Second Regular Session
Seventieth General Assembly
STATE OF COLORADO

INTRODUCED

LLS NO. 16-0081.01 Christy Chase x2008 **HOUSE BILL 16-1102**

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A BILL FOR AN ACT

CONCERNING A REQUIREMENT THAT DRUG MANUFACTURERS REPORT PRODUCTION COSTS FOR CERTAIN HIGH-COST 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://www.leg.state.co.us/billsummaries.)

The bill requires a drug manufacturer that produces a prescription drug made available in Colorado and for which the wholesale acquisition cost equals or exceeds $50,000 per year or per course of treatment to submit a report to the Colorado commission on affordable health care (commission) detailing the production costs for the drug. The report is to

include:

- Costs for research and development;
- Clinical trials and regulatory costs;
- Costs for materials, manufacturing, and administration attributable to the drug;
- Costs paid by another entity, including grants, subsidies, or other support;
- Acquisition costs, including patents and licensing costs;
- Marketing and advertising costs.

Additionally, a manufacturer must report the cumulative annual history of increases in the average wholesale price and wholesale acquisition cost of the drug, the total company profits attributable to the drug, and the total amount of financial assistance the manufacturer has provided through patient prescription assistance programs.

Manufacturers must submit the report to the commission by August 1, 2016.

By June 1, 2016, the commission must develop a form for manufacturers to use to submit the report. Additionally, the commission is to submit a report to the general assembly by December 1, 2016, that outlines the information reported by drug manufacturers and contains any recommendations the commission may have regarding legislative, administrative, or other policy changes based on the data received from drug manufacturers.

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

SECTION 1. In Colorado Revised Statutes, **add** article 48 to title 25 as follows:

ARTICLE 48

Drug Pricing Transparency

25-48-101. Short title. THE SHORT TITLE OF THIS ARTICLE IS THE "DRUG PRICING TRANSPARENCY ACT OF 2016".

25-48-102. Legislative declaration. (1) THE GENERAL ASSEMBLY FINDS AND DECLARES THAT:

(a) THE INTENT OF THIS ACT IS TO MAKE INFORMATION AVAILABLE TO THE PUBLIC ABOUT THE COST OF HIGH-PRICED PHARMACEUTICALS IN ORDER TO MAKE PHARMACEUTICAL PRICING AS TRANSPARENT AS THE

PRICING IN OTHER SECTORS OF THE HEALTH CARE INDUSTRY.

(b) TO FULFILL THIS GOAL, AS WELL AS TO AID POLICYMAKERS, GOVERNMENT AGENCIES, AND OTHERS IN UNDERSTANDING THE COSTS OF PHARMACEUTICALS, IT IS NECESSARY TO REQUIRE DRUG MANUFACTURERS THAT MAKE THEIR PRODUCTS AVAILABLE IN COLORADO TO REPORT COST DATA FOR THEIR MOST EXPENSIVE DRUG PRODUCTS.

25-48-103. Definitions. AS USED IN THIS ARTICLE, UNLESS THE CONTEXT OTHERWISE REQUIRES:

(1) "COMMISSION" MEANS THE COLORADO COMMISSION ON AFFORDABLE HEALTH CARE CREATED IN SECTION 25-46-103.

(2) "DRUG MANUFACTURER" MEANS A MANUFACTURER OF A QUALIFYING PRESCRIPTION DRUG THAT IS MADE AVAILABLE IN COLORADO.

(3) "QUALIFYING PRESCRIPTION DRUG" MEANS A PRESCRIPTION DRUG THAT HAS A WHOLESALE ACQUISITION COST OF FIFTY THOUSAND DOLLARS OR MORE ANNUALLY OR, IF THE AVERAGE COURSE OF TREATMENT FOR A PATIENT IS LESS THAN ONE YEAR, FIFTY THOUSAND DOLLARS OR MORE PER COURSE OF TREATMENT.

(4) "WHOLESALE ACQUISITION COST" MEANS THE COST TO PURCHASE, PRODUCE, OR ACQUIRE A PRESCRIPTION DRUG AT WHOLESALE.

25-48-104. Reporting requirement. (1) (a) BY AUGUST 1, 2016, A DRUG MANUFACTURER SHALL FILE A REPORT WITH THE COMMISSION IN ACCORDANCE WITH THIS SECTION ON THE COSTS FOR EACH QUALIFYING PRESCRIPTION DRUG. THE REPORT MUST INCLUDE, BUT IS NOT LIMITED TO, THE FOLLOWING INFORMATION:

(I) THE TOTAL COSTS TO PRODUCE THE QUALIFYING PRESCRIPTION DRUG, INCLUDING ALL OF THE FOLLOWING:

(A) THE TOTAL RESEARCH AND DEVELOPMENT COSTS PAID BY THE

DRUG MANUFACTURER AND, SEPARATELY, THE TOTAL RESEARCH AND DEVELOPMENT COSTS PAID BY ANY PREDECESSOR INVOLVED IN THE DEVELOPMENT OF THE QUALIFYING PRESCRIPTION DRUG;

(B) THE TOTAL COSTS OF CLINICAL TRIALS AND OTHER REGULATORY COSTS PAID BY THE DRUG MANUFACTURER AND, SEPARATELY, THE TOTAL COSTS OF CLINICAL TRIALS AND OTHER REGULATORY COSTS PAID BY ANY PREDECESSOR INVOLVED IN THE DEVELOPMENT OF THE QUALIFYING PRESCRIPTION DRUG;

(C) THE TOTAL COSTS FOR MATERIALS, MANUFACTURING, AND ADMINISTRATION ATTRIBUTABLE TO THE QUALIFYING PRESCRIPTION DRUG;

(D) THE TOTAL COSTS PAID BY ANY ENTITY OTHER THAN THE DRUG MANUFACTURER OR PREDECESSOR FOR RESEARCH AND DEVELOPMENT, INCLUDING ANY AMOUNT FROM FEDERAL, STATE, OR OTHER GOVERNMENT PROGRAMS OR ANY FORM OF SUBSIDY, GRANT, OR OTHER SUPPORT;

(E) ANY OTHER COMPONENTS OF THE WHOLESALE COST OF ACQUISITION OF THE QUALIFYING PRESCRIPTION DRUG, INCLUDING COSTS TO PURCHASE PATENTS OR FOR LICENSING OR ACQUIRING ANY CORPORATE ENTITY OWNING ANY RIGHTS TO THE QUALIFYING PRESCRIPTION DRUG;

(F) THE TOTAL MARKETING AND ADVERTISING COSTS TO PROMOTE THE QUALIFYING PRESCRIPTION DRUG DIRECTLY TO CONSUMERS, INCLUDING COSTS ASSOCIATED WITH DIRECT-TO-CONSUMER COUPONS AND AMOUNTS REDEEMED; TOTAL MARKETING AND ADVERTISING COSTS TO PROMOTE THE QUALIFYING PRESCRIPTION DRUG DIRECTLY OR INDIRECTLY TO PRESCRIBERS; AND ANY OTHER COSTS FOR ADVERTISING THE QUALIFYING PRESCRIPTION DRUG;

(II) A CUMULATIVE ANNUAL HISTORY OF INCREASES IN THE AVERAGE WHOLESALE PRICE AND WHOLESALE ACQUISITION COST FOR THE

QUALIFYING PRESCRIPTION DRUG, EXPRESSED AS PERCENTAGES, INCLUDING THE MONTHS EACH INCREASE IN EACH CATEGORY TOOK EFFECT;

(III) THE TOTAL PROFIT ATTRIBUTABLE TO THE QUALIFYING PRESCRIPTION DRUG, BOTH AS A DOLLAR FIGURE AND AS A PERCENTAGE OF THE TOTAL COMPANY PROFITS THAT WERE DERIVED FROM THE SALE OF THE QUALIFYING PRESCRIPTION DRUG; AND

(IV) THE TOTAL AMOUNT OF FINANCIAL ASSISTANCE THE DRUG MANUFACTURER HAS PROVIDED THROUGH PATIENT PRESCRIPTION ASSISTANCE PROGRAMS, IF AVAILABLE.

(b) THE DRUG MANUFACTURER SHALL ITEMIZE AND DOCUMENT THE INFORMATION SPECIFIED IN PARAGRAPH (a) OF THIS SUBSECTION (1).

(2) A DRUG MANUFACTURER SHALL FILE THE REPORT REQUIRED BY THIS SECTION WITH THE COMMISSION ON A FORM PRESCRIBED BY THE COMMISSION. THE COMMISSION SHALL DEVELOP THE FORM AND MAKE IT AVAILABLE TO DRUG MANUFACTURERS BY JUNE 1, 2016.

(3) UPON RECEIPT OF THE REPORTS FROM DRUG MANUFACTURERS, THE COMMISSION SHALL REVIEW AND ANALYZE THE DATA, AGGREGATE THE DATA TO DETERMINE ANY TRENDS IN THE VARIOUS COMPONENTS OF DRUG PRODUCTION COSTS, AND DETERMINE WHETHER THE DATA SUGGESTS THE NEED FOR ANY LEGISLATIVE, ADMINISTRATIVE, OR OTHER POLICY CHANGES.

(4) BY DECEMBER 1, 2016, THE COMMISSION SHALL ISSUE A REPORT TO THE HEALTH AND HUMAN SERVICES COMMITTEE OF THE SENATE OR ITS SUCCESSOR COMMITTEE AND THE HEALTH, INSURANCE, AND ENVIRONMENT COMMITTEE AND THE PUBLIC HEALTH CARE AND HUMAN SERVICES COMMITTEE OF THE HOUSE OF REPRESENTATIVES OR THEIR

SUCCESSOR COMMITTEES DETAILING THE INFORMATION SUBMITTED PURSUANT TO THIS SECTION, THE COMMISSION'S ANALYSIS OF THE DATA, AND ANY LEGISLATIVE, ADMINISTRATIVE, OR OTHER POLICY CHANGES THE COMMISSION RECOMMENDS BASED ON ITS REVIEW AND ANALYSIS OF THE DATA SUBMITTED BY DRUG MANUFACTURERS. ADDITIONALLY, THE COMMISSION SHALL POST THE REPORT PUBLICLY ON ITS WEBSITE AND PRESENT THE REPORT TO THE LEGISLATIVE COMMITTEES DURING THE COMMITTEES' HEARINGS HELD UNDER THE "STATE MEASUREMENT FOR ACCOUNTABLE, RESPONSIVE, AND TRANSPARENT (SMART) GOVERNMENT ACT", PART 2 OF ARTICLE 7 OF TITLE 2, C.R.S., THAT ARE HELD PRIOR TO THE START OF THE 2017 REGULAR LEGISLATIVE SESSION.

25-48-105. Repeal. THIS ARTICLE IS REPEALED, EFFECTIVE JULY 1, 2017.

SECTION 2. Safety clause. The general assembly hereby finds, determines, and declares that this act is necessary for the immediate preservation of the public peace, health, and safety.