

MEMORANDUM

To: Members of the 2015 Iowa General Assembly

From: Lloyd K. Jessen, Executive Director, Iowa Board of Pharmacy

Date: November 25, 2014

Re: Iowa Board of Pharmacy Pre-File Bill

The need for the bill:

The Board needs to revise current Iowa law in the following areas in order to better protect the health, safety and welfare of Iowans and to ensure patient access to pharmacy products and services: (1) telepharmacy, (2) contested case hearings, (3) dispensing of medical devices and equipment, (4) regulation of nonresident (out-of-state) pharmacies, and (5) pharmacy inspections. The Board also needs to create a new licensing category for "Outsourcing Facilities."

The purpose of the bill:

In the area of telepharmacy, the purpose of this bill is to clarify how pharmacy services may be safely provided to rural, underserved areas of the State.

In the area of administrative hearings, the purpose of this bill is to provide additional, qualified persons to hear and decide contested case disciplinary proceedings.

In the area of medical devices and equipment, the purpose of this bill is to provide definitions and ensure that patients may continue to receive medical devices and equipment from pharmacists as part of the practice of pharmacy.

In the area of out-of-state pharmacies, the purpose of this bill is to make the licensing and regulation of out-of-state pharmacies uniform and consistent with pharmacies located inside Iowa.

In the area of pharmacy inspections, the purpose of this bill is to ensure that the Iowa Board of Pharmacy may conduct inspections of licensed pharmacies and drug wholesalers regardless of location and that inspection reports may be shared with other state Boards of pharmacy via an established, national reporting network.

In the area of sterile compounding, the purpose of this bill is to license and regulate companies that distribute sterile human drug products in Iowa without a patient-specific prescription, in conformity with new federal law and regulations for outsourcing facilities.

The intent of the bill:

In the area of telepharmacy, the intent of this bill is to provide for remote pharmacist supervision of a certified pharmacy technician practicing in an approved telepharmacy practice site, pursuant to rules of the Board.

In the area of administrative hearings, the intent of this bill is to permit the Board

to recommend, subject to approval by the governor, a pool of up to seven qualified individuals to serve as alternate Board members to ensure the availability of an unbiased quorum of Board members to hear a contested case. The bill identifies the maximum term for an alternate Board member, provides that an individual who previously served on the Board may serve as an alternate Board member, provides for compensation when the alternate member serves on a hearing panel, establishes requirements for the composition of a hearing panel containing alternate Board members, and provides that the decision of a hearing panel containing alternate Board members is considered a final decision of the Board.

In the area of medical devices and equipment, the intent of this bill is to amend the definitions of “device” and “dispense” to more closely align with industry standards and to clarify the activities that may be included as a function of dispensing. The bill also defines the term “equipment” as it relates to the practice of pharmacy.

In the area of out-of-state pharmacies, the intent of this bill is to amend provisions relating to the licensure of nonresident pharmacies that provide prescription pharmaceuticals to patients located in Iowa. The bill requires the pharmacist in charge of a nonresident pharmacy to maintain a license to practice pharmacy in Iowa. The bill clarifies the information required for license application, including evidence of recent inspection of the pharmacy and defining the elements of an acceptable inspection. The bill describes and identifies various entities that may be employed to perform an inspection acceptable for Iowa licensure. The bill authorizes the Board to recoup from a nonresident pharmacy any costs incurred by the Board in completing an inspection of the nonresident pharmacy if the nonresident pharmacy cannot provide an acceptable inspection report. The number of licensed nonresident pharmacies, now more than 750, is fast approaching the number of licensed instate pharmacies, currently less than 950. During 2012 and 2013, the Board contracted with the National Association of Boards of Pharmacy (NABP) for inspection of then-licensed Iowa nonresident pharmacies. The average cost of conducting those 558 inspections amounted to more than \$700 per pharmacy. The bill also requires that an applicant for an Iowa nonresident pharmacy license must include with the application either evidence that the nonresident pharmacy has registered to submit controlled substances prescription records to the Iowa Prescription Monitoring Program – Data Collection (PMP) or has requested exemption from reporting to the PMP based on exemption criteria established by the Board pursuant to Iowa Code section 124.552. The bill eliminates the requirement that a nonresident pharmacy maintain minimum hours and days of operation, requiring in lieu thereof that a pharmacist, with access to patient records, be readily available to speak to patients via toll-free telephone for at least 40 hours and six days per week. The bill also authorizes the Board to deny an application for nonresident pharmacy license if the applicant fails to meet the application requirements and authorizes the Board to refuse to issue or renew a nonresident pharmacy license for any grounds under which the Board may impose discipline. The bill amends the grounds for discipline to include any violation of the federal Food, Drug, and Cosmetic Act or regulations promulgated under the act including the issuance by the FDA of a warning letter; conviction of a crime related to prescription drugs or the practice of pharmacy by the owner, managing officer, or the pharmacy; refusal to provide the Board’s agent access to the pharmacy or pharmacy records for purposes of inspection or investigation; and any violation of Iowa

law or rule of the Board relating to the practice of pharmacy and the distribution of prescription products in Iowa.

In the area of pharmacy inspections, the intent of this bill is to clarify that the officers, agents, inspectors, and representatives of the Board may perform functions and activities relating to authorized enforcement activities regardless of the location of the office or business that is the subject of the enforcement activities. The bill authorizes the Board to provide reports of inspections of Board licensees to the National Association of Boards of Pharmacy's inspection network, a closed network of information regarding individual states' licensees that compiles information and makes that information available to other state Boards of pharmacy for purposes of regulating the subject licensees.

In the area of sterile compounding, the intent of this bill is to add a new licensing category, "outsourcing facility," for the purpose of licensing and regulating any compounding facility that is registered under federal law as an outsourcing facility. The bill establishes the requirements for application and licensure; license renewal, cancellation, and denial; and establishes grounds for discipline of the outsourcing facility license.

Problems the bill is intended to address:

This bill is intended to address the following problems:

1. Current Iowa law restricts the practice of telepharmacy to practice settings that utilize automated medication dispensing systems. By way of waiver and pilot projects, the Board has allowed telepharmacy to occur in the absence of automated dispensing systems. Iowa law now needs to recognize the special needs of rural Iowa and allow for the safe dispensing of medications and the provision of pharmaceutical care by pharmacists who practice remotely with the assistance of certified pharmacy technicians.
2. The Board is composed of seven members who are volunteers and who serve on an "as needed" basis. As the frequency and complexity of contested case proceedings increases, these Board members are called upon to hear and decide an ever-increasing number of cases. The availability of Board members is limited by their employment and personal obligations. In addition, some Board members must recuse themselves from certain cases due to conflicts of interest. In order to provide a sufficient number of qualified individuals who may serve as decision makers in disciplinary cases, additional persons are needed to serve in this capacity.
3. For many years, Iowans have routinely received various medical devices and equipment from Iowa pharmacies as part of their medical care and treatment. This has included respiratory care products; diagnostic and testing products; assistive devices such as canes, crutches and walkers; specialized hosiery; diabetic footwear; and other health-related products. While this service by pharmacies has been long-standing and well accepted by both patients and health care providers, it has not been explicitly recognized in Iowa law. This bill seeks to recognize that the practice of pharmacy in Iowa includes the provision of medical devices and medical equipment to patients as necessary to meet their health needs.

4. Increasingly, Iowans receive their prescription drugs and related pharmacy services from pharmacies which are located outside of Iowa. Although such pharmacies have been required to be licensed by the Iowa Board of Pharmacy since 1991, these pharmacies have not been regulated to the same extent as those pharmacies which are located within the State. This disparity places Iowans at risk for substandard drug products and services. Not all states conduct routine pharmacy inspections. Not all states address all areas of concern relating to patient safety and drug product integrity. In order to protect Iowans from drug products and services which may fall below Iowa's minimum standards for pharmacy practice, new laws and rules are needed which ensure patient safety. Pharmacies located within Iowa must designate a pharmacist in charge who must be an Iowa-licensed pharmacist. Currently, pharmacies located outside of Iowa are *not* required to employ an Iowa-licensed pharmacist who is designated as the pharmacy's pharmacist in charge. This means that no individual pharmacist in an out-of-state pharmacy has demonstrated a minimum level of knowledge of Iowa pharmacy laws and rules. This lack of knowledge of Iowa law places Iowa patients at risk and is inconsistent with the Board's requirements for pharmacies located within Iowa. All pharmacies which provide drug products and services to Iowans, regardless of the location of the pharmacy, must meet certain minimum standards of practice which protect patients from harm.
5. The Iowa Board of Pharmacy routinely conducts periodic inspections and audits of pharmacies and drug wholesalers licensed and located within Iowa. The Board's ability to inspect such facilities which are licensed and located *outside* of Iowa is currently limited by the lack of express authority. Also, the Board's ability to share inspection reports and related information with other state boards of pharmacy is limited. This bill seeks to ensure adequate inspections and necessary sharing of information with other states, regardless of the location of facilities or providers.
6. New federal law contained in 21 USC § 353B requires compounding facilities to be registered with the U.S. Food and Drug Administration (FDA) as "Outsourcing Facilities" if they provide sterile compounded human drug products to patients without a patient-specific prescription. An example is a company that provides sterile stock solutions or injections to hospital or clinic patients without individual prescriptions. In the past, such companies have acted as drug manufacturers without meeting all manufacturing requirements. As a result, patient harm or death has resulted. The new federal law seeks to correct this. This bill provides a similar licensing requirement in Iowa to allow the Board to oversee and enforce minimum standards which are necessary to protect Iowa patients.