

1/18/2017

OUTSOURCING FACILITY APPLICATION FORMS AVAILABLE ONLINE

Effective Jan. 1, 2017, an outsourcing facility must have a license issued by the California State Board of Pharmacy before conducting business within or into California. Licenses must be renewed annually and are not transferrable.

Application forms for [in-state](#) and [nonresident](#) outsourcing facilities are available at the board's [website](#).

An in-state outsourcing facility must meet both of the following criteria:

- Located in California and engaged in compounding of sterile and nonsterile drugs; AND
- Registered with the federal Food and Drug Administration (FDA) under Section 503B of the federal Food Drug and Cosmetic Act.

A nonresident outsourcing facility must meet all of the following criteria:

- Located within the United States but outside of California and engaged in compounding of sterile and nonsterile drugs;
- Registered with the federal Food and Drug Administration (FDA) under Section 503B of the federal Food Drug and Cosmetic Act; AND
- Doing business into California.

Note: A facility licensed by the board as a sterile compounding pharmacy may not be concurrently licensed by the board as an outsourcing facility at the same location. Outsourcing facilities must comply with all laws and regulations during drug recalls.

SB 1193 (Hill, Chapter 484, Statutes of 2016) establishes a framework for the board to license and regulate outsourcing facilities. Information about provisions of SB 1193 governing outsourcing facilities is available in the [Winter 2016](#) edition of The Script.

For questions, contact the board staff at compounding.pharmacy@dca.ca.gov.

###