

12/20/2017

BOARD ADOPTS EMERGENCY COMPOUNDING REGULATION

The Board of Pharmacy announces the adoption of an [emergency regulation](#) related to establishing beyond use dates (BUDs) for compounded drug preparations. The regulation took effect Dec. 19, 2017, and will remain in effect for 180 days. It will expire on June 19, 2018.

The emergency regulation amends section 1735.2, subdivision (i), of Article 4.5 of Division 17 of Title 16 of the California Code of Regulations. The emergency rule allows for an extension of BUDs of nonsterile compounded drug preparations. It also makes clear that stability studies and suitability and integrity tests are required to extend the BUDs only for sterile compounded drug preparations.

During the 180-day period of the emergency regulation, the board will proceed with a regular rulemaking action for compounding drug preparations. The regular rulemaking process will include a public comment period. Additional information about the regular rulemaking process will be posted under [Pending Regulations](#) at the board's [website](#).

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