



## Senate

General Assembly

**File No. 147**

February Session, 2002

Substitute Senate Bill No. 187

*Senate, March 26, 2002*

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 ELECTRONIC MONITORING OF CONTROLLED SUBSTANCE PRESCRIPTIONS.**

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 Section 21a-254 of the general statutes is repealed and the  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, 2003*):

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]

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

81 identification. Such records shall be filed in chronological order and  
82 kept for a period 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] the  
90 commissioner's authorized agents. The keeping of a record required by  
91 or under the federal Controlled Substances Act, or federal food and  
92 drug laws, containing substantially the same information as is  
93 specified above, shall constitute compliance with this section, provided  
94 each record shall in addition contain a detailed list of any controlled  
95 substances lost, destroyed or stolen, the kind and quantity of such  
96 substances and the date of the discovery of such loss, destruction or  
97 theft and provided such record shall be made available to the  
98 commissioner or [his] the commissioner's authorized agents. All  
99 records required by this chapter shall be kept on the premises of the  
100 registrant and maintained current and separate from other business  
101 records in such form as to be readily available for inspection by the  
102 authorized agent at reasonable times. The use of a foreign language,  
103 codes or symbols to designate controlled substances or persons in the  
104 keeping of any required record is not deemed to be a compliance with  
105 this chapter.

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

111 (j) (1) The Commissioner of Consumer Protection shall implement a  
112 program to collect, by electronic means, prescription information for  
113 schedule II, III, IV and V controlled substances, as defined in

114 subdivision (9) of section 21a-240, that are dispensed by pharmacies  
115 and out-patient pharmacies in hospitals or institutions. The program  
116 shall be designed to provide information regarding the prescription of  
117 controlled substances in order to prevent the improper or illegal use of  
118 the 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 once monthly, by  
123 electronic means or, if a pharmacy does not maintain records  
124 electronically, in a format approved by the commissioner, the  
125 following information for all controlled substance prescriptions  
126 dispensed by such pharmacy or outpatient pharmacy: (A) The  
127 prescription number; (B) an indication of whether the prescription  
128 dispensed was a new prescription or a refill; (C) the date of dispensing;  
129 (D) if available in the system utilized by the pharmacy or outpatient  
130 pharmacy, the time of the dispensing of the prescription; (E) the name,  
131 address and date of birth or other designation of age of the person or  
132 animal for whom the prescription was dispensed; (F) the National  
133 Drug Code (NDC) of the controlled substance dispensed; (G) the  
134 quantity of the controlled substance dispensed; (H) the number of  
135 days' supply of the controlled substance dispensed; (I) the prescribing  
136 practitioner's federal Drug Enforcement Agency (DEA) registration  
137 number; and (J) the federal Drug Enforcement Agency (DEA) number  
138 of the pharmacy dispensing the controlled substance.

139 (3) Controlled substance prescription information reported to the  
140 commissioner pursuant to subdivision (2) of this subsection shall not  
141 be disclosed, except as authorized pursuant to the provisions of  
142 sections 21a-240 to 21a-283, inclusive, as amended. Nothing in this  
143 subsection shall be construed to prevent the commissioner from  
144 contracting with a vendor for purposes of electronically collecting such  
145 controlled substance prescription information, provided the  
146 information is maintained in a confidential manner by the vendor and  
147 is maintained in accordance with the general statutes.

148     (4) The commissioner shall provide, upon request, controlled  
 149     substance prescription information obtained in accordance with this  
 150     section to the following: (A) A prescribing practitioner who is treating  
 151     or has treated a specific patient, provided the information is obtained  
 152     for purposes related to the treatment of the patient, including the  
 153     monitoring of controlled substances obtained by the patient; (B) a  
 154     prescribing practitioner with whom a patient has made contact for the  
 155     purpose of seeking medical treatment, provided the request is  
 156     accompanied by a written consent, signed by the prospective patient,  
 157     for the release of controlled substance prescription information; (C) a  
 158     pharmacist who is dispensing controlled substances for a specific  
 159     patient, provided the information is obtained for purposes related to  
 160     the scope of the pharmacist's practice and management of the patient's  
 161     drug therapy, including the monitoring of controlled substances  
 162     obtained by the patient. A request for controlled substance  
 163     prescription information made by a prescribing practitioner or by a  
 164     pharmacist must be submitted to the commissioner in writing or by  
 165     facsimile transmission and must be signed by the prescribing  
 166     practitioner or the pharmacist making the request. Requests for  
 167     controlled substance prescription information made to the  
 168     commissioner pursuant to this section shall not be disclosed, except as  
 169     authorized pursuant to sections 21a-240 to 21a-283, inclusive, as  
 170     amended, or sections 20-570 to 20-630, inclusive, as amended.

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

This act shall take effect as follows:	
Section 1	October 1, 2003

**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:**

Fund-Type	Agency Affected	Current FY \$	FY 03 \$	FY 04 \$
GF - Cost	Consumer Protection, Dept.	-	-	up to 150,000

Note: GF=General Fund

**Municipal Impact:** None

**Explanation**

This bill requires the electronic submission of controlled substance prescriptions to the Commissioner of Consumer Protection in order to facilitate monitoring to prevent their improper or illegal use. It also requires the commissioner to adopt regulations concerning the reporting, evaluation, management, and storage of electronic substance information.

Currently, the Department of Consumer Protection’s Drug Control Agents have access to this information. However, the agents are required to go to the pharmacies in order to obtain the information. Since this bill requires the pharmacies to electronically transfer this information on a monthly basis, the department would need approximately \$150,000 on an on-going basis starting in FY 04 to purchase the necessary software to fully implement the program using an outside vendor.

It is anticipated that the commissioner will promulgate regulations within existing appropriations without the need for additional budgetary resources.

**OLR Bill Analysis**

sSB 187

**AN ACT CONCERNING ELECTRONIC MONITORING OF CONTROLLED SUBSTANCE PRESCRIPTIONS****SUMMARY:**

This bill requires the consumer protection commissioner to establish a program to collect prescription information about Schedule II, III, IV, and V controlled substances from pharmacies. 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 the legitimate prescribing of a controlled substance made in good faith and in the course of professional practice.

The bill (1) sets requirements for reporting; (2) makes reported prescription information non-disclosable except as authorized by the law on dependency-producing drugs, including this bill; and (3) requires the program to release reported information to certain prescribing practitioners and pharmacists.

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

EFFECTIVE DATE: October 1, 2003

**REPORTING**

The bill requires each pharmacy and outpatient pharmacy in a hospital or institution to report electronically at least once each month the following information for each dispensed controlled substance prescription: (1) prescription number; (2) whether the prescription was new or a refill; (3) prescription date; (4) time of dispensing the prescription, if the pharmacy's system makes this possible; (5) patient's name, address, and date of birth or other designation of age; (6) National Drug Code of the dispensed controlled substance; (7) the amount dispensed; (8) number of days supply; (9) prescribing

practitioner's federal Drug Enforcement Agency registration number; and (10) pharmacy's federal Drug Enforcement Agency number. The bill allows pharmacies that do not keep records electronically to submit the reports in a format approved by the consumer protection commissioner.

## **RELEASE OF REPORTED INFORMATION**

The bill requires the commissioner to provide controlled substance prescription 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 who has been contacted by a prospective patient seeking medical treatment, if the request is accompanied by the patient signed, written consent; and
3. a pharmacist who is dispensing controlled substances for a specific patient, if the information is being sought in relation to the pharmacist's scope of practice and management of the patient's drug therapy.

The bill requires information requests to be signed and written. It allows them to be sent by facsimile transmission. The bill makes such information requests non-disclosable, except as authorized under the law on dependency-producing drugs and the Pharmacy Practice Act. The bill provides that it may not be construed to prevent the consumer protection commissioner from contracting with a vendor to operate the electronic reporting system, if the vendor keeps the information confidential.

## **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.

## **COMMITTEE ACTION**

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General Law Committee

Joint Favorable Substitute

Yea 17    Nay 0