

PHARMACY BOARD[657]

Adopted and Filed

Pursuant to the authority of Iowa Code sections 147.76 and 155A.13B, the Board of Pharmacy hereby adopts new Chapter 24, “Pharmacy Internet Sites,” Iowa Administrative Code.

The rules establish the requirements for the Internet sale of prescriptions by pharmacies and for accreditation by the National Association of Boards of Pharmacy (NABP) as a verified Internet pharmacy practice site (VIPPS). The rules identify specific information that must be displayed on a pharmacy Internet site and establish requirements for site registration with the Board. Terms used in the chapter are defined, prescription requirements are identified and responsibilities established, and record-keeping requirements are established. The rules also establish grounds for denial of an application for pharmacy Internet site registration or registration renewal and for disciplinary action and identify appeal processes and sanctions relating to those actions.

Requests for waiver or variance of the discretionary provisions of these rules will be considered pursuant to 657—Chapter 34.

Notice of Intended Action was published in the October 5, 2011, Iowa Administrative Bulletin as **ARC 9789B**. The Board received written comments regarding the proposed amendments. A prescriber of veterinary medicines wrote in support of the rules. A national pharmacy association wrote, also supporting the rules but suggesting a change in the definition of “Internet pharmacy” to specifically exclude a pharmacy licensed and physically located in Iowa and with an associated Internet site. The Board considered the suggested change but did not agree to changing the definition. The Board believes that the adopted definition excludes those pharmacies, regardless of their location within or outside Iowa, that utilize an Internet site solely for the convenience of and communication with their patients.

Two minor changes have been made to the rules published under Notice. In the introductory paragraph of rule 657—24.7(155A), the phrase “shall apply for, obtain, and maintain from the board a pharmacy Internet site registration” was changed to “shall apply for, obtain, and maintain a pharmacy Internet site registration through the board.” In paragraphs 24.7(2)“a” and “b,” the phrase “at the time these rules became effective on February 1, 2012” was changed to “on or before February 1, 2012.”

The rules were approved during the November 10, 2011, meeting of the Board of Pharmacy.

After analysis and review of this rule making, no impact on jobs has been found.

These rules are intended to implement Iowa Code section 155A.13B.

These rules will become effective on February 1, 2012.

The following amendment is adopted.

Adopt the following new 657—Chapter 24:

CHAPTER 24
PHARMACY INTERNET SITES

657—24.1(155A) Purpose and scope. In the interests of public information, health, and safety, and pursuant to the provisions of Iowa Code section 155A.13B, this chapter establishes requirements for the Internet sale of prescription drugs by pharmacies and for VIPPS accreditation. This chapter identifies specific information that must be displayed on a pharmacy Internet site and establishes requirements for site registration. The requirements of this chapter apply to any Internet pharmacy and pharmacy Internet site as defined in rule 657—24.2(155A).

657—24.2(155A) Definitions. For the purposes of this chapter, the following definitions shall apply:

“*Board*” means the Iowa board of pharmacy.

“*DEA*” means the U.S. Department of Justice, Drug Enforcement Administration.

“*Electronic mail*” or “*e-mail*” means any message transmitted through the Internet, including but not limited to messages transmitted from or to any address affiliated with an Internet site.

“*Internet*” means the federated international system that is composed of allied electronic communication networks linked by telecommunication channels, that uses standardized protocols, and that facilitates electronic communication services, including but not limited to use of the World Wide Web; the transmission of electronic mail or messages; the transfer of files and data or other electronic information; and the transmission of voice, image, and video.

“*Internet broker*” means an entity that serves as an agent or intermediary or other capacity that causes the Internet to be used to bring together a buyer and seller.

“*Internet pharmacy*” means a pharmacy that delivers, distributes, or dispenses, by means of an Internet sale pursuant to a prescription drug order, a prescription product to a patient located in Iowa, whether the patient is human or animal. “Internet pharmacy” does not include a pharmacy that maintains an Internet site for the convenience of the pharmacy’s patients to request a prescription refill or to request or retrieve drug information but requires that the filled prescription be delivered to the patient from the licensed physical location of the pharmacy.

“*Internet sale*” means a transaction, initiated via an Internet site, which includes the order of and the payment for a prescription drug product.

“*Internet site*” means a specific location on the Internet that is determined by Internet protocol numbers, by a domain name, or by both, including but not limited to domain names that use the designations “.com”, “.edu”, “.gov”, “.org”, and “.net”.

“*Iowa PMP*” means the prescription monitoring program established pursuant to 657—Chapter 37.

“*NABP*” means the National Association of Boards of Pharmacy.

“*Prescription product*” means any prescription drug or device, including any controlled substance, as those terms are defined in Iowa Code section 155A.3.

“*Vet-VIPPS accreditation*” means that a pharmacy which dispenses prescription products for companion and non-food-producing animals has been evaluated by NABP and has been determined to be properly licensed and in compliance with federal and state laws, rules and regulations regarding the operation of a veterinary pharmacy.

“*VIPPS*” means verified Internet pharmacy practice site.

“*VIPPS accreditation*” means that a pharmacy has been evaluated by NABP and has been determined to be in compliance with federal and state laws, rules and regulations regarding the operation of a pharmacy and with NABP evaluation criteria. “VIPPS accreditation” includes Vet-VIPPS accreditation.

“*VIPPS seal*” means the symbol provided by NABP to a pharmacy for display on the pharmacy’s Internet site evidencing the pharmacy’s VIPPS accreditation.

657—24.3(155A) General requirements for Internet pharmacy. A pharmacy operating within or outside Iowa shall not provide any prescription product to any patient within Iowa through an Internet site or e-mail unless the pharmacy is in compliance with the provisions of this chapter.

24.3(1) Pharmacy license. A pharmacy, prior to providing any prescription drug, including any controlled substance, to any patient within Iowa, shall apply for, obtain, and maintain a pharmacy license pursuant to the provisions of rule 657—8.35(155A).

24.3(2) Pharmacist license. A pharmacist practicing in a pharmacy that provides any prescription drug, including any controlled substance, to any patient within Iowa shall be licensed by the pharmacist licensing authority in the state wherein the pharmacist practices.

24.3(3) Iowa PMP. A pharmacy located within Iowa that provides any controlled substance included in Schedules II through IV of Iowa Code chapter 124 to any patient within Iowa, unless the pharmacy is exempt from reporting pursuant to 657—subrule 37.3(1), shall report those dispensed prescriptions to the Iowa PMP as provided in rule 657—37.3(124).

24.3(4) VIPPS accreditation. An Internet pharmacy that provides any prescription drugs, including controlled substances, to any patient within Iowa shall obtain and maintain VIPPS accreditation and shall include evidence of such VIPPS accreditation on any Internet site identifying the pharmacy as provided in rule 657—24.7(155A).

657—24.4 and 24.5 Reserved.

657—24.6(155A) Prescription requirements. A prescription drug order issued by an authorized prescriber shall comply with the requirements for a prescription identified in Iowa Code section 155A.27. No prescription product may be delivered, distributed, or dispensed by means of, through, or on behalf of an Internet site or by means of an e-mail communication without a valid prescription drug order.

24.6(1) Prescriber licensed. A prescriber who authorizes a prescription drug order through an Internet site or e-mail for a patient located in Iowa shall:

- a. Be licensed by the licensing authority of the state in which the prescriber practices,
- b. Be in compliance with all applicable federal and state laws, rules and regulations relating to the prescriber's practice, and
- c. If the prescription drug order authorizes the dispensing of a controlled substance, be registered to prescribe controlled substances by the DEA and, if required, by the appropriate state agency or board.

24.6(2) Pharmacist responsibility. A licensed pharmacist practicing within or outside Iowa shall not fill a prescription drug order for a patient located in Iowa if the pharmacist knows or reasonably should have known that the prescription drug order was issued under both of the following conditions:

- a. Solely on the basis of an Internet questionnaire, an Internet consultation, or a telephonic consultation, and
- b. Without a valid patient-practitioner relationship.

657—24.7(155A) Internet site registration. An Internet site that intends to display, advertise, or solicit the Internet sale of prescription products to patients in Iowa shall apply for, obtain, and maintain a pharmacy Internet site registration through the board. A pharmacy Internet site registration shall be issued to the Internet site by the domain name and the owner of the Internet site.

24.7(1) Application for registration. Application for registration and registration renewal shall be on forms provided by the board. The application form shall include the following information:

- a. The common or searchable name, if such name exists, of the Internet site.
- b. The domain name including "dot" extension of the Internet site.
- c. The Internet protocol number of the Internet site.
- d. The name and address of the owner or owners of the Internet site. If the owner is a corporation, the names and addresses of the officers and directors of the corporation shall be included. If the owner is a partnership or limited partnership, the names and addresses of all partners shall be included.
- e. The name, address, and Iowa pharmacy license number of each Internet pharmacy that will be identified on the Internet site.
- f. The signature of the owner of the Internet site or the signature of the owner's, partnership's or corporation's authorized representative and the date the application is signed.

24.7(2) Timeliness of application. An application for pharmacy Internet site registration or registration renewal shall be timely submitted to the board.

a. *Existing Internet site.* If the application is for registration of a pharmacy Internet site that is operational on or before February 1, 2012, the application and registration fee shall be due no later than May 1, 2012.

b. *New Internet site.* If the application is for registration of a new pharmacy Internet site that was not operational on or before February 1, 2012, the application and registration fee shall be due no less than 30 days prior to implementation of the Internet site.

c. *Renewal.* If the application is for renewal of an existing pharmacy Internet site registration, the application and registration fee shall be due prior to expiration of the current registration.

24.7(3) Renewal of registration. A pharmacy Internet site registration shall be annually renewed prior to expiration of the registration on December 31. Registration renewal shall require the completion of a renewal application form provided by the board. A completed application shall include payment of the renewal fee and any applicable late payment penalty fee. A registration that is not timely renewed shall be delinquent unless previously canceled by written notification to the board. If a pharmacy Internet

site registration is canceled or delinquent, the Internet site shall discontinue association with any Internet pharmacy and shall discontinue the display, advertising, or solicitation of the Internet sale of prescription products to patients in Iowa.

24.7(4) Fees and term of registration. The following fees, as applicable, shall accompany an application for pharmacy Internet site registration or registration renewal:

a. Initial registration. The fee for initial registration of a pharmacy Internet site shall be \$150. All registrations shall expire annually on December 31.

b. Registration renewal. The fee for renewal of a pharmacy Internet site registration shall be \$150. Failure to renew a registration prior to expiration shall require payment of a late payment fee in the amount of \$150 in addition to the renewal fee. Failure to renew a registration within 30 days following expiration shall require payment of a late payment fee in the amount of \$250 in addition to the renewal fee. Failure to renew a registration within 60 days following expiration shall require payment of a late payment fee in the amount of \$350 in addition to the renewal fee. Failure to renew a registration within 90 days following expiration shall require payment of a late payment fee in the amount of \$450 in addition to the renewal fee. The total renewal and late payment fee shall not exceed \$600. Failure to timely renew a registration may subject the registrant to disciplinary action.

24.7(5) Internet site registration changes. The board shall be notified as provided in this subrule within ten days of any of the following:

a. Change of domain name or Internet protocol number. Change of domain name or Internet protocol number requires completion and submission of a new registration application and payment of the registration fee within ten days.

b. Change of ownership. Change of ownership requires completion and submission of a new registration application and payment of the registration fee within ten days. The sale or transfer of all or a portion of the stock of a corporation, or a change of the individual partners comprising a partnership, shall not constitute a change of ownership provided the corporation or partnership that owns the Internet site continues to exist as the owner of the Internet site following the transaction.

c. Discontinuation of the registered pharmacy Internet site. Prior to discontinuation of a registered pharmacy Internet site but no later than 30 days prior to removal of the pharmacy Internet site from public access, written notification shall be provided to the board. The written notice shall include the domain name and the Internet protocol number of the Internet site, the registration number issued by the board to the pharmacy Internet site, the date the Internet site will be removed from Internet access, the reason for discontinuation of the Internet site, the date of the notice, and the signature of the owner or the owner's authorized representative. If discontinuation of the Internet site also involves the sale or closing of a licensed pharmacy, the closing pharmacy shall comply with all requirements of 657—subrule 8.35(7).

657—24.8(155A) Internet site information. A pharmacy Internet site shall display on the home page of the Internet site or on a page directly linked to the home page the information identified in this rule. If the information is displayed on a page directly linked to the home page, the link on the home page shall be visible and clearly and conspicuously identified.

24.8(1) Registration number. The Internet site registration number shall be displayed. Display shall consist of the following statement or a statement substantially equivalent to the following statement: "In compliance with Iowa Code section 155A.13B and 657 IAC Chapter 24, this internet site is registered with the Iowa Board of Pharmacy, registration number ____."

24.8(2) Pharmacy identification. The following information shall be displayed for each pharmacy that delivers, distributes, or dispenses prescription drugs pursuant to orders made on, through, or on behalf of the Internet site:

- a.* The name of the pharmacy.
- b.* The address of the licensed physical location of the pharmacy.
- c.* The telephone number of the pharmacy.
- d.* The pharmacy license number issued to the pharmacy by the board.

24.8(3) VIPPS accreditation. The VIPPS seal shall be prominently displayed. The following links to information regarding the VIPPS accreditation maintained by each Internet pharmacy associated with the Internet site shall also be displayed.

a. A link to the NABP's VIPPS accreditation verification site.

b. A link to the certification issued by NABP which identifies the individual Internet pharmacy as a VIPPS-accredited site.

24.8(4) DEA requirements relating to controlled substances. A pharmacy Internet site identifying any pharmacy that dispenses controlled substances through the Internet site shall, in addition to the requirements of this rule for the posting of Internet site information, comply with DEA disclosure requirements found at 21 CFR 1304.45.

657—24.9 and 24.10 Reserved.

657—24.11(155A) Records. Records regarding the operation of a pharmacy and the dispensing of prescription products to patients within Iowa shall be maintained by each Internet pharmacy pursuant to the requirements of federal and state laws, rules and regulations. Required pharmacy and inventory records shall be available for inspection and copying by the board or its representative for at least two years from the date of the record or inventory unless a longer retention period is specified for a particular record or inventory.

657—24.12(155A) Pharmacy liability. An Internet pharmacy shall not disclaim, limit, or waive any liability to which the pharmacy otherwise is subject under law for the act or practice of selling, dispensing, distributing, or delivering prescription products to any patient in Iowa based on the patient's submission of the purchase order or refill request for the prescription product through an Internet site or by e-mail.

657—24.13(155A) Application denial.

24.13(1) The executive director or designee may deny an application for registration or renewal of a registration as a pharmacy Internet site for any violation of the laws of this state, another state, or the United States relating to prescription products, Internet pharmacy practices, or the distribution of prescription products utilizing the Internet or e-mail or for any violation of Iowa Code chapter 124, 124A, 124B, 126, 147, 155A, or 205 or any rule of the board.

24.13(2) An applicant whose application has been denied pursuant to this rule may, within 30 days after issuance of the notice of denial, appeal to the board for reconsideration of the application.

657—24.14(155A) Discipline.

24.14(1) Internet site. The board may impose discipline for any violation of the laws of this state, another state, or the United States relating to prescription products, Internet pharmacy practices, or the distribution of prescription products utilizing the Internet or e-mail or for any violation of Iowa Code chapter 124, 124A, 124B, 126, 147, 155A, or 205 or any rule of the board. The board may impose on the pharmacy Internet site registrant any disciplinary sanctions allowed by law as may be appropriate including, but not limited to, revocation of the registration, suspension of the registration for a specified period or until further order of the board, nonrenewal of a registration, the imposition of civil penalties not to exceed \$25,000, or issuance of a citation and warning.

24.14(2) Pharmacy, pharmacist, and other pharmacy staff. The board may impose discipline for any violation of the laws of this state, another state, or the United States relating to prescription products, Internet pharmacy practices, or the distribution of prescription products utilizing the Internet or e-mail or for any violation of Iowa Code chapter 124, 124A, 124B, 126, 147, 155A, or 205 or any rule of the board. The board may impose on the pharmacy, pharmacist, or other registered pharmacy staff any disciplinary

sanctions allowed by law as may be appropriate or as may be identified in Iowa law or rules of the board regarding sanctions that may be imposed on the specific license or registration.

These rules are intended to implement Iowa Code section 155A.13B.

[Filed 11/16/11, effective 2/1/12]

[Published 12/14/11]

EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 12/14/11.