



House of Representatives

General Assembly

File No. 202

January Session, 2001

House Bill No. 6696

House of Representatives, April 10, 2001

The Committee on General Law reported through REP. FOX of the 144th Dist., Chairperson of the Committee on the part of the House, that the bill ought to pass.

AN ACT CONCERNING THE PROVISION OF PHARMACY SERVICES TO CORRECTIONAL INSTITUTIONS.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

1 Section 1. Subsection (a) of section 21a-70 of the general statutes is
2 repealed and the following is substituted in lieu thereof:

3 (a) As used in this section: (1) "Wholesaler" or "distributor" means a
4 person, whether within or without the boundaries of the state of
5 Connecticut, who supplies drugs, medical devices or cosmetics
6 prepared, produced or packaged by manufacturers, to other
7 wholesalers, manufacturers, distributors, hospitals, prescribing
8 practitioners, as defined in subdivision (22) of section 20-571,
9 pharmacies, federal, state or municipal agencies, clinics or any other
10 person as permitted under subsection (h) of this section, except that a
11 retail pharmacy or a pharmacy within a licensed hospital which
12 supplies to another such pharmacy a quantity of a noncontrolled drug
13 or a schedule III, IV or V controlled substance normally stocked by

14 such pharmacies to provide for the immediate needs of a patient
15 pursuant to a prescription or medication order of an authorized
16 practitioner, a pharmacy within a licensed hospital which supplies
17 drugs to another hospital or an authorized practitioner for research
18 purposes, and a retail pharmacy which supplies a limited quantity of a
19 noncontrolled drug or of a schedule II, III, IV or V controlled substance
20 for emergency stock to a practitioner who is a medical director of a
21 chronic and convalescent nursing home, [or] of a rest home with
22 nursing supervision or of a state correctional institution shall not be
23 deemed a wholesaler under this section; (2) "manufacturer" means a
24 person whether within or without the boundaries of the state of
25 Connecticut who produces, prepares, cultivates, grows, propagates,
26 compounds, converts or processes, directly or indirectly, by extraction
27 from substances of natural origin or by means of chemical synthesis or
28 by a combination of extraction and chemical synthesis, or who
29 packages, repackages, labels or relabels a container under [his] such
30 manufacturer's own or any other trademark or label any drug, device
31 or cosmetic for the purpose of selling such items. The words "drugs",
32 "devices" and "cosmetics" shall have the meaning ascribed to them in
33 section 21a-92; and (3) "commissioner" means the Commissioner of
34 Consumer Protection.

35 Sec. 2. Subsection (d) of section 21a-250 of the general statutes is
36 repealed and the following is substituted in lieu thereof:

37 (d) (1) A retail pharmacy or pharmacy within a licensed hospital
38 may distribute small quantities of schedule III, IV or V controlled
39 substances to another pharmacy to provide for the immediate needs of
40 a patient pursuant to a prescription or medication order of a
41 practitioner. As used in this subsection "small quantities" means not
42 more than one ounce of a powder or ointment, not more than sixteen
43 ounces of a liquid and not more than one hundred dosage units of
44 tablets, capsules, suppositories or injectables. (2) A retail pharmacy
45 may distribute, in accordance with state and federal statutes and

46 regulations, a schedule II, III, IV or V controlled substance to a
47 practitioner who has a current federal and state registry number
48 authorizing [him] such practitioner to purchase such controlled
49 substances, and who is the medical director of a chronic and
50 convalescent nursing home, [or] of a rest home with nursing
51 supervision or of a state correctional institution, for use as emergency
52 stock within such facility. Such drugs shall be supplied in containers
53 which bear labels specifying the name of the drug and its strength,
54 expiration date, lot number and manufacturer. Drugs supplied
55 pursuant to this subsection shall be limited in type and quantity to
56 those specifically documented and authorized by such medical
57 director for use as emergency stock in such facility. (3) Pharmacies
58 distributing controlled substances in accordance with the provisions of
59 subdivisions (1) and (2) of this subsection shall keep a written record of
60 such transactions containing the name of the receiving pharmacy, or
61 the name and federal registry number of a medical director, date
62 distributed and name, form, strength and quantity of such controlled
63 substances distributed. Such records shall be kept on file separately, in
64 accordance with subsection (h) of section 21a-254. Receiving
65 pharmacies or medical directors, shall keep, in a separate file, a written
66 record in accordance with subsections (f) and (h) of section 21a-254.

67 Sec. 3. (NEW) (a) Each correctional institution shall return to the
68 vendor pharmacy which shall accept, for repackaging and
69 reimbursement to the Department of Correction, drug products that
70 were dispensed to a patient and not used if such drug products are (1)
71 prescription drug products that are not controlled substances, (2)
72 sealed in individually packaged units, (3) returned to the vendor
73 pharmacy within the recommended period of shelf life for the purpose
74 of redispensing such drug products, (4) determined to be of acceptable
75 integrity by a licensed pharmacist, and (5) oral and parenteral
76 medication in single-dose sealed containers approved by the federal
77 Food and Drug Administration, topical or inhalant drug products in
78 units of use containers approved by the federal Food and Drug

79 Administration or parenteral medications in multiple-dose sealed
80 containers approved by the federal Food and Drug Administration
81 from which no doses have been withdrawn.

82 (b) Notwithstanding the provisions of subsection (a) of this section:

83 (1) If such drug products are packaged in manufacturer's unit-dose
84 packages, such drug products shall be returned to the vendor
85 pharmacy for redispensing and reimbursement to the Department of
86 Correction if such drugs may be redispensed for use before the
87 expiration date, if any, indicated on the package.

88 (2) If such drug products are repackaged in manufacturer's unit-
89 dose or multiple-dose blister packs, such drug products shall be
90 returned to the vendor pharmacy for redispensing and reimbursement
91 to the Department of Correction if (A) the date on which such drug
92 product was repackaged, such drug product's lot number and
93 expiration date are indicated clearly on the package of such
94 repackaged drug; (B) ninety days or fewer have elapsed from the date
95 of repackaging of such drug product; and (C) a repackaging log is
96 maintained by the pharmacy in the case of drug products repackaged
97 in advance of immediate needs.

98 (3) No drug products dispensed in a bulk dispensing container may
99 be returned to the vendor pharmacy.

100 (c) Each correctional institution shall establish procedures for the
101 return of unused drug products to the vendor pharmacy from which
102 such drug products were purchased.

103 (d) The Department of Correction shall reimburse to the vendor
104 pharmacy the reasonable cost of services incurred in the operation of
105 this section, as determined by the Commissioner of Correction.

106 (e) The Department of Consumer Protection, in consultation with
107 the Department of Correction, shall adopt regulations, in accordance

108 with the provisions of chapter 54 of the general statutes, which shall
109 govern the repackaging and labeling of drug products returned
110 pursuant to subsections (a) and (b) of this section. The Department of
111 Consumer Protection shall implement the policies and procedures
112 necessary to carry out the provisions of this section until January 1,
113 2003, while in the process of adopting such policies and procedures in
114 regulation form, provided notice of intent to adopt the regulations is
115 published in the Connecticut Law Journal within twenty days after
116 implementation.

117 Sec. 4. This act shall take effect July 1, 2001.

GL *Joint Favorable*

The following fiscal impact statement and bill analysis are prepared for the benefit of members of the General Assembly, solely for the purpose of information, summarization, and explanation, and do not represent the intent of the General Assembly or either House thereof for any purpose:

OFA Fiscal Note

State Impact: Indeterminate Savings

Affected Agencies: Departments of Correction and Consumer Protection

Municipal Impact: None

Explanation**State Impact:**

Passage of the bill would result in indeterminate savings resulting from reimbursement for unused drug products. The Department of Correction (DOC) currently spends about \$70 million on inmate medical services with a significant portion being expended on prescription medication. It is estimated that approximately 5 - 10% of the drugs purchased by the department are unused and savings would result from the resale of these drugs, which are currently disposed of. It should be noted that the University of Connecticut Health Center is responsible for all inmate medical services for DOC and makes drug purchases for the department centrally.

The bill proposes that the Departments of Correction and Consumer Protection (DCP) develop regulations for the repackaging and labeling of unused drug products and there is no fiscal impact associated with this provision of the bill. Once repackaged, these drugs would be returned to the vendor pharmacies and DOC would be reimbursed for

their value. It is anticipated that cost related to repackaging would be absorbable within the agency's current resources. Finally, the states Medicaid program which spends \$70 million on prescription drugs annually, saved approximately \$3 - \$4 million in FY 01 under a similar plan.

OLR Bill Analysis

HB 6696

AN ACT CONCERNING THE PROVISION OF PHARMACY SERVICES TO CORRECTIONAL INSTITUTIONS.**SUMMARY:**

This bill sets conditions under which state correctional institutions must return specified unused drugs to vendor pharmacies for re-dispensing and reimbursement to the Department of Correction (DOC). The institutions must establish procedures for returning the unused drugs to pharmacies and DOC must reimburse the pharmacies for the reasonable costs they incur in complying with the bill. DOC and the Department of Consumer Protection (DCP) must adopt regulations for repackaging and labeling drugs returned in accordance with the bill.

The bill specifies that retail pharmacies that supply limited amounts of noncontrolled drugs or controlled substances for emergency use to the medical director of a state correctional institution are not drug wholesalers under state law. Retail pharmacies that supply these drugs to chronic and convalescent nursing homes and rest homes are already exempt. The bill also allows retail pharmacies to distribute certain controlled substances to a correctional institution's medical director for use as emergency stock. Current law already allows them to distribute these substances to chronic and convalescent nursing homes and rest homes.

EFFECTIVE DATE: July 1, 2001

RETURNS

Each correctional institution must establish procedures for returning unused drugs to the pharmacy from which they were purchased.

Except for drugs dispensed in a bulk dispensing container, which may not be returned, the bill requires each correctional institution to return

to vendor pharmacies, for repackaging and reimbursement, unused drugs that are:

1. prescription drugs that are not controlled substances;
2. sealed in individually packaged units;
3. returned to the vendor pharmacy within the recommended period of shelf life for re-dispensing;
4. determined to be of acceptable integrity by a licensed pharmacist;
5. oral and parenteral (taken by injection) drugs in single-dose sealed containers approved by the U.S. Food and Drug Administration (FDA);
6. topical or inhalant drugs in FDA-approved units-of-use containers ; or
7. parenteral drugs in FDA-approved, multiple-dose, sealed containers from which no doses have been withdrawn.

Drugs meeting these criteria must also meet specified packaging standards before they can be returned.

If drugs are packaged in the manufacturer's unit-dose packages, they must be returned to the vendor pharmacy if they can be re-dispensed for use before the expiration date, if any, stated on the package.

If drugs are repackaged in the manufacturer's unit-dose or multiple-dose blister packs, they must be returned to the vendor pharmacy if (1) the repackaged drug clearly indicates the date of repackaging, lot number, and expiration date; (2) 90 days or less have elapsed from the date of repackaging; and (3) the pharmacy keeps a repackaging log in the case of drugs that are repackaged before they are needed.

DOC must reimburse vendor pharmacies for the reasonable cost of services incurred in operating the program, as determined by the correction commissioner.

The bill requires the DCP commissioner, in consultation with the DOC, to adopt and carry out policies and procedures for repackaging and labeling returned drugs until January 1, 2003 when he must adopt regulations delineating those policies and procedures. He must publish notice of his intent to adopt the regulations in the *Connecticut Law Journal* within 20 days of implementing the policies and procedures.

COMMITTEE ACTION

General Law Committee

Joint Favorable Report

Yea 17 Nay 0