

CONTROLLED SUBSTANCE DATABASE

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
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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 prescribing practitioners;

- ▶ grants rulemaking authority to the Division of Occupational and Professional

31 Licensing in relation to the pilot program;

32 ▶ requires the Division of Occupational and Professional Licensing to report on the
33 pilot program and the advisability and cost of implementing the pilot program on a
34 statewide basis and the use of the controlled substance database by prescribing
35 practitioners;

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

39 ▶ makes technical changes.

40 **Monies Appropriated in this Bill:**

41 This bill appropriates:

42 ▶ \$175,000 as an ongoing appropriation from the General Fund, for fiscal year
43 2008-09, to the Division of Occupational and Professional Licensing; and

44 ▶ \$650,000 from the General Fund, for fiscal year 2008-09 only, to the Division of
45 Occupational and Professional Licensing, as nonlapsing funds.

46 **Other Special Clauses:**

47 This bill takes effect on July 1, 2008.

48 **Utah Code Sections Affected:**

49 AMENDS:

50 **26-1-36**, as enacted by Laws of Utah 2007, Chapter 200

51 **58-37-7.5**, as last amended by Laws of Utah 2007, Chapter 293

52 ENACTS:

53 **58-37-7.8**, Utah Code Annotated 1953



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

56 Section 1. Section **26-1-36** is amended to read:

57 **26-1-36. Duty to establish program to reduce deaths and other harm from**
58 **prescription opiates used for chronic noncancer pain.**

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

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

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

68 (b) study the risks, warning signs, and solutions to the risks associated with prescription
69 opiate medications for chronic pain, including risks and prevention of misuse and diversion of
70 those medications; ~~and~~

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

74 (d) educate the public regarding:

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

76 and

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

80 (3) The department shall report on the development and implementation of the program
81 required in Subsection (2) to the legislative Health and Human Services Interim Committee and
82 the legislative Business and Labor Interim Committee no later than the November interim
83 meetings in ~~[2007 and]~~ 2008 and 2009. Each report shall include:

84 (a) recommendations on:

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

- 87 (A) misuse of opiates;
- 88 (B) inappropriate prescribing; and
- 89 (C) adverse outcomes of prescription opiate medications;
- 90 (ii) interventions to prevent the diversion of prescription opiate medications; and
- 91 (iii) medical treatment and quality care guidelines that are:
- 92 (A) scientifically based; and
- 93 (B) peer reviewed; and
- 94 (b) (i) a measure of results against expectations under the program as of the date of the
- 95 report; and
- 96 (ii) an analysis of the application of the program, use of the appropriated funds, and the
- 97 impact and results of the use of the funds.

98 (4) The report provided under Subsection (3) for the 2008 interim shall also provide a

99 final cumulative analysis of the measurable effectiveness of the program implemented under this

100 section.

101 Section 2. Section **58-37-7.5** is amended to read:

102 **58-37-7.5. Controlled substance database -- Pharmacy reporting requirements --**

103 **Access -- Penalties.**

- 104 (1) As used in this section:
- 105 (a) "Board" means the Utah State Board of Pharmacy created in Section 58-17b-201.
- 106 ~~[(a)]~~ (b) "Database" means the controlled substance database created in this section.
- 107 ~~[(b)]~~ (c) "Database manager" means the person responsible for operating the database,
- 108 or ~~[(his)]~~ the person's designee.
- 109 ~~[(c)]~~ (d) "Division" means the Division of Occupational and Professional Licensing
- 110 created in Section 58-1-103.
- 111 ~~[(d)]~~ (e) "Health care facility" ~~[(has the same definition as)]~~ is as defined in Section
- 112 26-21-2.
- 113 ~~[(e)]~~ (f) "Pharmacy" or "pharmaceutical facility" ~~[(has the same definition as)]~~ is as
- 114 defined in Section 58-17b-102.

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

116 (b) The division shall administer and direct the functioning of the database in
117 accordance with this section. The division may under state procurement laws contract with
118 another state agency or private entity to establish, operate, or maintain the database. The
119 division in collaboration with the board shall determine whether to operate the database within
120 the division or contract with another entity to operate the database, based on an analysis of
121 costs and benefits.

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

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

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

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

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

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

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

137 (a) name of the prescribing practitioner;

138 (b) date of the prescription;

139 (c) date the prescription was filled;

140 (d) name of the person for whom the prescription was written;

141 (e) positive identification of the person receiving the prescription, including the type of
142 identification and any identifying numbers on the identification;

- 143 (f) name of the controlled substance;
 - 144 (g) quantity of controlled substance prescribed;
 - 145 (h) strength of controlled substance;
 - 146 (i) quantity of controlled substance dispensed;
 - 147 (j) dosage quantity and frequency as prescribed;
 - 148 (k) name of drug outlet dispensing the controlled substance;
 - 149 (l) name of pharmacist dispensing the controlled substance; and
 - 150 (m) other relevant information as required by division rule.
- 151 (5) The division shall maintain the database in an electronic file or by other means
- 152 established by the division to facilitate use of the database for identification of:
- 153 (a) prescribing practices and patterns of prescribing and dispensing controlled
 - 154 substances;
 - 155 (b) practitioners prescribing controlled substances in an unprofessional or unlawful
 - 156 manner;
 - 157 (c) individuals receiving prescriptions for controlled substances from licensed
 - 158 practitioners, and who subsequently obtain dispensed controlled substances from a drug outlet
 - 159 in quantities or with a frequency inconsistent with generally recognized standards of dosage for
 - 160 that controlled substance; and
 - 161 (d) individuals presenting forged or otherwise false or altered prescriptions for
 - 162 controlled substances to a pharmacy.
- 163 (6) (a) The division shall by rule establish the electronic format in which the information
- 164 required under this section shall be submitted to the administrator of the database.
- 165 (b) The division shall ensure the database system records and maintains for reference:
 - 166 (i) identification of each person who requests or receives information from the database;
 - 167 (ii) the information provided to each person; and
 - 168 (iii) the date and time the information is requested or provided.
- 169 (7) The division shall make rules to:
- 170 (a) effectively enforce the limitations on access to the database as described in

171 Subsection (8); and

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

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

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

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

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

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

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

190 (ii) the information relates specifically to an individual who has access to the
191 practitioner's Drug Enforcement Administration number, and the practitioner suspects that the
192 individual may have used the practitioner's Drug Enforcement Administration identification
193 number to fraudulently acquire or prescribe controlled substances; or

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

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

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

201 (i) regulating controlled substances; or

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

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

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

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

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

213 (11) (a) A person may not knowingly and intentionally use, release, publish, or
214 otherwise make available to any other person or entity any information obtained from the
215 database for any purpose other than those specified in Subsection (8). Each separate violation
216 of this Subsection (11) is a third degree felony and is also subject to a civil penalty not to exceed
217 \$5,000.

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

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

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

227 (i) refuse to issue a license to the individual;
228 (ii) refuse to renew the individual's license;
229 (iii) revoke, suspend, restrict, or place on probation the license;
230 (iv) issue a public or private reprimand to the individual;
231 (v) issue a cease and desist order; and
232 (vi) impose a civil penalty of not more than \$1,000 for each dispensed prescription
233 regarding which the required information is not submitted.

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

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

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

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

- 242 (a) the Commerce Service Fund; and
- 243 (b) the General Fund.

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

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

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

- 252 (i) a criminal proceeding; or
- 253 (ii) a civil, judicial, or administrative action brought to enforce the provisions of this
254 section, Section 58-37-7.7, or Section 58-37-7.8.

255 Section 3. Section **58-37-7.8** is enacted to read:

256 **58-37-7.8. Pilot program for real-time reporting for controlled substance database**

257 **-- Statewide implementation.**

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

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

261 (A) the entire state; or

262 (B) geographical areas within the state.

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

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

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

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

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

276 (5) (a) All provisions and requirements of the statewide database, described in Sections
277 58-37-7.5 and 58-37-7.7, are applicable to the database in the pilot area, to the extent that they
278 do not conflict with the requirements of this section.

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

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

283 database:

284 (a) in the pilot area; and

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

287 (7) The penalties and enforcement provisions described in Sections 58-37-7.5 and
288 58-37-7.7 apply to enforce the provisions of this section in relation to a pharmacy or
289 pharmaceutical facility that is located in, or operates in, the pilot area.

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

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

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

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

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

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

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

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

308 (b) Notwithstanding Subsection (11)(a), a pharmacy or pharmaceutical facility required
309 to comply with Subsection (6) may, instead of accepting installation of the software provided by
310 the division under Subsection (11)(a), modify its own software in order to comply with the

311 requirements of Subsection (6), if the modification is made:

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

314 (ii) in consultation with the division; and

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

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

321 (i) complies with the security standards described in 45 C.F.R. Parts 160, 162, and 164,
322 Health Insurance Reform: Security Standards;

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

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

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

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

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

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

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

338 (e) The division may reimburse a pharmacy described in Subsection (11)(d)(iv) for an

339 amount that is less than the reimbursement paid to other pharmacies described in Subsection
340 (11)(d)(iv), if:

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

343 (ii) the amount reimbursed to the pharmacy is equal to the amount established by the
344 proof of costs for in-house programming submitted by the pharmacy.

345 (f) Notwithstanding any other provision of this section, the division may, by rule, allow
346 up to 24 hours for the reporting of data to the database by a non-resident pharmacy, as defined
347 in Section 58-17b-102.

348 **Section 4. Appropriation.**

349 (1) There is appropriated:

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

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

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

356 (ii) if any of the funds described in this Subsection (1)(b) are available after paying the
357 costs to implement and operate the pilot program under Subsection (1)(b)(i), reimburse a
358 pharmacy for the costs of in-house programming, in accordance with Subsection
359 58-37-7.8(11)(d).

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

362 **Section 5. Effective date.**

363 This bill takes effect on July 1, 2008.