

**ASSEMBLY BILL**

**No. 2605**

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**Introduced by Assembly Member Bonilla**

February 21, 2014

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An act to amend Section 4127.2 of the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

AB 2605, as introduced, Bonilla. Pharmacy: sterile drug products.

The Pharmacy Law provides for the licensure and regulation of pharmacists and pharmacy corporations in this state by the California State Board of Pharmacy. Existing law, until July 1, 2014, prohibits a nonresident pharmacy from compounding injectable sterile drug products for shipment into the state without a license issued by the board, and specifies the information the board is required to receive before issuing the license. Existing law, commencing July 1, 2014, expands that provision to apply to nonresident pharmacies that compound any sterile drug products, and specifies different information the board is required to receive before issuing the license.

This bill would, with regard to the provisions that become inoperative July 1, 2014, prohibit the board from issuing a license to a nonresident pharmacy until the board receives any other information the board deems necessary.

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

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

1 SECTION 1. Section 4127.2 of the Business and Professions  
 2 Code is amended to read:

3 4127.2. (a) A nonresident pharmacy shall not compound  
 4 injectable sterile drug products for shipment into the State of  
 5 California without a license issued by the board pursuant to this  
 6 section. The license shall be renewed annually and shall not be  
 7 transferable.

8 (b) A license to compound injectable sterile drug products ~~may~~  
 9 ~~only~~ shall be issued *only* for a location that is licensed as a  
 10 nonresident pharmacy. Furthermore, the license to compound  
 11 injectable sterile drug products ~~may only~~ shall be issued *only* to  
 12 the owner of the nonresident pharmacy license at that location. A  
 13 license to compound injectable sterile drug products ~~may~~ shall not  
 14 be issued or renewed until the board receives the following from  
 15 the nonresident pharmacy:

16 (1) A copy of an inspection report issued by the pharmacy's  
 17 licensing agency, or a report from a private accrediting agency  
 18 approved by the board, in the prior 12 months documenting the  
 19 pharmacy's compliance with board regulations regarding the  
 20 compounding of injectable sterile drug products.

21 (2) A copy of the nonresident pharmacy's proposed policies  
 22 and procedures for sterile compounding.

23 (3) *Any other documentation the board deems necessary.*

24 (c) Nonresident pharmacies operated by entities that are licensed  
 25 as a hospital, home health agency, or a skilled nursing facility and  
 26 have current accreditation from the Joint Commission on  
 27 Accreditation of Healthcare Organizations, or other private  
 28 accreditation agencies approved by the board, are exempt from  
 29 the requirement to obtain a license pursuant to this section.

30 (d) On or before January 1, 2018, the board shall provide a  
 31 report to the Legislature regarding the regulation of nonresident  
 32 pharmacies. The report shall be submitted to the Legislature in the  
 33 manner required pursuant to Section 9795 of the Government  
 34 Code. At a minimum, the report shall address all of the following:

35 (1) A detailed description of board activities related to the  
 36 inspection and licensure of nonresident pharmacies.

37 (2) The status of proposed changes to federal law that are under  
 38 serious consideration and that would govern compounding

1 pharmacies, including legislation pending before the United States  
2 Congress, administrative rules, regulations, or orders under  
3 consideration by the federal Food and Drug Administration or  
4 other appropriate federal agency, and cases pending before the  
5 courts.

6 (3) If applicable, recommended modifications to the board's  
7 statutory duties related to nonresident pharmacies as a result of  
8 changes to federal law or any additional modifications necessary  
9 to protect the health and safety of the public.

10 (e) This section shall become inoperative on July 1, 2014, and,  
11 as of January 1, 2015, is repealed, unless a later enacted statute,  
12 that becomes operative on or before January 1, 2015, deletes or  
13 extends the dates on which it becomes inoperative and is repealed.