

By Senator Wasserman Schultz

34-2601-03

1 A bill to be entitled
2 An act relating to prescription drugs; creating
3 s. 409.960, F.S.; providing a popular name;
4 creating s. 409.962, F.S.; providing purpose of
5 the program; creating s. 409.964, F.S.;
6 providing definitions; creating s. 409.966,
7 F.S.; requiring the Secretary of Health Care
8 Administration to operate the LifeSaver Rx
9 Program as a state pharmaceutical assistance
10 program to provide discounts to participants
11 for prescription drugs covered by a rebate
12 agreement; requiring the secretary to negotiate
13 discount prices or rebates for prescription
14 drugs from manufacturers or labelers; providing
15 that the Agency for Health Care Administration
16 shall contract with participating retail
17 pharmacies to deliver discounted prices to
18 program participants; providing factors to be
19 considered in negotiating discounts or rebates;
20 providing for quarterly calculation of
21 discounts; creating s. 409.968, F.S.; providing
22 for calculation of payment by program
23 participants and the agency; requiring
24 participating retail pharmacies in the state to
25 charge the rate allowable under the Medicaid
26 program for prescription drugs sold to program
27 participants; providing for rate of
28 reimbursement of participating retail
29 pharmacies; creating s. 409.970, F.S.;
30 providing requirements for program eligibility;
31 requiring the Agency for Health Care

1 Administration to establish enrollment
2 procedures; providing for use of rebates from
3 drug manufacturers; creating s. 409.972, F.S.;
4 providing for operation of the program;
5 authorizing the Board of Pharmacy to adopt
6 certain rules; creating s. 409.974, F.S.;
7 providing procedure for resolution of
8 discrepancies in rebate amounts; creating s.
9 409.976, F.S.; requiring an annual report;
10 creating s. 409.978, F.S.; authorizing
11 coordination with other programs; creating s.
12 409.980, F.S.; authorizing the agency to adopt
13 rules; creating s. 409.982, F.S.; authorizing
14 the agency to seek certain waivers; providing a
15 contribution by the agency toward the cost of
16 prescription drugs purchased by program
17 participants; amending s. 409.9066, F.S.;
18 requiring the Agency for Health Care
19 Administration to publish on a website the
20 average wholesale prices of drugs provided
21 through the program; requiring the agency to
22 publish additional information to assist
23 consumers; requiring a report on methods of
24 pricing pharmaceutical products purchased by
25 the program; providing an appropriation;
26 providing for severability; providing for
27 construction of the act in pari materia with
28 laws enacted during the Regular Session of the
29 Legislature; providing an effective date.

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

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

3 409.960 Popular name.--Sections 409.960-409.982 shall
4 be known by the popular name "LifeSaver Rx Program."

5 Section 2. Section 409.962, Florida Statutes, is
6 created to read:

7 409.962 LifeSaver Rx Program established; findings;
8 purpose.--

9 (1) It is the finding of the Legislature that
10 approximately one in four residents of Florida have no
11 prescription drug insurance coverage or wholly inadequate
12 prescription drug insurance coverage. These uninsured
13 residents pay excessive prices for prescription drugs, far
14 higher prices than are paid by managed care organizations,
15 insurance companies, and the Federal Government for the same
16 medicines and dosages. In many cases, these excessive drug
17 prices have the effect of denying residents access to
18 medically necessary care, thereby threatening their health and
19 safety. Many Florida residents require repeated doctor or
20 medical clinic appointments, having become sicker because they
21 could not afford to purchase the prescription drugs prescribed
22 for them. Many residents are admitted to or treated at
23 hospitals each year because they cannot afford the
24 prescription drugs that could have prevented the need for
25 hospitalization. Many others enter expensive institutional
26 care settings because they cannot afford the necessary
27 prescription drugs that could have supported them outside of
28 an institution. In each of these circumstances, state medical
29 assistance programs, including the Medicaid program, literally
30 pay the price. One major reason uninsured residents pay such
31 high prices for prescription drugs is that, unlike insured

1 residents, they have no prescription benefits manager
2 negotiating a fair price with drug companies on their behalf.
3 State government currently provides prescription drugs and
4 acts as a prescription benefit manager through a variety of
5 health plans and assistance programs and, in 2001, the
6 Legislature expanded the state's role in negotiating better
7 prescription drug prices for Medicaid. State government is the
8 only agent that, as a practical matter, can play an effective
9 role as a market participant on behalf of all residents who
10 are uninsured or underinsured. The state can and should act as
11 a prescription benefit manager, negotiating drug rebates and
12 using these funds to reimburse retail pharmacies for offering
13 lower drug prices.

14 (2) Recognizing that the state already acts as a
15 prescription benefit manager for a variety of health plans and
16 assistance programs, including the Medicaid program, the
17 LifeSaver Rx Program is established within the Agency for
18 Health Care Administration. The purpose of the program is to
19 expand Medicaid eligibility for prescription drug benefits
20 only, at a level that does not exceed available funding,
21 thereby providing prescription drug coverage to new
22 populations by expanding the state's role as a participant in
23 the prescription drug marketplace, negotiating rebates from
24 drug companies, and using the funds from such rebates to make
25 prescription drugs more affordable to Florida residents. Each
26 program participant shall receive a discount toward the
27 purchase of all prescription drugs that are covered by the
28 Florida Medicaid program. The Legislature finds that such a
29 program will improve public health and welfare, promote the
30 economic strength of our society, and substantially benefit

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1 state health assistance programs, including the Medicaid
2 program.

3 Section 3. Section 409.964, Florida Statutes, is
4 created to read:

5 409.964 Definitions.--As used in this act, unless the
6 context otherwise indicates, the term:

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

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

14 (3) "Manufacturer" means a manufacturer of
15 prescription drugs and includes a subsidiary or affiliate of a
16 manufacturer.

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

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

21 (b) Agrees to participate in the LifeSaver Rx Program.

22 (5) "Program" means the LifeSaver Rx Program.

23 (6) "Secretary" means the Secretary of Health Care
24 Administration or the secretary's designee.

25 (7) "Qualified resident" means an uninsured resident
26 of the state who has obtained from the agency a LifeSaver Rx
27 Program enrollment card.

28 Section 4. Section 409.966, Florida Statutes, is
29 created to read:

30 409.966 Prescription drug discounts; negotiation of
31 discounts or rebates; calculation of discounts.--The secretary

1 shall operate the program as a state pharmaceutical assistance
2 program under 42 U.S.C. s. 1396r-8(c)(1)(C)(i)(III) to provide
3 discounts to participants for prescription drugs covered by a
4 rebate agreement.

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

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

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

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

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

18 (3) The secretary may consider any supplemental rebate
19 negotiated pursuant to s. 409.912(38)(a)7.

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

23 Section 5. Section 409.968, Florida Statutes, is
24 created to read:

25 409.968 Discounted prices for program participants.--

26 (1) Each program participant's payment shall be equal
27 to the Medicaid allowable charge for the prescription minus
28 the payment made by the agency. The payment made by the agency
29 shall include the estimated manufacturer rebate plus the state
30 subsidy per prescription as provided under this act and the

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1 federal matching share for the state general revenue
2 contribution.

3 (2) A participating retail pharmacy shall charge the
4 Medicaid allowable rate for prescription drugs sold to
5 participants in the program.

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

9 (4) The program as established in s. 409.962 is not an
10 entitlement.

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

13 409.970 Program eligibility.--

14 (1) An individual is eligible to participate in the
15 program if he or she:

16 (a) Is a resident of the state;

17 (b) Is 65 years of age or older and is a Medicare
18 participant;

19 (c) Has a net family income at or below 200 percent of
20 the federal poverty level in year 1 and at or below 300
21 percent of the federal poverty level in year 2 and thereafter;

22 (d) Has exhausted all third-party prescription
23 coverage; and

24 (e) Requests to be enrolled in the program.

25 (2) An individual is ineligible to participate in the
26 program if he or she is eligible for assistance under the
27 state's Medicaid program.

28 (3) The agency shall establish simple procedures for
29 enrolling program participants. The agency shall undertake
30 outreach efforts to build public awareness of the program and
31 maximize enrollment by eligible residents. Revenues generated

1 from rebates from drug manufacturers shall be used for, but
2 not be limited to, offsetting state costs to administer the
3 program, the purchase of prescription drugs, and any public
4 awareness campaigns.

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

7 409.972 Program operation.--

8 (1) The Board of Pharmacy, as created by s. 465.004,
9 in consultation with the agency, is authorized to adopt rules
10 pursuant to ss. 120.536(1) and 120.54 requiring disclosure by
11 participating retail pharmacies to program participants of the
12 amount of savings provided as a result of the program. Such
13 rules must protect information that 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 409.974, Florida Statutes, is
25 created to read:

26 409.974 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 409.976, Florida Statutes, is
23 created to read:

24 409.976 Report.--The agency shall provide a report on
25 the enrollment and financial status of the program to the
26 Governor, the President of the Senate, and the Speaker of the
27 House of Representatives by the second week in January each
28 year.

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

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1 409.978 Coordination with other programs.--The
2 secretary shall combine drug pricing negotiations to maximize
3 drug rebates when the secretary determines that the
4 combination of such negotiations is beneficial to both the
5 LifeSaver Rx Program and another state program, including the
6 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 Individuals eligible to participate in this program shall not
16 be subject to the limit of four brand name drugs per month per
17 recipient as specified in s. 409.912(38)(a).

18 Section 12. Section 409.982, Florida Statutes, is
19 created to read:

20 409.982 Waivers.--The agency shall seek any waivers of
21 federal law, rule, or regulation necessary to implement the
22 provisions of this act in year 1. In year 2 and thereafter,
23 the agency shall seek any additional waivers of federal law,
24 rule, or regulation necessary to implement the provisions of
25 this act.

26 Section 13. The agency shall contribute toward the
27 cost of each prescription purchased by the program
28 participant.

29 Section 14. Section 409.9066, Florida Statutes, is
30 amended to read:

31 409.9066 Medicare prescription discount program.--

1 (1) As a condition of participation in the Florida
2 Medicaid program or the pharmaceutical expense assistance
3 program, a pharmacy must agree to charge any individual who is
4 a Medicare beneficiary and who is a Florida resident showing a
5 Medicare card when he or she presents a prescription, a price
6 no greater than the cost of ingredients equal to the average
7 wholesale price minus 9 percent, and a dispensing fee of
8 \$4.50.

9 (2) In lieu of the provisions of subsection (1), and
10 as a condition of participation in the Florida Medicaid
11 program or the pharmaceutical expense assistance program, a
12 pharmacy must agree to:

13 (a) Provide a private voluntary prescription discount
14 program to state residents who are Medicare beneficiaries; or

15 (b) Accept a private voluntary discount prescription
16 program from state residents who are Medicare beneficiaries.

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18 Discounts under this subsection must be at least as great as
19 discounts under subsection (1).

20 (3) The Agency for Health Care Administration shall
21 publish, on a free website available to the public, the most
22 recent average wholesale prices for the 200 drugs most
23 frequently dispensed to the elderly and, to the extent
24 possible, shall provide a mechanism that consumers may use to
25 calculate the retail price that should be paid after the
26 discount required in subsection (1) is applied.

27 Section 15. By January 1, 2004, the Agency for Health
28 Care Administration shall submit to the Legislature a report
29 regarding the cost-effectiveness of, and alternatives to,
30 using average wholesale price in the pricing of pharmaceutical
31 products purchased by the Medicaid program.

1 Section 16. Implementation of the LifeSaver Rx Program
2 is contingent upon a specific appropriation authorized in the
3 General Appropriations Act. The Legislature shall limit
4 annual appropriations to no more than \$30 million from state
5 funds to the Agency for Health Care Administration to be used
6 as state matching funds for the LifeSaver Rx Program. This
7 annual appropriation limitation shall not apply to
8 pharmaceutical rebate revenue.

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

15 Section 18. If any law that is amended by this act was
16 also amended by a law enacted at the 2003 Regular Session of
17 the Legislature, such laws shall be construed as if they had
18 been enacted during the same session of the Legislature, and
19 full effect should be given to each if that is possible.

20 Section 19. This act shall take effect upon becoming a
21 law.

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24 SENATE SUMMARY

25 Creates the "LifeSaver Rx Program" as a state
26 pharmaceutical assistance program to provide discounts
27 for prescription drugs covered by a rebate agreement.
28 Requires the Secretary of Health Care Administration to
29 negotiate discount prices or rebates from drug
30 manufacturers and labelers. Provides for calculating
discounts and the rate of reimbursements to pharmacies.
Provides criteria for enrollment in the program.
Authorizes the Board of Pharmacy and the Agency for
Health Care Administration to adopt rules. (See bill for
details.)