

Amendment No. ____ (for drafter's use only)

	<u>Senate</u>	CHAMBER ACTION	<u>House</u>
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ORIGINAL STAMP BELOW

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Representative(s) Gelber offered the following:

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Amendment

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On page 3, between lines 9 and 10,

14

15

and insert:

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Section 3. Section 409.960, Florida Statutes, is created to read:

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409.960 Short title.--Sections 409.960-409.984 may be cited as the "Florida Prescription Drug Fair Pricing Act."

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Section 4. Section 409.962, Florida Statutes, is created to read:

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409.962 Florida Prescription Drug Fair Pricing Program established; findings; purpose.--

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(1) It is the finding of the Legislature that approximately one in four residents of Florida have no prescription drug insurance coverage or wholly inadequate prescription drug insurance coverage. These uninsured residents pay excessive prices for prescription drugs, far higher prices than are paid by managed care organizations, insurance companies, and the Federal Government for the same

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1 medicines and dosages. In many cases, these excessive drug
2 prices have the effect of denying residents access to
3 medically necessary care, thereby threatening their health and
4 safety. Many Florida residents require repeated doctor or
5 medical clinic appointments, having become sicker because they
6 could not afford to purchase the prescription drugs prescribed
7 for them. Many residents are admitted to or treated at
8 hospitals each year because they cannot afford the
9 prescription drugs that could have prevented the need for
10 hospitalization. Many others enter expensive institutional
11 care settings because they cannot afford the necessary
12 prescription drugs that could have supported them outside of
13 an institution. In each of these circumstances, state medical
14 assistance programs, including the Medicaid program, literally
15 pay the price. One major reason uninsured residents pay such
16 high prices for prescription drugs is that, unlike insured
17 residents, they have no prescription benefits manager
18 negotiating a fair price with drug companies on their behalf.
19 State government currently provides prescription drugs and
20 acts as a prescription benefit manager through a variety of
21 health plans and assistance programs and, in 2001, the
22 Legislature expanded the state's role in negotiating better
23 prescription drug prices for Medicaid. State government is the
24 only agent that, as a practical matter, can play an effective
25 role as a market participant on behalf of all residents who
26 are uninsured or underinsured. The state can and should act as
27 a prescription benefit manager, negotiating drug rebates and
28 using these funds to reimburse retail pharmacies for offering
29 lower drug prices.

30 (2) Recognizing that the state already acts as a
31 prescription benefit manager for a variety of health plans and

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1 assistance programs, including the Medicaid program, the
2 Florida Prescription Drug Fair Pricing Program is established
3 within the Agency for Health Care Administration. The purpose
4 of the program is to expand Medicaid eligibility for
5 prescription drug benefits only, at a level that does not
6 exceed available funding, thereby providing prescription drug
7 coverage to new populations by expanding the state's role as a
8 participant in the prescription drug marketplace, negotiating
9 rebates from drug companies, and using the funds from such
10 rebates to make prescription drugs more affordable to Florida
11 residents. Each program participant shall receive a discount
12 toward the purchase of any prescription drug included on the
13 state Medicaid preferred drug formulary established pursuant
14 to s. 409.912. No discount shall be applied toward the
15 purchase of any prescription drug that is not included on such
16 formulary. The Legislature finds that such a program will
17 improve public health and welfare, promote the economic
18 strength of our society, and substantially benefit state
19 health assistance programs, including the Medicaid program.

20 Section 5. Section 409.964, Florida Statutes, is
21 created to read:

22 409.964 Definitions.--As used in this act, unless the
23 context otherwise indicates, the following terms have the
24 following meanings:

25 (1) "Agency" means the Agency for Health Care
26 Administration.

27 (2) "Labeler" means an entity or person that receives
28 prescription drugs from a manufacturer or wholesaler and
29 repackages those drugs for later retail sale and that has a
30 labeler code from the federal Food and Drug Administration
31 under 21 C.F.R. s. 207.20 (1999).

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1 (3) "Manufacturer" means a manufacturer of
2 prescription drugs and includes a subsidiary or affiliate of a
3 manufacturer.

4 (4) "Participating retail pharmacy" means a retail
5 pharmacy or other business licensed to dispense prescription
6 drugs in this state that:

7 (a) Participates in the state Medicaid program; or

8 (b) Agrees to participate in the Florida Prescription
9 Drug Fair Pricing Program.

10 (5) "Program" means the Florida Prescription Drug Fair
11 Pricing Program.

12 (6) "Secretary" means the Secretary of Health Care
13 Administration, or the secretary's designee.

14 (7) "Qualified resident" means an uninsured resident
15 of the state who has obtained from the agency a Florida
16 Prescription Drug Fair Pricing Program enrollment card.

17 Section 6. Section 409.966, Florida Statutes, is
18 created to read:

19 409.966 Prescription drug discounts; negotiation of
20 discounts or rebates; calculation of discounts.--The Secretary
21 of Health Care Administration shall operate the Florida
22 Prescription Drug Fair Pricing Program as a state
23 pharmaceutical assistance program under 42 U.S.C. s.
24 1396r-8(c)(1)(C)(i)(III) to provide discounts to participants
25 for prescription drugs covered by a rebate agreement.

26 (1) The secretary shall negotiate discount prices or
27 rebates for prescription drugs from drug manufacturers and
28 labelers for the program. Using sums from negotiated rebates,
29 the agency shall contract with participating retail pharmacies
30 to deliver discounted prices to program participants.

31 (2) In negotiating discount or rebate terms, the

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1 secretary shall take into consideration:

2 (a) The rebate calculated under the Medicaid rebate
3 program pursuant to 42 U.S.C. s. 1396r-8;

4 (b) The price provided to eligible entities under 42
5 U.S.C. s. 256b; and

6 (c) Any other available information on prescription
7 drug prices, discounts, and rebates.

8 (3) The secretary may consider any supplemental rebate
9 negotiated pursuant to s. 409.912(37)(a)7.

10 (4) The drug discounts received by program
11 participants shall be calculated by the secretary on a
12 quarterly basis.

13 Section 7. Section 409.968, Florida Statutes, is
14 created to read:

15 409.968 Discounted prices for program participants.--

16 (1) Each participant enrolled in the Florida
17 Prescription Drug Fair Pricing Program shall pay a coinsurance
18 amount equal to the Medicaid allowable charge minus the amount
19 paid by the agency.

20 (2) A participating retail pharmacy shall charge the
21 Medicaid allowable rate for prescription drugs sold to
22 participants in the Florida Prescription Drug Fair Pricing
23 Program.

24 (3) The participating retail pharmacy shall be
25 reimbursed by the agency at the agency's manufacturer
26 estimated rebate amount.

27 (4) The Florida Prescription Drug Fair Pricing Program
28 as established in s. 409.962 is not an entitlement.

29 Section 8. Section 409.970, Florida Statutes, is
30 created to read:

31 409.970 Program eligibility.--

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1 (1) An individual is eligible to participate in the
2 Florida Prescription Drug Fair Pricing Program if he or she:

3 (a) Is a resident of the state;

4 (b) Has no health insurance coverage, or has health
5 insurance coverage, including Medicare, that does not include
6 coverage for prescription drugs;

7 (c) Has a net family income at or below 200 percent of
8 the federal poverty level; and

9 (d) Requests to be enrolled in the program.

10 (2) An individual is ineligible to participate in the
11 Florida Prescription Drug Fair Pricing Program if he or she is
12 eligible for assistance under the state's Medicaid program or
13 is covered by an insurance policy that provides benefits for
14 prescription drugs equal to or greater than the benefits
15 provided under the Florida Prescription Drug Fair Pricing
16 Program, as delineated by rules promulgated by the secretary.

17 (3) The agency shall establish simple procedures for
18 enrolling program participants. Such procedures shall include
19 the assessment of an annual enrollment fee of up to \$25 per
20 enrollee. The agency shall undertake outreach efforts to build
21 public awareness of the program and maximize enrollment by
22 eligible residents. Revenues generated from program enrollment
23 fees and rebates from drug manufacturers shall be used for,
24 but not be limited to, offsetting state costs to administer
25 the program, the purchase of prescription drugs, and any
26 public awareness campaigns.

27 Section 9. Section 409.972, Florida Statutes, is
28 created to read:

29 409.972 Program operation.--

30 (1) The Board of Pharmacy, as created by s. 465.004,
31 in consultation with the Agency for Health Care

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1 Administration, is authorized to adopt rules pursuant to ss.
2 120.536(1) and 120.54 requiring disclosure by participating
3 retail pharmacies to program participants of the amount of
4 savings provided as a result of the Florida Prescription Drug
5 Fair Pricing Program. Such rules must protect information that
6 is proprietary in nature.

7 (2) Participating retail pharmacies shall be paid in
8 advance for program discounts or shall be reimbursed by the
9 agency on a weekly or biweekly basis, in accordance with
10 contracts between the agency and such businesses.

11 (3) The agency shall collect from the participating
12 retail pharmacies utilization data necessary to calculate the
13 amount of the rebate from the manufacturer or labeler. The
14 agency shall protect the confidentiality of all information
15 subject to confidentiality protection under the laws of this
16 state or federal laws, rules, or regulations.

17 Section 10. Section 409.974, Florida Statutes, is
18 created to read:

19 409.974 Discrepancies in rebate
20 amounts.--Discrepancies in rebate amounts must be resolved
21 using the process established in this section.

22 (1) If there is a discrepancy in the manufacturer's or
23 labeler's favor between the amount claimed by a participating
24 retail pharmacy and the amount rebated by the manufacturer or
25 labeler, the agency, at the agency's expense, may hire a
26 mutually agreed-upon independent auditor. If a discrepancy
27 still exists following the audit, the manufacturer or labeler
28 shall justify the reason for the discrepancy or make payment
29 to the agency for any additional amount due.

30 (2) If there is a discrepancy against the interest of
31 the manufacturer or labeler in the information provided by the

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1 agency to the manufacturer or labeler regarding the
2 manufacturer's or labeler's rebate, the manufacturer or
3 labeler, at the manufacturer's or labeler's expense, may hire
4 a mutually agreed-upon independent auditor to verify the
5 accuracy of the data supplied to the agency. If a discrepancy
6 still exists following the audit, the agency shall justify the
7 reason for the discrepancy or refund the manufacturer or
8 labeler.

9 (3) Following the completion of procedures established
10 in subsection (1) or subsection (2), the agency, the
11 manufacturer, or the labeler may request a hearing. Hearings
12 shall be conducted pursuant to ss. 120.569 and 120.57.
13 Supporting documentation must accompany the request for a
14 hearing.

15 Section 11. Section 409.976, Florida Statutes, is
16 created to read:

17 409.976 Report.--The agency shall provide a report on
18 the enrollment and financial status of the Florida
19 Prescription Drug Fair Pricing Program to the Governor, the
20 President of the Senate, and the Speaker of the House of
21 Representatives by the second week in January each year.

22 Section 12. Section 409.978, Florida Statutes, is
23 created to read:

24 409.978 Coordination with other programs.--The
25 secretary shall combine drug pricing negotiations to maximize
26 drug rebates where the secretary determines that the
27 combination of such negotiations is beneficial to both the
28 Florida Prescription Drug Fair Pricing Program and another
29 state program, including the state Medicaid program.

30 Section 13. Section 409.980, Florida Statutes, is
31 created to read:

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1 409.980 Rulemaking.--The agency is authorized to adopt
2 rules pursuant to ss. 120.536(1) and 120.54 to implement the
3 provisions of this act. Such rules shall include eligibility
4 requirements, limits on participation, benefit limitations, a
5 requirement for generic drug substitution, and other program
6 parameters comparable to those of the Medicaid program.

7 Section 14. Section 409.982, Florida Statutes, is
8 created to read:

9 409.982 Waivers.--The agency may seek any waivers of
10 federal law, rule, or regulation necessary to implement the
11 provisions of this act.

12 Section 15. The agency shall contribute \$1 of general
13 revenue toward the purchase of prescription drugs under this
14 program.

15 Section 16. If any provision of this act or the
16 application thereof to any person or circumstance is held
17 invalid, the invalidity shall not affect other provisions or
18 applications of the act which can be given effect without the
19 invalid provision or application, and to this end the
20 provisions of this act are declared severable.

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23 ===== T I T L E A M E N D M E N T =====

24 And the title is amended as follows:

25 On page 1, line 15 after the semicolon,
26 remove:

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and insert:

29 creating s. 409.960, F.S.; providing a short
30 title; creating s. 409.962, F.S.; creating the
31 "Florida Prescription Drug Fair Pricing

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1 Program"; providing purpose of the program;
2 creating s. 409.964, F.S.; providing
3 definitions; creating s. 409.966, F.S.;
4 providing that the Secretary of Health Care
5 Administration shall operate the Florida
6 Prescription Drug Fair Pricing Program as a
7 state pharmaceutical assistance program to
8 provide discounts to participants for
9 prescription drugs covered by a rebate
10 agreement; providing that the secretary shall
11 negotiate discount prices or rebates for
12 prescription drugs from manufacturers or
13 labelers; providing that the Agency for Health
14 Care Administration shall contract with
15 participating retail pharmacies to deliver
16 discounted prices to program participants;
17 providing factors to be considered in
18 negotiating discounts or rebates; providing for
19 quarterly calculation of discounts; creating s.
20 409.968, F.S.; requiring program participants
21 to pay a specified coinsurance amount;
22 requiring participating retail pharmacies in
23 the state to charge the rate allowable under
24 the Medicaid program for prescription drugs
25 sold to program participants; providing for
26 rate of reimbursement of participating retail
27 pharmacies; creating s. 409.970, F.S.;
28 providing for program eligibility; requiring
29 the Agency for Health Care Administration to
30 establish enrollment procedures; providing for
31 an annual enrollment fee; providing for use of

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1 enrollment fees and rebates from drug
2 manufacturers; creating s. 409.972, F.S.;
3 providing for operation of the program;
4 authorizing the Board of Pharmacy to adopt
5 certain rules; creating s. 409.974, F.S.;
6 providing procedure for resolution of
7 discrepancies in rebate amounts; creating s.
8 409.976, F.S.; requiring an annual report;
9 creating s. 409.978, F.S.; authorizing
10 coordination with other programs; creating s.
11 409.980, F.S.; authorizing the agency to adopt
12 rules; creating s. 409.982, F.S.; authorizing
13 the agency to seek certain waivers; providing
14 severability;

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