

### Part 3 Licensing

#### **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, Utah Medical Practice Act, or Chapter 68, Utah Osteopathic Medical Practice Act, or other law.

Enacted by Chapter 180, 2010 General Session

#### **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 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) describe 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.

Enacted by Chapter 180, 2010 General Session

**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's 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.

Enacted by Chapter 180, 2010 General Session

**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 issued 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; or
    - (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.

Enacted by Chapter 180, 2010 General Session

**58-83-306 Drugs approved for online prescribing, dispensing, and facilitation -- Delivery of prescription drugs.**

- (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:
- (a) that have been approved by the Food and Drug Administration;
  - (b) that are prescribed to treat the condition for which the drug was approved, within the drug manufacturer's guidelines;
  - (c) that are specifically approved by the division for online prescribing by administrative rule adopted in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act;
  - (d) that are prescribed for a person who is:
    - (i) 18 years of age or older; or
    - (ii) at least 16 years of age:
      - (A) if permitted by the state or country in which the patient will receive the drug;
      - (B) with parental consent, if required by the state or country in which the patient will receive the drug; and
      - (C) only if the prescription is for a hormonal based contraceptive; and

- (e) to a person who is located in another country, if the country is designated by the division, by administrative rule, as a country with a regulatory framework for prescribing and dispensing of drugs.
- (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.

Amended by Chapter 321, 2015 General Session

**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.

Enacted by Chapter 180, 2010 General Session

**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.

Enacted by Chapter 180, 2010 General Session

