



House of Representatives

General Assembly

File No. 143

January Session, 2005

Substitute House Bill No. 6791

House of Representatives, April 4, 2005

The Committee on Program Review and Investigations reported through REP. SHARKEY of the 88th Dist., Chairperson of the Committee on the part of the House, that the substitute bill ought to pass.

***AN ACT IMPLEMENTING THE RECOMMENDATIONS OF THE
LEGISLATIVE PROGRAM REVIEW AND INVESTIGATIONS
COMMITTEE RELATIVE TO PHARMACY REGULATION.***

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

1 Section 1. (NEW) (*Effective from passage*) Not later than January 1,
2 2006, the Department of Consumer Protection shall submit to the joint
3 standing committee of the General Assembly having cognizance of
4 matters relating to general law, in accordance with the provisions of
5 section 11-4a of the general statutes, a report that summarizes the
6 activities of the department related to the regulation of the Pharmacy
7 Practice Act, the federal Food, Drug and Cosmetic Act and the state
8 controlled substance act. Such report shall include, but not be limited
9 to, information on the number and type of pharmacy inspections and
10 investigations conducted by the Department of Consumer Protection
11 concerning: (1) The number of investigations conducted, (2) the reason
12 for each investigation, (3) the subject matter of each investigation, (4)
13 the outcome of each investigation, (5) any action taken by any board of

14 the Department of Public Health or the Commission of Pharmacy, (6)
15 any action taken by the Commissioner of Consumer Protection on a
16 practitioner's controlled substance registration, and (7) the timeline for
17 such investigation beginning with the opening of such case
18 investigation and ending with the final board or commission action.
19 Such report shall be updated and resubmitted to the said joint standing
20 committee on January 1, 2007, and on January 1, 2008.

21 Sec. 2. (NEW) (*Effective from passage*) Not later than January 1, 2006,
22 in accordance with the provisions of section 11-4a of the general
23 statutes, The University of Connecticut Health Center shall submit a
24 report to the Legislative Program Review and Investigations
25 Committee that identifies deficiencies in the administration of drugs in
26 correctional facilities found within the previous calendar year. Such
27 report shall be updated on January 1, 2007, and on January 1, 2008.

28 Sec. 3. Section 20-577 of the general statutes is repealed and the
29 following is substituted in lieu thereof (*Effective from passage*):

30 (a) The commissioner shall employ inspectors whose duty it shall be
31 to inspect all pharmacies and other places in which drugs and devices
32 are or may be dispensed or retailed, and to report any violations of
33 sections 20-570 to 20-630, inclusive, or other laws relating to drugs and
34 devices and violations of laws regarding pharmacy licenses, nonlegend
35 drug permits, licenses of pharmacists and supervision of pharmacy
36 interns and pharmacy technicians.

37 (b) The commissioner shall inspect correctional or juvenile training
38 institutions and care-giving institutions throughout the state with
39 respect to the handling of drugs, shall report violations of law and
40 make recommendations for improvements in procedures to the
41 authority responsible for the operation of the institution and shall take
42 such other steps as may be necessary to ensure proper and adequate
43 storage, handling and administration of drugs in such institutions. The
44 commissioner may also inspect dispensing outpatient facilities and
45 institutional pharmacies and take such steps as the commissioner
46 considers appropriate to correct deficiencies found in such facilities or

47 institutional pharmacies with respect to their operation.

48 (c) The commissioner shall inspect each retail pharmacy not less
49 than once every four years and shall develop a methodology to sample
50 prescriptions dispensed by retail pharmacies for compliance with state
51 laws concerning the dispensing of prescriptions. Such methodology
52 shall be based on the number of prescriptions received by such retail
53 pharmacies.

54 Sec. 4. Section 21a-262 of the general statutes is repealed and the
55 following is substituted in lieu thereof (*Effective from passage*):

56 (a) The Commissioner of Consumer Protection may receive, take
57 into custody or destroy excess or undesired controlled substances and
58 may in his discretion deliver, upon application, to any hospital,
59 laboratory, incorporated college, scientific institution or any state or
60 municipal agency or institution not operated for private gain, any
61 controlled substances that have come into his custody by authority of
62 this section. In the case of a care-giving or correctional or juvenile
63 training institution having an institutional pharmacy, the
64 Commissioner of Consumer Protection shall deliver such controlled
65 substances only to the licensed pharmacist in charge of such
66 pharmacy. The Commissioner of Consumer Protection may receive
67 and take into custody excess or undesired controlled substances from
68 pharmacists, manufacturers and wholesalers or any other registrant.
69 Said commissioner shall keep a full and complete record of all
70 substances received and of all substances disposed of, showing the
71 exact kinds, quantities and forms of such substances, the persons from
72 whom received and to whom delivered, by whose authority received,
73 delivered and destroyed, and the dates of the receipt, disposal or
74 destruction. Controlled substances and preparations shall at all times
75 be properly safeguarded and securely kept. Minimum security and
76 safeguard standards for the storage, manufacture, sale or distribution
77 of all controlled substances shall be established by regulations adopted
78 hereunder. Controlled substances seized or held as contraband or
79 controlled substances, the title to which cannot be resolved, which

80 controlled substances are not held by law enforcement agencies or
81 court officials as evidence in criminal proceedings, shall be, upon the
82 order of the court, destroyed by the seizing authority or delivered to
83 the Commissioner of Consumer Protection as soon as possible upon
84 resolution of the case or upon ascertaining the status of the unclaimed
85 substance. The agent of the Commissioner of Consumer Protection
86 shall issue a receipt for all such substance obtained. Any loss,
87 destruction or theft of controlled substances shall be reported by a
88 registrant within seventy-two hours to the Commissioner of Consumer
89 Protection as follows: (1) Where, through breakage of the container or
90 other accident, otherwise than in transit, controlled substances are lost
91 or destroyed, the person having title thereto shall make a signed
92 statement as to the kinds and quantities of controlled substances lost or
93 destroyed and the circumstances involved, and immediately forward
94 the statement to the Commissioner of Consumer Protection. A copy of
95 such statement shall be retained by the registrant; (2) where controlled
96 substances are lost by theft, or otherwise lost or destroyed in transit,
97 the consignee shall, immediately upon ascertainment of the
98 occurrence, file with the Commissioner of Consumer Protection a
99 signed statement of the facts, including a list of the controlled
100 substances stolen, lost or destroyed and documentary evidence that
101 the local authorities were notified. A copy of the statement shall be
102 retained by the registrant. As used in this section, "care-giving
103 institution", "correctional or juvenile training institution", "institutional
104 pharmacy" and "pharmacist" shall have the same meaning as used in
105 section 20-571.

106 (b) For each long-term care facility, two or more of the following
107 persons may jointly dispose of excess stock of controlled substances: A
108 nursing home administrator, a pharmacist consultant, a director of
109 nursing services or an assistant director of nursing services. Such
110 facility shall maintain documentation of any such destruction and
111 disposal for a period of three years and such documentation shall be
112 maintained in a separate log and on a form prescribed by the
113 department.

114 (c) For each outpatient surgical facility, as defined in section 19a-
115 493b, two or more of the following persons may jointly dispose of
116 excess stock of controlled substances: An administrator, a clinical
117 director or chief of staff, or a nursing supervisor. Such facility shall
118 maintain documentation of any such destruction and disposal for a
119 period of three years and such documentation shall be maintained in a
120 separate log and on a form prescribed by the department.

121 Sec. 5. (NEW) (*Effective from passage*) Not less than once every three
122 months, the Department of Consumer Protection shall compile a
123 regulatory action report that contains information regarding: (1) Any
124 disciplinary action taken by the department against any person with a
125 controlled substance registration, and (2) any sanction by the
126 Commission of Pharmacy against a pharmacy or pharmacist. Such
127 report shall contain the reasons for any such action or sanction and
128 shall be posted on the web site of the department.

129 Sec. 6. (NEW) (*Effective from passage*) (a) On and after October 1,
130 2005, any person licensed as a pharmacist under part II of chapter 400j
131 of the general statutes may administer influenza vaccine to an adult,
132 provided the administration is conducted pursuant to the order of a
133 licensed health care provider and in accordance with the regulations
134 established pursuant to subsection (b) of this section.

135 (b) Not later than September 1, 2005, the Commissioner of
136 Consumer Protection, in consultation with the Commissioner of Public
137 Health and the Commission of Pharmacy, shall adopt regulations, in
138 accordance with chapter 54 of the general statutes, to implement the
139 provisions of this section. Such regulations shall (1) require any
140 pharmacist who administers influenza vaccine to an adult pursuant to
141 this section to successfully complete an immunization training
142 program for pharmacists; (2) define the basic requirements of such
143 training program, which shall include training and instruction in pre-
144 administration education and screening, vaccine storage and handling,
145 subcutaneous and intramuscular injections, recordkeeping, vaccine
146 safety, cardiopulmonary resuscitation, basic cardiac life support and

147 adverse event reporting; (3) identify qualifying training programs,
148 which are accredited by the National Centers for Disease Control
149 Prevention, the Accreditation Council for Pharmacy Education or other
150 appropriate national accrediting body; and (4) establish a system of
151 control and reporting.

152 (c) For purposes of this section, "adult" means an individual who
153 has attained the age of eighteen years.

This act shall take effect as follows and shall amend the following sections:		
Section 1	<i>from passage</i>	New section
Sec. 2	<i>from passage</i>	New section
Sec. 3	<i>from passage</i>	20-577
Sec. 4	<i>from passage</i>	21a-262
Sec. 5	<i>from passage</i>	New section
Sec. 6	<i>from passage</i>	New section

PRI *Joint Favorable Subst.*

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:

Agency Affected	Fund-Effect	FY 06 \$	FY 07 \$
UConn Health Ctr.	GF - Cost	Minimal	Minimal
Consumer Protection, Dept.	GF - None	None	None

Note: GF=General Fund

Municipal Impact: None

Explanation

The bill requires the Department of Consumer Protection (DCP) to inspect each retail pharmacy at least once every four years and develop a methodology to sample dispensed prescriptions for compliance with relevant state law. There are currently 609 retail pharmacies in the state. The bill also requires DCP to compile a quarterly regulatory action report and report to the General Law Committee on pharmacy inspections and investigations. Additionally, the bill authorizes long-term care facilities and outpatient surgical facilities to destroy excess controlled substances under specified conditions, which would result in a significant workload decrease for Drug Control Agents within DCP. In FY 04, Drug Control Agents made over 800 trips to long-term care facilities to destroy excess controlled substances. To the extent that there may be an increase in workload due to the requirement of investigating retail pharmacies once every four years, it would be offset by the workload reduction in long-term care pharmacies being able to destroy excess controlled substances.

The bill also requires the UConn Health Center to produce a report concerning drug administration deficiencies in correction facilities. This will lead to minimal additional administrative costs for the Health Center.

The bill also requires the DCP in consultation with the Commissioner of the Department of Public Health to adopt certain regulations. Both agencies can implement this provision of the bill within budgetary resources.

OLR Bill Analysis

sHB 6791

AN ACT IMPLEMENTING THE RECOMMENDATIONS OF THE LEGISLATIVE PROGRAM REVIEW AND INVESTIGATIONS COMMITTEE RELATIVE TO PHARMACY REGULATION**SUMMARY:**

This bill authorizes long-term care facilities and outpatient surgical facilities to dispose of excess controlled substances. It also authorizes pharmacists to administer flu shots.

The bill requires the Department of Consumer Protection (DCP) to (1) inspect retail pharmacies at least once every four years, (2) report to the General Law Committee on its pharmacy inspections and investigations, and (3) compile a quarterly regulatory action report. It requires the UCONN Health Center to report to the Program Review and Investigations Committee on drug administration deficiencies in correctional institutions.

EFFECTIVE DATE: Upon passage

DESTRUCTION OF CONTROLLED SUBSTANCES BY LONG-TERM CARE FACILITIES AND OUTPATIENT SURGICAL FACILITIES

This bill authorizes long-term care facilities and outpatient surgical facilities to destroy excess controlled substances under specified conditions. In each type of facility, two designated professionals may jointly dispose of excess stock. The facilities must keep records of any destruction for three years in a separate log and on a form prescribed by DCP. In long-term care facilities, the designated professionals are the nursing home administrator, a pharmacist consultant, a director or nursing services, or an assistant director of nursing services. In outpatient surgical facilities, the designated professionals are the administrator, a clinical director or chief of staff, or a nursing supervisor.

PHARMACISTS AUTHORIZED TO ADMINISTER FLU SHOTS

The bill authorizes licensed pharmacists to administer influenza vaccine to individuals at least 18 years old. The vaccination must be administered according to an order of a licensed health care provider and DCP's implementing regulations.

The bill requires DCP, in consultation with the public health commissioner and the Commission of Pharmacy, to adopt regulations:(1) requiring pharmacists who administer influenza vaccine to successfully complete a training program; (2) defining the basic components of the training program, including training and instruction in pre-administration education and screening, vaccine storage and handling, subcutaneous and intramuscular injections, recordkeeping, vaccine safety, cardiopulmonary resuscitation, basic cardiac life support, and adverse event reporting; (3) identifying qualifying training programs accredited by the National Centers for Disease Control and Prevention, the Accreditation Council for Pharmacy Education, or other appropriate national accrediting body; and (4) establishing a control and reporting system.

RETAIL PHARMACY INSPECTIONS

The bill requires DCP to inspect each retail pharmacy at least once every four years and to develop a methodology to sample dispensed prescriptions for compliance with relevant state law. The methodology must be based on the number of prescriptions received by a retail pharmacy. The law requires the DCP commissioner to employ inspectors to inspect pharmacies and every place where drugs are dispensed or sold to the public.

REPORT ON PHARMACY LAW ENFORCEMENT

The bill requires DCP to report to the General Law Committee on its pharmacy inspections by January 1, 2006. The report must include the number, reason, subject matter, timeline, and outcome of each pharmacy investigation undertaken in the previous year. The report must also include any action taken by a board within the Department of Public Health, the Pharmacy Commission, or, with respect to a medical practitioner's controlled substance registration, DCP. Each investigation timeline must begin when a case investigation is opened and end with a final board or commission action. The report must be submitted by January 1, 2006 and updated and resubmitted by January 1, 2007 and January 1, 2008.

REGULATORY ACTION REPORT

The bill requires DCP to compile a regulatory action report at least once every three months and post it on DCP's website. The report must include (1) any disciplinary action taken against someone holding a controlled substance registration, (2) any sanction imposed by the Commission of Pharmacy against a pharmacy or pharmacist, and (3) the reasons for the sanction or action.

REPORT ON CORRECTIONAL FACILITY DRUG ADMINISTRATION DEFICIENCIES

The bill requires the UCONN Health Center to report to the Program Review and Investigations Committee identifying drug administration deficiencies in correctional facilities found during the previous calendar year. The report must be submitted by January 1, 2006 and updated and resubmitted by January 1, 2007 and January 1, 2008.

BACKGROUND***Controlled Substances***

Controlled substances are grouped in Schedules I through V, according to their decreasing tendency to promote abuse or dependency. Schedule I substances are the most strictly controlled because of their high potential for abuse. State and federal laws authorize prescribing drugs on Schedules II through V; most Schedule I drugs do not have any approved medical use.

Controlled Substance Practitioner Registration

The law requires medical practitioners who distribute, administer, or dispense controlled substances to register with DCP.

COMMITTEE ACTION

Program Review and Investigations Committee

Joint Favorable Substitute
Yea 10 Nay 0