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THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 715 Session of 2005

INTRODUCED BY WALKO, DeWEESE, VEON, EACHUS, BEBKO-JONES, BELARDI, BELFANTI, BLAUM, BROWNE, CASORIO, CAWLEY, COSTA, CURRY, DERMODY, FABRIZIO, FRANKEL, FREEMAN, GOODMAN, GRUCELA, HALUSKA, HARHAI, HENNESSEY, JAMES, JOSEPHS, LaGROTTA, LEACH, LEVDANSKY, MANDERINO, MARKOSEK, McCALL, McGEEHAN, MELIO, MUNDY, PALLONE, PETRARCA, PISTELLA, PRESTON, RAMALEY, READSHAW, REICHLEY, ROONEY, RUFFING, SANTONI, SHANER, SOLOBAY, STABACK, STETLER, STURLA, SURRA, TANGRETTI, THOMAS, WANSACZ, WASHINGTON, WHEATLEY, WOJNAROSKI, YOUNGBLOOD, YUDICHAK AND TIGUE, MARCH 1, 2005

REFERRED TO COMMITTEE ON INSURANCE, MARCH 1, 2005

AN ACT

Providing for enhanced pharmaceutical availability and affordability; and establishing the Pharmaceutical Cost Management Council.

The General Assembly finds and declares as follows:

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

(2) The average cost per prescription for seniors rose significantly between 1992 and 2000 and is expected to continue increasing significantly through 2010.

(3) There is an increasing need for citizens of this Commonwealth to have affordable access to prescription drugs.

(4) The General Assembly does not intend the imposition of the program under this act to penalize or otherwise jeopardize the benefits of veterans and other recipients of Federal supply schedule drug prices.

(5) In an effort to promote healthy communities and to protect the public health and welfare of Pennsylvania residents, the General Assembly finds that it is its responsibility to make every effort to provide affordable prescription drugs for all residents of this Commonwealth.

The General Assembly of the Commonwealth of Pennsylvania hereby enacts as follows:

Section 1. Short title.

This act shall be known and may be cited as the Pharmaceutical Availability and Affordability Act.

Section 2. Definitions.

The following words and phrases when used in this act shall have the meanings given to them in this section unless the context clearly indicates otherwise:

"A-rated generic therapeutically equivalent drug." A drug product that the Commissioner of Food and Drugs of the United States Food and Drug Administration has approved as safe and effective and has determined to be therapeutically equivalent, as listed in "The Approved Drug Products with Therapeutic Equivalence Evaluations" (Food and Drug Administration "Orange Book"), with a specific "A" code designation only.

"Average wholesale price" or "AWP." The amount determined from the latest publication of the Blue Book, published annually by the Hearst corporation. The term may also be derived 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).

"Council." The council created pursuant to section 3 (relating to Pharmaceutical Cost Management Council).

"Dispensing fee." The fee charged by a pharmacy to dispense pharmaceuticals.

"Drug manufacturer" or "pharmaceutical manufacturer."

(1) Any entity which is engaged in any of the following:

(i) The production, preparation, propagation, compounding, conversion or processing of prescription drug product, either directly or indirectly by extraction from substance of natural origin or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis.

(ii) The packaging, repackaging, labeling, relabeling or distribution of prescription drug products.

(2) The term does not include a wholesale distributor of drugs or a retail pharmacy licensed in this Commonwealth.

"Federal supply schedule" or "FSS." The price available to all Federal agencies for the purchase of pharmaceuticals authorized in the Veterans Health Care Act of 1992 (Public Law 107-585, 106 Stat. 4943). FSS prices are intended to equal or better the price manufacturers charge their most-favored non-Federal customers under comparable terms and conditions.

"Labeler." 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 CFR 207.20 (relating to who must register and submit a drug list).

"Person." Any natural person or persons or any corporation, partnership, company, trust or association of persons.

"Pharmaceutical drug detailing" or "detailing." The function performed by a sales representative who is employed by a pharmaceutical manufacturer for the purpose of any of the following:

(1) Promotion of pharmaceutical drugs or related products.

(2) Education about pharmaceutical drugs or related products.

(3) Provision of samples of pharmaceutical drugs, related products or related materials, gifts, food or meals.

"Savings." The difference between the price of a prescription drug before the effective date of this section, including any discounts, rebates or price containments and the current price after the effective date of this section for the Children's Health Insurance Program, Medicaid or any other programs which are payors for prescription drugs.

"Sole source." A pharmaceutical that provides a unique and powerful advantage available in the market to a broad group of patients established under Federal law.

Section 3. Pharmaceutical Cost Management Council.

(a) Establishment.--There is created the Pharmaceutical Cost Management Council which shall consist of the following members or his or her designee:

(1) The Secretary of General Services.

(2) The Secretary of Aging.

(3) The Secretary of Public Welfare.

(4) The Secretary of Health.

(5) The chair of the Pennsylvania Employee Benefit Trust Fund.

(6) The director of the Bureau of Workers' Compensation.

(7) The director of the Office of Health Care Reform.

(8) The following members from the general public, each appointed by the Governor:

(i) One public member shall be a licensed pharmacist employed by a community retail pharmacy.

(ii) One public member shall be a representative of a pharmaceutical manufacturer with substantial operations located in this Commonwealth that has at least 1,000 employees.

(iii) One public member shall be a primary care physician.

(iv) One public member shall represent those who will receive benefit from the establishment of this program.

(v) One public member shall have experience in the financing, development or management of a health insurance company which provides pharmaceutical coverage.

(b) Term.--Each public member shall serve for a term of four years. Each public member shall serve until his or her successor is appointed and has been qualified.

(c) Removal.--A member of the council may be removed by the Governor for cause.

(d) Chairperson.--The Secretary of General Services shall serve as chairperson of the council.

(e) Quorum.--The council shall meet at the times and places specified by the chairperson or upon the request of a quorum of the members of the council.

(f) Compensation.--Members of the council shall not be compensated in their capacity as members but shall be reimbursed for reasonable expenses incurred in the performance of their

duties.

Section 4. Powers and duties of council.

The council has the power and duty to carry out all of the following:

(1) Contract for the purpose of implementing the cost containment provisions of this act.

(2) File suit.

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

(A) All departments, agencies, authorities, institutions, programs, agencies or programs of the Federal Government, quasi-public corporations and political subdivisions of this Commonwealth, including the Children's Health Insurance Program, the PACE or PACENET Program, the Department of Corrections, the Workers' Compensation Fund, State and local institutions such as nursing homes, public health departments and all State programs.

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

(C) Regional or multistate purchasing alliances or consortia formed for the purpose of pooling the combined purchasing power of the individual members in order to increase bargaining power.

(ii) Any contract or agreement executed under this paragraph shall contain all necessary provisions to comply with the provisions of Title XIX of the Social Security Act (49 Stat. 620, 42 U.S.C. § 1496 et seq.),

dealing with pharmacy services offered to recipients under the medical assistance plan of the Commonwealth.

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

(i) Explore the enactment of fair prescription drug pricing policies.

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

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

(iv) 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.

(v) 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 prescribing lower dosages of prescription drugs, when available and appropriate.

(vi) Explore disease management programs aimed at enhancing the effectiveness of treating certain diseases identified as prevalent among the population with

prescription drugs.

(vii) Explore prescription drug purchasing agreements with large private sector purchasers of prescription drugs, including those private entities in pharmacy benefit management contracts. Nothing in this subparagraph shall require a private entity to participate in a purchasing agreement.

(viii) 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, or any other appropriate referenced price to establish prescription drug pricing for brand name drugs.

(ix) To review and determine the dispensing fees for pharmacies.

(x) 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.

(xi) 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.

(xii) Explore policies which promote the use of generic drugs, where appropriate.

(xiii) Explore a policy that precludes a drug manufacturer from reducing the amounts of drug rebates or

otherwise penalizes 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.

(xiv) 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.

(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, aimed at managing escalating prescription drug prices and increasing affordable access to prescription drugs for all Commonwealth 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 this act.

(8) The council shall report to the State Government Committee of the Senate and the State Government Committee of the House of Representatives on or before September 1, 2005,

and December 31, 2005, and annually thereafter and provide recommendations on needed legislative action and other functions established by this act or requested by the State Government Committee of the Senate or the State Government Committee of the House of Representatives.

(9) 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.

(10) The council shall determine that the implementation of the programs under this act will not jeopardize, reduce or penalize the benefits of veterans or other recipients of FSS drug prices, considering their respective copay structures and the pricing mechanisms of their respective programs.

Section 5. Canadian drugs.

(a) Investigation.--The council is authorized to investigate the feasibility of purchasing prescription drugs from sources in Canada, which may include the feasibility of the Commonwealth or one of its political subdivisions serving as a wholesale distributor of prescription drugs in this Commonwealth.

(b) Waivers.--Upon determination by the council that the purchase under subsection (a) is feasible and in the best interests of the citizens of this Commonwealth, the council is authorized to pursue waivers from the Federal Government, including from the United States Food and Drug Administration, as necessary for the Commonwealth to accomplish prescription drug purchasing from sources in Canada. If a waiver is not granted, the council is authorized to take necessary legal action.

(c) Methodology.--

(1) Upon a favorable finding by the appropriate Federal agencies or courts under subsection (a), the Secretary of General Services shall transmit notice of the finding to the Legislative Reference Bureau and the Legislative Reference Bureau shall publish the notice in the Pennsylvania Bulletin.

(2) Upon publication of the notice in paragraph (1), the council may establish and implement a methodology to provide wholesale drugs to licensed pharmacies located within this Commonwealth.

Section 6. Management ability continued.

Nothing contained in this act shall be construed to limit the ability of the Commonwealth to enter into contracts or arrangements or to otherwise manage its pharmacy programs until the time when the programs created or authorized pursuant to this act are implemented.

Section 7. Advertising costs.

(a) Reporting.--Advertising costs for prescription drugs, based on aggregate national data, must be reported to the council by all manufacturers and labelers of prescription drugs dispensed in this Commonwealth that employ, direct or utilize marketing representatives. The reporting shall assist the Commonwealth in its role as a purchaser for prescription drugs and an administrator of prescription drug programs enabling the Commonwealth 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 the Commonwealth as guardian of the public interest.

(b) Requirements.--The council shall establish, by rule, the reporting requirements for 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 Commonwealth.

(c) Exemptions.--The following shall be exempt from disclosure requirements under this section:

(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 subsection, "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.

(3) All scholarship or other support for medical students, residents and fellows to attend significant educational, scientific or policymaking conferences 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) Manner of reporting.--The council is further authorized to establish timelines, the documentation, form and manner of reporting required as the council determines necessary to effectuate the purpose of this act. The council shall report to the State Government Committee of the Senate and the State Government Committee of the House of Representatives, in an aggregate form, the information provided in the required reporting.

(e) Confidentiality.--Notwithstanding any other provision of law, information submitted to the council pursuant to this section is confidential and not a public record and not available for release pursuant to the act of June 21, 1957 (P.L.390, No.212), referred to as the Right-to-Know Law. Data complied in aggregate form by the council for the purposes of reporting required by this section is a public record as defined in the Right-to-Know Law, as long as it does not reveal trade information that is protected by Federal or State law.

Section 8. State role.

For purposes of implementing this act, the Commonwealth shall have authority to negotiate pharmaceutical prices to be paid by program participants. These negotiated prices shall be available to all programs.

Section 9. 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 General Assembly. Savings, or any part thereof, created by the implementation of this program shall be designated and directed by the General Assembly towards the maintenance of existing State health programs and the expansion of insurance programs for the uninsured and underinsured.

Section 40. Rulemaking.

The council may promulgate rules to carry out the purposes of this act.

Section 41. Expiration.

The council shall expire July 1, 2009.

Section 42. Effective date.

This act shall take effect immediately.