Amendment No. ____ Barcode 832660

CHAMBER ACTION

	Senate House
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11	Senator Wasserman Schultz moved the following amendment to
12	House amendment (119969):
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14	Senate Amendment (with title amendment)
15	Lines 105-222, delete those lines
16	
17	and insert:
18	Section 5. Section 409.960, Florida Statutes, is
19	created to read:
20	409.960 Popular nameSections 409.960-409.982 shall
21	be known by the popular name "LifeSaver Rx Program."
22	Section 6. Section 409.962, Florida Statutes, is
23	created to read:
24	409.962 LifeSaver Rx Program established; findings;
25	purpose
26	(1) It is the finding of the Legislature that
27	approximately one in four residents of Florida have no
28	prescription drug insurance coverage or wholly inadequate
29	prescription drug insurance coverage. These uninsured
30	residents pay excessive prices for prescription drugs, far
31	higher prices than are paid by managed care organizations,

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insurance companies, and the Federal Government for the same medicines and dosages. In many cases, these excessive drug 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 medical clinic appointments, having become sicker because they 6 could not afford to purchase the prescription drugs prescribed 8 for them. Many residents are admitted to or treated at hospitals each year because they cannot afford the prescription drugs that could have prevented the need for 10 11 hospitalization. Many others enter expensive institutional care settings because they cannot afford the necessary 12 13 prescription drugs that could have supported them outside of an institution. In each of these circumstances, state medical 14 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 acts as a prescription benefit manager through a variety of 21 2.2 health plans and assistance programs and, in 2001, the Legislature expanded the state's role in negotiating better 23 prescription drug prices for Medicaid. State government is the 24 25 only agent that, as a practical matter, can play an effective role as a market participant on behalf of all residents who 26 are uninsured or underinsured. The state can and should act as 27 28 a prescription benefit manager, negotiating drug rebates and 29 using these funds to reimburse retail pharmacies for offering 30 lower drug prices. (2) Recognizing that the state already acts as a

- 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 <u>context otherwise indicates, the term:</u>
- 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 <u>labeler code from the federal Food and Drug Administration</u>
- 29 <u>under 21 C.F.R. s. 207.20 (1999).</u>
- 30 (3) "Manufacturer" means a manufacturer of
- 31 prescription drugs and includes a subsidiary or affiliate of a

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 discountsThe 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>U.S.C. s. 256b; and</u>

- (c) Any other available information on prescription 1 drug prices, discounts, and rebates. (3) The secretary may consider any supplemental 3 rebate negotiated pursuant to s. 409.912(38)(a)7. 4 5 (4) The drug discounts received by program participants shall be calculated by the secretary on a 6 7 quarterly basis. 8 Section 9. Section 409.968, Florida Statutes, is created to read: 9 409.968 Discounted prices for program participants.--10 (1) Each program participant's payment shall be equal 11 12 to the Medicaid allowable charge for the prescription minus the payment made by the agency. The payment made by the agency 13 shall include the estimated manufacturer rebate plus the state 14 15 subsidy per prescription as provided under this act and the 16 federal matching share for the state general revenue 17 contribution. (2) A participating retail pharmacy shall charge the 18 19 Medicaid allowable rate for prescription drugs sold to 20 participants in the program. (3) The participating retail pharmacy shall be 21 reimbursed by the agency at the agency's manufacturer estimated rebate amount. 23 (4) The program as established in s. 409.962 is not an 24 entitlement. 25 26 Section 10. Section 409.970, Florida Statutes, is created to read: 27
- 28 <u>409.970 Program eligibility.--</u>
- 29 (1) An individual is eligible to participate in the 30 program if he or she:
- (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
21	agengy on a weekly or hiwookly bagin in aggordange with

- 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 <u>state or federal laws, rules, or regulations.</u>
- 8 Section 12. Section 409.974, Florida Statutes, is
- 9 created to read:
- 10 <u>409.974 Discrepancies in rebate</u>
- 11 amounts.--Discrepancies in rebate amounts must be resolved
- 12 using the process established in this section.
- (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 <u>labeler</u>, 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

- 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 <u>hearing.</u>
- 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 <u>year.</u>
- 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 eliqible 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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Section 16. Section 409.982, Florida Statutes, is created to read:

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

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

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

409.9066 Medicare prescription discount program. --

- (1) As a condition of participation in the Florida Medicaid program or the pharmaceutical expense assistance program, a pharmacy must agree to charge any individual who is a Medicare beneficiary and who is a Florida resident showing a Medicare card when he or she presents a prescription, a price no greater than the cost of ingredients equal to the average wholesale price minus 9 percent, and a dispensing fee of \$4.50.
- (2) In lieu of the provisions of subsection (1), and as a condition of participation in the Florida Medicaid program or the pharmaceutical expense assistance program, a pharmacy must agree to:
- (a) Provide a private voluntary prescription discount program to state residents who are Medicare beneficiaries; or
- (b) Accept a private voluntary discount prescription program from state residents who are Medicare beneficiaries.

2.2

Bill No. CS for SB 2322, 1st Eng. Amendment No. Barcode 832660 1 | Discounts under this subsection must be at least as great as discounts under subsection (1). (3) The Agency for Health Care Administration shall 3 publish, on a free website available to the public, the most 4 recent average wholesale prices for the 200 drugs most frequently dispensed to the elderly and, to the extent 6 possible, shall provide a mechanism that consumers may use to 8 calculate the retail price that should be paid after the discount required in subsection (1) is applied. 9 Section 19. By January 1, 2004, the Agency for Health 10 11 Care Administration shall submit to the Legislature a report 12 regarding the cost-effectiveness of, and alternatives to, using average wholesale price in the pricing of pharmaceutical 13 14 products purchased by the Medicaid program. 15 Section 20. The Legislature shall limit annual 16 appropriations to no more than \$30 million from state funds to the Agency for Health Care Administration to be used as state 17 matching funds for the LifeSaver Rx Program. This annual 18 appropriation limitation shall not apply to pharmaceutical 19 20 rebate revenue. Section 21. If any provision of this act or the 21 2.2 application thereof to any person or circumstance is held 23 invalid, the invalidity shall not affect other provisions or 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 27 28 (Redesignate subsequent sections.) 29 30

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1 | ======== T I T L E A M E N D M E N T ========== And the title is amended as follows: 3 Lines 232-235, delete those lines 4 5 and insert: application; creating s. 409.960, F.S.; 6 7 providing a popular name; creating s. 409.962, F.S.; creating "The LifeSaver Rx Program"; 8 9 providing purpose of the program; creating s. 409.964, F.S.; providing definitions; creating 10 11 s. 409.966, F.S.; providing that the Secretary of Health Care Administration shall operate the 12 13 LifeSaver Rx Program as a state pharmaceutical assistance program to provide discounts to 14 15 participants for prescription drugs covered by 16 a rebate agreement; providing that the secretary shall negotiate discount prices or 17 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 2.2 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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participants; providing for rate of 1 2 reimbursement of participating retail 3 pharmacies; creating s. 409.970, F.S.; providing requirements for program eligibility; 4 5 requiring the Agency for Health Care Administration to establish enrollment 6 procedures; providing for use of rebates from 7 8 drug manufacturers; creating s. 409.972, F.S.; providing for operation of the program; 9 authorizing the Board of Pharmacy to adopt 10 11 certain rules; creating s. 409.974, F.S.; 12 providing procedure for resolution of 13 discrepancies in rebate amounts; creating s. 409.976, F.S.; requiring an annual report; 14 15 creating s. 409.978, F.S.; authorizing 16 coordination with other programs; creating s. 409.980, F.S.; authorizing the agency to adopt 17 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 2.2 participants; amending s. 409.9066, F.S.; requiring the Agency for Health Care 23 Administration to publish on a website the 24 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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