



Senate

General Assembly

File No. 158

February Session, 2006

Substitute Senate Bill No. 505

Senate, March 28, 2006

The Committee on General Law reported through SEN. COLAPIETRO of the 31st Dist., Chairperson of the Committee on the part of the Senate, that the substitute bill ought to pass.

AN ACT CONCERNING THE ESTABLISHMENT OF AN ELECTRONIC PRESCRIPTION DRUG MONITORING PROGRAM AND WORK GROUP.

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

1 Section 1. Section 21a-254 of the general statutes is repealed and the
2 following is substituted in lieu thereof (*Effective October 1, 2006*):

3 (a) The Commissioner of Consumer Protection, after investigation
4 and hearing, may by regulation designate certain substances as
5 restricted drugs or substances by reason of their exceptional danger to
6 health or exceptional potential for abuse so as to require written
7 records of receipt, use and dispensation, and may, after investigation
8 and hearing, remove the designation as restricted drugs or substances
9 from any substance so previously designated.

10 (b) Each physician, dentist, veterinarian or other person who is
11 authorized to administer or professionally use schedule I substances
12 shall keep a record of such schedule I substances received by him and

13 a record of all such schedule I substances administered, dispensed or
14 professionally used by him. The record of schedule I substances
15 received shall in each case show the date of receipt, the name and
16 address of the person from whom received and the kind and quantity
17 of schedule I substances received. The record of all schedule I
18 substances administered, dispensed or otherwise disposed of shall
19 show the date of administering or dispensing, the name and address of
20 the person to whom, or for whose use, or the owner and species of
21 animal for which, the substances were administered or dispensed and
22 the kind and quantity of substances.

23 (c) Practitioners obtaining and dispensing controlled substances
24 shall keep a record of all such controlled substances, received and
25 dispensed by them in accordance with the provisions of subsections (f)
26 and (h) of this section.

27 (d) Manufacturers and wholesalers shall keep records of all
28 controlled substances, compounded, mixed, cultivated or grown, or by
29 any other process produced or prepared, and of all controlled
30 substances received and disposed of by them in accordance with the
31 provisions of subsections (f) and (h) of this section.

32 (e) Pharmacies, hospitals, chronic and convalescent nursing homes,
33 rest homes with nursing supervision, clinics, infirmaries, free-standing
34 ambulatory surgical centers and laboratories shall keep records of all
35 controlled substances, received and disposed of by them in accordance
36 with the provisions of subsections (f) and (h) of this section, except that
37 hospitals and chronic and convalescent nursing homes using a unit
38 dose drug distribution system may instead keep such records in
39 accordance with the provisions of subsections (g) and (h) of this
40 section, and except that hospitals and free-standing ambulatory
41 surgical centers shall not be required to maintain separate disposition
42 records for schedule V controlled substances or records of
43 administering of individual doses for ultra-short-acting depressants,
44 including but not limited to, Methohexital, Thiamylal and Thiopental.

45 (f) The form of record to be kept under subsection (c), (d) or (e) of

46 this section shall in each case show the date of receipt, the name and
47 address of the person from whom received, and the kind and quantity
48 of controlled substances received, or, when applicable, the kind and
49 quantity of controlled substances produced or removed from process
50 of manufacture and the date of such production or removal from
51 process of manufacture; and the record shall in each case show the
52 proportion of controlled substances. The record of all controlled
53 substances sold, administered, dispensed or otherwise disposed of
54 shall show the date of selling, administering or dispensing, the name
55 of the person to whom or for whose use, or the owner and species of
56 animal for which, the substances were sold, administered or
57 dispensed, the address of such person or owner in the instance of
58 records of other than hospitals, chronic and convalescent nursing
59 homes, rest homes with nursing supervision and infirmaries, and the
60 kind and quantity of substances. In addition, hospital and infirmary
61 records shall show the time of administering or dispensing, the
62 prescribing physician and the nurse administering or dispensing the
63 substance. Each such record of controlled substances shall be
64 separately maintained apart from other drug records and kept for a
65 period of three years from the date of the transaction recorded.

66 (g) Hospitals using a unit dose drug distribution system shall
67 maintain a record noting all dispositions of controlled substances from
68 any area of the hospital to other hospital locations. Such record shall
69 include, but need not be limited to, the name, form, strength and
70 quantity of the drug dispensed, the date dispensed and the location
71 within the hospital to which the drug was dispensed. Such dispensing
72 record shall be separately maintained, apart from other drug or
73 business records, for a period of three years. Such hospital shall, in
74 addition, maintain for each patient a record which includes, but need
75 not be limited to, the full name of the patient and a complete
76 description of each dose of medication administered, including the
77 name, form, strength and quantity of the drug administered, the date
78 and time administered and identification of the nurse or practitioner
79 administering each drug dose. Entries for controlled substances shall
80 be specially marked in a manner which allows for ready identification.

81 Such records shall be filed in chronological order and kept for a period
82 of three years.

83 (h) A complete and accurate record of all stocks of controlled
84 substances on hand shall, on and after July 1, 1981, be prepared
85 biennially within four days of the first day of May of the calendar year,
86 except that a registrant may change this date provided the general
87 physical inventory date of such registrant is not more than six months
88 from the biennial inventory date, and kept on file for three years; and
89 shall be made available to the commissioner or his authorized agents.
90 The keeping of a record required by or under the federal Controlled
91 Substances Act, or federal food and drug laws, containing substantially
92 the same information as is specified above, shall constitute compliance
93 with this section, provided each record shall in addition contain a
94 detailed list of any controlled substances lost, destroyed or stolen, the
95 kind and quantity of such substances and the date of the discovery of
96 such loss, destruction or theft and provided such record shall be made
97 available to the commissioner or his authorized agents. All records
98 required by this chapter shall be kept on the premises of the registrant
99 and maintained current and separate from other business records in
100 such form as to be readily available for inspection by the authorized
101 agent at reasonable times. The use of a foreign language, codes or
102 symbols to designate controlled substances or persons in the keeping
103 of any required record is not deemed to be a compliance with this
104 chapter.

105 (i) Whenever any record is removed by a person authorized to
106 enforce the provisions of this chapter or the provisions of the state
107 food, drug and cosmetic laws for the purpose of investigation or as
108 evidence, such person shall tender a receipt in lieu thereof and the
109 receipt shall be kept for a period of three years.

110 (j) (1) The commissioner shall, within available appropriations,
111 establish an electronic prescription drug monitoring program to
112 collect, by electronic means, prescription information for schedules II,
113 III, IV and V controlled substances, as defined in subdivision (9) of

114 section 21a-240, that are dispensed by pharmacies and outpatient
115 pharmacies in hospitals or institutions. The program shall be designed
116 to provide information regarding the prescription of controlled
117 substances in order to prevent the improper or illegal use of the
118 controlled substances and shall not infringe on the legitimate
119 prescribing of a controlled substance by a prescribing practitioner
120 acting in good faith and in the course of professional practice.

121 (2) Each pharmacy and each outpatient pharmacy in a hospital or
122 institution shall report to the commissioner, at least twice monthly, by
123 electronic means or, if a pharmacy or outpatient pharmacy does not
124 maintain records electronically, in a format approved by the
125 commissioner, the following information for all controlled substance
126 prescriptions dispensed by such pharmacy or outpatient pharmacy:
127 (A) Dispenser identification number; (B) the date the prescription for
128 the controlled substance was filled; (C) the prescription number; (D)
129 whether the prescription for the controlled substance is new or a refill;
130 (E) the national drug code number for the drug dispensed; (F) the
131 amount of the controlled substance dispensed and the number of days'
132 supply of the controlled substance; (G) a patient identification number;
133 (H) the patient's first name, last name and street address, including
134 postal code; (I) the date of birth of the patient; (J) the date the
135 prescription for the controlled substance was issued by the prescribing
136 practitioner and the prescribing practitioner's Drug Enforcement
137 Agency's identification number; (K) the name of the person receiving
138 the controlled substance from the dispenser, if other than the patient;
139 (L) the type of payment for the controlled substance and the name of
140 the governmental program or health insurer paying for the controlled
141 substance, if applicable; and (M) the state issued serial number, if
142 applicable.

143 (3) The commissioner may contract with a vendor for purposes of
144 electronically collecting such controlled substance prescription
145 information. The commissioner and any such vendor shall maintain
146 the information in accordance with the provisions of chapter 400j.

147 (4) The commissioner and any such vendor shall not disclose
148 controlled substance prescription information reported pursuant to
149 subdivision (2) of this subsection, except as authorized pursuant to the
150 provisions of sections 21a-240 to 21a-283, inclusive. Any person who
151 knowingly violates any provision of this subdivision or subdivision (3)
152 of this subsection shall be guilty of a class D felony.

153 (5) The commissioner shall provide, upon request, controlled
154 substance prescription information obtained in accordance with
155 subdivision (2) of this subsection to the following: (A) The prescribing
156 practitioner who is treating or has treated a specific patient, provided
157 the information is obtained for purposes related to the treatment of the
158 patient, including the monitoring of controlled substances obtained by
159 the patient; (B) the prescribing practitioner with whom a patient has
160 made contact for the purpose of seeking medical treatment, provided
161 the request is accompanied by a written consent, signed by the
162 prospective patient, for the release of controlled substance prescription
163 information; or (C) the pharmacist who is dispensing controlled
164 substances for a patient, provided the information is obtained for
165 purposes related to the scope of the pharmacist's practice and
166 management of the patient's drug therapy, including the monitoring of
167 controlled substances obtained by the patient. The prescribing
168 practitioner or pharmacist shall submit a written and signed request to
169 the commissioner for controlled substance prescription information.
170 Such prescribing practitioner or pharmacist shall not disclose any such
171 request except as authorized pursuant to sections 20-570 to 20-630,
172 inclusive, or sections 21a-240 to 21a-283, inclusive.

173 (6) The commissioner shall adopt regulations, in accordance with
174 chapter 54, concerning the reporting, evaluation, management and
175 storage of electronic controlled substance prescription information.

176 Sec. 2. (NEW) (*Effective October 1, 2006*) The Commissioner of
177 Consumer Protection shall appoint a prescription drug monitoring
178 working group for the purpose of advising the commissioner on the
179 implementation of the electronic prescription drug monitoring

180 program established pursuant to section 21a-254 of the general
 181 statutes, as amended by this act, including the adoption of regulations
 182 by the commissioner. Such advice shall include, but not be limited to,
 183 recommendations on how to effectively use the data collected
 184 pursuant to such program to detect fraud while protecting the
 185 legitimate use of controlled substances. The working group shall
 186 include, but not be limited to: (1) A physician, licensed pursuant to
 187 chapter 370 of the general statutes, specializing in internal medicine;
 188 (2) a board certified oncologist; (3) a person licensed to perform
 189 advanced level nursing practice activities pursuant to subsection (b) of
 190 section 20-87a of the general statutes; (4) a representative from an acute
 191 care hospital licensed pursuant to chapter 368v of the general statutes;
 192 (5) a state police officer appointed in accordance with section 29-4 of
 193 the general statutes; (6) a municipal police chief; (7) a representative
 194 from the Division of Criminal Justice; (8) a representative from a
 195 hospice licensed by the Department of Public Health or certified
 196 pursuant to 42 USC 1395x; (9) a pain management specialist, as defined
 197 in section 38a-492i of the general statutes; (10) a pharmacist licensed
 198 pursuant to section 20-590, 20-591 or 20-592 of the general statutes; and
 199 (11) a representative from the Department of Mental Health and
 200 Addiction Services.

This act shall take effect as follows and shall amend the following sections:		
Section 1	October 1, 2006	21a-254
Sec. 2	October 1, 2006	New section

GL *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 07 \$	FY 08 \$
Consumer Protection, Dept.	GF - Cost	See Below	See Below
Criminal Justice, Div.	GF - Cost	Minimal	Minimal
Judicial Dept. (Probation); Correction, Dept.; Judicial Dept.	GF - Revenue Gain	Potential	Potential
Various	Various - Cost	Potential	Potential

Note: GF=General Fund

Municipal Impact: None

Explanation

The bill requires the commissioner of the Department of Consumer Protection (DCP) to establish an electronic prescription drug monitoring program to electronically collect prescription information of controlled substances.

The bill requires the commissioner to do this within available appropriations. It is anticipated that DCP will receive a federal grant from the Department of Justice’s Harold Rogers Prescription Drug Monitoring Program at an estimated amount of \$350,000 - \$500,000.¹ The grant program requires the recipient state to have legislation pending or in place that requires the submission of dispensing data to a centralized database and that such legislation authorize a state agency to implement and administer the program. If DCP does not receive the grant, the implementation of the bill will be delayed until they have adequate funding.

The bill also establishes a prescription drug monitoring working group and requires various state agencies and a municipal police chief

¹ In FY 05, the Harold Roger’s Prescription Drug Monitoring Program disbursed \$6.71 million in grants to 23 state agencies. The average amount of each grant was \$291,890.

to participate. The Division of Criminal Justice and the participating municipality could incur minimal costs resulting from participation that could be accommodated within budgeted resources.

The bill also makes it a crime, punishable by a fine of up to \$5,000 and/or up to five years' imprisonment, for any person to knowingly disclose controlled substance prescription information. To the extent that offenders are subject to incarceration or probation supervision in the community as a result of the bill, a potential cost to criminal justice agencies exists. On average, it costs the state \$2,150 to supervise an offender on probation in the community as compared to \$35,040 to incarcerate the offender (note that both figures include fringe benefits).

To the extent that the bill places a reporting burden on any state agency that owns a pharmacy, the reporting requirements in the bill could result in additional costs.

The Out Years

The annualized ongoing fiscal impact identified above would continue into the future subject to inflation.

OLR Bill Analysis
sSB 505

***AN ACT CONCERNING THE ESTABLISHMENT OF AN
ELECTRONIC PRESCRIPTION DRUG MONITORING PROGRAM
AND WORK GROUP.***

SUMMARY:

This bill requires the commissioner of the Department Consumer Protection (DCP), within available appropriations, to establish an electronic prescription drug monitoring program to collect prescription information from pharmacies about Schedules II, III, IV, and V controlled substances. It requires the program to be designed to provide information about the prescription of these substances to prevent their improper or illegal use. It prohibits the program from infringing on legitimate prescriptions of controlled substances made in good faith and in the course of professional practice.

The bill (1) sets requirements for information reporting, (2) makes the information confidential and establishes a mechanism allowing it to be reported, and (3) establishes a prescription drug monitoring working group and sets its duties.

The bill requires the commissioner to adopt regulations about the reporting, evaluation, management, and storage of electronic controlled substance prescription information.

EFFECTIVE DATE: October 1, 2006

REPORTING

The bill requires each pharmacy and outpatient pharmacy in a hospital or institution to report electronically at least twice monthly the following information for each dispensed controlled substance prescription:

1. dispenser identification number;
2. dispensing date;
3. prescription number;
4. whether it was a new or refilled prescription;
5. the national drug code number of the dispensed drug;
6. the amount dispensed and number of days' supply;
7. patient identification number;
8. patient's name, address, and date of birth;
9. date the prescription was issued and prescriber's Drug Enforcement Agency's identification number;
10. name of any individual other than the patient receiving the prescription from the dispenser;
11. type of payment and name of government program or insurer paying for the prescription; and
12. state-issued serial number, if any.

The bill allows pharmacies that do not keep records electronically to submit the reports in a format approved by the consumer protection commissioner.

CONFIDENTIALITY AND RELEASE OF REPORTED INFORMATION

The bill allows the commissioner to contract with a vendor to collect the information. It requires the commissioner and vendor to keep the information in accordance with the state's Pharmacy Practice Act. The bill prohibits the disclosure of collected information, except as specifically authorized. It makes a violator guilty of a class D felony, punishable by one to five years imprisonment, a fine of up to \$5,000, or both.

The bill requires the commissioner to release the information, on request, to the following:

1. a prescribing practitioner who is treating, or has treated, a specific patient, if the information is to be used in relation to the patient's treatment, including the monitoring of these drugs;
2. a prescribing practitioner contacted by a prospective patient seeking medical treatment, if the request is accompanied by the patient's signed, written consent; and
3. a pharmacist dispensing controlled substances for a patient, if the information is being sought for purposes related to the pharmacist's scope of practice and management of the patient's drug therapy, including the monitoring of these drugs.

The bill requires prescribing practitioners and pharmacists to request the information in writing and to sign their requests. They may not disclose the request except as authorized by the law on dependency-producing drugs and the Pharmacy Practice Act.

WORKING GROUP

The bill requires the DCP commissioner to appoint a prescription drug monitoring working group. The group must advise the commissioner on (1) program implementation, including adoption of regulations and (2) how to effectively use the data to detect fraud while protecting legitimate use of controlled substances.

The group must include:

1. an internal medicine specialist,
2. a board-certified oncologist,
3. an advanced practice registered nurse,
4. a representative from an acute care hospital,
5. a state police officer,

6. a local police chief,
7. a representative from the Division of Criminal Justice,
8. a representative from a hospice,
9. a pain management specialist,
10. a pharmacist, and
11. a representative from the Department of Mental Health and Addiction Services.

It may also include additional members.

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 in Schedules II through V; most Schedule I drugs do not have any approved medical use.

COMMITTEE ACTION

General Law Committee

Joint Favorable Substitute

Yea 15 Nay 0 (03/14/2006)