Second Regular Session
Seventy-first General Assembly
STATE OF COLORADO

INTRODUCED

LLS NO. 18-0504.01 Kip Kolkmeier x4510 **HOUSE BILL 18-1009**

HOUSE SPONSORSHIP

Roberts,

SENATE SPONSORSHIP

Donovan,

House Committees
Health, Insurance, & Environment

Senate Committees

A BILL FOR AN ACT

CONCERNING TRANSPARENCY IN DIABETES PRESCRIPTION DRUGS PRICING.

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 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.

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

SECTION 1. In Colorado Revised Statutes, **add** article 51 to title 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".

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

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

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

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

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

(e) THE INTENT OF THIS ARTICLE 51 IS TO MAKE INFORMATION

AVAILABLE TO THE PUBLIC ABOUT THE COST OF DIABETES PRESCRIPTION DRUGS IN ORDER TO MAKE DRUG PRICING AS TRANSPARENT AS POSSIBLE.

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

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

(2) "DRUG MANUFACTURER" MEANS THE MANUFACTURER OF A PRESCRIPTION DRUG THAT IS MADE AVAILABLE IN COLORADO AND IS USED FOR THE TREATMENT OF DIABETES, INCLUDING ALL FORMS OF INSULIN AND BIGUANIDES.

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

(4) "STATE BOARD" MEANS THE STATE BOARD OF HEALTH CREATED IN SECTION 25-1-103.

(5) "WHOLESALE ACQUISITION COST" MEANS A DRUG MANUFACTURER'S LIST PRICE FOR A PRESCRIPTION DRUG OFFERED FOR SALE TO WHOLESALERS OR DIRECT PURCHASERS IN THE UNITED STATES, NOT INCLUDING ANY DISCOUNTS, REBATES, OR REDUCTIONS IN PRICE, AS REPORTED IN WHOLESALE PRICE GUIDES OR OTHER PUBLICATIONS OF DRUG PRICING DATA.

25-51-104. State board list of diabetes prescription drugs. (1) ON OR BEFORE FEBRUARY 1, 2019, AND BY FEBRUARY 1 EACH YEAR THEREAFTER, THE STATE BOARD SHALL COMPILE:

(a) A LIST OF PRESCRIPTION DRUGS THAT THE STATE BOARD DETERMINES TO BE ESSENTIAL FOR TREATING DIABETES IN THIS STATE, INCLUDING ALL FORMS OF INSULIN AND BIGUANIDES THAT ARE MADE AVAILABLE IN COLORADO, TOGETHER WITH THE WHOLESALE ACQUISITION

COST OF EACH DRUG ON THE LIST; AND

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

(I) THE PERCENTAGE INCREASE IN THE MEDICAL CARE COMPONENTS OF THE CONSUMER PRICE INDEX FOR DENVER-AURORA-LAKEWOOD FOR THE IMMEDIATELY PRECEDING CALENDAR YEAR; OR

(II) TWICE THE SUM OF THE PERCENTAGE INCREASES IN THE MEDICAL CARE COMPONENTS OF THE CONSUMER PRICE INDEX FOR THE TWO IMMEDIATELY PRECEDING CALENDAR YEARS. FOR PURPOSES OF THE CALCULATION REQUIRED BY THIS SUBSECTION (1)(b)(II), FOR YEARS PRIOR TO 2018, THE MEDICAL CARE COMPONENTS OF THE CONSUMER PRICE INDEX FOR DENVER-BOULDER-GREELEY APPLY TO THIS SUBSECTION (1)(b)(II) AND FOR 2018 AND SUCCEEDING YEARS, THE MEDICAL CARE COMPONENTS OF THE CONSUMER PRICE INDEX FOR DENVER-AURORA-LAKEWOOD APPLY.

(2) THE DEPARTMENT SHALL, BY FEBRUARY 1, 2019, AND BY EACH FEBRUARY 1 THEREAFTER, POST THE LISTS REQUIRED TO BE COMPILED BY SUBSECTION (1) OF THIS SECTION ON THE DEPARTMENT'S WEBSITE.

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

(2) ON OR BEFORE MAY 1, 2019, AND BY EACH MAY 1

THEREAFTER, EACH DRUG MANUFACTURER OF A PRESCRIPTION DRUG APPEARING ON THE MOST CURRENT LIST COMPILED BY THE STATE BOARD IN ACCORDANCE WITH SECTION 25-51-104 (1)(b) SHALL PREPARE AND SUBMIT TO THE STATE BOARD A COMPLETED REPORT FORM FOR EACH LISTED DRUG, WHICH FORM INCLUDES:

(a) THE TOTAL COST TO PRODUCE THE DRUG;

(b) THE TOTAL ADMINISTRATIVE EXPENDITURES DIRECTLY RELATED TO THE DRUG, INCLUDING MARKETING AND ADVERTISING COSTS;

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

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

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

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

(g) THE WHOLESALE ACQUISITION COST OF THE DRUG;

(h) A RECORD OF EACH INCREASE IN THE WHOLESALE ACQUISITION COST OF THE DRUG OVER THE FIVE YEARS IMMEDIATELY PRECEDING THE DATE ON WHICH THE REPORT IS SUBMITTED, INCLUDING:

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

(II) THE MONTH AND YEAR IN WHICH EACH INCREASE BECAME

EFFECTIVE; AND

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

(i) THE AGGREGATE AMOUNT OF ALL REBATES THAT THE DRUG MANUFACTURER PROVIDED TO PHARMACY BENEFIT MANAGERS FOR SALES OF THE DRUG WITHIN THE STATE; AND

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

25-51-106. Pharmacy benefit manager pricing reports. (1) THE STATE BOARD SHALL PREPARE A REPORT FORM TO BE COMPLETED BY PHARMACY BENEFIT MANAGERS. THE REPORT FORM SHALL SPECIFY THE APPLICABLE TIME PERIODS FOR THE INFORMATION REQUIRED TO BE REPORTED.

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

(a) THE TOTAL AMOUNT OF ALL REBATES THE PHARMACY BENEFIT MANAGER NEGOTIATED WITH DRUG MANUFACTURERS DURING THE IMMEDIATELY PRECEDING CALENDAR YEAR FOR PRESCRIPTION DRUGS INCLUDED ON THE LIST COMPILED BY THE DEPARTMENT IN ACCORDANCE WITH SECTION 25-51-104 (1)(b);

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

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

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

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

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

(IV) PERSONS ENROLLED IN PRIVATE HEALTH INSURANCE PLANS OTHER THAN PLANS INCLUDED IN SUBSECTION (2)(c)(III) OF THIS SECTION.

25-51-107. State board analysis of pricing reports - report to general assembly. (1) ON OR BEFORE AUGUST 1, 2019, AND BY EACH AUGUST 1 THEREAFTER, THE STATE BOARD SHALL ANALYZE DATA IN THE REPORTS SUBMITTED BY DRUG MANUFACTURERS AND PHARMACY BENEFIT MANAGERS PURSUANT TO SECTIONS 25-51-105 AND 25-51-106 AND PRODUCE A REPORT ON PRESCRIPTION DRUG PRICES FOR DRUGS INCLUDED IN THE DRUG MANUFACTURER AND PHARMACY BENEFIT MANAGER REPORTS. BASED ON THE STATE BOARD'S ANALYSIS, THE STATE BOARD REPORT SHALL INCLUDE THE STATE BOARD'S CONCLUSIONS REGARDING THE SPECIFIC REASONS FOR AN INCREASE IN THE PRICE OF EACH LISTED DRUG. BY AUGUST 1, 2019, AND BY EACH AUGUST 1 THEREAFTER, THE DEPARTMENT SHALL POST A COPY OF THE STATE BOARD'S REPORT ON THE DEPARTMENT'S WEBSITE.

(2) BY AUGUST 1, 2019, AND BY EACH AUGUST 1 THEREAFTER, NOTWITHSTANDING SECTION 24-1-136 (11)(a)(I), THE DEPARTMENT SHALL

SUBMIT THE REPORT REQUIRED BY THIS SECTION TO THE JOINT BUDGET COMMITTEE OF THE GENERAL ASSEMBLY, THE HEALTH AND HUMAN SERVICES COMMITTEE OF THE SENATE, AND THE PUBLIC HEALTH CARE AND HUMAN SERVICES AND THE HEALTH, INSURANCE, AND ENVIRONMENT COMMITTEES OF THE HOUSE OF REPRESENTATIVES, OR ANY SUCCESSOR COMMITTEES.

25-51-108. State board may accept gifts and grants - rules - penalties. (1) THE STATE BOARD MAY SEEK, ACCEPT, AND EXPEND GIFTS, GRANTS, OR DONATIONS FROM PRIVATE OR PUBLIC SOURCES FOR THE PURPOSES OF THIS ARTICLE 51.

(2) THE STATE BOARD MAY PROMULGATE RULES NECESSARY FOR THE ADMINISTRATION OF THIS ARTICLE 51.

(3) THE STATE BOARD MAY IMPOSE A PENALTY ON A DRUG MANUFACTURER OR PHARMACY BENEFIT MANAGER FOR A FAILURE TO SUBMIT INFORMATION REQUIRED BY THIS ARTICLE 51. THE PENALTY MAY NOT EXCEED TEN THOUSAND DOLLARS PER DAY FOR EACH DAY THE DRUG MANUFACTURER OR PHARMACY BENEFIT MANAGER FAILS TO SUBMIT THE INFORMATION REQUIRED BY THIS ARTICLE 51. IN ANY ADMINISTRATIVE ACTION BY THE STATE BOARD TO IMPOSE A PENALTY PURSUANT TO THIS SUBSECTION (3), THE PROCESS MUST BE CONSISTENT WITH SECTION 24-4-105.

25-51-109. Nonprofit organization reports. (1) ON OR BEFORE MAY 1, 2019, AND BY EACH MAY 1 THEREAFTER, A NONPROFIT ORGANIZATION THAT ADVOCATES ON BEHALF OF PATIENTS WITH DIABETES OR FUNDS DIABETES MEDICAL RESEARCH IN COLORADO THAT HAS RECEIVED A PAYMENT, DONATION, SUBSIDY, OR THING OF VALUE FROM A DRUG MANUFACTURER OF A PRESCRIPTION DRUG APPEARING ON THE LIST

COMPILED BY THE STATE BOARD IN ACCORDANCE WITH SECTION 25-51-104 (1)(b) DURING THE IMMEDIATELY PRECEDING CALENDAR YEAR SHALL COMPILE A REPORT THAT INCLUDES:

(a) THE AMOUNT OF EACH PAYMENT, DONATION, SUBSIDY, OR THING OF VALUE RECEIVED FROM EACH DRUG MANUFACTURER; AND

(b) THE PERCENTAGE OF THE NONPROFIT ORGANIZATION'S TOTAL GROSS INCOME ATTRIBUTABLE TO PAYMENTS, DONATIONS, SUBSIDIES, OR OTHER THINGS OF VALUE RECEIVED FROM EACH DRUG MANUFACTURER IN THE PREVIOUS CALENDAR YEAR.

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

25-51-110. Information subject to public disclosure. INFORMATION REQUIRED TO BE SUBMITTED PURSUANT TO THIS ARTICLE 51 IS NOT EXEMPT FROM DISCLOSURE UNDER SECTION 24-72-204 (3)(a)(IV) OR ANY OTHER EXEMPTION CONTAINED IN PART 2 OF ARTICLE 72 OF TITLE 24.

SECTION 2. Act subject to petition - effective date. This act takes effect at 12:01 a.m. on the day following the expiration of the ninety-day period after final adjournment of the general assembly (August 8, 2018, if adjournment sine die is on May 9, 2018); except that, if a

referendum petition is filed pursuant to section 1 (3) of article V of the state constitution against this act or an item, section, or part of this act within such period, then the act, item, section, or part will not take effect unless approved by the people at the general election to be held in November 2018 and, in such case, will take effect on the date of the official declaration of the vote thereon by the governor.