

# **Legislative & Regulatory**

## *Fall 2018 Update*

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## **DISCLOSURES**

I have no applicable conflicts of interest.

### **State Bar Required Disclaimer**

- This program is intended for general education only and does not constitute legal advice.
- Steve is not your attorney.
- Legal advice should be fact-situation specific.
- No Attorney-Client Privilege is created by this program, including questions and responses.

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## BRIEF COURSE DESCRIPTION

This Course will present and discuss recent and anticipated pharmacy law changes. The emphasis will be on California pharmacy law changes effective in 2018 and early 2019.

Some of the most prominent pharmacy pre-2018 law changes will be reviewed.

Time permitting, some of the National pharmacy related law changes will be discussed.

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## Learning Objectives

By the end of the course, participants will be able to identify some of the most prominent pre-2018 law changes affecting pharmacy practice in California.

By the end of the course will be able to identify selected pharmacy law changes for 2018 and 2019 affecting pharmacy practice in California.

By the end of the course will be able to identify some anticipated pharmacy law changes that may affect pharmacy practice in California.

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## Pre-Assessment Questions

Re: 2017 Changes

1. T or F – Starting on October 2nd, Pharmacists must check CURES before “dispensing” a Schedule II, III or IV Controlled Substance.
2. Which of the following is NOT current pharmacy law?
  - A. All licensees must enroll in BOP’s Alert system.
  - B. BOP can license “Outsourcing Facilities”.
  - C. All ADDS’s, as defined, must be registered with BOP.
  - D. Satellite pharmacies must purchase, procure or obtain all components through the licensed hospital pharmacy.
  - E. Report to the board any adverse effects or recalls within 12 hours if compounded in a hospital satellite pharmacy.
  - F. Outpatient Rx Label must say “generic for \_\_\_”
  - G. Written warning required re driving care or “vessel” for certain drugs/classes.
  - H. Beginning 7/1/19, need 2 hours of BoP *provided* Law and Ethics.

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## Pre-Assessment Questions

Re: 2018 Changes

3. T or F – A “Remote Dispensing Site Pharmacy” does not have to have a pharmacist on site.
4. T or F – A pharmacist may now partially fill a C-II Rx for any reason at any.
5. T or F – Every California Licensed pharmacist must enroll for access to CURES.
6. Which of the following is the best statement?
  - A. Pharmacies must only dispense diabetic test strips per a prescription.
  - B. Pharmacies must keep records of acquisition and sale (A&S) of all diabetic test strips.
  - C. Pharmacies must keep Acquisition and Sales records of diabetic test strips dispensed on prescription.

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## Pharmacy Law Changes *FOR ...2018*

1. BOP may now also employ “Legal Counsel” as well as “Inspectors”.
2. Designated Representatives” must also join the BOP’s email alert system.
3. A “Designated Representative-In-Charge” can be “DR-Reverse Distributor” or a Pharmacist.
4. BOP can now license “emergency medical services automated drug delivery systems” (EMSADDs).
5. Now must have BOP license as a Reverse Distributor to handle outdated or non-saleable “Dangerous DEVICES” on behalf of a pharmacy, wholesaler, etc.
6. BOP can now “officially” license hospital satellite pharmacies separately.
7. Does a hospital pharmacy in and off-site facility need a separate license if it DOES NOT do sterile compounding?

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## Pharmacy Law Changes *FOR ...2018*

“(b) A hospital pharmacy also includes ***may include*** a pharmacy that ~~may be located outside of the hospital in another~~ ***is located in any*** physical plant that is regulated under a hospital’s consolidated license issued pursuant to ~~Section 1250.8~~ ***the license of a general acute care hospital as defined in subdivision (a) of Section 1250*** of the Health and Safety Code. As a condition of licensure by the board, the pharmacy in another physical plant shall provide pharmaceutical services only to registered hospital patients who are on the premises of the same physical plant in which the pharmacy is located, except as provided in Article 7.6 (commencing with Section 4128). The pharmacy services provided shall be directly related to the services or treatment plan administered in the physical plant. Nothing in this subdivision shall be construed to restrict or expand the services that a hospital pharmacy may provide.

***“(c) Hospital satellite compounding pharmacy” means an area licensed by the board to perform sterile compounding that is separately licensed by the board pursuant to Section 4127.15 to perform that compounding and is located outside of the hospital in another physical plant that is regulated as a general acute care hospital as defined in subdivision (a) of Section 1250 of the Health and Safety Code.***

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## Pharmacy Law Changes *FOR* ...2018

8. BOP may now also BOP can now license a “Remote Dispensing Site Pharmacy” (RDSP) that is owned and overseen by a **specified** “Supervising Pharmacy” within 150 miles and in Calif.
- The RDSP must be at least 10 miles from a traditional pharmacy.
- The “Supervising Pharmacy” can only oversee one RDSP and must be owned and operated by a pharmacist or a company where a pharmacist has majority beneficial interest.
- The “Supervising Pharmacy” must use a “Telepharmacy” system (as defined) to monitor and perform the professional functions, e.g. DUR, product verification and patient counseling.
- The RDSP can be staffed by only a pharmacist one or more “qualified” Pharmacy Technicians for preparing and dispensing prescriptions . The Tech. may receive and sign for all dangerous drugs if video recorded and such recording is available to the Supervising Pharmacy for 120 days. But received controlled substances must then be stored separately and reviewed and signed for by a pharmacist.
- MANY Other requirements – see B&P Sections 4130 - 4135

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## Pharmacy Law Changes *FOR* ...2018

9. Effective July 1, 2018, pharmacist “may” dispense a “partial fill” of a C-II controlled substance prescription **“if requested by the patient or the prescriber.”** May dispense subsequent partial fills of same Rx up to 30 day after Rx issue day – up to the total quantity prescribed. Must report to CURES only actual amounts dispensed each date. Must record details of each dispensing. May charge separate dispensing fee for each partial fill. *Note: May still partially fill as before, if insufficient stock, under current State and federal rules.*

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## Pharmacy Law Changes *FOR* ...2018

10. Pharmacies that dispense diabetic test devices (strips or meters) ***pursuant to a prescription*** must keep their records of acquisition and sales for 3 years. The BOP can embargo such items if not purchased from an authorized source and the pharmacist can be disciplined for Unprofessional Conduct.
11. A pharmacy may now furnish up to 48 (vs. 24) oral or suppository dosage units for emergency facility supplies per H&S Code 1261.5.
12. A pharmacy or wholesaler may issue dangerous drugs to an Emergency Medical Services Automated Drug Delivery System (EMSADDS) (*think fire department*). Medical Director, licensed paramedic and pharmacist must develop the P&Ps and can transport and restock the devices or remove the products from the EMSADDS to restock supplies containers. Lots of record and audit requirements.
13. BOP can issue a license to a Hospital Satellite Compounding Pharmacy for preparation of products to only treat patients in that "plant".

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## Pharmacy Law Changes *FOR* ...2018

14. Wholesalers must report suspicious order of controlled substances to the BOP – e.g. unusual amounts, deviations from normal type, frequency, etc.
15. Podiatrists and Osteopaths added officially to the list of "prescribers" that cannot own or operate a pharmacy.
16. Two Licensed "Clinics" can now share the same facility space but must keep drug stocks locked and separate and not be "loaned" to each other
17. May now re-take the CPSJE in 45 days.
18. BOP can license "Designated Paramedics".
19. BOP Exec Officer can issue cease and desist orders.
20. Starting October 1<sup>st</sup>, 2018, a person may obtain access to CURES for the purpose of assisting a practitioner or pharmacist. *In Theory*, the CURES can be accessed directly via an HIT system beginning 10/1/2018. (H&S Code 11165.1)
21. For purposes of narcotic replacement, the prescribing or furnishing of controlled substances – EXCEPT for FDA MAT approved drugs, shall be discontinued.

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## Recent CA Pharmacy Regulation Changes

### 1. Re:Continuing Education. Effective July 1, 2017

Reg. 1732.05, 1732.2 & 1732.5

Changed approved agency PFC to CPhA.

Pharmacist on CPSJE committee gets 6 hours CE credit.

Pharmacist or Tech gets 6 hrs for FULL BoP and 2 hrs for BoP Committee attendance.

Three hours for passing exam from Commission on Geriatric Pharmacy.

Beginning 7/1/19, need 2 hours of BoP "**provided**"  
 Law and Ethics.

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## Recent CA Pharmacy Regulation Changes

### 2. Section 1715.65 - Federal C-II Inventory Reconciliation. Effective April 1, 2018

PIC, or Pharmacist Consultant for a "Licensed Clinic", must conduct a physical count of all FEDERAL C-II products on hand, reconcile the count with acquisitions and dispositions, identify in writing for the report possible causes of overages, and report in writing any losses and known causes within 30 days, or a loss by theft, diversion or self-use in 14 days. New PIC to also complete this in 30 days and an outgoing PIC do it – "whenever possible". Keep all such records for 3 years.

### 3. Section 1760 - Disciplinary Guidelines. Effective April 1, 2018

Many changes – reportedly more strict?

### 4. Section 1746.5 Pharmacist Furnishing Travel Medications. Effective June 8, 2017– significant additional detail over statute – SB 493

### 5. Sections 1776 – 1776.6 – Take Back Regulations. Effective June 6, 2017 – Substantially more restrictive and detailed than DEA's corresponding regulations.

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## Recent CA Pharmacy Regulation Changes

### 6. Section 1705.5 Patient-Centered Rx Labels. Effective 7/1/2017

In the 50% of Label dedicated to 4 things, the name of the drug must be trade name or the generic name and the phrase “generic for \_\_\_\_\_” where the brand name is inserted. In pharmacist’s judgment, if brand name no longer used, generic name ok and “may” list the identity of the mfr. OUTSIDE the dedicated space.

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## Recent CA Pharmacy Regulation Changes

### 7. Section 1744 Drug Warnings. Effective April 1, 2017.

Regulation 1744.

Must put *WRITTEN* warning about ability to operate a vehicle or *vessel* or if risk with alcohol, on Rx container. Oral not sufficient.

Regulation a has list of affected drugs/classes – PLUS ANY other drug based upon a pharmacist professional judgment.

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## Recent CA Pharmacy Regulation Changes

8. Sections 1702, 1702.1, 1702.2 & 1702.5. Renewal Requirements: Effective Date January 1, 2018; Applies to Pharmacists, Techs and Designate Reps.

- Reference to “under \$300/\$500” omitted re traffic violations – BUT still must report all traffic violations re alcohol, drugs or controlled substances.
- Must disclose any discipline against any license.
- Technicians must submit fingerprints.

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## Other Recently Enacted Pharmacy Legislation FOR 2018 or Earlier

1. Price transparency – SB 17 – Effective 1/1/18 *plus*
2. Limits on discounts, coupons, etc. to patients – AB 265
3. Cleaning Product Right to Know – SB 258
4. Pro-rated Dispensing fees for partial fills 1/1/19.

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## Recently Enacted *Or Pending* Pharmacy Legislation FOR 2019

### ***BOP Sponsored***

1. AB 1751 – CURES Database and CS Schedules. = ENACTED
  - Requires DOJ to adopt access regulations by 7/1/20. Will allow INTER-state access to CURES under certain conditions.
2. AB 1752 – CURES Database. = Died in Appropriations Cmte.
  - Would have added C-V and require upload in 1 working day, etc.
3. AB 2086 – CURES Database. = ENACTED
  - Allows prescribers a list of their “attributed” patients.
4. AB 2783 – CS Schedules = ENACTED
  - Moves hydrocodone combination products to C-II ***in California***. Note: Still uses “dihydrocodeinone” (old name) when referring to “Oral liquid preparations”
5. AB 2789 – Electronic Prescriptions. = ENACTED
  - Adds B&P Section 688. Requires all RXs by 1/1/22 – ***Lots*** of exceptions; Dispensing pharmacist not responsible for an invalid exception.

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## Recently Enacted *Or Pending* Pharmacy Legislation FOR 2019

6. SB 1447 ADDS (etc.) Licensing – To Governor
  - Sponsored by the BoP. COMPLICATED – Repeals and redefines ADDSs, APDSs, and AUDs. ***Read carefully if “Enacted”.***

***Of Interest to the BOP or Impacting the Practice of Pharmacy***
7. AB 1953 SNF Disclosure of Business Interest = To Governor
8. AB 2256 Law Enforcement Access to Naloxone = ENACTED
9. AB 2576 Clinic Emergency Access to Rx Drugs = ENACTED
10. AB 2859 Safe Storage of CSs. = ENACTED
  - Requires non-pharmacist owners of more than 4 pharmacies to display “safe storage products”, as defined.

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## Recently Enacted *Or Pending* Pharmacy Legislation FOR 2019

10.5 AB 2760 – ENACTED - Prescriber must (1) Offer a prescription opioid antagonist if: (A) Rx is 90 MMEs per day. (B) with a benzodiazepine. (C) Patient has increased risk for, or history of overdose, or substance use disorder, or returning to a high dose of opioid medication and no longer tolerant.

(2) Provide education to such patients on overdose prevention and the use of antagonists.

(3) Provide same to one or more persons designated by the patient, or, for a patient who is a minor, to the minor's parent or guardian.

A prescriber who fails the above shall be referred to the appropriate licensing board *solely* for the imposition of administrative sanctions deemed appropriate by that board. This section does *not* create a private right of action against a prescriber, BUT it does *not* limit a prescriber's liability for negligent failure to diagnose or treat a patient.

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## Recently Enacted *Or Pending* Pharmacy Legislation FOR 2019

11. AB 2863 Prescription Pricing = ENACTED - This law now:

- Limits the amount a health care service plan or health insurer may require an enrollee or insured to pay at the point of sale for a covered prescription to the lesser of the applicable cost-sharing amount or the **retail price**.
- Prohibits a health care service plan or health insurer from requiring a pharmacy to charge or collect a cost-sharing amount from an enrollee or insured that exceeds the total retail price for the prescription drug
- Provides the payment rendered by an enrollee/ insured constitutes the applicable cost sharing, as specified.
- Requires a pharmacy to **inform** a customer whether the retail price for a covered prescription is lower than the applicable cost-sharing amount, unless the pharmacy automatically charges the customer the lower price.
- If the customer pays the retail price, **requires** the pharmacy to submit the claim to the health care service plan or health insurer in the same manner as if the customer had purchased the prescription drug by paying the cost-sharing amount when submitted by the network pharmacy.
- Makes a contract provision that is inconsistent with these provisions **void and unenforceable**.

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### Recently Enacted *Or Pending* Pharmacy Legislation FOR 2019

- 12 SB 1109 Schedule II Opioids Education and Warnings = To Governor
- Would require physicians, optometrists and dentists to have C-II CE. Requires NPs and APs to have specified education. Requires discussion with parents, etc. before treating a minor with a opioid.
  - Requires pharmacists to display on container “Caution: Opioid. Risk of overdose and addiction.”
- 13 SB 1442 Pharmacy Staffing – ENACTED
- Requires a “Community Pharmacy” have another employee in the pharmacy working anytime a pharmacist is on duty. Does not not apply to hospitals and certain other facilities.
- 14 AB 1753 Authorized CS Blank Printer = ENACTED
- DOJ may reduce the number to three. Add as serial number to each blank. Requires printer to submit order info “the next working day”.

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### Recently Enacted *Or Pending* Pharmacy Legislation FOR 2019

- 15.AB 1998 -**Would have** required a Safe Prescribing policy for opioids. = **Died in Committee.**
- 16.AB 2037 -Pharmacy may operate ADDS in 340B Clinic. = ENACTED as an “Urgency Statute”. i.e. effective 9/21/18
- 17.AB 2486 –**Would Have** required Wholesaler and Manufacturer Reporting of Opioid Sales. = **DIED**
- 18.SB 212 – Solid Waste: Drugs and Sharps = To Governor – ENACTED
- » **Will** establish a State-wide stewardship program for disposal of drugs and sharps. “CalRecycle” regulations by 1/1/21.

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### Recently Enacted *Or Pending* Pharmacy Legislation FOR 2019

19. SB 1021 – Drug Coverage. = ENACTED  
 Requires “Retail Price”(?) as maximum copay and ALSO to apply to the maximum Out-Of-Pocket limits.  
 Extends existing coverage requirements for current antiretroviral drug treatments until 1/1/2023.  
 Extends existing “cost sharing” tier limits (\$250/\$500/\$600) to 1/1/2024.  
 BUT these provisions do NOT apply to contracts with DHCS.
20. SB1254 – Hospital *ACCURATE* Med. Lists for High Risk Patients = ENACTED.  
 Places responsibility on a pharmacist to do or oversee the list creation for each applicable patient. Hospital to define own “high-risk” patients. Applies to more than 100 beds.

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### Recently Enacted *Or Pending* Pharmacy Regulations FOR 2018 and/or 2019

1. Regulation 1715.65 Inventory Reconciliation Reports for CSs
  - » Effective April 1, 2018.
  - » “Periodic” physical inventory for ***all*** Controlled Substances.
  - » Requires a physical inventory (count not estimate) and report for FEDERAL C-IIs every “three months”. ***Reconciliation*** includes of all C-II acquisitions and dispositions documents and a comparison with the physical count “on hand” in pharmacy and satellite(s).
  - » Requires a “report” of findings to be on file and signed and dated by the PIC. Report of losses or overages must be followed by a written plan to address. Reports AND documents kept RR for 3 years.
  - » Reports of all “confirmed” losses to the BoP in 30 days and “theft, diversion or self-use” in 14 days.
  - » Report must include verification of only authorized access.
2. Regulation 1702, et. Seq. – Pharmacist, Tech., etc. Renewal Requirements.
  - » Requires reporting of conviction by any state or country.
  - » Does NOT require reporting of traffic violations not involving “dangerous drugs” or alcohol.

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### What About “Pharmacist Corresponding Responsibility” (CRR)?

- Pharmacist duties include preventing opioid abuse. In 2013, the BoP revoked both a pharmacy and pharmacist’s licenses who failed CRR requirements. Four patients died as a result of the pharmacist’s actions.
- The case officially identified “red flags” a pharmacist is *legally obligated* to watch for (*AND RESOLVE*) before filling each CS prescription. These “red flags” include:
  - (1) Irregularities on the face of the prescription itself.
  - (2) Nervous patient demeanor.
  - (3) The age or presentation of patient (e.g., youthful patients seeking chronic pain medications).
  - (4) Multiple patients all with the same address.
  - (5) Multiple prescriptions for the same patient for duplicate therapy.
  - (6) Requests for early refills of prescriptions.

### What About “Pharmacist Corresponding Responsibility” (CRR)?

#### “Red Flags” (continued)

- (7) Prescriptions written for an unusually large quantity of drugs.
- (8) Prescriptions written for duplicative drug therapy.
- (9) Initial prescriptions written for strong opiates.
- (10) Long distances traveled from the patient’s home to the prescriber’s office or to the pharmacy.
- (11) Irregularities in the prescriber’s qualifications in relation to the type of medications prescribed.
- (12) Prescriptions that are written outside of the prescriber’s medical specialty.
- (13) Prescriptions for medications with no logical connection to an illness or condition.

