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By Senator Wasserman Schultz

34-657-03 See HB 161

A bill to be entitled An act relating to prescription drugs; creating s. 409.960, F.S.; providing a popular name; creating s. 409.962, F.S.; creating "The LifeSaver Rx Program"; providing purpose of the program; creating s. 409.964, F.S.; providing definitions; creating s. 409.966, F.S.; providing that the Secretary of Health Care Administration shall operate the LifeSaver Rx Program as a state pharmaceutical assistance program to provide discounts to participants for prescription drugs covered by a rebate agreement; providing that the secretary shall negotiate discount prices or rebates for prescription drugs from manufacturers or labelers; providing that the Agency for Health Care Administration shall contract with participating retail pharmacies to deliver discounted prices to program participants; providing factors to be considered in negotiating discounts or rebates; providing for quarterly calculation of discounts; creating s. 409.968, F.S.; providing for calculation of payment by program participants and the agency; requiring participating retail pharmacies in the state to charge the rate allowable under the Medicaid program for prescription drugs sold to program participants; providing for rate of reimbursement of participating retail pharmacies; creating s. 409.970, F.S.; providing requirements for program eligibility;

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	specified contribution by the agency toward the
18	cost of prescription drugs purchased by program
19	participants; providing severability; providing
20	an appropriation; providing an effective date.
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22	Be It Enacted by the Legislature of the State of Florida:
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24	Section 1. Section 409.960, Florida Statutes, is
25	created to read:
26	409.960 Popular nameSections 409.960-409.982 shall
27	be known by the popular name "LifeSaver Rx Program."
28	Section 2. Section 409.962, Florida Statutes, is
29	created to read:
30	409.962 LifeSaver Rx Program established; findings;
31	purpose

1 (1) It is the finding of the Legislature that approximately one in four residents of Florida have no 2 3 prescription drug insurance coverage or wholly inadequate prescription drug insurance coverage. These uninsured 4 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 prices have the effect of denying residents access to 9 medically necessary care, thereby threatening their health and 10 11 safety. Many Florida residents require repeated doctor or medical clinic appointments, having become sicker because they 12 could not afford to purchase the prescription drugs prescribed 13 for them. Many residents are admitted to or treated at 14 hospitals each year because they cannot afford the 15 prescription drugs that could have prevented the need for 16 17 hospitalization. Many others enter expensive institutional care settings because they cannot afford the necessary 18 19 prescription drugs that could have supported them outside of an institution. In each of these circumstances, state medical 20 21 assistance programs, including the Medicaid program, literally pay the price. One major reason uninsured residents pay such 22 high prices for prescription drugs is that, unlike insured 23 24 residents, they have no prescription benefits manager negotiating a fair price with drug companies on their behalf. 25 State government currently provides prescription drugs and 26 27 acts as a prescription benefit manager through a variety of health plans and assistance programs and, in 2001, the 28 Legislature expanded the state's role in negotiating better 29 30 prescription drug prices for Medicaid. State government is the only agent that, as a practical matter, can play an effective 31

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Administration.

role as a market participant on behalf of all residents who are uninsured or underinsured. The state can and should act as 2 3 a prescription benefit manager, negotiating drug rebates and using these funds to reimburse retail pharmacies for offering 4 5 lower drug prices. 6 (2) Recognizing that the state already acts as a prescription benefit manager for a variety of health plans and 7 8 assistance programs, including the Medicaid program, the 9 LifeSaver Rx Program is established within the Agency for 10 Health Care Administration. The purpose of the program is to 11 expand Medicaid eligibility for prescription drug benefits only, at a level that does not exceed available funding, 12 thereby providing prescription drug coverage to new 13 populations by expanding the state's role as a participant in 14 the prescription drug marketplace, negotiating rebates from 15 drug companies, and using the funds from such rebates to make 16 17 prescription drugs more affordable to Florida residents. Each program participant shall receive a discount toward the 18 19 purchase of all prescription drugs that are covered by the Florida Medicaid program. The Legislature finds that such a 20 program will improve public health and welfare, promote the 21 economic strength of our society, and substantially benefit 22 state health assistance programs, including the Medicaid 23 24 program. Section 3. Section 409.964, Florida Statutes, is 25 created to read: 26 27 409.964 Definitions.--As used in this act, unless the 28 context otherwise indicates, the term:

(1) "Agency" means the Agency for Health Care

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1 (2) "Labeler" means an entity or person that receives prescription drugs from a manufacturer or wholesaler and 2 3 repackages those drugs for later retail sale and that has a 4 labeler code from the federal Food and Drug Administration 5 under 21 C.F.R. s. 207.20 (1999). (3) "Manufacturer" means a manufacturer of 6 7 prescription drugs and includes a subsidiary or affiliate of a 8 manufacturer. 9 (4) "Participating retail pharmacy" means a retail 10 pharmacy or other business licensed to dispense prescription 11 drugs in this state that: (a) Participates in the state Medicaid program; or 12 Agrees to participate in the LifeSaver Rx Program. 13 (b) 14 (5) "Program" means the LifeSaver Rx Program. "Secretary" means the Secretary of Health Care 15 (6) Administration or the secretary's designee. 16 17 "Qualified resident" means an uninsured resident 18 of the state who has obtained from the agency a LifeSaver Rx 19 Program enrollment card. Section 4. Section 409.966, Florida Statutes, is 20 21 created to read: 409.966 Prescription drug discounts; negotiation of 22 discounts or rebates; calculation of discounts. -- The secretary 23 24 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 25 discounts to participants for prescription drugs covered by a 26 rebate agreement. 27 28 The secretary shall negotiate discount prices or 29 rebates for prescription drugs from drug manufacturers and

labelers for the program. Using sums from negotiated rebates,

estimated rebate amount.

the agency shall contract with participating retail pharmacies to deliver discounted prices to program participants. 2 3 (2) In negotiating discount or rebate terms, the secretary shall take into consideration: 4 5 The rebate calculated under the Medicaid rebate (a) 6 program pursuant to 42 U.S.C. s. 1396r-8; 7 The price provided to eligible entities under 42 8 U.S.C. s. 256b; and 9 (c) Any other available information on prescription 10 drug prices, discounts, and rebates. 11 (3) The secretary may consider any supplemental rebate negotiated pursuant to s. 409.912(38)(a)7. 12 The drug discounts received by program 13 participants shall be calculated by the secretary on a 14 15 quarterly basis. Section 5. Section 409.968, Florida Statutes, is 16 17 created to read: 409.968 Discounted prices for program participants.--18 19 (1) Each program participant's payment shall be equal to the Medicaid allowable charge for the prescription minus 20 21 the payment made by the agency. The payment made by the agency 22 shall include the estimated manufacturer rebate plus the state subsidy of 2 percent per prescription as provided under this 23 24 act and the federal matching share for the state general 25 revenue contribution. (2) A participating retail pharmacy shall charge the 26 27 Medicaid allowable rate for prescription drugs sold to 28 participants in the program. 29 The participating retail pharmacy shall be (3) 30 reimbursed by the agency at the agency's manufacturer

1	(4) The program as established in s. 409.962 is not an
2	entitlement.
3	Section 6. Section 409.970, Florida Statutes, is
4	created to read:
5	409.970 Program eligibility
6	(1) An individual is eligible to participate in the
7	program if he or she:
8	(a) Is a resident of the state;
9	(b) Is 65 years of age or older and is a Medicare
10	<pre>participant;</pre>
11	(c) Has a net family income at or below 300 percent of
12	the federal poverty level;
13	(d) Has exhausted all third-party prescription
14	coverage; and
15	(e) Requests to be enrolled in the program.
16	(2) An individual is ineligible to participate in the
17	program if he or she is eligible for assistance under the
18	state's Medicaid program.
19	(3) The agency shall establish simple procedures for
20	enrolling program participants. Such procedures shall include
21	the assessment of an annual enrollment fee of up to \$50 per
22	enrollee. The agency shall undertake outreach efforts to build
23	public awareness of the program and maximize enrollment by
24	eligible residents. Revenues generated from program enrollment
25	fees and rebates from drug manufacturers shall be used for,
26	but not be limited to, offsetting state costs to administer
27	the program, the purchase of prescription drugs, and any
28	<pre>public awareness campaigns.</pre>
29	Section 7. Section 409.972, Florida Statutes, is
30	created to read:
31	409 972 Program operation

- (1) The Board of Pharmacy, as created by s. 465.004, in consultation with the agency, is authorized to adopt rules pursuant to ss. 120.536(1) and 120.54 requiring disclosure by participating retail pharmacies to program participants of the amount of savings provided as a result of the program. Such rules must protect information that is proprietary in nature.
- (2) Participating retail pharmacies shall be paid in advance for program discounts or shall be reimbursed by the agency on a weekly or biweekly basis, in accordance with contracts between the agency and such businesses.
- (3) The agency shall collect from the participating retail pharmacies utilization data necessary to calculate the amount of the rebate from the manufacturer or labeler. The agency shall protect the confidentiality of all information subject to confidentiality protection under the laws of this state or federal laws, rules, or regulations.

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

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

- (1) If there is a discrepancy in the manufacturer's or labeler's favor between the amount claimed by a participating retail pharmacy and the amount rebated by the manufacturer or labeler, the agency, at the agency's expense, may hire a mutually agreed-upon independent auditor. If a discrepancy still exists following the audit, the manufacturer or labeler shall justify the reason for the discrepancy or make payment to the agency for any additional amount due.
- (2) If there is a discrepancy against the interest of the manufacturer or labeler in the information provided by the

31 created to read:

1 agency to the manufacturer or labeler regarding the manufacturer's or labeler's rebate, the manufacturer or 2 3 labeler, at the manufacturer's or labeler's expense, may hire a mutually agreed-upon independent auditor to verify the 4 5 accuracy of the data supplied to the agency. If a discrepancy 6 still exists following the audit, the agency shall justify the 7 reason for the discrepancy or refund the manufacturer or 8 labeler. 9 (3) Following the completion of procedures established 10 in subsection (1) or subsection (2), the agency, the 11 manufacturer, or the labeler may request a hearing. Hearings shall be conducted pursuant to ss. 120.569 and 120.57. 12 13 Supporting documentation must accompany the request for a 14 hearing. Section 9. Section 409.976, Florida Statutes, is 15 created to read: 16 17 409.976 Report.--The agency shall provide a report on 18 the enrollment and financial status of the program to the 19 Governor, the President of the Senate, and the Speaker of the 20 House of Representatives by the second week in January each 21 year. 22 Section 10. Section 409.978, Florida Statutes, is created to read: 23 24 409.978 Coordination with other programs. -- The 25 secretary shall combine drug pricing negotiations to maximize drug rebates when the secretary determines that the 26 27 combination of such negotiations is beneficial to both the LifeSaver Rx Program and another state program, including the 28 29 state Medicaid program. 30 Section 11. Section 409.980, Florida Statutes, is

1 409.980 Rulemaking. -- The agency is authorized to adopt rules pursuant to ss. 120.536(1) and 120.54 to implement the 2 3 provisions of this act. Such rules shall include eligibility requirements, limits on participation, benefit limitations, a 4 5 requirement for generic drug substitution, and other program 6 parameters comparable to those of the Medicaid program. 7 Section 12. Section 409.982, Florida Statutes, is 8 created to read: 9 409.982 Waivers. -- The agency shall seek any waivers of 10 federal law, rule, or regulation necessary to implement the 11 provisions of this act. The agency shall contribute 2 percent 12 Section 13. 13 toward the cost of each prescription purchased by the program 14 participant. Section 14. The Legislature shall appropriate from the 15 General Revenue Fund to the Agency for Health Care 16 17 Administration an amount that is sufficient to implement the provisions of this act. 18 19 Section 15. If any provision of this act or the 20 application thereof to any person or circumstance is held 21 invalid, the invalidity shall not affect other provisions or applications of the act which can be given effect without the 22 invalid provision or application, and to this end the 23 24 provisions of this act are declared severable. 25 Section 16. This act shall take effect upon becoming a 26 law. 27 28 29 30 31