

1 **ONLINE PHARMACY AMENDMENTS**

2 2010 GENERAL SESSION

3 STATE OF UTAH

4 **Chief Sponsor: Curtis S. Bramble**

5 House Sponsor: _____

7 **LONG TITLE**

8 **General Description:**

9 This bill creates a Limited Online Prescribing, Fulfillment, and Facilitation Licensing
10 Act.

11 **Highlighted Provisions:**

12 This bill:

- 13 ▶ amends unlawful conduct provisions;
- 14 ▶ defines terms;
- 15 ▶ requires a license with the state to engage in the practice of limited online
16 prescribing, fulfillment, and facilitation licensing;
- 17 ▶ establishes requirements for a license;
- 18 ▶ allows certain online prescribers, online pharmacies, and Internet facilitators to
19 continue prescribing online while an application for license is pending with the
20 division;
- 21 ▶ establishes duties for a licensed online prescriber, online pharmacy, and online
22 facilitator;
- 23 ▶ limits the type of drugs that can be prescribed online;
- 24 ▶ requires the use of an Internet facilitator and a contractual pharmacy to prescribe
25 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



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

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

52 **58-1-501. Unlawful and unprofessional conduct.**

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

55 (a) practicing or engaging in, representing oneself to be practicing or engaging in, or
56 attempting to practice or engage in any occupation or profession requiring licensure under this
57 title if the person is:

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

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

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

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

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

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

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

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

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

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

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

85 (ii) Subsection (1)(f) does not apply to treatment rendered in an emergency, on-call or
86 cross coverage situation, provided that the person who issues the prescription has prescriptive
87 authority conferred by a license under this title, or is exempt from licensure under this title.

88 (2) "Unprofessional conduct" means conduct, by a licensee or applicant, that is defined
89 as unprofessional conduct under this title or under any rule adopted under this title and

90 includes:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

147 **CHAPTER 83. LIMITED ONLINE PRESCRIBING, FULFILLMENT, AND**
 148 **FACILITATION LICENSE ACT**

149 **Part 1. General Provisions**

150 **58-83-101. Title.**

151 This chapter is known as the "Limited Online Prescribing, Fulfillment, and Facilitation

152 License Act."

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

154 **58-83-102. Definitions.**

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

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

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

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

161 (4) "Internet facilitator" means a licensed provider of a web-based system for electronic
162 communication between and among a limited online prescribing practitioner, the limited online
163 prescribing practitioner's patient, and the online patient's pharmacy.

164 (5) "Limited online prescribing" means the practice of prescribing one or more of the
165 drugs listed in Section 58-83-306 by a limited online prescribing practitioner.

166 (6) "Limited online prescribing practitioner" means a person:

167 (a) licensed under another chapter of this title;

168 (b) whose license under another chapter of this title includes assessing, diagnosing, and
169 prescribing authority for humans; and

170 (c) who has obtained a license under this chapter to engage in limited online
171 prescribing.

172 (7) "Online contract pharmacy" means a pharmacy licensed and in good standing under
173 Chapter 17b, Pharmacy Practice Act, as either a Class A Retail Pharmacy or a Class B Closed
174 Door Pharmacy that is licensed to fulfill prescriptions issued by a limited online prescribing
175 practitioner through a specific Internet facilitator.

176 (8) "Unlawful conduct" is as defined in Sections 58-1-501 and 58-83-501.

177 (9) "Unprofessional conduct" is as defined in Sections 58-1-203 and 58-83-502, and as
178 further defined by the division in accordance with Title 63G, Chapter 3, Utah Administrative
179 Rulemaking Act.

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

181 **Part 2. Board**

182 **58-83-201. Board.**

183 (1) There is created the Limited Online Prescribing, Fulfillment, and Facilitation
184 Licensing Board consisting of four persons licensed in accordance with this title and one
185 member of the general public.

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

187 (3) (a) The duties and responsibilities of the board shall be in accordance with Sections
188 58-1-202 and 58-1-203 and as otherwise provided in this chapter.

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

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

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

193 (4) A board member who has, under Subsection (3), reviewed a complaint or advised
194 in its investigation may be disqualified from participating with the board when the board serves
195 as a presiding officer of an administrative proceeding concerning the complaint.

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

197 **Part 3. Licensing**

198 **58-83-301. Licensure required -- Issuance of licenses.**

199 (1) Beginning July 1, 2010, and except as provided in Sections 58-1-307, a physician
200 licensed under Chapter 67, Utah Medical Practice Act, or Chapter 68, Utah Osteopathic
201 Medical Practice Act, online contract pharmacies and Internet facilitators are required to be
202 licensed under this chapter to engage in or facilitate the limited practice of online prescribing or
203 fulfillment and the facilitation of those activities.

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

205 (a) to engage in the limited practice of online prescribing;

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

207 (c) to operate as an Internet facilitator.

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

209 **58-83-302. Qualifications for licensure.**

210 (1) Each applicant for licensure as a limited online prescribing practitioner under this
211 chapter shall:

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

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

- 214 (c) be of good moral character;
- 215 (d) document that the applicant holds a Utah license that is active and in good standing
- 216 and authorizes the licensee to engage in the assessment, diagnosis, and treatment of human
- 217 ailments and the prescription of medications;
- 218 (e) document that any other professional license the applicant possesses from other
- 219 jurisdictions is in good standing;
- 220 (f) (i) submit to the division an outline of the applicant's proposed online assessment,
- 221 diagnosis, and prescribing tool, such as a branching questionnaire; and
- 222 (ii) demonstrate the proposed online assessment, diagnosis, and prescribing tool to the
- 223 board and establish to the board's satisfaction that the utilization of that assessment tool to
- 224 facilitate the prescription of the drugs approved for online prescribing under Section 58-83-306
- 225 does not compromise the public's health, safety, or welfare;
- 226 (g) submit policies and procedures that address patient confidentiality, including
- 227 measures that will be taken to ensure that the age and other identifying information of the
- 228 person completing the online branching questionnaire are accurate;
- 229 (h) describe the mechanism by which the limited online prescribing practitioner and
- 230 patient will communicate with one another, including electronic and telephonic
- 231 communication;
- 232 (i) describe how the limited online prescribing practitioner/patient relationship will be
- 233 established and maintained;
- 234 (j) submit the name, address, and contact person of the Internet facilitator with whom
- 235 the limited online prescribing practitioner has contracted to provide services that the limited
- 236 online prescribing practitioner will use to engage in online assessment, diagnosis, and
- 237 prescribing; and
- 238 (k) submit documentation satisfactory to the board regarding public health, safety, and
- 239 welfare demonstrating:
- 240 (i) how the limited online prescribing practitioner will comply with the requirements of
- 241 Section 58-83-303;
- 242 (ii) the contractual services arrangement between the limited online prescribing
- 243 practitioner and:
- 244 (A) the Internet facilitator; and

245 (B) the online contract pharmacy; and
246 (iii) how the limited online prescribing practitioner will allow and facilitate the
247 division's ability to conduct audits in accordance with Section 58-83-308.
248 (2) A limited online prescribing practitioner may not use the services of an Internet
249 facilitator or online contract pharmacy that is engaging in or has engaged in unlawful or
250 unprofessional conduct under this title, or Section 58-83-501 or 58-83-502 within the past three
251 years.
252 (3) Each applicant for licensure as an online contract pharmacy under this chapter
253 shall:
254 (a) be licensed in good standing in Utah as a Class A Retail Pharmacy or a Class B
255 Closed Door Pharmacy;
256 (b) submit a written application in the form prescribed by the division;
257 (c) pay a fee as determined by the department under Section 63J-1-504;
258 (d) submit any contract between the applicant and the Internet facilitator with which
259 the applicant is or will be affiliated;
260 (e) submit proof of liability insurance acceptable to the division that expressly covers
261 all activities the online contract pharmacy will engage in under this chapter, which coverage
262 shall be in a minimum amount of \$1,000,000 per occurrence with a policy limit of not less than
263 \$3,000,000;
264 (f) sign an affidavit attesting that the applicant and its principals, and any entities
265 affiliated with them, will not dispense any drug, whether controlled or non-controlled, other
266 than those specifically approved by the division in Section 58-53-306;
267 (g) sign an affidavit attesting that the applicant and its principals, and any entities
268 affiliated with them, will only fulfill prescriptions received from the Internet facilitator named
269 on the license approved by the division;
270 (h) document that any other professional license the applicant possesses from other
271 jurisdictions is in good standing; and
272 (i) in accordance with Section 58-17b-307, submit to a criminal background check by
273 the division of all key personnel involved in the operation of the online contract pharmacy,
274 including the most senior personnel responsible for facility operation, purchasing, and
275 inventory control and the persons they report to in order to determine if an applicant or others

276 associated with the ownership, management, or operations of the online contract pharmacy
277 have committed acts that would constitute grounds for denial of licensure.

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

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

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

281 (c) submit any contract between the applicant and any of the following with which the
282 applicant will be affiliated:

283 (i) an online prescribing practitioner; and

284 (ii) an online contract pharmacy;

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

286 (i) address patient privacy;

287 (ii) ensure compliance with all applicable laws by all health care personnel in addition
288 to the limited online prescribing practitioner who will process patient communications;

289 (iii) list the hours of operation;

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

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

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

294 (vii) establish quality oversight mechanisms;

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

297 (f) submit a description of the mechanism for patients to access, supplement, and
298 amend patient-provided personal health information and provide back-up regarding the Internet
299 facilitator electronic interface and the quality of information and services provided via the
300 interface;

301 (g) submit a description of the mechanism for patients to register complaints regarding
302 the Internet facilitator, the limited online prescribing practitioner, or the online contract
303 pharmacy;

304 (h) submit a copy of the Internet facilitator's website;

305 (i) sign an affidavit attesting that the applicant will not access any medical records or
306 information contained therein except as necessary to administer the website and the branching

307 questionnaire;

308 (j) sign an affidavit attesting that the applicant and its principals, and any entities
309 affiliated with them, will only use the services of the online contract pharmacy named on the
310 license approved by the division; and

311 (k) submit any other information required by the division.

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

313 **58-83-303. Term of license -- Expiration -- Renewal.**

314 (1) The limited online prescribing license shall be associated with the limited online
315 prescribing practitioner's primary professional license and may be renewed at the time the
316 primary license is renewed in accordance with Subsection 58-1-308(1).

317 (2) The online contract pharmacy license shall be associated with the online contract
318 pharmacy's primary professional license and may be renewed at the time the primary license is
319 renewed in accordance with Subsection 58-1-308(1).

320 (3) The Internet facilitator license shall be renewed in accordance with Section
321 58-1-308.

322 (4) Each licensee shall, at the time of applying for renewal, demonstrate compliance
323 with this chapter.

324 (5) Each license shall automatically expire on the expiration date shown on the license
325 unless the licensee renews it in accordance with Section 58-1-308.

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

327 **58-83-304. Existing written agreements for online prescribing -- Pending**
328 **applications.**

329 (1) (a) Subject to the provisions of this section, and until December 31, 2010, an entity
330 or individual not licensed by the division to engage in Internet prescribing, fulfillment, or
331 facilitation activities may nevertheless engage in such activities if permitted by the division to
332 do so prior to December 31, 2009, under either:

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

334 (ii) a letter agreement with the division.

335 (b) An entity or individual subject to Subsection (1)(a) shall only be permitted to
336 engage in online prescribing, fulfillment, or facilitation activities after December 31, 2010, if,
337 on or before that date, it has obtained a license to do so in accordance with the provisions of

338 this chapter.

339 (2) An entity or individual engaging in online prescribing, fulfillment, or facilitation
340 activities with the written consent or agreement of the division, as permitted under the
341 provisions of Subsection (1), may continue to operate in accordance with the terms and
342 conditions of such written consent or agreement subject to the following:

343 (a) On or before June 1, 2010, the entity or individual shall file an application with the
344 division in accordance with this chapter for a limited online prescribing license, online contract
345 pharmacy license, or Internet facilitator license.

346 (b) After the application for a limited online prescribing license, online contract
347 pharmacy license, or Internet facilitator license is filed, the applicant may continue to operate
348 under the terms and conditions of the prior written consent until the division has issued its
349 decision on the application.

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

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

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

354 (d) If the application for license under this chapter is denied, the applicant may not
355 operate under the prior written consent or agreement after the date the application for a license
356 under this chapter is denied.

357 (3) (a) The following provisions shall apply to any application for authorization to
358 engage in online prescribing, fulfillment, or facilitation that was pending with the division on
359 the effective date of this chapter:

360 (i) the application shall comply with this section;

361 (ii) the applicant:

362 (A) may, by no later than June 30, 2010, provide supplemental documentation to the
363 division to correct any deficiency in the application; and

364 (B) shall notify the division in writing that the application is ready to be acted upon by
365 the division; and

366 (iii) may rely upon the existing application to the division without any supplementation
367 if the applicant notifies the division in writing that the application is ready to be acted upon by
368 the division.

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

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

374 **58-83-305. Duties and responsibilities.**

375 (1) The limited online prescribing practitioner shall:

376 (a) be held to the same standards of appropriate practice as those applicable in
377 traditional settings;

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

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

382 (d) conduct the online assessment and diagnosis only through the approved Internet
383 facilitator identified in the limited online prescribing practitioner's application;

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

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

386 (g) guide the patient regarding the optimal course of action, but honor the patient's
387 decision to accept or refuse medical treatment;

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

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

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

394 (k) be available for ongoing consultation with the patient through e-mail or other forms
395 of communication;

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

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

398 (ii) consult with the patient electronically or through other means about the patient's
399 medical condition; and

- 400 (iii) diagnose and prescribe medications to the patient;
- 401 (m) conduct the online assessment and diagnosis, the electronic communication
- 402 between the limited online prescribing practitioner and the patient, and the maintenance of
- 403 online medical records if delegated by the limited online prescribing practitioner, only through
- 404 the approved Internet facilitator;
- 405 (n) inform a patient of the patient's freedom of choice in selecting who will dispense a
- 406 prescription; and
- 407 (o) authorize the Internet facilitator to provide the online pharmacy, should the patient
- 408 elect to use one, with the patient's:
- 409 (i) full name;
- 410 (ii) current address and telephone number;
- 411 (iii) date of birth or age and gender;
- 412 (iv) height, weight, and vital signs (if known);
- 413 (v) medication allergies or drug reactions; and
- 414 (vi) current medications, including over-the-counter products, and any additional
- 415 comments relevant to the patient's drug use.
- 416 (2) The online contract pharmacy shall:
- 417 (a) fill or dispense only prescriptions written by a licensed online prescribing
- 418 practitioner;
- 419 (b) maintain a toll-free number for patients utilizing the services of the online
- 420 pharmacy to receive medications prescribed online;
- 421 (c) use a tracking identification number system when shipping medications prescribed
- 422 for patients by a limited online prescribing practitioner; and
- 423 (d) provide to the division a quarterly report of all drugs dispensed in accordance with
- 424 this rule.
- 425 (3) The Internet facilitator shall:
- 426 (a) provide services that the limited online prescribing practitioner will use in
- 427 implementing the branching questionnaire;
- 428 (b) provide electronic or telephonic communication between the limited online
- 429 prescribing practitioner and the patient that:
- 430 (i) is secure and confidential;

431 (ii) allows the limited online prescribing practitioner to be directly accessible to a
432 patient to answer questions regarding the patient's treatment plan; and

433 (iii) provides security that complies with the provisions of 42 C.F.R. Parts 160, 162,
434 and 164, Health Insurance Portability and Accountability Act of 1996;

435 (c) disclose on its website:

436 (i) the owner of the website;

437 (ii) the specific services provided by any associated online prescribing practitioners;

438 and

439 (iii) such other information as the division shall require by rule; and

440 (d) only facilitate online pharmaceutical services with respect to the precise legend

441 drugs approved by the division for online prescription and fulfillment, and shall not either

442 directly or indirectly, through related entities or affiliates or otherwise, facilitate the

443 dissemination of any other drug, whether controlled or legend.

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

445 **58-83-306. Drugs approved for online prescribing, fulfillment, and facilitation.**

446 (1) In accordance with Subsection 58-1-501(4), a limited online prescribing
447 practitioner may only prescribe, an online contract pharmacy may only fulfill, and an Internet
448 facilitator may only facilitate the prescribing and fulfillment of, non-controlled, legend drugs
449 that have been:

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

451 (b) prescribed to treat the condition for which the drug was approved; and

452 (c) specifically approved by the division for online prescribing by administrative rule
453 adopted in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act.

454 (2) If, after January 1, 2010, the Food and Drug Administration issues a clinical black
455 box warning with respect to any drug approved by the board under Subsection (1), a person or
456 entity licensed under this chapter shall immediately cease prescribing, fulfilling, or facilitating
457 the prescribing or fulfillment of prescriptions for such drug.

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

459 **58-83-307. Approval of additional drugs -- Request to facilitate.**

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

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

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

466 **58-83-308. Audits.**

467 (1) The limited online prescribing practitioner shall allow and facilitate the ability of
468 the division to conduct audits of the records of the limited online prescribing practitioner,
469 online contract pharmacy, and Internet facilitator to ensure compliance with state and federal
470 statutes, rules, and regulations including:

471 (a) ensuring that a comprehensive history and assessment have been obtained and a
472 diagnosis has been made for a patient before any medications are prescribed; and

473 (b) ensuring that only the approved medications are being prescribed.

474 (2) The division shall be provided with, in the manner that allows access from the
475 division's office:

476 (a) full remote, read-only access rights to all of the data used and stored in the system
477 to conduct its audits; and

478 (b) the ability to access and review all of the information available to the limited online
479 prescribing practitioner.

480 (3) The limited online prescribing practitioner shall provide to the division, on a
481 quarterly basis or other basis as directed by the division, a report containing the following
482 information:

483 (a) number of prescriptions written by drug name;

484 (b) number of comprehensive histories/assessments received;

485 (c) number of comprehensive histories/assessments reviewed;

486 (d) the demographic data of the patients receiving prescriptions under this chapter;

487 (e) the number of prescriptions:

488 (i) dispensed by the online contract pharmacy;

489 (ii) sent to a patient's pharmacy of choice; and

490 (iii) sent directly to a patient; and

491 (f) any other information requested by the division.

492 (4) The division's authority to conduct an audit pursuant to this chapter shall survive

493 any termination or expiration of any prescriptive authority for online prescribing, fulfillment, or
494 facilitation.

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

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

497 **58-83-401. Grounds for denial of license -- Disciplinary proceedings --**

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

499 (1) Grounds for refusing to issue a license to an applicant, for refusing to renew the
500 license of a licensee, for revoking, suspending, restricting, or placing on probation the license
501 of a licensee, for issuing a public or private reprimand to a licensee, and for issuing a cease and
502 desist order:

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

504 (b) includes:

505 (i) prescribing, fulfilling, or facilitating the prescription or fulfillment of a drug not
506 expressly approved by the board for online prescribing, fulfillment, or facilitation; or

507 (ii) any other violation of this chapter.

508 (2) The termination or expiration of a limited online prescribing, fulfillment, or
509 facilitation license for any reason does not limit the division's authority to commence or
510 continue any investigation or adjudicative proceeding.

511 (3) Because of the working business relationship between and among the limited
512 online prescribing practitioner, the Internet facilitator, and the online contract pharmacy, each
513 entity's ability to comply with this chapter may depend in some respects on the actions of the
514 others. It is possible that a particular action or inaction by the limited online prescribing
515 practitioner, Internet facilitator, or online contract pharmacy could have the effect of causing
516 the other licensed entities to be out of compliance with this chapter, and each entity may
517 therefore be held accountable for any related party's non-compliance.

518 (4) A limited online prescribing practitioner may lose the practitioner's professional
519 license to prescribe any drug under this title if the provisions of this chapter are violated by the
520 limited online prescribing practitioner, the Internet facilitator, or the online contract pharmacy.
521 It is not a defense to an alleged violation under this chapter that the alleged violation was a
522 result of an action or inaction not by the charged party but by the related online prescribing
523 practitioner, online contract pharmacy or Internet facilitator.

524 (5) The following actions will result in an immediate suspension of the limited online
525 prescribing practitioner's license, the online contract pharmacy's license, or the Internet
526 facilitator's license, and each is considered an immediate and significant danger to the public
527 health, safety, or welfare requiring immediate action by the division pursuant to Section
528 63G-4-502 to terminate the prescriptive, fulfillment, and facilitation authority for online
529 prescribing:

530 (a) online prescribing, fulfillment, or facilitation with respect to a person under the age
531 of 18 years;

532 (b) online prescribing, fulfillment, or facilitation with respect to a legend drug not
533 authorized by the division by administrative rule;

534 (c) online prescribing, fulfillment or facilitation with respect to any controlled
535 substance;

536 (d) violating this chapter after having been given reasonable opportunity to cure the
537 violation;

538 (e) using the name or official seal of the state of Utah, the Utah Department of
539 Commerce, the Utah Division of Occupational and Professional Licensing, or its boards in an
540 unauthorized manner; or

541 (f) failing to respond to a request from the division within the time frame requested for:

542 (i) an audit of the website; or

543 (ii) records of the limited online prescribing practitioner, Internet facilitator or online
544 contract pharmacy.

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

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

547 **58-83-501. Unlawful conduct.**

548 "Unlawful conduct" includes, in addition to the definition in Section 58-1-501,
549 engaging in the practice of Internet prescribing, fulfillment, or facilitation without a license
550 under this chapter.

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

552 **58-83-502. Unprofessional conduct.**

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

555 (1) online prescribing, fulfillment, or facilitation with respect to a person under the age
556 of 18 years;

557 (2) online prescribing, fulfillment, or facilitation with respect to a legend drug not
558 authorized by the division by administrative rule;

559 (3) online prescribing, fulfillment, or facilitation with respect to any controlled
560 substance;

561 (4) using the name or official seal of the state, the Utah Department of Commerce, the
562 Utah Division of Occupational and Professional Licensing, or its boards in an unauthorized
563 manner;

564 (5) failing to respond promptly to a request by the division for information including:

565 (a) an audit of the website; or

566 (b) records of the limited online prescribing practitioner, Internet facilitator, or online
567 contract pharmacy;

568 (6) using a limited online prescribing practitioner, online contract pharmacy, or Internet
569 facilitator without approval of the division;

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

572 (8) failing to keep the division informed of the name and contact information of the
573 Internet facilitator or online contract pharmacy.

Legislative Review Note
as of 2-9-10 11:06 AM

Office of Legislative Research and General Counsel

S.B. 274 - Online Pharmacy Amendments

Fiscal Note

2010 General Session
State of Utah

State Impact

Enactment of this bill will generate \$2,100 per year in revenue to the General Fund. The bill will require one new FTE and a new board estimated to cost \$79,900 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	\$2,100	\$2,100
Commerce Service Fund	\$0	\$79,900	\$79,900	\$0	\$79,900	\$79,900
Total	\$0	\$79,900	\$79,900	\$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.
