



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 IV: Legislative Proposal to Establish a Separate Licensure Category for Outsourcing Facilities

At the January Board Meeting, the board voted to sponsor legislation this year to license outsourcing facilities. Currently this proposal is contained in a spot bill, and has been introduced as SB 619. We have Senator Morrell as lead author and Senator Jeff Stone as a co-author on this bill.

Outsourcing facilities were created in November 2013 by enactment of the federal Drug Quality Security Act, the law that also preempted California's e-pedigree requirements. Outsourcing facilities compound large quantities of medication at one time, usually without a patient-specific prescription (which is typical of pharmacy compounding). The FDA has stated that they will use current good manufacturing practices as the standards to which outsourcing facilities will be held. There are currently about 59 outsourcing facilities registered with the FDA to do business in the US.

In early 2013, the board sponsored legislation (SB 294, Emmerson) that strengthened requirements for pharmacies that perform sterile compounding of products for California. This legislation was enacted nearly three months before the federal legislation. We now have approximately 1,000 in state and non-resident sterile compounding pharmacies licensed in California.

In the short span of just over one year, most states are now either grappling with or have established separate requirements to regulate outsourcing facilities as a different group than pharmacies.

The licensure of outsourcing facilities by California would harmonize California's regulation of entities that compound large quantities of non-patient specific sterile medications with federal requirements that permit such compounding. It would allow differentiation of these entities from compounding pharmacies, and focus manufacturing-like requirements on outsourcing facilities while continuing to foster the patient-pharmacist relationships of pharmacy.

Specific provisions will be developed in the near future to establish licensure requirements for in-state and out-of-state outsourcing facilities that will be added into SB 619. The guidance documents released by the FDA and scheduled for discussion under Section VIII of the agenda at this meeting will be possible sources of some components for the legislation. Additionally, the FDA's national meeting in mid-March regarding compounding pharmacies and outsourcing facilities will likely be additional origins of components for the regulation.