A BILL TO BE ENTITLED

AN ACT

To amend Chapter 5A of Title 31 of the Official Code of Georgia Annotated, relating to the Department of Community Health, so as to provide for a price schedule of maximum manufacturer prices for patented prescription drugs and certain other drugs sold in this state for use with humans; to define certain terms; to provide for implementation and enforcement by the Department of Community Health; to provide for establishment of the maximum price schedule by the Public Service Commission; to provide for calculation of actual Georgia average wholesale prices and the effect thereof; to provide for licensing of manufacturers; to provide for violations; to provide for related powers and duties; to repeal conflicting laws; and for other purposes.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

SECTION 1.

Chapter 5A of Title 31 of the Official Code of Georgia Annotated, relating to the Department of Community Health, is amended by adding a new Code Section 31-5A-7 to read as follows:

"31-5A-7.

(a) As used in this Code section, the term:

(1) 'Health benefit plan or policy' means any individual or group plan, policy, or contract for health care services issued, delivered, issued for delivery, or renewed in this state, including, but not limited to, by a health care corporation, health maintenance organization, preferred provider organization, accident and sickness insurer, fraternal benefit society, hospital service corporation, medical service corporation, workers´ compensation insurance carrier in accordance with Chapter 9 of Title 34, other insurer or similar entity, the state health benefit plan under Article 1 of Chapter 18 of Title 45, the medical assistance program under Article 7 of Chapter 4 of Title 49, the PeachCare for Kids program under Article 13 of Chapter 5 of Title 49, or any other health benefit plan or policy administered by or on behalf of the state.

(2) 'Insurer' means an accident and sickness insurer, fraternal benefit society, hospital service corporation, workers´ compensation insurance carrier, medical service corporation, health care corporation, health maintenance organization, managed care plan other than a dental plan, or any similar entity authorized to issue contracts under Title 33, and shall also include the state for purposes of the state health benefit plan under Article 1 of Chapter 18 of Title 45, the medical assistance program under Article 7 of Chapter 4 of Title 49, the PeachCare for Kids program under Article 13 of Chapter 5 of Title 49, or any other health benefit plan or policy administered by or on behalf of the state.

(3) 'Prescription drug' has the meaning provided by Code Section 26-4-5.

(b)(1) The Public Service Commission shall establish, by rule or regulation, a price schedule of maximum manufacturer prices for all patented prescription drugs sold in this state for use with humans and for any other prescription drug sold in this state for use with humans concerning which the commission has determined that no effectively competitive market exists in this state. The first price schedule shall be established on or before January 1, 2005. The commission shall review the price schedule on or before January 1 of each year thereafter and may revise the price schedule at any time as new drugs are introduced in the market or other circumstances warrant. Such maximum manufacturer prices as established or revised by the commission shall apply to contracts entered into or renewed on or after January 1, 2005.

(2) The price schedule established by the commission shall prohibit excessive and discriminatory pricing of patented prescription drugs sold in this state, for the purpose of providing affordable access to medically necessary prescription drugs for all residents of this state.

(3) The commission shall establish its price schedule of maximum manufacturer prices for patented prescription drugs sold in this state after consideration of prices charged for patented prescription drugs sold in Canada and other industrialized countries, prices listed on the federal supply schedule, and any other relevant information.

(4) The Public Service Commission shall evaluate at least semiannually the wholesale prices actually charged to pharmacies in this state for patented prescription drugs sold in this state and shall calculate the Georgia average wholesale prices for such drugs. Such Georgia average wholesale prices as determined by the commission shall be used by any insurer as the reasonable and customary prices for patented prescription drugs for purposes of reimbursing pharmacies in this state under any health benefit plan or policy of the insurer.

(5)(A) The Public Service Commission may grant an exemption from the commission´s price schedule upon its own determination or upon the request of any manufacturer of patented prescription drugs. Any person making a request for

exemption shall have the burden of proof by a preponderance of the evidence in demonstrating the need for an exemption. In considering the request for exemption, the commission may consider:

(i) Changed circumstances since the price schedule was established;

(ii) Reasonable costs of production, distribution, marketing, and research;

(iii) The availability of one or more drugs essential to the health of residents of this state, or any other reason related to the health and safety of residents of this state; and

(iv) Any other relevant information.

(B) Any prescription drug exempted under subparagraph (A) of this paragraph shall be subject to prior approval by the Department of Community Health for purposes of coverage under the state health benefit plan under Article 1 of Chapter 18 of Title 45, the medical assistance program under Article 7 of Chapter 4 of Title 49, the PeachCare for Kids program under Article 13 of Chapter 5 of Title 49, or any other health benefit plan or policy administered by or on behalf of the state.

(c) In carrying out its duties, the Public Service Commission shall have all the powers reasonable and necessary to carry out the purposes of this Code section, including without limitation:

(1) The power to adopt administrative rules or regulations, including the adoption of emergency rules to implement the provisions of this Code section in a timely manner; and

(2) The power to collect from any manufacturer, wholesaler, or retailer of patented prescription drugs sold in this state and the Department of Community Health such information as is necessary for the commission to carry out its duties under this Code section. Pursuant to the power granted under this paragraph:

(A) Any manufacturer, wholesaler, or retailer of patented prescription drugs sold in this state and the Department of Community Health shall file with the commission, on request, such data, statistics, schedules, or information as the commission may require to enable it to carry out its duties;

(B) The commission shall have the power to examine books and accounts of any manufacturer, wholesaler, or retailer of patented prescription drugs sold in this state, to subpoena witnesses and documents, to administer oaths to witnesses, and to examine them on all matters of which the commission has jurisdiction; and

(C) For the purpose of supporting fair and effective competition and price transparency in the market for prescription drugs, the commission, in consultation with the Attorney General, shall adopt rules or regulations for the designation of information collected by the commission under this paragraph as public records or as trade secrets for purposes of Article 4 of Chapter 18 of Title 50.

(d)(1) The Department of Community Health shall administer implementation and enforcement of the patented prescription drug price schedule established by the Public Service Commission.

(2) The commissioner of community health shall distribute the manufacturer´s maximum price schedule and the Georgia average wholesale prices to all retail pharmacies in this state and shall post the price schedule and Georgia average wholesale prices on the department´s Internet web site.

(3) Semiannually, the commissioner of community health shall conduct and release a survey of representative retail prices for the most commonly used patented prescription drugs in this state, as determined by the commissioner.

(4)(A) No person shall sell a patented prescription drug in this state unless the manufacturer of the prescription drug has been licensed by the commissioner of community health.

(B) No agent or other representative of a manufacturer shall offer in this state any product, promotional, or other information during visits to practitioners authorized to prescribe, pharmacists, and other health care providers concerning a patented prescription drug unless the agent´s or representative´s manufacturer has been licensed by the commissioner of community health; provided that a license shall not be required for advertising and other marketing activities that the commissioner, in consultation with the Attorney General, determines to be constitutionally protected speech.

(C) The commissioner of community health shall establish by rule or regulation standards and procedures to carry out the purposes of this subsection. Such rules or regulations shall require each licensee to pay an annual fee on or before October 1. The annual license fee for manufacturers shall be $2,500.00. Such license fee shall be deposited into the general treasury.

(D) A license granted under this subsection may be revoked upon a finding by the commissioner of community health after notice and opportunity for hearing that:

(i) A provision of this Code section or a rule or regulation adopted under this Code section has been violated by a licensed manufacturer or an agent or representative thereof; or

(ii) A licensed manufacturer has sold a patented prescription drug at a price in this state that exceeds the maximum price listed on the manufacturer price schedule established by the Public Service Commission.

(5)(A) In addition to other powers granted by law, the commissioner of community health or his or her designee shall have all the powers reasonable and necessary to carry out the purposes of this Code section, including without limitation the power to collect from any manufacturer, wholesaler, or retailer of patented prescription drugs sold in

this state such information as is necessary for the commissioner to carry out his or her duties under this Code section. Pursuant to the power granted under this paragraph:

(i) Any manufacturer, wholesaler, or retailer of patented prescription drugs sold in this state shall file with the commissioner, on request, such data, statistics, schedules, or information as the commissioner may require to enable the commissioner to carry out his or her duties; and

(ii) The commissioner or his or her designee shall have the power to examine books and accounts of any manufacturer, wholesaler, or retailer of patented prescription drugs sold in this state, to subpoena witnesses and documents, to administer oaths to witnesses and to examine them on all matters of which the commissioner has jurisdiction.

(B) For the purpose of supporting fair and effective competition and price transparency in the market for prescription drugs, the commissioner, in consultation with the Attorney General, shall adopt rules or regulations for the designation of information collected by the commissioner under this paragraph as public records or as trade secrets for purposes of Article 4 of Chapter 18 of Title 50.

(e)(1) The following shall constitute, and be subject to the rights, remedies, and other judicial procedures established for, an unfair or deceptive act or practice under Part 2 of Article 15 of Chapter 1 of Title 10, the 'Fair Business Practices Act of 1975':

(A) A violation of a provision of this Code section; or

(B) The sale of a patented prescription drug in this state by a manufacturer in excess of a maximum manufacturer´s price authorized by the Public Service Commission´s price schedule established under subsection (b) of this Code section.

(2) The commissioner of community health or his or her designee shall act in lieu of the administrator appointed pursuant to subsection (a) of Code Section 10-1-395 for purposes of this subsection.

(f) The Public Service Commission and the commissioner of community health shall report to the General Assembly on or before January 1 of each year on patented prescription drug prices in this state. Such report shall include:

(1) The Public Service Commission´s price schedule of maximum manufacturer prices established for patented prescription drugs sold in this state;

(2) The commissioner of community health´s most recent calculation of Georgia average wholesale prices for patented prescription drugs and survey of retail prices for the most commonly used patented prescription drugs in this state;

(3) A financial analysis of the effect on patented prescription drug costs for residents of this state of the patented prescription drug pricing program established under this Code

section, including financial savings to public and private health insurance programs and financial savings to individual residents of this state and employers in this state; and

(4) Any other findings and recommendations offered by the Public Service Commission and the commissioner of community health.″

SECTION 2.

All laws and parts of laws in conflict with this Act are repealed.