## Florida Senate - 2003

## CS for SB 2098

 $\mathbf{By}$  the Committee on Health, Aging, and Long-Term Care; and Senator Wasserman Schultz

	317-2484-03
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.; creating "The
5	LifeSaver Rx Program"; providing purpose of the
6	program; creating s. 409.964, F.S.; providing
7	definitions; creating s. 409.966, F.S.;
8	providing that the Secretary of Health Care
9	Administration shall operate the LifeSaver Rx
10	Program as a state pharmaceutical assistance
11	program to provide discounts to participants
12	for prescription drugs covered by a rebate
13	agreement; providing that the secretary shall
14	negotiate discount prices or rebates for
15	prescription drugs from manufacturers or
16	labelers; providing that the Agency for Health
17	Care Administration shall contract with
18	participating retail pharmacies to deliver
19	discounted prices to program participants;
20	providing factors to be considered in
21	negotiating discounts or rebates; providing for
22	quarterly calculation of discounts; creating s.
23	409.968, F.S.; providing for calculation of
24	payment by program participants and the agency;
25	requiring participating retail pharmacies in
26	the state to charge the rate allowable under
27	the Medicaid program for prescription drugs
28	sold to program participants; providing for
29	rate of reimbursement of participating retail
30	pharmacies; creating s. 409.970, F.S.;
31	providing requirements for program eligibility;
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1	requiring the Agency for Health Care
2	Administration to establish enrollment
3	procedures; providing for an annual enrollment
4	fee; providing for use of enrollment fees and
5	rebates from drug manufacturers; creating s.
6	409.972, F.S.; providing for operation of the
7	program; authorizing the Board of Pharmacy to
8	adopt certain rules; creating s. 409.974, F.S.;
9	providing procedure for resolution of
10	discrepancies in rebate amounts; creating s.
11	409.976, F.S.; requiring an annual report;
12	creating s. 409.978, F.S.; authorizing
13	coordination with other programs; creating s.
14	409.980, F.S.; authorizing the agency to adopt
15	rules; creating s. 409.982, F.S.; authorizing
16	the agency to seek certain waivers; providing a
17	contribution by the agency toward the cost of
18	prescription drugs purchased by program
19	participants; amending s. 409.9066, F.S.;
20	requiring the Agency for Health Care
21	Administration to publish on a website the
22	average wholesale prices of drugs provided
23	through the program; requiring the agency to
24	publish additional information to assist
25	consumers; requiring a report on methods of
26	pricing pharmaceutical products purchased by
27	the program; providing an appropriation;
28	providing for severability; providing an
29	effective date.
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31	Be It Enacted by the Legislature of the State of Florida: 2
	TNC Newda stuicher and deletions: words underlined are addit

1 Section 1. Section 409.960, Florida Statutes, is 2 created to read: 3 409.960 Popular name.--Sections 409.960-409.982 shall be known by the popular name "LifeSaver Rx Program." 4 5 Section 2. Section 409.962, Florida Statutes, is б 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 prescription drug insurance coverage. These uninsured 12 residents pay excessive prices for prescription drugs, far 13 higher prices than are paid by managed care organizations, 14 insurance companies, and the Federal Government for the same 15 medicines and dosages. In many cases, these excessive drug 16 17 prices have the effect of denying residents access to medically necessary care, thereby threatening their health and 18 19 safety. Many Florida residents require repeated doctor or medical clinic appointments, having become sicker because they 20 21 could not afford to purchase the prescription drugs prescribed for them. Many residents are admitted to or treated at 22 hospitals each year because they cannot afford the 23 24 prescription drugs that could have prevented the need for 25 hospitalization. Many others enter expensive institutional care settings because they cannot afford the necessary 26 27 prescription drugs that could have supported them outside of an institution. In each of these circumstances, state medical 28 29 assistance programs, including the Medicaid program, literally 30 pay the price. One major reason uninsured residents pay such high prices for prescription drugs is that, unlike insured 31

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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 б context otherwise indicates, the term: (1) "Agency" means the Agency for Health Care 7 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 labeler code from the federal Food and Drug Administration 12 under 21 C.F.R. s. 207.20 (1999). 13 14 (3) "Manufacturer" means a manufacturer of 15 prescription drugs and includes a subsidiary or affiliate of a 16 manufacturer. 17 "Participating retail pharmacy" means a retail (4) pharmacy or other business licensed to dispense prescription 18 19 drugs in this state that: (a) Participates in the state Medicaid program; or 20 (b) Agrees to participate in the LifeSaver Rx Program. 21 22 (5) "Program" means the LifeSaver Rx Program. "Secretary" means the Secretary of Health Care 23 (6) Administration or the secretary's designee. 24 25 "Qualified resident" means an uninsured resident (7) of the state who has obtained from the agency a LifeSaver Rx 26 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 5

1 shall operate the program as a state pharmaceutical assistance program under 42 U.S.C. s. 1396r-8(c)(1)(C)(i)(III) to provide 2 3 discounts to participants for prescription drugs covered by a 4 rebate agreement. 5 The secretary shall negotiate discount prices or (1) rebates for prescription drugs from drug manufacturers and б 7 labelers for the program. Using sums from negotiated rebates, 8 the agency shall contract with participating retail pharmacies to deliver discounted prices to program participants. 9 10 (2) In negotiating discount or rebate terms, the 11 secretary shall take into consideration: The rebate calculated under the Medicaid rebate 12 (a) program pursuant to 42 U.S.C. s. 1396r-8; 13 14 (b) The price provided to eligible entities under 42 15 U.S.C. s. 256b; and Any other available information on prescription 16 (C) 17 drug prices, discounts, and rebates. The secretary may consider any supplemental 18 (3) 19 rebate negotiated pursuant to s. 409.912(38)(a)7. 20 The drug discounts received by program (4) participants shall be calculated by the secretary on a 21 22 quarterly basis. Section 5. Section 409.968, Florida Statutes, is 23 24 created to read: 25 409.968 Discounted prices for program participants.--Each program participant's payment shall be equal 26 (1)27 to the Medicaid allowable charge for the prescription minus the payment made by the agency. The payment made by the agency 28 29 shall include the estimated manufacturer rebate plus the state 30 subsidy per prescription as provided under this act and the 31

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1 federal matching share for the state general revenue 2 contribution. 3 (2) A participating retail pharmacy shall charge the Medicaid allowable rate for prescription drugs sold to 4 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 The program as established in s. 409.962 is not an (4) 10 entitlement. 11 Section 6. Section 409.970, Florida Statutes, is created to read: 12 13 409.970 Program eligibility.--14 (1) An individual is eligible to participate in the 15 program if he or she: (a) Is a resident of the state; 16 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 the federal poverty level in year 1 and at or below 300 20 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. (3) The agency shall establish simple procedures for 28 29 enrolling program participants. Such procedures shall include 30 the assessment of an annual enrollment fee of up to \$50 per 31 enrollee. The agency shall undertake outreach efforts to build 7

1 public awareness of the program and maximize enrollment by eligible residents. Revenues generated from program enrollment 2 3 fees and rebates from drug manufacturers shall be used for, but not be limited to, offsetting state costs to administer 4 5 the program, the purchase of prescription drugs, and any б public awareness campaigns. 7 Section 7. Section 409.972, Florida Statutes, is 8 created to read: 9 409.972 Program operation .--10 (1)The Board of Pharmacy, as created by s. 465.004, 11 in consultation with the agency, is authorized to adopt rules pursuant to ss. 120.536(1) and 120.54 requiring disclosure by 12 participating retail pharmacies to program participants of the 13 amount of savings provided as a result of the program. Such 14 rules must protect information that is proprietary in nature. 15 (2) Participating retail pharmacies shall be paid in 16 17 advance for program discounts or shall be reimbursed by the agency on a weekly or biweekly basis, in accordance with 18 19 contracts between the agency and such businesses. The agency shall collect from the participating 20 (3) 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 24 subject to confidentiality protection under the laws of this 25 state or federal laws, rules, or regulations. Section 8. Section 409.974, Florida Statutes, is 26 27 created to read: 28 409.974 Discrepancies in rebate 29 amounts.--Discrepancies in rebate amounts must be resolved 30 using the process established in this section. 31

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1	(1) If there is a discrepancy in the manufacturer's or
2	labeler's favor between the amount claimed by a participating
3	retail pharmacy and the amount rebated by the manufacturer or
4	labeler, the agency, at the agency's expense, may hire a
5	mutually agreed-upon independent auditor. If a discrepancy
6	still exists following the audit, the manufacturer or labeler
7	shall justify the reason for the discrepancy or make payment
8	to the agency for any additional amount due.
9	(2) If there is a discrepancy against the interest of
10	the manufacturer or labeler in the information provided by the
11	agency to the manufacturer or labeler regarding the
12	manufacturer's or labeler's rebate, the manufacturer or
13	labeler, at the manufacturer's or labeler's expense, may hire
14	a mutually agreed-upon independent auditor to verify the
15	accuracy of the data supplied to the agency. If a discrepancy
16	still exists following the audit, the agency shall justify the
17	reason for the discrepancy or refund the manufacturer or
18	labeler.
19	(3) Following the completion of procedures established
20	in subsection (1) or subsection (2), the agency, the
21	manufacturer, or the labeler may request a hearing. Hearings
22	shall be conducted pursuant to ss. 120.569 and 120.57.
23	Supporting documentation must accompany the request for a
24	hearing.
25	Section 9. Section 409.976, Florida Statutes, is
26	created to read:
27	409.976 ReportThe agency shall provide a report on
28	the enrollment and financial status of the program to the
29	Governor, the President of the Senate, and the Speaker of the
30	House of Representatives by the second week in January each
31	year.

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           Section 10. Section 409.978, Florida Statutes, is
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    created to read:
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           409.978 Coordination with other programs.--The
    secretary shall combine drug pricing negotiations to maximize
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    drug rebates when the secretary determines that the
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    combination of such negotiations is beneficial to both the
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    LifeSaver Rx Program and another state program, including the
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    state Medicaid program.
                        Section 409.980, Florida Statutes, is
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           Section 11.
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    created to read:
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           409.980 Rulemaking.--The agency is authorized to adopt
    rules pursuant to ss. 120.536(1) and 120.54 to implement the
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   provisions of this act. Such rules shall include eligibility
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    requirements, limits on participation, benefit limitations, a
    requirement for generic drug substitution, and other program
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   parameters comparable to those of the Medicaid program.
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           Section 12. Section 409.982, Florida Statutes, is
    created to read:
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           409.982 Waivers.--The agency shall seek any waivers of
    federal law, rule, or regulation necessary to implement the
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    provisions of this act in year 1. In year 2 and thereafter,
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    the agency shall seek any additional waivers of federal law,
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    rule, or regulation necessary to implement the provisions of
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    this act.
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           Section 13. The agency shall contribute toward the
    cost of each prescription purchased by the program
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    participant.
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           Section 14. Section 409.9066, Florida Statutes, is
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    amended to read:
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           409.9066 Medicare prescription discount program.--
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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 a Medicare beneficiary and who is a Florida resident showing a 4 5 Medicare card when he or she presents a prescription, a price б 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 program to state residents who are Medicare beneficiaries; or 14 15 (b) Accept a private voluntary discount prescription program from state residents who are Medicare beneficiaries. 16 17 Discounts under this subsection must be at least as great as 18 19 discounts under subsection (1). (3) The Agency for Health Care Administration shall 20 21 publish, on a free website available to the public, the most recent average wholesale prices for the 200 drugs most 22 frequently dispensed to the elderly and, to the extent 23 24 possible, shall provide a mechanism that consumers may use to 25 calculate the retail price that should be paid after the discount required in subsection (1) is applied. 26 27 By January 1, 2004, the Agency for Health Section 15. 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.

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1 Section 16. The Legislature shall appropriate from the General Revenue Fund to the Agency for Health Care 2 3 Administration an amount that is sufficient to implement the 4 provisions of this act. 5 Section 17. If any provision of this act or the 6 application thereof to any person or circumstance is held 7 invalid, the invalidity shall not affect other provisions or 8 applications of the act which can be given effect without the 9 invalid provision or application, and to this end the 10 provisions of this act are declared severable. Section 18. This act shall take effect upon becoming a 11 12 law. 13 STATEMENT OF SUBSTANTIAL CHANGES CONTAINED IN COMMITTEE SUBSTITUTE FOR Senate Bill 2098 14 15 16 17 This Committee Substitute for Senate Bill 2098 does the following: 18 Changes the income eligibility, requiring that an individual have a net family income at or below 200 percent of the FPL in year one of the program and at or below 300 percent of the FPL in year two and thereafter. 19 20 Removes the requirement of a two percent state contribution from general revenue for each prescription, but retains 21 22 language that a state contribution for prescriptions will be made. 23 Requires the Agency for Health Care Administration to publish on its website the most recent average wholesale prices for the 200 drugs most frequently dispensed to the elderly and to 24 the 200 drugs most frequently dispensed to the elderly and to provide a mechanism for consumers to calculate the retail price that should be paid under the Medicare prescription discount program. The agency is required to submit a report by January 1, 2004, regarding alternatives to using the average wholesale price in pricing drugs purchased by the Medicaid 25 26 27 Program. 28 29 30 31 12