

**Representative Bradley M. Daw** proposes the following substitute bill:

**CONTROLLED SUBSTANCE DATABASE**

**AMENDMENTS**

2008 GENERAL SESSION

STATE OF UTAH

**Chief Sponsor: Bradley M. Daw**

**Senate Sponsor: Curtis S. Bramble**

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**LONG TITLE**

**General Description:**

This bill amends provisions of the Utah Controlled Substances Act relating to the controlled substance database and establishes a pilot program for real-time reporting of data to, and access from, the controlled substance database.

**Highlighted Provisions:**

This bill:

▶ defines terms;

**⚡→ ▶ provides for education of the public regarding the controlled substance database; ←⚡**

▶ makes it a third degree felony to obtain or attempt to obtain information from the controlled substances database for a purpose other than a purpose authorized by statute or rule;

▶ prohibits access to, and use of, identifying information in the controlled substance database, by discovery, subpoena, or similar process, in certain civil, judicial, administrative, or legislative proceedings;

▶ establishes a pilot program, beginning on July 1, 2008, and ending on July 1, 2010, for the real-time reporting of, and access to, controlled substance database

information by pharmacies, pharmaceutical facilities, and **⚡→ [physicians] prescribing practitioners ←⚡** ;

▶ grants rulemaking authority to the Division of Occupational and Professional



26 Licensing in relation to the pilot program;

27       ▶ requires the Division of Occupational and Professional Licensing to report on the  
28 pilot program and the advisability and cost of implementing the pilot program on a

29 statewide basis ~~H→~~ **and the use of the controlled substance database by prescribing**  
29a **practitioners** ~~←H~~ ;

30       ▶ requires the Division of Occupational and Professional Licensing to implement the  
31 pilot program established in this bill as a permanent program on a statewide basis,  
32 on or before July 1, 2010; and

33       ▶ makes technical changes.

#### 34 **Monies Appropriated in this Bill:**

35 This bill appropriates:

36       ▶ \$175,000 as an ongoing appropriation from the General Fund, for ~~H→~~ [the] ~~←H~~  
36a fiscal year

37 2008-09, to the Division of Occupational and Professional Licensing; and

38       ▶ \$650,000 from the General Fund, for ~~H→~~ [the] ~~←H~~ fiscal year 2008-09 only,  
38a to the Division of

39 Occupational and Professional Licensing, as nonlapsing funds.

#### 40 **Other Special Clauses:**

41 This bill takes effect on July 1, 2008.

#### 42 **Utah Code Sections Affected:**

43 AMENDS:

43a ~~H→~~ **26-1-36, as enacted by Laws of Utah 2007, Chapter 200** ~~←H~~

44 **58-37-7.5**, as last amended by Laws of Utah 2007, Chapter 293

45 ENACTS:

46 **58-37-7.8**, Utah Code Annotated 1953

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48 *Be it enacted by the Legislature of the state of Utah:*

48a ~~H→~~ **Section 1. Section 26-1-36 is amended to read:**

48b **26-1-36. Duty to establish program to reduce deaths and other harm from prescription opiates**  
48c **used for chronic noncancer pain.**

48d **(1) As used in this section, "opiate" means any drug or other substance having an**  
48e **addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion**  
48f **into a drug having addiction-forming or addiction-sustaining liability.**

48g **(2) In addition to the duties listed in Section 26-1-30, the department shall develop and**  
48h **implement a two-year program in coordination with the Division of Professional Licensing, the Utah**  
48i **Labor Commission, and the Utah attorney general, to:**

48j **(a) investigate the causes of and risk factors for death and nonfatal complications**

48k of prescription opiate use and misuse in Utah for chronic pain by utilizing the Utah Controlled  
48l Substance Database created in Section 58-37-7.5;

48m (b) study the risks, warning signs, and solutions to the risks associated with prescription opiate  
48n medications for chronic pain, including risks and prevention of misuse and diversion of those  
48o medications;

48p [and]

48q (c) provide education to health care providers, patients, insurers, and the general public on the  
48r appropriate management of chronic pain, including the effective use of medical treatment and quality  
48s care guidelines that are scientifically based and peer reviewed [-] ; and

48t (d) educate the public regarding:

48u (i) the purpose of the Controlled Substance Database established in Section 58-37-7.5; and

48v (ii) the requirement that a person's name and prescription information be recorded on the  
48w database when the person fills a prescription for a schedule II, III, IV, or V controlled substance.

48x (3) The department shall report on the development and implementation of the program  
48y required in Subsection (2) to the legislative Health and Human Services Interim Committee and the  
48z legislative Business and Labor Interim Committee no later than the November interim meetings in  
48aa ~~§~~ [2007 and] ~~←~~ 2008 ~~→~~ and 2009 ~~←~~ . Each report shall include:

48ab (a) recommendations on:

48ac (i) use of the Utah Controlled Substance Database created in Section 58-37-7.5 to identify  
48ad and prevent:

48ae (A) misuse of opiates;

48af (B) inappropriate prescribing; and

48ag (C) adverse outcomes of prescription opiate medications;

48ah (ii) interventions to prevent the diversion of prescription opiate medications; and

48ai (iii) medical treatment and quality care guidelines that are:

48aj (A) scientifically based; and

48ak (B) peer reviewed; and

48al (b) (i) a measure of results against expectations under the program as of the date of the  
48am report; and

48an (ii) an analysis of the application of the program, use of the appropriated funds, and the  
48ao impact and results of the use of the funds.

48ap (4) The report provided under Subsection (3) for the 2008 interim shall also provide a final  
48aq cumulative analysis of the measurable effectiveness of the program implemented under this  
48ar section. ~~←~~

49 Section ~~→~~ [1] 2 ~~←~~ . Section 58-37-7.5 is amended to read:

50 58-37-7.5. Controlled substance database -- Pharmacy reporting requirements --

51 Access -- Penalties.

52 (1) As used in this section:

53 (a) "Board" means the Utah State Board of Pharmacy created in Section 58-17b-201.

54            [~~(a)~~] (b) "Database" means the controlled substance database created in this section.  
55            [~~(b)~~] (c) "Database manager" means the person responsible for operating the database,  
56 or [~~his~~] the person's designee.

57           [~~(e)~~] (d) "Division" means the Division of Occupational and Professional Licensing  
58 created in Section 58-1-103.

59           [~~(d)~~] (e) "Health care facility" [~~has the same definition as~~] is as defined in Section  
60 26-21-2.

61           [~~(e)~~] (f) "Pharmacy" or "pharmaceutical facility" [~~has the same definition as~~] is as  
62 defined in Section 58-17b-102.

63           (2) (a) There is created within the division a controlled substance database.

64           (b) The division shall administer and direct the functioning of the database in  
65 accordance with this section. The division may under state procurement laws contract with  
66 another state agency or private entity to establish, operate, or maintain the database. The  
67 division in collaboration with the board shall determine whether to operate the database within  
68 the division or contract with another entity to operate the database, based on an analysis of  
69 costs and benefits.

70           (c) The purpose of the database is to contain data as described in this section regarding  
71 every prescription for a controlled substance dispensed in the state to any person other than an  
72 inpatient in a licensed health care facility.

73           (d) Data required by this section shall be submitted in compliance with this section to  
74 the manager of the database by the pharmacist in charge of the drug outlet where the controlled  
75 substance is dispensed.

76           (3) The [~~Utah State Board of Pharmacy created in Section 58-17b-201~~] board shall  
77 advise the division regarding:

78           (a) establishing, maintaining, and operating the database;

79           (b) access to the database and how access is obtained; and

80           (c) control of information contained in the database.

81           (4) The pharmacist in charge shall, regarding each controlled substance dispensed by a  
82 pharmacist under [~~his~~] the pharmacist's supervision other than those dispensed for an inpatient  
83 at a health care facility, submit to the manager of the database the following information, by a  
84 procedure and in a format established by the division:

85           (a) name of the prescribing practitioner;

86           (b) date of the prescription;

87           (c) date the prescription was filled;

- 88 (d) name of the person for whom the prescription was written;
- 89 (e) positive identification of the person receiving the prescription, including the type of  
90 identification and any identifying numbers on the identification;
- 91 (f) name of the controlled substance;
- 92 (g) quantity of controlled substance prescribed;
- 93 (h) strength of controlled substance;
- 94 (i) quantity of controlled substance dispensed;
- 95 (j) dosage quantity and frequency as prescribed;
- 96 (k) name of drug outlet dispensing the controlled substance;
- 97 (l) name of pharmacist dispensing the controlled substance; and
- 98 (m) other relevant information as required by division rule.
- 99 (5) The division shall maintain the database in an electronic file or by other means  
100 established by the division to facilitate use of the database for identification of:
  - 101 (a) prescribing practices and patterns of prescribing and dispensing controlled  
102 substances;
  - 103 (b) practitioners prescribing controlled substances in an unprofessional or unlawful  
104 manner;
  - 105 (c) individuals receiving prescriptions for controlled substances from licensed  
106 practitioners, and who subsequently obtain dispensed controlled substances from a drug outlet  
107 in quantities or with a frequency inconsistent with generally recognized standards of dosage for  
108 that controlled substance; and
  - 109 (d) individuals presenting forged or otherwise false or altered prescriptions for  
110 controlled substances to a pharmacy.
- 111 (6) (a) The division shall by rule establish the electronic format in which the  
112 information required under this section shall be submitted to the administrator of the database.
- 113 (b) The division shall ensure the database system records and maintains for reference:
  - 114 (i) identification of each person who requests or receives information from the  
115 database;
  - 116 (ii) the information provided to each person; and
  - 117 (iii) the date and time the information is requested or provided.
- 118 (7) The division shall make rules to:

- 119 (a) effectively enforce the limitations on access to the database as described in  
120 Subsection (8); and
- 121 (b) establish standards and procedures to ensure accurate identification of individuals  
122 requesting information or receiving information without request from the database.
- 123 (8) The manager of the database shall make information in the database available only  
124 to the following persons, and in accordance with the limitations stated and division rules:
- 125 (a) personnel of the division specifically assigned to conduct investigations related to  
126 controlled substances laws under the jurisdiction of the division;
- 127 (b) authorized division personnel engaged in analysis of controlled substance  
128 prescription information as a part of the assigned duties and responsibilities of their  
129 employment;
- 130 (c) employees of the Department of Health whom the director of the Department of  
131 Health assigns to conduct scientific studies regarding the use or abuse of controlled substances,  
132 provided that the identity of the individuals and pharmacies in the database are confidential and  
133 are not disclosed in any manner to any individual who is not directly involved in the scientific  
134 studies;
- 135 (d) a licensed practitioner having authority to prescribe controlled substances, to the  
136 extent:
- 137 (i) the information relates specifically to a current patient of the practitioner, to whom  
138 the practitioner is prescribing or considering prescribing any controlled substance;
- 139 (ii) the information relates specifically to an individual who has access to the  
140 practitioner's Drug Enforcement Administration number, and the practitioner suspects that the  
141 individual may have used the practitioner's Drug Enforcement Administration identification  
142 number to fraudulently acquire or prescribe controlled substances; or
- 143 (iii) the information relates to the practitioner's own prescribing practices, except when  
144 specifically prohibited by the division by administrative rule;
- 145 (e) a licensed pharmacist having authority to dispense controlled substances to the  
146 extent the information relates specifically to a current patient to whom that pharmacist is  
147 dispensing or considering dispensing any controlled substance;
- 148 (f) federal, state, and local law enforcement authorities, and state and local prosecutors,  
149 engaged as a specified duty of their employment in enforcing laws:

150 (i) regulating controlled substances; or  
151 (ii) investigating insurance fraud, Medicaid fraud, or Medicare fraud; and  
152 (g) an individual who is the recipient of a controlled substance prescription entered into  
153 the database, upon providing evidence satisfactory to the database manager that the individual  
154 requesting the information is in fact the person about whom the data entry was made.

155 (9) Any person who knowingly and intentionally releases any information in the  
156 database in violation of the limitations under Subsection (8) is guilty of a third degree felony.

157 (10) (a) Any person who obtains or attempts to obtain information from the database  
158 by misrepresentation or fraud is guilty of a third degree felony.

159 (b) Any person who obtains or attempts to obtain information from the database for a  
160 purpose other than a purpose authorized by this section or by rule is guilty of a third degree  
161 felony.

162 (11) (a) A person may not knowingly and intentionally use, release, publish, or  
163 otherwise make available to any other person or entity any information obtained from the  
164 database for any purpose other than those specified in Subsection (8). Each separate violation  
165 of this Subsection (11) is a third degree felony and is also subject to a civil penalty not to  
166 exceed \$5,000.

167 (b) The procedure for determining a civil violation of this Subsection (11) shall be in  
168 accordance with Section 58-1-108, regarding adjudicative proceedings within the division.

169 (c) Civil penalties assessed under this Subsection (11) shall be deposited in the General  
170 Fund as a dedicated credit to be used by the division under Subsection 58-37-7.7(1).

171 (12) (a) The failure of a pharmacist in charge to submit information to the database as  
172 required under this section after the division has submitted a specific written request for the  
173 information or when the division determines the individual has a demonstrable pattern of  
174 failing to submit the information as required is grounds for the division to take the following  
175 actions in accordance with Section 58-1-401:

- 176 (i) refuse to issue a license to the individual;
- 177 (ii) refuse to renew the individual's license;
- 178 (iii) revoke, suspend, restrict, or place on probation the license;
- 179 (iv) issue a public or private reprimand to the individual;
- 180 (v) issue a cease and desist order; and



181 (vi) impose a civil penalty of not more than \$1,000 for each dispensed prescription  
 182 regarding which the required information is not submitted.

183 (b) Civil penalties assessed under Subsection (12)(a)(vi) shall be deposited in the  
 184 General Fund as a dedicated credit to be used by the division under Subsection 58-37-7.7(1).

185 (c) The procedure for determining a civil violation of this Subsection (12) shall be in  
 186 accordance with Section 58-1-108, regarding adjudicative proceedings within the division.

187 (13) An individual who has submitted information to the database in accordance with  
 188 this section may not be held civilly liable for having submitted the information.

189 (14) All department and the division costs necessary to establish and operate the  
 190 database shall be funded by appropriations from:

191 (a) the Commerce Service Fund; and

192 (b) the General Fund.

193 (15) All costs associated with recording and submitting data as required in this section  
 194 shall be assumed by the submitting pharmacy.

195 (16) (a) Except as provided in Subsection (16)(b), data provided to, maintained in, or  
 196 accessed from the database that may be identified to, or with, a particular person is not subject  
 197 to discovery, subpoena, or similar compulsory process in any civil, judicial, administrative, or  
 198 legislative proceeding, nor shall any individual or organization with lawful access to the data  
 199 be compelled to testify with regard to the data.

200 (b) The restrictions in Subsection (16)(a) do not apply to:

201 (i) a criminal proceeding; or

202 (ii) a civil, judicial, or administrative action brought to enforce the provisions of this  
 203 section, Section 58-37-7.7, or Section 58-37-7.8.

204 Section ~~H~~→ [2] 3 ←~~H~~ . Section 58-37-7.8 is enacted to read:

205 **58-37-7.8. Pilot program for ~~H~~→ [real-time] real-time ←~~H~~ reporting for controlled**  
 205a **substance database**

206 **-- Statewide implementation.**

207 (1) (a) As used in this section:

208 (i) "Pilot area" means the areas of the state that the division determines to operate the  
 209 pilot program in, under Subsection (3), which may include:

210 (A) the entire state; or

211 (B) geographical areas within the state.

212 (ii) "Pilot program" means the pilot program described in this section.

213 (b) The definitions in Subsection 58-37-7.5(1) apply to this section.

214 (2) There is established a pilot program for real-time reporting of data to, and access to  
215 data from, the database by a pharmacy, a pharmaceutical facility, or a ~~H~~→ [physician] prescribing  
215a practitioner ←~~H~~ beginning on  
216 July 1, 2008, and ending on July 1, 2010.

217 (3) In addition to fulfilling the requirements of Sections 58-37-7.5 and 58-37-7.7 on a  
218 statewide basis, the division shall, in accordance with Subsection (4), upgrade, administer, and  
219 direct the functioning of the database in geographical areas specified by the division, or on a  
220 statewide basis, in a manner that provides for real-time reporting of information entered into,  
221 and accessed from, the database by a pharmacy or pharmaceutical facility.

222 (4) The division shall, under state procurement laws, and with the technical assistance  
223 of the Department of Technology Services, contract with a private entity to upgrade, operate,  
224 and maintain the database in the pilot area.

225 (5) (a) All provisions and requirements of the ~~H~~→ [state-wide] statewide ←~~H~~ database,  
225a described in  
226 Sections 58-37-7.5 and 58-37-7.7, are applicable to the database in the pilot area, to the extent  
227 that they do not conflict with the requirements of this section.

228 (b) For purposes of Section 58-37-7.5, Section 58-37-7.7, and this section, the database  
229 in the pilot area is considered part of the statewide database.

230 (6) A pharmacy or pharmaceutical facility shall cooperate with the division, or the  
231 division's designee, to provide real-time submission of, and access to, information for the  
232 database:

233 (a) in the pilot area; and

234 (b) when the division implements the pilot program as a permanent program under  
235 Subsection (10), on a statewide basis.

236 (7) The penalties and enforcement provisions described in Sections 58-37-7.5 and  
237 58-37-7.7 apply to enforce the provisions of this section in relation to a pharmacy or  
238 pharmaceutical facility that is located in, or operates in, the pilot area.

239 (8) The division may make rules, in accordance with Title 63, Chapter 46a, Utah  
240 Administrative Rulemaking Act, to provide for the real-time reporting of, and access to,  
241 information in accordance with the requirements of this section.

242 (9) During the Legislature's 2009 interim, the division shall report to the Health and

243 Human Services Interim Committee regarding:

244 (a) the implementation, operation, and impact of the pilot program established in this  
245 section:

246 (b) the progress made by the division in implementing the pilot program on a statewide  
247 basis; ~~H~~→ [and] ←~~H~~

248 (c) the advisability of, and projected costs of, implementing the pilot program on a  
249 statewide basis ~~H~~→ [;] ; and

249a (d) **the use of the database by prescribing practitioners.** ←~~H~~

250 (10) The division shall, on or before July 1, 2010, implement the pilot program as a  
251 permanent program on a statewide basis.

252 (11) (a) The division shall, through the private entity contracted with under Subsection  
253 (4), provide, free of charge, to a pharmacy or pharmaceutical facility that is required to comply  
254 with Subsection (6), software, software installation assistance, and training, that will enable the  
255 pharmacy or pharmaceutical facility to comply with Subsection (6).

256 (b) Notwithstanding Subsection (11)(a), a pharmacy or pharmaceutical facility required  
257 to comply with Subsection (6) may, instead of accepting installation of the software provided  
258 by the division under Subsection (11)(a), modify its own software in order to comply with the  
259 requirements of Subsection (6), if the modification is made:

260 (i) ~~H~~→ **except as provided in Subsection (11)(d),** ←~~H~~ at the expense of the pharmacy or  
260a pharmaceutical facility;

261 (ii) in consultation with the division; and

262 (iii) within six months after the division notifies the pharmacy or pharmaceutical  
263 facility, in writing, of the division's intention to install the software described in Subsection  
264 (11)(a).

265 (c) The division shall, through the private entity contracted with under Subsection (4),  
266 cooperate with a pharmacy or pharmaceutical facility that is required to comply with  
267 Subsection (6), to ensure that the installation and operation of the software described in  
268 Subsection (11)(a), or the provision of information from the pharmacy or pharmaceutical  
269 facility to the database:

270 (i) ~~H~~→ [~~is secure~~] **complies with the security standards described in 45 CFR Parts 160,**  
270a **162, and 164, Health Insurance Reform: Security Standards** [;and] ←~~H~~

271 (ii) does not interfere with the proper functioning of the pharmacy's or pharmaceutical  
272 facility's software or computer system ~~H~~→ [;] ; and

272a (iii) **in order to minimize changes in existing protocols, provides, to the extent**  
272b **practicable, for the transmission of data in the same manner that pharmacies currently**  
272c **transmit information to insurance companies.**

272d (d) **The division may, within funds appropriated by the Legislature for this**

272e purpose, reimburse a pharmacy for all or part of the costs of the in-house programing  
 272f described in Subsection (11)(b), if:

272g (i) the pharmacy requests the reimbursement, in writing;

272h (ii) the pharmacy provides proof of the costs for the in-house programming to  
 272i the division;

272j (iii) the pharmacy requests the reimbursement prior to a deadline established by  
 272k the division; and

272l (iv) except as provided in Subsection (11)(e), the division pays an equal  
 272m reimbursement amount to each pharmacy that complies with Subsections (11)(d)(i)  
 272n through (iii).

272o (e) The division may reimburse a pharmacy described in Subsection (11)(d)(iv)  
 272p for an amount that is less than the reimbursement paid to other pharmacies described in  
 272q Subsection (11)(d)(iv), if:

272r (i) the proof of costs for in-house programming provided by the pharmacy  
 272s establishes a cost less than the amount reimbursed to the other pharmacies; and

272t (ii) the amount reimbursed to the pharmacy is equal to the the amount established  
 272u by the proof of costs for in-house programming submitted by the pharmacy. ←Ĥ

272v Ŧ→ (f) Notwithstanding any other provision of this section, the division may, by rule, allow up  
 272w to 24 hours for the reporting of data to the database by a non-resident pharmacy, as defined in  
 272x Section 58-17b-102. ←Ŧ

273 Section Ĥ→ [3] 4 ←Ĥ . Appropriation.

274           ~~H~~→ (1) ←~~H~~ There is appropriated:  
 275           ~~H~~→ [~~1~~] (a) ←~~H~~ as an ongoing appropriation, subject to future budget constraints,  
 275a       \$175,000 from  
 276       the General Fund for the fiscal year 2008-09, to the Division of Occupational and Professional  
 277       Licensing to maintain and operate the controlled substance database; and  
 278           ~~H~~→ [~~2~~] (b) ←~~H~~ \$650,000 from the General Fund, for the fiscal year 2008-09 only,  
 278a       to the Division  
 279       of Occupational and Professional Licensing to ~~H~~→ ;  
 279a               (i) ←~~H~~ implement and operate the pilot program  
 280       described in this bill ~~H~~→ ; and  
 280a               (ii)   **if any of the funds described in this Subsection (1)(b) are available after**  
 280b       **paying the costs to implement and operate the pilot program under Subsection (1)(b)(i),**  
 280c       **reimburse a pharmacy for the costs of in-house programming, in accordance with Subsection**  
 280d       **58-37-7.8(11)(d) ←~~H~~ .**  
 281           ~~H~~→ [~~3~~] (2) ←~~H~~ The \$650,000 appropriated from the General Fund, under Subsection (2),  
 281a       shall be  
 282       nonlapsing.  
 283           Section 4. **Effective date.**  
 284           This bill takes effect on July 1, 2008.

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**H.B. 119 1st Sub. (Buff) - Controlled Substance Database Amendments**

**Fiscal Note**

2008 General Session  
State of Utah

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**State Impact**

Enactment of this bill appropriates \$650,000 one-time and \$175,000 ongoing from the General Fund to develop a real time controlled substance database on a statewide basis.

	<u>FY 2008</u> <u>Approp.</u>	<u>FY 2009</u> <u>Approp.</u>	<u>FY 2010</u> <u>Approp.</u>	<u>FY 2008</u> <u>Revenue</u>	<u>FY 2009</u> <u>Revenue</u>	<u>FY 2010</u> <u>Revenue</u>
General Fund	\$0	\$175,000	\$175,000	\$0	\$0	\$0
General Fund, One-Time	\$0	\$650,000	\$0	\$0	\$0	\$0
<b>Total</b>	<b>\$0</b>	<b>\$825,000</b>	<b>\$175,000</b>	<b>\$0</b>	<b>\$0</b>	<b>\$0</b>

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**Individual, Business and/or Local Impact**

Enactment of this bill likely will not result in direct, measurable costs and/or benefits for individuals or local governments. Some businesses may be affected due to increased requirements for software and computer hardware