

HB 893

2009

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 Drug
4 Donation Program for the state correctional system;
5 providing a purpose; providing definitions; providing
6 conditions for the donation of drugs and supplies to the
7 program; providing conditions for the acceptance of drugs
8 and supplies into the program, inspection of drugs and
9 supplies, and dispensing of drugs and supplies to eligible
10 prisoners; requiring a participant facility that accepts
11 donated drugs and supplies through the program to comply
12 with certain state and federal laws; authorizing a
13 participant facility to charge fees under certain
14 conditions; requiring the Department of Health, upon
15 recommendation of the Department of Corrections and the
16 Board of Pharmacy, to adopt certain rules; requiring the
17 Department of Health to establish and maintain a
18 participant facility registry; providing for the contents
19 and availability of the participant facility registry;
20 providing immunity from civil and criminal liability for
21 the Department of Corrections, donors, and pharmaceutical
22 manufacturers in certain circumstances; providing that the
23 provisions of the act control in the event of a conflict
24 between provisions of the act and provisions in ch. 465 or
25 ch. 499, F.S.; authorizing a position and providing an
26 appropriation; providing an effective date.

27
28 Be It Enacted by the Legislature of the State of Florida:

Page 1 of 7

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

hb0893-00

HB 893

2009

29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56

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

499.0295 Drug Donation Program.--

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

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

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

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

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

(c) "Drug" means a prescription drug that has been approved under s. 505 of the Federal Food, Drug, and Cosmetic Act. The term does not include a substance listed in Schedule

57 II, Schedule III, Schedule IV, or Schedule V of s. 893.03.

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

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

65 (f) "Prescribing practitioner" means a physician licensed
66 under chapter 458 or chapter 459 or any other medical
67 professional who is authorized under state law to prescribe
68 medication.

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

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

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

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

85 participant facility shall provide dispensing and consulting
86 services to the Department of Corrections.

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

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

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

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

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

HB 893

2009

113 dispensed to any prisoner under the program.

114 (7) (a) A donation of drugs or supplies shall be made only
115 at a participant facility. A participant facility may decline to
116 accept a donation. A participant facility that accepts donated
117 drugs or supplies under the program shall comply with all
118 applicable provisions of state and federal law relating to the
119 storage and dispensing of the donated drugs or supplies.

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

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

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

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

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

139 (d) The maximum handling fee that may be charged by a
140 participant facility that accepts and distributes or dispenses

HB 893

2009

141 donated drugs or supplies.

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

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

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

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

165 (11) A pharmaceutical manufacturer is not liable for any
166 claim or injury arising from the transfer of any drug under this
167 section, including, but not limited to, liability for failure to
168 transfer or communicate product or consumer information

HB 893

2009

169 regarding the transferred drug, as well as the expiration date
170 of the transferred drug.

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

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

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