

Senator Howard A. Stephenson proposes the following substitute bill:

CONTROLLED SUBSTANCE AMENDMENTS

2008 GENERAL SESSION

STATE OF UTAH

Chief Sponsor: Bradley M. Daw

Senate Sponsor: Curtis S. Bramble

Cosponsors:	David Litvack	Phil Riesen
Greg J. Curtis	Rebecca D. Lockhart	Stephen E. Sandstrom
John Dougall	Paul Ray	Stephen H. Urquhart
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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. This bill also requires reporting regarding hospital admissions for drug overdoses.

Highlighted Provisions:

This bill:

- ▶ makes admission to a hospital for drug overdose a reportable event to the Department of Health in the same manner that communicable diseases and trauma are reported;
- ▶ specifies how the Department of Health may use the collected data;
- ▶ adds to the duties of the Department of Health's program to reduce deaths and harm from substance abuse;
- ▶ defines terms;
- ▶ provides for education of the public regarding the controlled substance database;



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

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

33 ▶ establishes a pilot program, beginning on July 1, 2008, and ending on July 1, 2010,
34 for the real-time reporting of, and access to, controlled substance database
35 information by pharmacies, pharmaceutical facilities, and prescribing practitioners;

36 ▶ grants rulemaking authority to the Division of Occupational and Professional
37 Licensing in relation to the pilot program;

38 ▶ requires the Division of Occupational and Professional Licensing to report on the
39 pilot program and the advisability and cost of implementing the pilot program on a
40 statewide basis and the use of the controlled substance database by prescribing
41 practitioners;

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

45 ▶ makes technical changes.

46 **Monies Appropriated in this Bill:**

47 This bill appropriates:

48 ▶ \$175,000 as an ongoing appropriation from the General Fund, for fiscal year 2008-
49 09, to the Division of Occupational and Professional Licensing; and

50 ▶ \$650,000 from the General Fund, for fiscal year 2008-09 only, to the Division of
51 Occupational and Professional Licensing, as nonlapsing funds.

52 **Other Special Clauses:**

53 This bill takes effect on July 1, 2008.

54 **Utah Code Sections Affected:**

55 AMENDS:

56 **26-1-36**, as enacted by Laws of Utah 2007, Chapter 200

57 **26-7-1**, as enacted by Laws of Utah 1981, Chapter 126

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

59 ENACTS:

60 26-7-4, Utah Code Annotated 1953

61 58-37-7.8, Utah Code Annotated 1953



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

64 Section 1. Section 26-1-36 is amended to read:

65 **26-1-36. Duty to establish program to reduce deaths and other harm from**
66 **prescription opiates used for chronic noncancer pain.**

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

70 (2) In addition to the duties listed in Section 26-1-30, the department shall develop and
71 implement a [~~two-year~~] three-year program in coordination with the Division of Professional
72 Licensing, the Utah Labor Commission, and the Utah attorney general, to:

73 (a) investigate the causes of and risk factors for death and nonfatal complications of
74 prescription opiate use and misuse in Utah for chronic pain by utilizing the Utah Controlled
75 Substance Database created in Section 58-37-7.5;

76 (b) study the risks, warning signs, and solutions to the risks associated with
77 prescription opiate medications for chronic pain, including risks and prevention of misuse and
78 diversion of those medications; [~~and~~]

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

82 (d) educate the public regarding:

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

84 and

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

88 (3) The department shall report on the development and implementation of the

89 program required in Subsection (2) to the legislative Health and Human Services Interim
 90 Committee and the legislative Business and Labor Interim Committee no later than the
 91 November interim meetings in 2007 [~~and~~], 2008, and 2009. Each report shall include:

92 (a) recommendations on:

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

95 (A) misuse of opiates;

96 (B) inappropriate prescribing; and

97 (C) adverse outcomes of prescription opiate medications;

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

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

100 (A) scientifically based; and

101 (B) peer reviewed; and

102 (b) (i) a measure of results against expectations under the program as of the date of the
 103 report; and

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

106 (4) The report provided under Subsection (3) for the 2008 and 2009 interim shall also:

107 (a) assess the effectiveness of the data collected under Section 26-7-4;

108 (b) evaluate the impact of the department and the Division of Occupational and
 109 Professional Licensing efforts to educate health care providers on effective prescribing
 110 practices for controlled substances; and

111 (c) provide a final cumulative analysis of the measurable effectiveness of the program
 112 implemented under this section.

113 Section 2. Section **26-7-1** is amended to read:

114 **26-7-1. Identification of major risk factors by department -- Education of public**
 115 **-- Establishment of programs.**

116 (1) The department shall identify the major risk factors contributing to injury, sickness,
 117 death, and disability within the state and where it determines that a need exists, educate the
 118 public regarding these risk factors[~~, and the~~].

119 (2) (a) The department may establish programs to reduce or eliminate [~~these factors~~

120 ~~except that such programs shall not be] the risk factors identified under Subsection (1), unless~~
121 ~~the private sector has established [if] adequate programs [exist in the private sector].~~

122 (b) The department shall establish a program under Section 26-7-4 and Section 26-1-36
123 for the education and prevention of substance abuse in the state.

124 Section 3. Section **26-7-4** is enacted to read:

125 **26-7-4. Duty to report an individual admitted to a hospital for an overdose of a**
126 **controlled substance - department duties.**

127 (1) Beginning October 1, 2008, a health care provider who admits an individual into a
128 hospital for an accidental or intentional drug overdose shall:

129 (a) report to the department, in accordance with Subsection (4):

130 (i) the patient's name;

131 (ii) whether the drug overdose appears to be accidental or intentional;

132 (iii) the drug found in the patient's system; and

133 (iv) the name of the prescribing practitioner if known; and

134 (b) send notice to the prescribing practitioner, if known, which informs the practitioner
135 that the prescribing practitioner's patient was admitted to the hospital for a drug overdose.

136 (2) (a) Data collected under this section shall be subject to Chapter 3, Health Statistics.

137 (b) The department shall use the data collected to:

138 (i) carry out its duties under Section 26-1-36;

139 (ii) in conjunction with the Division of Occupational and Professional Licensing, as an
140 ongoing effort:

141 (A) to develop practice guidelines for the appropriate use and prescribing of opiates
142 and controlled substances; and

143 (B) to identify practitioners who may need additional assistance or training in
144 appropriate prescribing practices for opiates and controlled substances; and

145 (iii) assess and evaluate the effectiveness of efforts to decrease the incidence of
146 substance abuse in the state.

147 (3) No person may be held civilly liable for having provided data to the department in
148 accordance with this section.

149 (4) The department shall, by administrative rule, establish:

150 (a) the data elements subject to reporting under this section;

151 (b) the medical care providers that must report under this section; and

152 (c) the time frame and format for reporting under this section.

153 Section 4. Section **58-37-7.5** is amended to read:

154 **58-37-7.5. Controlled substance database -- Pharmacy reporting requirements --**

155 **Access -- Penalties.**

156 (1) As used in this section:

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

158 [~~(a)~~] (b) "Database" means the controlled substance database created in this section.

159 [~~(b)~~] (c) "Database manager" means the person responsible for operating the database,
160 or [~~his~~] the person's designee.

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

163 [~~(d)~~] (e) "Health care facility" [~~has the same definition as~~] is as defined in Section
164 26-21-2.

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

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

168 (b) The division shall administer and direct the functioning of the database in
169 accordance with this section. The division may under state procurement laws contract with
170 another state agency or private entity to establish, operate, or maintain the database. The
171 division in collaboration with the board shall determine whether to operate the database within
172 the division or contract with another entity to operate the database, based on an analysis of
173 costs and benefits.

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

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

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

- 182 (a) establishing, maintaining, and operating the database;
- 183 (b) access to the database and how access is obtained; and
- 184 (c) control of information contained in the database.

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

- 189 (a) name of the prescribing practitioner;
- 190 (b) date of the prescription;
- 191 (c) date the prescription was filled;
- 192 (d) name of the person for whom the prescription was written;
- 193 (e) positive identification of the person receiving the prescription, including the type of
194 identification and any identifying numbers on the identification;
- 195 (f) name of the controlled substance;
- 196 (g) quantity of controlled substance prescribed;
- 197 (h) strength of controlled substance;
- 198 (i) quantity of controlled substance dispensed;
- 199 (j) dosage quantity and frequency as prescribed;
- 200 (k) name of drug outlet dispensing the controlled substance;
- 201 (l) name of pharmacist dispensing the controlled substance; and
- 202 (m) other relevant information as required by division rule.

203 (5) The division shall maintain the database in an electronic file or by other means
204 established by the division to facilitate use of the database for identification of:

- 205 (a) prescribing practices and patterns of prescribing and dispensing controlled
206 substances;
- 207 (b) practitioners prescribing controlled substances in an unprofessional or unlawful
208 manner;
- 209 (c) individuals receiving prescriptions for controlled substances from licensed
210 practitioners, and who subsequently obtain dispensed controlled substances from a drug outlet
211 in quantities or with a frequency inconsistent with generally recognized standards of dosage for
212 that controlled substance; and

213 (d) individuals presenting forged or otherwise false or altered prescriptions for
214 controlled substances to a pharmacy.

215 (6) (a) The division shall by rule establish the electronic format in which the
216 information required under this section shall be submitted to the administrator of the database.

217 (b) The division shall ensure the database system records and maintains for reference:

218 (i) identification of each person who requests or receives information from the
219 database;

220 (ii) the information provided to each person; and

221 (iii) the date and time the information is requested or provided.

222 (7) The division shall make rules to:

223 (a) effectively enforce the limitations on access to the database as described in
224 Subsection (8); and

225 (b) establish standards and procedures to ensure accurate identification of individuals
226 requesting information or receiving information without request from the database.

227 (8) The manager of the database shall make information in the database available only
228 to the following persons, and in accordance with the limitations stated and division rules:

229 (a) personnel of the division specifically assigned to conduct investigations related to
230 controlled substances laws under the jurisdiction of the division;

231 (b) authorized division personnel engaged in analysis of controlled substance
232 prescription information as a part of the assigned duties and responsibilities of their
233 employment;

234 (c) employees of the Department of Health whom the director of the Department of
235 Health assigns to conduct scientific studies regarding the use or abuse of controlled substances,
236 provided that the identity of the individuals and pharmacies in the database are confidential and
237 are not disclosed in any manner to any individual who is not directly involved in the scientific
238 studies;

239 (d) a licensed practitioner having authority to prescribe controlled substances, to the
240 extent:

241 (i) the information relates specifically to a current patient of the practitioner, to whom
242 the practitioner is prescribing or considering prescribing any controlled substance;

243 (ii) the information relates specifically to an individual who has access to the

244 practitioner's Drug Enforcement Administration number, and the practitioner suspects that the
245 individual may have used the practitioner's Drug Enforcement Administration identification
246 number to fraudulently acquire or prescribe controlled substances; or

247 (iii) the information relates to the practitioner's own prescribing practices, except when
248 specifically prohibited by the division by administrative rule;

249 (e) a licensed pharmacist having authority to dispense controlled substances to the
250 extent the information relates specifically to a current patient to whom that pharmacist is
251 dispensing or considering dispensing any controlled substance;

252 (f) federal, state, and local law enforcement authorities, and state and local prosecutors,
253 engaged as a specified duty of their employment in enforcing laws:

254 (i) regulating controlled substances; or

255 (ii) investigating insurance fraud, Medicaid fraud, or Medicare fraud; and

256 (g) an individual who is the recipient of a controlled substance prescription entered into
257 the database, upon providing evidence satisfactory to the database manager that the individual
258 requesting the information is in fact the person about whom the data entry was made.

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

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

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

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

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

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

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

- 280 (i) refuse to issue a license to the individual;
- 281 (ii) refuse to renew the individual's license;
- 282 (iii) revoke, suspend, restrict, or place on probation the license;
- 283 (iv) issue a public or private reprimand to the individual;
- 284 (v) issue a cease and desist order; and
- 285 (vi) impose a civil penalty of not more than \$1,000 for each dispensed prescription
286 regarding which the required information is not submitted.

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

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

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

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

- 295 (a) the Commerce Service Fund; and
- 296 (b) the General Fund.

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

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

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

- 305 (i) a criminal proceeding; or

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

308 Section 5. Section **58-37-7.8** is enacted to read:

309 **58-37-7.8. Pilot program for real-time reporting for controlled substance database**
310 **-- Statewide implementation.**

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

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

314 (A) the entire state; or

315 (B) geographical areas within the state.

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

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

318 (2) There is established a pilot program for real-time reporting of data to, and access to
319 data from, the database by a pharmacy, a pharmaceutical facility, or a prescribing practitioner
320 beginning on July 1, 2008, and ending on July 1, 2010.

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

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

329 (5) (a) All provisions and requirements of the statewide database, described in Sections
330 58-37-7.5 and 58-37-7.7, are applicable to the database in the pilot area, to the extent that they
331 do not conflict with the requirements of this section.

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

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

337 (a) in the pilot area; and
338 (b) when the division implements the pilot program as a permanent program under
339 Subsection (10), on a statewide basis.

340 (7) The penalties and enforcement provisions described in Sections 58-37-7.5 and
341 58-37-7.7 apply to enforce the provisions of this section in relation to a pharmacy or
342 pharmaceutical facility that is located in, or operates in, the pilot area.

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

346 (9) During the Legislature's 2009 interim, the division shall report to the Health and
347 Human Services Interim Committee regarding:

348 (a) the implementation, operation, and impact of the pilot program established in this
349 section;

350 (b) the progress made by the division in implementing the pilot program on a statewide
351 basis;

352 (c) the advisability of, and projected costs of, implementing the pilot program on a
353 statewide basis; and

354 (d) the use of the database by prescribing practitioners.

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

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

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

365 (i) except as provided in Subsection (11)(d), at the expense of the pharmacy or
366 pharmaceutical facility;

367 (ii) in consultation with the division; and

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

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

376 (i) complies with the security standards described in 45 CFR Parts 160, 162, and 164,
377 Health Insurance Reform: Security Standards;

378 (ii) does not interfere with the proper functioning of the pharmacy's or pharmaceutical
379 facility's software or computer system; and

380 (iii) in order to minimize changes in existing protocols, provides, to the extent
381 practicable, for the transmission of data in the same manner that pharmacies currently transmit
382 information to insurance companies.

383 (d) The division may, within funds appropriated by the Legislature for this purpose,
384 reimburse a pharmacy for all or part of the costs of the in-house programing described in
385 Subsection (11)(b), if:

386 (i) the pharmacy requests the reimbursement, in writing;

387 (ii) the pharmacy provides proof of the costs for the in-house programming to the
388 division;

389 (iii) the pharmacy requests the reimbursement prior to a deadline established by the
390 division; and

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

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

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

398 (ii) the amount reimbursed to the pharmacy is equal to the amount established by the

399 proof of costs for in-house programming submitted by the pharmacy.

400 Section 6. **Appropriation.**

401 (1) There is appropriated:

402 (a) as an ongoing appropriation, subject to future budget constraints, \$175,000 from the
403 General Fund for the fiscal year 2008-09, to the Division of Occupational and Professional
404 Licensing to maintain and operate the controlled substance database; and

405 (b) \$650,000 from the General Fund, for the fiscal year 2008-09 only, to the Division
406 of Occupational and Professional Licensing to:

407 (i) implement and operate the pilot program described in this bill; and

408 (ii) if any of the funds described in this Subsection (1)(b) are available after paying the
409 costs to implement and operate the pilot program under Subsection (1)(b)(i), reimburse a
410 pharmacy for the costs of in-house programming, in accordance with Subsection
411 58-37-7.8(11)(d).

412 (2) The \$650,000 appropriated from the General Fund, under Subsection (2), shall be
413 nonlapsing.

414 Section 7. **Effective date.**

415 This bill takes effect on July 1, 2008.