

Senator Curtis S. Bramble proposes the following substitute bill:

ONLINE PHARMACY AMENDMENTS

2010 GENERAL SESSION

STATE OF UTAH

Chief Sponsor: Curtis S. Bramble

House Sponsor: Rebecca D. Lockhart

Cosponsor: Peter C. Knudson

LONG TITLE

General Description:

This bill creates an Online Prescribing, Dispensing, and Facilitation Licensing Act.

Highlighted Provisions:

This bill:

- ▶ amends unlawful conduct provisions;
- ▶ defines terms;
- ▶ requires licenses with the state to engage in online prescribing, online dispensing, or online facilitation;
- ▶ establishes requirements for the licenses;
- ▶ allows certain online prescribers, online contract pharmacies, and Internet facilitators to continue delivering online pharmaceutical services while their applications for licensure are pending with the division;
- ▶ establishes duties for a licensed online prescriber, online contract pharmacy, and Internet facilitator;
- ▶ limits the type of drugs that can be prescribed online;
- ▶ requires the use of an Internet facilitator and an online contract pharmacy to prescribe online; and



26 ▶ provides enforcement mechanisms for the division.

27 **Monies Appropriated in this Bill:**

28 None

29 **Other Special Clauses:**

30 None

31 **Utah Code Sections Affected:**

32 **AMENDS:**

33 **58-1-501**, as last amended by Laws of Utah 2007, Chapter 162

34 **ENACTS:**

35 **58-83-101**, Utah Code Annotated 1953

36 **58-83-102**, Utah Code Annotated 1953

37 **58-83-201**, Utah Code Annotated 1953

38 **58-83-301**, Utah Code Annotated 1953

39 **58-83-302**, Utah Code Annotated 1953

40 **58-83-303**, Utah Code Annotated 1953

41 **58-83-304**, Utah Code Annotated 1953

42 **58-83-305**, Utah Code Annotated 1953

43 **58-83-306**, Utah Code Annotated 1953

44 **58-83-307**, Utah Code Annotated 1953

45 **58-83-308**, Utah Code Annotated 1953

46 **58-83-401**, Utah Code Annotated 1953

47 **58-83-501**, Utah Code Annotated 1953

48 **58-83-502**, Utah Code Annotated 1953

49 **58-83-503**, Utah Code Annotated 1953



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

52 Section 1. Section **58-1-501** is amended to read:

53 **58-1-501. Unlawful and unprofessional conduct.**

54 (1) "Unlawful conduct" means conduct, by any person, that is defined as unlawful
55 under this title and includes:

56 (a) practicing or engaging in, representing oneself to be practicing or engaging in, or

57 attempting to practice or engage in any occupation or profession requiring licensure under this
58 title if the person is:

59 (i) not licensed to do so or not exempted from licensure under this title; or

60 (ii) restricted from doing so by a suspended, revoked, restricted, temporary,
61 probationary, or inactive license;

62 (b) impersonating another licensee or practicing an occupation or profession under a
63 false or assumed name, except as permitted by law;

64 (c) knowingly employing any other person to practice or engage in or attempt to
65 practice or engage in any occupation or profession licensed under this title if the employee is
66 not licensed to do so under this title;

67 (d) knowingly permitting the person's authority to practice or engage in any occupation
68 or profession licensed under this title to be used by another, except as permitted by law;

69 (e) obtaining a passing score on a licensure examination, applying for or obtaining a
70 license, or otherwise dealing with the division or a licensing board through the use of fraud,
71 forgery, or intentional deception, misrepresentation, misstatement, or omission; or

72 (f) (i) [~~unless Subsection (2)(m) or (4) applies,~~] issuing, or aiding and abetting in the
73 issuance of, an order or prescription for a drug or device to a person located in this state:

74 (A) without prescriptive authority conferred by a license issued under this title, or by
75 an exemption to licensure under this title; or

76 (B) with prescriptive authority conferred by an exception issued under this title or a
77 multistate practice privilege recognized under this title, if the prescription was issued[~~:(f)~~]
78 without first obtaining information, in the usual course of professional practice, that is
79 sufficient to establish a diagnosis, to identify underlying conditions, and to identify
80 contraindications to the proposed treatment; [~~or~~] and

81 [~~(H) based on a questionnaire completed by the patient on the internet, or toll-free~~
82 ~~telephone number, when there exists no other bona fide patient-practitioner relationship; or]~~

83 [~~(C) in violation of Subsection (2)(m), when the licensed person who issued, or aided~~
84 ~~and abetted another in the issuance of the prescription has violated Subsection (2)(m) on more~~
85 ~~than 100 prescriptions within a 30 day period of time; and]~~

86 (ii) Subsection (1)(f)(i) does not apply to treatment rendered in an emergency, on-call
87 or cross coverage situation, provided that the person who issues the prescription has

88 prescriptive authority conferred by a license under this title, or is exempt from licensure under
89 this title.

90 (2) "Unprofessional conduct" means conduct, by a licensee or applicant, that is defined
91 as unprofessional conduct under this title or under any rule adopted under this title and
92 includes:

93 (a) violating, or aiding or abetting any other person to violate, any statute, rule, or order
94 regulating an occupation or profession under this title;

95 (b) violating, or aiding or abetting any other person to violate, any generally accepted
96 professional or ethical standard applicable to an occupation or profession regulated under this
97 title;

98 (c) engaging in conduct that results in conviction, a plea of nolo contendere, or a plea
99 of guilty or nolo contendere which is held in abeyance pending the successful completion of
100 probation with respect to a crime of moral turpitude or any other crime that, when considered
101 with the functions and duties of the occupation or profession for which the license was issued
102 or is to be issued, bears a reasonable relationship to the licensee's or applicant's ability to safely
103 or competently practice the occupation or profession;

104 (d) engaging in conduct that results in disciplinary action, including reprimand,
105 censure, diversion, probation, suspension, or revocation, by any other licensing or regulatory
106 authority having jurisdiction over the licensee or applicant in the same occupation or profession
107 if the conduct would, in this state, constitute grounds for denial of licensure or disciplinary
108 proceedings under Section 58-1-401;

109 (e) engaging in conduct, including the use of intoxicants, drugs, narcotics, or similar
110 chemicals, to the extent that the conduct does, or might reasonably be considered to, impair the
111 ability of the licensee or applicant to safely engage in the occupation or profession;

112 (f) practicing or attempting to practice an occupation or profession regulated under this
113 title despite being physically or mentally unfit to do so;

114 (g) practicing or attempting to practice an occupation or profession regulated under this
115 title through gross incompetence, gross negligence, or a pattern of incompetency or negligence;

116 (h) practicing or attempting to practice an occupation or profession requiring licensure
117 under this title by any form of action or communication which is false, misleading, deceptive,
118 or fraudulent;

119 (i) practicing or attempting to practice an occupation or profession regulated under this
120 title beyond the scope of the licensee's competency, abilities, or education;

121 (j) practicing or attempting to practice an occupation or profession regulated under this
122 title beyond the scope of the licensee's license;

123 (k) verbally, physically, mentally, or sexually abusing or exploiting any person through
124 conduct connected with the licensee's practice under this title or otherwise facilitated by the
125 licensee's license;

126 (l) acting as a supervisor without meeting the qualification requirements for that
127 position that are defined by statute or rule;

128 (m) ~~[unless Subsection (4) applies,]~~ issuing, or aiding and abetting in the issuance of,
129 an order or prescription for a drug or device:

130 (i) without first obtaining information in the usual course of professional practice, that
131 is sufficient to establish a diagnosis, to identify conditions, and to identify contraindications to
132 the proposed treatment; or

133 ~~[(ii) based on a questionnaire completed by the patient on the internet, or toll free
134 telephone number when there exists no other bona fide patient-practitioner relationship or bona
135 fide referral by a practitioner involved in an existing patient-practitioner relationship; or]~~

136 (ii) with prescriptive authority conferred by an exception issued under this title, or a
137 multi-state practice privilege recognized under this title, if the prescription was issued without
138 first obtaining information, in the usual course of professional practice, that is sufficient to
139 establish a diagnosis, to identify underlying conditions, and to identify contraindications to the
140 proposed treatment; or

141 (n) violating a provision of Section 58-1-501.5.

142 ~~[(3) Subsection (2)(m) does not apply to treatment rendered in an emergency, on-call,
143 or cross coverage situation.]~~

144 ~~[(4) Notwithstanding Subsections (1)(f) and (2)(m), the division may permit a person
145 licensed to prescribe under this title to prescribe a legend drug to a person located in this state
146 if the division in collaboration with the appropriate professional board has permitted the
147 specific prescriptive practice of the legend drug by rule.]~~

148 Section 2. Section **58-83-101** is enacted to read:

149 **CHAPTER 83. ONLINE PRESCRIBING, DISPENSING,**

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AND FACILITATION LICENSING ACT

Part 1. General Provisions

58-83-101. Title.

This chapter is known as the "Online Prescribing, Dispensing, and Facilitation Licensing Act."

Section 3. Section **58-83-102** is enacted to read:

58-83-102. Definitions.

In addition to the definitions in Section 58-1-102, as used in this chapter:

(1) "Board" means the Online Prescribing, Dispensing, and Facilitation Licensing Board created in Section 58-83-201.

(2) "Branching questionnaire" means an adaptive and progressive assessment tool approved by the board.

(3) "Delivery of online pharmaceutical services" means the process in which a prescribing practitioner diagnoses a patient and prescribes one or more of the drugs authorized by Section 58-83-306, using:

(a) a branching questionnaire or other assessment tool approved by the division for the purpose of diagnosing and assessing a patient's health status;

(b) an Internet contract pharmacy to:

(i) dispense the prescribed drug; or

(ii) transfer the prescription to another pharmacy; and

(c) an Internet facilitator to facilitate the practices described in Subsections (3)(a) and (b).

(4) "Division" means the Utah Division of Occupational and Professional Licensing.

(5) "Internet facilitator" means a licensed provider of a web-based system for electronic communication between and among an online prescriber, the online prescriber's patient, and the online contract pharmacy.

(6) "Online contract pharmacy" means a pharmacy licensed and in good standing under Chapter 17b, Pharmacy Practice Act, as either a Class A Retail Pharmacy or a Class B Closed Door Pharmacy and licensed under this chapter to fulfill prescriptions issued by an online prescriber through a specific Internet facilitator.

(7) "Online prescriber" means a person:

- 181 (a) licensed under another chapter of this title;
- 182 (b) whose license under another chapter of this title includes assessing, diagnosing, and
- 183 prescribing authority for humans; and
- 184 (c) who has obtained a license under this chapter to engage in online prescribing.
- 185 (8) "Unlawful conduct" is as defined in Sections 58-1-501 and 58-83-501.
- 186 (9) "Unprofessional conduct" is as defined in Sections 58-1-203 and 58-83-502, and as
- 187 further defined by the division in accordance with Title 63G, Chapter 3, Utah Administrative
- 188 Rulemaking Act.

189 Section 4. Section **58-83-201** is enacted to read:

190 **Part 2. Board**

191 **58-83-201. Board.**

192 (1) There is created the Online Prescribing, Dispensing, and Facilitation Licensing

193 Board consisting of the following seven members:

194 (a) two members who are licensed under either Chapter 67, Utah Medical Practices

195 Act, or Chapter 68, Utah Osteopathic Medical Practices Act, of which:

196 (i) one shall be engaged in the delivery of online pharmaceutical services; and

197 (ii) one may not be an online prescriber licensed under this chapter;

198 (b) two members who are licensed as a pharmacist under Chapter 17b, Pharmacy

199 Practice Act, of which:

200 (i) one shall be associated with an online contract pharmacy; and

201 (ii) one may not be associated with an online contract pharmacy;

202 (c) two members of the general public who are not associated with:

203 (i) an online prescriber;

204 (ii) an online contract pharmacy; or

205 (iii) an Internet facilitator; and

206 (d) one member who is licensed under this chapter as an Internet facilitator.

207 (2) Notwithstanding any other requirement for membership on the board, no more than

208 one member of the board may be associated in any of the following ways with the same

209 Internet facilitator:

210 (a) as an owner;

211 (b) as an employee;

- 212 (c) as an officer;
- 213 (d) as a director;
- 214 (e) contracted with;
- 215 (f) as an agent of; or
- 216 (g) having any direct or indirect financial interest.

217 (3) The board shall be appointed and serve in accordance with Section 58-1-201.

218 (4) (a) The duties and responsibilities of the board shall be in accordance with Sections
219 58-1-202 and 58-1-203, and as otherwise provided in this chapter.

220 (b) The board may designate one of its members on a permanent or rotating basis to:

221 (i) assist the division in reviewing complaints concerning the unlawful or
222 unprofessional conduct of a licensee; and

223 (ii) advise the division in its investigation of a complaint.

224 (5) A board member who has, under Subsection (4), reviewed a complaint or advised
225 in its investigation may be disqualified from participating with the board when the board serves
226 as a presiding officer of an administrative proceeding concerning the complaint.

227 Section 5. Section **58-83-301** is enacted to read:

228 **Part 3. Licensing**

229 **58-83-301. Licensure required -- Issuance of licenses.**

230 (1) Beginning July 1, 2010, and except as provided in Section 58-1-307:

231 (a) a physician licensed under Chapter 67, Utah Medical Practice Act, or Chapter 68,
232 Utah Osteopathic Medical Practice Act, shall be licensed under this chapter to engage in the
233 delivery of online pharmaceutical services;

234 (b) an online contract pharmacy shall be licensed under this chapter to engage in the
235 delivery of online pharmaceutical services; and

236 (c) an Internet facilitator shall be licensed under this chapter to engage in the delivery
237 of online pharmaceutical services.

238 (2) The division shall issue, to any person who qualifies under this chapter, a license:

239 (a) to prescribe online;

240 (b) to operate as an online contract pharmacy; or

241 (c) to operate as an Internet facilitator.

242 (3) (a) A license under this chapter is not required to engage in electronic prescribing

243 under Chapter 82, Electronic Prescribing Act; and

244 (b) nothing in this chapter shall prohibit a physician licensed under Chapter 67, Utah
245 Medical Practice Act, or Chapter 68, Utah Osteopathic Medical Practice Act, from electronic
246 prescribing or Internet prescribing as permitted by Chapter 67 or 68, or other law.

247 Section 6. Section **58-83-302** is enacted to read:

248 **58-83-302. Qualifications for licensure.**

249 (1) Each applicant for licensure as an online prescriber under this chapter shall:

250 (a) submit an application in a form prescribed by the division;

251 (b) pay a fee determined by the department under Section 63J-1-504;

252 (c) be of good moral character;

253 (d) document that the applicant holds a Utah license that is active and in good standing
254 and authorizes the licensee to engage in the assessment, diagnosis, and treatment of human
255 ailments and the prescription of medications;

256 (e) document that any other professional license the applicant possesses from other
257 jurisdictions is in good standing;

258 (f) (i) submit to the division an outline of the applicant's proposed online assessment,
259 diagnosis, and prescribing tool, such as a branching questionnaire; and

260 (ii) demonstrate the proposed online assessment, diagnosis, and prescribing tool to the
261 board and establish to the board's satisfaction that the utilization of that assessment tool to
262 facilitate the prescription of the drugs approved for online prescribing under Section 58-83-305
263 does not compromise the public's health, safety, or welfare;

264 (g) submit policies and procedures that address patient confidentiality, including
265 measures that will be taken to ensure that the age and other identifying information of the
266 person completing the online branching questionnaire are accurate;

267 (h) describe the mechanism by which the online prescriber and patient will
268 communicate with one another, including electronic and telephonic communication;

269 (i) describe how the online prescriber/patient relationship will be established and
270 maintained;

271 (j) submit the name, address, and contact person of the Internet facilitator with whom
272 the online prescriber has contracted to provide services that the online prescriber will use to
273 engage in online assessment, diagnosis, and prescribing; and

274 (k) submit documentation satisfactory to the board regarding public health, safety, and
275 welfare demonstrating:

276 (i) how the online prescriber will comply with the requirements of Section 58-83-305;

277 (ii) the contractual services arrangement between the online prescriber and:

278 (A) the Internet facilitator; and

279 (B) the online contract pharmacy; and

280 (iii) how the online prescriber will allow and facilitate the division's ability to conduct
281 audits in accordance with Section 58-83-308.

282 (2) An online prescriber may not use the services of an Internet facilitator or online
283 contract pharmacy whose license is not active and in good standing.

284 (3) Each applicant for licensure as an online contract pharmacy under this chapter
285 shall:

286 (a) be licensed in good standing in Utah as a Class A Retail Pharmacy or a Class B
287 Closed Door Pharmacy;

288 (b) submit a written application in the form prescribed by the division;

289 (c) pay a fee as determined by the department under Section 63J-1-504;

290 (d) submit any contract between the applicant and the Internet facilitator with which
291 the applicant is or will be affiliated;

292 (e) submit proof of liability insurance acceptable to the division that expressly covers
293 all activities the online contract pharmacy will engage in under this chapter, which coverage
294 shall be in a minimum amount of \$1,000,000 per occurrence with a policy limit of not less than
295 \$3,000,000;

296 (f) submit a signed affidavit to the division attesting that the online contract pharmacy
297 will not dispense a drug that is prescribed by an online prescriber engaged in the delivery of
298 online pharmaceutical services under the provisions of this chapter unless:

299 (i) the drug is specifically approved by the division under Section 58-83-306; and

300 (ii) both the prescribing and the dispensing of the drug were facilitated by the Internet
301 facilitator with whom the Internet contract pharmacy is associated under Subsection
302 58-83-302(3)(d);

303 (g) document that any other professional license the applicant possesses from other
304 jurisdictions is active and in good standing; and

305 (h) demonstrate to the division that the applicant has satisfied any background check
306 required by Section 58-17b-307, and each owner, officer, or manager of the applicant online
307 contract pharmacy has not engaged in any act, practice, or omission, which when considered
308 with the duties and responsibilities of a licensee under this chapter indicates there is cause to
309 believe that issuing a license under this chapter is inconsistent with the public's health, safety,
310 or welfare.

311 (4) Each applicant for licensure as an Internet facilitator under this chapter shall:

312 (a) submit a written application in the form prescribed by the division;

313 (b) pay a fee as determined by the department under Section 63J-1-504;

314 (c) submit any contract between the applicant and the following with which the
315 applicant will be affiliated:

316 (i) each online prescriber; and

317 (ii) the single online contract pharmacy;

318 (d) submit written policies and procedures satisfactory to the division that:

319 (i) address patient privacy, including compliance with 45 C.F.R. Parts 160, 162, and
320 164, Health Insurance Portability and Accountability Act of 1996;

321 (ii) ensure compliance with all applicable laws by health care personnel and the online
322 prescriber who will process patient communications;

323 (iii) list the hours of operation;

324 (iv) describe the types of services that will be permitted electronically;

325 (v) describe the required patient information to be included in the communication, such
326 as patient name, identification number, and type of transaction;

327 (vi) establish procedures for archiving and retrieving information; and

328 (vii) establish quality oversight mechanisms;

329 (e) submit written documentation of the applicant's security measures to ensure the
330 confidentiality and integrity of any user-identifiable medical information;

331 (f) submit a description of the mechanism for:

332 (i) patients to access, supplement, and amend patient-provided personal health
333 information;

334 (ii) back-up regarding the Internet facilitator electronic interface;

335 (iii) the quality of information and services provided via the interface; and

- 336 (iv) patients to register complaints regarding the Internet facilitator, the online
- 337 prescriber, or the online contract pharmacy;
- 338 (g) submit a copy of the Internet facilitator's website;
- 339 (h) sign an affidavit attesting that:
- 340 (i) the applicant will not access any medical records or information contained in the
- 341 medical record except as necessary to administer the website and the branching questionnaire;
- 342 and
- 343 (ii) the applicant and its principals, and any entities affiliated with them, will only use
- 344 the services of a single online contract pharmacy named on the license approved by the
- 345 division; and

346 (i) submit any other information required by the division.

347 Section 7. Section **58-83-303** is enacted to read:

348 **58-83-303. Term of license -- Expiration -- Renewal.**

349 (1) The online prescriber's license shall be associated with the online prescriber's

350 primary professional license and may be renewed at the time the primary license is renewed in

351 accordance with Subsection 58-1-308(1).

352 (2) The online contract pharmacy license shall be associated with the online contract

353 pharmacy's primary professional license and may be renewed at the time the primary license is

354 renewed in accordance with Subsection 58-1-308(1).

355 (3) The Internet facilitator license shall be renewed in accordance with Section

356 58-1-308.

357 (4) Each licensee shall, at the time of applying for renewal, demonstrate compliance

358 with this chapter.

359 (5) Each license shall automatically expire on the expiration date shown on the license

360 unless the licensee renews it in accordance with Section 58-1-308.

361 Section 8. Section **58-83-304** is enacted to read:

362 **58-83-304. Existing written agreements for online prescribing -- Pending**

363 **applications.**

364 (1) (a) Subject to the provisions of this section, and until December 31, 2010, an entity

365 or individual not licensed by the division to engage in the delivery of online pharmaceutical

366 services under this chapter may nevertheless engage in the delivery of online pharmaceutical

367 services if permitted by the division to do so prior to December 31, 2009, under either:

368 (i) a non-disciplinary stipulation and consent order with the division; or

369 (ii) a letter agreement with the division.

370 (b) An entity or individual subject to Subsection (1)(a) shall only be permitted to
371 engage in the delivery of online pharmaceutical services after December 31, 2010, if, on or
372 before that date, it has obtained a license in accordance with the provisions of this chapter.

373 (2) An entity or individual engaged in the delivery of online pharmaceutical services
374 under the provisions of Subsection (1), may continue to operate in accordance with the terms
375 and conditions of the written consent or agreement subject to the following:

376 (a) On or before June 1, 2010, the entity or individual shall file an application with the
377 division in accordance with this chapter for:

378 (i) an online prescriber license;

379 (ii) an online contract pharmacy license; or

380 (iii) an Internet facilitator license.

381 (b) After the application for a license under this chapter is filed in accordance with
382 Subsection (2)(a), the applicant may continue to operate under the terms and conditions of the
383 written consent agreement under Subsection (1)(a) until the division has issued its decision on
384 the application.

385 (c) If the application is approved and a license is issued, the licensee:

386 (i) shall operate under the terms of the license under this chapter; and

387 (ii) may not operate under the terms and conditions of the prior written consent or
388 agreement of the division.

389 (d) If the application for license under this chapter is denied, the applicant may not
390 operate under the prior written consent or agreement with the division after the date the
391 application for a license under this chapter is denied by the division.

392 (3) (a) The following provisions apply to any application for authorization to engage in
393 the delivery of online pharmaceutical services that was pending with the division on the
394 effective date of this chapter:

395 (i) the applicant shall:

396 (A) no later than June 30, 2010, provide supplemental documentation to the division to
397 correct any deficiency in the application; and

398 (B) notify the division in writing that the application is ready to be acted upon by the
399 division; or

400 (ii) the applicant may rely upon the existing application submitted to the division
401 without any supplementation under Subsection (1)(a)(i), if the applicant notifies the division in
402 writing that the application is ready to be acted upon by the division.

403 (b) The division shall not, prior to June 30, 2010, act on an application pending with
404 the division on the effective date of this chapter unless the division prior to June 30, 2010,
405 receives a notification from the applicant that the application is ready to be acted upon by the
406 division.

407 Section 9. Section **58-83-305** is enacted to read:

408 **58-83-305. Duties and responsibilities.**

409 (1) The online prescriber shall:

410 (a) be held to the same standards of appropriate practice as those applicable in
411 traditional settings which, for purposes of this chapter, include the delivery of online
412 pharmaceutical services;

413 (b) conduct an assessment and diagnosis based upon a comprehensive health history
414 and an assessment tool such as a branching questionnaire;

415 (c) ensure that a comprehensive health history, assessment, and diagnosis have been
416 made before prescribing any medication;

417 (d) conduct the online assessment and diagnosis only through the approved Internet
418 facilitator identified in the online prescriber's application;

419 (e) comply with all applicable state and federal laws, rules, regulations, and orders;

420 (f) inform the patient electronically of the benefits and risks of appropriate treatment;

421 (g) guide the patient regarding the optimal course of action;

422 (h) treat the patient with courtesy, respect, dignity, responsiveness, and timely attention
423 to the patient's needs;

424 (i) comply with the requirements for confidentiality as required by this title and
425 applicable federal law;

426 (j) continue to provide the user with reasonable assistance and sufficient opportunity to
427 make alternative arrangements for care;

428 (k) be available for ongoing consultation with the patient through e-mail or other forms

429 of communication;

430 (l) not delegate to a third party the professional responsibility to:

431 (i) review and evaluate the results of the branching questionnaire;

432 (ii) consult with the patient electronically or through other means about the patient's

433 medical condition; and

434 (iii) diagnose and prescribe medications to the patient;

435 (m) conduct the online assessment and diagnosis and the electronic communication

436 between the online prescriber and the patient only through the approved Internet facilitator;

437 (n) (i) maintain the online medical records of the patient; and

438 (ii) if maintenance of the records is delegated by the online prescriber, delegate that

439 authority only to the approved Internet facilitator;

440 (o) inform a patient of the patient's freedom of choice to select the pharmacy to

441 dispense the patient's prescription by providing the patient with the phone number of the online

442 contract pharmacy so that the patient may contact the online contract pharmacy and request a

443 transfer of the prescription to another pharmacy; and

444 (p) authorize the Internet facilitator to provide the online contract pharmacy with the

445 patient's:

446 (i) full name;

447 (ii) current address and telephone number;

448 (iii) date of birth or age and gender;

449 (iv) height, weight, and vital signs (if known);

450 (v) medication allergies or drug reactions; and

451 (vi) current medications, including over-the-counter products, and any additional

452 comments relevant to the patient's drug use.

453 (2) The online contract pharmacy shall:

454 (a) only dispense prescription drugs that:

455 (i) are approved by the division in accordance with Section 58-83-306; and

456 (ii) were prescribed by an online prescriber who is using the Internet facilitator that is

457 under contract with the online contract pharmacy;

458 (b) maintain a toll-free number with a pharmacist available for patients using the

459 services of the online contract pharmacy to receive medications prescribed online;

460 (c) use a tracking identification number system when shipping medications prescribed
461 for patients by an online prescriber; and

462 (d) provide to the division a quarterly report of all drugs dispensed in accordance with
463 this chapter.

464 (3) The Internet facilitator shall:

465 (a) provide services that the online prescriber will use in implementing the branching
466 questionnaire;

467 (b) provide electronic or telephonic communication between the online prescriber and
468 the patient that:

469 (i) is secure and confidential;

470 (ii) allows the online prescriber to be directly accessible to a patient to answer
471 questions regarding the patient's treatment plan; and

472 (iii) provides privacy and security that complies with the provisions of 45 C.F.R. Parts
473 160, 162, and 164, Health Insurance Portability and Accountability Act of 1996;

474 (c) facilitate secure and confidential communication of the prescription issued by the
475 online prescriber to the online contract pharmacy in accordance with Subsection (1)(p);

476 (d) disclose on its website:

477 (i) the owner of the website;

478 (ii) the specific services provided by any associated online prescribers; and

479 (iii) other information the division may require by rule; and

480 (e) (i) only facilitate the delivery of online pharmaceutical services for the specific
481 legend drugs approved by the division in accordance with Section 58-83-306; or

482 (ii) not facilitate, directly or indirectly, through related entities or affiliates, the
483 dispensing or online prescribing of any drug whether controlled or legend that is not
484 specifically approved under Section 58-83-306.

485 Section 10. Section **58-83-306** is enacted to read:

486 **58-83-306. Drugs approved for online prescribing, dispensing, and facilitation.**

487 (1) An online prescriber may only prescribe, an online contract pharmacy may only
488 dispense, and an Internet facilitator may only facilitate the prescribing and dispensing of,
489 non-controlled, legend drugs that have been:

490 (a) approved by the Food and Drug Administration;

491 (b) prescribed to treat the condition for which the drug was approved; and
492 (c) specifically approved by the division for online prescribing by administrative rule
493 adopted in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act.

494 (2) If, after January 1, 2010, the Food and Drug Administration issues a clinical black
495 box warning with respect to any drug approved by the board under Subsection (1), the division
496 shall determine what action, if any, is necessary to protect the public health or welfare as a
497 result of the black box warning.

498 Section 11. Section **58-83-307** is enacted to read:

499 **58-83-307. Approval of additional drugs -- Request to facilitate.**

500 (1) An Internet facilitator licensed under this chapter may seek the division's approval
501 to facilitate the online prescribing and dispensing of prescriptions for additional drugs.

502 (2) The Internet facilitator shall make a request for approval of additional drugs by
503 petitioning for an amendment to the administrative rule adopted by the division in accordance
504 with Section 58-83-306 and Title 63G, Chapter 3, Utah Administrative Rulemaking Act.

505 Section 12. Section **58-83-308** is enacted to read:

506 **58-83-308. Audits.**

507 (1) Each licensee under this chapter shall allow and facilitate an audit by the division
508 regarding the licensee's delivery of online pharmaceutical services to ensure compliance with
509 state and federal statutes, rules, and regulations including ensuring that:

510 (a) a comprehensive history and assessment have been obtained and a diagnosis has
511 been made for a patient before any medications are prescribed; and

512 (b) only the approved medications are being prescribed and dispensed.

513 (2) The division shall be provided with the following, in the manner that allows access
514 from the division's office for the purpose of conducting an audit:

515 (a) full remote, read-only access rights to the data related to the online prescribing and
516 dispensing of a drug under this chapter and that is used and stored in the Internet facilitator's
517 system; and

518 (b) the information available to the online prescriber.

519 (3) An Internet facilitator licensed under this chapter shall provide to the division, at
520 the times designated by the division by administrative rule, a report containing the following
521 information:

- 522 (a) the number of prescriptions issued by the online prescribers associated with the
- 523 Internet facilitator by drug name;
- 524 (b) the number of comprehensive histories/assessments received by the Internet
- 525 facilitator;
- 526 (c) the number of comprehensive histories/assessments reviewed by an online
- 527 prescriber;
- 528 (d) the demographic data of the patients receiving prescriptions through the Internet
- 529 facilitator;
- 530 (e) the number of prescriptions:
- 531 (i) dispensed by the online contract pharmacy; or
- 532 (ii) transferred to a different pharmacy at the patient's request; and
- 533 (f) any other information specified by the division by administrative rule.
- 534 (4) The division's authority to conduct an audit pursuant to this chapter shall survive
- 535 any termination or expiration of any prescriptive authority for online prescribing, dispensing, or
- 536 facilitation.

537 Section 13. Section **58-83-401** is enacted to read:

538 **Part 4. License Denial and Discipline**

539 **58-83-401. Grounds for denial of license -- Disciplinary proceedings --**

540 **Termination of authority to prescribe -- Immediate and significant danger.**

541 (1) Grounds for refusing to issue a license to an applicant, for refusing to renew the

542 license of a licensee, for revoking, suspending, restricting, or placing on probation the license

543 of a licensee, for issuing a public or private reprimand to a licensee, and for issuing a cease and

544 desist order:

545 (a) shall be in accordance with Section 58-1-401; and

546 (b) includes:

547 (i) prescribing, dispensing, or facilitating the prescribing or dispensing of a drug not

548 approved by the board under Section 58-83-306; or

549 (ii) any other violation of this chapter.

550 (2) The termination or expiration of a license under this chapter for any reason does not

551 limit the division's authority to start or continue any investigation or adjudicative proceeding.

552 (3) Because of the working business relationship between and among the online

553 prescriber, the Internet facilitator, and the online contract pharmacy, each entity's ability to
554 comply with this chapter may depend in some respects on the actions of the others. It is
555 possible that a particular action or inaction by the online prescriber, the Internet facilitator, or
556 the online contract pharmacy could have the effect of causing the other licensed entities to be
557 out of compliance with this chapter, and each entity may, therefore, be held accountable for any
558 related party's non-compliance, if the party knew or reasonably should have known of the other
559 person's non-compliance.

560 (4) An online prescriber may lose the practitioner's professional license to prescribe
561 any drug under this title if the online prescriber knew or reasonably should have known that the
562 provisions of this chapter were violated by the online prescriber, the Internet facilitator, or the
563 online contract pharmacy. It is not a defense to an alleged violation under this chapter that the
564 alleged violation was a result of an action or inaction not by the charged party but by the related
565 online prescriber, the online contract pharmacy, or the Internet facilitator.

566 (5) The following actions may result in an immediate suspension of the online
567 prescriber's license, the online contract pharmacy's license, or the Internet facilitator's license,
568 and each is considered an immediate and significant danger to the public health, safety, or
569 welfare requiring immediate action by the division pursuant to Section 63G-4-502 to terminate
570 the delivery of online pharmaceutical services by the licensee:

571 (a) online prescribing, dispensing, or facilitation with respect to:

572 (i) a person under the age of 18 years;

573 (ii) a legend drug not authorized by the division in accordance with Section 58-83-306;

574 and

575 (iii) any controlled substance;

576 (b) violating this chapter after having been given reasonable opportunity to cure the
577 violation;

578 (c) using the name or official seal of the state, the Utah Department of Commerce, or
579 the Utah Division of Occupational and Professional Licensing, or their boards, in an
580 unauthorized manner; or

581 (d) failing to respond to a request from the division within the time frame requested
582 for:

583 (i) an audit of the website; or

584 (ii) records of the online prescriber, the Internet facilitator, or the online contract
585 pharmacy.

586 Section 14. Section **58-83-501** is enacted to read:

587 **Part 5. Unlawful and Unprofessional Conduct - Penalties**

588 **58-83-501. Unlawful conduct.**

589 "Unlawful conduct" includes, in addition to the definition in Section 58-1-501,
590 engaging in the practice of Internet prescribing without a license under this chapter.

591 Section 15. Section **58-83-502** is enacted to read:

592 **58-83-502. Unprofessional conduct.**

593 "Unprofessional conduct" includes, in addition to the definition in Section 58-1-501 and
594 as may be further defined by administrative rule:

595 (1) online prescribing, dispensing, or facilitation with respect to a person under the age
596 of 18 years;

597 (2) using the name or official seal of the state, the Utah Department of Commerce, or
598 the Utah Division of Occupational and Professional Licensing, or their boards, in an
599 unauthorized manner;

600 (3) failing to respond promptly to a request by the division for information including:

601 (a) an audit of the website; or

602 (b) records of the online prescriber, the Internet facilitator, or the online contract
603 pharmacy;

604 (4) using an online prescriber, online contract pharmacy, or Internet facilitator without
605 approval of the division;

606 (5) failing to inform a patient of the patient's freedom of choice in selecting who will
607 dispense a prescription in accordance with Subsection 58-83-305(1)(n); and

608 (6) failing to keep the division informed of the name and contact information of the
609 Internet facilitator or online contract pharmacy.

610 Section 16. Section **58-83-503** is enacted to read:

611 **58-83-503. Unlawful conduct.**

612 Unlawful conduct includes, in addition to the definition in Section 58-1-501:

613 (1) online prescribing, dispensing or facilitating of a legend drug not authorized by the
614 division in accordance with Section 58-83-306; or

615

(2) online prescribing, dispensing or facilitating of a controlled substance.

S.B. 274 2nd Sub. (Salmon) - Online Pharmacy Amendments

Fiscal Note

2010 General Session
State of Utah

State Impact

Enactment of this bill will generate \$1,200 in revenue to the General Fund annually. The bill will require one new FTE and a new board estimated to cost \$80,800 per year from the Commerce Service Fund. License fee revenue is estimated at \$82,000 per year. Commerce Service Fund revenue and appropriations impact year-end transfers to the General Fund.

	<u>FY 2010</u> <u>Approp.</u>	<u>FY 2011</u> <u>Approp.</u>	<u>FY 2012</u> <u>Approp.</u>	<u>FY 2010</u> <u>Revenue</u>	<u>FY 2011</u> <u>Revenue</u>	<u>FY 2012</u> <u>Revenue</u>
General Fund	\$0	\$0	\$0	\$0	\$1,200	\$1,200
Commerce Service Fund	\$0	\$80,800	\$80,800	\$0	\$80,800	\$80,800
Total	\$0	\$80,800	\$80,800	\$0	\$82,000	\$82,000

Individual, Business and/or Local Impact

Individuals and businesses who are eligible for licensure will need to pay the fee for that license. Enactment of this bill likely will not result in direct, measurable costs and/or benefits for local governments.
