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**BUSINESS AND PROFESSIONS CODE - BPC**

**DIVISION 2. HEALING ARTS [500 - 4999.129]** ( *Division 2 enacted by Stats. 1937, Ch. 399.*  )

**CHAPTER 9. Pharmacy [4000 - 4427.8]** ( *Chapter 9 repealed and added by Stats. 1996, Ch. 890, Sec. 3.*  )

**ARTICLE 11. Wholesalers, Third-Party Logistics Providers, and Manufacturers [4160 - 4169.1]** ( *Heading of Article 11 amended by Stats. 2014, Ch. 507, Sec. 16.*  )

**4160.** (a) A person shall not act as a wholesaler or third-party logistics provider of any dangerous drug or dangerous device unless he or she has obtained a license from the board.

(b) Upon approval by the board and the payment of the required fee, the board shall issue a license to the applicant.

(c) (1) A separate license shall be required for each place of business owned or operated by a wholesaler or third-party logistics provider. Each place of business may only be issued a single license by the board, except as provided in paragraph (2). Each license shall be renewed annually and shall not be transferable. At all times during which a place of business is open for business, at least one designated representative, in the case of a wholesaler, or designated representative-3PL in the case of a third-party logistics provider, shall be present. A wholesaler that only acts as a reverse distributor may use either a designated representative or a designated representative-reverse distributor to fulfill this requirement.

(2) A wholesaler and a third-party logistics provider under common ownership may be licensed at the same place of business provided that all of the following requirements are satisfied:

(A) The wholesaler and the third-party logistics provider each separately maintain the records required under Section 4081.

(B) Dangerous drugs and dangerous devices owned by the wholesaler are not commingled with the dangerous drugs and dangerous devices handled by the third-party logistics provider.

(C) Any individual acting as a designated representative for the wholesaler is not concurrently acting as a designated representative-3PL on behalf of the third-party logistics provider. Nothing in this subparagraph shall be construed to prohibit an individual from concurrently holding a license to act as a designated representative and to act as a designated representative-3PL.

(D) The wholesaler has its own designated representative-in-charge responsible for the operations of the wholesaler and the third-party logistics provider has its own responsible manager responsible for the operations of the third-party logistics provider. The same individual shall not concurrently serve as the responsible manager and the designated representative-in-charge for a wholesaler and a third-party logistics provider licensed at the same place of business.

(E) The third-party logistics provider does not handle the prescription drugs or prescription devices owned by a prescriber.

(F) The third-party logistics provider is not a reverse third-party logistics provider.

(G) The wholesaler is not acting as a reverse distributor.

(d) Every wholesaler shall be supervised or managed by a designated representative-in-charge. The designated representative-in-charge shall be responsible for the wholesaler's compliance with state and federal laws governing wholesalers. As part of its initial application for a license, and for each renewal, each wholesaler shall, on a form designed by the board, provide identifying information and the California license number for a designated representative or pharmacist proposed to serve as the designated representative-in-charge. The proposed designated representative-in-charge shall be subject to approval by the board. The board shall not issue or renew a wholesaler license without identification of an approved designated representative-in-charge for the wholesaler. The designated representative-in-charge shall maintain an active license as a designated representative with the board

at all times during which he or she is designated as the designated representative-in-charge. A wholesaler that only acts as a reverse distributor may identify and allow a designated representative-reverse distributor to perform in this capacity. That individual shall maintain an active license as a designated representative-reverse distributor.

(e) Each place of business of a third-party logistics provider shall be supervised and managed by a responsible manager. The responsible manager shall be responsible for the compliance of the place of business with state and federal laws governing third-party logistics providers and with the third-party logistics provider's customer specifications, except where the customer's specifications conflict with state or federal laws. As part of its initial application for a license, and for each renewal, each third-party logistics provider shall, on a form designated by the board, provide identifying information and the California license number for a designated representative-3PL proposed to serve as the responsible manager. The proposed responsible manager shall be subject to approval by the board. The board shall not issue or renew a third-party logistics provider license without identification of an approved responsible manager for the third-party logistics provider. The responsible manager shall maintain an active license as a designated representative-3PL with the board at all times during which he or she is designated as the responsible manager.

(f) A wholesaler shall notify the board in writing, on a form designed by the board, within 30 days of the date when a designated representative-in-charge ceases to act as the designated representative-in-charge, and shall on the same form propose another authorized licensee to take over as the designated representative-in-charge. The proposed replacement designated representative-in-charge shall be subject to approval by the board. If disapproved, the wholesaler shall propose another replacement within 15 days of the date of disapproval, and shall continue to name proposed replacements until a designated representative-in-charge is approved by the board.

(g) A third-party logistics provider shall notify the board in writing, on a form designed by the board, within 30 days of the date when a responsible manager ceases to act as the responsible manager, and shall on the same form propose another designated representative-3PL to take over as the responsible manager. The proposed replacement responsible manager shall be subject to approval by the board. If disapproved, the third-party logistics provider shall propose another replacement within 15 days of the date of disapproval, and shall continue to name proposed replacements until a responsible manager is approved by the board.

(h) A drug manufacturer premises licensed by the Food and Drug Administration or licensed pursuant to Section 111615 of the Health and Safety Code that only distributes dangerous drugs and dangerous devices of its own manufacture is exempt from this section and Section 4161.

(i) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. A temporary license fee shall be required in an amount established by the board as specified in subdivision (f) of Section 4400. When needed to protect public safety, a temporary license may be issued for a period not to exceed 180 days, subject to terms and conditions that the board deems necessary. If the board determines that a temporary license was issued by mistake or denies the application for a permanent license, the temporary license shall terminate upon either personal service of the notice of termination upon the licenseholder or service by certified mail, return receipt requested, at the licenseholder's address of record with the board, whichever occurs first. For purposes of retaining a temporary license, or for purposes of any disciplinary or license denial proceeding before the board, the temporary licenseholder shall not be deemed to have a vested property right or interest in the license.

*(Amended by Stats. 2017, Ch. 598, Sec. 7. (SB 752) Effective January 1, 2018.)*

**4160.5.** Within 30 days of the effective date of the act adding this section, a manufacturer of a nonprescription diabetes test device shall make the names of its authorized distributors available on its Internet Web site and shall provide the board with the names of its authorized distributors. Within 30 days of receiving that information from a manufacturer of a nonprescription diabetes test device, the board shall post the names of authorized distributors of nonprescription diabetes test devices on the board's Internet Web site. A manufacturer of a nonprescription diabetes test device shall, within 30 days of making changes to its authorized distributors, update its Internet Web site and inform the board of changes to its authorized distributors. Within 30 days of receiving notice of any change from a manufacturer of a nonprescription diabetes test device, the board shall post the updated list of the manufacturer's authorized distributors on its Internet Web site.

*(Added by Stats. 2017, Ch. 139, Sec. 5. (AB 602) Effective July 31, 2017.)*

**4161.** (a) A person located outside this state that (1) ships, sells, mails, warehouses, distributes, or delivers dangerous drugs or dangerous devices into this state or (2) sells, brokers, warehouses, or distributes dangerous drugs or devices within this state shall be considered a nonresident wholesaler or a nonresident third-party logistics provider.

(b) A nonresident wholesaler or nonresident third-party logistics provider shall be licensed by the board prior to shipping, selling, mailing, warehousing, distributing, or delivering dangerous drugs or dangerous devices to a site located in this state or selling, brokering, warehousing, or distributing dangerous drugs or devices within this state.

(c) (1) A separate license shall be required for each place of business owned or operated by a nonresident wholesaler or nonresident third-party logistics provider from or through which dangerous drugs or dangerous devices are shipped, sold, mailed, warehoused, distributed, or delivered to a site located in this state or sold, brokered, warehoused, or distributed within this state. Each place of

business may only be issued a single license by the board, except as provided in paragraph (2). A license shall be renewed annually and shall not be transferable.

(2) A nonresident wholesaler and a nonresident third-party logistics provider under common ownership may be licensed at the same place of business provided that all of the following requirements are satisfied:

(A) The wholesaler and the third-party logistics provider each separately maintain the records required under Section 4081.

(B) Dangerous drugs and dangerous devices owned by the wholesaler are not commingled with the dangerous drugs and dangerous devices handled by the third-party logistics provider.

(C) Any individual acting as a designated representative for the wholesaler is not concurrently acting as a designated representative-3PL on behalf of the third-party logistics provider. Nothing in this subparagraph shall be construed to prohibit an individual from concurrently holding a license to act as a designated representative and to act as a designated representative-3PL.

(D) The wholesaler has its own designated representative-in-charge responsible for the operations of the wholesaler and the third-party logistics provider has its own responsible manager responsible for the operations of the third-party logistics provider. The same individual shall not concurrently serve as the responsible manager and the designated representative-in-charge for a wholesaler and a third-party logistics provider licensed at the same place of business.

(E) The third-party logistics provider does not handle the prescription drugs or prescription devices owned by a prescriber.

(F) The third-party logistics provider is not a reverse third-party logistics provider.

(G) The wholesaler is not acting as a reverse distributor.

(d) The following information shall be reported, in writing, to the board at the time of initial application for licensure by a nonresident wholesaler or a nonresident third-party logistics provider, on renewal of a nonresident wholesaler or nonresident third-party logistics provider license, or within 30 days of a change in that information:

(1) Its agent for service of process in this state.

(2) Its principal corporate officers, as specified by the board, if any.

(3) Its general partners, as specified by the board, if any.

(4) Its owners if the applicant is not a corporation or partnership.

(e) A report containing the information in subdivision (d) shall be made within 30 days of any change of ownership, office, corporate officer, or partner.

(f) A nonresident wholesaler or nonresident third-party logistics provider shall comply with all directions and requests for information from the regulatory or licensing agency of the state in which it is licensed, as well as with all requests for information made by the board.

(g) A nonresident wholesaler or nonresident third-party logistics provider shall maintain records of dangerous drugs and dangerous devices sold, traded, transferred, warehoused, or distributed to persons in this state or within this state, so that the records are in a readily retrievable form.

(h) A nonresident wholesaler or nonresident third-party logistics provider shall at all times maintain a valid, unexpired license, permit, or registration to conduct the business of the wholesaler or nonresident third-party logistics provider in compliance with the laws of the state in which it is a resident. An application for a nonresident wholesaler or nonresident third-party logistics provider license in this state shall include a license verification from the licensing authority in the applicant's state of residence. The board may waive the home state licensure requirement for a nonresident third-party logistics provider if the board inspects the location and finds it to be in compliance with this article and any regulations adopted by the board or the applicant provides evidence of its accreditation by the Drug Distributor Accreditation program of the National Association of Boards of Pharmacy. The nonresident third-party logistics provider shall reimburse the board for all actual and necessary costs incurred by the board in conducting an inspection of the location, pursuant to subdivision (v) of Section 4400.

(i) (1) The board shall not issue or renew a nonresident wholesaler license until the nonresident wholesaler identifies a designated representative-in-charge and notifies the board in writing of the identity and license number of the designated representative-in-charge.

(2) The board shall not issue or renew a nonresident third-party logistics provider license until the nonresident third-party logistics provider identifies a responsible manager and notifies the board in writing of the identity and license number of the designated representative-3PL who will be the responsible manager.

(j) The designated representative-in-charge shall be responsible for the compliance of the nonresident wholesaler with state and federal laws governing wholesalers. The responsible manager shall be responsible for the compliance of the nonresident third-party logistics provider's place of business with state and federal laws governing third-party logistics providers. A nonresident wholesaler or nonresident third-party logistics provider shall identify and notify the board of a new designated representative-in-charge or responsible manager within 30 days of the date that the prior designated representative-in-charge or responsible manager ceases to be the designated representative-in-charge or responsible manager.

(k) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. When needed to protect public safety, a temporary license may be issued for a period not to exceed 180 days, subject to terms and conditions that the board deems necessary. If the board determines that a temporary license was issued by mistake or denies the application for a permanent license, the temporary license shall terminate upon either personal service of the notice of termination upon the licenseholder or service by certified mail, return receipt requested, at the licenseholder's address of record with the board, whichever occurs first. Neither for purposes of retaining a temporary license, nor for purposes of any disciplinary or license denial proceeding before the board, shall the temporary licenseholder be deemed to have a vested property right or interest in the license.

(l) The registration fee shall be the fee specified in subdivision (f) of Section 4400.

(m) This section shall become operative on January 1, 2025.

*(Repealed (in Sec. 10) and added by Stats. 2023, Ch. 723, Sec. 11. (SB 816) Effective January 1, 2024. Operative January 1, 2025, by its own provisions.)*

**4161.5.** At such time as federal regulations are promulgated to implement Section 584 of the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 360eee-3), the board shall immediately identify any standard, requirement, or regulation in California law governing interstate commerce that is in conflict with the federal regulations and act to remove the conflict in the manner permitted by law.

*(Added by Stats. 2014, Ch. 507, Sec. 19. (AB 2605) Effective January 1, 2015.)*

**4162.** (a) (1) An applicant for the issuance or renewal of a wholesaler license, which is not government owned and operated, shall submit a surety bond of one hundred thousand dollars (\$100,000) or other equivalent means of security acceptable to the board payable to the Pharmacy Board Contingent Fund. The purpose of the surety bond is to secure payment of any administrative fine imposed by the board and any cost recovery ordered pursuant to Section 125.3.

(2) An applicant for the issuance or renewal of a third-party logistics provider license, which is not government owned and operated, shall submit a surety bond of ninety thousand dollars (\$90,000) or other equivalent means of security acceptable to the board payable to the Pharmacy Board Contingent Fund. The purpose of the surety bond is to secure payment of any administrative fine imposed by the board and any cost recovery ordered pursuant to Section 125.3.

(3) For purposes of paragraphs (1) and (2), the board may accept a surety bond less than the amount required under paragraph (1) or (2) if the annual gross receipts of the previous tax year for the wholesaler or third-party logistics provider is ten million dollars (\$10,000,000) or less, in which case the surety bond shall be twenty-five thousand dollars (\$25,000).

(4) A person to whom an approved new drug application has been issued by the United States Food and Drug Administration who engages in the wholesale distribution of only the dangerous drug specified in the new drug application, and is licensed or applies for licensure as a wholesaler or third-party logistics provider, shall not be required to post a surety bond as provided in paragraph (1) or (2).

(5) For licensees subject to paragraph (3) or (4), the board may require a bond up to one hundred thousand dollars (\$100,000) for any licensee who has been disciplined by any state or federal agency or has been issued an administrative fine pursuant to this chapter.

(b) The board may make a claim against the bond if the licensee fails to pay a fine within 30 days after the order imposing the fine, or costs become final.

(c) A single surety bond or other equivalent means of security acceptable to the board shall satisfy the requirement of subdivision (a) for all licensed sites under common control as defined in Section 4126.5.

*(Amended by Stats. 2014, Ch. 507, Sec. 20. (AB 2605) Effective January 1, 2015.)*

**4162.5.** (a) (1) An applicant for the issuance or renewal of a nonresident wholesaler license shall submit a surety bond of one hundred thousand dollars (\$100,000), or other equivalent means of security acceptable to the board, such as an irrevocable letter of credit, or a deposit in a trust account or financial institution, payable to the Pharmacy Board Contingent Fund. The purpose of the

surety bond is to secure payment of any administrative fine imposed by the board and any cost recovery ordered pursuant to Section 125.3.

(2) An applicant for the issuance or renewal of a nonresident third-party logistics provider license shall submit a surety bond of ninety thousand dollars (\$90,000), or other equivalent means of security acceptable to the board, such as an irrevocable letter of credit, or a deposit in a trust account or financial institution, payable to the Pharmacy Board Contingent Fund. The purpose of the surety bond is to secure payment of any administrative fine imposed by the board and any cost recovery ordered pursuant to Section 125.3.

(3) For purposes of paragraphs (1) and (2), the board may accept a surety bond less than the amount required under paragraph (1) or (2) if the annual gross receipts of the previous tax year for the nonresident wholesaler or the nonresident third-party logistics provider is ten million dollars (\$10,000,000) or less, in which case the surety bond shall be twenty-five thousand dollars (\$25,000).

(4) For applicants who satisfy paragraph (3), the board may require a bond up to one hundred thousand dollars (\$100,000) for any nonresident wholesaler or nonresident third-party logistics provider who has been disciplined by any state or federal agency or has been issued an administrative fine pursuant to this chapter.

(5) A person to whom an approved new drug application or a biologics license application has been issued by the United States Food and Drug Administration who engages in the wholesale distribution of only the dangerous drug specified in the new drug application or biologics license application, and is licensed or applies for licensure as a nonresident wholesaler or a nonresident third-party logistics provider, shall not be required to post a surety bond as provided in this section.

(b) The board may make a claim against the bond if the licensee fails to pay a fine within 30 days of the issuance of the fine or when the costs become final.

(c) A single surety bond or other equivalent means of security acceptable to the board shall satisfy the requirement of subdivision (a) for all licensed sites under common control as defined in Section 4126.5.

*(Amended by Stats. 2014, Ch. 507, Sec. 21. (AB 2605) Effective January 1, 2015.)*

**4163.** (a) A manufacturer, wholesaler, repackager, or pharmacy shall not furnish a dangerous drug or dangerous device to an unauthorized person.

(b) Except as provided in subdivision (c), dangerous drugs or dangerous devices shall be acquired from a person authorized by law to possess or furnish dangerous drugs or dangerous devices. If the person acquiring the dangerous drugs or dangerous devices is a wholesaler, the obligation of the wholesaler shall be limited to obtaining confirmation of licensure of those sources from whom it has not previously acquired dangerous drugs or dangerous devices.

(c) Upon approval of the board, a reverse distributor licensed as a wholesaler may acquire a dangerous drug or dangerous device from an unlicensed source that was previously licensed with the board for the sole purpose of destruction of the dangerous drug or dangerous device.

*(Amended by Stats. 2019, Ch. 213, Sec. 2. (SB 655) Effective January 1, 2020.)*

**4164.** (a) A wholesaler or third-party logistics provider licensed by the board that distributes controlled substances, dangerous drugs, or dangerous devices within or into this state shall report to the board all distributions of dangerous drugs and controlled substances that are subject to abuse, as determined by the board.

(b) Each wholesaler shall develop and maintain a system for tracking individual sales of dangerous drugs at preferential or contract prices to pharmacies that primarily or solely dispense prescription drugs to patients of long-term care facilities. The system shall be capable of identifying purchases of any dangerous drug at preferential or contract prices by customers that vary significantly from prior ordering patterns for the same customer, including by identifying purchases in the preceding 12 calendar months by that customer or similar customers and identifying current purchases that exceed prior purchases by either that customer or similar customers by a factor of 20 percent.

(c) Upon written, oral, or electronic request by the board, a wholesaler shall furnish data tracked pursuant to subdivision (b) to the board in written, hardcopy, or electronic form. The board shall specify the dangerous drugs, the customers, or both the dangerous drugs and customers for which data are to be furnished, and the wholesaler shall have 30 calendar days to comply with the request.

(d) As used in this section, "preferential or contract prices" means and refers to purchases by contract of dangerous drugs at prices below the market wholesale price for those drugs.

*(Amended by Stats. 2014, Ch. 507, Sec. 22. (AB 2605) Effective January 1, 2015.)*

**4165.** A wholesaler or third-party logistics provider licensed by the board who sells or transfers any dangerous drug or dangerous device into this state or who receives, by sale or otherwise, any dangerous drug or dangerous device from any person in this state shall, on request, furnish an authorized officer of the law with all records or other documentation of that sale or transfer.

*(Amended by Stats. 2014, Ch. 507, Sec. 23. (AB 2605) Effective January 1, 2015.)*

**4166.** (a) A wholesaler that uses the services of a third-party logistics provider or carrier, including, but not limited to, the United States Postal Service or a common carrier, shall be liable for the security and integrity of any dangerous drugs or dangerous devices through that provider or carrier until the drugs or devices are delivered to the transferee at its board-licensed premises.

(b) A third-party logistics provider that uses the services of a carrier, including, but not limited to, the United States Postal Service or a common carrier, shall have in place and comply with written policies and procedures that provide for both of the following:

(1) Verification that the third-party logistics provider, or the owner of the dangerous drugs or dangerous devices stored at the third-party logistics provider, has imposed obligations on the carrier that provide for the security and integrity of any dangerous drugs or dangerous devices transported by the carrier until the drugs or devices are delivered to the transferee at its premises.

(2) Confirmation, prior to shipping a dangerous drug or dangerous device, that the intended recipient is legally authorized to receive the dangerous drug or dangerous device.

(c) Nothing in this section is intended to affect the liability of a wholesaler, third-party logistics provider, or other distributor for dangerous drugs or dangerous devices after their delivery to the transferee.

*(Amended by Stats. 2014, Ch. 507, Sec. 24. (AB 2605) Effective January 1, 2015.)*

**4167.** A wholesaler or third-party logistics provider shall not obtain, by purchase or otherwise, any dangerous drugs or dangerous devices that it cannot maintain, in a secure manner, at the place of business licensed by the board.

*(Amended by Stats. 2014, Ch. 507, Sec. 25. (AB 2605) Effective January 1, 2015.)*

**4168.** A county or municipality shall not issue a business license for any establishment that requires a wholesaler or third-party logistics provider license unless the establishment possesses a current wholesaler or third-party logistics provider license issued by the board. For purposes of this section, an "establishment" is the licensee's physical location in California.

*(Amended by Stats. 2014, Ch. 507, Sec. 26. (AB 2605) Effective January 1, 2015.)*

**4169.** (a) A person or entity shall not do any of the following:

(1) Purchase, trade, sell, warehouse, distribute, or transfer dangerous drugs or dangerous devices at wholesale with a person or entity that is not licensed with the board as a wholesaler, third-party logistics provider, or pharmacy.

(2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

(3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code.

(4) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices after the beyond use date on the label.

(5) Fail to maintain records of the acquisition or disposition of dangerous drugs or dangerous devices for at least three years.

(b) Notwithstanding any other law, a violation of this section may subject the person or entity that has committed the violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence, pursuant to a citation issued by the board.

(c) Amounts due from any person under this section shall be offset as provided under Section 12419.5 of the Government Code. Amounts received by the board under this section shall be deposited into the Pharmacy Board Contingent Fund.

(d) This section shall not apply to a pharmaceutical manufacturer licensed by the Food and Drug Administration or by the State Department of Public Health.

*(Amended by Stats. 2014, Ch. 507, Sec. 27. (AB 2605) Effective January 1, 2015.)*

**4169.1.** A wholesaler, upon discovery, shall notify the board in writing of any suspicious orders of controlled substances placed by a California-licensed pharmacy or wholesaler by providing the board a copy of the information that the wholesaler provides to the United States Drug Enforcement Administration. Suspicious orders include, but are not limited to, orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

*(Added by Stats. 2017, Ch. 548, Sec. 8. (AB 401) Effective January 1, 2018.)*