J1 5lr0433

By: **Delegates Boutin and Morhaim**
Introduced and read first time: January 28, 2005
Assigned to: Health and Government Operations

A BILL ENTITLED

AN ACT concerning

Prescription Drugs - Price Controls

FOR the purpose of requiring the Health Services Cost Review Commission to regulate prices at which pharmaceutical manufacturers may sell prescription drugs in the State; requiring the Commission to periodically participate in or do analyses and studies that relate to prescription drug costs; prohibiting the Commission from including the amount of a certain penalty in the cost of a prescription drug for the purpose of regulating the price of the drug; requiring a pharmaceutical manufacturer to provide certain information and documents to the Commission within the time period and in the form the Commission requires; requiring a pharmaceutical manufacturer to obtain approval from the Commission before the pharmaceutical manufacturer may increase the price of a prescription drug or sell a prescription drug not previously sold in the State; requiring the Commission to review the proposed price increase or proposed price for a prescription drug submitted by a pharmaceutical manufacturer and approve or disapprove the proposed price increase or proposed price within a certain time period; requiring the Commission to disapprove the proposed price increase or proposed price, if the commission finds that the proposed price increase or proposed price for a prescription drug is excessive, and order the pharmaceutical manufacturer to reduce the proposed price increase or proposed price to a level the Commission considers not excessive; requiring the Commission to provide the pharmaceutical manufacturer with an opportunity for a hearing; requiring the Commission to take into consideration certain factors in determining whether a price increase or a price is excessive; authorizing the Commission in certain circumstances to order a person to provide certain information and documents to the Commission in the time period and the form that the Commission requires; providing that the information and documents are confidential and may not be disclosed without permission; requiring the Commission to assess and collect user fees on pharmaceutical manufacturers to cover certain costs; providing for the payment and assessment of the user fees; authorizing a certain penalty; requiring the Commission to make a certain annual report; providing for a delayed effective date; and generally relating to regulation by the Health Services Cost Review Commission of prices charged by pharmaceutical manufacturers for prescription drugs.

BY repealing and reenacting, with amendments,
Article - Health - General
Section 19-207
Annotated Code of Maryland
(2000 Replacement Volume and 2004 Supplement)

BY adding to
Article - Health - General
Section 19-230 through 19-236, inclusive, to be under the new part "Part III. Prescription Drug Pricing"
Annotated Code of Maryland
(2000 Replacement Volume and 2004 Supplement)

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:

Article - Health - General

19-207.

(a) In addition to the powers set forth elsewhere in this subtitle, the Commission may:

(1) Adopt rules and regulations to carry out the provisions of this subtitle;

(2) Create committees from among its members;

(3) Appoint advisory committees, which may include individuals and representatives of interested public or private organizations;

(4) Apply for and accept any funds, property, or services from any person or government agency;

(5) Make agreements with a grantor or payor of funds, property, or services, including an agreement to make any study, plan, demonstration, or project;

(6) Publish and give out any information that relates to the financial aspects of health care and is considered desirable in the public interest; and

(7) Subject to the limitations of this subtitle, exercise any other power that is reasonably necessary to carry out the purposes of this subtitle.

(b) In addition to the duties set forth elsewhere in this subtitle, the Commission shall:

(1) Adopt rules and regulations that relate to its meetings, minutes, and transactions;

(2) Keep minutes of each meeting;

(3) Prepare annually a budget proposal that includes the estimated income of the Commission and proposed expenses for its administration and operation;

(4) Within a reasonable time after the end of each facility's fiscal year or more often as the Commission determines, prepare from the information filed with the Commission any summary, compilation, or other supplementary report that will advance the purposes of this subtitle;

(5) Periodically participate in or do analyses and studies that relate to:

(i) Health care costs;

(ii) The financial status of any facility; [or]

(III) PRESCRIPTION DRUG COSTS; OR

[(iii)] (IV) Any other appropriate matter;

(6) On or before October 1 of each year, submit to the Governor, to the Secretary, and, subject to § 2-1246 of the State Government Article, to the General Assembly an annual report on the operations and activities of the Commission during the preceding fiscal year, including:

(i) A copy of each summary, compilation, and supplementary report required by this subtitle; and

(ii) Any other fact, suggestion, or policy recommendation that the Commission considers necessary; [and]

(7) Oversee and administer the Maryland Trauma Physician Services Fund in conjunction with the Maryland Health Care Commission; AND

(8) REGULATE PRICES AT WHICH PHARMACEUTICAL MANUFACTURERS MAY SELL PRESCRIPTION DRUGS IN THE STATE.

(c) (1) The Commission shall set deadlines for the filing of reports required under this subtitle.

(2) The Commission may adopt rules or regulations that impose penalties for failure to file a report as required.

(3) The amount of any penalty under paragraph (2) of this subsection may not be included in the costs of:

(I) [a] A facility in regulating its rates; OR

(II) A PRESCRIPTION DRUG IN REGULATING ITS PRICE.

(d) Except for privileged medical information AND EXCEPT AS OTHERWISE PROVIDED IN THIS SUBTITLE, the Commission shall make:

(1) Each report filed and each summary, compilation, and report required under this subtitle available for public inspection at the office of the Commission during regular business hours; and

(2) Each summary, compilation, and report available to any agency on request.

(e) (1) The Commission may contract with a qualified, independent third party for any service necessary to carry out the powers and duties of the Commission.

(2) Unless permission is granted specifically by the Commission, a third party hired by the Commission may not release, publish, or otherwise use any information to which the third party has access under its contract.

PART III. PRESCRIPTION DRUG PRICING.

19-230.

(A) A PHARMACEUTICAL MANUFACTURER SHALL PROVIDE THE COMMISSION WITH INFORMATION AND DOCUMENTS, AS REQUIRED BY REGULATION, ON:

(1) THE IDENTITY OF A PRESCRIPTION DRUG;

(2) THE PRICE AT WHICH THE PRESCRIPTION DRUG IS BEING OR HAS BEEN SOLD IN ANY MARKET IN THE STATE AND ELSEWHERE;

(3) THE COSTS OF MAKING AND MARKETING THE PRESCRIPTION DRUG, TO THE EXTENT THAT INFORMATION IS AVAILABLE TO THE PHARMACEUTICAL MANUFACTURER OR IS WITHIN THE KNOWLEDGE OR CONTROL OF THE MANUFACTURER;

(4) THE FACTORS LISTED IN § 19-233 OF THIS PART; AND

(5) ANY OTHER FACTORS NEEDED TO CARRY OUT THE REQUIREMENTS OF THIS PART.

(B) A PHARMACEUTICAL MANUFACTURER SHALL PROVIDE THE INFORMATION AND DOCUMENTS REQUIRED UNDER SUBSECTION (A) OF THIS SECTION WITHIN THE TIME LIMITS AND IN THE FORM ESTABLISHED BY THE COMMISSION.

19-231.

(A) BEFORE A PHARMACEUTICAL MANUFACTURER MAY INCREASE THE PRICE OF A PRESCRIPTION DRUG SOLD IN THE STATE, THE PHARMACEUTICAL MANUFACTURER SHALL OBTAIN APPROVAL FROM THE COMMISSION.

(B) THE COMMISSION SHALL REVIEW THE PROPOSED PRICE INCREASE SUBMITTED BY A PHARMACEUTICAL MANUFACTURER FOR A PRESCRIPTION DRUG AND, WITHIN 90 DAYS, APPROVE OR DISAPPROVE THE PROPOSED PRICE INCREASE.

(C) IF THE COMMISSION FINDS THAT THE PROPOSED PRICE INCREASE FOR A PRESCRIPTION DRUG IS EXCESSIVE, THE COMMISSION SHALL DISAPPROVE THE PROPOSED PRICE INCREASE AND ORDER THE PHARMACEUTICAL MANUFACTURER TO REDUCE THE PROPOSED PRICE INCREASE TO A LEVEL THE COMMISSION CONSIDERS NOT EXCESSIVE.

(D) BEFORE MAKING AN ORDER UNDER SUBSECTION (C) OF THIS SECTION, THE COMMISSION SHALL PROVIDE THE PHARMACEUTICAL MANUFACTURER WITH AN OPPORTUNITY FOR A HEARING.

19-232.

(A) BEFORE A PHARMACEUTICAL MANUFACTURER SELLS A PRESCRIPTION DRUG THAT HAS NOT BEEN PREVIOUSLY SOLD IN THE STATE, THE PHARMACEUTICAL MANUFACTURER SHALL OBTAIN APPROVAL FOR THE PROPOSED PRICE OF THE PRESCRIPTION DRUG FROM THE COMMISSION.

(B) THE COMMISSION SHALL REVIEW THE PROPOSED PRICE SUBMITTED BY A PHARMACEUTICAL MANUFACTURER FOR A NEW PRESCRIPTION DRUG AND, WITHIN 90 DAYS, APPROVE OR DISAPPROVE THE PROPOSED PRICE.

(C) IF THE COMMISSION FINDS THAT THE PROPOSED PRICE FOR A NEW PRESCRIPTION DRUG IS EXCESSIVE, THE COMMISSION SHALL DISAPPROVE THE PROPOSED PRICE AND ORDER THE PHARMACEUTICAL MANUFACTURER TO REDUCE THE PROPOSED PRICE TO A LEVEL THE COMMISSION CONSIDERS NOT EXCESSIVE.

(D) BEFORE MAKING AN ORDER UNDER SUBSECTION (C) OF THIS SECTION, THE COMMISSION SHALL PROVIDE THE PHARMACEUTICAL MANUFACTURER WITH AN OPPORTUNITY FOR A HEARING.

19-233.

IN DETERMINING UNDER § 19-231 OR § 19-232 OF THIS PART WHETHER A PROPOSED PRICE INCREASE OR A PROPOSED PRICE FOR A NEW PRESCRIPTION DRUG IS EXCESSIVE, THE COMMISSION SHALL TAKE INTO CONSIDERATION THE FOLLOWING FACTORS TO THE EXTENT THAT INFORMATION ON THE FACTORS IS AVAILABLE TO THE COMMISSION:

(1) THE COSTS OF MAKING AND MARKETING THE PRESCRIPTION DRUG;

(2) THE PRICES AT WHICH THE PRESCRIPTION DRUG HAS BEEN SOLD IN THE STATE;

(3) THE PRICES AT WHICH OTHER PRESCRIPTION DRUGS IN THE SAME THERAPEUTIC CLASS HAVE BEEN SOLD IN THE STATE;

(4) THE PRICES AT WHICH THE PRESCRIPTION DRUG AND OTHER PRESCRIPTION DRUGS IN THE SAME THERAPEUTIC CLASS HAVE BEEN SOLD IN OTHER STATES AND OTHER COUNTRIES;

(5) CHANGES IN THE U.S. CONSUMER PRICE INDEX; AND

(6) ANY OTHER FACTORS AS SPECIFIED IN REGULATION.

19-234.

(A) A PHARMACEUTICAL MANUFACTURER SHALL, AS REQUIRED BY REGULATION OR AS THE COMMISSION MAY BY ORDER REQUIRE, PROVIDE THE COMMISSION WITH THE INFORMATION AND DOCUMENTS THAT THE REGULATIONS OR THE ORDER SPECIFY REGARDING:

(1) THE IDENTITY OF THE DISTRIBUTORS OF THE PHARMACEUTICAL MANUFACTURER IN THE STATE;

(2) THE REVENUE OF THE PHARMACEUTICAL MANUFACTURER FROM SALES OF PRESCRIPTION DRUGS IN THE STATE; AND

(3) THE EXPENDITURES OF THE PHARMACEUTICAL MANUFACTURER ON RESEARCH AND DEVELOPMENT FOR PRESCRIPTION DRUGS.

(B) IF THE COMMISSION BELIEVES THAT ANY PERSON HAS INFORMATION OR DOCUMENTS PERTAINING TO THE VALUE OF SALES OF PRESCRIPTION DRUGS IN THE STATE BY A PHARMACEUTICAL MANUFACTURER OR EXPENDITURES ON RESEARCH AND DEVELOPMENT FOR PRESCRIPTION DRUGS, THE COMMISSION MAY BY ORDER REQUIRE THE PERSON TO PROVIDE THE COMMISSION WITH ANY OF THE INFORMATION OR DOCUMENTS THAT ARE SPECIFIED IN THE ORDER.

(C) INFORMATION AND DOCUMENTS REQUIRED BY THE COMMISSION UNDER THIS SECTION SHALL BE PROVIDED WITHIN THE TIME PERIOD AND IN THE FORM ESTABLISHED BY THE COMMISSION.

(D) ANY INFORMATION OR DOCUMENTS PROVIDED TO THE COMMISSION UNDER THIS SECTION ARE CONFIDENTIAL AND MAY NOT BE DISCLOSED WITHOUT THE PERMISSION OF THE PERSON PROVIDING THE INFORMATION OR DOCUMENTS.

19-235.

(A) THE COMMISSION SHALL ASSESS AND COLLECT USER FEES ON PHARMACEUTICAL MANUFACTURERS SELLING PRESCRIPTION DRUGS IN THE STATE.

(B) THE TOTAL USER FEES ASSESSED BY THE COMMISSION SHALL BE SET TO APPROXIMATE THE COST OF CARRYING OUT THE ACTIVITIES REQUIRED UNDER THIS PART.

(C) THE TOTAL USER FEES ASSESSED BY THE COMMISSION SHALL BE USED EXCLUSIVELY TO COVER THE ACTUAL DOCUMENTED DIRECT COSTS OF FULFILLING

THE STATUTORY AND REGULATORY DUTIES OF THE COMMISSION IN ACCORDANCE WITH THE PROVISIONS OF THIS PART.

(D) THE COMMISSION SHALL PAY ALL FUNDS COLLECTED FROM FEES ASSESSED IN ACCORDANCE WITH THIS SECTION INTO THE HEALTH SERVICES COST REVIEW COMMISSION FUND.

(E) THE COMMISSION SHALL ASSESS USER FEES FOR EACH PHARMACEUTICAL MANUFACTURER IN A REASONABLE AND EQUITABLE MANNER.

(F) THE COMMISSION SHALL ASSESS EACH PHARMACEUTICAL MANUFACTURER ON OR BEFORE JUNE 30 OF EACH YEAR.

(G) ON OR BEFORE SEPTEMBER 1 OF EACH YEAR, EACH PHARMACEUTICAL MANUFACTURER ASSESSED UNDER THIS SECTION SHALL MAKE PAYMENT TO THE COMMISSION.

(H) ANY BILL NOT PAID WITHIN 30 DAYS OF THE DUE DATE MAY BE SUBJECT TO AN INTEREST PENALTY TO BE DETERMINED BY THE COMMISSION.

19-236.

(A) ON OR BEFORE JANUARY 1, 2007, AND ANNUALLY THEREAFTER, THE COMMISSION SHALL REPORT TO THE GOVERNOR AND, SUBJECT TO § 2-1246 OF THE STATE GOVERNMENT ARTICLE, THE GENERAL ASSEMBLY ON:

(1) PRICE INCREASES THE COMMISSION APPROVED IN THE PRECEDING YEAR FOR PRESCRIPTION DRUGS SOLD BY PHARMACEUTICAL MANUFACTURERS IN THE STATE; AND

(2) THE COMMISSION'S ESTIMATE OF THE PERCENTAGE THAT THE TOTAL OF THE EXPENDITURES OF PHARMACEUTICAL MANUFACTURERS IN THE STATE IN THE PRECEDING YEAR ON RESEARCH AND DEVELOPMENT RELATING TO PRESCRIPTION DRUGS ARE OF THE TOTAL REVENUES OF THE PHARMACEUTICAL MANUFACTURERS FROM SALES OF PRESCRIPTION DRUGS IN THE STATE IN THAT YEAR.

(B) THE REPORT SHALL BE BASED ON AN ANALYSIS OF INFORMATION AND DOCUMENTS PROVIDED TO THE COMMISSION UNDER THIS PART.

SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2006.