

1 **CONTROLLED SUBSTANCE DATABASE AMENDMENTS**

2 2015 GENERAL SESSION

3 STATE OF UTAH

4 **Chief Sponsor: Edward H. Redd**

5 Senate Sponsor: Curtis S. Bramble

6 Cosponsors: Michael E. Noel Raymond P. Ward
7 Brad M. Daw Robert M. Spendlove

8
9 **LONG TITLE**

10 **General Description:**

11 This bill modifies provisions of the Controlled Substance Database Act.

12 **Highlighted Provisions:**

13 This bill:

14 ▶ requires the Division of Occupational and Professional Licensing to implement
15 options for:

- 16 • real-time submission of data into the controlled substance database; and
- 17 • 24-hour daily or next business day batch submission of data;

18 ▶ requires a pharmacist to comply with the real-time or 24-hour submission
19 requirements on and after January 1, 2016;

20 ▶ provides that a physician employed as medical director for a licensed workers'
21 compensation insurer or an approved self-insured employer may have access to the
22 database regarding requests for workers' compensation;

- 23 ▶ authorizes additional rulemaking authority;
- 24 ▶ repeals provisions of a pilot program; and
- 25 ▶ makes technical corrections.

26 **Money Appropriated in this Bill:**

27 This bill appropriates in fiscal year 2016:

- 28 ▶ to the Department of Commerce - Division of Occupational and Professional

29 Licensing - Controlled Substance Database, as an ongoing appropriation:

- 30 • from the General Fund, \$46,000.

31 **Other Special Clauses:**

32 This bill provides a special effective date.

33 **Utah Code Sections Affected:**

34 AMENDS:

35 **58-37f-203**, as last amended by Laws of Utah 2014, Chapter 72

36 **58-37f-301**, as last amended by Laws of Utah 2014, Chapters 68 and 401

37 REPEALS:

38 **58-37f-801**, as last amended by Laws of Utah 2013, Chapter 167



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

41 Section 1. Section **58-37f-203** is amended to read:

42 **58-37f-203. Submission, collection, and maintenance of data.**

43 (1) (a) The division shall implement on a statewide basis, including non-resident
44 pharmacies as defined in Section 58-17b-102, the following two options for a pharmacist to
45 submit information:

46 (i) real-time submission of the information required to be submitted under this part to
47 the controlled substance database; and

48 (ii) 24-hour daily or next business day, whichever is later, batch submission of the
49 information required to be submitted under this part to the controlled substance database.

50 (b) (i) On and after January 1, 2016, a pharmacist shall comply with either:

51 (A) the submission time requirements established by the division under Subsection
52 (1)(a)(i); or

53 (B) the submission time requirements established by the division under Subsection
54 (1)(a)(ii).

55 (ii) Prior to January 1, 2016, a pharmacist may submit information using either option
56 under this Subsection (1).

57 (c) The division shall comply with Title 63G, Chapter 6a, Utah Procurement Code.

58 ~~[(+)]~~ (2) (a) The pharmacist in charge of the drug outlet where a controlled substance is
59 dispensed shall submit the data described in this section to the division:

- 60 (i) in accordance with the requirements of this section;
- 61 (ii) in accordance with the procedures established by the division; and
- 62 (iii) in the format established by the division.

63 (b) A dispensing medical practitioner licensed under Chapter 17b, Part 8, Dispensing
64 Medical Practitioner and Dispensing Medical Practitioner Clinic Pharmacy, shall comply with
65 the provisions of this section and the dispensing medical practitioner shall assume the duties of
66 the pharmacist under this chapter.

67 ~~[(2)]~~ (3) The pharmacist described in Subsection ~~[(+)]~~ (2) shall, for each controlled
68 substance dispensed by a pharmacist under the pharmacist's supervision other than those
69 dispensed for an inpatient at a health care facility, submit to the division the following
70 information:

- 71 (a) the name of the prescribing practitioner;
- 72 (b) the date of the prescription;
- 73 (c) the date the prescription was filled;
- 74 (d) the name of the individual for whom the prescription was written;
- 75 (e) positive identification of the individual receiving the prescription, including the
76 type of identification and any identifying numbers on the identification;
- 77 (f) the name of the controlled substance;
- 78 (g) the quantity of the controlled substance prescribed;
- 79 (h) the strength of the controlled substance;
- 80 (i) the quantity of the controlled substance dispensed;
- 81 (j) the dosage quantity and frequency as prescribed;
- 82 (k) the name of the drug outlet dispensing the controlled substance;
- 83 (l) the name of the pharmacist dispensing the controlled substance; and
- 84 (m) other relevant information as required by division rule.

85 ~~[(3)]~~ ~~(a)~~ (4) The division shall make rules, in accordance with Title 63G, Chapter 3,
86 Utah Administrative Rulemaking Act, to establish submission requirements under this part,
87 including the electronic format in which the information required under this section shall be
88 submitted to the division.

89 ~~[(b)]~~ (5) The division shall ensure that the database system records and maintains for
90 reference:

91 ~~[(i)]~~ (a) the identification of each individual who requests or receives information from
92 the database;

93 ~~[(ii)]~~ (b) the information provided to each individual; and

94 ~~[(iii)]~~ (c) the date and time that the information is requested or provided.

95 Section 2. Section **58-37f-301** is amended to read:

96 **58-37f-301. Access to database.**

97 (1) The division shall make rules, in accordance with Title 63G, Chapter 3, Utah
98 Administrative Rulemaking Act, to:

99 (a) effectively enforce the limitations on access to the database as described in this
100 part; and

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

103 (2) The division shall make information in the database and information obtained from
104 other state or federal prescription monitoring programs by means of the database available only
105 to the following individuals, in accordance with the requirements of this chapter and division
106 rules:

107 (a) personnel of the division specifically assigned to conduct investigations related to
108 controlled substance laws under the jurisdiction of the division;

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

112 (c) in accordance with a written agreement entered into with the department,

113 employees of the Department of Health:

114 (i) whom the director of the Department of Health assigns to conduct scientific studies
115 regarding the use or abuse of controlled substances, if the identity of the individuals and
116 pharmacies in the database are confidential and are not disclosed in any manner to any
117 individual who is not directly involved in the scientific studies; or

118 (ii) when the information is requested by the Department of Health in relation to a
119 person or provider whom the Department of Health suspects may be improperly obtaining or
120 providing a controlled substance;

121 (d) in accordance with a written agreement entered into with the department, a
122 designee of the director of the Department of Health, who is not an employee of the
123 Department of Health, whom the director of the Department of Health assigns to conduct
124 scientific studies regarding the use or abuse of controlled substances pursuant to an application
125 process established in rule by the Department of Health, if:

126 (i) the designee provides explicit information to the Department of Health regarding
127 the purpose of the scientific studies;

128 (ii) the scientific studies to be conducted by the designee:

129 (A) fit within the responsibilities of the Department of Health for health and welfare;

130 (B) are reviewed and approved by an Institutional Review Board that is approved for
131 human subject research by the United States Department of Health and Human Services; and

132 (C) are not conducted for profit or commercial gain; and

133 (D) are conducted in a research facility, as defined by division rule, that is associated
134 with a university or college in the state accredited by [~~the Northwest Commission on Colleges
135 and Universities~~] one or more regional or national accrediting agencies recognized by the
136 United States Department of Education;

137 (iii) the designee protects the information as a business associate of the Department of
138 Health; and

139 (iv) the identity of the prescribers, patients, and pharmacies in the database are
140 de-identified, confidential, not disclosed in any manner to the designee or to any individual

141 who is not directly involved in the scientific studies;

142 (e) in accordance with the written agreement entered into with the department and the
143 Department of Health, authorized employees of a managed care organization, as defined in 42
144 C.F.R. Sec. 438, if:

145 (i) the managed care organization contracts with the Department of Health under the
146 provisions of Section 26-18-405 and the contract includes provisions that:

147 (A) require a managed care organization employee who will have access to information
148 from the database to submit to a criminal background check; and

149 (B) limit the authorized employee of the managed care organization to requesting either
150 the division or the Department of Health to conduct a search of the database regarding a
151 specific Medicaid enrollee and to report the results of the search to the authorized employee;
152 and

153 (ii) the information is requested by an authorized employee of the managed care
154 organization in relation to a person who is enrolled in the Medicaid program with the managed
155 care organization, and the managed care organization suspects the person may be improperly
156 obtaining or providing a controlled substance;

157 (f) a licensed practitioner having authority to prescribe controlled substances, to the
158 extent the information:

159 (i) (A) relates specifically to a current or prospective patient of the practitioner; and

160 (B) is provided to or sought by the practitioner for the purpose of:

161 (I) prescribing or considering prescribing any controlled substance to the current or
162 prospective patient;

163 (II) diagnosing the current or prospective patient;

164 (III) providing medical treatment or medical advice to the current or prospective
165 patient; or

166 (IV) determining whether the current or prospective patient:

167 (Aa) is attempting to fraudulently obtain a controlled substance from the practitioner;

168 or

169 (Bb) has fraudulently obtained, or attempted to fraudulently obtain, a controlled
170 substance from the practitioner;

171 (ii) (A) relates specifically to a former patient of the practitioner; and
172 (B) is provided to or sought by the practitioner for the purpose of determining whether
173 the former patient has fraudulently obtained, or has attempted to fraudulently obtain, a
174 controlled substance from the practitioner;

175 (iii) relates specifically to an individual who has access to the practitioner's Drug
176 Enforcement Administration identification number, and the practitioner suspects that the
177 individual may have used the practitioner's Drug Enforcement Administration identification
178 number to fraudulently acquire or prescribe a controlled substance;

179 (iv) relates to the practitioner's own prescribing practices, except when specifically
180 prohibited by the division by administrative rule;

181 (v) relates to the use of the controlled substance database by an employee of the
182 practitioner, described in Subsection (2)(g); or

183 (vi) relates to any use of the practitioner's Drug Enforcement Administration
184 identification number to obtain, attempt to obtain, prescribe, or attempt to prescribe, a
185 controlled substance;

186 (g) in accordance with Subsection (3)(a), an employee of a practitioner described in
187 Subsection (2)(f), for a purpose described in Subsection (2)(f)(i) or (ii), if:

188 (i) the employee is designated by the practitioner as an individual authorized to access
189 the information on behalf of the practitioner;

190 (ii) the practitioner provides written notice to the division of the identity of the
191 employee; and

192 (iii) the division:

193 (A) grants the employee access to the database; and
194 (B) provides the employee with a password that is unique to that employee to access
195 the database in order to permit the division to comply with the requirements of Subsection
196 [58-37f-203\[\(3\)\(b\)\]\(5\)](#) with respect to the employee;

197 (h) an employee of the same business that employs a licensed practitioner under
198 Subsection (2)(f) if:

199 (i) the employee is designated by the practitioner as an individual authorized to access
200 the information on behalf of the practitioner;

201 (ii) the practitioner and the employing business provide written notice to the division of
202 the identity of the designated employee; and

203 (iii) the division:

204 (A) grants the employee access to the database; and

205 (B) provides the employee with a password that is unique to that employee to access
206 the database in order to permit the division to comply with the requirements of Subsection
207 [58-37f-203](#)~~(3)(b)~~(5) with respect to the employee;

208 (i) a licensed pharmacist having authority to dispense a controlled substance to the
209 extent the information is provided or sought for the purpose of:

210 (i) dispensing or considering dispensing any controlled substance; or

211 (ii) determining whether a person:

212 (A) is attempting to fraudulently obtain a controlled substance from the pharmacist; or

213 (B) has fraudulently obtained, or attempted to fraudulently obtain, a controlled
214 substance from the pharmacist;

215 (j) in accordance with Subsection (3)(a), a licensed pharmacy technician who is an
216 employee of a pharmacy as defined in Section [58-17b-102](#), for the purposes described in
217 Subsection (2)(h)(i) or (ii), if:

218 (i) the employee is designated by the pharmacist-in-charge as an individual authorized
219 to access the information on behalf of a licensed pharmacist employed by the pharmacy;

220 (ii) the pharmacist-in-charge provides written notice to the division of the identity of
221 the employee; and

222 (iii) the division:

223 (A) grants the employee access to the database; and

224 (B) provides the employee with a password that is unique to that employee to access

225 the database in order to permit the division to comply with the requirements of Subsection
226 58-37f-203[(3)(b)](5) with respect to the employee;

227 (k) federal, state, and local law enforcement authorities, and state and local
228 prosecutors, engaged as a specified duty of their employment in enforcing laws:

229 (i) regulating controlled substances;

230 (ii) investigating insurance fraud, Medicaid fraud, or Medicare fraud; or

231 (iii) providing information about a criminal defendant to defense counsel, upon request
232 during the discovery process, for the purpose of establishing a defense in a criminal case;

233 (l) employees of the Office of Internal Audit and Program Integrity within the
234 Department of Health who are engaged in their specified duty of ensuring Medicaid program
235 integrity under Section 26-18-2.3;

236 (m) a mental health therapist, if:

237 (i) the information relates to a patient who is:

238 (A) enrolled in a licensed substance abuse treatment program; and

239 (B) receiving treatment from, or under the direction of, the mental health therapist as
240 part of the patient's participation in the licensed substance abuse treatment program described
241 in Subsection (2)(m)(i)(A);

242 (ii) the information is sought for the purpose of determining whether the patient is
243 using a controlled substance while the patient is enrolled in the licensed substance abuse
244 treatment program described in Subsection (2)(m)(i)(A); and

245 (iii) the licensed substance abuse treatment program described in Subsection
246 (2)(m)(i)(A) is associated with a practitioner who:

247 (A) is a physician, a physician assistant, an advance practice registered nurse, or a
248 pharmacist; and

249 (B) is available to consult with the mental health therapist regarding the information
250 obtained by the mental health therapist, under this Subsection (2)(m), from the database;

251 (n) an individual who is the recipient of a controlled substance prescription entered into
252 the database, upon providing evidence satisfactory to the division that the individual requesting

253 the information is in fact the individual about whom the data entry was made;

254 (o) the inspector general, or a designee of the inspector general, of the Office of
255 Inspector General of Medicaid Services, for the purpose of fulfilling the duties described in
256 Title 63A, Chapter 13, Part 2, Office and Powers; and

257 (p) the following licensed physicians for the purpose of reviewing and offering an
258 opinion on an individual's request for workers' compensation benefits under Title 34A, Chapter
259 2, Workers' Compensation Act, or Title 34A, Chapter 3, Utah Occupational Disease Act:

260 (i) a member of the medical panel described in Section 34A-2-601; [~~or~~]

261 (ii) a physician employed as medical director for a licensed workers' compensation
262 insurer or an approved self-insured employer; or

263 [~~it~~] (iii) a physician offering a second opinion regarding treatment.

264 (3) (a) (i) A practitioner described in Subsection (2)(f) may designate up to three
265 employees to access information from the database under Subsection (2)(g), (2)(h), or (4)(c).

266 (ii) A pharmacist described in Subsection (2)(i) who is a pharmacist-in-charge may
267 designate up to three employees to access information from the database under Subsection
268 (2)(j).

269 (b) The division shall make rules, in accordance with Title 63G, Chapter 3, Utah
270 Administrative Rulemaking Act, to:

271 (i) establish background check procedures to determine whether an employee
272 designated under Subsection (2)(g), (2)(h), or (4)(c) should be granted access to the database;
273 and

274 (ii) establish the information to be provided by an emergency room employee under
275 Subsection (4).

276 (c) The division shall grant an employee designated under Subsection (2)(g), (2)(h), or
277 (4)(c) access to the database, unless the division determines, based on a background check, that
278 the employee poses a security risk to the information contained in the database.

279 (4) (a) An individual who is employed in the emergency room of a hospital may
280 exercise access to the database under this Subsection (4) on behalf of a licensed practitioner if

281 the individual is designated under Subsection (4)(c) and the licensed practitioner:

282 (i) is employed in the emergency room;

283 (ii) is treating an emergency room patient for an emergency medical condition; and

284 (iii) requests that an individual employed in the emergency room and designated under

285 Subsection (4)(c) obtain information regarding the patient from the database as needed in the
286 course of treatment.

287 (b) The emergency room employee obtaining information from the database shall,
288 when gaining access to the database, provide to the database the name and any additional
289 identifiers regarding the requesting practitioner as required by division administrative rule
290 established under Subsection (3)(b).

291 (c) An individual employed in the emergency room under this Subsection (4) may
292 obtain information from the database as provided in Subsection (4)(a) if:

293 (i) the employee is designated by the practitioner as an individual authorized to access
294 the information on behalf of the practitioner;

295 (ii) the practitioner and the hospital operating the emergency room provide written
296 notice to the division of the identity of the designated employee; and

297 (iii) the division:

298 (A) grants the employee access to the database; and

299 (B) provides the employee with a password that is unique to that employee to access
300 the database in order to permit the division to comply with the requirements of Subsection
301 [58-37f-203\[\(3\)\(b\)\]\(5\)](#) with respect to the employee.

302 (d) The division may impose a fee, in accordance with Section [63J-1-504](#), on a
303 practitioner who designates an employee under Subsection (2)(g), (2)(h), or (4)(c) to pay for the
304 costs incurred by the division to conduct the background check and make the determination
305 described in Subsection (3)(b).

306 (5) (a) An individual who is granted access to the database based on the fact that the
307 individual is a licensed practitioner or a mental health therapist shall be denied access to the
308 database when the individual is no longer licensed.

309 (b) An individual who is granted access to the database based on the fact that the
310 individual is a designated employee of a licensed practitioner shall be denied access to the
311 database when the practitioner is no longer licensed.

312 Section 3. **Repealer.**

313 This bill repeals:

314 Section **58-37f-801, Pilot program for real-time reporting for controlled substance**
315 **database -- Statewide implementation.**

316 Section 4. **Appropriation.**

317 Under the terms and conditions of Title 63J, Chapter 1, Budgetary Procedures Act, for
318 the fiscal year beginning July 1, 2015, and ending June 30, 2016, the following sums of money
319 are appropriated from resources not otherwise appropriated, or reduced from amounts
320 previously appropriated, out of the funds or accounts indicated. These sums of money are in
321 addition to any amounts previously appropriated for fiscal year 2016.

322 To Department of Commerce - Division of Occupational and Professional Licensing

323 From General Fund \$46,000

324 Schedule of Programs:

325 Controlled Substance Database \$46,000

326 Section 5. **Effective date.**

327 This bill takes effect on July 1, 2015.