

By Senator Silver

38-1488-02

See HB

1                                   A bill to be entitled  
2           An act relating to prescription drugs; creating  
3           s. 499.101, F.S.; providing a short title;  
4           creating s. 499.103, F.S.; creating the  
5           "Florida Prescription Drug Fair Pricing  
6           Program"; providing purpose of the program;  
7           creating s. 499.105, F.S.; providing  
8           definitions; creating s. 499.107, F.S.;  
9           providing that the Secretary of Health Care  
10          Administration shall operate the Florida  
11          Prescription Drug Fair Pricing Program as a  
12          state pharmaceutical assistance program to  
13          provide discounts to participants for  
14          prescription drugs covered by a rebate  
15          agreement; providing that the secretary shall  
16          negotiate discount prices or rebates for  
17          prescription drugs from manufacturers or  
18          labelers; providing that the Agency for Health  
19          Care Administration shall contract with  
20          participating retail pharmacies to deliver  
21          discounted prices to program participants;  
22          providing factors to be considered in  
23          negotiating discounts or rebates; providing for  
24          quarterly calculation of discounts; creating s.  
25          499.109, F.S.; requiring program participants  
26          to pay a specified coinsurance amount;  
27          requiring participating retail pharmacies in  
28          the state to charge the rate allowable under  
29          the Medicaid program for prescription drugs  
30          sold to program participants; providing for  
31          rate of reimbursement of participating retail

1 pharmacies; creating s. 499.201, F.S.;  
2 providing for program eligibility; requiring  
3 the Agency for Health Care Administration to  
4 establish enrollment procedures; providing for  
5 an annual enrollment fee; providing for use of  
6 enrollment fees and rebates from drug  
7 manufacturers; creating s. 499.203, F.S.;  
8 providing for operation of the program;  
9 authorizing the Board of Pharmacy to adopt  
10 certain rules; creating s. 499.205, F.S.;  
11 providing procedure for resolution of  
12 discrepancies in rebate amounts; creating s.  
13 499.207, F.S.; requiring an annual report;  
14 creating s. 499.209, F.S.; authorizing  
15 coordination with other programs; creating s.  
16 499.301, F.S.; authorizing the agency to adopt  
17 rules; creating s. 499.303, F.S.; authorizing  
18 the agency to seek certain waivers; providing  
19 severability; providing an effective date.

20  
21 Be It Enacted by the Legislature of the State of Florida:

22  
23 Section 1. Section 499.101, Florida Statutes, is  
24 created to read:

25 499.101 Short title.--Sections 499.101-499.303 may be  
26 cited as the "Florida Prescription Drug Fair Pricing Act."

27 Section 2. Section 499.103, Florida Statutes, is  
28 created to read:

29 499.103 Florida Prescription Drug Fair Pricing Program  
30 established; findings; purpose.--

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1           (1) It is the finding of the Legislature that  
2 approximately one in four residents of Florida have no  
3 prescription drug insurance coverage or wholly inadequate  
4 prescription drug insurance coverage. These uninsured  
5 residents pay excessive prices for prescription drugs, far  
6 higher prices than are paid by managed care organizations,  
7 insurance companies, and the Federal Government for the same  
8 medicines and dosages. In many cases, these excessive drug  
9 prices have the effect of denying residents access to  
10 medically necessary care, thereby threatening their health and  
11 safety. Many Florida residents require repeated doctor or  
12 medical clinic appointments, having become sicker because they  
13 could not afford to purchase the prescription drugs prescribed  
14 for them. Many residents are admitted to or treated at  
15 hospitals each year because they cannot afford the  
16 prescription drugs that could have prevented the need for  
17 hospitalization. Many others enter expensive institutional  
18 care settings because they cannot afford the necessary  
19 prescription drugs that could have supported them outside of  
20 an institution. In each of these circumstances, state medical  
21 assistance programs, including the Medicaid program, literally  
22 pay the price. One major reason uninsured residents pay such  
23 high prices for prescription drugs is that, unlike insured  
24 residents, they have no prescription benefits manager  
25 negotiating a fair price with drug companies on their behalf.  
26 State government currently provides prescription drugs and  
27 acts as a prescription benefit manager through a variety of  
28 health plans and assistance programs and, in 2001, the  
29 Legislature expanded the state's role in negotiating better  
30 prescription drug prices for Medicaid. State government is the  
31 only agent that, as a practical matter, can play an effective

1 role as a market participant on behalf of all residents who  
2 are uninsured or underinsured. The state can and should act as  
3 a prescription benefit manager, negotiating drug rebates and  
4 using these funds to reimburse retail pharmacies for offering  
5 lower drug prices.

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

27 Section 3. Section 499.105, Florida Statutes, is  
28 created to read:

29 499.105 Definitions.--As used in this act, unless the  
30 context otherwise indicates, the following terms have the  
31 following meanings:

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

3           (2) "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 under 21 C.F.R. s. 207.20 (1999).

8           (3) "Manufacturer" means a manufacturer of  
9 prescription drugs and includes a subsidiary or affiliate of a  
10 manufacturer.

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

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

15           (b) Agrees to participate in the Florida Prescription  
16 Drug Fair Pricing Program.

17           (5) "Program" means the Florida Prescription Drug Fair  
18 Pricing Program.

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

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

24           Section 4. Section 499.107, Florida Statutes, is  
25 created to read:

26           499.107 Prescription drug discounts; negotiation of  
27 discounts or rebates; calculation of discounts.--The Secretary  
28 of Health Care Administration shall operate the Florida  
29 Prescription Drug Fair Pricing Program as a state  
30 pharmaceutical assistance program under 42 U.S.C. s.  
31

1 1396r-8(c)(1)(C)(i)(III) to provide discounts to participants  
2 for prescription drugs covered by a rebate agreement.

3 (1) The secretary shall negotiate discount prices or  
4 rebates for prescription drugs from drug manufacturers and  
5 labelers for the program. Using sums from negotiated rebates,  
6 the agency shall contract with participating retail pharmacies  
7 to deliver discounted prices to program participants.

8 (2) In negotiating discount or rebate terms, the  
9 secretary shall take into consideration:

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

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

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

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

18 (4) The drug discounts received by program  
19 participants shall be calculated by the secretary on a  
20 quarterly basis.

21 Section 5. Section 499.109, Florida Statutes, is  
22 created to read:

23 499.109 Discounted prices for program participants.--

24 (1) Each participant enrolled in the Florida  
25 Prescription Drug Fair Pricing Program shall pay a coinsurance  
26 amount equal to the Medicaid allowable charge minus the amount  
27 paid by the agency.

28 (2) A participating retail pharmacy shall charge the  
29 Medicaid allowable rate for prescription drugs sold to  
30 participants in the Florida Prescription Drug Fair Pricing  
31 Program.

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

4           (4) The Florida Prescription Drug Fair Pricing Program  
5 as established in s. 409.103 is not an entitlement.

6           Section 6. Section 499.201, Florida Statutes, is  
7 created to read:

8           499.201 Program eligibility.--

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

11           (a) Is a resident of the state;

12           (b) Is a Medicare recipient whose benefits do not  
13 include coverage for prescription drugs;

14           (c) Has a net family income at or below 300 percent of  
15 the federal poverty level; and

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

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

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

3 Section 7. Section 499.203, Florida Statutes, is  
4 created to read:

5 499.203 Program operation.--

6 (1) The Board of Pharmacy, as created by s. 465.004,  
7 in consultation with the Agency for Health Care  
8 Administration, is authorized to adopt rules pursuant to ss.  
9 120.536(1) and 120.54 requiring disclosure by participating  
10 retail pharmacies to program participants of the amount of  
11 savings provided as a result of the Florida Prescription Drug  
12 Fair Pricing Program. Such rules must protect information that  
13 is proprietary in nature.

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

18 (3) The agency shall collect from the participating  
19 retail pharmacies utilization data necessary to calculate the  
20 amount of the rebate from the manufacturer or labeler. The  
21 agency shall protect the confidentiality of all information  
22 subject to confidentiality protection under the laws of this  
23 state or federal laws, rules, or regulations.

24 Section 8. Section 499.205, Florida Statutes, is  
25 created to read:

26 499.205 Discrepancies in rebate

27 amounts.--Discrepancies in rebate amounts must be resolved  
28 using the process established in this section.

29 (1) If there is a discrepancy in the manufacturer's or  
30 labeler's favor between the amount claimed by a participating  
31 retail pharmacy and the amount rebated by the manufacturer or



1 labeler, the agency, at the agency's expense, may hire a  
2 mutually agreed-upon independent auditor. If a discrepancy  
3 still exists following the audit, the manufacturer or labeler  
4 shall justify the reason for the discrepancy or make payment  
5 to the agency for any additional amount due.

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

16 (3) Following the completion of procedures established  
17 in subsection (1) or subsection (2), the agency, the  
18 manufacturer, or the labeler may request a hearing. Hearings  
19 shall be conducted pursuant to ss. 120.569 and 120.57.  
20 Supporting documentation must accompany the request for a  
21 hearing.

22 Section 9. Section 499.207, Florida Statutes, is  
23 created to read:

24 499.207 Report.--The agency shall provide a report on  
25 the enrollment and financial status of the Florida  
26 Prescription Drug Fair Pricing Program to the Governor, the  
27 President of the Senate, and the Speaker of the House of  
28 Representatives by the second week in January each year.

29 Section 10. Section 499.209, Florida Statutes, is  
30 created to read:

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1           499.209 Coordination with other programs.--The  
2 secretary shall combine drug pricing negotiations to maximize  
3 drug rebates where the secretary determines that the  
4 combination of such negotiations is beneficial to both the  
5 Florida Prescription Drug Fair Pricing Program and another  
6 state program, including the state Medicaid program.

7           Section 11. Section 499.301, Florida Statutes, is  
8 created to read:

9           499.301 Rulemaking.--The agency is authorized to adopt  
10 rules pursuant to ss. 120.536(1) and 120.54 to implement the  
11 provisions of this act. Such rules shall include eligibility  
12 requirements, limits on participation, benefit limitations, a  
13 requirement for generic drug substitution, and other program  
14 parameters comparable to those of the Medicaid program.

15           Section 12. Section 499.303, Florida Statutes, is  
16 created to read:

17           499.303 Waivers.--The agency may seek any waivers of  
18 federal law, rule, or regulation necessary to implement the  
19 provisions of this act.

20           Section 13. If any provision of this act or the  
21 application thereof to any person or circumstance is held  
22 invalid, the invalidity shall not affect other provisions or  
23 applications of the act which can be given effect without the  
24 invalid provision or application, and to this end the  
25 provisions of this act are declared severable.

26           Section 14. This act shall take effect July 1, 2002.  
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HOUSE SUMMARY

Creates the "Florida Prescription Drug Fair Pricing Act."  
Provides purposes of the act. Provides that the Secretary  
of Health Care Administration shall operate the Florida  
Prescription Drug Fair Pricing Program as a state  
pharmaceutical assistance program to provide discounts to  
participants for prescription drugs covered by a rebate  
agreement. Provides that the secretary shall negotiate  
discount prices or rebates for prescription drugs from  
manufacturers or labelers. Provides that the Agency for  
Health Care Administration shall contract with  
participating retail pharmacies to deliver discounted  
prices to program participants. Provides factors to be  
considered in negotiating discounts or rebates. Provides  
for quarterly calculation of discounts. Requires program  
participants to pay a specified coinsurance amount.  
Requires participating retail pharmacies in the state to  
charge the rate allowable under the Medicaid program for  
prescription drugs sold to program participants. Provides  
for rate of reimbursement of participating retail  
pharmacies. Provides for program eligibility. Requires  
the Agency for Health Care Administration to establish  
enrollment procedures. Provides for an annual enrollment  
fee of \$25 per enrollee. Provides for use of enrollment  
fees and rebates from drug manufacturers. Provides for  
operation of the program. Provides procedure for  
resolution of discrepancies in rebate amounts. Requires  
an annual report. Authorizes coordination with other  
programs. Authorizes the agency to adopt rules and seek  
certain waivers.