

By Representatives Gelber, Rubio, Barreiro and Seiler

1 A bill to be entitled
2 An act relating to prescription drugs; creating
3 s. 409.960, F.S.; providing a short title;
4 creating s. 409.962, F.S.; creating the
5 "Florida Prescription Drug Fair Pricing
6 Program"; providing purpose of the program;
7 creating s. 409.964, F.S.; providing
8 definitions; creating s. 409.966, 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.
25 409.968, 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. 409.970, 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. 409.972, F.S.;
8 providing for operation of the program;
9 authorizing the Board of Pharmacy to adopt
10 certain rules; creating s. 409.974, F.S.;
11 providing procedure for resolution of
12 discrepancies in rebate amounts; creating s.
13 409.976, F.S.; requiring an annual report;
14 creating s. 409.978, F.S.; authorizing
15 coordination with other programs; creating s.
16 409.980, F.S.; authorizing the agency to adopt
17 rules; creating s. 409.982, F.S.; authorizing
18 the agency to seek certain waivers; providing
19 severability; providing an effective date.

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

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23 Section 1. Section 409.960, Florida Statutes, is
24 created to read:

25 409.960 Short title.--Sections 409.960-409.984 may be
26 cited as the "Florida Prescription Drug Fair Pricing Act."

27 Section 2. Section 409.962, Florida Statutes, is
28 created to read:

29 409.962 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 409.964, Florida Statutes, is
28 created to read:

29 409.964 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 409.966, Florida Statutes, is
25 created to read:
- 26 409.966 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 409.968, Florida Statutes, is
22 created to read:

23 409.968 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. 409.962 is not an entitlement.

6 Section 6. Section 409.970, Florida Statutes, is
7 created to read:

8 409.970 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) Has no health insurance coverage, or has health
13 insurance coverage, including Medicare, that does not include
14 coverage for prescription drugs;

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

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

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

25 (3) The agency shall establish simple procedures for
26 enrolling program participants. Such procedures shall include
27 the assessment of an annual enrollment fee of up to \$25 per
28 enrollee. The agency shall undertake outreach efforts to build
29 public awareness of the program and maximize enrollment by
30 eligible residents. Revenues generated from program enrollment
31 fees and rebates from drug manufacturers shall be used for,

1 but not be limited to, offsetting state costs to administer
2 the program, the purchase of prescription drugs, and any
3 public awareness campaigns.

4 Section 7. Section 409.972, Florida Statutes, is
5 created to read:

6 409.972 Program operation.--

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

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

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

25 Section 8. Section 409.974, Florida Statutes, is
26 created to read:

27 409.974 Discrepancies in rebate

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

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

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

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

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

23 Section 9. Section 409.976, Florida Statutes, is
24 created to read:

25 409.976 Report.--The agency shall provide a report on
26 the enrollment and financial status of the Florida
27 Prescription Drug Fair Pricing Program to the Governor, the
28 President of the Senate, and the Speaker of the House of
29 Representatives by the second week in January each year.

30 Section 10. Section 409.978, Florida Statutes, is
31 created to read:

1 409.978 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 409.980, Florida Statutes, is
8 created to read:

9 409.980 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 409.982, Florida Statutes, is
16 created to read:

17 409.982 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 up to \$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.