

Amendment No. \_\_\_\_ (for drafter's use only)

	<u>Senate</u>	CHAMBER ACTION	<u>House</u>
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Representative(s) Gelber offered the following:

**Amendment (with title amendment)**

On page 3, lines 6 through 7,

insert:

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

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

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

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

(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. However,  
29 the agency shall provide a subsidy in the amount of \$1 toward  
30 the purchase of prescription drugs under this program.

31 Section 8. Section 409.970, Florida Statutes, is

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1 created to read:

2 409.970 Program eligibility.--

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

5 (a) Is a resident of the state;

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

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

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

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

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

29 Section 9. Section 409.972, Florida Statutes, is  
30 created to read:

31 409.972 Program operation.--

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1           (1) The Board of Pharmacy, as created by s. 465.004,  
2 in consultation with the Agency for Health Care  
3 Administration, is authorized to adopt rules pursuant to ss.  
4 120.536(1) and 120.54 requiring disclosure by participating  
5 retail pharmacies to program participants of the amount of  
6 savings provided as a result of the Florida Prescription Drug  
7 Fair Pricing Program. Such rules must protect information that  
8 is proprietary in nature.

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

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

19           Section 10. Section 409.974, Florida Statutes, is  
20 created to read:

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

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

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1           (2) If there is a discrepancy against the interest of  
2 the manufacturer or labeler in the information provided by the  
3 agency to the manufacturer or labeler regarding the  
4 manufacturer's or labeler's rebate, the manufacturer or  
5 labeler, at the manufacturer's or labeler's expense, may hire  
6 a mutually agreed-upon independent auditor to verify the  
7 accuracy of the data supplied to the agency. If a discrepancy  
8 still exists following the audit, the agency shall justify the  
9 reason for the discrepancy or refund the manufacturer or  
10 labeler.

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

17           Section 11. Section 409.976, Florida Statutes, is  
18 created to read:

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

24           Section 12. Section 409.978, Florida Statutes, is  
25 created to read:

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



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1 Section 13. Section 409.980, Florida Statutes, is  
2 created to read:

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

9 Section 14. Section 409.982, Florida Statutes, is  
10 created to read:

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

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

20 Section 16. This act shall take effect July 1, 2002

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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 12 after the semicolon,  
26 remove:

27  
28 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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