

Second Regular Session
Seventy-first General Assembly
STATE OF COLORADO

ENGROSSED

*This Version Includes All Amendments Adopted
on Second Reading in the House of Introduction*

LLS NO. 18-0504.01 Kip Kolkmeier x4510

HOUSE BILL 18-1009

HOUSE SPONSORSHIP

Roberts,

SENATE SPONSORSHIP

Donovan,

House Committees
Health, Insurance, & Environment
Appropriations

Senate Committees

A BILL FOR AN ACT

101 **CONCERNING TRANSPARENCY IN DIABETES PRESCRIPTION DRUGS**
102 **PRICING, AND, IN CONNECTION THEREWITH, MAKING AN**
103 **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>.)

The bill creates the "Diabetes Drug Pricing Transparency Act of 2018". The state board of health is responsible for implementing the act. Drug manufacturers and pharmacy benefit managers must submit annual reports to the state board regarding drugs used to treat diabetes that are subject to price increases of certain percentages. The state board analyzes

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.

HOUSE
Amended 2nd Reading
April 19, 2018

the submitted information and publishes a report. The state board may impose penalties on drug manufacturers or pharmacy benefit managers who do not comply with reporting requirements. Nonprofit organizations advocating for patients with diabetes or funding diabetes medical research that receive contributions from certain diabetes drug manufacturers must annually report those contributions.

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

2 **SECTION 1.** In Colorado Revised Statutes, **add** article 51 to title
3 25 as follows:

ARTICLE 51

Diabetes Drug Pricing Transparency

25-51-101. Short title. THE SHORT TITLE OF THIS ARTICLE 51 IS
THE "DIABETES DRUG PRICING TRANSPARENCY ACT OF 2018".

8 **25-51-102. Legislative declaration.** (1) THE GENERAL ASSEMBLY
9 FINDS AND DECLARES THAT:

10 (a) ALMOST TWENTY THOUSAND COLORADANS ARE DIAGNOSED
11 WITH DIABETES EACH YEAR. AS OF JANUARY 1, 2018, NEARLY THREE
12 HUNDRED THOUSAND COLORADO ADULTS HAVE BEEN DIAGNOSED WITH
13 DIABETES AND ANOTHER ONE HUNDRED TEN THOUSAND ARE
14 UNDIAGNOSED BUT LIVING WITH THE DISEASE.

15 (b) EVERY COLORADAN WITH TYPE 1 DIABETES AND MANY WITH
16 TYPE 2 DIABETES RELY ON DAILY DOSES OF INSULIN TO SURVIVE:

17 (c) THE ANNUAL MEDICAL COST RELATED TO DIABETES IN
18 COLORADO IS ALMOST FOUR BILLION DOLLARS. APPROXIMATELY
19 EIGHTEEN PERCENT OF THAT AMOUNT, OR SEVEN HUNDRED MILLION
20 DOLLARS, IS FOR PRESCRIPTION DRUGS TO TREAT DIABETES.

21 (d) INSULIN PRICES ROSE BY FORTY-FIVE PERCENT BETWEEN 2014
22 AND 2017; AND

4 **25-51-103. Definitions.** AS USED IN THIS ARTICLE 51, UNLESS THE
5 CONTEXT OTHERWISE REQUIRES:

6 (1) "DEPARTMENT" MEANS THE DEPARTMENT OF PUBLIC HEALTH
7 AND ENVIRONMENT CREATED IN SECTION 25-1-102.

8 (2) "DRUG MANUFACTURER" MEANS A MANUFACTURER OF
9 PRESCRIPTION INSULIN DRUGS THAT ARE MADE AVAILABLE IN COLORADO
10 AND THAT ARE USED FOR THE TREATMENT OF DIABETES.

11 (3) "HEALTH COVERAGE PLAN" HAS THE SAME MEANING AS SET
12 FORTH IN SECTION 10-16-102 (34).

13 (4) "INSURER" HAS THE SAME MEANING AS SET FORTH IN SECTION
14 10-1-102 (13).

15 (5) "PHARMACY BENEFIT MANAGER" HAS THE SAME MEANING AS
16 SET FORTH IN SECTION 25-37-102(13)

17 (6) "STATE BOARD" MEANS THE STATE BOARD OF HEALTH
18 CREATED IN SECTION 25-1-103

25 25-51-104. State board list of diabetes prescription drugs.

26 (1) ON OR BEFORE FEBRUARY 1, 2019, AND BY FEBRUARY 1 EACH YEAR
27 THEREAFTER, THE STATE BOARD SHALL COMPILE;

5 (b) A LIST OF PRESCRIPTION DRUGS DESCRIBED IN SUBSECTION
6 (1)(a) OF THIS SECTION THAT WERE SUBJECT TO AN INCREASE IN THE
7 WHOLESALE ACQUISITION COST BY A PERCENTAGE GREATER THAN:

25-51-105. Drug manufacturer drug pricing reports. (1) THE
STATE BOARD SHALL PREPARE A REPORT FORM TO BE COMPLETED BY DRUG
MANUFACTURERS OF PRESCRIPTION DRUGS APPEARING ON THE LIST
COMPILED BY THE STATE BOARD IN ACCORDANCE WITH SECTION 25-51-104

1 (1)(a). THE REPORT FORM SHALL SPECIFY THE APPLICABLE TIME PERIODS
2 FOR THE INFORMATION REQUIRED TO BE REPORTED.

3 (2) ON OR BEFORE MAY 1, 2019, AND BY EACH MAY 1
4 THEREAFTER, EACH DRUG MANUFACTURER OF A PRESCRIPTION DRUG
5 APPEARING ON THE MOST CURRENT LIST COMPILED BY THE STATE BOARD
6 IN ACCORDANCE WITH SECTION 25-51-104 (1)(a) SHALL PREPARE AND
7 SUBMIT TO THE STATE BOARD A COMPLETED REPORT FORM FOR EACH
8 LISTED DRUG, WHICH FORM INCLUDES:

9 (a) THE TOTAL COST TO PRODUCE THE DRUG;
10 (b) THE TOTAL ADMINISTRATIVE EXPENDITURES DIRECTLY
11 RELATED TO THE DRUG, INCLUDING EXPENDITURES TO MARKET OR
12 ADVERTIZE THE DRUG TO COLORADO RESIDENTS;

13 (c) THE TOTAL ANNUAL PROFIT THE DRUG MANUFACTURER
14 EARNED FROM THE DRUG, IDENTIFIED BY YEAR;

15 (d) THE PERCENTAGE OF THE DRUG MANUFACTURER'S TOTAL
16 PROFIT ATTRIBUTABLE TO THE PROFIT FROM THE DRUG, IDENTIFIED BY
17 YEAR;

18 (e) THE TOTAL AMOUNT OF FINANCIAL ASSISTANCE THAT THE
19 DRUG MANUFACTURER PROVIDED THROUGH ANY PATIENT PRESCRIPTION
20 ASSISTANCE PROGRAM FOR THE DRUG;

21 (f) THE TOTAL COST ASSOCIATED WITH COUPONS OR REBATES
22 PROVIDED DIRECTLY TO CONSUMERS AND THE TOTAL COST OF PROGRAMS
23 ASSISTING CONSUMERS IN PAYING COPAYMENTS ATTRIBUTABLE TO THE
24 DRUG;

25 (g) THE WHOLESALE ACQUISITION COST OF THE DRUG;

26 (h) A RECORD OF EACH INCREASE IN THE WHOLESALE ACQUISITION
27 COST OF THE DRUG OVER THE FIVE YEARS IMMEDIATELY PRECEDING THE

1 DATE ON WHICH THE REPORT IS SUBMITTED, INCLUDING:

2 (I) THE AMOUNT OF EACH INCREASE, EXPRESSED AS A PERCENTAGE
3 OF THE TOTAL WHOLESALE ACQUISITION COST OF THE DRUG;

4 (II) THE MONTH AND YEAR IN WHICH EACH INCREASE BECAME
5 EFFECTIVE; AND

6 (III) A SPECIFIC EXPLANATION FOR THE INCREASE, LISTING EACH
7 FACTOR THAT CONTRIBUTED TO THE INCREASE, THE PERCENTAGE OF THE
8 TOTAL INCREASE THAT IS ATTRIBUTABLE TO EACH FACTOR, AND AN
9 EXPLANATION OF HOW EACH FACTOR AFFECTED THE INCREASE;

10 (i) THE AGGREGATE AMOUNT OF ALL REBATES ~~AND, SEPARATELY,~~
11 ~~THE AGGREGATE AMOUNT OF ALL ADMINISTRATIVE FEES THAT THE DRUG~~
12 ~~MANUFACTURER PROVIDED TO PHARMACY BENEFIT MANAGERS FOR SALES~~
13 ~~OF THE DRUG WITHIN THE STATE, IDENTIFIED BY YEAR;~~

14 (j) THE AGGREGATE AMOUNT OF ALL RESEARCH AND
15 ~~DEVELOPMENT COSTS ATTRIBUTABLE TO DIABETES PRESCRIPTION DRUGS,~~
16 ~~IDENTIFIED BY YEAR; AND~~

17 (k) ANY ADDITIONAL INFORMATION REQUIRED BY THE STATE
18 BOARD TO ANALYZE THE COST OF PRESCRIPTION DRUGS THAT APPEAR ON
19 THE LIST COMPILED IN ACCORDANCE WITH SECTION 25-51-104 (1)(a).

20 **25-51-106. Pharmacy benefit manager pricing reports.**

21 (1) THE STATE BOARD SHALL PREPARE A REPORT FORM TO BE COMPLETED
22 BY PHARMACY BENEFIT MANAGERS. THE REPORT FORM SHALL SPECIFY THE
23 APPLICABLE TIME PERIODS FOR THE INFORMATION REQUIRED TO BE
24 REPORTED.

25 (2) ON OR BEFORE MAY 1, 2019, AND BY EACH MAY 1
26 THEREAFTER, A PHARMACY BENEFIT MANAGER SHALL SUBMIT TO THE
27 STATE BOARD A REPORT THAT INCLUDES:

6 (b) THE TOTAL AMOUNT OF ALL REBATES DESCRIBED IN
7 SUBSECTION (2)(a) OF THIS SECTION RETAINED BY THE PHARMACY BENEFIT
8 MANAGER;

9 (c) THE TOTAL AMOUNT OF ADMINISTRATIVE FEES RECEIVED FROM
10 DRUG MANUFACTURERS AND INSURERS FOR PRESCRIPTION DRUGS LISTED
11 IN SECTION 25-51-104 (1)(a), INCLUDING ALL FEES RECEIVED TO PROCESS
12 UTILIZATION MANAGEMENT REQUESTS;

13 (d) THE TOTAL AMOUNT OF ALL REBATES DESCRIBED IN
14 SUBSECTION (2)(a) OF THIS SECTION NEGOTIATED FOR PURCHASES OF
15 DRUGS FOR USE BY:

16 (I) COLORADO MEDICARE RECIPIENTS IN ACCORDANCE WITH 42
17 U.S.C. SEC. 1395 ET SEQ.;

18 (II) COLORADO MEDICAID RECIPIENTS IN ACCORDANCE WITH 42
19 U.S.C. SEC. 1396 ET SEQ.;

20 (III) PERSONS ENROLLED IN PRIVATE HEALTH INSURANCE PLANS,
21 THE PREMIUMS FOR WHICH ARE PAID AT LEAST IN PART BY A GOVERNMENT
22 ENTITY: AND

23 (IV) COLORADO RESIDENTS ENROLLED IN PRIVATE HEALTH
24 INSURANCE PLANS OTHER THAN PLANS INCLUDED IN SUBSECTION
25 (2)(c)(III) OF THIS SECTION:

26 (e) THE TOTAL ANNUAL PAYMENTS, INCLUDING REIMBURSEMENTS
27 AND FEES, PAID TO COLORADO PHARMACIES FOR DISPENSING

1 PRESCRIPTION DRUGS ON THE LIST COMPILED IN ACCORDANCE WITH
2 SECTION 25-51-104 (1)(a). THIS INFORMATION MUST SEPARATELY
3 IDENTIFY:

4 (I) THE AMOUNT ATTRIBUTABLE TO DISPENSING FEES; AND
5 (II) THE AMOUNT ATTRIBUTABLE TO SERVICE OR ADMINISTRATIVE
6 FEES;

7 (f) THE TOTAL ANNUAL PAYMENTS RECEIVED FROM COLORADO
8 PHARMACIES FOR PRESCRIPTION DRUGS ON THE LIST COMPILED IN
9 ACCORDANCE WITH SECTION 25-51-104 (1)(a); AND
10 (g) THE TOTAL ANNUAL PAYMENTS RECEIVED FROM COLORADO
11 INSURERS AND EMPLOYERS FOR PRESCRIPTION DRUGS ON THE LIST
12 COMPILED IN ACCORDANCE WITH SECTION 25-51-104 (1)(a).

13 **25-51-107. Insurer pricing reports.** (1) INSURERS ISSUING
14 HEALTH COVERAGE PLANS TO COLORADO RESIDENTS SHALL ANNUALLY
15 REPORT TO THE STATE BOARD THE FOLLOWING:

16 (a) THE PERCENTAGE OF TOTAL PREMIUMS CHARGED TO
17 COLORADO RESIDENTS IN THE PRIOR CALENDAR YEAR THAT ARE DIRECTLY
18 ATTRIBUTABLE TO THE COST OF COVERED PRESCRIPTION DRUGS ON THE
19 LIST COMPILED IN ACCORDANCE WITH SECTION 25-51-104 (1)(a);

20 (b) THE ESTIMATED PERCENTAGE OF TOTAL PREMIUMS TO BE
21 CHARGED TO COLORADO RESIDENTS FOR THE NEXT CALENDAR YEAR
22 DIRECTLY ATTRIBUTABLE TO THE COST OF COVERED PRESCRIPTION DRUGS
23 ON THE LIST COMPILED IN ACCORDANCE WITH SECTION 25-51-104 (1)(a);

24 (c) THE ANNUAL PERCENTAGE INCREASE OR DECREASE IN TOTAL
25 COSTS FROM THE PRIOR CALENDAR YEAR PAID BY THE INSURER FOR
26 PRESCRIPTION DRUGS ON THE LIST COMPILED IN ACCORDANCE WITH
27 SECTION 25-51-104 (1)(a);

1 (d) THE AVERAGE MONTHLY COST PER ENROLLEE FOR THE PRIOR
2 CALENDAR YEAR INCURRED BY THE INSURER FOR PRESCRIPTION DRUGS ON
3 THE LIST COMPILED IN ACCORDANCE WITH SECTION 25-51-104 (1)(a)
4 DIVIDED BY THE NUMBER OF PERSONS ENROLLED IN THE HEALTH
5 COVERAGE PLAN;

6 (e) THE AVERAGE ANNUAL COST FOR THE PRIOR CALENDAR YEAR
7 TO AN ENROLLEE IN A HEALTH COVERAGE PLAN FOR PRESCRIPTION DRUGS
8 ON THE LIST COMPILED IN ACCORDANCE WITH SECTION 25-51-104 (1)(a).

9 (f) A STATEMENT DESCRIBING THE INSURER'S USE OF PHARMACY
10 BENEFIT MANAGERS IN MANAGING COSTS UNDER HEALTH COVERAGE
11 PLANS;

12 (g) THE AMOUNT OF REBATES AND DISCOUNTS RECEIVED FROM
13 PHARMACY BENEFIT MANAGERS IN THE PRIOR CALENDAR YEAR
14 ATTRIBUTABLE TO PRESCRIPTION DRUGS ON THE LIST COMPILED IN
15 ACCORDANCE WITH SECTION 25-51-104 (1)(a);

16 (h) A STATEMENT DESCRIBING HOW THE INSURER ADJUSTS
17 ENROLLEE COST SHARING IN HEALTH COVERAGE PLANS AS A RESULT OF
18 PHARMACY BENEFIT MANAGER REBATES AND DISCOUNTS;

19 (i) THE ADMINISTRATIVE FEES PAID IN THE PRIOR CALENDAR YEAR
20 TO PHARMACY BENEFIT MANAGERS AND THE PERCENTAGE OF THOSE
21 ADMINISTRATIVE FEES ATTRIBUTABLE TO PRESCRIPTION DRUGS ON THE
22 LIST COMPILED IN ACCORDANCE WITH SECTION 25-51-104 (1)(a); AND

23 (j) THE AVERAGE AMOUNT EACH ENROLLEE PAYS FOR
24 PRESCRIPTION DRUGS ON THE LIST COMPILED IN ACCORDANCE WITH
25 SECTION 25-51-104 (1)(a).

26 **25-51-108. Pharmacy pricing reports. (1) PERSONS ENGAGED IN**

27 THE PRACTICE OF PHARMACY AS THAT TERM IS DEFINED IN SECTION

1 12-42.5-102 (31) SHALL ANNUALLY REPORT TO THE STATE BOARD THE
2 FOLLOWING INFORMATION FROM THE PRIOR CALENDAR YEAR:

3 (a) THE TOTAL PAYMENTS RECEIVED FROM PHARMACY BENEFIT
4 MANAGERS FOR PRESCRIPTION DRUGS ON THE LIST COMPILED IN
5 ACCORDANCE WITH SECTION 25-51-104 (1)(a);

6 (b) THE TOTAL PAYMENTS RECEIVED FROM INSURERS FOR
7 PRESCRIPTION DRUGS ON THE LIST COMPILED IN ACCORDANCE WITH
8 SECTION 25-51-104 (1)(a);

9 (c) THE TOTAL PAYMENTS TO PRESCRIPTION DRUG WHOLESALERS,
10 DISTRIBUTORS, AND MANUFACTURERS FOR PRESCRIPTION DRUGS ON THE
11 LIST COMPILED IN ACCORDANCE WITH SECTION 25-51-104 (1)(a); AND

12 (d) THE TOTAL FEES, INCLUDING ADMINISTRATIVE FEES PAID TO
13 PHARMACY BENEFIT MANAGERS, FOR DISPENSING PRESCRIPTION DRUGS ON
14 THE LIST COMPILED IN ACCORDANCE WITH SECTION 25-51-104 (1)(a).

15 **25-51-109. State board analysis of pricing reports - report to**
16 **general assembly.** (1) ON OR BEFORE AUGUST 1, 2019, AND BY EACH
17 AUGUST 1 THEREAFTER, THE STATE BOARD SHALL ANALYZE DATA IN THE
18 REPORTS SUBMITTED BY DRUG MANUFACTURERS AND PHARMACY BENEFIT
19 MANAGERS PURSUANT TO SECTIONS 25-51-105 AND 25-51-106 AND
20 PRODUCE A REPORT ON PRESCRIPTION DRUG PRICES FOR DRUGS INCLUDED
21 IN THE DRUG MANUFACTURER AND PHARMACY BENEFIT MANAGER
22 REPORTS. BASED ON THE STATE BOARD'S ANALYSIS, THE STATE BOARD
23 REPORT SHALL INCLUDE THE STATE BOARD'S CONCLUSIONS REGARDING
24 THE SPECIFIC REASONS FOR AN INCREASE IN THE PRICE OF EACH LISTED
25 DRUG. BY AUGUST 1, 2019, AND BY EACH AUGUST 1 THEREAFTER, THE
26 DEPARTMENT SHALL POST A COPY OF THE STATE BOARD'S REPORT ON THE
27 DEPARTMENT'S WEBSITE.

9 **25-51-110. State board may accept gifts and grants - rules -**

10 **penalties - exemption.** (1) THE STATE BOARD MAY SEEK, ACCEPT, AND
11 EXPEND GIFTS, GRANTS, OR DONATIONS FROM PRIVATE OR PUBLIC SOURCES
12 FOR THE PURPOSES OF THIS ARTICLE 51.

24 (4) NOTHING CONTAINED IN THIS ARTICLE 51 SHALL APPLY TO THE
25 COVERAGE OF PRESCRIPTION DRUGS UNDER A HEALTH COVERAGE PLAN
26 THAT IS SUBJECT TO THE FEDERAL "EMPLOYEE RETIREMENT INCOME
27 SECURITY ACT OF 1974".

1 **25-51-111. Nonprofit organization reports.** (1) ON OR BEFORE
2 MAY 1, 2019, AND BY EACH MAY 1 THEREAFTER, A NONPROFIT
3 ORGANIZATION THAT ADVOCATES ON BEHALF OF PATIENTS WITH DIABETES
4 OR FUNDS DIABETES MEDICAL RESEARCH IN COLORADO THAT HAS
5 RECEIVED A PAYMENT, DONATION, SUBSIDY, OR THING OF VALUE FROM A
6 DRUG MANUFACTURER OF A PRESCRIPTION DRUG APPEARING ON THE LIST
7 COMPILED BY THE STATE BOARD IN ACCORDANCE WITH SECTION 25-51-104
8 (1)(b) DURING THE IMMEDIATELY PRECEDING CALENDAR YEAR SHALL
9 COMPILE A REPORT THAT INCLUDES:

10 (a) THE AMOUNT OF EACH PAYMENT, DONATION, SUBSIDY, OR
11 THING OF VALUE RECEIVED FROM EACH DRUG MANUFACTURER; AND
12 (b) THE PERCENTAGE OF THE NONPROFIT ORGANIZATION'S TOTAL
13 GROSS INCOME ATTRIBUTABLE TO PAYMENTS, DONATIONS, SUBSIDIES, OR
14 OTHER THINGS OF VALUE RECEIVED FROM EACH DRUG MANUFACTURER IN
15 THE PREVIOUS CALENDAR YEAR.

16 (2) BY MAY 1, 2019, AND BY EACH MAY 1 THEREAFTER,
17 NONPROFIT ORGANIZATIONS REQUIRED TO COMPILE A REPORT UNDER
18 SUBSECTION (1) OF THIS SECTION MUST POST THE REPORT ON A WEBSITE
19 THAT IS ACCESSIBLE TO THE PUBLIC AND MAINTAINED BY THE NONPROFIT
20 ORGANIZATION. IF THE NONPROFIT ORGANIZATION DOES NOT MAINTAIN A
21 WEBSITE THAT IS ACCESSIBLE TO THE PUBLIC, THE NONPROFIT
22 ORGANIZATION SHALL SUBMIT THE REPORT TO THE DEPARTMENT EACH
23 YEAR BY MAY 1. THE DEPARTMENT SHALL POST A COPY OF EACH REPORT
24 SUBMITTED ON THE DEPARTMENT'S WEBSITE.

25 **25-51-112. Information subject to public disclosure.**
26 INFORMATION REQUIRED TO BE SUBMITTED PURSUANT TO THIS ARTICLE 51
27 IS NOT EXEMPT FROM DISCLOSURE UNDER SECTION 24-72-204 (3)(a)(IV)

1 OR ANY OTHER EXEMPTION CONTAINED IN PART 2 OF ARTICLE 72 OF TITLE
2 24.

3 **SECTION 2. Appropriation.** (1) For the 2018-19 state fiscal
4 year, \$287,602 is appropriated to the department of public health and
5 environment for use by the administration and support division. This
6 appropriation is from the general fund. To implement this act, the division
7 may use this appropriation as follows:

8 (a) \$205,057 for personal services, which amount is based on an
9 assumption that the division will require an additional 2.5 FTE;
10 (b) \$71,889 for operating expenses; and
11 (c) \$10,656 for legal services.

12 (2) For the 2018-19 state fiscal year, \$10,656 is appropriated to
13 the department of law. This appropriation is from reappropriated funds
14 received from the department of public health and environment under
15 subsection (1)(c) of this section. To implement this act, the department of
16 law may use this appropriation to provide legal services for the
17 department of public health and environment.

18 **SECTION 3. Act subject to petition - effective date.** This act
19 takes effect at 12:01 a.m. on the day following the expiration of the
20 ninety-day period after final adjournment of the general assembly (August
21 8, 2018, if adjournment sine die is on May 9, 2018); except that, if a
22 referendum petition is filed pursuant to section 1 (3) of article V of the
23 state constitution against this act or an item, section, or part of this act
24 within such period, then the act, item, section, or part will not take effect
25 unless approved by the people at the general election to be held in
26 November 2018 and, in such case, will take effect on the date of the
27 official declaration of the vote thereon by the governor.