

ASSEMBLY BILL

No. 497

Introduced by Assembly Member Negrete McLeod

February 16, 2005

An act to amend Section 4161 of the Business and Professions Code, relating to pharmacy practices.

LEGISLATIVE COUNSEL'S DIGEST

AB 497, as introduced, Negrete McLeod. Drug wholesalers and manufacturers: licensure exemption.

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.

This bill would exempt from this licensure requirement certain intracompany transactions and transactions between affiliated or related companies, as defined.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

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

- 1 SECTION 1. Section 4161 of the Business and Professions
- 2 Code, as added by Chapter 887 of the Statutes of 2004, is
- 3 amended to read:

1 4161. (a) A person located outside this state that ships, mails,
2 or delivers dangerous drugs or dangerous devices into this state
3 shall be considered a nonresident wholesaler.

4 (b) A nonresident wholesaler shall be licensed by the board
5 prior to shipping, mailing, or delivering dangerous drugs or
6 dangerous devices to a site located in this state.

7 (c) A separate license shall be required for each place of
8 business owned or operated by a nonresident wholesaler from or
9 through which dangerous drugs or dangerous devices are
10 shipped, mailed, or delivered to a site located in this state. A
11 license shall be renewed annually and shall not be transferable.

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

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

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

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

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

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

25 (f) A nonresident wholesaler shall comply with all directions
26 and requests for information from the regulatory or licensing
27 agency of the state in which it is licensed, as well as with all
28 requests for information made by the board.

29 (g) A nonresident wholesaler shall maintain records of
30 dangerous drugs and dangerous devices sold, traded, or
31 transferred to persons in this state, so that the records are in a
32 readily retrievable form.

33 (h) A nonresident wholesaler shall at all times maintain a
34 valid, unexpired license, permit, or registration to conduct the
35 business of the wholesaler in compliance with the laws of the
36 state in which it is a resident. An application for a nonresident
37 wholesaler license in this state shall include a license verification
38 from the licensing authority in the applicant's state of residence.

39 (i) The board may not issue or renew a nonresident wholesaler
40 license until the nonresident wholesaler identifies a designated

1 representative-in-charge and notifies the board in writing of the
2 identity and license number of the designated
3 representative-in-charge.

4 (j) The designated representative-in-charge shall be
5 responsible for the nonresident wholesaler's compliance with
6 state and federal laws governing wholesalers. A nonresident
7 wholesaler shall identify and notify the board of a new
8 designated representative-in-charge within 30 days of the date
9 that the prior designated representative-in-charge ceases to be the
10 designated representative-in-charge.

11 (k) The board may issue a temporary license, upon conditions
12 and for periods of time as the board determines to be in the
13 public interest. A temporary license fee shall be fixed by the
14 board at an amount not to exceed the annual fee for renewal of a
15 license to conduct business as a nonresident wholesaler.

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

18 (m) ~~A pharmacy that meets the requirements of Section~~
19 ~~4001.2, as added by Senate Bill 1149 of the 2003-04 Regular~~
20 ~~Session, including any subsequent amendment thereto, shall not~~
21 ~~be considered a nonresident wholesaler for purposes of this~~
22 ~~section. The licensure requirements of this section shall not apply~~
23 ~~to a person located outside this state that ships, mails, or delivers~~
24 ~~dangerous drugs or dangerous devices into this state if that~~
25 ~~transaction is either of the following:~~

26 (1) *An intracompany transaction between the person and a*
27 *division, subsidiary, or parent of the person.*

28 (2) *A transaction between the person and an affiliated or*
29 *related company for purposes of stocking or restocking that*
30 *company. For purposes of this paragraph, an affiliated or related*
31 *company is one where the person and company are under*
32 *common ownership and control of the same corporate entity.*

33 (n) This section shall become operative January 1, 2006.