PHARMACY BOARD [657]

Adopted and Filed

The Board of Pharmacy hereby amends 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 adopted 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

The amendments update accreditation options for entities involved in the drug supply chain, wholesale distributors and third-party logistics providers (3PLs), and update the name of one of the approved accreditation program.

At the initiation of accreditation as a minimum standard for wholesale distributors and 3PLs, there was one accreditation program available offered by the National Association of Boards of Pharmacy (NABP). The NABP accreditation program was named Verified-Accredited Wholesale Distributors (VAWD). Since the original accreditation requirement, NABP has change the name of their program to Drug Distributor Accreditation. Additionally, a second program has been initiated by the National Coalition for Drug Quality and Security (NCDQS) to provide accreditation for entities within the drug supply chain (named "Quality and Security" or "QAS" accreditation). The Board recognizes the new accreditation program as a sufficiently equivalent alternative to the NABP accreditation program. The amendments allow a wholesale distributor or 3PL to attain accreditation with either identified accreditation program, or another accreditation program approved by the Board.

Public Comment and Changes to Rule Making

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on September 29, 2020, as **ARC 5171C**. The noticed rulemaking allowed NCDQS

accreditation only as an alternative for initial licensure but continued to require NABP accreditation prior to second renewal of the license. The Board received numerous comments which overwhelmingly recommended that the NCDQS accreditation be a permanent alternative to NABP accreditation. Commenters provided that the standards required to attain NCDQS accreditation is substantially equivalent to those required by NABP. The Board determined that drug supply chain security, and thus public safety, can be reasonably assured with either accreditation. As such, the amendments were changed to reflect that either accreditation would meet the minimum standard for initial licensure or renewal. The Board also determined that additional accreditation programs may be initiated and added language to allow future accreditation programs if found to be equivalent.

Adoption of Rule Making

This rule making was adopted by the Board on _____, 2020.

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 can be determined.

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.

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).

Effective Date

This rule making will become effective on _____, 2020.

The following rule-making action is adopted:

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), the National Coalition for Drug Quality and Security (NCDQS), or another accreditation body approved by the board. 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~~ drug distributor accreditation on or before license renewal.

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), the National Coalition for Drug Quality and Security (NCDQS), or another accreditation body approved by the board. 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~~ drug distributor accreditation on or before license renewal. 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).