

By Senator Wilson

33-775-03

See HB 977

1 A bill to be entitled
 2 An act relating to prescription drugs;
 3 providing a program for fair market drug
 4 pricing in Florida, to be administered by the
 5 Agency for Health Care Administration;
 6 providing a popular name; providing findings
 7 and purpose; providing definitions; providing
 8 for negotiated drug discounts and rebates;
 9 requiring establishment of an Rx Card program
 10 as a state pharmaceutical assistance program
 11 for drugs covered by a rebate agreement;
 12 providing a beginning date for Rx Card program
 13 discounts; providing for resolution of
 14 discrepancies in rebate amounts; requiring an
 15 annual report to the Legislature; providing for
 16 coordination with other programs; requiring the
 17 agency to adopt rules to implement the program;
 18 authorizing the agency to seek waivers of
 19 federal laws, rules, or regulations; providing
 20 for severability; providing an effective date.

21
 22 Be It Enacted by the Legislature of the State of Florida:

23
 24 Section 1. Fair market drug pricing.--
 25 (1) POPULAR NAME.--This section shall be known by the
 26 popular name the "Florida Fair Market Drug Pricing Act."
 27 (2) FINDINGS AND PURPOSE.--
 28 (a) Findings.--The Legislature finds that:
 29 1. The state has successfully negotiated supplemental
 30 rebates on certain prescription drugs causing the state to
 31 realize significant savings in the Medicaid program.

1 2. In this time of economic difficulty, Florida needs
2 to maximize its financial resources in order to provide as
3 much health coverage as possible for low-income residents. Now
4 more than ever, Florida needs to continue to lower the prices
5 it pays for prescription drugs.

6 3. Approximately one in four Florida residents are
7 uninsured or underinsured for prescription drug coverage and
8 do not qualify for Medicaid or the Silver Saver drug program
9 which is limited to residents at 120 percent of the federal
10 poverty level. The uninsured or underinsured residents pay
11 excessive prices for prescription drugs. In many cases, these
12 excessive prices have the effect of denying residents access
13 to medically necessary care, thereby threatening their health
14 and safety.

15 4. Among these uninsured and underinsured residents,
16 many require repeated doctor or medical clinic appointments,
17 having gotten sicker because they cannot afford to take the
18 drugs prescribed for them. Many are admitted to or treated at
19 hospitals each year because they cannot afford the drugs
20 prescribed for them that could have prevented the need for
21 hospitalization. Many others enter expensive institutional
22 care settings because they cannot afford the prescription
23 drugs that could have supported them outside of an
24 institution. In each of these circumstances, uninsured and
25 underinsured residents too often become Medicaid recipients
26 because of their inability to afford prescription drugs.
27 Therefore, helping secure lower drug prices for the uninsured
28 and underinsured directly benefits and supports Medicaid.

29 5. The state government is the only agent that, as a
30 practical matter, can play an effective role as a market
31 participant on behalf of all residents who are uninsured,

1 underinsured, or Medicaid beneficiaries. The state already
2 provides drugs and acts as a prescription benefits manager for
3 a variety of programs, including Medicaid. The state should
4 expand this role to negotiate voluntary drug rebates, using
5 these funds to maintain and expand Medicaid services while
6 offering lower drug prices to the uninsured, including
7 Medicare beneficiaries, who do not qualify for Medicaid.

8 (b) Purpose.--Recognizing that the state already acts
9 as a prescription benefits manager for a variety of health
10 plans and assistance programs, the Legislature enacts this
11 section to cover new populations by expanding the state's role
12 as a participant in the prescription drug marketplace,
13 negotiating voluntary rebates from drug companies at the same
14 or lower rates as Medicaid, and making these discounted drugs
15 available to all residents who are in the Medicare program or
16 have a net family income at or below 300 percent of the
17 federal poverty level and are without any other adequate
18 prescription drug coverage.

19 (3) DEFINITIONS.--As used in this section:

20 (a) "Secretary" means the Secretary of Health Care
21 Administration, or the secretary's designee.

22 (b) "Agency" means the Agency for Health Care
23 Administration.

24 (c) "Manufacturer" means a manufacturer of
25 prescription drugs as defined in 42 U.S.C. s. 1396r-8(k)(5),
26 including a subsidiary or affiliate of a manufacturer.

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

1 (e) "Participating retail pharmacy" means a retail
2 pharmacy or other business licensed to dispense prescription
3 drugs in this state that participates in the state Medicaid
4 program or voluntarily agrees to participate in the Rx Card
5 program.

6 (f) "Wholesaler" means a business licensed under
7 chapter 499, Florida Statutes, to distribute prescription
8 drugs in this state.

9 (4) NEGOTIATED DRUG DISCOUNTS AND REBATES.--

10 (a) Drug discount and rebate agreements.--The
11 secretary shall negotiate discount prices or rebates for
12 prescription drugs from drug manufacturers and labelers. A
13 drug manufacturer or labeler that sells prescription drugs in
14 this state may voluntarily elect to negotiate:

15 1. Supplemental rebates for the Medicaid program over
16 and above those required under 42 U.S.C. s. 1396r-8.

17 2. Discount prices or rebates for the Rx Card program.

18 3. Discount prices or rebates for any other state
19 program that pays for or acquires prescription drugs.

20 (b) Rebate amounts.--In negotiating rebate terms, the
21 secretary shall take into consideration the rebate calculated
22 under the Medicaid rebate program pursuant to 42 U.S.C. s.
23 1396r-8, the price provided to eligible entities under 42
24 U.S.C. s. 256b, and any other available information on
25 prescription drug prices, discounts, and rebates.

26 (c) Failure to agree.--

27 1. The secretary shall prompt a review of whether to
28 place a manufacturer's or labeler's products on the prior
29 authorization list for the state Medicaid program and take
30 similar actions involving prior authorization or formularies
31

1 for any other state-funded or state-operated prescription drug
2 program, if:
3 a. The secretary and a manufacturer or labeler fail to
4 reach an agreement on the terms of a supplemental Medicaid
5 rebate or a discount or rebate for the Rx Card program; and
6 b. The discounts or rebates offered by the
7 manufacturer or labeler are not as favorable to the state as
8 the prices provided to eligible entities under 42 U.S.C. s.
9 256b.
10 2. Any prior authorization must meet the requirements
11 of 42 U.S.C. s. 1396r-8(d)(5) and be done in accordance with
12 sections 409.91195 and 409.912, Florida Statutes. The agency
13 shall adopt rules creating clear procedures for the
14 implementation of this subsection.
15 3. The names of manufacturers and labelers that do not
16 enter into rebate agreements are public information, and the
17 agency shall release this information to the public and
18 actively distribute it to doctors, pharmacists, and other
19 health professionals.
20 (5) RX CARD PROGRAM.--
21 (a) Rx Card program established.--The agency shall
22 establish the Rx Card program as a state pharmaceutical
23 assistance program under 42 U.S.C. s.
24 1396r-8(c)(1)(C)(i)(III), to provide discounts to participants
25 for drugs covered by a rebate agreement. Using funds from
26 negotiated rebates, the agency shall contract with wholesalers
27 and participating retail pharmacies to deliver discounted
28 prices to Rx Card program participants. Discounts to
29 participants in the Rx Card program shall begin by January 1,
30 2004.
31

1 (b) Amount of discount.--The drug discounts received
2 by Rx Card program participants shall be calculated by the
3 secretary on a quarterly basis. That calculation shall provide
4 discounts approximately equal to the average amount of the
5 negotiated drug rebate minus an amount to cover the reasonable
6 administrative costs of the Rx Card program.

7 (c) Eligibility for participation.--

8 1. An individual is eligible to participate in the Rx
9 Card program if he or she is a resident of the state and is
10 eligible for participation in the Medicare program or has a
11 net family income below 300 percent of the federal poverty
12 level.

13 2. An individual is ineligible to participate in the
14 Rx Card program if he or she is eligible for assistance under
15 the state's Medicaid program or is covered by an insurance
16 policy that provides benefits for prescription drugs equal to
17 or greater than the benefits provided under the Rx Card
18 program, as delineated by rules adopted by the agency.

19 3. The agency shall establish simple procedures for
20 enrolling Rx Card program participants and shall undertake
21 outreach efforts to build public awareness of the program and
22 maximize enrollment by eligible residents.

23 (d) Operation.--

24 1. The agency shall adopt rules requiring disclosure
25 by participating retail pharmacies to Rx Card program
26 participants of the amount of savings provided as a result of
27 the Rx Card program. The rules must protect information that
28 is proprietary in nature.

29 2. A participating retail pharmacy shall verify to the
30 agency the amounts charged to Rx Card program participants and
31 nonparticipants and shall provide the agency with utilization

1 data necessary to calculate rebates from manufacturers and
2 labelers. The agency shall protect the confidentiality of all
3 information subject to confidentiality protection under state
4 or federal law, rule, or regulation. The agency may not impose
5 transaction charges on wholesalers or participating retail
6 pharmacies that submit claims or receive payments under the
7 program.

8 3. Wholesalers and participating retail pharmacies
9 shall be paid in advance for Rx Card program discounts or
10 shall be reimbursed by the agency on a weekly basis.

11 4. The agency may require a wholesaler or
12 participating retail pharmacy to segregate drugs under the Rx
13 Card program from other drug inventory. The agency may require
14 a wholesaler or participating retail pharmacy to maintain
15 records of acquisition and disposition of drugs under the Rx
16 Card program separately from the wholesaler's or pharmacy's
17 other records.

18 (6) ADMINISTRATION.--

19 (a) Discrepancies in rebate amounts.--Disputes or
20 discrepancies in rebate amounts must be resolved using the
21 process established in this subsection.

22 1. If there is a discrepancy in the manufacturer's or
23 labeler's favor between the amount claimed by a pharmacy and
24 the amount rebated by the manufacturer or labeler, the agency,
25 at the agency's expense, may hire a mutually agreed-upon
26 independent auditor. If a discrepancy still exists following
27 the audit, the manufacturer or labeler shall justify the
28 reason for the discrepancy or make payment to the agency for
29 any additional amount due.

30 2. If there is a discrepancy against the interest of
31 the manufacturer or labeler in the information provided by the

1 agency to the manufacturer or labeler regarding the
2 manufacturer's or labeler's rebate, the manufacturer or
3 labeler, at the manufacturer's or labeler's expense, may hire
4 a mutually agreed-upon independent auditor to verify the
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 provide a refund to the
8 manufacturer or labeler.

9 3. Following the procedures established in
10 subparagraph 1. or subparagraph 2., either the agency or the
11 manufacturer or labeler may request a hearing. Supporting
12 documentation must accompany the request for a hearing.

13 (b) Annual summary report.--The agency shall report
14 the enrollment and financial status of the Rx Card program and
15 report savings from supplemental Medicaid rebates to the
16 President of the Senate and the Speaker of the House of
17 Representatives by February 1 each year.

18 (c) Coordination with other programs.--Where the
19 secretary finds that it is beneficial to both the Rx Card
20 program and another state program, including the state
21 Medicaid program, to combine drug pricing negotiations to
22 maximize drug rebates, the secretary shall do so.

23 (d) Rulemaking.--The agency shall adopt rules pursuant
24 to sections 120.536(1) and 120.54, Florida Statutes, to
25 implement the provisions of this section.

26 (e) Waivers.--The agency may seek any waivers of
27 federal law, rule, or regulation necessary to implement the
28 provisions of this section.

29 Section 2. The provisions of this act are severable;
30 and, if any phrase, clause, sentence, or provision is declared
31 to be invalid or is preempted by federal law or regulation,

1 the validity of the remainder of this act shall not be
2 affected.

3 Section 3. This act shall take effect July 1, 2003.
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31