

ONLINE PRESCRIBING, DISPENSING, AND FACILITATION LICENSING ACT

58-83-101. Title.

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

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

58-83-201. Board.

- (1) There is created the Online Prescribing, Dispensing, and Facilitation Licensing Board consisting of the following seven members:
 - (a) two members who are licensed under either Chapter 67, Utah Medical Practices Act, or Chapter 68, Utah Osteopathic Medical Practices Act, of which:
 - (i) one shall be engaged in the delivery of online pharmaceutical services; and
 - (ii) one may not be an online prescribed licensed under this chapter;
 - (b) two members who are licensed as a pharmacist under Chapter 17b, Pharmacy Practice Act, of which:
 - (i) one shall be associated with an online contract pharmacy; and
 - (ii) one may not be associated with an online contract pharmacy;

- (c) two members of the general public who are not associated with:
 - (i) an online prescriber;
 - (ii) an online contract pharmacy; or
 - (iii) an Internet facilitator; and
 - (d) one member who is licensed under this chapter as an Internet facilitator.
- (2) Notwithstanding any other requirement for membership on the board, no more than one member of the board may be associated in any of the following ways with the same Internet facilitator:
- (a) as an owner;
 - (b) as an employee;
 - (c) as an officer;
 - (d) as a director;
 - (e) contracted with;
 - (f) as an agent of; or
 - (g) having any direct or indirect financial interest.
- (3) The board shall be appointed and serve in accordance with Section 58-1-201.
- (4) (a) The duties and responsibilities of the board shall be in accordance with Sections 58-1-202 and 58-1-203, and as otherwise provided in this chapter.
- (b) The board may designate one of its members on a permanent or rotating basis to:
- (i) assist the division in reviewing complaints concerning the unlawful or unprofessional conduct of a licensee; and
 - (ii) advise the division in its investigation of a complaint.
- (5) A board member who has, under Subsection (4), reviewed a complaint or advised in its investigation may be disqualified from participating with the board when the board serves as a presiding officer of an administrative proceeding concerning the complaint.

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

- (1) Beginning July 1, 2010, and except as provided in Section 58-1-307:
- (a) a physician licensed under Chapter 67, Utah Medical Practice Act, or Chapter 68, Utah Osteopathic Medical Practice Act, shall be licensed under this chapter to engage in the delivery of online pharmaceutical services;
 - (b) an online contract pharmacy shall be licensed under this chapter to engage in the delivery of online pharmaceutical services; and
 - (c) an Internet facilitator shall be licensed under this chapter to engage in the delivery of online pharmaceutical services.
- (2) The division shall issue, to any person who qualifies under this chapter, a license:
- (a) to prescribe online;
 - (b) to operate as an online contract pharmacy; or
 - (c) to operate as an Internet facilitator.
- (3) (a) A license under this chapter is not required to engage in electronic prescribing under Chapter 82, Electronic Prescribing Act; and
- (b) nothing in this chapter shall prohibit a physician licensed under Chapter 67, Utah Medical Practice Act, or Chapter 68, Utah Osteopathic Medical Practice Act, from electronic prescribing or Internet prescribing as permitted by Chapter 67 or 68, or other law.

58-83-302. Qualifications for licensure.

- (1) Each applicant for licensure as an online prescriber under this chapter shall:
- (a) submit an application in a form prescribed by the division;
 - (b) pay a fee determined by the department under Section 63J-1-504;

- (c) be of good moral character;
 - (d) document that the applicant holds a Utah license that is active and in good standing and authorizes the licensee to engage in the assessment, diagnosis, and treatment of human ailments and the prescription of medications;
 - (e) document that any other professional license the applicant possesses from other jurisdictions is in good standing;
 - (f)
 - (i) submit to the division an outline of the applicant's proposed online assessment, diagnosis, and prescribing tool, such as a branching questionnaire; and
 - (ii) demonstrate the proposed online assessment, diagnosis, and prescribing tool to the board and establish to the board's satisfaction that the utilization of that assessment tool to facilitate the prescription of the drugs approved for online prescribing under Section 58-83-305 does not compromise the public's health, safety, or welfare;
 - (g) submit policies and procedures that address patient confidentiality, including measures that will be taken to ensure that the age and other identifying information of the person completing the online branching questionnaire are accurate;
 - (h) describe the mechanism by which the online prescriber and patient will communicate with one another, including electronic and telephonic communication;
 - (i) describe how the online prescriber/patient relationship will be established and maintained;
 - (j) submit the name, address, and contact person of the Internet facilitator with whom the online prescriber has contracted to provide services that the online prescriber will use to engage in online assessment, diagnosis, and prescribing; and
 - (k) submit documentation satisfactory to the board regarding the public health, safety, and welfare demonstrating:
 - (i) how the online prescriber will comply with the requirements of Section 58-83-305;
 - (ii) the contractual services arrangement between the online prescriber and:
 - (A) the Internet facilitator; and
 - (B) the online contract pharmacy; and
 - (iii) how the online prescriber will allow and facilitate the division's ability to conduct audits in accordance with Section 58-83-308.
- (2) An online prescriber may not use the services of an Internet facilitator or online contract pharmacy whose license is not active and in good standing.
- (3) Each applicant for licensure as an online contract pharmacy under this chapter shall:
- (a) be licensed in good standing in Utah as a Class A Retail Pharmacy or a Class B Closed Door Pharmacy;
 - (b) submit a written application in the form prescribed by the division;
 - (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 the applicant is or will be affiliated;
 - (e) submit proof of liability insurance acceptable to the division that expressly covers all activities the online contract pharmacy will engage in under this chapter, which coverage shall be in a minimum amount of \$1,000,000 per occurrence with a policy limit of not less than \$3,000,000;
 - (f) submit a signed affidavit to the division attesting that the online contract pharmacy will not dispense a drug that is prescribed by an online prescriber engaged in the delivery of online pharmaceutical services under the provisions of this chapter unless:

- (i) the drug is specifically approved by the division under Section 58-83-306; and
 - (ii) both the prescribing and the dispensing of the drug were facilitated by the Internet facilitator with whom the Internet contract pharmacy is associated under Subsection 58-83-302(3)(d);
 - (g) document that any other professional license the applicant possesses from other jurisdictions is active and in good standing; and
 - (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 contract pharmacy has not engaged in any act, practice, or omission, which when considered with the duties and responsibilities of a licensee under this chapter indicates there is cause to believe that issuing a license under this chapter is inconsistent with the public's health, safety, or welfare.
- (4) Each applicant for licensure as an Internet facilitator under this chapter shall:
- (a) submit a written application in the form prescribed by the division;
 - (b) pay a fee as determined by the department under Section 63J-1-504;
 - (c) submit any contract between the applicant and the following with which the applicant will be affiliated:
 - (i) each online prescriber; and
 - (ii) the single online contract pharmacy;
 - (d) submit written policies and procedures satisfactory to the division that:
 - (i) address patient privacy, including compliance with 45 C.F.R. Parts 160, 162, and 164, Health Insurance Portability and Accountability Act of 1996;
 - (ii) ensure compliance with all applicable laws by health care personnel and the online prescriber who will process patient communications;
 - (iii) list the hours of operation;
 - (iv) described the types of services that will be permitted electronically;
 - (v) describe the required patient information to be included in the communication, such as patient name, identification number, and type of transaction;
 - (vi) establish procedures for archiving and retrieving information; and
 - (vii) establish quality oversight mechanisms;
 - (e) submit written documentation of the applicant's security measures to ensure the confidentiality and integrity of any user-identifiable medical information;
 - (f) submit a description of the mechanism for:
 - (i) patients to access, supplement, and amend patient-provided personal health information;
 - (ii) back-up regarding the Internet facilitator electronic interface;
 - (iii) the quality of information and services provided via the interface; and
 - (iv) patients to register complaints regarding the Internet facilitator, the online prescriber, or the online contract pharmacy;
 - (g) submit a copy of the Internet facilitator's website;
 - (h) sign an affidavit attesting that:
 - (i) the applicant will not access any medical records or information contained in the medical record except as necessary to administer the website and the branching questionnaire; and
 - (ii) the applicant and its principals, and any entities affiliated with them, will only use the services of a single online contract pharmacy named on the license approved by the division; and
 - (i) submit any other information required by the division.

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

- (1) The online prescriber's license shall be associated with the online prescriber's primary professional license and may be renewed at the time the primary license is renewed in accordance with Subsection 58-1-308(1).
- (2) The online contract pharmacy license shall be associated with the online contract pharmacy' primary professional license and may be renewed at the time the primary license is renewed in accordance with Subsection 58-1-308(1).
- (3) The Internet facilitator license shall be renewed in accordance with Section 58-1-308.
- (4) Each licensee shall, at the time of applying for renewal, demonstrate compliance with this chapter.
- (5) Each license shall automatically expire on the expiration date shown on the license unless the licensee renews it in accordance with Section 58-1-308.

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

- (1) (a) Subject to the provisions of this section, and until December 31, 2010, an entity or individual not licensed by the division to engage in the delivery of online pharmaceutical services under this chapter may nevertheless engage in the delivery of online pharmaceutical services if permitted by the division to do so prior to December 31 2009, under either:
 - (i) a non-disciplinary stipulation and consent order with the division; or
 - (ii) a letter agreement with the division.
- (b) An entity or individual subject to Subsection (1)(a) shall only be permitted to engage in the delivery of online pharmaceutical services after December 31, 2010, if, on or before that date, it has obtained a license in accordance with the provision of this chapter.
- (2) An entity or individual engaged in the delivery of online pharmaceutical services under the provisions of Subsection (1), may continue to operate in accordance with the terms and conditions of the written consent or agreement subject to the following:
 - (a) On or before June 1, 2010, the entity or individual shall file an application with the division in accordance with this chapter for:
 - (i) an online prescriber license;
 - (ii) an online contract pharmacy license; or
 - (iii) an Internet facilitator license.
 - (b) After the application for a license under this chapter is filed in accordance with Subsection (2)(a), the applicant may continue to operate under the terms and conditions of the written consent agreement under Subsection (1)(a) until the division has issued its decision on the application.
 - (c) If the application is approved and a license is issued, the licensee:
 - (i) shall operate under the terms of the license under this chapter; and
 - (ii) may not operate under the terms and conditions of the prior written consent or agreement of the division.
 - (d) If the application for license under this chapter is denied, the applicant may not operate under the prior written consent or agreement with the division after the date the application for a license under this chapter is denied by the division.
- (3) (a) The following provisions apply to any application for authorization to engage in the delivery of online pharmaceutical services that was pending with the division on the effective date of this chapter:
 - (i) the applicant shall:

- (A) no later than June 30, 2010, provide supplemental documentation to the division to correct any deficiency in the application; and
- (B) notify the division in writing that the application is ready to be acted upon by the division; or
- (ii) the applicant may rely upon the existing application submitted to the division without any supplementation under Subsection (1)(a)(i), if the applicant notifies the division in writing that the application is ready to be acted upon by the division.
- (b) The division shall not, prior to June 30, 2010, act on an application pending with the division on the effective date of this chapter unless the division prior to June 30, 2010, receives a notification from the applicant that the application is ready to be acted upon by the division.

58-83-305. Duties and responsibilities.

- (1) The online prescriber shall:
 - (a) be held to the same standards of appropriate practice as those applicable in traditional settings which, for purposes of this chapter, include the delivery of online pharmaceutical services;
 - (b) conduct an assessment and diagnosis based upon a comprehensive health history and an assessment tool such as a branching questionnaire;
 - (c) ensure that a comprehensive health history, assessment, and diagnosis have been made before prescribing any medication;
 - (d) conduct the online assessment and diagnosis only through the approved Internet facilitator identified in the online prescriber's application;
 - (e) comply with all applicable state and federal laws, rules, regulations, and orders;
 - (f) inform the patient electronically of the benefits and risks of appropriate treatment;
 - (g) guide the patient regarding the optimal course of action;
 - (h) treat the patient with courtesy, respect, dignity, responsiveness, and timely attention to the patient's needs;
 - (i) comply with the requirements for confidentiality as required by this title and applicable federal law;
 - (j) continue to provide the user with reasonable assistance and sufficient opportunity to make alternative arrangements for care;
 - (k) be available for ongoing consultation with the patient through e-mail or other forms of communication;
 - (l) not delegate to a third party the professional responsibility to:
 - (i) review and evaluate the results of the branching questionnaire;
 - (ii) consult with the patient electronically or through other means about the patient's medical condition; and
 - (iii) diagnose and prescribe medications to the patient;
 - (m) conduct the online assessment and diagnosis and the electronic communication between the online prescriber and the patient only through the approved Internet facilitator;
 - (n) (i) maintain the online medical records of the patient; and
 (ii) if maintenance of the records is delegated by the online prescriber, delegate that authority only to the approved Internet facilitator;
 - (o) inform a patient of the patient's freedom of choice to select the pharmacy to dispense the patient's prescription by providing the patient with the phone number of the online contract pharmacy so that the patient may contact the online contract pharmacy and request a transfer of the prescription to another pharmacy; and
 - (p) authorize the Internet facilitator to provide the online contract pharmacy with the patient's:
 - (i) full name;

- (ii) current address and telephone number;
 - (iii) date of birth or age and gender;
 - (iv) height, weight, and vital signs (if known);
 - (v) medication allergies or drug reactions; and
 - (vi) current medications, including over-the-counter products, and any additional comments relevant to the patient's drug use.
- (2) The online contract pharmacy shall:
- (a) only dispense prescription drugs that:
 - (i) are approved by the division in accordance with Section 58-83-306; and
 - (ii) were prescribed by an online prescriber who is using the Internet facilitator that is under contract with the online contract pharmacy;
 - (b) maintain a toll-free number with a pharmacist available for patients using the services of the online contract pharmacy to receive medications prescribed online;
 - (c) use a tracking identification number system when shipping medications prescribed for patients by an online prescriber; and
 - (d) provide to the division a quarterly report of all drugs dispensed in accordance with this chapter.
- (3) The Internet facilitator shall:
- (a) provide services that the online prescriber will use in implementing the branching questionnaire;
 - (b) provide electronic or telephonic communication between the online prescriber and the patient that:
 - (i) is secure and confidential;
 - (ii) allows the online prescriber to be directly accessible to a patient to answer questions regarding the patient's treatment plan; and
 - (iii) provides privacy and security that complies with the provisions of 45 C.F.R. Parts 160, 162, and 164, Health Insurance Portability and Accountability Act of 1996;
 - (c) facilitate secure and confidential communication of the prescription issues by the online prescriber to the online contract pharmacy in accordance with Subsection (1) (p);
 - (d) disclose on its website:
 - (i) the owner of the website;
 - (ii) the specific services provided by any associated online prescribers; and
 - (iii) other information the division may require by rule; and
 - (e)
 - (i) only facilitate the delivery of online pharmaceutical services for the specific legend drugs approved by the division in accordance with Section 58-83-306; and
 - (ii) not facilitate, directly or indirectly, through related entities or affiliates, the dispensing or online prescribing of any drug whether controlled or legend that is not specifically approved under Section 58-83-306.

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

- (1) An online prescriber may only prescribe, an online contract pharmacy may only dispense, and an Internet facilitator may only facilitate the prescribing and dispensing of, non-controlled, legend drugs that have been:
 - (a) approved by the Food and Drug Administration;
 - (b) prescribed to treat the condition for which the drug was approved; and
 - (c) specifically approved by the division for online prescribing by administrative rule adopted in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act.
- (2) If, after January 1, 2010, the Food and Drug Administration issues a clinical black box warning with respect to any drug approved by the board under

Subsection (1), the division shall determine what action, if any, is necessary to protect the public health or welfare as a result of the black box warning.

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

- (1) An Internet facilitator licensed under this chapter may seek the division's approval to facilitate the online prescribing and dispensing of prescriptions for additional drugs.
- (2) The Internet facilitator shall make a request for approval of additional drugs by petitioning for an amendment to the administrative rule adopted by the division in accordance with Section 58-83-306 and Title 63G, Chapter 3, Utah Administrative Rulemaking Act.

58-83-308. Audits.

- (1) Each licensee under this chapter shall allow and facilitate an audit by the division regarding the licensee's delivery of online pharmaceutical services to ensure compliance with state and federal statutes, rules, and regulations including ensuring that:
 - (a) a comprehensive history and assessment have been obtained and a diagnosis has been made for a patient before any medications are prescribed; and
 - (b) only the approved medications are being prescribed and dispensed.
- (2) The division shall be provided with the following, in the manner that allows access from the division's office for the purpose of conducting an audit:
 - (a) full remote, read-only access rights to the data related to the online prescribing and dispensing of a drug under this chapter and that is used and stored in the Internet facilitator's system; and
 - (b) the information available to the online prescriber.
- (3) An Internet facilitator licensed under this chapter shall provide to the division, at the times designated by the division by administrative rule, a report containing the following information:
 - (a) the number of prescriptions issued by the online prescribers associated with the Internet facilitator by drug name;
 - (b) the number of comprehensive histories/assessments received by the Internet facilitator;
 - (c) the number of comprehensive histories/assessments reviewed by an online prescriber;
 - (d) the demographic data of the patients receiving prescriptions through the Internet facilitator;
 - (e) the number of prescriptions:
 - (i) dispensed by the online contract pharmacy; or
 - (ii) transferred to a different pharmacy at the patient's request; and
 - (f) any other information specified by the division by administrative rule.
- (4) The division's authority to conduct an audit pursuant to this chapter shall survive any termination or expiration of any prescriptive authority for online prescribing, dispensing, or facilitation.

58-83-401. Grounds for denial of license - Disciplinary proceedings - Termination of authority to prescribe - Immediate and significant danger.

- (1) Grounds for refusing to issue a license to an applicant, for refusing to renew the license of a licensee, for revoking, suspending, restricting, or placing on probation the license of a licensee, for issuing a public reprimand to a licensee, and for issuing a cease and desist order:
 - (a) shall be in accordance with Section 58-1-401; and
 - (b) includes:

- (i) prescribing, dispensing, or facilitating the prescribing or dispensing of a drug not approved by the board under Section 58-83-306; or
 - (ii) any other violation of this chapter.
- (2) The termination or expiration of a license under this chapter for any reason does not limit the division's authority to start or continue any investigation or adjudicative proceeding.
- (3)
 - (a) Because of the working business relationship between and among the online prescriber, the Internet facilitator, and the online contract pharmacy, each entity's ability to comply with this chapter may depend in some respects on the actions of the others.
 - (b) It is possible that a particular action or inaction by the online prescriber, the Internet facilitator, or the online contract pharmacy could have the effect of causing the other licensed entities to be out of compliance with this chapter, and each entity may, therefore, be held accountable for any related party's non-compliance, if the party knew or reasonably should have know of the other persons' non-compliance.
- (4)
 - (a) An online prescriber may lose the practitioner's professional license to prescribe any drug under this title if the online prescriber knew or reasonably should have known that the provisions of this chapter were violated by the online prescriber, the Internet facilitator, or the online contract pharmacy.
 - (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 prescriber, the online contract pharmacy, or the Internet facilitator.
- (5) The following actions may result in an immediate suspension of the online prescriber's license, the online contract pharmacy's license, or the Internet facilitator's license, and each is considered an immediate and significant danger to the public health, safety, or welfare requiring immediate action by the division pursuant to Section 63G-4-502 to terminate the delivery of online pharmaceutical services by the licensee:
 - (a) online prescribing, dispensing, or facilitation with respect to:
 - (i) a person under the age of 18 years;
 - (ii) a legend drug not authorized by the division in accordance with Section 58-83-306; and
 - (iii) any controlled substance;
 - (b) violating this chapter after having been given reasonable opportunity to cure the violation;
 - (c) using the name or official seal of the state, the Utah Department of Commerce, or the Utah Division of Occupational and Professional Licensing, or their boards, in an unauthorized manner; or
 - (d) failing to respond to a request from the division within the time frame requested for:
 - (i) an audit of the website; or
 - (ii) records of the online prescriber, the Internet facilitator, or the online contract pharmacy.

58-83-501. Practice without a license.

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

58-83-502. Unprofessional conduct.

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

- (1) online prescribing, dispensing, or facilitation with respect to a person under the age of 18 years;
- (2) using the name or official seal of the state, the Utah Department of Commerce, or the Utah Division of Occupational and Professional Licensing, or their boards, in an unauthorized manner;
- (3) failing to respond promptly to a request by the division for information including:
 - (a) an audit of the website; or
 - (b) records of the online prescriber, the Internet facilitator, or the online contract pharmacy;
- (4) using an online prescriber, online contract pharmacy, or Internet facilitator without approval of the division;
- (5) failing to inform a patient of the patient's freedom of choice in selecting who will dispense a prescription in accordance with Subsection 58-83-305(1)(n);
- (6) failing to keep the division informed of the name and contact information of the Internet facilitator or online contract pharmacy; and
- (7) violating the dispensing and labeling requirements of Section 58-17b-309.

58-83-503. Unlawful conduct.

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

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

ONLINE PRESCRIBING, DISPENSING, AND FACILITATION LICENSING ACT

**Title 58, Chapter 83
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