PHARMACY BOARD [657]

Notice of Intended Action

The Board of Pharmacy hereby proposes to amend Chapter 17, "Wholesale Distributor Licenses," and Chapter 43, "Third-Party Logistics Provider Licenses," Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is proposed under the authority provided in Iowa Code sections 155A.17 and 155A.17A.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code sections 155A.17 and 155A.17A.

Purpose and Summary

These proposed amendments would allow wholesale distributors and third-party logistics providers (3PL) which are seeking initial licensure in Iowa to attain Quality and Security (QAS) accreditation through National Coalition for Drug Quality and Security (NCDQS) in lieu of accreditation through National Associations of Boards of Pharmacy (NABP), but requires accreditation through NABP by the licensee's second renewal. Following passage of the federal Drug Quality and Security Act, including the Drug Supply Chain Security Act, in November 2013, the Board implemented a requirement that entities involved in the drug supply chain must be accredited as a requirement for licensure in Iowa. At the time of implementation of the requirement, NABP's accreditation program (Verified Accredited Wholesale Distributors or "VAWD") was the only accreditation program in the marketplace. A second program is now available and has been authorized by the Board in a number of waiver petitions as an initial accreditation to meet the minimum standard until VAWD accreditation can be attained. Due to the limited time since initiation of the QAS program and the reported length of time to attain accreditation through NABP, the board is proposing to allow QAS accreditation in lieu of NABP's accreditation to initiate licensure in Iowa and continue to require NABP's accreditation for the licensee's second renewal. Additionally, NABP has renamed its accreditation program to "NABP Drug Distributor Accreditation."

Fiscal Impact

This rule making has no fiscal impact to the state of Iowa.

Jobs Impact

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

Waivers

Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Board for a waiver of the discretionary provisions, if any, pursuant to 657—Chapter 34.

Public Comment

Any interested person may submit comments concerning this proposed rule making. Written comments in response to this rule making must be received by the Board no later than 4:30 p.m. on _____, 2020. Comments should be directed to:

Sue Mears, RPh

Iowa Board of Pharmacy

400 SW 8th Street, Suite E

Des Moines, IA 50309

Public Hearing

No public hearing is scheduled at this time. As provided in Iowa Code section 17A.4(1)*"b,"* an oral presentation regarding this rule making may be demanded by 25 interested persons, a governmental subdivision, the Administrative Rules Review Committee, an agency, or an association having 25 or more members.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its regular monthly meeting or at a special meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

The following rule-making action is proposed:

ITEM 1. Amend paragraph **17.3(1)"c"** as follows:

c. Evidence of current ~~verified accredited wholesale distributors (VAWD)~~ drug distributor accreditation by the National Association of Boards of Pharmacy (NABP). This requirement does not apply to new applicants located in Iowa which must undergo an opening inspection by a board compliance officer or agent of the board prior to issuance of an initial license.

Wholesale distributors located in Iowa shall provide evidence of ~~VAWD~~ NABP drug distributor accreditation on or before license renewal, except as provided in this subrule. In lieu of NABP drug distributor accreditation for initial licensure in Iowa, an applicant may submit evidence of current Quality and Security (QAS) accreditation by the National Coalition for Drug Quality and Security (NCDQS). The licensee shall submit evidence of current NABP drug distributor accreditation prior to the second renewal of the license.

ITEM 2. Amend subrule 43.3(1) as follows:

43.3(1) *Application.* The applicant shall complete an application which requires demographic information about the 3PL, ownership information, information about the 3PL's registered agent located in Iowa, information about the 3PL's licensure or registration with other state and federal regulatory authorities, criminal and disciplinary history information, and a description of the scope of services to be provided in Iowa. If the applicant is not located in Iowa, the applicant shall submit evidence that the applicant has a valid license or registration in the home state or provide evidence that the home state does not require licensure. The applicant shall provide evidence of current ~~verified accredited wholesale distributors (VAWD)~~ drug distributor accreditation by the National Association of Boards of Pharmacy (NABP). This requirement does not apply to new applicants located in Iowa which must undergo an opening inspection by a board compliance officer or agent of the board prior to issuance of an initial license pursuant to subrule 43.3(3). 3PL distributors located in Iowa shall provide evidence of ~~VAWD~~ NABP drug distributor accreditation on or before license renewal, except as provided in this subrule. In lieu of NABP drug distributor accreditation, an applicant for initial licensure may provide evidence of current Quality and Security (QAS) accreditation through National Coalition for Drug Quality and Security (NCDQS). The licensee shall provide evidence of current NABP drug distributor

accreditation prior to the second renewal of the license. An application for a 3PL license, including an application for registration pursuant to 657—Chapter 10, if applicable, will become null and void if the applicant fails to complete the licensure process, including opening for business, within six months of receipt by the board of the required application(s).