

By Senator Wise

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1 A bill to be entitled
2 An act relating to prescription drugs; creating s.
3 499.0295, F.S.; providing a short title; creating the
4 Drug Donation Program for the state correctional
5 system; providing a purpose; providing definitions;
6 providing conditions for the donation of drugs and
7 supplies to the program; providing conditions for the
8 acceptance of drugs and supplies into the program,
9 inspection of drugs and supplies, and dispensing of
10 drugs and supplies to eligible prisoners; requiring a
11 participant facility that accepts donated drugs and
12 supplies through the program to comply with certain
13 state and federal laws; authorizing a participant
14 facility to charge fees under certain conditions;
15 requiring the Department of Health, upon
16 recommendation of the Department of Corrections and
17 the Board of Pharmacy, to adopt certain rules;
18 requiring the department to establish and maintain a
19 participant facility registry; providing for the
20 contents and availability of the participant facility
21 registry; providing immunity from civil and criminal
22 liability for the Department of Corrections, donors,
23 or pharmaceutical manufacturers in certain
24 circumstances; providing that in the event of conflict
25 between the provisions of the act and provisions in
26 ch. 465 or ch. 499, F.S., the provisions of the act
27 control; providing an appropriation; providing an
28 effective date.
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30 Be It Enacted by the Legislature of the State of Florida:

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32 Section 1. Section 499.0295, Florida Statutes, is created
33 to read:

34 499.0295 Drug Donation Program.-

35 (1) This section may be cited as the "Drug Donation Program
36 Act."

37 (2) There is created a Drug Donation Program within the
38 Department of Health for the purpose of authorizing and
39 facilitating the donation of drugs to the Department of
40 Corrections.

41 (3) As used in this section, the term:

42 (a) "Drug" means a prescription drug that has been approved
43 under s. 505 of the federal Food, Drug, and Cosmetic Act. The
44 term does not include a substance listed in Schedule II,
45 Schedule III, Schedule IV, or Schedule V of s. 893.03.

46 (b) "Closed drug delivery system" means a system in which
47 the actual control of the unit-dose medication package is
48 maintained by the facility rather than by the individual
49 patient.

50 (c) "Donor" means a patient or patient representative who
51 donates drugs or supplies needed to administer drugs that have
52 been maintained within a closed drug delivery system; health
53 care facilities, nursing homes, hospices, or hospitals that have
54 closed drug delivery systems; or pharmacies, drug manufacturers,
55 medical device manufacturers or suppliers, or wholesalers of
56 drugs or supplies, in accordance with this section. The term
57 includes a physician licensed under chapter 458 or chapter 459
58 who receives drugs directly from a drug manufacturer, wholesale

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59 distributor, or pharmacy.

60 (d) "Eligible prisoner" means a prisoner who the Department
61 of Corrections determines is eligible to receive drugs from the
62 program.

63 (e) "Participant facility" means a class II hospital
64 pharmacy that has elected to participate in the program and that
65 accepts donated drugs and supplies under the rules adopted by
66 the department for the program.

67 (f) "Prescribing practitioner" means a physician licensed
68 under chapter 458 or any other medical professional who is
69 authorized under state law to prescribe medication.

70 (g) "Prisoner" means any person committed to or detained in
71 any state prison, prison farm, or penitentiary, or to the
72 custody of the Department of Corrections under lawful authority.

73 (h) "Program" means the Drug Donation Program created by
74 this section.

75 (i) "Supplies" means any supplies used in the
76 administration of a drug.

77 (4) Any donor may donate drugs or supplies to a participant
78 facility that elects to participate in the program and meets
79 criteria established by the Department of Health for such
80 participation. Drugs or supplies may not be donated to a
81 specific prisoner, and donated drugs or supplies may not be
82 resold by the program. Drugs billed to and paid for by Medicaid
83 in long-term care facilities that are eligible for return to
84 stock under federal Medicaid regulations shall be credited to
85 Medicaid and are not eligible for donation under the program. A
86 participant facility shall provide dispensing and consulting
87 services to the Department of Corrections.

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88 (5) The drugs or supplies donated to the program may be
89 prescribed only by a prescribing practitioner for use by an
90 eligible prisoner and may be dispensed only by a pharmacist.

91 (6) (a) A drug may be accepted or dispensed under the
92 program only if the drug is in its original, unopened, and
93 sealed container, or in tamper-evident and unit-dose packaging,
94 except that a drug packaged in single-unit doses may be accepted
95 and dispensed if the outside packaging is opened but the single-
96 unit-dose packaging is unopened and the tamper-resistant
97 packaging is intact.

98 (b) A drug may not be accepted or dispensed under the
99 program if the drug bears an expiration date that is less than 6
100 months after the date the drug was donated or if the drug
101 appears to have been tampered with or mislabeled as determined
102 in paragraph (c).

103 (c) Before being dispensed to an eligible prisoner, the
104 drug or supplies donated under the program shall be inspected by
105 a pharmacist to determine if the drug and supplies appear to
106 have been tampered with or mislabeled.

107 (d) A dispenser of donated drugs or supplies may not submit
108 a claim or otherwise seek reimbursement from the Department of
109 Corrections or any public or private third-party payor for
110 donated drugs or supplies dispensed to any prisoner under the
111 program, and a public or private third-party payor or the
112 Department of Corrections is not required to provide
113 reimbursement to a dispenser for donated drugs or supplies
114 dispensed to any prisoner under the program.

115 (7) (a) A donation of drugs or supplies shall be made only
116 at a participant facility. A participant facility may decline to

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117 accept a donation. A participant facility that accepts donated
118 drugs or supplies under the program shall comply with all
119 applicable provisions of state and federal law relating to the
120 storage and dispensing of the donated drugs or supplies.

121 (b) A participant facility that voluntarily takes part in
122 the program may charge a handling fee sufficient to cover the
123 cost of preparation and dispensing of drugs or supplies under
124 the program. The fee shall be established in rules adopted by
125 the department.

126 (8) Upon the recommendation of the Board of Pharmacy and
127 the Department of Corrections, the Department of Health shall
128 adopt rules to administer this section. Initial rules under this
129 section must be adopted by October 1, 2009. The rules must
130 include, but need not be limited to:

131 (a) Eligibility criteria, including a method to determine
132 priority of eligible prisoners under the program.

133 (b) Standards and procedures for participant facilities
134 that accept, store, distribute, or dispense donated drugs or
135 supplies.

136 (c) Necessary forms for administration of the program,
137 including, but not limited to, forms for use by entities that
138 donate, accept, distribute, or dispense drugs or supplies under
139 the program.

140 (d) The maximum handling fee that may be charged by a
141 participant facility that accepts and distributes or dispenses
142 donated drugs or supplies.

143 (e) Categories of drugs and supplies which the program will
144 accept for dispensing; however, the department may exclude any
145 drug based on its therapeutic effectiveness or high potential

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146 for abuse or diversion.

147 (f) Maintenance and distribution of the participant
148 facility registry established in subsection (9).

149 (9) The Department of Health shall establish and maintain a
150 participant facility registry for the program. The participant
151 facility registry shall include a participant facility's name,
152 address, and telephone number. The department shall make the
153 participant facility registry available on the department's
154 website to any donor wishing to donate drugs or supplies to the
155 program. The department's website must also contain links to
156 drug manufacturers that offer drug assistance programs or free
157 medication.

158 (10) The Department of Corrections, any donor of drugs or
159 supplies, or any participant in the program who exercises
160 reasonable care in donating, accepting, distributing, or
161 dispensing drugs or supplies under the program and the rules
162 adopted under this section is immune from civil or criminal
163 liability and from professional disciplinary action of any kind
164 for any injury, death, or loss to person or property relating to
165 such activities.

166 (11) A pharmaceutical manufacturer is not liable for any
167 claim or injury arising from the transfer of any drug under this
168 section, including, but not limited to, liability for failure to
169 transfer or communicate product or consumer information
170 regarding the transferred drug, as well as the expiration date
171 of the transferred drug.

172 (12) If any conflict exists between the provisions in this
173 section and the provisions in this chapter or chapter 465, the
174 provisions in this section control the operation of the Drug

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175 Donation Program.

176 Section 2. There is appropriated one full-time equivalent
177 position at salary rate 42,715 and recurring funding from the
178 Florida Drug, Device, and Cosmetic Trust Fund pursuant to s.
179 499.057, Florida Statutes, in the sum of \$65,308 for the 2009-
180 2010 fiscal year for the purpose of implementing the Drug
181 Donation Program as created by this act.

182 Section 3. This act shall take effect July 1, 2009.