

By Senator Campbell

32-479-05

1 A bill to be entitled
2 An act relating to state pharmaceutical
3 programs; providing definitions; creating a
4 prescription drug assistance clearinghouse
5 program; requiring costs of the program to be
6 paid by drug manufacturers; providing for the
7 transfer of ownership of the program to the
8 state; establishing a pharmaceutical discount
9 card program; providing for eligibility for
10 participation in the pharmaceutical discount
11 card program; creating a program to obtain
12 favorable pharmaceutical prices for state
13 agencies and other entities; requiring a
14 proposed pricing schedule; creating the
15 Pharmaceutical Cost Management Commission
16 within the Executive Office of the Governor;
17 establishing membership; establishing powers
18 and responsibilities of the commission;
19 providing reporting requirements; authorizing
20 an investigation into the feasibility of
21 purchasing Canadian drugs; authorizing the
22 establishment of a pricing schedule;
23 authorizing exploration of numerous strategies,
24 policies, and programs, including, but not
25 limited to, referenced prices for prescription
26 drug purchases and pricing in the state;
27 authorizing implementation of certain
28 designated programs; prohibiting restraint of
29 trade; providing civil and criminal penalties;
30 providing for advertising costs to be reported
31 to the Governor and the Legislature; providing

1 rulemaking authority; providing an effective
2 date.

3
4 WHEREAS, the rising cost of prescription drugs has
5 caused a significant hardship on individuals who have limited
6 budgets, are uninsured, or have prescription coverage that is
7 insufficient to cover costs successfully due to cost shifting
8 and disparate pricing policies, and

9 WHEREAS, the average cost per prescription for seniors
10 rose significantly between 1992 and 2000, and is expected to
11 continue increasing significantly through 2010, and

12 WHEREAS, there is an increasing need for the residents
13 of this state to have affordable access to prescription drugs,
14 and

15 WHEREAS, the Legislature does not intend the imposition
16 of the programs under this act to penalize or otherwise
17 jeopardize the benefits of veterans and other beneficiaries of
18 federal drug prices, and

19 WHEREAS, in an effort to promote healthy communities
20 and to protect the health and welfare of residents of this
21 state, the Legislature finds that it is its responsibility to
22 make every effort to provide affordable prescription drugs for
23 all residents of this state, NOW, THEREFORE,

24
25 Be It Enacted by the Legislature of the State of Florida:

26
27 Section 1. (1) SHORT TITLE.--This section may be
28 cited as the "Pharmaceutical Availability and Affordability
29 Act."

30 (2) DEFINITIONS.--As used in this section, the term:
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1 (a) "Advertising or marketing" means any manner of
2 communication of information, directly or indirectly, which is
3 paid for and usually persuasive in nature concerning products,
4 services, or ideas related to pharmaceuticals by identified
5 sponsors through various media, persons, or other forms as
6 further defined by rule.

7 (b) "Average wholesale price" or "AWP" means the
8 amount determined from the latest publication of the Bluebook,
9 a universally subscribed pharmacists' reference guide annually
10 published by the Hearst Corporation. Average wholesale price
11 or AWP may also be derived electronically from the drug
12 pricing database synonymous with the latest publication of the
13 Bluebook and furnished in the National Drug Data File (NDDF)
14 by First DataBank, Inc., a provider of comprehensive drug
15 information to health care professionals and a subsidiary of
16 the Hearst Corporation.

17 (c) "Dispensing fee" means the fee charged by a
18 pharmacy to dispense pharmaceuticals.

19 (d) "Drug manufacturer" or "pharmaceutical
20 manufacturer" means any entity that is engaged in:

21 1. The production, preparation, propagation,
22 compounding, conversion, or processing of prescription drug
23 products, directly or indirectly, by extraction from
24 substances of natural origin, independently by means of
25 chemical synthesis, or by a combination of extraction or
26 chemical synthesis; or

27 2. The packaging, repackaging, labeling, relabeling,
28 or distribution of prescription drug products. Drug
29 manufacturer or pharmaceutical manufacturer does not include a
30 wholesale distributor of drugs or a retail pharmacy licensed
31 under state law.

1 (e) "Federal supply schedule" or "FSS" means the price
2 available to all federal agencies for the purchase of
3 pharmaceuticals authorized in the Veterans Health Care Act of
4 1992, Public Law 102-585. FSS prices are intended to equal or
5 better the prices manufacturers charge their most-favored
6 nonfederal customers under comparable terms and conditions.

7 (f) "Multiple-source drug" means a drug for which
8 there are two or more drug products that are rated as
9 therapeutically equivalent according to the federal Food and
10 Drug Administration's most recent publication of "Approved
11 Drug Products with Therapeutic Equivalence Evaluations,"
12 except as otherwise provided in this subsection, and that are
13 pharmaceutically equivalent and bioequivalent, as determined
14 by the federal Food and Drug Administration.

15 (g) "Innovator drug" means a drug that is produced or
16 distributed under an original new drug application approved by
17 the federal Food and Drug Administration, including a drug
18 product marketed by any cross-licensed producer or distributor
19 operating under the new drug application and any
20 multiple-source drug that was originally marketed under an
21 original new drug application approved by the federal Food and
22 Drug Administration. An innovator drug may be referred to as a
23 "brand" drug.

24 (h) "Noninnovator drug" means a multiple-source drug
25 that is not an innovator drug. A noninnovator drug may be
26 referred to as a "generic" drug.

27
28 Paragraphs (f), (g), and (h) do not apply if the federal Food
29 and Drug Administration changes by regulation the requirement
30 that, for purposes of the publication described in paragraph
31 (f), in order for drug products to be rated as therapeutically

1 equivalent, they must be pharmaceutically equivalent and
2 bioequivalent.

3 (i) "Labeler" means an entity or person that receives
4 prescription drugs from a manufacturer or wholesaler and
5 repackages those drugs for later retail sale and that has a
6 labeler code from the federal Food and Drug Administration
7 pursuant to 21 C.F.R. s. 207.20 (1999).

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

10 (k) "Pharmaceutical drug detailing" or "detailing"
11 means the function performed by a sales representative who is
12 employed by a pharmaceutical manufacturer for the purpose of
13 promoting pharmaceutical drugs or related products, providing
14 education about pharmaceutical drugs or related products, or
15 providing samples of pharmaceutical drugs, related products,
16 or related materials, gifts, food, or meals.

17 (l) "Savings" means the difference between the
18 previous price of a prescription drug, including any
19 discounts, rebates, or price containments, and the current
20 price after July 1, 2005, for the Department of Management
21 Services, the state children's health insurance program, the
22 Medicaid and workers' compensation programs, or other programs
23 that are payors for prescription drugs.

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

27 (n) "Pharmaceutical Cost Management Commission" or
28 "commission" means the commission created pursuant to
29 subsection (7).

30 (3) CREATION OF CLEARINGHOUSE PROGRAM.--
31

1 (a) There is created the state prescription drug
2 assistance clearinghouse program. Each brand pharmaceutical
3 manufacturer shall create and implement a program to assist
4 state residents who have low incomes or are uninsured to gain
5 access to prescription medications through existing private
6 and public programs and prescription drug assistance programs
7 offered by manufacturers, including discount and coverage
8 programs. Each brand pharmaceutical manufacturer shall use
9 available computer software programs that provide an eligible
10 individual with access to the appropriate private or public
11 programs relating to the individual's medically necessary
12 drugs. Each brand pharmaceutical manufacturer shall provide
13 education to individuals and providers to promote the program
14 and to expand enrollment and access to necessary medications
15 for low-income or uninsured individuals qualifying for the
16 programs. A participating brand pharmaceutical manufacturer is
17 responsible for the cost of establishing the program and
18 running the program until June 20, 2006, when the ownership of
19 the technology, the website, and other program features shall
20 be transferred to the state. The Secretary of Health and the
21 Director of the Office of Insurance Regulation shall provide
22 joint oversight over the establishment and construction of the
23 program and program features prior to the transfer of
24 ownership to the state. The commission shall recommend the
25 state agency that will own, control, and operate the program,
26 technology, and program features, and shall include such
27 recommendation in its report on or before September 1, 2005,
28 to the Governor, the President of the Senate, and the Speaker
29 of the House of Representatives. In addition, each
30 pharmaceutical manufacturer shall report to the Office of
31 Program Policy Analysis and Government Accountability on a

1 monthly basis all activities related to the implementation of
2 this program, including the number of residents served and the
3 services provided.

4 (b) Each participating brand pharmaceutical
5 manufacturer shall contribute funding for promoting the
6 public-relations program attendant to the establishment of the
7 program. Each participating brand pharmaceutical manufacturer
8 is responsible for the cost of establishing the program and
9 the cost of the ongoing program, regardless of the date of
10 transfer of ownership of the program to the state, until
11 December 31, 2005.

12 (4) PHARMACEUTICAL DISCOUNT CARD PROGRAM;
13 ESTABLISHMENT; ELIGIBLE INDIVIDUALS; DISCOUNT PASS THROUGH;
14 TERMS.--

15 (a) There is established a discount card program to
16 provide low-income, uninsured individuals with access to
17 prescription drugs from participating brand pharmaceutical
18 companies and pharmacists through a state-sponsored discount
19 card program or a program that extends current prescription
20 drug assistance programs by brand pharmaceutical
21 manufacturers.

22 1. Eligible individuals include uninsured residents
23 having incomes of up to 200 percent of the federal poverty
24 level who have not been covered by a prescription drug
25 program, whether public or private, for at least 6 months
26 before applying for the discount card program.

27 2. The state may negotiate voluntary discounts with
28 brand pharmaceutical manufacturers and pharmacists if the
29 total discount received from the manufacturer passes through
30 to the eligible resident.

31

1 3. Failure of a brand pharmaceutical manufacturer to
2 participate in the voluntary discount card program shall not
3 result in prior authorization on drugs in the Medicaid program
4 which would not otherwise be subject to prior authorization
5 but for the failure of the manufacturer to participate in this
6 program.

7 4. The state may not establish a formulary or
8 preferred drug list as part of the discount card program.

9 (b) Each brand pharmaceutical manufacturer may extend
10 existing prescription drug assistance programs to eligible
11 residents of this state. Eligible individuals include
12 uninsured residents of this state having incomes of up to 200
13 percent of the federal poverty level who have not been covered
14 by a prescription drug program, whether public or private, for
15 at least 6 months before applying for the program.

16 (c) The program established under this section shall
17 be structured so that a member presenting a discount card at a
18 participating pharmacy will receive the full benefit of the
19 pharmacy discount, as well as the manufacturer's discount, at
20 the point of sale. The program or the pharmacy benefit manager
21 contracted by the program shall coordinate the drug discount
22 information provided by participating pharmacies and
23 manufacturers so that the available drug discounts are
24 provided to the member at the point of sale.

25 (d) A manufacturer participating in the voluntary
26 program established under this section shall cooperate with
27 the program or the pharmacy benefit manager contracted by the
28 program to provide the current list of drugs and the
29 percentage of discount from the AWP for such drugs, or the
30 rebates that the manufacturer provides under the program. It
31 is the intent of the Legislature that adequate drug price and

1 discount or rebate information be provided by the manufacturer
2 such that the program and participating pharmacies will have
3 available drug prices and discounts or rebates at the point of
4 sale. A retail pharmacy is responsible for no more than 50
5 percent of the discount offered by the manufacturer to the
6 participant.

7 1. A pharmacy participating in a voluntary program
8 established under this section is responsible for no more than
9 50 percent of the discount offered by the manufacturer to the
10 participant, and shall be paid a dispensing fee of no more
11 that \$3.50 per prescription with regard to prescriptions
12 filled under the program.

13 2. Upon the presentation of a valid discount card,
14 payment for the prescription, and satisfaction of other
15 appropriate criteria for having his or her prescription
16 filled, the cardholder's prescription shall be filled by a
17 participating pharmacy. To accomplish the transaction, the
18 participating pharmacy shall electronically transmit the
19 transaction to the program or pharmacy benefit manager
20 contracted by the program for processing. The program, or the
21 program's pharmacy benefit manager, shall determine the
22 discounted cost of the drug, including the discount provided,
23 the discount provided by the pharmacy, the discount or rebate
24 provided by the manufacturer, the pharmacy dispensing fee, and
25 any pharmacy benefit manager transaction fee. The program or
26 the pharmacy benefit manager shall then transmit to the
27 manufacturer an electronic statement of the amount the
28 manufacturer owes on the transaction to cover the
29 manufacturer's discount or rebate and the program's or
30 pharmacy benefit manager's processing fee. The manufacturer
31 shall, at least every 14 days, transmit such monetary amounts

1 for the transaction to the program or the program's pharmacy
2 benefit manager, and the program or the program's pharmacy
3 benefit manager shall immediately pass the discount or rebate
4 amounts back to the participating pharmacy that originated the
5 transaction.

6 (e) Each pharmaceutical manufacturer shall report
7 monthly to the Office of Program Policy Analysis and
8 Government Accountability all activities related to the
9 implementation of this program, including the number of
10 residents served and the services provided, as well as the
11 benefits, costs, and discounts obtained.

12 (5) CREATION OF PROGRAM; ADMINISTRATIVE SUPPORT;
13 MEDICAID AND CHIP PROGRAMS.--

14 (a) There is created a program to obtain favorable
15 pharmaceutical prices for state agencies and other qualified
16 entities.

17 (b) The Medicaid program and this state's children's
18 health insurance program are exempt from participating in this
19 program until approval by the Centers for Medicare and
20 Medicaid Services has been granted if it is determined to be
21 required by the commission.

22 (c) Administrative staff support for the program shall
23 be provided by the departments represented on the commission.

24 (d) The commission shall establish a pricing schedule
25 using or referencing the FSS prices, or using or referencing
26 the price, as adjusted for currency valuations, set by the
27 Patented Medicine Prices Review Board in Canada or any other
28 appropriate referenced price that will maximize savings to the
29 broadest percentage of the population of this state.

30 (e) By September 15, 2005, the commission shall report
31 to the Legislature the pricing schedule developed and a

1 strategic plan for implementation. The commission shall
2 implement the proposed pricing schedule and strategic plan
3 upon approval by the Legislature that the proposed pricing
4 schedule and strategy are the most effective method of
5 reducing pharmaceutical prices for the residents of this
6 state.

7 (f) A qualified entity, including, but not limited to,
8 licensed private insurers, self-insured employers, free
9 clinics, and other entities that provide pharmaceuticals
10 directly or through some form of coverage to the residents of
11 this state shall have an option to apply for participation in
12 the program in the form and manner established by the
13 commission. The commission may approve or deny participation
14 through review of documentation determined to be necessary for
15 full consideration and as established by rule. The commission
16 shall consider, but not be limited to, the fiscal stability
17 and size of each applicant.

18 (g) A pharmaceutical manufacturer may request that a
19 waiver from the pricing schedule be granted by the commission
20 for a particular drug in which the development, production,
21 distribution costs, and other reasonable costs and reasonable
22 profits, exclusive of all marketing and advertising costs as
23 determined by the commission, are more than the pricing
24 schedule rate of the pharmaceutical or in those cases in which
25 the pharmaceutical in question has a sole source. The
26 determination of reasonable costs and reasonable profits may
27 fluctuate between different pharmaceuticals under
28 consideration by the commission. The commission shall
29 determine by rule the fees to be paid by the applicant at the
30 time a waiver request is made and the required documentation
31 is submitted.

1 (6) MULTISTATE DISCUSSION GROUP.--For the purposes of
2 reviewing or amending the program establishing the process for
3 making pharmaceuticals more available and affordable to the
4 residents of this state, the state may continue to enter into
5 multistate discussions and agreements. For purposes of
6 participating in these discussions, the state shall be
7 represented by members of the commission.

8 (7) PHARMACEUTICAL COST MANAGEMENT COMMISSION.--

9 (a) There is created the Pharmaceutical Cost
10 Management Commission within the Executive Office of the
11 Governor consisting of 10 members.

12 1. The following five state officials shall be members
13 of the commission:

14 a. The Secretary of Management Services, or his or her
15 designee;

16 b. The Secretary of Elderly Affairs, or his or her
17 designee;

18 c. The Secretary of Health Care Administration, or his
19 or her designee;

20 d. The executive director of the Office of Insurance
21 Regulation, or his or her designee; and

22 e. The deputy secretary of the Division of Health
23 Quality Assurance within the Agency for Health Care
24 Administration, or his or her designee.

25 2. The Governor shall appoint the following public
26 members to the commission:

27 a. A licensed pharmacist employed by a community
28 retail pharmacy;

29 b. A representative of a pharmaceutical manufacturer
30 having substantial operations located in this state and which
31 has at least 750 employees;

- 1 c. A primary care physician;
2 d. A citizen of this state who will directly benefit
3 from the establishment of discount drug programs; and
4 e. A citizen of this state who has experience in the
5 finance, development, or management of a health insurance
6 company that provides pharmaceutical coverage.
- 7 3. Commission members shall be appointed to terms of 4
8 years each. Any vacancy on the commission shall be filled in
9 the same manner as the original appointment. A member may be
10 removed by the Governor for cause. Any member appointed to
11 fill a vacancy occurring because of death, resignation, or
12 ineligibility for membership shall serve only for the
13 unexpired term of the member's predecessor. A member is
14 eligible for reappointment.
- 15 4. Members of the commission shall serve without
16 compensation, but are entitled to reimbursement for per diem
17 and travel expenses as provided in section 112.061, Florida
18 Statutes.
- 19 5. The Secretary of Management Services shall serve as
20 chairperson of the commission, which shall meet at times and
21 places specified by the chairperson or upon request of two
22 members of the commission.
- 23 (b) The commission has the power and authority to:
24 1. Contract for the purpose of implementing the
25 cost-containment provisions of this section;
26 2. File suit;
27 3. Execute, as permitted by applicable federal law,
28 prescription drug purchasing agreements with:
29 a. Any department, agency, authority, institution,
30 program, any agency or program of the federal government, a
31 quasi-public corporation and political subdivision of this

1 state, including, but not limited to, the children's health
2 insurance program, the Department of Corrections, the
3 Department of Juvenile Justice, the Workers' Compensation
4 Administration Trust Fund, a state college or university, a
5 public hospital, a state or local institution such as a
6 nursing home, a veterans' home, the Agency for Persons with
7 Disabilities, a public health department, a state program,
8 including, but not limited to, a program established by this
9 section or the Division of Health Quality Assurance, if the
10 contract or agreement executed with or on behalf of the
11 Division of Health Quality Assurance contains all necessary
12 provisions to comply with Title XIX of the Social Security
13 Act, 42 U.S.C. s. 1396 et seq., dealing with pharmacy services
14 offered to recipients under the federal medical assistance
15 program;

16 b. A government of another state or jurisdiction and
17 its individual departments, agencies, authorities,
18 institutions, programs, quasi-public corporations and
19 political subdivisions; and

20 c. A regional or multistate purchasing alliance or
21 consortium that is formed for the purpose of pooling the
22 combined purchasing power of the individual members in order
23 to increase bargaining power.

24 4. Consider strategies by which this state may manage
25 the increasing costs of prescription drugs and increase access
26 to prescription drugs for all of the state's residents,
27 including the authority to explore:

28 a. The enactment of fair prescription-drug-pricing
29 policies;

30 b. Discount prices or rebate programs for seniors and
31 persons without prescription drug coverage;

1 c. Programs offered by pharmaceutical manufacturers
2 which provide prescription drugs free of charge or at reduced
3 prices;

4 d. Requirements and criteria, including the level of
5 detail, for prescription drug manufacturers to disclose to the
6 commission expenditures for advertising, marketing, and
7 promotion, based on aggregate national data;

8 e. The establishment of counter-detailing programs
9 aimed at educating health care practitioners authorized to
10 prescribe prescription drugs about the relative costs and
11 benefits of various prescription drugs, with an emphasis on
12 generic substitution for brand name drugs when available and
13 appropriate; prescribing older, less costly drugs instead of
14 newer, more expensive drugs when appropriate; and prescribing
15 lower dosages of prescription drugs when available and
16 appropriate;

17 f. State management programs for diseases aimed at
18 enhancing the effectiveness of treating certain diseases
19 identified as prevalent among this state's population;

20 g. Prescription drug purchasing agreements with large
21 private-sector purchasers of prescription drugs and including
22 those private entities in pharmacy benefit management
23 contracts if a private entity is not compelled to participate
24 in a purchasing agreement;

25 h. The feasibility of using or referencing the federal
26 supply schedule or referencing the price, as adjusted for
27 currency valuations, set by the Patented Medicine Prices
28 Review Board in Canada or any other appropriate referenced
29 price in order to establish prescription drug pricing for
30 brand name drugs in the state, and to review and determine the
31 dispensing fees for pharmacies;

1 i. Joint negotiations for drug purchasing and a shared
2 prescription drug pricing schedule and shared preferred drug
3 list for use by the state insurance program, the Medicaid
4 program, other state payors, and private insurers, if
5 possible;

6 j. Coordination between the Medicaid program, the
7 state insurance program and, to the extent possible, hospitals
8 and private insurers, for the purpose of developing a uniform
9 preferred prescription drug list that is clinically
10 appropriate and that leverages retail prices;

11 k. Policies that promote the use of generic drugs
12 where appropriate;

13 l. A policy that precludes a drug manufacturer from
14 reducing the amounts of drug rebates or otherwise penalizing
15 an insurer, health plan, or other entity that pays for
16 prescription drugs based upon the fact that the entity uses
17 step therapy or other clinical programs before a drug is
18 covered or otherwise authorized for payment;

19 m. Arrangements with entities in the private sector,
20 including self-funded benefit plans and nonprofit
21 corporations, toward combined purchasing of health care
22 services, health care management services, pharmacy benefits
23 management services, or pharmaceutical products on the
24 condition that no private entity be compelled to participate
25 in the prescription drug purchasing pool;

26 n. Other strategies, as permitted under state and
27 federal law, aimed at managing escalating prescription drug
28 prices and increasing affordable access to prescription drugs
29 for all residents of this state; and

30 o. The licensing and regulation of pharmaceutical
31 detailers, including the requirement of continuing

1 professional education, the imposition of fees for licensing
2 and continuing education, the establishment of a special
3 revenue account for deposit of the fees, and the imposition of
4 penalties for noncompliance with licensing and continuing
5 education requirements.

6 5. Contract with appropriate legal, actuarial, and
7 other service providers required to accomplish any function
8 within the powers of the commission and to develop other
9 strategies, as permitted under state and federal law, aimed at
10 managing escalating prescription drug prices and increasing
11 affordable access to prescription drugs for all residents of
12 this state.

13 (c) The commission shall report to the Office of
14 Program Policy Analysis and Government Accountability on or
15 before September 1, 2005, and annually thereafter to the
16 Legislature on December 31, and shall provide recommendations
17 on needed legislative action and other functions established
18 by this section or requested by the Office of Program Policy
19 Analysis and Government Accountability.

20 (d) The commission shall immediately commence a study
21 of the fiscal impact to this state of the federal Medicare
22 Prescription Drug Improvement and Modernization Act of 2003
23 and shall report to the Office of Program Policy Analysis and
24 Government Accountability on or before October 15, 2005, as to
25 the findings of the commission.

26 (e) The commission shall develop an evaluation
27 methodology to certify and audit savings in the discount card
28 program by determining its impact on the growth and profit of
29 the pharmaceutical manufacturers in order to ensure that
30 prices have not been inflated to offset the value or the
31 discount card.

1 (f) The commission shall evaluate the clearinghouse
2 program and the discount card program and report to the Office
3 of Program Policy Analysis and Government Accountability its
4 findings and recommendations for further action by the
5 Legislature.

6 (g) In addition, the commission shall:

7 1. Determine whether the implementation of the
8 programs under this section will jeopardize, reduce, or
9 penalize the benefits of veterans or other recipients of FSS
10 drug prices, considering their respective copay structures and
11 the pricing mechanisms of their respective programs;

12 2. Commence negotiations to obtain independent
13 agreements or multistate agreements in as many as 10 states to
14 use or reference a pricing schedule; and

15 3. Determine the ability to establish a savings of 42
16 percent of the retail cost to be reported to the Office of
17 Program Policy Analysis and Government Accountability.

18 (8) INVESTIGATION OF CANADIAN DRUGS; WHOLESALING;
19 FEDERAL WAIVERS.--

20 (a) The commission and the director of the Office of
21 Insurance Regulation may investigate the feasibility of
22 purchasing prescription drugs from sources in Canada, which
23 may include the feasibility of the state or an instrumentality
24 thereof serving as a wholesale distributor of prescription
25 drugs in the state.

26 (b) Upon a determination by the commission or the
27 Director of the Office of Insurance Regulation that such
28 purchases are feasible and in the best interests of the
29 residents of the state, the commission or the director may
30 pursue waivers from the Federal Government, including without
31 limitation the United States Food and Drug Administration, as

1 necessary for the state to accomplish prescription drug
2 purchasing from sources in Canada. However, if such waiver is
3 not granted, the commission may take necessary legal action.

4 (c) Upon a favorable finding by the appropriate
5 federal agency or court, notwithstanding any provision of law
6 to the contrary, the commission or the Director of the Office
7 of Insurance Regulation may establish and implement a
8 methodology to provide wholesale drugs to licensed pharmacies
9 located within this state.

10 (9) DIRECTOR'S POWERS; ABILITY TO ENTER DRUG
11 PURCHASING CONTRACTS.--Notwithstanding any provision of law to
12 the contrary, this section does not limit the powers and
13 authority granted to the Director of the Office of Insurance
14 Regulation. Notwithstanding any provision of law to the
15 contrary, the Director of the Office of Insurance Regulation
16 may execute prescription drug purchasing agreements.

17 (10) AGENCY'S MANAGEMENT ABILITY CONTINUED.--This
18 section does not limit the ability of a state agency to enter
19 into contracts or arrangements or to otherwise manage its
20 pharmacy programs until such time as the programs created or
21 authorized pursuant to this section are implemented.

22 (11) RESTRAINT OF TRADE; CIVIL AND CRIMINAL VIOLATIONS
23 DEFINED.--

24 (a) Two or more persons may not contract or conspire:

25 1. For the purpose or with the intent, to fix,
26 control, or maintain the market price, rate, or fee of
27 pharmaceuticals; or

28 2. To allocate or divide customers or markets, whether
29 functional or geographic, for any pharmaceutical.

30 (b) A person may not establish, maintain, or use a
31 monopoly or attempt to establish a monopoly of trade or

1 commerce, any part of which is within this state, for the
2 purpose of or with the intent to exclude competition or to
3 control, fix, or maintain pharmaceutical prices.

4 (c) Any person who violates this subsection commits a
5 felony of the third degree, punishable as provided in section
6 775.082, section 775.083, or section 775.084, Florida
7 Statutes, and may be fined in an amount consistent with the
8 Clayton Act, 15 U.S.C. s. 15 et seq., which may include treble
9 damages.

10 (d) Any person who violates this subsection is liable
11 for a civil penalty and fine in an amount consistent with the
12 Clayton Act, 15 U.S.C. s. 15 et seq., which may include treble
13 damages for each violation.

14 (e) Any state attorney may investigate suspected
15 violations of, and institute criminal proceedings pursuant to,
16 the provisions of this subsection.

17 (f) The Attorney General shall represent the state in
18 all civil proceedings brought on behalf of the state to
19 enforce the provisions of this section. After payment of all
20 attorney's fees and costs, no less than 50 percent of each
21 judgment or settlement shall be placed in the General Revenue
22 Fund.

23 (12) ADVERTISING COSTS.--

24 (a) A manufacturer and labeler of prescription drugs
25 dispensed in this state which employs, directs, or uses
26 marketing representatives shall report advertising costs for
27 prescription drugs, based on aggregate national data, to the
28 commission. This reporting assists the state in its role as a
29 purchaser of prescription drugs and as an administrator of
30 prescription drug programs, enabling the state to determine
31 the scope of prescription drug advertising costs and their

1 effect on the cost, utilization, and delivery of health care
2 services, and furthering the role of the state as guardian of
3 the public interest.

4 (b) The commission shall establish the reporting
5 requirements concerning information by labelers and
6 manufacturers, which shall include all national aggregate
7 expenses associated with advertising and direct promotion of
8 prescription drugs through radio, television, magazines,
9 newspapers, direct mail, and telephone communications as they
10 pertain to residents of this state.

11 (c) The following are exempt from disclosure
12 requirements:

13 1. Free samples of prescription drugs intended to be
14 distributed to patients;

15 2. Payments of reasonable compensation and
16 reimbursement of expenses in connection with a bona fide
17 clinical trial. As used in this subsection, "clinical trial"
18 means an approved clinical trial conducted in connection with
19 a research study designed to answer specific questions about
20 vaccines, new therapies, or new ways of using known
21 treatments; and

22 3. Medical scholarships or other support for medical
23 students, residents, and fellows to attend significant
24 educational, scientific, or policy-making conferences of
25 national, regional, or specialty medical or other professional
26 associations if the recipient of the scholarship or other
27 support is selected by the association.

28 (d) The commission may establish deadlines for
29 reporting and the form, manner, and documentation of reporting
30 required as the commission determines are necessary to
31 effectuate the purpose of this subsection. The commission

1 shall report to the Office of Program Policy Analysis and
2 Government Accountability, in an aggregate form, the
3 information provided in the required reporting.

4 (13) STATE ROLE.--For purposes of implementing this
5 section, the commission may negotiate pharmaceutical prices to
6 be paid by program participants. These negotiated prices shall
7 be available to all programs.

8 (14) RULEMAKING.--The commission may adopt rules to
9 administer this section.

10 (15) POTENTIAL USE OF SAVINGS.--Savings identified by
11 all program participants shall be quantified and certified to
12 the commission and included in the annual report of the
13 commission to the Governor, the President of the Senate, and
14 the Speaker of the House of Representatives. Savings, or any
15 part thereof, created by the implementation of this section
16 may, in the sole discretion of the Legislature, be directed
17 towards the maintenance of existing state health programs and
18 the expansion of insurance programs for the uninsured and
19 underinsured.

20 Section 2. This act shall take effect July 1, 2005.
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SENATE SUMMARY

Creates a prescription drug assistance clearinghouse program. Requires that costs of program be paid by drug manufacturers. Provides for the transfer of ownership of the program to the state. Establishes a pharmaceutical discount card program. Provides for eligibility for participation in the pharmaceutical discount card program. Creates the Pharmaceutical Cost Management Commission. Establishes membership. Establishes powers and responsibilities. Provides reporting requirements. Authorizes an investigation into the feasibility of purchasing Canadian drugs. Authorizes the establishment of a pricing schedule. Authorizes exploration of numerous strategies, policies, and programs. Authorizes implementation of certain designated programs. Prohibits restraint of trade. Provides civil and criminal penalties. Provides for reporting advertising costs and other reporting to the Governor and Legislature. Provides rulemaking authority. (See bill for details.)