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ONLINE PRESCRIBING AND DISPENSING OF MEDICAL DEVICES

2016 GENERAL SESSION

STATE OF UTAH

Chief Sponsor: Val L. Peterson

None

Money Appropriated in this Bill:

| 26 | Other Special Clauses: |
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| 27 | None |
| 28 | Utah Code Sections Affected: |
| 29 | AMENDS: |
| 30 | 58-83-102, as enacted by Laws of Utah 2010, Chapter 180 |
| 31 | 58-83-301, as enacted by Laws of Utah 2010, Chapter 180 |
| 32 | 58-83-302, as enacted by Laws of Utah 2010, Chapter 180 |
| 33 | 58-83-305, as enacted by Laws of Utah 2010, Chapter 180 |
| 34 | 58-83-306, as last amended by Laws of Utah 2015, Chapter 321 |
| 35 | 58-83-307, as enacted by Laws of Utah 2010, Chapter 180 |
| 36 | 58-83-308, as enacted by Laws of Utah 2010, Chapter 180 |
| 37 | 58-83-401, as last amended by Laws of Utah 2011, Chapter 367 |
| 38 | 58-83-501, as enacted by Laws of Utah 2010, Chapter 180 |
| 39 | 58-83-503, as enacted by Laws of Utah 2010, Chapter 180 |
| 40 | |
| 41 | Be it enacted by the Legislature of the state of Utah: |
| 42 | Section 1. Section 58-83-102 is amended to read: |
| 43 | 58-83-102. Definitions. |
| 44 | In addition to the definitions in Section 58-1-102, as used in this chapter: |
| 45 | (1) "Board" means the Online Prescribing, Dispensing, and Facilitation Licensing |
| 46 | Board created in Section 58-83-201. |
| 47 | (2) "Branching questionnaire" means an adaptive and progressive assessment tool |
| 48 | approved by the board. |
| 49 | (3) "Controlled substance" means the same as that term is defined in Section |
| 50 | <u>58-17b-102.</u> |
| 51 | $[\frac{(3)}{4}]$ "Delivery of online pharmaceutical services" means the process in which $[\frac{1}{4}]$ |
| 52 | prescribing practitioner] an online prescriber diagnoses a patient and prescribes one or more of |
| 53 | the drugs or devices authorized by Section 58-83-306, using: |
| 54 | (a) (i) for a drug: |
| 55 | (A) a branching questionnaire approved by the division for the purpose of diagnosing |
| 56 | and assessing a patient's health status; or [other] |

| 57 | (B) another assessment tool approved by the division for the purpose of diagnosing and |
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| 58 | assessing a patient's health status; or |
| 59 | (ii) for a device: |
| 60 | (A) a branching questionnaire approved by the division for the purpose of diagnosing |
| 61 | and assessing a patient's health status; or |
| 62 | (B) another assessment tool that is consistent with industry-recognized, standardized |
| 63 | requirements for prescribing the device and is approved by the division, with the opportunity |
| 64 | for input from the respective boards, for the purpose of diagnosing and assessing a patient's |
| 65 | health status and the propriety of the particular device for the patient; |
| 66 | (b) an Internet contract pharmacy to: |
| 67 | (i) dispense the prescribed drug <u>or device</u> ; or |
| 68 | (ii) transfer the prescription to another pharmacy; and |
| 69 | (c) an Internet facilitator to facilitate the practices described in Subsections $[(3)]$ (4) (a) |
| 70 | and (b). |
| 71 | (5) "Device": |
| 72 | (a) means the following prescription medical devices: |
| 73 | (i) a catheter intended for insertion by the patient; |
| 74 | (ii) a contact lens, as that term is defined in Section 58-16a-102; |
| 75 | (iii) a device that provides continuous positive airway pressure; |
| 76 | (iv) a device used by a patient for the care or management of diabetes; or |
| 77 | (v) a hearing aid, as that term is defined in Section 58-41-17; and |
| 78 | (b) does not mean a prescription medical device that: |
| 79 | (i) requires surgical implantation; |
| 80 | (ii) is a Class III medical device, as defined by the United States Food and Drug |
| 81 | Administration; or |
| 82 | (iii) is intended for use or application by only a licensed healthcare professional. |
| 83 | (6) "Dispense" means the same as that term is defined in Section 58-17b-102. |
| 84 | [(4)] (7) "Division" means the Utah Division of Occupational and Professional |
| 85 | Licensing. |
| 86 | (8) "Drug" means the same as that term is defined in Section 58-17b-102. |
| 87 | [(5)] (9) "Internet facilitator" means a licensed provider of a web-based system for |

| 88 | electronic communication between and among an online prescriber, the online prescriber's |
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| 89 | patient, and the online contract pharmacy. |
| 90 | (10) "Legend drug" means a prescription drug. |
| 91 | [(6)] (11) "Online contract pharmacy" means a pharmacy licensed and in good standing |
| 92 | under Chapter 17b, Pharmacy Practice Act, as either a [Class A Retail Pharmacy] class A retail |
| 93 | pharmacy or a [Class B Closed Door Pharmacy] class B closed-door pharmacy and licensed |
| 94 | under this chapter to fulfill prescriptions issued by an online prescriber through a specific |
| 95 | Internet facilitator. |
| 96 | [(7)] (12) "Online prescriber" means [a person: (a) licensed under another chapter of |
| 97 | this title; (b) whose license under another chapter of this title includes assessing, diagnosing, |
| 98 | and prescribing authority for humans; and (c)]: |
| 99 | (a) a physician licensed under Chapter 67, Utah Medical Practice Act, or Chapter 68, |
| 100 | Utah Osteopathic Medical Practice Act, who has obtained a license under [this chapter to |
| 101 | engage in online prescribing.] Part 3, Licensing, to prescribe online; or |
| 102 | (b) an optometrist licensed under Chapter 16A, Utah Optometry Practice Act, who has |
| 103 | obtained a license under Part 3, Licensing, to prescribe online. |
| 104 | (13) "Pharmacist" means the same as that term is defined in Section 58-17b-102. |
| 105 | (14) "Pharmacy" means the same as that term is defined in Section 58-17b-102. |
| 106 | (15) "Prescribe" means the same as that term is defined in Section 58-17b-102. |
| 107 | (16) "Prescription" means the same as that term is defined in Section 58-17b-102. |
| 108 | (17) "Prescription drug" means the same as that term is defined in Section 58-17b-102. |
| 109 | (18) "Respective board": |
| 110 | (a) means, for a device, the licensing board in Title 58, Occupations and Professions, |
| 111 | for an online prescriber within whose scope of practice it is to prescribe the device; and |
| 112 | (b) includes: |
| 113 | (i) the Optometrist Licensing Board, created by Section 58-16a-201; |
| 114 | (ii) the Utah State Board of Pharmacy, created by Section 58-17b-201; |
| 115 | (iii) the Physicians Licensing Board, created by Section 58-67-201; and |
| 116 | (iv) the Osteopathic Physician and Surgeon's Licensing Board, created by Section |
| 117 | <u>58-68-201.</u> |
| 118 | [(8)] (19) "Unlawful conduct" [is as] means the same as that term is defined in Section |

| 119 | 58-1-501 [and], 58-83-501, and 58-83-503. |
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| 120 | [(9)] (20) "Unprofessional conduct" [is as defined in Sections 58-1-203 and 58-83-502, |
| 121 | and as further defined by the division in accordance with Title 63G, Chapter 3, Utah |
| 122 | Administrative Rulemaking Act] means the same as that term is defined: |
| 123 | (a) in Sections 58-1-501, 58-1-203, and 58-83-502; and |
| 124 | (b) by rule made pursuant to Section 58-1-203 or 58-83-502. |
| 125 | Section 2. Section 58-83-301 is amended to read: |
| 126 | 58-83-301. Licensure required Issuance of licenses. |
| 127 | (1) [Beginning July 1, 2010, and except] Except as provided in Section 58-1-307: |
| 128 | (a) an optometrist licensed under Chapter 16A, Utah Optometry Practice Act, shall be |
| 129 | licensed under this chapter to engage in the delivery of online pharmaceutical services; |
| 130 | [(a)] (b) a physician licensed under Chapter 67, Utah Medical Practice Act, or Chapter |
| 131 | 68, Utah Osteopathic Medical Practice Act, shall be licensed under this chapter to engage in the |
| 132 | delivery of online pharmaceutical services; |
| 133 | [(b)] (c) an online contract pharmacy shall be licensed under this chapter to engage in |
| 134 | the delivery of online pharmaceutical services; and |
| 135 | [(c)] (d) an Internet facilitator shall be licensed under this chapter to engage in the |
| 136 | delivery of online pharmaceutical services. |
| 137 | (2) The division shall issue, to any person who qualifies under this chapter, a license: |
| 138 | (a) to prescribe online; |
| 139 | (b) to operate as an online contract pharmacy; or |
| 140 | (c) to operate as an Internet facilitator. |
| 141 | (3) (a) A license under this chapter is not required to engage in electronic prescribing |
| 142 | under Chapter 82, Electronic Prescribing Act[; and]. |
| 143 | (b) Nothing in this chapter shall prohibit [a] an optometrist licensed under Chapter |
| 144 | 16A, Utah Optometry Practice Act, or physician licensed under Chapter 67, Utah Medical |
| 145 | Practice Act, or Chapter 68, Utah Osteopathic Medical Practice Act, from electronic |
| 146 | prescribing or Internet prescribing as permitted by Chapter 16A, Utah Optometry Practice Act, |
| 147 | Chapter 67, Utah Medical Practice Act, [or] Chapter 68, Utah Osteopathic Medical Practice |
| 148 | Act, or other law. |
| 149 | Section 3. Section 58-83-302 is amended to read: |

| 150 | 58-83-302. Qualifications for licensure. |
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| 151 | (1) Each applicant for licensure as an online prescriber under this chapter shall: |
| 152 | (a) submit an application in a form prescribed by the division; |
| 153 | (b) pay a fee determined by the department under Section 63J-1-504; |
| 154 | (c) be of good moral character; |
| 155 | (d) document that the applicant holds a Utah license that is active and in good standing |
| 156 | and authorizes the licensee to engage in the assessment, diagnosis, and treatment of human |
| 157 | ailments and the [prescription] prescribing of medications or devices; |
| 158 | (e) document that any other professional license the applicant possesses from other |
| 159 | jurisdictions is in good standing; |
| 160 | (f) (i) submit to the division an outline of the applicant's proposed online assessment, |
| 161 | diagnosis, and prescribing tool, such as a branching questionnaire; and |
| 162 | (ii) demonstrate the proposed online assessment, diagnosis, and prescribing tool to the |
| 163 | board and establish to the board's satisfaction that the utilization of that assessment tool to |
| 164 | facilitate the [prescription] prescribing of the drugs or devices approved for online prescribing |
| 165 | under Section [58-83-305] 58-83-306 does not compromise the public's health, safety, or |
| 166 | welfare; |
| 167 | (g) submit policies and procedures that address patient confidentiality, including |
| 168 | measures that will be taken to ensure that the age and other identifying information of the |
| 169 | person completing the online branching questionnaire are accurate; |
| 170 | (h) describe the mechanism by which the online prescriber and patient will |
| 171 | communicate with one another, including electronic and telephonic communication; |
| 172 | (i) describe how the online prescriber/patient relationship will be established and |
| 173 | maintained; |
| 174 | (j) submit the name, address, and contact person of the Internet facilitator with whom |
| 175 | the online prescriber has contracted to provide services that the online prescriber will use to |
| 176 | engage in online assessment, diagnosis, and prescribing; and |
| 177 | (k) submit documentation satisfactory to the board regarding public health, safety, and |
| 178 | welfare demonstrating: |
| 179 | (i) how the online prescriber will comply with the requirements of Section 58-83-305; |
| 180 | (ii) the contractual services arrangement between the online prescriber and: |

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181 (A) the Internet facilitator; and 182 (B) the online contract pharmacy; and 183 (iii) how the online prescriber will allow and facilitate the division's ability to conduct 184 audits in accordance with Section 58-83-308. 185 (2) An online prescriber may not use the services of an Internet facilitator or online 186 contract pharmacy whose license is not active and in good standing. 187 (3) Each applicant for licensure as an online contract pharmacy under this chapter 188 shall: 189 (a) be licensed in good standing [in Utah] under Chapter 17b, Pharmacy Practice Act, as a [Class A Retail Pharmacy] class A retail pharmacy or a [Class B Closed Door Pharmacy] 190 191 class B closed-door pharmacy; 192 (b) submit a written application in the form prescribed by the division; 193 (c) pay a fee as determined by the department under Section 63J-1-504; (d) submit any contract between the applicant and the Internet facilitator with which 194 195 the applicant is or will be affiliated; 196 (e) submit proof of liability insurance acceptable to the division that expressly covers 197 all activities the online contract pharmacy will engage in under this chapter, which coverage 198 shall be in a minimum amount of \$1,000,000 per occurrence with a policy limit of not less than 199 \$3,000,000; 200 (f) submit a signed affidavit to the division attesting that the online contract pharmacy 201 will not dispense a drug or device that is prescribed by an online prescriber engaged in the 202 delivery of online pharmaceutical services under the provisions of this chapter unless: 203 (i) the drug or device is specifically approved by the division under Section 58-83-306; 204 and 205 (ii) both the prescribing and the dispensing of the drug or device were facilitated by the 206 Internet facilitator with whom the Internet contract pharmacy is associated under Subsection 207 58-83-302(3)(d); 208 (g) document that any other professional license the applicant possesses from other 209 jurisdictions is active and in good standing; and 210 (h) demonstrate to the division that the applicant has satisfied any background check

required by Section 58-17b-307, and each owner, officer, or manager of the applicant online

| 212 | contract pharmacy has not engaged in any act, practice, or omission, which when considered |
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| 213 | with the duties and responsibilities of a licensee under this chapter indicates there is cause to |
| 214 | believe that issuing a license under this chapter is inconsistent with the public's health, safety, |
| 215 | or welfare. |
| 216 | (4) Each applicant for licensure as an Internet facilitator under this chapter shall: |
| 217 | (a) submit a written application in the form prescribed by the division; |
| 218 | (b) pay a fee as determined by the department under Section 63J-1-504; |
| 219 | (c) submit any contract between the applicant and the following with which the |
| 220 | applicant will be affiliated: |
| 221 | (i) each online prescriber; and |
| 222 | (ii) the single online contract pharmacy; |
| 223 | (d) submit written policies and procedures satisfactory to the division that: |
| 224 | (i) address patient privacy, including compliance with 45 C.F.R. Parts 160, 162, and |
| 225 | 164, Health Insurance Portability and Accountability Act of 1996; |
| 226 | (ii) ensure compliance with all applicable laws by health care personnel and the online |
| 227 | prescriber who will process patient communications; |
| 228 | (iii) list the hours of operation; |
| 229 | (iv) describe the types of services that will be permitted electronically; |
| 230 | (v) describe the required patient information to be included in the communication, such |
| 231 | as patient name, identification number, and type of transaction; |
| 232 | (vi) establish procedures for archiving and retrieving information; and |
| 233 | (vii) establish quality oversight mechanisms; |
| 234 | (e) submit written documentation of the applicant's security measures to ensure the |
| 235 | confidentiality and integrity of any user-identifiable medical information; |
| 236 | (f) submit a description of the mechanism for: |
| 237 | (i) patients to access, supplement, and amend patient-provided personal health |
| 238 | information; |
| 239 | (ii) back-up regarding the Internet facilitator electronic interface; |
| 240 | (iii) the quality of information and services provided via the interface; and |
| 241 | (iv) patients to register complaints regarding the Internet facilitator, the online |
| 242 | prescriber, or the online contract pharmacy; |

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

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| 244 | (h) sign an affidavit attesting that: |
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| 245 | (i) the applicant will not access any medical records or information contained in the |
| 246 | medical record except as necessary to administer the website and the branching questionnaire; |
| 247 | and |
| 248 | (ii) the applicant and its principals, and any entities affiliated with them, will only use |
| 249 | the services of a single online contract pharmacy named on the license approved by the |
| 250 | division; and |
| 251 | (i) submit any other information required by the division. |
| 252 | Section 4. Section 58-83-305 is amended to read: |
| 253 | 58-83-305. Duties and responsibilities. |
| 254 | (1) The online prescriber shall: |
| 255 | (a) be held to the same standards of appropriate practice as those applicable in |
| 256 | traditional settings which, for purposes of this chapter, include the delivery of online |
| 257 | pharmaceutical services; |
| 258 | (b) conduct an assessment and diagnosis based upon a comprehensive health history |
| 259 | and an assessment tool such as a branching questionnaire; |
| 260 | (c) ensure that a comprehensive health history, assessment, and diagnosis have been |
| 261 | made before prescribing [any] a medication or device; |
| 262 | (d) conduct the online assessment and diagnosis only through the approved Internet |
| 263 | facilitator identified in the online prescriber's application; |
| 264 | (e) comply with all applicable state and federal laws, rules, regulations, and orders; |
| 265 | (f) inform the patient electronically of the benefits and risks of appropriate treatment; |
| 266 | (g) guide the patient regarding the optimal course of action; |
| 267 | (h) treat the patient with courtesy, respect, dignity, responsiveness, and timely attention |
| 268 | to the patient's needs; |
| 269 | (i) comply with the requirements for confidentiality as required by this title and |
| 270 | applicable federal law; |
| 271 | (j) continue to provide the user with reasonable assistance and sufficient opportunity to |
| 272 | make alternative arrangements for care; |
| 273 | (k) be available for ongoing consultation with the patient through e-mail or other forms |

| 274 | of communication; |
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| 275 | (l) not delegate to a third party the professional responsibility to: |
| 276 | (i) review and evaluate the results of the branching questionnaire; |
| 277 | (ii) consult with the patient electronically or through other means about the patient's |
| 278 | medical condition; and |
| 279 | (iii) diagnose and prescribe [medications] a medication or device to the patient; |
| 280 | (m) conduct the online assessment and diagnosis and the electronic communication |
| 281 | between the online prescriber and the patient only through the approved Internet facilitator; |
| 282 | (n) (i) maintain the online medical records of the patient; and |
| 283 | (ii) if maintenance of the records is delegated by the online prescriber, delegate that |
| 284 | authority only to the approved Internet facilitator; |
| 285 | (o) inform a patient of the patient's freedom of choice to select the pharmacy to |
| 286 | dispense the patient's prescription by providing the patient with the phone number of the online |
| 287 | contract pharmacy so that the patient may contact the online contract pharmacy and request a |
| 288 | transfer of the prescription to another pharmacy; and |
| 289 | (p) authorize the Internet facilitator to provide the online contract pharmacy with the |
| 290 | patient's: |
| 291 | (i) full name; |
| 292 | (ii) current address and telephone number; |
| 293 | (iii) date of birth or age and gender; |
| 294 | (iv) height, weight, and vital signs (if known); |
| 295 | (v) medication allergies or drug reactions; and |
| 296 | (vi) current medications, including over-the-counter products, and any additional |
| 297 | comments relevant to the patient's drug or device use. |
| 298 | (2) The online contract pharmacy shall: |
| 299 | (a) only dispense <u>a</u> prescription [drugs] <u>drug or device</u> that: |
| 300 | (i) [are] is approved by the division in accordance with Section 58-83-306; and |
| 301 | (ii) [were] is prescribed by an online prescriber who is using the Internet facilitator that |
| 302 | is under contract with the online contract pharmacy; |
| 303 | (b) maintain a toll-free number with a pharmacist available for patients using the |
| 304 | services of the online contract pharmacy to receive [medications] a medication or device |

| 305 | prescribed online; |
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| 306 | (c) use a tracking identification number system when shipping [medications] a |
| 307 | medication or device prescribed for [patients] a patient by an online prescriber; and |
| 308 | (d) provide to the division a quarterly report of all drugs and devices dispensed in |
| 309 | accordance with this chapter. |
| 310 | (3) The Internet facilitator shall: |
| 311 | (a) provide services that the online prescriber will use in implementing the branching |
| 312 | questionnaire or other assessment tool; |
| 313 | (b) provide electronic or telephonic communication between the online prescriber and |
| 314 | the patient that: |
| 315 | (i) is secure and confidential; |
| 316 | (ii) allows the online prescriber to be directly accessible to a patient to answer |
| 317 | questions regarding the patient's treatment plan; and |
| 318 | (iii) provides privacy and security that complies with the provisions of 45 C.F.R. Parts |
| 319 | 160, 162, and 164, Health Insurance Portability and Accountability Act of 1996; |
| 320 | (c) facilitate secure and confidential communication of the prescription issued by the |
| 321 | online prescriber to the online contract pharmacy in accordance with Subsection (1)(p); |
| 322 | (d) disclose on its website: |
| 323 | (i) the owner of the website; |
| 324 | (ii) the specific services provided by any associated online prescribers; and |
| 325 | (iii) other information the division may require by rule; and |
| 326 | (e) (i) only facilitate the delivery of online pharmaceutical services for the specific |
| 327 | legend drugs or devices approved by the division in accordance with Section 58-83-306; or |
| 328 | (ii) not facilitate, directly or indirectly, through related entities or affiliates, the |
| 329 | dispensing or online prescribing of any drug [whether controlled or legend] or device that is no |
| 330 | specifically approved under Section 58-83-306. |
| 331 | Section 5. Section 58-83-306 is amended to read: |
| 332 | 58-83-306. Completion of branching questionnaire required for prescription |
| 333 | Drugs and devices approved for online prescribing, dispensing, and facilitation |
| 334 | Delivery of prescription drugs or devices Limit on contact lenses Health insurance |
| 335 | not required to cover online prescribing and dispensing. |

| 336 | (1) An online prescriber may prescribe a device or a legend drug that is not a controlled |
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| 337 | substance only if the patient has completed, and the online prescriber has evaluated, a |
| 338 | branching questionnaire or other assessment, diagnosis, and prescribing tool approved by the |
| 339 | division and described by Subsections 58-83-102(3)(a), 58-83(302)(1)(f), and 58-83-305(1)(b) |
| 340 | and (c). |
| 341 | [(1)] (2) An online prescriber may only prescribe, an online contract pharmacy may |
| 342 | only dispense, and an Internet facilitator may only facilitate the prescribing and dispensing of[5, |
| 343 | non-controlled,] a device or a legend [drugs] drug that is not a controlled substance: |
| 344 | (a) that [have] has been approved by the Food and Drug Administration; |
| 345 | (b) that [are] is prescribed to treat the condition for which the drug or device was |
| 346 | approved, within the drug or device manufacturer's guidelines; |
| 347 | (c) that [are] is, subject to Subsection (4), specifically approved by the division for |
| 348 | online prescribing by administrative rule adopted in accordance with Title 63G, Chapter 3, |
| 349 | Utah Administrative Rulemaking Act[;]. |
| 350 | (3) An online prescriber may only prescribe, an online contract pharmacy may only |
| 351 | dispense, and an Internet facilitator may only facilitate the prescribing and dispensing of a |
| 352 | legend drug that is not a controlled substance: |
| 353 | [(d)] (a) that [are] is prescribed for a person who is: |
| 354 | (i) 18 years of age or older; or |
| 355 | (ii) at least 16 years of age: |
| 356 | (A) if permitted by the state or country in which the patient will receive the drug; |
| 357 | (B) with parental consent, if required by the state or country in which the patient will |
| 358 | receive the drug; and |
| 359 | (C) only if the prescription is for a hormonal based contraceptive; and |
| 360 | [(e)] (b) to a person who is located in another country, if the country is designated by |
| 361 | the division, by administrative rule, as a country with a regulatory framework for prescribing |
| 362 | and dispensing of drugs. |
| 363 | (4) (a) The division may not approve a drug or device under Subsection (2)(c) for |
| 364 | online prescribing unless: |
| 365 | (i) for a device, the division has provided the respective boards with the opportunity for |
| 366 | input as to whether the device should be approved; and |

| 367 | (ii) the division determines that online prescribing of the drug or device does not |
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| 368 | compromise the public's health, safety, or welfare. |
| 369 | (b) The division may approve a drug or device for online prescribing by an optometrist |
| 370 | only if an optometrist may prescribe the drug or device under Chapter 16a, Utah Optometry |
| 371 | Practice Act. |
| 372 | [(2)] (5) If[, after January 1, 2010,] the Food and Drug Administration issues a clinical |
| 373 | black box warning with respect to any drug or device approved by the board under Subsection |
| 374 | (1), the division shall determine what action, if any, is necessary to protect the public health or |
| 375 | welfare as a result of the black box warning. |
| 376 | (6) An online prescriber may issue an online prescription for contact lenses only if: |
| 377 | (a) a branching questionnaire or other assessment, diagnosis, and prescribing tool has |
| 378 | been completed as required by Subsection (1); |
| 379 | (b) the patient provides the online prescriber with proof of an expired contact lens |
| 380 | prescription, as defined in Subsection 58-16a-102(3) and issued in accordance with 15 U.S.C. |
| 381 | Sec. 7604; and |
| 382 | (c) the prescription issued by the online prescriber is for one renewal of the expired |
| 383 | contact lens prescription. |
| 384 | (7) An online prescriber may issue an online prescription for a catheter intended for |
| 385 | insertion by the patient, or for a device used by the patient for the care or management of |
| 386 | diabetes, only if a branching questionnaire or other assessment, diagnosis, and prescribing tool |
| 387 | has been completed as required by Subsection (1). |
| 388 | (8) Nothing in this chapter requires health insurance, as defined in Section 31A-1-301, |
| 389 | to pay for the online prescribing, the online dispensing, or the facilitation of online prescribing |
| 390 | or online dispensing of a device, including contact lenses. |
| 391 | Section 6. Section 58-83-307 is amended to read: |
| 392 | 58-83-307. Approval of additional drugs or devices Request to facilitate. |
| 393 | (1) An Internet facilitator licensed under this chapter may seek the division's approval |
| 394 | to facilitate the online prescribing and dispensing of prescriptions for additional drugs or |
| 395 | devices. |
| 396 | (2) The Internet facilitator shall make a request for approval of additional drugs or |
| 397 | devices by petitioning for an amendment to the administrative rule adopted by the division in |

| 398 | accordance with Section 58-83-306 and Title 63G, Chapter 3, Utah Administrative Rulemaking |
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| 399 | Act. |
| 400 | Section 7. Section 58-83-308 is amended to read: |
| 401 | 58-83-308. Audits. |
| 402 | (1) Each licensee under this chapter shall allow and facilitate an audit by the division |
| 403 | regarding the licensee's delivery of online pharmaceutical services to ensure compliance with |
| 404 | state and federal statutes, rules, and regulations including ensuring that: |
| 405 | (a) a comprehensive history and assessment have been obtained and a diagnosis has |
| 406 | been made for a patient before [any medications are] a medication or device is prescribed; and |
| 407 | (b) only [the] approved medications or devices are being prescribed [and] or dispensed. |
| 408 | (2) The division shall be provided with the following, in the manner that allows access |
| 409 | from the division's office for the purpose of conducting an audit: |
| 410 | (a) full remote, read-only access rights to the data related to the online prescribing and |
| 411 | dispensing of a drug or device under this chapter and that is used and stored in the Internet |
| 412 | facilitator's system; and |
| 413 | (b) the information available to the online prescriber. |
| 414 | (3) An Internet facilitator licensed under this chapter shall provide to the division, at |
| 415 | the times designated by the division by administrative rule, a report containing the following |
| 416 | information: |
| 417 | (a) the number of prescriptions issued by the online prescribers associated with the |
| 418 | Internet facilitator by drug or device name; |
| 419 | (b) the number of comprehensive histories/assessments received by the Internet |
| 420 | facilitator; |
| 421 | (c) the number of comprehensive histories/assessments reviewed by an online |
| 422 | prescriber; |
| 423 | (d) the demographic data of the patients receiving prescriptions through the Internet |
| 424 | facilitator; |
| 425 | (e) the number of prescriptions: |
| 426 | (i) dispensed by the online contract pharmacy; or |
| 427 | (ii) transferred to a different pharmacy at the patient's request; and |
| 428 | (f) any other information specified by the division by administrative rule. |

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| 429 | (4) The division's authority to conduct an audit pursuant to this chapter shall survive |
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| 430 | any termination or expiration of any prescriptive authority for online prescribing, dispensing, or |
| 431 | facilitation. |
| 432 | Section 8. Section 58-83-401 is amended to read: |
| 433 | 58-83-401. Grounds for denial of license Disciplinary proceedings |
| 434 | Termination of authority to prescribe Immediate and significant danger. |
| 435 | (1) Grounds for refusing to issue a license to an applicant, for refusing to renew the |
| 436 | license of a licensee, for revoking, suspending, restricting, or placing on probation the license |
| 437 | of a licensee, for issuing a public reprimand to a licensee, and for issuing a cease and desist |
| 438 | order: |
| 439 | (a) shall be in accordance with Section 58-1-401; and |
| 440 | (b) includes: |
| 441 | (i) prescribing, dispensing, or facilitating the prescribing or dispensing of a drug or |
| 442 | device not approved by the board under Section 58-83-306; or |
| 443 | (ii) any other violation of this chapter. |
| 444 | (2) The termination or expiration of a license under this chapter for any reason does not |
| 445 | limit the division's authority to start or continue any investigation or adjudicative proceeding. |
| 446 | (3) (a) Because of the working business relationship between and among the online |
| 447 | prescriber, the Internet facilitator, and the online contract pharmacy, each entity's ability to |
| 448 | comply with this chapter may depend in some respects on the actions of the others. |
| 449 | (b) It is possible that a particular action or inaction by the online prescriber, the Internet |
| 450 | facilitator, or the online contract pharmacy could have the effect of causing the other licensed |
| 451 | entities to be out of compliance with this chapter, and each entity may, therefore, be held |
| 452 | accountable for any related party's non-compliance, if the party knew or reasonably should |
| 453 | have known of the other person's non-compliance. |
| 454 | (4) (a) An online prescriber may lose the [practitioner's] online prescriber's |
| 455 | professional license to prescribe [any] a drug or device under this title if the online prescriber |
| 456 | knew or reasonably should have known that the provisions of this chapter were violated by the |
| 457 | online prescriber, the Internet facilitator, or the online contract pharmacy. |
| 458 | (b) It is not a defense to an alleged violation under this chapter that the alleged |

violation was a result of an action or inaction not by the charged party but by the related online

| 460 | prescriber, the online contract pharmacy, or the Internet facilitator. |
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| 461 | (5) The following actions may result in an immediate suspension of the online |
| 462 | prescriber's license, the online contract pharmacy's license, or the Internet facilitator's license, |
| 463 | and each is considered an immediate and significant danger to the public health, safety, or |
| 464 | welfare requiring immediate action by the division pursuant to Section 63G-4-502 to terminate |
| 465 | the delivery of online pharmaceutical services by the licensee: |
| 466 | (a) online prescribing, dispensing, or facilitation with respect to: |
| 467 | (i) a person under the age of 18 years; |
| 468 | (ii) a legend drug or device not authorized by the division in accordance with Section |
| 469 | 58-83-306; and |
| 470 | (iii) any controlled substance; |
| 471 | (b) violating this chapter after having been given reasonable opportunity to cure the |
| 472 | violation; |
| 473 | (c) using the name or official seal of the state, the Utah Department of Commerce, or |
| 474 | the Utah Division of Occupational and Professional Licensing, or their boards, in an |
| 475 | unauthorized manner; or |
| 476 | (d) failing to respond to a request from the division within the time frame requested |
| 477 | for: |
| 478 | (i) an audit of the website; or |
| 479 | (ii) records of the online prescriber, the Internet facilitator, or the online contract |
| 480 | pharmacy. |
| 481 | Section 9. Section 58-83-501 is amended to read: |
| 482 | 58-83-501. Practice without a license. |
| 483 | ["Unlawful conduct"] Unlawful conduct includes, in addition to the definition in |
| 484 | Section 58-1-501, engaging in the practice of Internet prescribing without a license under this |
| 485 | chapter. |
| 486 | Section 10. Section 58-83-503 is amended to read: |
| 487 | 58-83-503. Unlawful conduct. |
| 488 | Unlawful conduct includes, in addition to the definition in Section 58-1-501: |
| 489 | (1) online prescribing, dispensing, or facilitating of a legend drug or device not |

authorized by the division in accordance with Section 58-83-306; or

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