

1 **CONTROLLED SUBSTANCE DATABASE AMENDMENTS**

2 2015 GENERAL SESSION

3 STATE OF UTAH

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

5 Senate Sponsor: _____

7 **LONG TITLE**

8 **General Description:**

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

10 **Highlighted Provisions:**

11 This bill:

12 ▶ requires the Division of Occupational and Professional Licensing to implement a
13 program for:

- 14 • real-time submission of data into the controlled substance database; and
- 15 • 24-hour daily batch submission of data;

16 ▶ authorizes additional rulemaking authority;

17 ▶ provides that those accessing data from the database are responsible for costs
18 associated with accessing the data;

19 ▶ repeals provisions of a pilot program; and

20 ▶ makes technical corrections.

21 **Money Appropriated in this Bill:**

22 This bill appropriates in fiscal year 2016:

23 ▶ to the Department of Commerce - Division of Occupational and Professional
24 Licensing - Controlled Substance Database, as an ongoing appropriation:

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

26 **Other Special Clauses:**

27 This bill provides a special effective date.



28 **Utah Code Sections Affected:**

29 AMENDS:

30 **58-37f-203**, as last amended by Laws of Utah 2014, Chapter 72

31 **58-37f-301**, as last amended by Laws of Utah 2014, Chapters 68 and 401

32 **58-37f-501**, as enacted by Laws of Utah 2010, Chapter 287 and last amended by
33 Coordination Clause, Laws of Utah 2010, Chapter 287

34 REPEALS:

35 **58-37f-801**, as last amended by Laws of Utah 2013, Chapter 167



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

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

39 **58-37f-203. Submission, collection, and maintenance of data.**

40 (1) (a) The division shall implement on a statewide basis, including non-resident
41 pharmacies as defined in Section 58-17b-102, a program of:

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

44 (ii) 24-hour daily batch submission of the information required to be submitted under
45 this part to the controlled substance database.

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

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

49 (i) in accordance with the requirements of this section;

50 (ii) in accordance with the procedures established by the division; and

51 (iii) in the format established by the division.

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

56 ~~[(2)]~~ (3) The pharmacist described in Subsection ~~[(+)]~~ (2) shall, for each controlled
57 substance dispensed by a pharmacist under the pharmacist's supervision other than those
58 dispensed for an inpatient at a health care facility, submit to the division the following

59 information:

- 60 (a) the name of the prescribing practitioner;
- 61 (b) the date of the prescription;
- 62 (c) the date the prescription was filled;
- 63 (d) the name of the individual for whom the prescription was written;
- 64 (e) positive identification of the individual receiving the prescription, including the
- 65 type of identification and any identifying numbers on the identification;
- 66 (f) the name of the controlled substance;
- 67 (g) the quantity of the controlled substance prescribed;
- 68 (h) the strength of the controlled substance;
- 69 (i) the quantity of the controlled substance dispensed;
- 70 (j) the dosage quantity and frequency as prescribed;
- 71 (k) the name of the drug outlet dispensing the controlled substance;
- 72 (l) the name of the pharmacist dispensing the controlled substance; and
- 73 (m) other relevant information as required by division rule.

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

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

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

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

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

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

85 **58-37f-301. Access to database.**

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

- 88 (a) effectively enforce the limitations on access to the database as described in this
- 89 part; and

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

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

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

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

101 (c) in accordance with a written agreement entered into with the department,
102 employees of the Department of Health:

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

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

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

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

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

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

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

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

122 (D) are conducted in a research facility, as defined by division rule, that is associated
 123 with a university or college in the state accredited by ~~H→ [the Northwest Commission on Colleges~~
 124 ~~and Universities]~~ **one or more regional or national accrediting agencies recognized by the U.S.**

124a **Department of Education** ←H ;

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

127 (iv) the identity of the prescribers, patients, and pharmacies in the database are
 128 de-identified, confidential, not disclosed in any manner to the designee or to any individual
 129 who is not directly involved in the scientific studies;

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

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

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

137 (B) limit the authorized employee of the managed care organization to requesting either
 138 the division or the Department of Health to conduct a search of the database regarding a
 139 specific Medicaid enrollee and to report the results of the search to the authorized employee;
 140 and

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

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

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

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

149 (I) prescribing or considering prescribing any controlled substance to the current or
 150 prospective patient;

151 (II) diagnosing the current or prospective patient;

152 (III) providing medical treatment or medical advice to the current or prospective
153 patient; or

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

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

156 or

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

159 (ii) (A) relates specifically to a former patient of the practitioner; and

160 (B) is provided to or sought by the practitioner for the purpose of determining whether
161 the former patient has fraudulently obtained, or has attempted to fraudulently obtain, a
162 controlled substance from the practitioner;

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

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

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

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

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

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

178 (ii) the practitioner provides written notice to the division of the identity of the
179 employee; and

180 (iii) the division:

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

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

183 the database in order to permit the division to comply with the requirements of Subsection
184 58-37f-203[(3)(b)](5) with respect to the employee;

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

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

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

191 (iii) the division:

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

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

194 the database in order to permit the division to comply with the requirements of Subsection
195 58-37f-203[(3)(b)](5) with respect to the employee;

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

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

199 (ii) determining whether a person:

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

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

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

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

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

210 (iii) the division:

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

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

213 the database in order to permit the division to comply with the requirements of Subsection

214 58-37f-203[(3)(b)](5) with respect to the employee;

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

217 (i) regulating controlled substances;

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

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

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

224 (m) a mental health therapist, if:

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

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

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

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

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

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

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

239 (n) an individual who is the recipient of a controlled substance prescription entered into
240 the database, upon providing evidence satisfactory to the division that the individual requesting
241 the information is in fact the individual about whom the data entry was made;

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

245 (p) the following licensed physicians for the purpose of reviewing and offering an
246 opinion on an individual's request for workers' compensation benefits under Title 34A, Chapter
247 2, Workers' Compensation Act, or Title 34A, Chapter 3, Utah Occupational Disease Act:

248 (i) a member of the medical panel described in Section 34A-2-601; or

249 (ii) a physician offering a second opinion regarding treatment.

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

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

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

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

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

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

265 (4) (a) An individual who is employed in the emergency room of a hospital may
266 exercise access to the database under this Subsection (4) on behalf of a licensed practitioner if
267 the individual is designated under Subsection (4)(c) and the licensed practitioner:

268 (i) is employed in the emergency room;

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

270 (iii) requests that an individual employed in the emergency room and designated under
271 Subsection (4)(c) obtain information regarding the patient from the database as needed in the
272 course of treatment.

273 (b) The emergency room employee obtaining information from the database shall,
274 when gaining access to the database, provide to the database the name and any additional
275 identifiers regarding the requesting practitioner as required by division administrative rule

276 established under Subsection (3)(b).

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

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

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

283 (iii) the division:

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

285 (B) provides the employee with a password that is unique to that employee to access
286 the database in order to permit the division to comply with the requirements of Subsection
287 58-37f-203[~~(3)(b)~~](5) with respect to the employee.

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

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

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

298 Section 3. Section 58-37f-501 is amended to read:

299 **58-37f-501. Costs of operating database and recording, submitting, and accessing**
300 **information.**

301 (1) All department and division costs necessary to establish and operate the database
302 shall be funded by appropriations from:

303 (a) the Commerce Service Account; and

304 (b) the General Fund.

305 (2) All costs associated with recording and submitting ~~[data]~~ information as required in
306 this chapter shall be assumed by the submitting pharmacy.

307 ~~Ĥ→ [(3) All costs associated with accessing the information contained in the controlled~~
 308 ~~substance database shall be assumed by the accessing pharmacy, pharmaceutical facility, or~~
 309 ~~prescribing practitioner.] ←Ĥ~~

310 Section 4. **Repealer.**

311 This bill repeals:

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

314 Section 5. **Appropriation.**

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

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

<u>From General Fund</u>	<u>\$46,000</u>
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322 Schedule of Programs:

<u>Controlled Substance Database</u>	<u>\$46,000</u>
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324 Section 6. **Effective date.**

325 This bill takes effect on July 1, 2015.

Legislative Review Note
 as of 2-23-15 4:33 PM

Office of Legislative Research and General Counsel