION OF
15 INSURANCE, THE DEPARTMENTS, AND ANY OTHER SOURCES THAT HAVE
16 RELEVANT INFORMATION.

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

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

22 (II) THE STATE DEPARTMENT SHALL SELECT A THIRD-PARTY
23 CONTRACTOR THAT:

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

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

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

10 **25.5-1-805. Reporting requirements - departments to compile**
11 **list of high-cost prescription drugs - information from manufacturers**
12 **- data analysis - legislative reports.** (1) (a) (I) BY DECEMBER 1, 2020,
13 AND BY EACH DECEMBER 1 THEREAFTER, THE DEPARTMENTS SHALL
14 JOINTLY COMPILE A COMPREHENSIVE LIST CONTAINING THE NAMES AND
15 WHOLESALE ACQUISITION COSTS OF THE FOLLOWING PRESCRIPTION DRUGS
16 THAT EACH DEPARTMENT PURCHASED OR PAID FOR DURING THE
17 IMMEDIATELY PRECEDING STATE FISCAL YEAR:

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

20 (B) THE TWENTY HIGHEST-COST PRESCRIPTION DRUGS BASED ON
21 THE VOLUME OF THE DRUG PAID FOR OR PURCHASED.

22 (II) THE DEPARTMENTS SHALL DETERMINE THE PRESCRIPTION
23 DRUGS TO INCLUDE ON THE COMPREHENSIVE LIST BASED ON THE PRICE
24 PAID BY THE DEPARTMENTS FOR EACH PRESCRIPTION DRUG.

25 (b) THE DEPARTMENTS SHALL PROVIDE THE COMPREHENSIVE LIST
26 TO THE STATE DEPARTMENT, AND, IF THE STATE DEPARTMENT HAS
27 CONTRACTED WITH A THIRD-PARTY CONTRACTOR PURSUANT TO SECTION

1 25.5-1-804, THE STATE DEPARTMENT SHALL MAKE THE COMPREHENSIVE
2 LIST AVAILABLE TO THE DESIGNATED CONTRACTOR.

3 (2) (a) BY FEBRUARY 1, 2021, AND BY EACH FEBRUARY 1
4 THEREAFTER, THE STATE DEPARTMENT OR DESIGNATED CONTRACTOR, AS
5 APPLICABLE, SHALL SUBMIT A WRITTEN REQUEST TO EACH
6 MANUFACTURER FOR INFORMATION SHOWING THE BASIS FOR AND
7 COMPONENTS OF THE WHOLESALE ACQUISITION COST OF EACH
8 PRESCRIPTION DRUG ON THE COMPREHENSIVE LIST THAT THE
9 MANUFACTURER PRODUCED, INCLUDING THE FOLLOWING:

10 (I) RESEARCH AND DEVELOPMENT COSTS;

11 (II) CLINICAL TRIAL COSTS;

12 (III) REGULATORY COSTS;

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

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

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

21 (VII) PATENT AND LICENSING COSTS; AND

22 (VIII) PROMOTIONAL MARKETING COSTS, INCLUDING THE COSTS
23 OF DIRECT-TO-CONSUMER ADVERTISING.

24 (b) WITHIN ONE HUNDRED TWENTY DAYS AFTER RECEIPT OF A
25 WRITTEN REQUEST UNDER SUBSECTION (2)(a) OF THIS SECTION BUT NO
26 LATER THAN JUNE 1 OF THE SAME YEAR, A MANUFACTURER SHALL
27 PROVIDE TO THE STATE DEPARTMENT OR DESIGNATED CONTRACTOR, AS

1 APPLICABLE, FULL AND COMPLETE DOCUMENTATION SHOWING THE BASIS
2 FOR THE WHOLESALE ACQUISITION COST OF EACH PRESCRIPTION DRUG ON
3 THE COMPREHENSIVE LIST THAT THE MANUFACTURER PRODUCED.

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

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

27 (b) NOTWITHSTANDING SECTION 24-1-136 (11)(a)(I), THE

1 REPORTING REQUIREMENT IN THIS SUBSECTION (4) CONTINUES
2 INDEFINITELY.

3 (5) THE STATE DEPARTMENT AND THE DESIGNATED CONTRACTOR,
4 IF THE STATE DEPARTMENT CONTRACTS WITH A DESIGNATED CONTRACTOR
5 PURSUANT TO SECTION 25.5-1-804, SHALL MAINTAIN CONFIDENTIALITY OF
6 ALL PROPRIETARY INFORMATION OBTAINED FROM A MANUFACTURER, AND
7 ANY PROPRIETARY INFORMATION IS EXEMPT FROM THE "COLORADO OPEN
8 RECORDS ACT", PART 2 OF ARTICLE 72 OF THIS TITLE 24.

9 **25.5-1-806. Rules.** THE EXECUTIVE DIRECTOR MAY ADOPT RULES
10 AS NECESSARY TO IMPLEMENT AND ADMINISTER THIS PART 8.

11 **25.5-1-807. Enforcement - civil penalties.** (1) A
12 MANUFACTURER THAT FAILS TO REPORT THE INFORMATION REQUESTED BY
13 THE STATE DEPARTMENT IN ACCORDANCE WITH SECTION 25.5-1-805 (2) IS
14 SUBJECT TO A CIVIL PENALTY OF UP TO TEN THOUSAND DOLLARS PER DAY
15 FOR EACH DAY THE MANUFACTURER FAILS TO REPORT THE INFORMATION.

16 (2) THE EXECUTIVE DIRECTOR SHALL REPORT MANUFACTURER
17 VIOLATIONS OF THE REPORTING REQUIREMENTS SPECIFIED IN SECTION
18 25.5-1-805 (2) TO THE ATTORNEY GENERAL. THE ATTORNEY GENERAL AND
19 THE DISTRICT ATTORNEYS OF THE JUDICIAL DISTRICTS OF THE STATE ARE
20 AUTHORIZED TO INSTITUTE APPROPRIATE PROCEEDINGS IN THE PROPER
21 COURTS TO PROSECUTE THE MATTER IN THE MANNER REQUIRED BY LAW.

22 **SECTION 2. Effective date.** This act takes effect July 1, 2020.

23 **SECTION 3. Safety clause.** The general assembly hereby finds,
24 determines, and declares that this act is necessary for the immediate
25 preservation of the public peace, health, or safety.