WEST VIRGINIA LEGISLATURE

SECOND REGULAR SESSION, 2004

ENROLLED

House Bill No. 4084

(By Delegates Michael, Mezzatesta, Leach, Warner, Foster, Varner and Stalnaker)

Passed March 13, 2004

In Effect from Passage

ENROLLED

H. B. 4084

(BY DELEGATES MICHAEL, MEZZATESTA, LEACH, WARNER, FOSTER, VARNER AND STALNAKER)

[Passed March 13, 2004; in effect from passage.]

AN ACT to amend the code of West Virginia, 1931, as amended, by adding thereto a new article, designated §5A-3C-1, §5A-3C-2, §5A-3C-3, §5A-3C-4, §5A-3C-5, §5A-3C-6, §5A-3C-7, §5A-3C-8, §5A-3C-9, §5A-3C-10, §5A-3C-11, §5A-3C-12, §5A-3C-13, §5A-3C-14, §5A-3C-15, §5A-3C-16 and §5A-3C-17, all relating generally to the creation of a pharmaceutical program for the state; legislative findings; definitions; creation of the prescription drug assistance clearinghouse program; requiring costs of program to be paid by drug manufacturers; transfer of ownership of the program to the state; establishment of pharmaceutical discount program; eligibility for participation in the pharmaceutical discount program; discount pass through; creation of a West Virginia pharmaceutical cost management council; establishing membership; establishing powers and responsibilities; reporting requirements; authority to investigate the feasibility of purchasing Canadian drugs; authority to establish a pricing schedule to be implemented upon concurrent resolution of the legislature; authority to explore numerous strategies, policies, and programs, including, but not limited to, referenced prices for prescription drug purchases and pricing in the state; authority to

implement certain designated programs; state responsibilities; prohibiting restraint of trade; providing civil and criminal penalties for restraint of trade; advertising costs and reporting; rule-making authority; sunset provisions; and identifying potential use of savings.

Be it enacted by the Legislature of West Virginia:

That the code of West Virginia, 1931, as amended, be amended by adding thereto a new article, designated §5A-3C-1, §5A-3C-2, §5A-3C-3, §5A-3C-4, §5A-3C-5, §5A-3C-6, §5A-3C-7, §5A-3C-8, §5A-3C-9,§5A-3C-10,§5A-3C-11,§5A-3C-12,§5A-3C-13,§5A-3C-14, §5A-3C-15, §5A-3C-16 and §5A-3C-17, all to read as follows:

ARTICLE 3C. PHARMACEUTICAL AVAILABILITY AND AFFORDABILITY ACT OF 2004.

§5A-3C-1. Title.

The provisions of this article shall be known as and referred to as the "West Virginia Pharmaceutical Availability and Affordability Act".

§5A-3C-2. Purpose.

(a) The Legislature finds:

(1) That the rising cost of prescription drugs has imposed a significant hardship on individuals who have limited budgets, are uninsured or who have prescription coverage that is unable to control costs successfully due to cost shifting and disparate pricing policies;

(2) That the average cost per prescription for seniors rose significantly between one thousand nine hundred ninety-two and two thousand, and is expected to continue increasing significantly through two thousand ten;

(3) That there is an increasing need for citizens of West Virginia to have affordable access to prescription drugs; and

(4) That the Legislature does not intend the imposition of the programs under this article to penalize or otherwise jeopardize the benefits of veterans and other recipients of federal supply schedule drug prices.

(b) In an effort to promote healthy communities and to protect the public health and welfare of West Virginia residents, the Legislature finds that it is its responsibility to make every effort to provide affordable prescription drugs for all residents of West Virginia.

§5A-3C-3. Definitions.

In this article:

(1) "Advertising or marketing" means any manner of communication of information, either directly or indirectly, that is paid for and usually persuasive in nature about products, services or ideas related to pharmaceuticals by identified sponsors through various media, persons or other forms as further defined by legislative rule.

(2) "AWP" or "average wholesale price" means the amount determined from the latest publication of the blue book, a universally subscribed pharmacist reference guide annually published by the Hearst corporation. "AWP" or "average wholesale price" may also be derived electronically from the drug pricing database synonymous with the latest publication of the blue book and furnished in the national drug data file (NDDF) by first data bank (FDB), a service of the Hearst corporation.

(3) "Dispensing fee" means the fee charged by a pharmacy to dispense pharmaceuticals.

(4) "Drug manufacturer" or "pharmaceutical manufacturer" means any entity which is engaged in: (A) The production, preparation, propagation, compounding, conversion or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis; or (B) in the packaging, repackaging, labeling, relabeling or distribution of prescription drug products. "Drug manufacturer" or "pharmaceutical manufacturer" does not include a wholesale distributor of drugs or a retail pharmacy licensed under state law.

(5) "Federal supply schedule" or "FSS" means the price available to all federal agencies for the purchase of pharmaceuticals authorized in the Veterans Health Care Act of 1992, PL 102-585. FSS prices are intended to equal or better the prices manufacturers charge their "most-favored" non-federal customers under comparable terms and conditions.

(6) "Multiple-source drug", "innovator drug" and "noninnovator drug" mean the following:

(A) The term "multiple-source drug" means, for which there are two or more drug products which are: Rated as therapeutically equivalent (under the food and drug administration's most recent publication of "Approved Drug Products with Therapeutic Equivalence Evaluations"), except as provided in paragraph (B) of this subdivision, are pharmaceutically equivalent and bioequivalent, as determined by the food and drug administration, and the term "innovator drug" shall hereinafter be referred to as "brand". The term "innovator drug" means a drug which is produced or distributed under an original new drug application approved by the food and drug administration, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application and any multiple-source drug that was origi-

nally marketed under an original new drug application approved by the food and drug administration. The term "noninnovator drug" shall hereinafter be referred to as "generic". The term "noninnovator drug" means a multiple-source drug that is not an "innovator drug".

(B) Paragraph (A) of this subdivision shall not apply if the food and drug administration changes by regulation the requirement that, for purposes of the publication described in paragraph (A) of this subdivision, in order for drug products to be rated as therapeutically equivalent, they must be pharmaceutically equivalent and bioequivalent.

(7) "Labeler" means an entity or person that receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale and that has a labeler code from the federal food and drug administration pursuant to 21 C. F. R. §207.20 (1999).

(8) "Person" means any natural person or persons or any corporation, partnership, company, trust or association of persons.

(9) "Pharmaceutical drug detailing" or "detailing" means the function performed by a sales representative who is employed by a pharmaceutical manufacturer for the purpose of: Promotion of pharmaceutical drugs or related products; education about pharmaceutical drugs or related products; or to provide samples of pharmaceutical drugs, related products or related materials, gifts, food or meals.

(10) "Savings" means the difference between the previous price of a prescription drug including any discounts, rebates or price containments and the current price after the effective date of this article for the public employees insurance agency, children's health insurance program, medicaid and workers'

compensation programs or other programs which are payors for prescription drugs.

(11) "Sole source" means a pharmaceutical that provides a unique and powerful advantage available in the market to a broad group of patients established under federal law.

(12) "West Virginia Pharmaceutical Cost Management Council" or "council" means the council created pursuant to section eight of this article.

§5A-3C-4. Creation of clearinghouse program.

(a) There is hereby created the state prescription drug assistance clearinghouse program. The brand pharmaceutical manufacturers shall create and implement a program to assist state residents of who are low income or uninsured to gain access to prescription medications through existing private and public sector programs and prescription drug assistance programs offered by manufacturers, including discount and coverage programs. The brand pharmaceutical manufacturers shall use available computer software programs that access an eligible individual with the appropriate private or public programs relating to the individual's medically necessary drugs. The brand pharmaceutical manufacturers shall provide education to individuals and providers to promote the program and to expand enrollment and access to necessary medications for low-income or uninsured individuals qualifying for the programs. The participating brand pharmaceutical manufacturers shall be responsible for the cost of the establishment of the program, and be responsible for running the program, regardless of the date of transfer of the program to the state, for the period of time until a date no earlier than the thirtieth day of June, two thousand five, and ownership of the technology, website and other program features shall be transferred to the state on the same date. The secretary of the department of health and human

resources and the director of the public employees insurance agency shall provide joint oversight over the establishment and construction of the program and program features for the period of time prior to the transfer of ownership to the state. The pharmaceutical council shall recommend the state agency to own, control and operate the program, technology and program features, and shall include such recommendation in its report on or before the first day of September, two thousand four, to the joint committee on government and finance, as provided for in section eight of this article. In addition, the pharmaceutical manufacturers shall report to the Joint Committee on Government and Finance on a monthly basis all activities related to the implementation of this program including the number of citizens serviced and the services provided.

(b) The participating brand pharmaceutical manufacturers shall contribute the funding for the promotion of the public relations program attendant to the establishment of the program. The participating brand pharmaceutical manufacturers shall be responsible for the cost of the establishment of the program and the cost of the ongoing program, regardless of the date of transfer of ownership of the program to the state, for the period of time until the thirty-first day of December, two thousand four.

§5A-3C-5. Pharmaceutical discount program; establishment; eligible individuals; discount pass through; terms.

There is hereby established a discount drug program to provide low-income, uninsured individuals with access to prescription drugs from participating brand pharmaceutical companies and pharmacists through either a state-sponsored discount card program or a program that extends current brand pharmaceutical manufacturer prescription drug assistance programs:

(a) The state hereby establishes a state-sponsored prescription drug discount card program for certain eligible residents of West Virginia:

(1) Eligible individuals include uninsured residents of West Virginia up to two hundred per cent of the federal poverty guideline who have not been covered by a prescription drug program, whether public or private, at least six months prior to applying to the discount card program;

(2) The state may negotiate voluntary discounts with brand pharmaceutical manufacturers and pharmacists: *Provided,* That the total discount received from the manufacturer shall pass through to the eligible resident;

(3) Failure of a brand pharmaceutical manufacturer to participate in the voluntary discount card program will not result in prior authorization on drugs in the medicaid program which would not otherwise be subject to prior authorization but for the failure of the manufacturer to participate in this program; and

(4) The state shall not establish a formulary or preferred drug list as part of the discount card program.

(b) The brand pharmaceutical manufacturers may extend existing prescription drug assistance programs to eligible residents of West Virginia. Eligible individuals include uninsured residents of West Virginia up to two hundred percent of the federal poverty level who have not been covered by a prescription drug program, whether public or private, at least six months prior to applying to the program.

(c) The program established under this section shall be structured so that a member presenting a discount card at a participating pharmacy will receive the full benefit of the pharmacy discount, as well as the manufacturer's discount, at

a point of sale transaction. The program, or the pharmacy benefit manager contracted by the program, shall coordinate the drug discount information provided by participating pharmacies and manufacturers so that the available drug discounts are provided to the member at the point of sale.

(d) Manufacturers participating in the voluntary program established under this section shall cooperate with the program, or the pharmacy benefit manager contracted by the program, to provide the current list of drugs and the percentage of discount from the AWP for such drugs, or the rebates that the manufacturer will provide under the program. It is the intent of this program that adequate drug price and discount or rebate information be provided by the manufacturer, such that the program and participating pharmacies will have available such drug prices and discounts or rebates at a point of sale pharmaceutical drug transaction. Retail pharmacies will be responsible for no more than fifty percent of the discount offered by the manufacturer to the participant.

(1) Pharmacies participating in the voluntary program(s) established under this section will be responsible for no more than fifty percent of the discount offered by the manufacturer to the participant, and be paid a dispensing fee of no more than three dollars and fifty cents per prescription with regard to prescriptions filled under the program(s).

(2) Upon the presentation of a valid discount card, payment for the prescription and otherwise meeting appropriate criteria to have their prescription filled, the card-holder will have their prescription filled by a participating pharmacy. To accomplish the transaction, the participating pharmacy shall electronically transmit the transaction to the program or pharmacy benefit manager contracted by the program for processing. The program, or the program's pharmacy benefit manager, shall determine the discounted cost of the drug, including the

discount provided, the discount provided by the pharmacy, the discount or rebate provided by the manufacturer, the pharmacy dispensing fee, and any pharmacy benefit manager transaction fee. The program, or the program's pharmacy benefit manager, shall then transmit to the manufacturer an electronic statement of the amount the manufacturer owes on the transaction to cover the manufacturer's discount or rebate and the program's or the pharmacy benefit manager's processing fee. The manufacturer shall, in turn, at least every fourteen days, transmit such monetary amounts for the transaction to the program, or the program's pharmacy benefit manager, and the program, or the program's pharmacy benefit manager, shall pass such discount or rebate amounts back to the participating pharmacy which originated the transaction immediately.

(e) The pharmaceutical manufacturers shall report to the Joint Committee on Government and Finance on a monthly basis all activities related to the implementation of this program including the number of citizens serviced and the services provided, as well as, the benefits, the costs and the discounts obtained.

§5A-3C-6. Creation of program; administrative support; medicaid and chip program.

(a) There is hereby created in the state a program to obtain favorable pharmaceutical prices for state agencies and other qualified entities pursuant to this article.

(b) The medicaid program and the West Virginia children's health insurance program may be exempt from participation in this program until approval by the center for medicare and medicaid services has been granted if it is determined to be required by the council.

(c) Administrative staff support for the council created by this article shall be provided by the departments represented on the council.

(d) The council shall establish a pricing schedule using or referencing the FSS prices, or using or referencing to the price, as adjusted for currency valuations, set by Canada patented medicine prices review board (PMPRB) or any other appropriate referenced price that will maximize savings to the broadest percentage of the population of this state.

(e) By September fifteenth of two thousand four, the council shall report back to the Legislature the pricing schedule developed and a strategic plan for implementation. The council shall implement the proposed pricing schedule and strategic plan upon concurrent resolution of the Legislature. If, at the time of the acceptance or rejection of the concurrent resolution to implement the proposed pricing schedule and strategy, the concurrent resolution is not passed due to the Legislature's lack of acceptance of the same, the Legislature shall accept or reject a concurrent resolution to implement the pricing schedule and strategy using or referencing the FSS: *Provided*, That acceptance or rejection of the above referenced resolutions shall occur prior to the end of the regular session of the Legislature in two thousand five.

(f) If neither of the above referenced resolutions pass during the regular session of the Legislature in two thousand five, the Legislature may, at any time in the future, pass a concurrent resolution to implement the above referenced pricing schedule and strategy or any subsequent recommendation of the council to the Legislature and the Legislature determines that the proposed pricing schedule and strategy are the most effective method of reducing pharmaceutical prices for the citizens of the state.

(g) Qualified entities, including but not limited to, licensed private insurers, self insured employers, free clinics and other entities who provide pharmaceuticals either directly or through some form of coverage to the citizens of West Virginia shall have an option to apply for participation in the program established by this article in the form and manner established by the council. The council, in it's sole discretion, shall approve or deny participation through review of documentation determined to be necessary for full consideration and as established by rule. The council shall consider, but not be limited to, the fiscal stability and the size of each applicant.

(h) Pharmaceutical manufacturers may request a waiver from the pricing schedule to be granted by the council for a particular drug in which the development, production, distribution costs, other reasonable costs and reasonable profits, but exclusive of all marketing and advertising costs as determined by the council, is more than the pricing schedule rate of the pharmaceutical or in those cases in which the pharmaceutical in question has a sole source. The determination of reasonable costs and reasonable profits may fluctuate between different pharmaceuticals under consideration by the council. The council shall determine by legislative rule fees to be paid by the applicant at the time a waiver request is made and documentation required to be submitted at the time of the waiver request.

§5A-3C-7. Multistate discussion group.

For the purposes of reviewing or amending the program establishing the process for making pharmaceuticals more available and affordable to the citizens of West Virginia, the state may continue to enter into multistate discussions and agreements. For purposes of participating in these discussions, the state shall be represented by members of the council created in section eight of this article.

§5A-3C-8. West Virginia pharmaceutical cost management council.

(a) There is hereby created the West Virginia pharmaceutical cost management council which consists of the secretary of the department of administration or his or her designee, the director of the public employees insurance agency or his or her designee, the commissioner of the bureau of medical services of the department of health and human resources or his or her designee, the secretary of the department of health and human resources or his or her designee, the executive director of the workers' compensation commission or his or her designee, bureau of senior services or his or her designee and five members from the public who shall be appointed by the governor with the advice and consent of the Senate. One public member shall be a licensed pharmacist employed by a community retail pharmacy, one public member shall be a representative of a pharmaceutical manufacturer with substantial operations located in the state of West Virginia that has at least seven hundred fifty employees, one public member shall be a primary care physician, one public member shall represent those who will receive benefit from the establishment of this program and one public member shall have experience in the financing, development or management of a health insurance company which provides pharmaceutical coverage. Each public member shall serve for a term of four years. Of the public members of the council first appointed, one shall be appointed for a term ending the thirtieth day of June, two thousand six, and two each for terms of three and four years. Each public member shall serve until his or her successor is appointed and has qualified. A member of the council may be removed by the governor for cause.

(b) The secretary of the department of administration shall serve as chairperson of the council, which shall meet at times

and places specified by the chairperson or upon the request of two members of the council.

(c) Authority members shall not be compensated in their capacity as members but shall be reimbursed for reasonable expenses incurred in the performance of their duties.

(d) The council has the power and authority to:

(1) Contract for the purpose of implementing the cost containment provisions of this article;

(2) File suit;

(3) Execute as permitted by applicable federal law, prescription drug purchasing agreements with:

(A) All departments, agencies, authorities, institutions, programs, any agencies or programs of the federal government, quasi public corporations and political subdivisions of this state, including, but not limited to, the children's health insurance program, the division of corrections, the division of juvenile services, the regional jail and correctional facility authority, the workers' compensation fund, state colleges and universities, public hospitals, state or local institutions, such as nursing homes, veterans' homes, the division of rehabilitation, public health departments, state programs, including, but not limited to, programs established in sections four and five of this article, and the bureau of medical services: *Provided*, That any contract or agreement executed with or on behalf of the bureau of medical services shall contain all necessary provisions to comply with the provisions of Title XIX of the Social Security Act, 42 U. S. C. §1396 *et seq.*, dealing with pharmacy services offered to recipients under the medical assistance plan of West Virginia;

(B) Governments of other states and jurisdictions and their individual departments, agencies, authorities, institutions, programs, quasi-public corporations and political subdivisions; and

(C) Regional or multi-state purchasing alliances or consortia, formed for the purpose of pooling the combined purchasing power of the individual members in order to increase bargaining power; and

(4) Consider strategies by which West Virginia may manage the increasing costs of prescription drugs and increase access to prescription drugs for all of the state's citizens, including the authority to:

(A) Explore the enactment of fair prescription drug pricing policies;

(B) Explore discount prices or rebate programs for seniors and persons without prescription drug coverage;

(C) Explore programs offered by pharmaceutical manufacturers that provide prescription drugs for free or at reduced prices;

(D) Explore requirements and criteria, including the level of detail, for prescription drug manufacturers to disclose to the council expenditures for advertising, marketing and promotion, based on aggregate national data;

(E) Explore the establishment of counter-detailing programs aimed at educating health care practitioners authorized to prescribe prescription drugs about the relative costs and benefits of various prescription drugs, with an emphasis on generic substitution for brand name drugs when available and appropriate; prescribing older, less costly drugs instead of newer, more expensive drugs, when appropriate; and prescrib-

ing lower dosages of prescription drugs, when available and appropriate;

(F) Explore disease state management programs aimed at enhancing the effectiveness of treating certain diseases identified as prevalent among this state's population with prescription drugs;

(G) Explore prescription drug purchasing agreements with large private sector purchasers of prescription drugs and including those private entities in pharmacy benefit management contracts: *Provided,* That no private entity may be compelled to participate in a purchasing agreement;

(H) Explore the feasibility of using or referencing, the federal supply schedule or referencing to the price, as adjusted for currency valuations, set by the Canada patented medicine prices review board ("PMPRB"), or any other appropriate referenced price to establish prescription drug pricing for brand name drugs in the state; and to review and determine the dispensing fees for pharmacies in such as established in section six of this article;

(I) Explore , if possible, joint negotiations for drug purchasing and a shared prescription drug pricing schedule and shared preferred drug list for use by the public employees insurance agency, the medicaid program, other state payors and private insurers;

(J) Explore coordination between the medicaid program, the public employees insurance agency and, to the extent possible, in-state hospitals and private insurers toward the development of a uniform preferred prescription drug list which is clinically appropriate and which leverages retail prices;

(K) Explore policies which promote the use of generic drugs, where appropriate;

(L) Explore a policy that precludes a drug manufacturer from reducing the amounts of drug rebates or otherwise penalize an insurer, health plan or other entity which pays for prescription drugs based upon the fact that the entity uses step therapy or other clinical programs before a drug is covered or otherwise authorized for payment;

(M) Explore arrangements with entities in the private sector, including self-funded benefit plans and nonprofit corporations, toward combined purchasing of health care services, health care management services, pharmacy benefits management services or pharmaceutical products on the condition that no private entity be compelled to participate in the prescription drug purchasing pool; and

(N) Explore other strategies, as permitted under state and federal law, aimed at managing escalating prescription drug prices and increasing affordable access to prescription drugs for all West Virginia citizens;

(5) Contract with appropriate legal, actuarial and other service providers required to accomplish any function within the powers of the council;

(6) Develop other strategies, as permitted under state and federal law, aimed at managing escalating prescription drug prices and increasing affordable access to prescription drugs for all West Virginia citizens;

(7) Explore the licensing and regulation of pharmaceutical detailers, including the requirement of continuing professional education, the imposition of fees for licensing and continuing education, the establishment of a special revenue account for deposit of the fees and the imposition of penalties for noncompliance with licensing and continuing education requirements, and rules to establish procedures to implement the provisions of the subdivision;

(8) The council shall report to the Legislature's joint committee on government and finance on or before the first day of September, two thousand four, and report on or before the thirty-first day of December, two thousand four, and annually thereafter to the Legislature, and provide recommendations to the Legislature on needed legislative action and other functions established by the article or requested by the joint committee on government and finance of the Legislature; and

(9) The council shall, upon the passage of this article, immediately commence to study the fiscal impact to this state of the federal "Medicare Prescription Drug Improvement and Modernization Act of 2003" and shall report to the Legislature's joint committee on government and finance on or before the fifteenth day of October, two thousand four, as to the findings of the council.

(10) The council shall develop an evaluation methodology to certify and audit savings in the discount savings program by determining the impact on growth and profit of the pharmaceutical manufacturers to ensure that prices have not been inflated to offset the discount card value.

(11) The council shall evaluate the clearinghouse established by this article and the discount card program established by this article to report to the Joint Committee on Government and Finance, and the Legislative Oversight Commission on Health and Human Resources Accountability, their findings and recommendations for further action by the Legislature.

(12) The council shall further (1)review determine that the implementation of the programs under this article will not jeopardize, reduce or penalize the benefits of veterans or other recipients of FSS drug prices, considering their respective co-pay structures, and the pricing mechanisms of their respective programs; (2) commence negotations to obtain independent

agreements or multi-state agreements as many as ten states to use or reference a pricing schedule as set forth in section six of this article; (3) and determine the ability to establish a savings of forty two percent of the retail cost to be reported to the Joint Committee on Government and Finance and the Legislative Oversight Commission on Health and Human Resources Accountability, as established in section eight of this article.

§5A-3C-9. Investigation of Canadian drugs; wholesaling; federal waivers.

The council created in section eight of this article and the director of the public employees insurance agency are authorized to investigate the feasibility of purchasing prescription drugs from sources in Canada, which may include the feasibility of the state or an instrumentality thereof serving as a wholesale distributor of prescription drugs in the state.

(a) Upon a determination by the council or the director of the public employees insurance agency that the same is feasible and in the best interests of the citizens of the state, the council or the director is authorized to pursue waivers from the federal government, including, but not limited to, from the United States food and drug administration, as necessary for the state to accomplish prescription drug purchasing from sources in Canada provided, however, if a waiver is not granted, the council is authorized to take necessary legal action.

(b) Upon a favorable finding by the appropriate federal agencies or courts, notwithstanding any provision of this code to the contrary, the council or the director of the public employees insurance agency may establish and implement a methodology to provide wholesale drugs to licensed pharmacies located within West Virginia, provided however, prior to the implementation, the Legislature must adopt a concurrent resolution authorizing such action.

§5A–3C-10. Director's powers; ability to enter drug purchasing contracts.

Notwithstanding any provision of this code to the contrary, nothing contained in this article shall be construed to limit the powers and authority granted to the director of the public employees insurance agency pursuant to article sixteen-c, chapter five of this code. Notwithstanding any provision of this code to the contrary and specifically subdivision four, subsection (a), section four, article five-c, chapter five of this code, the director is authorized to execute prescription drug purchasing agreements without further enactment of the Legislature.

§5A–3C-11. Agency's management ability continued.

Nothing contained in this article shall be construed to limit the ability of the various state agencies to enter into contracts or arrangements or to otherwise manage their pharmacy programs until such time as the programs created or authorized pursuant to this article are implemented.

§5A-3C-12. Restraint of trade; civil and criminal violations defined.

(a) The following are considered to restrain trade or commerce unreasonably and shall be unlawful:

(1) A contract, combination or conspiracy between two or more persons:

(A) For the purpose or with the intent to fix, control or maintain the market price, rate or fee of pharmaceuticals; or

(B) Allocate or divide customers or markets, functional or geographic, for any pharmaceutical.

(2) The establishment, maintenance or use of a monopoly or an attempt to establish a monopoly of trade or commerce, any part of which is within this state, by any persons for the purpose of or with the intent to exclude competition or control, fix or maintain pharmaceutical prices.

(b) Any person violating the provisions of this section is guilty of a felony and, upon conviction thereof, shall be confined in a state correctional facility for not less than one nor more than ten years, or fined in an amount consistent with the Clayton Act 15 U.S.C. §15 et seq. which may include treble damages, or both fined and confined.

(c) Any person violating the provisions of this section is liable for a civil penalty and fine in an amount consistent with the Clayton Act 15 U.S.C. §15 et seq. which may include treble damages, for each violation.

(d) The county prosecutor shall investigate suspected violations of, and institute criminal proceedings pursuant to, the provisions of this section.

(e) The attorney general or special counsel appointed by the governor, in his or her discretion, shall represent the state in all civil proceedings brought on behalf of the state to enforce the provisions of this section. After payment of all attorney fees and costs, no less than fifty percent of all judgments or settlements shall be placed in the general revenue fund of the state.

§5A-3C-13. Advertising costs; reporting of same.

(a) Advertising costs for prescription drugs, based on aggregate national data, must be reported to the state council by all manufacturers and labelers of prescription drugs dispensed in this state that employs, directs or utilizes marketing representatives. The reporting shall assist this state in its role as a purchaser of prescription drugs and an administrator of pre-

scription drug programs, enabling this state to determine the scope of prescription drug advertising costs and their effect on the cost, utilization and delivery of health care services and furthering the role of this state as guardian of the public interest.

(b) The council shall establish, by legislative rule, the reporting requirements of information by labelers and manufacturers which shall include all national aggregate expenses associated with advertising and direct promotion of prescription drugs through radio, television, magazines, newspapers, direct mail and telephone communications as they pertain to residents of this state.

(c) The following shall be exempt from disclosure requirements:

(1) All free samples of prescription drugs intended to be distributed to patients;

(2) All payments of reasonable compensation and reimbursement of expenses in connection with a bona fide clinical trial. As used in this subdivision, "clinical trial" means an approved clinical trial conducted in connection with a research study designed to answer specific questions about vaccines, new therapies or new ways of using known treatments; or

(3) All scholarship or other support for medical students, residents and fellows to attend significant educational, scientific or policy-making conference of national, regional or specialty medical or other professional association if the recipient of the scholarship or other support is selected by the association.

(d) The council is further authorized to establish time lines, the documentation, form and manner of reporting required as the council determines necessary to effectuate the purpose of this article. The council shall report to the joint committee on

government and finance, in an aggregate form, the information provided in the required reporting.

(e) Notwithstanding any provision of law to the contrary, information submitted to the council pursuant to this section is confidential and is not a public record and is not available for release pursuant to the West Virginia freedom of information act. Data compiled in aggregate form by the council for the purposes of reporting required by this section is a public record as defined in the West Virginia freedom of information act, as long as it does not reveal trade information that is protected by state or federal law.

§5A-3C-14. State role.

For purpose of implementing this article, the state represented by the council shall have authority to negotiate pharmaceutical prices to be paid by program participants. These negotiated prices shall be available to all programs.

§5A-3C-15. Rulemaking.

The council may promulgate emergency rules pursuant to the provisions of section fifteen, article three, chapter twenty-nine-a of this code to implement any section of this article.

§5A-3C-16. Sunset provision.

The council shall continue to exist, pursuant to the provisions of article ten, chapter four of this code, until the first day of July, two thousand eight, unless sooner terminated, continued or reestablished pursuant to the provisions of that article.

§5A-3C-17. Potential use of savings.

Savings identified by all program participants shall be quantified and certified to the council and included in the

annual report of the council to the Legislature provided for in section eight of this article. Savings, or any part thereof, created by the implementation of this program may, in the sole discretion of the Legislature, be directed towards the maintenance of existing state health programs and the expansion of insurance programs for the uninsured and underinsured.

That Joint Committee on Enrolled Bills hereby certifies that the foregoing bill is correctly enrolled.

Chairman Senate Committee

Chairman House Committee

Originating in the House.

In effect from passage.

Clerk of the Senate

Clerk of the House of Delegates

President of the Senate

Speaker of the House of Delegates

The within is approved this the ten day of April, 2004.

Governor

PRESENTED TO THE
GOVERNOR
DATE 3/22/04
TIME 9:30a