

Bill No. CS for SB 2322, 1st Enq.

Amendment No. ____ Barcode 840164

CHAMBER ACTION

Senate

House

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Senator Wasserman Schultz moved the following **amendment to House amendment** (119969):

Senate Amendment (with title amendment)

Lines 105-222, delete those lines

and insert:

Section 5. Section 409.960, Florida Statutes, is created to read:

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

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

409.962 LifeSaver Rx 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,

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

31 (2) Recognizing that the state already acts as a

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1 prescription benefit manager for a variety of health plans and
2 assistance programs, including the Medicaid program, the
3 LifeSaver Rx Program is established within the Agency for
4 Health Care Administration. The purpose of the program is to
5 expand Medicaid eligibility for prescription drug benefits
6 only, at a level that does not exceed available funding,
7 thereby providing prescription drug coverage to new
8 populations by expanding the state's role as a participant in
9 the prescription drug marketplace, negotiating rebates from
10 drug companies, and using the funds from such rebates to make
11 prescription drugs more affordable to Florida residents. Each
12 program participant shall receive a discount toward the
13 purchase of all prescription drugs that are covered by the
14 Florida Medicaid program. The Legislature finds that such a
15 program will improve public health and welfare, promote the
16 economic strength of our society, and substantially benefit
17 state health assistance programs, including the Medicaid
18 program.

19 Section 7. Section 409.964, Florida Statutes, is
20 created to read:

21 409.964 Definitions.--As used in this act, unless the
22 context otherwise indicates, the term:

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

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

30 (3) "Manufacturer" means a manufacturer of
31 prescription drugs and includes a subsidiary or affiliate of a

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1 manufacturer.

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

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

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

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

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

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

13 Section 8. Section 409.966, Florida Statutes, is
14 created to read:

15 409.966 Prescription drug discounts; negotiation of
16 discounts or rebates; calculation of discounts.--The secretary
17 shall operate the program as a state pharmaceutical assistance
18 program under 42 U.S.C. s. 1396r-8(c)(1)(C)(i)(III) to provide
19 discounts to participants for prescription drugs covered by a
20 rebate agreement.

21 (1) The secretary shall negotiate discount prices or
22 rebates for prescription drugs from drug manufacturers and
23 labelers for the program. Using sums from negotiated rebates,
24 the agency shall contract with participating retail pharmacies
25 to deliver discounted prices to program participants.

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

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

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

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

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

5 (4) The drug discounts received by program
6 participants shall be calculated by the secretary on a
7 quarterly basis.

8 Section 9. Section 409.968, Florida Statutes, is
9 created to read:

10 409.968 Discounted prices for program participants.--

11 (1) Each program participant's payment shall be equal
12 to the Medicaid allowable charge for the prescription minus
13 the payment made by the agency. The payment made by the agency
14 shall include the estimated manufacturer rebate plus the state
15 subsidy per prescription as provided under this act and the
16 federal matching share for the state general revenue
17 contribution.

18 (2) A participating retail pharmacy shall charge the
19 Medicaid allowable rate for prescription drugs sold to
20 participants in the program.

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

24 (4) The program as established in s. 409.962 is not an
25 entitlement.

26 Section 10. Section 409.970, Florida Statutes, is
27 created to read:

28 409.970 Program eligibility.--

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

31 (a) Is a resident of the state;

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

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

6 (d) Has exhausted all third-party prescription
7 coverage; and

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

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

12 (3) The agency shall establish simple procedures for
13 enrolling program participants. The agency shall undertake
14 outreach efforts to build public awareness of the program and
15 maximize enrollment by eligible residents. Revenues generated
16 from rebates from drug manufacturers shall be used for, but
17 not be limited to, offsetting state costs to administer the
18 program, the purchase of prescription drugs, and any public
19 awareness campaigns.

20 Section 11. Section 409.972, Florida Statutes, is
21 created to read:

22 409.972 Program operation.--

23 (1) The Board of Pharmacy, as created by s. 465.004,
24 in consultation with the agency, is authorized to adopt rules
25 pursuant to ss. 120.536(1) and 120.54 requiring disclosure by
26 participating retail pharmacies to program participants of the
27 amount of savings provided as a result of the program. Such
28 rules must protect information that is proprietary in nature.

29 (2) Participating retail pharmacies shall be paid in
30 advance for program discounts or shall be reimbursed by the
31 agency on a weekly or biweekly basis, in accordance with

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1 contracts between the agency and such businesses.

2 (3) The agency shall collect from the participating
3 retail pharmacies utilization data necessary to calculate the
4 amount of the rebate from the manufacturer or labeler. The
5 agency shall protect the confidentiality of all information
6 subject to confidentiality protection under the laws of this
7 state or federal laws, rules, or regulations.

8 Section 12. Section 409.974, Florida Statutes, is
9 created to read:

10 409.974 Discrepancies in rebate
11 amounts.--Discrepancies in rebate amounts must be resolved
12 using the process established in this section.

13 (1) If there is a discrepancy in the manufacturer's or
14 labeler's favor between the amount claimed by a participating
15 retail pharmacy and the amount rebated by the manufacturer or
16 labeler, the agency, at the agency's expense, may hire a
17 mutually agreed-upon independent auditor. If a discrepancy
18 still exists following the audit, the manufacturer or labeler
19 shall justify the reason for the discrepancy or make payment
20 to the agency for any additional amount due.

21 (2) If there is a discrepancy against the interest of
22 the manufacturer or labeler in the information provided by the
23 agency to the manufacturer or labeler regarding the
24 manufacturer's or labeler's rebate, the manufacturer or
25 labeler, at the manufacturer's or labeler's expense, may hire
26 a mutually agreed-upon independent auditor to verify the
27 accuracy of the data supplied to the agency. If a discrepancy
28 still exists following the audit, the agency shall justify the
29 reason for the discrepancy or refund the manufacturer or
30 labeler.

31 (3) Following the completion of procedures established

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1 in subsection (1) or subsection (2), the agency, the
2 manufacturer, or the labeler may request a hearing. Hearings
3 shall be conducted pursuant to ss. 120.569 and 120.57.
4 Supporting documentation must accompany the request for a
5 hearing.

6 Section 13. Section 409.976, Florida Statutes, is
7 created to read:

8 409.976 Report.--The agency shall provide a report on
9 the enrollment and financial status of the program to the
10 Governor, the President of the Senate, and the Speaker of the
11 House of Representatives by the second week in January each
12 year.

13 Section 14. Section 409.978, Florida Statutes, is
14 created to read:

15 409.978 Coordination with other programs.--The
16 secretary shall combine drug pricing negotiations to maximize
17 drug rebates when the secretary determines that the
18 combination of such negotiations is beneficial to both the
19 LifeSaver Rx Program and another state program, including the
20 state Medicaid program.

21 Section 15. Section 409.980, Florida Statutes, is
22 created to read:

23 409.980 Rulemaking.--The agency is authorized to adopt
24 rules pursuant to ss. 120.536(1) and 120.54 to implement the
25 provisions of this act. Such rules shall include eligibility
26 requirements, limits on participation, benefit limitations, a
27 requirement for generic drug substitution, and other program
28 parameters comparable to those of the Medicaid program.
29 Individuals eligible to participate in this program shall not
30 be subject to the limit of four brand name drugs per month per
31 recipient as specified in s. 409.912(38)(a).

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1 Section 16. Section 409.982, Florida Statutes, is
2 created to read:

3 409.982 Waivers.--The agency shall seek any waivers of
4 federal law, rule, or regulation necessary to implement the
5 provisions of this act in year 1. In year 2 and thereafter,
6 the agency shall seek any additional waivers of federal law,
7 rule, or regulation necessary to implement the provisions of
8 this act.

9 Section 17. The agency shall contribute toward the
10 cost of each prescription purchased by the program
11 participant.

12 Section 18. Section 409.9066, Florida Statutes, is
13 amended to read:

14 409.9066 Medicare prescription discount program.--

15 (1) As a condition of participation in the Florida
16 Medicaid program or the pharmaceutical expense assistance
17 program, a pharmacy must agree to charge any individual who is
18 a Medicare beneficiary and who is a Florida resident showing a
19 Medicare card when he or she presents a prescription, a price
20 no greater than the cost of ingredients equal to the average
21 wholesale price minus 9 percent, and a dispensing fee of
22 \$4.50.

23 (2) In lieu of the provisions of subsection (1), and
24 as a condition of participation in the Florida Medicaid
25 program or the pharmaceutical expense assistance program, a
26 pharmacy must agree to:

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

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

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

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

10 Section 19. By January 1, 2004, the Agency for Health
11 Care Administration shall submit to the Legislature a report
12 regarding the cost-effectiveness of, and alternatives to,
13 using average wholesale price in the pricing of pharmaceutical
14 products purchased by the Medicaid program.

15 Section 20. Implementation of the LifeSaver Rx Program
16 is contingent upon a specific appropriation authorized in the
17 General Appropriations Act. The Legislature shall limit
18 annual appropriations to no more than \$30 million from state
19 funds to the Agency for Health Care Administration to be used
20 as state matching funds for the LifeSaver Rx Program. This
21 annual appropriation limitation shall not apply to
22 pharmaceutical rebate revenue.

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

29
30 (Redesignate subsequent sections.)
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1 ===== T I T L E A M E N D M E N T =====

2 And the title is amended as follows:

3 Lines 232-235, delete those lines

4

5 and insert:

6 application; creating s. 409.960, F.S.;

7 providing a popular name; creating s. 409.962,

8 F.S.; creating "The LifeSaver Rx Program";

9 providing purpose of the program; creating s.

10 409.964, F.S.; providing definitions; creating

11 s. 409.966, F.S.; providing that the Secretary

12 of Health Care Administration shall operate the

13 LifeSaver Rx Program as a state pharmaceutical

14 assistance program to provide discounts to

15 participants for prescription drugs covered by

16 a rebate agreement; providing that the

17 secretary shall negotiate discount prices or

18 rebates for prescription drugs from

19 manufacturers or labelers; providing that the

20 Agency for Health Care Administration shall

21 contract with participating retail pharmacies

22 to deliver discounted prices to program

23 participants; providing factors to be

24 considered in negotiating discounts or rebates;

25 providing for quarterly calculation of

26 discounts; creating s. 409.968, F.S.; providing

27 for calculation of payment by program

28 participants and the agency; requiring

29 participating retail pharmacies in the state to

30 charge the rate allowable under the Medicaid

31 program for prescription drugs sold to program

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1 participants; providing for rate of
2 reimbursement of participating retail
3 pharmacies; creating s. 409.970, F.S.;
4 providing requirements for program eligibility;
5 requiring the Agency for Health Care
6 Administration to establish enrollment
7 procedures; providing for use of rebates from
8 drug manufacturers; creating s. 409.972, F.S.;
9 providing for operation of the program;
10 authorizing the Board of Pharmacy to adopt
11 certain rules; creating s. 409.974, F.S.;
12 providing procedure for resolution of
13 discrepancies in rebate amounts; creating s.
14 409.976, F.S.; requiring an annual report;
15 creating s. 409.978, F.S.; authorizing
16 coordination with other programs; creating s.
17 409.980, F.S.; authorizing the agency to adopt
18 rules; creating s. 409.982, F.S.; authorizing
19 the agency to seek certain waivers; providing a
20 contribution by the agency toward the cost of
21 prescription drugs purchased by program
22 participants; amending s. 409.9066, F.S.;
23 requiring the Agency for Health Care
24 Administration to publish on a website the
25 average wholesale prices of drugs provided
26 through the program; requiring the agency to
27 publish additional information to assist
28 consumers; requiring a report on methods of
29 pricing pharmaceutical products purchased by
30 the program; providing an appropriation;
31 providing for severability; providing

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effective dates.