Representative Edward H. Redd proposes the following substitute bill:

CONTROLLED SUBSTANCE DATABASE AMENDMENTS	
2015 GENERAL SESSION	
STATE OF UTAH	
Chief Sponsor: Edward H. Redd	
Senate Sponsor: Curtis S. Bramble	
LONG TITLE	
General Description:	
This bill modifies provisions of the Controlled Substance Database Act.	
Highlighted Provisions:	
This bill:	
 requires the Division of Occupational and Professional Licensing to implement 	
options for:	
 real-time submission of data into the controlled substance database; and 	
 24-hour daily or next business day batch submission of data; 	
 requires a pharmacist to comply with the real-time or 24-hour submission 	
requirements on and after January 1, 2016;	
 authorizes additional rulemaking authority; 	
 repeals provisions of a pilot program; and 	
 makes technical corrections. 	
Money Appropriated in this Bill:	
This bill appropriates in fiscal year 2016:	
 to the Department of Commerce - Division of Occupational and Professional 	
Licensing - Controlled Substance Database, as an ongoing appropriation:	
• 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	REPEALS:
33	58-37f-801, as last amended by Laws of Utah 2013, Chapter 167
34	
35	Be it enacted by the Legislature of the state of Utah:
36	Section 1. Section 58-37f-203 is amended to read:
37	58-37f-203. Submission, collection, and maintenance of data.
38	(1) (a) The division shall implement on a statewide basis, including non-resident
39	pharmacies as defined in Section 58-17b-102, the following two options for a pharmacist to
40	submit information:
41	(i) real-time submission of the information required to be submitted under this part to
42	the controlled substance database; and
43	(ii) 24-hour daily or next business day, whichever is later, batch submission of the
44	information required to be submitted under this part to the controlled substance database.
45	(b) (i) On and after January 1, 2016, a pharmacist shall comply with either:
46	(A) the submission time requirements established by the division under Subsection
47	<u>(1)(a)(i); or</u>
48	(B) the submission time requirements established by the division under Subsection
49	<u>(1)(a)(ii).</u>
50	(ii) Prior to January 1, 2016, a pharmacist may submit information using either option
51	under this Subsection (1).
52	(c) The division shall comply with Title 63G, Chapter 6a, Utah Procurement Code.
53	[(1)] (2) (a) The pharmacist in charge of the drug outlet where a controlled substance is
54	dispensed shall submit the data described in this section to the division:
55	(i) in accordance with the requirements of this section;
56	(ii) in accordance with the procedures established by the division; and

57	(iii) in the format established by the division.
58	(b) A dispensing medical practitioner licensed under Chapter 17b, Part 8, Dispensing
59	Medical Practitioner and Dispensing Medical Practitioner Clinic Pharmacy, shall comply with
60	the provisions of this section and the dispensing medical practitioner shall assume the duties of
61	the pharmacist under this chapter.
62	[(2)] (3) The pharmacist described in Subsection $[(1)]$ (2) shall, for each controlled
63	substance dispensed by a pharmacist under the pharmacist's supervision other than those
64	dispensed for an inpatient at a health care facility, submit to the division the following
65	information:
66	(a) the name of the prescribing practitioner;
67	(b) the date of the prescription;
68	(c) the date the prescription was filled;
69	(d) the name of the individual for whom the prescription was written;
70	(e) positive identification of the individual receiving the prescription, including the
71	type of identification and any identifying numbers on the identification;
72	(f) the name of the controlled substance;
73	(g) the quantity of the controlled substance prescribed;
74	(h) the strength of the controlled substance;
75	(i) the quantity of the controlled substance dispensed;
76	(j) the dosage quantity and frequency as prescribed;
77	(k) the name of the drug outlet dispensing the controlled substance;
78	(1) the name of the pharmacist dispensing the controlled substance; and
79	(m) other relevant information as required by division rule.
80	[(3) (a)] (4) The division shall make rules, in accordance with Title 63G, Chapter 3,
81	Utah Administrative Rulemaking Act, to establish submission requirements under this part,
82	including the electronic format in which the information required under this section shall be
83	submitted to the division.
84	[(b)] (5) The division shall ensure that the database system records and maintains for
85	reference:
86	[(i)] (a) the identification of each individual who requests or receives information from
87	the database;

88	[(ii)] (b) the information provided to each individual; and
89	$\left[\frac{(iii)}{(c)}\right]$ the date and time that the information is requested or provided.
90	Section 2. Section 58-37f-301 is amended to read:
91	58-37f-301. Access to database.
92	(1) The division shall make rules, in accordance with Title 63G, Chapter 3, Utah
93	Administrative Rulemaking Act, to:
94	(a) effectively enforce the limitations on access to the database as described in this
95	part; and
96	(b) establish standards and procedures to ensure accurate identification of individuals
97	requesting information or receiving information without request from the database.
98	(2) The division shall make information in the database and information obtained from
99	other state or federal prescription monitoring programs by means of the database available only
100	to the following individuals, in accordance with the requirements of this chapter and division
101	rules:
102	(a) personnel of the division specifically assigned to conduct investigations related to
103	controlled substance laws under the jurisdiction of the division;
104	(b) authorized division personnel engaged in analysis of controlled substance
105	prescription information as a part of the assigned duties and responsibilities of their
106	employment;
107	(c) in accordance with a written agreement entered into with the department,
108	employees of the Department of Health:
109	(i) whom the director of the Department of Health assigns to conduct scientific studies
110	regarding the use or abuse of controlled substances, if the identity of the individuals and
111	pharmacies in the database are confidential and are not disclosed in any manner to any
112	individual who is not directly involved in the scientific studies; or
113	(ii) when the information is requested by the Department of Health in relation to a
114	person or provider whom the Department of Health suspects may be improperly obtaining or
115	providing a controlled substance;
116	(d) in accordance with a written agreement entered into with the department, a
117	designee of the director of the Department of Health, who is not an employee of the
118	Department of Health, whom the director of the Department of Health assigns to conduct

119	scientific studies regarding the use or abuse of controlled substances pursuant to an application
120	process established in rule by the Department of Health, if:
121	(i) the designee provides explicit information to the Department of Health regarding
122	the purpose of the scientific studies;
123	(ii) the scientific studies to be conducted by the designee:
124	(A) fit within the responsibilities of the Department of Health for health and welfare;
125	(B) are reviewed and approved by an Institutional Review Board that is approved for
126	human subject research by the United States Department of Health and Human Services; and
127	(C) are not conducted for profit or commercial gain; and
128	(D) are conducted in a research facility, as defined by division rule, that is associated
129	with a university or college in the state accredited by [the Northwest Commission on Colleges
130	and Universities] one or more regional or national accrediting agencies recognized by the
131	United States Department of Education;
132	(iii) the designee protects the information as a business associate of the Department of
133	Health; and
134	(iv) the identity of the prescribers, patients, and pharmacies in the database are
135	de-identified, confidential, not disclosed in any manner to the designee or to any individual
136	who is not directly involved in the scientific studies;
137	(e) in accordance with the written agreement entered into with the department and the
138	Department of Health, authorized employees of a managed care organization, as defined in 42
139	C.F.R. Sec. 438, if:
140	(i) the managed care organization contracts with the Department of Health under the
141	provisions of Section 26-18-405 and the contract includes provisions that:
142	(A) require a managed care organization employee who will have access to information
143	from the database to submit to a criminal background check; and
144	(B) limit the authorized employee of the managed care organization to requesting either
145	the division or the Department of Health to conduct a search of the database regarding a
146	specific Medicaid enrollee and to report the results of the search to the authorized employee;
147	and
148	(ii) the information is requested by an authorized employee of the managed care
149	organization in relation to a person who is enrolled in the Medicaid program with the managed

150	care organization, and the managed care organization suspects the person may be improperly
151	obtaining or providing a controlled substance;
152	(f) a licensed practitioner having authority to prescribe controlled substances, to the
153	extent the information:
154	(i) (A) relates specifically to a current or prospective patient of the practitioner; and
155	(B) is provided to or sought by the practitioner for the purpose of:
156	(I) prescribing or considering prescribing any controlled substance to the current or
157	prospective patient;
158	(II) diagnosing the current or prospective patient;
159	(III) providing medical treatment or medical advice to the current or prospective
160	patient; or
161	(IV) determining whether the current or prospective patient:
162	(Aa) is attempting to fraudulently obtain a controlled substance from the practitioner;
163	or
164	(Bb) has fraudulently obtained, or attempted to fraudulently obtain, a controlled
165	substance from the practitioner;
166	(ii) (A) relates specifically to a former patient of the practitioner; and
167	(B) is provided to or sought by the practitioner for the purpose of determining whether
168	the former patient has fraudulently obtained, or has attempted to fraudulently obtain, a
169	controlled substance from the practitioner;
170	(iii) relates specifically to an individual who has access to the practitioner's Drug
171	Enforcement Administration identification number, and the practitioner suspects that the
172	individual may have used the practitioner's Drug Enforcement Administration identification
173	number to fraudulently acquire or prescribe a controlled substance;
174	(iv) relates to the practitioner's own prescribing practices, except when specifically
175	prohibited by the division by administrative rule;
176	(v) relates to the use of the controlled substance database by an employee of the
177	practitioner, described in Subsection (2)(g); or
178	(vi) relates to any use of the practitioner's Drug Enforcement Administration
179	identification number to obtain, attempt to obtain, prescribe, or attempt to prescribe, a
180	controlled substance;

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181 (g) in accordance with Subsection (3)(a), an employee of a practitioner described in 182 Subsection (2)(f), for a purpose described in Subsection (2)(f)(i) or (ii), if: 183 (i) the employee is designated by the practitioner as an individual authorized to access 184 the information on behalf of the practitioner; 185 (ii) the practitioner provides written notice to the division of the identity of the 186 employee; and 187 (iii) the division: 188 (A) grants the employee access to the database; and 189 (B) provides the employee with a password that is unique to that employee to access 190 the database in order to permit the division to comply with the requirements of Subsection 191 58-37f-203[(3)(b)](5) with respect to the employee; 192 (h) an employee of the same business that employs a licensed practitioner under 193 Subsection (2)(f) if: 194 (i) the employee is designated by the practitioner as an individual authorized to access 195 the information on behalf of the practitioner; 196 (ii) the practitioner and the employing business provide written notice to the division of 197 the identity of the designated employee; and 198 (iii) the division: 199 (A) grants the employee access to the database; and 200 (B) provides the employee with a password that is unique to that employee to access 201 the database in order to permit the division to comply with the requirements of Subsection 58-37f-203[(3)(b)](5) with respect to the employee; 202 203 (i) a licensed pharmacist having authority to dispense a controlled substance to the 204 extent the information is provided or sought for the purpose of: 205 (i) dispensing or considering dispensing any controlled substance; or 206 (ii) determining whether a person: 207 (A) is attempting to fraudulently obtain a controlled substance from the pharmacist; or 208 (B) has fraudulently obtained, or attempted to fraudulently obtain, a controlled 209 substance from the pharmacist; 210 (i) in accordance with Subsection (3)(a), a licensed pharmacy technician who is an 211 employee of a pharmacy as defined in Section 58-17b-102, for the purposes described in

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212 Subsection (2)(h)(i) or (ii), if: 213 (i) the employee is designated by the pharmacist-in-charge as an individual authorized 214 to access the information on behalf of a licensed pharmacist employed by the pharmacy; 215 (ii) the pharmacist-in-charge provides written notice to the division of the identity of 216 the employee; and 217 (iii) the division: (A) grants the employee access to the database; and 218 219 (B) provides the employee with a password that is unique to that employee to access 220 the database in order to permit the division to comply with the requirements of Subsection 221 58-37f-203[(3)(b)](5) with respect to the employee; 222 (k) federal, state, and local law enforcement authorities, and state and local 223 prosecutors, engaged as a specified duty of their employment in enforcing laws: 224 (i) regulating controlled substances: 225 (ii) investigating insurance fraud, Medicaid fraud, or Medicare fraud; or 226 (iii) providing information about a criminal defendant to defense counsel, upon request 227 during the discovery process, for the purpose of establishing a defense in a criminal case; 228 (1) employees of the Office of Internal Audit and Program Integrity within the 229 Department of Health who are engaged in their specified duty of ensuring Medicaid program 230 integrity under Section 26-18-2.3; 231 (m) a mental health therapist, if: 232 (i) the information relates to a patient who is: 233 (A) enrolled in a licensed substance abuse treatment program; and 234 (B) receiving treatment from, or under the direction of, the mental health therapist as 235 part of the patient's participation in the licensed substance abuse treatment program described 236 in Subsection (2)(m)(i)(A); 237 (ii) the information is sought for the purpose of determining whether the patient is 238 using a controlled substance while the patient is enrolled in the licensed substance abuse 239 treatment program described in Subsection (2)(m)(i)(A); and 240 (iii) the licensed substance abuse treatment program described in Subsection 241 (2)(m)(i)(A) is associated with a practitioner who: 242 (A) is a physician, a physician assistant, an advance practice registered nurse, or a

243	pharmacist; and
244	(B) is available to consult with the mental health therapist regarding the information
245	obtained by the mental health therapist, under this Subsection (2)(m), from the database;
246	(n) an individual who is the recipient of a controlled substance prescription entered into
247	the database, upon providing evidence satisfactory to the division that the individual requesting
248	the information is in fact the individual about whom the data entry was made;
249	(o) the inspector general, or a designee of the inspector general, of the Office of
250	Inspector General of Medicaid Services, for the purpose of fulfilling the duties described in
251	Title 63A, Chapter 13, Part 2, Office and Powers; and
252	(p) the following licensed physicians for the purpose of reviewing and offering an
253	opinion on an individual's request for workers' compensation benefits under Title 34A, Chapter
254	2, Workers' Compensation Act, or Title 34A, Chapter 3, Utah Occupational Disease Act:
255	(i) a member of the medical panel described in Section 34A-2-601; or
256	(ii) a physician offering a second opinion regarding treatment.
257	(3) (a) (i) A practitioner described in Subsection (2)(f) may designate up to three
258	employees to access information from the database under Subsection (2)(g), (2)(h), or (4)(c).
259	(ii) A pharmacist described in Subsection (2)(i) who is a pharmacist-in-charge may
260	designate up to three employees to access information from the database under Subsection
261	(2)(j).
262	(b) The division shall make rules, in accordance with Title 63G, Chapter 3, Utah
263	Administrative Rulemaking Act, to:
264	(i) establish background check procedures to determine whether an employee
265	designated under Subsection (2)(g), (2)(h), or (4)(c) should be granted access to the database;
266	and
267	(ii) establish the information to be provided by an emergency room employee under
268	Subsection (4).
269	(c) The division shall grant an employee designated under Subsection (2)(g), (2)(h), or
270	(4)(c) access to the database, unless the division determines, based on a background check, that
271	the employee poses a security risk to the information contained in the database.
272	(4) (a) An individual who is employed in the emergency room of a hospital may
273	exercise access to the database under this Subsection (4) on behalf of a licensed practitioner if

274 the individual is designated under Subsection (4)(c) and the licensed practitioner: 275 (i) is employed in the emergency room; 276 (ii) is treating an emergency room patient for an emergency medical condition; and 277 (iii) requests that an individual employed in the emergency room and designated under 278 Subsection (4)(c) obtain information regarding the patient from the database as needed in the 279 course of treatment. 280 (b) The emergency room employee obtaining information from the database shall, 281 when gaining access to the database, provide to the database the name and any additional 282 identifiers regarding the requesting practitioner as required by division administrative rule 283 established under Subsection (3)(b). 284 (c) An individual employed in the emergency room under this Subsection (4) may 285 obtain information from the database as provided in Subsection (4)(a) if: 286 (i) the employee is designated by the practitioner as an individual authorized to access 287 the information on behalf of the practitioner; 288 (ii) the practitioner and the hospital operating the emergency room provide written 289 notice to the division of the identity of the designated employee; and 290 (iii) the division: 291 (A) grants the employee access to the database: and 292 (B) provides the employee with a password that is unique to that employee to access 293 the database in order to permit the division to comply with the requirements of Subsection 294 58-37f-203[(3)(b)](5) with respect to the employee. 295 (d) The division may impose a fee, in accordance with Section 63J-1-504, on a 296 practitioner who designates an employee under Subsection (2)(g), (2)(h), or (4)(c) to pay for the 297 costs incurred by the division to conduct the background check and make the determination 298 described in Subsection (3)(b). 299 (5) (a) An individual who is granted access to the database based on the fact that the 300 individual is a licensed practitioner or a mental health therapist shall be denied access to the 301 database when the individual is no longer licensed. 302 (b) An individual who is granted access to the database based on the fact that the 303 individual is a designated employee of a licensed practitioner shall be denied access to the 304 database when the practitioner is no longer licensed.

305	Section 3. Repealer.
306	This bill repeals:
307	Section 58-37f-801, Pilot program for real-time reporting for controlled substance
308	database Statewide implementation.
309	Section 4. Appropriation.
310	Under the terms and conditions of Title 63J, Chapter 1, Budgetary Procedures Act, for
311	the fiscal year beginning July 1, 2015, and ending June 30, 2016, the following sums of money
312	are appropriated from resources not otherwise appropriated, or reduced from amounts
313	previously appropriated, out of the funds or accounts indicated. These sums of money are in
314	addition to any amounts previously appropriated for fiscal year 2016.
315	To Department of Commerce - Division of Occupational and Professional Licensing
316	From General Fund \$46,000
317	Schedule of Programs:
318	Controlled Substance Database \$46,000
319	Section 5. Effective date.
320	This bill takes effect on July 1, 2015.