QUICK UPDATE EXPLANATION: DECEMBER 2015

This update is quite lengthy – the Legislature and the Board (and federal agencies and the courts) have been busy making changes affecting pharmacy the last few years. This explanation is intended as a "statement of contents" pointing to only the *most important* categories of update for most pharmacies and pharmacists, focusing on finalized government initiatives – allowing for a "quick look" until you have time for the rest.

Preface

Licensees can now contact the Pharmacy Board via email, fax, or telephone with questions pertaining to pharmacy law and regulations.

Chapter II – Drug Classifications

25-26 – *Biologics* – The FDA has approved the first generic biologic (or biosimilar), Zarxio, and has published its views on how these products should be named. There has been considerable controversy about the naming issue.

As of 2016 there is a substitution law for biosimilars; see the update at pp. 188-189 for an explanation.

30 – *The Case of "Medical Marijuana"* – California has a suite of new laws to regulate the medical marijuana industry; none appears to have a direct impact on the practice of pharmacy.

Chapter III – Licensing Pharmacists and Other Individuals

The Board, beginning in July 2016, is required to expedite the licensure process for applicants who have been honorably discharged from the Armed Forces.

The Board may require applicants to submit to psychological examination if it appears they may be unable to practice pharmacy safely.

43 – *The Internship* – Internship hours must now include experience both in community and institutional pharmacy practice settings. For 2016 and later graduates of ACPE-accredited pharmacy schools recognized by the Board there will be automatic recognition that they have met the pharmacy practice experience requirements.

Intern hours earned in another state may be certified by that state's licensing agency.

Intern pharmacists may now play an expanded role in the health facility pharmacy.

46 – *Character Requirements* – Licensure may not be denied solely on the basis of criminal convictions that have been dismissed under certain Penal Code sections. The Board may issue a "letter of admonishment" to any applicant for licensure.

48 – *Recognition of Out-of-State Licensure (Reciprocity)* – There must be an expedited licensure process for spouses and domestic partners of members of the military assigned to active duty in California.

48 – *Licensure Fees* – Fees and CE requirements must be waived for licensees called to active duty in the US military or California National Guard.

All Board fees have been raised to their statutory maximums.

52 – *The Pharmacy Technician/Functions* – Pharmacy technicians may now play an expanded role in a licensed health care facility.

Chapter IV – Licensing Pharmacies

72 – *The Pharmacist-in-Charge* – A new self-assessment must also be prepared within 30 days of a change in the licensed location of a pharmacy.

74-77 – *The Hospital Pharmacy* **–** The Board now recognizes and licenses a "centralized hospital packaging pharmacy."

78 – *Specialty Pharmacies* – The Board now recognizes and licenses a "correctional pharmacy."

79 – *Compounding Injectable Sterile Drug Products* – see p. 145, below. There have been significant changes in both federal and state law that impact compounding.

Chapter V – Other Pharmacy Board Licensees

96 – *Wholesalers* – Federal law supersedes state law on tracking-and-tracing. Pharmacies are required to notify FDA and their trading partners immediately of any products identified as, or suspected to be, illegitimate.

97 – *Hypodermic Dealers* – The hypodermic law has been extended to January 1, 2021; there is no longer a quantity limitation.

101, n. 28 – *Clinics* – Surgical clinics no longer must be licensed by the Board, but they cannot buy drugs at wholesale for communal stock unless they are licensed.

Medical assistants in licensed clinics now have expanded authority.

Chapter VI – Scope of Practice for Pharmacists

105-06 – *The Changing Role of the Pharmacist* – New law still being implemented has created expanded authority for all pharmacists and the new "advanced practice pharmacist," for whom there is even broader authority. It is important to read the requirements for furnishing self-administered hormonal contraceptives, nicotine replacement products, and prescription medications recommended for people traveling outside of the United States, and to order and interpret tests to monitor and manage the efficacy and toxicity of drug therapies, and to independently initiate and administer routine vaccinations. The update includes references to the relevant regulations.
You need to be recognized by the Board as an "advanced practice pharmacist," and once you are you may practice within or outside of a licensed pharmacy. The update describes the requirements.

Pharmacies may now dispense epinephrine auto-injectors more broadly.

108-10 – *Emergency Contraception* – The EC protocol has changed modestly.

Pharmacists may now furnish naloxone hydrochloride (in a manner parallel to the furnishing of EC); the update describes the requirements.

112-13 – *Skin Puncture and Other Patient Assessment Procedures* – Pharmacists now have expanded authority with respect to lab tests.

Chapter VII – Ordering, Receipt, Maintenance and Transfer of Drugs and Devices

128-29 – *Loss and Theft* – At the top of p. 129, note that the pharmacy must report any of the listed events *within 14 days*, not 30 days.

134 – *Counterfeit Drugs* – Pharmacies and others that have reason to believe that a dangerous drug or dangerous device is counterfeit or the subject of a fraudulent transaction must notify the Board within 72 hours.

134-137 – *Return and Destruction of Drugs* – There has been a lot of activity with respect to drug takebacks, including some city and county requirements. DEA has adopted a rule on secure disposal of controlled substances by registrants and ultimate users. It is now legal for those legally entitled to dispose of a deceased person's property to possess controlled substances in order to dispose of them.

138 – *Import and Export* – It remains illegal to import pharmaceuticals from overseas.

Chapter VIII – Preparation of Drugs by a Pharmacy

145 – *Pharmacy Compounding* – There are significant changes in federal law on compounding, including a licensure category for compounding pharmacies, called "outsourcing facilities," whose business model looks more like a manufacturer than a traditional pharmacy.

California continues to require any pharmacy compounding sterile products for California residents or practitioners to have a California license, even if it is registered with FDA as an outsourcing facility. The Board amended its compounding regulations in 2013 but continues to consider additional changes.

Chapter IX – The Prescription Process: From Receipt to Labeling

164-65 – *Nurses* – Nurses have some expanded authority with respect to drug dispensing.

181-82 – *Electronic Monitoring (CURES)* – Reporting to the CURES system remains mandatory. As of July 1, 2016, all pharmacists must be registered to access CURES system.

182-83 – *Receipt of the Prescription* – The requirement that oral or electronically-transmitted controlled substance prescriptions must be reduced to writing can be avoided if the pharmacy has received Board and DOJ approval for electronic entry of prescription data from outside. The address and DEA number of the prescriber must be on the prescription itself.

The Board has clarified a prior publication on electronically-transmitted prescriptions (*The Script*, Fall 2015, p. 21, www.pharmacy.ca.gov/publications/15_fall_script.pdf).

187 – *Partial filling* **–** The Board regulation on partial filling of Schedule II prescriptions has been modified to conform to an earlier DEA change, allowing the pharmacist to record the date and amount of each partial fill *either* in a readily retrievable form *or* on the original prescription.

188-89 – *Filling the Order/Substitution* – Pharmacists may dispense refills, except of controlled substances or psychotropics, in up to a 90-day supply pursuant to a prescription specifying a smaller initial quantity and providing for refills; see details in the update.

As of 2016 a pharmacist may substitute an interchangeable biologic, but only if the prescriber does not prohibit substitution. Notice to the prescriber is required for the initial substitution, but can be satisfied via entry into an electronic medical records system. As with generics, the cost to the patient must be the same or less than the cost of the prescribed product, and the patient must be notified of the substitution.

191 – *The Prescription Label* – The condition or purpose for which the drug is prescribed must be included if it is indicated on the prescription.

Upon reevaluating its patient-centered label requirements, the Board made two modifications, one limiting the items that can be clustered in one required label area that comprises 50 percent of the label and the other increasing the typeface required for those items. The Board has also proposed requiring that the drug name, if a recently-approved generic, contain the statement "generic for ___" and the brand name.

A new law effective in 2016 requires pharmacists to use their professional judgment to provide patients with understandable directions for use, including translations into another language (where the Board has made such translations available). Check the update for a full explanation.

Chapter X – The Prescription Process: Dispensing and Beyond

197-201 – *Patient Consultation* – The Board and several California county district attorneys have brought lawsuits, leading to significant settlements, for failure-to-consult and unfair business practices.

198 – A statutory change (and regulations now under consideration) requires *written* warning labels, not just oral *or* written notice, concerning the risk of impairment of a person's ability to operate a vehicle or (in a new addition) a vessel.

200 – *Suppose the patient … does not understand English?* – In addition to its general "Notice to Consumers," every pharmacy must post a notice (or communicate in alternative ways) that interpreter services are available at no cost for at least 12 designated languages.

204-06 – *Refills* – see 188-89 – *Filling the Order/Substitution*, above. Some refills may be for a longer time period/more medication than the original prescription.

214-15 – *Prescription Price Information* – Pharmacies may use a video or other formats for display of the information in the notice to consumers poster. That poster reflects recent patient-centered labeling changes and availability of translation service.

Chapter XI – Record-Keeping

222 – *The Inventory* – The Board has proposed a regulation to require pharmacies and clinics to perform a physical count inventory at least every three months of all Schedule II controlled substances and at least one other identified by the Board based on drug loss reports.

Chapter XII – Practice Pitfalls

235-236 – *Failure to Supervise* – A recent court decision underscored the responsibility of the pharmacist-in-charge for the legal operations of the pharmacy; the case involved an employee's theft of a million dollars' worth of narcotics (*Sternberg v. California State Board of Pharmacy*, ___ Cal. App. ___ (2nd Dist. 2015), http://bit.ly/1itkZcp).

238 – *Improper Filling of Controlled Substance Prescriptions*
245 – *Meeting Patients' Needs for Controlled Substances: Pain Management*
The update contains a lengthy description of actions taken by various players to deal with the ongoing problem of opioid abuse. The Board adopted a "precedential decision" that gives guidance on the pharmacist's corresponding responsibility with respect to these drugs and has proposed enhanced controlled substance inventory requirements. DEA has rescheduled hydrocodone combination drugs like Vicodin to Schedule II from Schedule III. California pharmacists may now furnish naloxone hydrochloride without a prescription, in accordance with standardized procedures.

Chapter XIV – Other Law Relevant To Pharmacy

282 – California law now explicitly prohibits disclosures to the insurance policyholder about other insured individuals under the policy without their consent or knowledge.

Chapter XV – Ethics and Law

The End of Life Option Act will be effective from January 1, 2016, to January 1, 2026. It enables Californians with a diagnosed terminal illness, who are physically and mentally capable of making and implementing their decision, to choose to end their lives through the ingestion of a fatal dose of drugs. The law provides for pharmacist as well as physician dispensing of the necessary drugs; see the update for more details.

The Board has adopted a policy statement recommending the elimination of tobacco and e-cigarette sales from California pharmacies.

297 – *Conscience Clause* – The law prohibiting the obstruction of patient access to legally-prescribed drugs, while affording the right to refuse to dispense on grounds of conscience, now applies to self-administered hormonal contraceptives as well as EC.

Appendix A – Study Guide for the CPJE

The Board has released a new content outline for the CPJE:
www.pharmacy.ca.gov/meetings/agendas/2015/15_jun_bd_content_outline.pdf.