

Assembly Bill No. 497

Passed the Assembly August 29, 2005

Chief Clerk of the Assembly

Passed the Senate August 22, 2005

Secretary of the Senate

This bill was received by the Governor this _____ day
of _____, 2005, at _____ o'clock ____M.

Private Secretary of the Governor

CHAPTER _____

An act to amend Sections 4162.5 and 4400 of the Business and Professions Code, relating to pharmacy practices.

LEGISLATIVE COUNSEL'S DIGEST

AB 497, Negrete McLeod. Drug wholesalers and manufacturers: nonresident wholesalers.

Existing law, the Pharmacy Law, provides for the licensure and regulation by the California State Board of Pharmacy of pharmacies and other persons. Under that law, a person located outside of this state that ships, mails, or delivers dangerous drugs or dangerous devices into this state at wholesale is considered an out-of-state distributor that must be licensed by the board prior to engaging in those activities. Existing law, operative January 1, 2006, to January 1, 2011, requires an applicant for the issuance or renewal of a nonresident wholesaler license to submit a surety bond of \$100,000, or an equivalent means of security, for each site to be licensed by the nonresident wholesaler through which dangerous drugs or dangerous devices are to be shipped, mailed, or delivered to a site located in California. Existing law requires a fee of \$550, which may be increased up to \$600, for a wholesaler or nonresident wholesaler license and annual renewal.

This bill would instead require a single \$100,000 surety bond, or an equivalent means of security, to be submitted by an applicant for the issuance or renewal of a nonresident wholesaler license. The bill would except from that bond requirement certain nonresident wholesalers to whom an approved new drug application has been issued by the federal Food and Drug Administration, as specified. The bill would also reduce certain application fee amounts required to be paid for a nonresident wholesaler license.

The people of the State of California do enact as follows:

SECTION 1. Section 4162.5 of the Business and Professions Code is amended to read:

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) For purpose of paragraph (1), the board may accept a surety bond less than one hundred thousand dollars (\$100,000) if the annual gross receipts of the previous tax year for the nonresident wholesaler is ten million dollars (\$10,000,000) or less in which the surety bond shall be twenty-five thousand dollars (\$25,000).

(3) For applicants who satisfy paragraph (2), the board may require a bond up to one hundred thousand dollars (\$100,000) for any nonresident wholesaler who has been disciplined by any state or federal agency or has been issued an administrative fine pursuant to this chapter.

(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 nonresident wholesaler, 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.

(d) This section shall become operative on January 1, 2006, and shall become inoperative and is repealed on, January 1, 2011, unless a later enacted statute, that is enacted before January 1, 2011, deletes or extends those dates.

SEC. 2. Section 4400 of the Business and Professions Code, as added by Section 50 of Chapter 857 of the Statutes of 2004, is amended to read:

4400. The amount of fees and penalties prescribed by this chapter, except as otherwise provided is that fixed by the board according to the following schedule:

(a) The fee for a nongovernmental pharmacy license shall be three hundred forty dollars (\$340) and may be increased to four hundred dollars (\$400).

(b) The fee for a nongovernmental pharmacy annual renewal shall be one hundred seventy-five dollars (\$175) and may be increased to two hundred fifty dollars (\$250).

(c) The fee for the pharmacist application and examination shall be one hundred fifty-five dollars (\$155) and may be increased to one hundred eighty-five dollars (\$185).

(d) The fee for regrading an examination shall be seventy-five dollars (\$75) and may be increased to eighty-five dollars (\$85). If an error in grading is found and the applicant passes the examination, the regrading fee shall be refunded.

(e) The fee for a pharmacist license and biennial renewal shall be one hundred fifteen dollars (\$115) and may be increased to one hundred fifty dollars (\$150).

(f) The fee for a wholesaler license and annual renewal shall be five hundred fifty dollars (\$550) and may be increased to six hundred dollars (\$600), except as provided in subdivision (j).

(g) The fee for a hypodermic license and renewal shall be ninety dollars (\$90) and may be increased to one hundred twenty-five dollars (\$125).

(h) The fee for application and investigation for a designated representative license issued pursuant to Section 4053 shall be seventy-five dollars (\$75) and may be increased to one hundred dollars (\$100), except for a veterinary food-animal drug retailer designated representative, for whom the fee shall be one hundred dollars (\$100).

(i) The fee for a designated representative license and annual renewal under Section 4053 shall be one hundred ten dollars (\$110) and may be increased to one hundred fifty dollars (\$150), except that the fee for the issuance of a veterinary food-animal drug retailer designated representative license shall be one hundred fifty dollars (\$150), for renewal one hundred ten dollars (\$110), which may be increased to one hundred fifty dollars (\$150), and for filing a late renewal fifty-five dollars (\$55).

(j) (1) The application fee for a nonresident wholesaler's license issued pursuant to Section 4161 shall be five hundred fifty dollars (\$550) and may be increased to six hundred dollars (\$600).

(2) For nonresident wholesalers who have 21 or more wholesaler facilities operating nationwide the application fees for the first 20 locations shall be five hundred fifty dollars (\$550) and may be increased to six hundred dollars (\$600). The application fee for any additional location after licensure of the first 20 locations shall be two hundred twenty-five dollars (\$225) and may be increased to three hundred dollars (\$300).

(3) The annual renewal fee for a nonresident wholesaler's license issued pursuant to Section 4161 shall be five hundred fifty dollars (\$550) and may be increased to six hundred dollars (\$600).

(k) The fee for registration and annual renewal of providers of continuing education shall be one hundred dollars (\$100) and may be increased to one hundred thirty dollars (\$130).

(l) The fee for evaluation of continuing education courses for accreditation shall be set by the board at an amount not to exceed forty dollars (\$40) per course hour.

(m) The fee for evaluation of applications submitted by graduates of foreign colleges of pharmacy or colleges of pharmacy not recognized by the board shall be one hundred sixty-five dollars (\$165) and may be increased to one hundred seventy-five dollars (\$175).

(n) The fee for an intern license or extension shall be sixty-five dollars (\$65) and may be increased to seventy-five dollars (\$75). The fee for transfer of intern hours or verification of licensure to another state shall be fixed by the board not to exceed twenty dollars (\$20).

(o) The board may, by regulation, provide for the waiver or refund of the additional fee for the issuance of a certificate where the certificate is issued less than 45 days before the next succeeding regular renewal date.

(p) The fee for the reissuance of any license, or renewal thereof, that has been lost or destroyed or reissued due to a name change is thirty dollars (\$30).

(q) The fee for the reissuance of any license, or renewal thereof, that must be reissued because of a change in the

information, is sixty dollars (\$60) and may be increased to one hundred dollars (\$100).

(r) It is the intent of the Legislature that, in setting fees pursuant to this section, the board shall seek to maintain a reserve in the Pharmacy Board Contingent Fund equal to approximately one year's operating expenditures.

(s) The fee for any applicant for a clinic permit is three hundred forty dollars (\$340) and may be increased to four hundred dollars (\$400) for each permit. The annual fee for renewal of the permit is one hundred seventy-five dollars (\$175) and may be increased to two hundred fifty dollars (\$250) for each permit.

(t) The board shall charge a fee for the processing and issuance of a registration to a pharmacy technician and a separate fee for the biennial renewal of the registration. The registration fee shall be twenty-five dollars (\$25) and may be increased to fifty dollars (\$50). The biennial renewal fee shall be twenty-five dollars (\$25) and may be increased to fifty dollars (\$50).

(u) The fee for a veterinary food-animal drug retailer license shall be four hundred dollars (\$400). The annual renewal fee for a veterinary food-animal drug retailer shall be two hundred fifty dollars (\$250).

(v) The fee for issuance of a retired license pursuant to Section 4200.5 shall be thirty dollars (\$30).

(w) This section shall become operative on January 1, 2006.

Approved _____, 2005

Governor