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1 A bill to be entitled

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

18
19 Be It Enacted by the Legislature of the State of Florida:

20
21 Section 1. Fair market drug pricing.--

22 (1) POPULAR NAME.--This section shall be known by the
23 popular name the "Florida Fair Market Drug Pricing Act."

24 (2) FINDINGS AND PURPOSE.--

25 (a) Findings.--The Legislature finds that:

26 1. The state has successfully negotiated supplemental
27 rebates on certain prescription drugs causing the state to
28 realize significant savings in the Medicaid program.

29 2. In this time of economic difficulty, Florida needs to
30 maximize its financial resources in order to provide as much



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31 health coverage as possible for low-income residents. Now more
32 than ever, Florida needs to continue to lower the prices it pays
33 for prescription drugs.

34 3. Approximately one in four Florida residents are
35 uninsured or underinsured for prescription drug coverage and do
36 not qualify for Medicaid or the Silver Saver drug program which
37 is limited to residents at 120 percent of the federal poverty
38 level. The uninsured or underinsured residents pay excessive
39 prices for prescription drugs. In many cases, these excessive
40 prices have the effect of denying residents access to medically
41 necessary care, thereby threatening their health and safety.

42 4. Among these uninsured and underinsured residents, many
43 require repeated doctor or medical clinic appointments, having
44 gotten sicker because they cannot afford to take the drugs
45 prescribed for them. Many are admitted to or treated at
46 hospitals each year because they cannot afford the drugs
47 prescribed for them that could have prevented the need for
48 hospitalization. Many others enter expensive institutional care
49 settings because they cannot afford the prescription drugs that
50 could have supported them outside of an institution. In each of
51 these circumstances, uninsured and underinsured residents too
52 often become Medicaid recipients because of their inability to
53 afford prescription drugs. Therefore, helping secure lower drug
54 prices for the uninsured and underinsured directly benefits and
55 supports Medicaid.

56 5. The state government is the only agent that, as a
57 practical matter, can play an effective role as a market
58 participant on behalf of all residents who are uninsured,
59 underinsured, or Medicaid beneficiaries. The state already
60 provides drugs and acts as a prescription benefits manager for a



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61 variety of programs, including Medicaid. The state should expand
62 this role to negotiate voluntary drug rebates, using these funds
63 to maintain and expand Medicaid services while offering lower
64 drug prices to the uninsured, including Medicare beneficiaries,
65 who do not qualify for Medicaid.

66 (b) Purpose.--Recognizing that the state already acts as a
67 prescription benefits manager for a variety of health plans and
68 assistance programs, the Legislature enacts this section to
69 cover new populations by expanding the state's role as a
70 participant in the prescription drug marketplace, negotiating
71 voluntary rebates from drug companies at the same or lower rates
72 as Medicaid, and making these discounted drugs available to all
73 residents who are in the Medicare program or have a net family
74 income at or below 300 percent of the federal poverty level and
75 are without any other adequate prescription drug coverage.

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

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

79 (b) "Agency" means the Agency for Health Care
80 Administration.

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

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

89 (e) "Participating retail pharmacy" means a retail
90 pharmacy or other business licensed to dispense prescription



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91 drugs in this state that participates in the state Medicaid
92 program or voluntarily agrees to participate in the Rx Card
93 program.

94 (f) "Wholesaler" means a business licensed under chapter
95 499, Florida Statutes, to distribute prescription drugs in this
96 state.

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

98 (a) Drug discount and rebate agreements.--The secretary
99 shall negotiate discount prices or rebates for prescription
100 drugs from drug manufacturers and labelers. A drug manufacturer
101 or labeler that sells prescription drugs in this state may
102 voluntarily elect to negotiate:

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

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

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

108 (b) Rebate amounts.--In negotiating rebate terms, the
109 secretary shall take into consideration the rebate calculated
110 under the Medicaid rebate program pursuant to 42 U.S.C. s.
111 1396r-8, the price provided to eligible entities under 42 U.S.C.
112 s. 256b, and any other available information on prescription
113 drug prices, discounts, and rebates.

114 (c) Failure to agree.--

115 1. The secretary shall prompt a review of whether to place
116 a manufacturer's or labeler's products on the prior
117 authorization list for the state Medicaid program and take
118 similar actions involving prior authorization or formularies for
119 any other state-funded or state-operated prescription drug
120 program, if:



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121 a. The secretary and a manufacturer or labeler fail to
122 reach an agreement on the terms of a supplemental Medicaid
123 rebate or a discount or rebate for the Rx Card program; and

124 b. The discounts or rebates offered by the manufacturer or
125 labeler are not as favorable to the state as the prices provided
126 to eligible entities under 42 U.S.C. s. 256b.

127 2. Any prior authorization must meet the requirements of
128 42 U.S.C. s. 1396r-8(d)(5) and be done in accordance with ss.
129 409.91195 and 409.912, Florida Statutes. The agency shall adopt
130 rules creating clear procedures for the implementation of this
131 subsection.

132 3. The names of manufacturers and labelers that do not
133 enter into rebate agreements are public information, and the
134 agency shall release this information to the public and actively
135 distribute it to doctors, pharmacists, and other health
136 professionals.

137 (5) RX CARD PROGRAM.--

138 (a) Rx Card program established.--The agency shall
139 establish the Rx Card program as a state pharmaceutical
140 assistance program under 42 U.S.C. s. 1396r-8(c)(1)(C)(i)(III),
141 to provide discounts to participants for drugs covered by a
142 rebate agreement. Using funds from negotiated rebates, the
143 agency shall contract with wholesalers and participating retail
144 pharmacies to deliver discounted prices to Rx Card program
145 participants. Discounts to participants in the Rx Card program
146 shall begin by January 1, 2004.

147 (b) Amount of discount.--The drug discounts received by Rx
148 Card program participants shall be calculated by the secretary
149 on a quarterly basis. That calculation shall provide discounts
150 approximately equal to the average amount of the negotiated drug



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151 rebate minus an amount to cover the reasonable administrative
152 costs of the Rx Card program.

153 (c) Eligibility for participation.--

154 1. An individual is eligible to participate in the Rx Card
155 program if he or she is a resident of the state and is eligible
156 for participation in the Medicare program or has a net family
157 income below 300 percent of the federal poverty level.

158 2. An individual is ineligible to participate in the Rx
159 Card program if he or she is eligible for assistance under the
160 state's Medicaid program or is covered by an insurance policy
161 that provides benefits for prescription drugs equal to or
162 greater than the benefits provided under the Rx Card program, as
163 delineated by rules adopted by the agency.

164 3. The agency shall establish simple procedures for
165 enrolling Rx Card program participants and shall undertake
166 outreach efforts to build public awareness of the program and
167 maximize enrollment by eligible residents.

168 (d) Operation.--

169 1. The agency shall adopt rules requiring disclosure by
170 participating retail pharmacies to Rx Card program participants
171 of the amount of savings provided as a result of the Rx Card
172 program. The rules must protect information that is proprietary
173 in nature.

174 2. A participating retail pharmacy shall verify to the
175 agency the amounts charged to Rx Card program participants and
176 nonparticipants and shall provide the agency with utilization
177 data necessary to calculate rebates from manufacturers and
178 labelers. The agency shall protect the confidentiality of all
179 information subject to confidentiality protection under state or
180 federal law, rule, or regulation. The agency may not impose



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181 transaction charges on wholesalers or participating retail
182 pharmacies that submit claims or receive payments under the
183 program.

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

187 4. The agency may require a wholesaler or participating
188 retail pharmacy to segregate drugs under the Rx Card program
189 from other drug inventory. The agency may require a wholesaler
190 or participating retail pharmacy to maintain records of
191 acquisition and disposition of drugs under the Rx Card program
192 separately from the wholesaler's or pharmacy's other records.

193 (6) ADMINISTRATION.--

194 (a) Discrepancies in rebate amounts.--Disputes or
195 discrepancies in rebate amounts must be resolved using the
196 process established in this subsection.

197 1. If there is a discrepancy in the manufacturer's or
198 labeler's favor between the amount claimed by a pharmacy and the
199 amount rebated by the manufacturer or labeler, the agency, at
200 the agency's expense, may hire a mutually agreed-upon
201 independent auditor. If a discrepancy still exists following the
202 audit, the manufacturer or labeler shall justify the reason for
203 the discrepancy or make payment to the agency for any additional
204 amount due.

205 2. If there is a discrepancy against the interest of the
206 manufacturer or labeler in the information provided by the
207 agency to the manufacturer or labeler regarding the
208 manufacturer's or labeler's rebate, the manufacturer or labeler,
209 at the manufacturer's or labeler's expense, may hire a mutually
210 agreed-upon independent auditor to verify the accuracy of the



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211 data supplied to the agency. If a discrepancy still exists
212 following the audit, the agency shall justify the reason for the
213 discrepancy or provide a refund to the manufacturer or labeler.

214 3. Following the procedures established in subparagraph 1.
215 or subparagraph 2., either the agency or the manufacturer or
216 labeler may request a hearing. Supporting documentation must
217 accompany the request for a hearing.

218 (b) Annual summary report.--The agency shall report the
219 enrollment and financial status of the Rx Card program and
220 report savings from supplemental Medicaid rebates to the
221 President of the Senate and the Speaker of the House of
222 Representatives by February 1 each year.

223 (c) Coordination with other programs.--Where the secretary
224 finds that it is beneficial to both the Rx Card program and
225 another state program, including the state Medicaid program, to
226 combine drug pricing negotiations to maximize drug rebates, the
227 secretary shall do so.

228 (d) Rulemaking.--The agency shall adopt rules pursuant to
229 ss. 120.536(1) and 120.54, Florida Statutes, to implement the
230 provisions of this section.

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

234 Section 2. The provisions of this act are severable; and,
235 if any phrase, clause, sentence, or provision is declared to be
236 invalid or is preempted by federal law or regulation, the
237 validity of the remainder of this act shall not be affected.

238 Section 3. This act shall take effect July 1, 2003.