



California State Board of Pharmacy

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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

To: Board Members

Subject: Agenda Item III - Discussion and Consideration of Board Approval of Training Program for Designated Representative-Reverse Distributor

Attachment 1

Relevant Law:

Business and Professions Code (BPC) section 4022.6 establishes the definition of the designated representative-reverse distributor.

BPC section 4053.2 establishes the licensing requirements for the designated representative-reverse distributor, including experience and training requirements.

A copy of BPC sections 4022.6 and 4053.2 may be found in **Attachment 1**.

Background:

With the enactment of SB 752 (Stone, Chapter 598, Statutes of 2017), effective January 1, 2018, the board is required to issue a license to individuals who qualify for a designated representative-reverse distributor license. Staff is working with the department to implement this license type in the board's licensing database. The Designated Representative-Reverse Distributor application was made available on the board's website March 1, 2018.

One of the licensing requirements specified in BPC section 4053.2(b)(3)(A) requires an individual to complete a training program approved by the board. The board has not yet approved a training program.

The board has received a request from SkillsPlus Inc. to provide an approved designated representative-reverse distributor training program. The program content has been reviewed by Supervising Inspector Janice Dang, PharmD., who has determined that it meets the criteria established in BPC section 4053.2. Skills Plus Inc. currently offers a training program for individuals to qualify to become licensed as a designated representative and a designated representative-3PL.

Due to proprietary concerns, the actual content of the training program was reviewed by Dr. Dang. Included in **Attachment 1** is a document provided by SkillsPlus Inc. that lists the laws and regulations covered in its designated representative-reverse distributor program. The program consists of approximately 7.25 hours of training and includes a final examination of approximately 90-100 questions.

Upon board approval, SkillsPlus Inc. could offer the training program immediately. At least one individual is waiting to enroll in a board-approved program to qualify for a designated representative-reverse distributor license.

At this Meeting:

The board will have the opportunity to discuss the designated representative-reverse distributor training program offered by SkillsPlus Inc. Based on the review by Dr. Dang, staff recommends approval of the designated representative-reverse distributor program offered by SkillsPlus, Inc.

Staff Recommendation:

Should the board agree with the staff recommendation, the following motion could be used.

Motion: Approve the designated representative-reverse distributor training program offered by SkillsPlus Inc. for a period of five years and require SkillsPlus Inc. to submit annual updates regarding the content of the training plan to be reviewed by a Supervising Inspector.

Attachment 1

4022.6. Designated Representative-Reverse Distributor

“Designated representative-reverse distributor” means an individual to whom a license has been granted pursuant to Section 4053.2, who is responsible for supervision over a licensed wholesaler that only acts as a reverse distributor. A pharmacist fulfilling the duties of Section 4053.2 shall not be required to obtain a license as a designated representative-reverse distributor.

4053.2. Designated Representative-Reverse Distributor – Licensing; Requirements

(a) Notwithstanding Sections 4051 and 4053, the board may issue a designated representative-reverse distributor license to a qualified individual who shall provide sufficient and qualified supervision over a licensed wholesaler that only acts as a reverse distributor. The designated representative-reverse distributor shall protect the public health and safety in the handling, storage, warehousing, and destruction of outdated or nonsaleable dangerous drugs and dangerous devices.

(b) An individual who is at least 18 years of age may apply for a designated representative-reverse distributor license. In order to obtain and maintain that license, the individual shall meet all of the following requirements:

(1) He or she shall be a high school graduate or possess a general education development certificate equivalent.

(2) He or she shall meet one of the following requirements:

(A) Have a minimum of one year of paid work experience in the past three years with a licensed wholesaler, third-party logistics provider, or pharmacy performing duties related to the distribution, dispensing, or destruction of dangerous drugs or dangerous devices.

(B) Have a minimum of one year of paid work experience in the destruction of outdated or nonsaleable dangerous drugs or dangerous devices pharmaceutical waste.

(C) Meet all of the prerequisites to take the examination required for licensure as a pharmacist by the board.

(3) (A) He or she shall complete a training program approved by the board that, at a minimum, addresses each of the following subjects:

(i) Knowledge and understanding of California law and federal law relating to the distribution of dangerous drugs and dangerous devices.

(ii) Knowledge and understanding of California law and federal law relating to the distribution of controlled substances.

(iii) Knowledge and understanding of California law and federal law relating to the removal and destruction of dangerous drugs, dangerous devices, and pharmaceutical waste.

(iv) Knowledge and understanding of the United States Pharmacopoeia or federal Food and Drug Administration standards relating to the safe storage, handling, and transport of dangerous drugs and dangerous devices.

(B) The board may, by regulation, require the training program required under this paragraph to include additional material.

(C) The board shall not issue a license as a designated representative-reverse distributor until the applicant provides proof of completion of the training required by this paragraph to the board.

(c) A reverse distributor shall not operate without at least one designated representative or designated representative-reverse distributor present at each of its licensed places of business as required under Section 4160.

This document shows the flow of the class by sequence of the laws and regulations referenced.

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