

## CUMULATIVE UPDATE OCTOBER 2016

(This update incorporates information from all updates since publication of the 7th edition.)

### Preface

#### ii – Resources

California statutes and bills under consideration in the California Legislature: New website is at <http://leginfo.legislature.ca.gov/>

California courts (including recent appellate decisions): New website is at [www.courts.ca.gov/opinions.htm](http://www.courts.ca.gov/opinions.htm)

Links to all publications of the federal government, including the Code of Federal Regulations and the Federal Register: [www.gpo.gov/fdsys/search/home.action](http://www.gpo.gov/fdsys/search/home.action)

Federal and state judicial decisions: comprehensive information about how to access them is at [www.loc.gov/law/help/judicial-decisions.php](http://www.loc.gov/law/help/judicial-decisions.php)

General pharmacy news: the DRUG TOPICS magazine back-issue archive is at <http://drugtopics.modernmedicine.com>

Pharmacy Board licensees can now contact the Board via email, fax, or telephone with questions pertaining to pharmacy law and regulations. On Tuesday and Thursday from 8:30 a.m. to 4:30 p.m. a Board inspector will be available to answer telephone inquiries. Board staff cannot provide legal advice, but will attempt to assist by identifying any relevant statutory or regulatory sections. By email, write to [ask.inspector@dca.ca.gov](mailto:ask.inspector@dca.ca.gov) (include your name, organization, contact phone number, and best time to contact you); by fax, (916) 574-8618; or by phone: (916) 574-7900.

#### iii – About the Authors

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### Chapter I – Law and the Pharmacist

10 – FDA proposed a rule in 2013 that would create parity between brand-name and generic drug manufacturers by requiring the latter also to propose and make, in advance of their approval, label changes to add necessary warnings, under the “changes-being-effected” authority. It reopened the comment period through April 2015. If adopted, the rule would in essence reverse the result in *Pliva v. Mensing* and enable lawsuits by harmed patients whether the injurious drug was the name brand or a generic equivalent (*Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products*, [www.regulations.gov/#!docketBrowser;rpp=25;po=0;D=FDA-2013-N-0500](http://www.regulations.gov/#!docketBrowser;rpp=25;po=0;D=FDA-2013-N-0500)). FDA announced in May 2016 that its decision on the proposed rule would not be made until 2017. For a discussion of potential impact on pharmacy, see Jill Sederstrom, *Proposed new FDA rule might allow altered labeling of generic meds*, DRUG TOPICS, Aug. 2014, <http://drugtopics.modernmedicine.com/drug-topics/content/tags/amcp/proposed-new-fda-rule-might-allow-altered-labeling-generic-meds>.

An attempt to work around the *Pliva* result failed in *Mutual Pharmaceutical Co. v. Bartlett*, \_\_\_ U.S. \_\_\_, 133 S.Ct. 2466 (2013). In a 5-4 decision, the Supreme Court held the plaintiff’s suit preempted, as in *Pliva*, even though it was framed as a design-defect rather than a failure-to-warn claim, and the plaintiff argued that since the manufacturer could not change the generic drug’s composition it should have stopped selling it to protect consumers.

## Chapter II – Drug Classifications

18 – *New Drugs* – FDA has proposed prohibiting drug manufacturers from distributing professional labeling information in paper form, in order to "ensure that the most current prescribing information for prescription drugs will be available and readily accessible to health care professionals at the time of clinical decision-making and dispensing." *Electronic Distribution of Prescribing Information for Human Prescription Drugs, Including Biological Products* (79 Fed. Reg. 75506, Dec. 18, 2014; <http://1.usa.gov/1DGRoTh>). Various legislators and patient groups have expressed concern ([www.raps.org/Regulatory-Focus/News/2015/03/25/21809/FDAs-Electronic-Drug-Labeling-Proposal-Comes-Under-Fire](http://www.raps.org/Regulatory-Focus/News/2015/03/25/21809/FDAs-Electronic-Drug-Labeling-Proposal-Comes-Under-Fire)).

18 n. 4 – FDA has revised its guidance on unapproved drugs to clarify that “any unapproved new drugs introduced onto the market after September 19, 2011, will be subject to immediate enforcement action, without prior notice and without regard to the enforcement priorities set out” in the guidance ([www.fda.gov/drugs/guidancecomplianceregulatoryinformation/enforcementactivitiesbyfda/selectedenforcementactionsonunapproveddrugs/ucm270834.htm](http://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/enforcementactivitiesbyfda/selectedenforcementactionsonunapproveddrugs/ucm270834.htm)).

19 – A controversial bill called the “21st Century Cures Act” (H.R. 6), currently before the U.S. Congress, would make significant changes in the drug approval process (see [www.nejm.org/doi/full/10.1056/NEJMp1506964](http://www.nejm.org/doi/full/10.1056/NEJMp1506964)).

21 – A “right-to-try” law was passed by the Legislature in 2016, effective in 2017. It allows manufacturers of investigational drugs, biologics, and devices to make their unapproved products available to eligible patients with an immediately life-threatening disease or condition, allows health plans to provide coverage, and prohibits disciplinary action by the Medical and Osteopathic Medical Boards against licensees involved in prescribing these products. Pharmacies are not affected by the law (Stats. 2016, ch. 684 (AB 1668), adding H&SC sections 111548-111548.5).

22-23 – *Generics* – In a divided decision, the United States Supreme Court allowed the FTC’s antitrust challenge to a “pay-for-delay” settlement of a pharmaceutical patent dispute to proceed (*FTC v. Actavis*, 570 U.S. 756, 133 S.Ct. 2223 (2013)). (For an explanation of the controversy and the decision, go to [www.fdalawblog.com/2013/06/articles/ip-and-technology-transactions/ftc-v-actavis-what-does-it-mean-for-reverse-payment-settlements/](http://www.fdalawblog.com/2013/06/articles/ip-and-technology-transactions/ftc-v-actavis-what-does-it-mean-for-reverse-payment-settlements/).) In its first action on this subject following the Supreme Court decision, the FTC in September 2014 charged Abbott Labs, AbbVie, and Teva with antitrust violations with respect to “reverse payment” (or pay-for-delay) deals that postpone the availability of AndroGel. There are also more than a dozen lawsuits by private plaintiffs challenging such deals, some of which do not involve cash payments but other benefits, such as the name brand company agreeing not to market an “authorized generic.” A discussion of the impact of the *Actavis* decision may be found here: [www.fdalawblog.net/fda\\_law\\_blog\\_hyman\\_phelps/2014/12/ftc-issues-first-post-actavis-staff-report-on-drug-patent-settlement-agreements-no-meaningful-conclu.html](http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2014/12/ftc-issues-first-post-actavis-staff-report-on-drug-patent-settlement-agreements-no-meaningful-conclu.html).

24-25 – *Over-the-Counter Drugs* – FDA was reported in mid-2012 to be considering allowing some categories of prescription medications to be distributed OTC if certain conditions are met, but no proposal to that effect has yet been presented (Jill Sederstrom, *Revising the non-Rx drug category*, DRUG TOPICS, May 15, 2012, <http://drugtopics.modernmedicine.com/drug-topics/news/modernmedicine/modern-medicine-news/revising-nonrx-drug-category?page=full>).

25-26 – *Biologics* – The FDA approved the first generic biologic (or biosimilar), Zarxio, in March 2015 ([www.fda.gov/newsevents/newsroom/pressannouncements/ucm436648.htm](http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm436648.htm)). On August 27, 2015, FDA published its views on how these products should be named. Small-molecule generic drugs share a generic name with the brand originator, as the products are required to be chemically identical. In contrast, biosimilars may or may not be interchangeable, and their dissimilarities could result in divergent risk profiles. There has been considerable controversy about the naming issue; this blogpost and the

materials to which it links elucidate the issues:

[www.fdalawblog.net/fda\\_law\\_blog\\_hyman\\_phelps/2015/10/using-bad-names-the-ftc-says-that-fdas-naming-proposal-for-biologics-will-impede-competition-from-bi.html](http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2015/10/using-bad-names-the-ftc-says-that-fdas-naming-proposal-for-biologics-will-impede-competition-from-bi.html).

Lobbyists have been active in state houses nationwide seeking favorable substitution rules; the two sides (the originator biotech firms and those who will make biosimilars) appear to have reached a compromise on the controversial requirement of notification to the prescriber of substitution (Ed Silverman, *Biotechs and Generic Drug Makers Compromise on Biosimilar Lobbying*, WALL STREET JOURNAL, Oct. 10, 2014, <http://blogs.wsj.com/pharmalot/2014/12/10/biotechs-and-generic-drug-makers-compromise-on-biosimilar-lobbying/>). A substitution law (SB 598) that passed the California Legislature in 2013 was vetoed by the Governor because of the “highly controversial” nature of the notification requirement. A similar bill, SB 671, was signed by the Governor and went into effect in 2016; see pp. 188-189 below for an explanation of its provisions.

30 – *The Case of “Medical Marijuana”* – Notwithstanding the dramatic increase in state laws allowing medical use of marijuana, and four states (Alaska, Colorado, Oregon, and Washington) and the District of Columbia legalizing and regulating all uses of marijuana, under federal controlled substances law marijuana remains in Schedule I, with possession and sale remaining illegal. An attempt to reschedule marijuana from Schedule I failed in 2013, and DEA denied rescheduling petitions as recently as August 12, 2016, even though a conclusion that there is “no currently accepted medical use in treatment in the United States” contradicts the findings of the Institute of Medicine, cited in n. 17 (*Americans for Safe Access v. DEA*, 706 F.3d 438 (2013), *rehearing en banc denied; rehearing denied; cert. den. sub nom. Olsen v. DEA*, \_\_\_ U.S. \_\_\_, 134 S. Ct. 673 (2013)). As a consequence, a pharmacy that gets involved in dispensing marijuana is risking its DEA license (not to mention that there are no legitimate sources of dispensable supply and no label information about dosages or warnings). DEA did announce in August 2016 that it would consider registering additional cultivators of marijuana for research (there is now only one), and joined with USDA and HHS in a statement of principles on industrial hemp (Gilbert JA, Houck LK. *DEA issues a trifecta of significant marijuana and industrial hemp decisions, including rejecting rescheduling for legitimate medical use*, FDA Law Blog 2016 Aug 12; <http://bit.ly/2cRXJmr>).

Five new laws that regulate the medical marijuana industry went into effect in 2016. These laws, among other things, create a Bureau of Medical Marijuana Regulation within the Department of Consumer Affairs to license people and premises in the industry and enforce rules ([www.sacbee.com/news/politics-government/capitol-alert/article35016513.html](http://www.sacbee.com/news/politics-government/capitol-alert/article35016513.html)). None of the laws appears to have a direct impact on the practice of pharmacy. (They are AB 243 (ch. 688), AB 266 (ch. 689), AB 730 (ch. 77), SB 303 (ch. 713), and SB 643 (ch. 719), all stats. 2015.) An additional law effective in 2017 (stats. 2016, ch. 32 (SB 837)) changes the Bureau’s name to the Bureau of Medical *Cannabis* Regulation, and changes all other medical marijuana references to cannabis as well, but also contains no provisions that would appear to impact pharmacy. Connecticut law restricting the distribution of medical marijuana to licensed dispensaries allows only licensed pharmacists to apply for dispensary licenses. Connecticut has switched marijuana to Schedule II (but federal law supersedes); DEA’s reaction with respect to individual licensees will be interesting to follow.

California Proposition 64, on the November 2016 ballot, would provide for marijuana legalization (although under federal law marijuana remains a Schedule I controlled substance). The lengthy initiative measure contains no references to pharmacy ([www.sos.ca.gov/elections/ballot-measures/qualified-ballot-measures/](http://www.sos.ca.gov/elections/ballot-measures/qualified-ballot-measures/)).

30 n. 18 – The most up-to-date information on state laws on medical marijuana is available at <http://norml.org/states>.

37-38 – *Chemicals and Precursors* – The federal Designer Anabolic Steroid Control Act of 2014 (H.R. 4771 (Pub. L. 113-260)) adds more than 20 specific substances to the federal list of “anabolic steroids”

and provides that an unlisted drug or hormonal substance (other than estrogens, progestins, corticosteroids, or dehydroepiandrosterone) that is derived from, or has a chemical structure substantially similar to, an anabolic steroid, shall be considered an anabolic steroid if it was created to produce a substance that promotes muscle growth or otherwise causes a testosterone-like effect or is, or is intended to be, promoted to suggest that its consumption will create a testosterone-like effect. The Act excludes herbs, botanicals, and dietary ingredients as defined by the Food, Drug, and Cosmetic Act. It speeds the classification of new substances as anabolic steroids and contains large fines for illegally importing, exporting, manufacturing, distributing, or dispensing anabolic steroids (<http://bit.ly/13YaWUD>).

### **Chapter III – Licensing Pharmacists and Other Individuals**

A new law effective on July 1, 2017 (stats. 2016, ch. 484 (SB 1193), adding §4013(d)) requires all individual licensees to join the Board's email notification list within 60 days of licensure and to notify the Board of any changes in email address. Email addresses will not be posted on the Board's online license verification system.

A new law relevant to applicants for all individual licenses provides that the Board, after July 1, 2016, shall expedite, and may assist, the initial licensure process for an applicant who has been honorably discharged from active duty service in the Armed Forces (stats. 2014, ch. 657 (SB 1226), adding B&PC §115.4).

A new regulation relevant to applicants for all individual licenses enables the Board or its designee to require the applicant to submit to examination, at the Board's expense, by one or more physicians or psychologists designated by the Board "if it appears that the applicant may be unable to safely practice due to mental illness or physical illness affecting competency." If the Board, after receiving the report of the evaluation, determines that the applicant is unable to practice safely, the application may be denied (§1769(a)).

43 – *The Internship* – Law effective in 2016 requires that the 1,500 hours of pharmacy practice experience prior to taking the licensure examination include experience both in community and institutional pharmacy practice settings (stats. 2015, ch. 147 (SB 590), adding §4209(a)(3)). The same new law provides automatic recognition that the pharmacy practice experience requirements in section 4209(a) and (b) are met by 2016 and later graduates of ACPE-accredited colleges of pharmacy or schools of pharmacy recognized by the Board (§4209(d)).

Intern hours earned in another state may be certified by that state's licensing agency, circumventing the need to obtain Board-approved affidavits for them (§4209(b)). Section 4209(c) has been clarified to provide that an applicant to take the California exam who has been licensed as a pharmacist in any state for at least one year may submit certification of that experience to satisfy the 1,500 intern hours as long as the applicant obtained at least 900 hours of practice experience in a pharmacy as a pharmacist (stats. 2012, ch. 799 (SB 1575)). The Board's proposed rule to require a Self-Query Report has been finalized (§1727.2).

Interns may now play an expanded role in the health facility pharmacy. Under new section 4119.6, an intern pharmacist, under the direct supervision and control of a pharmacist, may stock, replenish, and inspect the emergency pharmaceutical supplies container and the emergency medical system supplies of a licensed health care facility and, under new section 4119.7(c), may inspect the drugs maintained in the health care facility at least once per month under written policies and procedures established by the facility for inspections (stats. 2014, ch. 319 (SB 1039)).

46 – *Character Requirements* – The Board is now prohibited from denying a license based solely on a criminal conviction that has been dismissed under section 1203.4, 1203.4a, or 1203.41 of the Penal Code

(stats. 2014, ch. 737 (AB 2396)). Another new law gives the Board authority to issue a “letter of admonishment” to any applicant for licensure; see below at p. 232.

The Board has proposed changes to renewal requirements in section 1702 that would require a pharmacist, at the time of renewal, to disclose disciplinary action by any government agency. The proposal simultaneously proposes the adoption of the same fingerprint submission requirements as pharmacists for pharmacy technicians and designated representatives, as well as mandating disclosure of disciplinary action by any government agency by pharmacy technicians, designated representatives, nonresident wholesalers, and nonresident pharmacies (proposed §§1702.1, 1702.2, 1702.5). The comment period ended September 26, 2016. The text is at [www.pharmacy.ca.gov/laws\\_regs/1702\\_pt.pdf](http://www.pharmacy.ca.gov/laws_regs/1702_pt.pdf).

48 – *Recognition of Out-of-State Licensure (Reciprocity)* – The law now requires an expedited licensure process for spouses and domestic partners of members of the military assigned to active duty in California (stats. 2012, ch. 399 (AB 1904), adding B&PC §115.5). It does not appear to mandate reciprocity, only expedited handling for the application.

Just as federal employees practicing pharmacy at federal installations within California do not need California licenses, health care practitioners licensed in any state and employed by a tribal health program, as specified in the law, are now recognized as exempt from California licensure requirements when they perform services solely for the program (stats. 2012, ch. 119 (AB 1896) and ch. 799 (SB 1575), adding B&PC §719).

48 – *Licensure Fees* – The Board must waive license fees and continuing education requirements for licensees called to active duty in the US military or California National Guard, and allow them time to meet necessary requirements upon their return from active duty (stats. 2012, ch. 742 (AB 1588), adding B&PC §114.3).

All Board fees have been raised to their statutory maximums (see p. 265, below; §1749). The fee for application and examination as a pharmacist is now \$260 and for issuance of an original pharmacist license and for biennial renewal is \$195.

50-51 – *Continuing Education* – The Board withdrew the proposed changes to section 1732.2 noted in the text. It is now considering comments received after a comment period that ended in August 2016 on a revised version of a re-proposal first offered for comment in 2015. The current revision would expand Board-accredited CE to include credit for service on the Board’s CPJE subcommittee, for passing the Commission for Certification in Geriatric Pharmacy examination, and, for technicians as well as pharmacists, for attending Board and committee meetings (proposed §1732.2). In addition, the proposal would require, for pharmacist license renewal after July 1, 2019, the completion of a Board-provided CE course in Law and Ethics (§1732.5). The text of the proposal is at [www.pharmacy.ca.gov/laws\\_regs/2015\\_1732\\_2\\_mt.pdf](http://www.pharmacy.ca.gov/laws_regs/2015_1732_2_mt.pdf); the initial statement of reasons is at [www.pharmacy.ca.gov/laws\\_regs/2015\\_1732\\_2\\_isr.pdf](http://www.pharmacy.ca.gov/laws_regs/2015_1732_2_isr.pdf).

52 – *The Pharmacy Technician/Functions* – Pharmacy technicians may now play an expanded role in a licensed health care facility. Technicians’ duties may include packaging emergency supplies for use in the health care facility and the hospital’s emergency medical system, sealing emergency containers for use in the health care facility, and performing monthly checks of the drug supplies stored throughout the health care facility (stats. 2014, ch.319 (SB 1039), adding §4115(i)).

The Board adopted modest changes in the technician application, including to conform to a name change of the organization cited in fn. 15, effective January 1, 2016. Starting in 2017, applicants can be certified by any pharmacy technician certification program accredited by the National Commission for Certifying Agencies that is approved by the Board (stats. 2016, ch. 150 (SB 952), amending §4202 (a)(4)).

At its July 2016 meeting, the Board, concerned that people are signing up for pharmacy technician courses who might never be eligible for licensure, voted to amend the technician regulations to require that, prior to admission to training, the program administrator conduct a criminal background check and at least one drug screening and counsel applicants about the risks of not obtaining licensure if they have a criminal history or a positive drug screen. Students must be at least 18 before beginning instruction, and the course must include a final examination that demonstrates understanding and ability to perform or apply the subjects set forth in the regulation. (Proposed amendments to section 1793.6.)

58-59 – *Designated Representatives* – The required paid work experience must be in a licensed pharmacy, or with a drug wholesaler, drug distributor, or drug manufacturer (stats. 2013, ch. 473 (SB 821)). The applicant must be at least 18 years of age (stats. 2014, ch. 316 (SB 1466), amending §4053(b)).

## **Chapter IV – Licensing Pharmacies**

A new law effective in 2017 (stats. 2016, ch. 484 (SB 1193), adding §4013(a)-(c)) requires all facilities to provide an email address for the Board’s email notification list within 60 days of licensure or at time of renewal and to notify the Board within 30 days of any change in email address.

66 – *Pharmacy Benefit Management Companies* – A law effective in 2016 seeks to bring fair standards and transparency to pharmacy reimbursements based upon maximum allowable cost formulae by requiring PBM/pharmacy contracts to identify price data sources used to determine MAC and to provide for an appeal process. PBMs will also be required to make available in an easily-accessible format the most up-to-date MAC lists used for a pharmacy’s patients (stats. 2015, ch. 74 (AB 627)).

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.

The pharmacist-in-charge can be disciplined, even for acts like employee theft of which he or she had no actual knowledge, based upon failure to supervise, failure to maintain records, and failure to maintain adequate security (*Sternberg v. California State Bd. of Pharmacy*, 239 Cal. App. 4th 1159 (2d Dist. 2015)); see discussion at pp. 235-236, below.

74-77 – *The Hospital Pharmacy* – A new category of licensee, the centralized hospital packaging pharmacy, may prepare medications for administration to inpatients of the license-holder general acute care hospital and one or more other general acute care hospitals as long as the hospitals share common ownership and are located within a 75-mile radius of each other (stats. 2012, ch. 687 (AB 377), adding §§4128-4128.7). The pharmacy may prepare unit dose packages for single administration to inpatients and compounded unit dose drugs for parenteral therapy or for administration as long as each dose is barcoded to include at least the information set forth in section 4128.4 and to be readable at the patient’s bedside. This specialty pharmacy (which must obtain a license in addition to the hospital pharmacy license to perform these functions) may prepare a limited quantity of unit dose drugs in advance of patient-specific orders to ensure continuity of care for an identified population of inpatients, based on prescription history (§4128.3). Label requirements are set forth in section 4128.5. The law was later amended to modify requirements that exceeded current technological capabilities of some hospitals and were burdensome for the Board to administer (stats. 2015, ch. 241 (AB486), amending §§ 4128, 4128.4, and 4128.5).

Because section 4107 limited the Board to issuance of one site license at a single premises without a specific exemption, the Board sought and obtained a law change to allow it to issue centralized hospital packaging licenses pursuant to section 4128 (stats. 2013, ch. 473 (SB 821), adding §4107(a)(3)). A hospital pharmacy serving a general acute care facility may now furnish drugs and devices pursuant to preprinted or electronic standing orders, order sets, or protocols established under the facility’s policies

and procedures, as long as the order is dated, timed, and authenticated in the patient's medical record (stats. 2014, ch. 319 (SB 1039), adding §4119.7).

78 – *Specialty Pharmacies* – see pp. 74-77, above.

The Legislature has created a new category of pharmacy, the “correctional pharmacy,” defined as “a pharmacy, licensed by the board, located within a state correctional facility for the purpose of providing pharmaceutical care to inmates of a state correctional facility (stats. 2013, ch. 473 (SB 821), adding §4021.5; amended to include the word “state” by SB 1466 (stats. 2014, ch. 316)).

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

84 – New law effective in 2017 defines and provides for registration of an “automated drug delivery system” (stats. 2016, ch. 484 (SB 1193), adding §4105.5), with requirements for security and inventory monitoring. This law essentially resurrects the provisions of H&SC §1261.6, which had been allowed to expire.

## **Chapter V – Other Pharmacy Board Licensees**

96 – *Wholesalers* – For a decade the Pharmacy Board has worked to implement the described “pedigree” system. Repeated delays to await federal action had been replaced by a firm schedule of implementation, beginning January 1, 2015. Committees met, and rules were proposed. And then the United States Congress adopted the Drug Quality and Security Act (PL 113-54 (113th Cong., 1st Sess.), Nov. 27, 2013). Title I is about compounding; Title II, on Drug Supply Chain Security, adds sections 360eee to 360eee-4 to Title 21 of the U.S. Code, providing federal standards and a federal system for tracking and tracing prescription drugs throughout the pharmaceutical distribution chain.

The federal law supersedes any state law on this subject that is not consistent with it (21 USC §360eee-4(a)). Because California law expressly provided that when federal law addressing pedigree or serialization measures for dangerous drugs became effective state law would become inoperative, the Board published a notice indicating that B&P Code §§4034, 4163, 4163.1, 4163.2, 4163.4, and 4163.5 became inoperative as of November 27, 2013. (Those sections are now formally repealed (Stats. 2014, ch. 492 (SB 600)).)

Primary responsibility for creating a secure drug supply chain has thus shifted to the federal government. A general description of Title II (also called the Drug Supply Chain Security Act) can be found in this presentation: [www.fda.gov/downloads/drugs/developmentapprovalprocess/smallbusinessassistance/ucm388945.pdf](http://www.fda.gov/downloads/drugs/developmentapprovalprocess/smallbusinessassistance/ucm388945.pdf). A presentation for dispensers is here: [www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/UCM453236.pdf](http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/UCM453236.pdf). A July 1, 2015, compliance deadline was extended to November 1, 2015, and then to March 1, 2016. Pharmacists are now required to receive from wholesalers, and to store, transaction information, transaction history, and transaction statements for drug products. A checklist for pharmacies on compliance with these provisions, created by APhA, may be found at [www.pharmacist.com/sites/default/files/files/Track\\_and\\_Trace\\_Checklist\\_UPDATED.pdf](http://www.pharmacist.com/sites/default/files/files/Track_and_Trace_Checklist_UPDATED.pdf).

Pharmacies are also now required to notify FDA and their trading partners immediately of any products identified as, or suspected to be, illegitimate (Ned Milenkovich, *FDA unveils new drug pedigree requirements*, DRUG TOPICS, Aug. 10, 2014, <http://drugtopics.modernmedicine.com/drug-topics/content/tags/dqsa/fda-unveils-new-drug-pedigree-requirements?page=full>). FDA published a proposed Guidance for Industry on implementation of the law, including the requirement (which applies to pharmacies) to identify, notify, and quarantine suspect products. A link to the draft guidance as well as

explanatory information may be found here: [www.fda.gov/drugs/developmentapprovalprocess/smallbusinessassistance/ucm402366.htm](http://www.fda.gov/drugs/developmentapprovalprocess/smallbusinessassistance/ucm402366.htm).

The federal law threw one monkey wrench into California's regulation of wholesalers. As described at the January 2014 Pharmacy Board meeting (Minutes, pp. 35-36), it contains provisions directing FDA to establish national standards for wholesalers and establish specialized regulation of third party logistics providers (3PLs). If a state does not regulate wholesalers and 3PLs, national registration will be required. California has long regulated wholesalers, and in 2008 adopted law that regulated 3PLs as a subcategory of wholesalers. However, the federal law prohibits regulation of 3PLs as wholesalers. A statute effective in 2015 (stats. 2014, ch. 507 (AB 2605)) separates out 3PLs from wholesalers in California law, providing for a separate license category and designation of appropriate supervision ("designated representative-3PL" and "responsible manager"). Amended section 4045 defines the third-party logistics provider as "an entity that provides or coordinates warehousing or other logistics services for a dangerous drug or dangerous device in intrastate or interstate commerce on behalf of a manufacturer, wholesaler, or dispenser \* \* \* but does not take ownership of the dangerous drug or dangerous device, nor have responsibility to direct its sale or disposition." The Board now needs to amend its regulations to ensure that third-party logistics providers adhere to regulations for all other drug distributors, such as to ensure the integrity of drug products, as well as to create a self-assessment for this new category of licensee. New self-assessment forms for wholesalers (as well as hospitals and community pharmacies) were effective on April 20, 2016 (although they are designated as "Rev 10/14," reflecting the time of their proposal). The Board has discussed amending sections 1780-1786 related to third-party logistics providers but has not yet done so.

97 – *Hypodermic Dealers* – Changes in hypodermic law adopted in 2012 and slated to expire at the end of 2014 have been extended to January 1, 2021, with a major change: the limitation to "30 or fewer" hypodermic needles and syringes has been eliminated. Because the law still provides that furnishing of hypodermics is for personal use (for humans or animals), pharmacists will have a continued obligation to consider whether a particular request is appropriate. Pharmacists are also required to counsel consumers on safe disposal and offer disposal options, as well as to provide written information or verbal counseling on how to access drug treatment and testing and treatment for HIV and hepatitis C (stats. 2014, ch. 331 (AB 1743)).

101, n. 28 – *Clinics* – The Legislature has provided a solution to the problem created by the *Capen v. Shewry* decision. Surgical clinics will no longer be required to obtain a license from the Board, although they cannot buy drugs at wholesale for communal stock unless they are licensed. Drug distribution at these clinics remains limited to drugs for administration and for dispensing no more than a 72-hour supply of pain and nausea drugs to patients (stats. 2012, ch. 454 (SB 1095), amending §§4190 and 4195).

Medical assistants in clinics licensed under sections 4180 or 4190 (except those operated by the state) may now hand prepackaged prescription drugs, excluding controlled substances, to patients, as long as they are properly labeled and ordered, bear the patient's name, have been verified as the correct medication and dosage, and if appropriate consultation has been provided (stats. 2014, ch. 333 (AB 1841)).

Section 4190, cited in this section, has been modified to broaden the clinics to which it applies (new §4190(a)) and to eliminate the restriction formerly in section 4190(e) that a separate license is required for each clinic location. Renumbering of other sections makes the specific citations in the text now incorrect (stats. 2012, ch. 454 (SB 1095)).

## Chapter VI – Scope of Practice for Pharmacists

105-06 – *The Changing Role of the Pharmacist* – FDA reportedly has had under consideration for several years a proposal to allow pharmacists to make initial medication recommendations, including their dosage and strength, for cholesterol, high blood pressure, and other common conditions after patients receive a physician diagnosis, with the understanding that the pharmacist could then monitor the medications and make needed changes without physician input. The expectation is that pharmacists would charge professional fees for this service (Nick Smock, *Affordable Care Act opens door to charge professional fees*, DRUG TOPICS, Dec. 1, 2012, <http://drugtopics.modernmedicine.com/drug-topics/news/modernmedicine/modern-medicine-now/affordable-care-act-opens-door-charge-profession?page=full>). Because FDA does not have authority over professional scope of practice, it could recommend but not implement any such proposal: state laws would require changes.

California took a major step toward increased responsibility for pharmacists with the passage in 2013 of SB 493 (stats. 2013, ch. 469), which both creates additional authority for all pharmacists and a new category of pharmacist, the “advanced practice pharmacist,” for whom there is even broader authority. This new authority modifies numerous sections of this chapter of the text. Probably most important for the profession is new section 4050(c), in which the Legislature “declares that pharmacists are health care providers who have the authority to provide health care services.” This recognition of pharmacists as service providers should help to unlock reimbursements to pharmacists by government programs and insurers for providing these services. Legalizing additional roles for pharmacists also aligns California law with federal programs (Department of Defense, Veterans Administration, Indian Health Service) in which pharmacists have played these roles for many years.

The Pharmacy Board has been working to implement the statute since its passage. The materials from six months of meetings of its SB 493 Implementation Committee can be found at [www.pharmacy.ca.gov/about/meetings.shtml#sb493](http://www.pharmacy.ca.gov/about/meetings.shtml#sb493).

The statute allows all pharmacists to furnish self-administered hormonal contraceptives (as well as emergency contraception drug therapy, previously authorized), nicotine replacement products, and prescription medications recommended for people traveling outside of the United States (§4052(a)(10)). It also authorizes pharmacists to order and interpret tests to monitor and manage the efficacy and toxicity of drug therapies, and to independently initiate and administer routine vaccinations.

Each element of this new authority is governed by various requirements. A pharmacist must furnish self-administered hormonal contraceptives in accordance with standardized procedures or protocols developed and approved by the Pharmacy and Medical Boards (in consultation with ACOG, CPhA, and “other appropriate entities”). The protocol must require that the patient use a self-screening tool to identify risk factors, based on criteria developed by the CDC. The pharmacist must refer the patient to a physician or clinic upon furnishing these drugs or determining that they are not recommended for use (§4052.3). The Board has adopted a new regulation, §1746.1, entitled Protocol for Pharmacists Furnishing Self-Administered Hormonal Contraception, effective April 8, 2016. The text is at [www.pharmacy.ca.gov/laws\\_regs/1746\\_1\\_oa.pdf](http://www.pharmacy.ca.gov/laws_regs/1746_1_oa.pdf); the initial and final statements of reasons are at [www.pharmacy.ca.gov/laws\\_regs/1746\\_1\\_srisr.pdf](http://www.pharmacy.ca.gov/laws_regs/1746_1_srisr.pdf) and [www.pharmacy.ca.gov/laws\\_regs/1746\\_1\\_fsr.pdf](http://www.pharmacy.ca.gov/laws_regs/1746_1_fsr.pdf).

The pharmacist’s right to use a self-screening tool to identify patient risk factors for the use of self-administered hormonal contraceptives by a patient, and then after appropriate examination to furnish those drugs, without it being considered the practice of medicine, was confirmed by the addition of B&PC section 2242.2, effective in 2016 (stats. 2015, ch. 387 (SB 464)).

Nicotine replacement products may be furnished only in accordance with standardized procedures and protocols developed and approved by the Pharmacy and Medical Boards, subject to maintenance of records and physician notification, and only by a pharmacist who has received certification in smoking cessation therapy and regularly completes CE on the subject (§4052.9). The Board's regulation, effective January 25, 2016, adopts new section 1746.2. The text of the Protocol for Pharmacists Furnishing Nicotine Replacement Products is at [www.pharmacy.ca.gov/laws\\_regs/1746\\_2\\_oaa.pdf](http://www.pharmacy.ca.gov/laws_regs/1746_2_oaa.pdf) and the initial and final statements of reasons at [www.pharmacy.ca.gov/laws\\_regs/1746\\_2\\_isr.pdf](http://www.pharmacy.ca.gov/laws_regs/1746_2_isr.pdf) and [www.pharmacy.ca.gov/laws\\_regs/1746\\_2\\_fsr.pdf](http://www.pharmacy.ca.gov/laws_regs/1746_2_fsr.pdf).

Initiation and administration of vaccines listed on routine immunization schedules recommended by federal authorities (for persons age three or older) requires the pharmacist to complete an immunization training program endorsed by the CDC or ACPE, be certified in basic life support, and comply with recordkeeping and reporting requirements (including to primary care providers and state immunization registries). This authority also extends to initiation and administration of epinephrine or diphenhydramine by injection for the treatment of a severe allergic reaction (§4052.8). For its implementation the Board has adopted section 1746.4, entitled Pharmacists Initiating and Administering Vaccines, effective August 26, 2016. The text is at [www.pharmacy.ca.gov/laws\\_regs/1746\\_4\\_oa.pdf](http://www.pharmacy.ca.gov/laws_regs/1746_4_oa.pdf); the initial and final statements of reasons are at [www.pharmacy.ca.gov/laws\\_regs/1746\\_4\\_isr.pdf](http://www.pharmacy.ca.gov/laws_regs/1746_4_isr.pdf) and [www.pharmacy.ca.gov/laws\\_regs/1746\\_4\\_fsr.pdf](http://www.pharmacy.ca.gov/laws_regs/1746_4_fsr.pdf).

The Board's current proposal concerning the furnishing of prescription medications recommended for people traveling outside the United States is found at [www.pharmacy.ca.gov/laws\\_regs/1746\\_5\\_smt.pdf](http://www.pharmacy.ca.gov/laws_regs/1746_5_smt.pdf). It provides for furnishing such medications for conditions not requiring a diagnosis (as defined) or for prophylaxis, and mandates a 10-hour training program and notification to the patient's primary care provider, among other requirements. The initial statement of reasons is at [www.pharmacy.ca.gov/laws\\_regs/1746\\_5\\_isr.pdf](http://www.pharmacy.ca.gov/laws_regs/1746_5_isr.pdf); the proposal is currently under review by the Department of Consumer Affairs.

The new category of "advanced practice pharmacist" requires each licensed pharmacist to be recognized as such by the Board. Once receiving that license designation, advanced practice pharmacy may be practiced within or outside of a licensed pharmacy (§4016.5). To be recognized as an advanced practice pharmacist, a pharmacist in good standing must satisfy two of these three additional criteria: certification in a relevant area of practice; completion of a postgraduate residency; and one year of providing clinical services under a collaborative practice agreement or protocol with a physician, advanced practice pharmacist, pharmacist practicing collaborative drug therapy management, or health system. Initial certification is valid for two years; a fee of up to \$300 may be charged for issuance and renewal (§4210). Each renewal cycle an advanced practice pharmacist will be required to complete an additional 10 hours of CE in one or more areas relevant to his or her clinical practice (§4233). The Board approved regulations implementing the advanced practice pharmacist law; the text, with proposed sections 1730, 1730.1, and 1749, is available at [www.pharmacy.ca.gov/laws\\_regs/1730\\_3rd\\_mt.pdf](http://www.pharmacy.ca.gov/laws_regs/1730_3rd_mt.pdf). These regulations are awaiting final approvals by the Department of Consumer Affairs and Office of Administrative Law. The Board regulation, section 1730.2, concerning programs that will certify applicants to be advanced practice pharmacists, was adopted and became effective in August 2016 ([www.pharmacy.ca.gov/laws\\_regs/1730\\_2\\_oa.pdf](http://www.pharmacy.ca.gov/laws_regs/1730_2_oa.pdf)).

Pharmacists recognized with the advanced practice designation may perform patient assessments; order and interpret drug therapy-related tests; refer patients to other health care providers; participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers; and initiate, adjust, or discontinue drug therapy (in accordance with section 4052.2 (a)(4)). Notification, recordkeeping, and coordination requirements are included in the statute (§4052.6). Pharmacists have already been engaging in most of these functions in health care facilities, clinics, and physician offices; the statutes allowing those practices are unchanged, so pharmacists need not have the advanced practice designation to engage in them.

Pharmacies may now dispense epinephrine auto-injectors to prehospital emergency medical care personnel or lay rescuers to render emergency care, as long as there is a written order specifying the number to be dispensed and the recipient is trained and qualified (under H&SC section 1797.197a) to use them, and the auto-injectors are properly labeled as required in the statute (stats. 2013, ch. 725 (SB 669), adding §4119.3). They may also be furnished to a school district, county office of education, or charter school if furnished exclusively for use at a school district site, county office of education, or charter school; a physician provides a written order specifying the quantity of epinephrine auto-injectors to be furnished; and records are maintained for three years (stats. 2014, ch. 321 (SB 1266), adding §4119.2). A law effective in 2017 (stats. 2016, ch. 374 (AB 1386), adding §4119.4) further expands this authority, allowing furnishing to any “authorized entity” as defined in the amended H&S Code §1797.197a. The definition is “any for-profit, nonprofit, or government entity or organization that employs at least one person or utilizes at least one volunteer or agent that has voluntarily completed a training course as described in subdivision (c).” Various labeling and record-keeping provisions apply.

A 2014 law requiring general acute care and acute psychiatric hospitals to adopt policies and procedures regarding the responsibility for ensuring proper methods of repackaging and labeling of bulk cleaning agents, solvents, chemicals, and nondrug hazardous substances used throughout the hospital provides that the hospital need not consult a pharmacist regarding the repackaging and labeling of these substances, except for areas where sterile compounding is performed (stats. 2014, ch. 391 (SB 1039), adding §1250.06).

108-10 – *Emergency Contraception* – Modest changes in the emergency contraception protocol regulation (§1746), developed with the Medical Board of California, were effective in July 2013. Changes to the status of emergency contraception drugs, however, have now eliminated the need for the law and regulations that enabled pharmacists to make these drugs easily available. After a federal trial court ordered FDA to grant a citizen’s petition requesting unrestricted OTC access to Plan B (*Tummino v. Hamburg*, No. 12-CV-763 (EDNY, Apr. 4, 2013)), and a split ruling in an appeal, FDA decided not to continue its appeal and allow Plan B One-Step to be an OTC product. For the history of EC, see Ned Milenkovich, *Emergency contraceptive’s curious path to OTC status*, DRUG TOPICS, Aug. 2013 (<http://drugtopics.modernmedicine.com/drug-topics/content/tags/contraception/emergency-contraceptive-s-curious-path-otc?page=full>).

In a parallel to its approach to emergency contraception, the Legislature has authorized pharmacists to make naloxone hydrochloride more readily available to the public, notwithstanding its prescription status. The law became effective January 1, 2015 (stats. 2014, ch. 326 (AB 1535), adding §4052.01). The furnishing must be in accordance with standardized procedures or protocols developed by the Pharmacy and Medical Boards. In accordance with a provision of the statute, the Board adopted an emergency regulation, section 1746.3, entitled Protocol for Pharmacists Furnishing Naloxone Hydrochloride, which was readopted and set to expire on April 6, 2016. The Board has now adopted a permanent regulation, which was effective on January 27, 2016, the text of which covers the same points as the protocol in the emergency regulation, but in a slightly different order. It also contains additional information, and references the Board’s website for examples of package labeling. The text of section 1746.3 is here: [www.pharmacy.ca.gov/laws\\_regs/1746\\_3\\_mod\\_15day.pdf](http://www.pharmacy.ca.gov/laws_regs/1746_3_mod_15day.pdf); the initial and final statements of reasons are at [www.pharmacy.ca.gov/laws\\_regs/1746\\_3\\_isr.pdf](http://www.pharmacy.ca.gov/laws_regs/1746_3_isr.pdf) and [www.pharmacy.ca.gov/laws\\_regs/1746\\_3\\_fsr.pdf](http://www.pharmacy.ca.gov/laws_regs/1746_3_fsr.pdf).

112-13 – *Skin Puncture and Other Patient Assessment Procedures* – Pharmacists now have expanded authority with respect to lab tests. New Business and Professions Code section 1206.6 (stats. 2012, ch. 874 (SB 1481)) exempts pharmacists at a community pharmacy, under specified circumstances, from compliance with Business and Professions Code section 1206.5, which requires laboratory director supervision for performance of certain types of lab tests. Pharmacists are now able, upon customer request, to perform blood glucose, hemoglobin A1c, and cholesterol tests that are classified as “waived” and approved by FDA for sale to the public in the form of an OTC kit. Requirements for doing so include

registration with the Department of Public Health, obtaining a valid federal Clinical Laboratory Improvement Amendments (CLIA) certificate of waiver (administered through DPH), and complying with all other requirements for waived clinical laboratory tests, as well as assuring the tests are performed only by a pharmacist in the course of performing routine patient assessment procedures. The new law deems the pharmacist-in-charge to be the equivalent of the laboratory director for these purposes.

116 – *Home Health Care* – New law creates the Standards of Service for Providers of Blood Clotting Products for Home Use Act (stats. 2012, ch. 75 (AB 389), adding H&SC §125286.10 *et seq.*). Eligible providers include a variety of types of pharmacy as well as health care service plans that contract with a single medical group in a geographical area to provide this service. A list of requirements is set forth in the law; the Pharmacy Board is mandated to administer and enforce it (H&SC §125286.30).

117 – *Prescribers’ Offices and Clinics* – Recognition that drugs dispensed by physicians are more expensive than the same drugs dispensed by pharmacies has led to concern by PBMs and workers’ compensation insurance managers (Fred Gebhart, *States face physician dispensing costs*, DRUG TOPICS, Mar. 15, 2013, <http://drugtopics.modernmedicine.com/drug-topics/news/drug-topics/associations/states-face-physician-dispensing-costs?page=full>).

## **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.

The loss and theft problem is massive. At its April 23-24, 2014, meeting, the Board’s executive officer stated that 3.06 million units of controlled substances were reported to the Board as lost in the prior calendar year, of which 1.7 million units were from a major manufacturer’s truck theft. The Board’s counsel opined that the numbers are only estimates and likely significantly lower than actual losses.

134 – *Counterfeit Drugs* – Section 4107.5 (effective January 1, 2015) requires any manufacturer, wholesaler, third-party logistics provider, or pharmacy that has reason to believe that a dangerous drug or dangerous device that it has or had in its possession to be counterfeit or the subject of a fraudulent transaction to notify the Board within 72 hours of obtaining that knowledge (stats. 2014, ch. 507 (AB 2605)).

134-137 – *Return and Destruction of Drugs* – In July 2012, the Alameda County Board of Supervisors passed an ordinance requiring drug producers to take responsibility for the disposal of unwanted drugs, giving them until July 2013 to provide their compliance plans (Stephanie Lee, *Makers must pay for drug disposal*, SAN FRANCISCO CHRONICLE, July 25, 2012, p. C-1). The law was challenged in federal court, and upheld by the United States Court of Appeals (*Pharmaceutical Research and Manufacturers of America v. County of Alameda*, 768 F.3d 1037 (9th Cir., Sept. 30, 2014)); a petition for review by the United States Supreme Court was denied on May 26, 2015. The ordinance requires manufacturers to operate and finance a “Product Stewardship Program” providing for the transportation and disposal of any unwanted prescription drugs. Multiple jurisdictions have created safe drug disposal laws, with varying approaches. A San Luis Obispo County program mandates pharmacy participation; San Francisco’s safe drug disposal ordinance, like Alameda’s, directs its mandate to producers of drugs ([www.sfbos.org/ftp/uploadedfiles/bdsupvrs/ordinances15/o0031-15.pdf](http://www.sfbos.org/ftp/uploadedfiles/bdsupvrs/ordinances15/o0031-15.pdf)). The City of Santa Cruz recently adopted a program that requires pharmacies and drug manufacturers to collect and dispose of prescription drugs (with implementation required by November 12, 2016). The Pharmacy Board’s October 2015 approval of a draft statewide plan for drug takeback that calls for voluntary pharmacy participation and preempts local ordinances ([www.californiahealthline.org/insight/2015/local-drug-takeback-programs-could-be-preempted-by-state-regulations](http://www.californiahealthline.org/insight/2015/local-drug-takeback-programs-could-be-preempted-by-state-regulations)) has led to criticism that it is insufficiently protective of public

health (Tim Goncharoff, *California takes a big step back on drug safety*, SACRAMENTO BEE (Nov. 11, 2015), [www.sacbee.com/opinion/op-ed/soapbox/article44158146.html](http://www.sacbee.com/opinion/op-ed/soapbox/article44158146.html)).

DEA has adopted a rule on secure disposal of controlled substances by registrants and ultimate users (DEA, *Disposal of Controlled Substances*, 79 FR 53520 (Sept. 9, 2014)) that implements the Secure and Responsible Drug Disposal Act of 2010, cited on p. 135, and provides a roadmap for expansion of the options for controlled substances collection from ultimate users for disposal through such means as events, mail-back programs, and collection receptacles. While continuing to allow law enforcement to engage in these activities, the regulations also allow authorized manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with an on-site pharmacy, and retail pharmacies to do so; collection receptacles are also allowed at long-term care facilities. The rules take the logical step of legalizing possession for disposal of controlled substances by those legally entitled to dispose of a deceased person's property. They also allow the commingling of controlled and non-controlled substances in take-back programs. The rules took effect on October 9, 2014.

A change in California law effective January 1, 2015, clarifies that for disposal or other purposes it is not unlawful for a person other than the prescription holder to possess a controlled substance at the direction or with express authorization of the prescription holder and if the possessor's intent is to deliver it to the prescription holder or discard it lawfully (Stats. 2014, ch. 540 (AB 2603) adding H&SC §11350(e)-(f)).

In 2016 the Board proposed comprehensive regulations, a new Article 9.1 (sections 1776-1776.6), entitled "Prescription Drug Take-Back Programs," to provide regulatory oversight for these programs. A third comment period, on the third modified text of the regulations (available at [www.pharmacy.ca.gov/laws\\_regs/1776\\_mt3.pdf](http://www.pharmacy.ca.gov/laws_regs/1776_mt3.pdf)) ended on October 14, 2016; Board review of comments will follow.

The Legislature has exempted reverse distributors from some medical waste generation requirements by defining pharmaceutical waste as not including pharmaceuticals sent out of state to a reverse distributor, sent offsite by a reverse distributor for legal treatment and disposal, or sent to a licensed reverse distributor that is a wholesaler and a permitted transfer station (AB 1442 (ch. 689, stats. 2012), adding H&SC §117748).

136 – *Limited Reuse of Returned Drugs* – In 2012, the Legislature made significant changes to the existing program for reuse of drugs previously prescribed to a patient, expanding the types of facilities eligible to donate (including pharmacies with practice limited to such facilities) as well as the entities eligible to operate a repository and distribution program (stats. 2012, ch. 709 (SB 1329), amending H&SC §§150200-150205). Of particular note is that the law provides that a "physician at a participating entity," not just a pharmacist, may "use his or her professional judgment in determining whether donated medication meets the standards" of the law before accepting or dispensing it (H&SC §150204(e)). It also provides that a physician or a pharmacist "shall adhere to standard pharmacy practices, as required by state and federal law, when dispensing all medications" (H&SC §150204(f)). The law provides immunity for harm caused when donating, accepting, or dispensing prescription drugs in compliance with this law (H&SC §150205). Pharmacy Board staff was sufficiently concerned that the amendments could compromise the pharmaceutical supply that the Board requested that the Governor veto the law, but it was signed into law.

Later legislation, effective April 9, 2014 (as "urgency" legislation), defined and provided for licensure by the Board of the "surplus medication collection and distribution intermediary," an entity established to facilitate medication donations or their transfer between participating entities under the unused medication repository and distribution program previously established. The intermediary may not take possession, custody, or control of the drugs or devices, but is allowed to charge fees for the reasonable costs of its services. Complete records of transactions must be kept for three years. A license fee of \$300

annually (from which government and nonprofit entities are exempt) was set. (Stats. 2014, ch. 10 (AB467), adding §§4046 and 4169.5, amending H&SC §§150200-150205, and adding H&SC §150208.)

A minor change was subsequently made to H&SC §150204 to assure that surplus medication distribution is in compliance with requirements set for particular drugs under FDA's risk evaluation and mitigation strategies (REMS) authority (Stats. 2014, ch. 155 (AB 1727)).

A law effective in 2017 (stats. 2016, ch. 316 (AB 1069)) amends H&SC section 150204 (adding (i)(2)) to allow a pharmacy that exists solely to operate a repository and distribution program to repackage a reasonable quantity of donated medicine in anticipation of dispensing it to its patient population. Repackaging policies and procedures are required to allow for identification and recall of medication, and repackaged medication must be labeled with the earliest applicable expiration date.

The Santa Clara County Public Health Department has opened a pharmacy offering free medication to redistribute previously sold, unexpired, and unopened prescription medications (Barbara Feder Ostrov, *New San Jose pharmacy offers free meds*, THE REPORTER, Feb. 13, 2016, [www.thereporter.com/health/20160213/new-san-jose-pharmacy-offers-free-meds](http://www.thereporter.com/health/20160213/new-san-jose-pharmacy-offers-free-meds)).

138 – *Import and Export* – The State of Maine adopted amendments to the Maine Pharmacy Act in 2013 to allow imports from international pharmacies. The law was challenged by pharmacists and pharmacy associations arguing federal preemption and declared unconstitutional by the federal district court on February 23, 2015 (*Ouellette v. Mills*, 2015 U.S. Dist. Lexis 21137 (D. Me.)). The judge found that the federal Food, Drug, and Cosmetic Act “occupies the field of importation of pharmaceuticals from foreign countries” and thus preempts state law. (A bill introduced in the United States Congress in 2015 to allow drug importation has not progressed toward passage.)

A San Diego pharmacist was prosecuted for filling cancer prescriptions with drugs illegally purchased from Canada; he pled guilty and was sentenced to eight months of home confinement, among other penalties, and ordered to repay Medicare a million dollars (Mark Lowery, *Pharmacist must repay Medicaid [sic] \$1 million*, DRUG TOPICS, Mar. 13, 2014, <http://drugtopics.modernmedicine.com/drug-topics/content/tags/alvarado-medical-plaza/pharmacist-must-repay-medicaid-1-million?page=full>). The Pharmacy Board said it was investigating the matter.

## **Chapter VIII – Preparation of Drugs by a Pharmacy**

145 – *Pharmacy Compounding* – A nationwide fungal meningitis outbreak that caused several dozen deaths and many more illnesses, and was traced back to compounding done on a large scale by the New England Compounding Center (NECC), focused intense interest on the regulation of compounding and the “line” between traditional pharmacy compounding and drug manufacturing (see, e.g., Sabrina Tavernise, *F.D.A. and States Discuss Regulation of Drug Compounders*, NEW YORK TIMES, Dec. 19, 2012). California had already increased regulation of sterile injectable compounding after illness and death traced back to sterility failure in pharmacy compounding in northern California (see text, pp. 79-81).

The significant increases in large-scale compounding in recent years surely arose from its profitability (see, e.g., Andrew Pollack, *In the Alchemist's Lab*, NEW YORK TIMES, Aug. 15, 2014, p. B1). But while some called for reining in this business after the NECC fiasco, others urged caution because compounders have been meeting the demand for critical drugs in short supply (Katie Thomas, *Drug Shortages Persist in U.S., Harming Care*, NEW YORK TIMES, Nov. 17, 2012, p. A-1). Federal law now requires that manufacturers report potential drug shortages, but those warnings cannot create supply (Kathryn Foxhall, *Generic drug shortages show no signs of abating; Independent pharmacists, compounders respond in different ways*, DRUG TOPICS, Aug. 10, 2012, [14](http://drugtopics.modernmedicine.com/drug-</a></p></div><div data-bbox=)

[topics/news/modernmedicine/modern-medicine-feature-articles/generic-drug-shortages-show-no-sign?page=full](http://topics/news/modernmedicine/modern-medicine-feature-articles/generic-drug-shortages-show-no-sign?page=full)).

As noted in the text, federal law on compounding has been complex, confusing, and, because of court decisions, not uniform. Title I of the federal Drug Quality and Security Act (PL 113-54 (113th Cong., 1st Sess.), Nov. 27, 2013) addressed this problem, creating a new section 503B of the Food, Drug, and Cosmetic Act (21 USC §353b) on compounding, which stands alongside an amended section 353a (§503A of the Food, Drug, and Cosmetic Act), the compounding law whose provisions were partly found unconstitutional. Amended section 353a now exempts traditional pharmacy compounding from new drug, misbranding, and adulteration provisions applicable to manufacturers, but without the restriction on advertising or promotion. These exemptions, however, apply only to compounding for an identified individual patient based on the receipt of a valid prescription order.

In contrast, new section 353b creates a licensure category for compounding pharmacies whose business model looks more like a manufacturer than a traditional pharmacy. Registration with FDA as an “outsourcing facility” is voluntary, but those who are registered are exempt from federal new drug approval, track-and-trace, and misbranding rules. Outsourcing facilities must comply with current good manufacturing practices and adverse event reporting rules, must provide information about what they are compounding, and are subject to FDA inspections. Compounders that do not choose to register may qualify for exemptions under section 353a; if they do not qualify, they are subject to FDA regulation as conventional manufacturers.

Outsourcing facilities are subject to restrictions relating to their use of certain bulk drug substances and other ingredients; may not compound drugs that have been withdrawn or removed from the market because they were unsafe or not effective or that are essentially a copy of an approved drug; may not compound drugs that present demonstrable difficulties for compounding that are reasonably likely to lead to an adverse effect on their safety or effectiveness; and, if compounding a drug subject to a risk evaluation and mitigation strategy, must utilize controls comparable to those required under the strategy to assure safe use. The compounded drugs may not be sold or transferred (at the wholesale level) by an entity other than the outsourcing facility (21 USC §353b(a)(2)-(8)). Labeling requirements include clear identification of the product as a compounded drug (21 USC §353b(a)(10)).

In February 2015 FDA published five draft guidance documents on compounding and sought comments. The documents are: (1) for entities considering whether to register as outsourcing facilities; (2) on repackaging of certain human drugs by pharmacies and outsourcing facilities; (3) on mixing, diluting, or repackaging biological products outside the scope of an approved biologics license application; (4) on adverse event reporting for outsourcing facilities; and (5) a draft memorandum of understanding between states and FDA on interstate distribution of compounded drugs. Links may be found at [www.fda.gov/newsevents/newsroom/pressannouncements/ucm434270.htm](http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm434270.htm). In October 2015, FDA published additional draft guidance documents concerning the agency’s approach to exercising enforcement discretion over compounding with certain bulk drug substances while it develops and publishes, as required, final lists of those substances that may be used (<http://www.fda.gov/drugs/drugsafety/ucm469252.htm>). For more information on outsourcing and FDA, see <http://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/pharmacycompounding/ucm393571.htm>.

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 intends, unless it is told by FDA it has no authority to do so, to enforce its compounding and regular pharmacy licensing requirements against both in-state and out-of-state facilities that dispense compounded medications to California patients. One potential area of federal-state conflict concerns non-

patient-specific compounding for use by a doctor's office, which is allowed under California law but which FDA deems to be a violation of its traditional pharmacy compounding law (21 USC §353a).

As of 2017 (stats. 2016, ch. 484 (SB 1193), adding §4034), the law includes a definition of outsourcing facility that includes compounders of both sterile and nonsterile drugs, requires that these facilities be registered with FDA, and mandates that their records be open to Board inspection (amending §4081(a)) as well as requiring licensure before they distribute within or to California. Requirements for these facilities are in sections 4129-4129.9. The Board is required to report to the Legislature by January 1, 2018, on its regulation of nonresident outsourcing facilities (§4129.3). There is an exception to the prohibition on granting more than one site license to any premises to allow the Board to issue a license to a pharmacy to compound sterile (broadened from sterile injectable) drugs (stats. 2016, ch. 484 (SB 1193), amending §4107(a)).

New authority granted at the Board's request in 2013 (stats. 2013, ch. 565 (SB294)) expanded the requirement to have a sterile compounding pharmacy license to all pharmacies that compound sterile drug products for injection, administration into the eye, or inhalation (§4127(a)); both resident and nonresident pharmacies are subject to the requirements (§§4127.1-.2). Prior to initial licensure or renewal, these facilities are subject to a Board inspection. These requirements went into effect on July 1, 2014, necessitating significant expenditure of Board resources for implementation. (The Board had estimated that more than 600 sterile compounding pharmacies would require inspection prior to July 1, 2014, and another 150 before the end of 2014.) The law eliminated an exemption to licensure requirements for sterile compounding pharmacies accredited by the Joint Commission or other accrediting agencies. Further expansion will occur in 2017 under a law (stats. 2016, ch. 484 (SB 1193)) which amends numerous code sections to eliminate the word "injectable," thus expanding the scope of regulation. One important addition is new section 4126.9, which requires notification of a recipient pharmacy, prescriber, or patient as well as the Board within 12 hours after a recall notice is issued for a *nonsterile* compounded drug product if serious adverse health consequences or death could occur and the recalled drug was dispensed, or intended for use, in California. This provision is a parallel to the existing section 4127.9, added by stats. 2013, ch. 302 (AB 1045), which imposed the same requirement upon recall of a *sterile* compounded drug product. If a pharmacy is advised that a patient has been harmed by a nonsterile compounded product potentially attributable to the pharmacy it must report the event to the FDA's MedWatch database within 72 hours after receiving that information (stats. 2016, ch. 484 (SB 1193), adding §4126.9(c)).

Another provision in the law passed in 2013 provided that if the home state license of a non-resident pharmacy is revoked or suspended for any reason the California license will immediately be suspended by operation of law. The incentive for the law change was clearly concern for public protection in situations like the NECC disaster, which involved harm in multiple states (stats. 2013, ch. 302 (AB 1045), adding §4303(c)). A parallel provision effective in 2017 applies to all nonresident outsourcing facilities licensed under section 4129.2 (stats. 2016, ch. 484 (SB 1193), adding §4303.1).

The Board had adopted changes to its compounding regulations (§§1735.1-.3, 1751.2) that went into effect on April 1, 2013. To implement the new authority granted in 2013, the Board adopted changes and additions to numerous sections of its regulations; the lengthy text is at [www.pharmacy.ca.gov/laws\\_regs/1735\\_oaa\\_clean.pdf](http://www.pharmacy.ca.gov/laws_regs/1735_oaa_clean.pdf) (50 pages in length). The effective date of the new regulations is January 1, 2017.

## **Chapter IX – The Prescription Process: From Receipt to Labeling**

161 – *Who May Issue a Drug Order?* – See pp. 105-06, above, on the expanded authority of the pharmacist.

163 n. 9 – Requirements for, and terminology surrounding, optometrist use of therapeutic pharmaceutical agents were modified by a bill passed in 2015 (stats. 2015, ch. 443 (AB 1359), amending B&PC §3041.3).

164-65 – *Nurses* – Amendments to Business and Professions Code section 2725.1 and the addition of Business and Professions Code section 2725.2 (stats. 2012, ch. 460 (AB 2348)) authorize registered nurses to dispense specified drugs or devices upon an order issued by a certified nurse-midwife, nurse practitioner, or physician assistant if the nurse is functioning within a specified clinic, and authorize registered nurses to dispense or administer hormonal contraceptives in strict adherence to specified standardized procedures. This expanded authority for RNs should not change anything a pharmacist might encounter on a prescription or order.

168-69 – *Federal Employees* – Like practitioners in federal facilities, employees of tribal health plans need not be licensed in California, just in some state, as clarified in AB 1896 (Stats. 2012, ch. 119). Presumably their prescriptions, when presented outside the tribal health plan, should be treated as those of out-of-state prescribers (see p. 169, n. 15).

172 – *Who May Transmit the Order and in What Form?* – New law effective in 2017 (stats. 2016, ch. 484 (SB 1193)) repeals H&SC §11164.5 (a) and (b) (renumbering the rest). These sections allowed pharmacies and hospitals to receive electronic data transmission and computer entry prescriptions for controlled substances if authorized by federal law and in accordance with DEA regulations, but after a request and specific Board approval. It also prohibited approved pharmacies receiving such transmissions from being required to reduce them to writing or hard copy. A specific approval mechanism for what now is commonplace is no longer deemed necessary.

While e-prescribing of controlled substances had already been legal for four years, because of delays in review and approval of software by DEA-approved auditors many pharmacies and prescribers were found in 2014 to still be using a hybrid of e-prescribing and traditional methods. Management of refill requests is a particular issue. Observers at that time expressed the view that universal use of e-prescribing would not happen soon (Kristin Sankwich and Richard Molitor, *E-Rxs for controlled substances: The system has glitches*, DRUG TOPICS, July 10, 2014, <http://drugtopics.modernmedicine.com/drug-topics/content/tags/e-prescribing/e-rxs-controlled-substances-system-has-glitches?page=full>).

181-82 – *Electronic Monitoring (CURES)* – Reporting to the CURES system remains mandatory. However, the CURES system has been run in recent years by the Department of Justice rather than the now defunct (because of the California budget crisis) Bureau of Narcotic Enforcement. To provide stable funding for CURES and to upgrade the system, the Legislature passed a statute that, beginning April 1, 2014, required assessment of an annual fee of \$6 on various licenses, including those of pharmacists, pharmacies, and physicians; the fee proceeds go into a CURES Fund to support the operation of the system. The law also required, by a deadline extended to July 1, 2016 (stats. 2015, ch. 778 (AB 679)) or thereafter upon receipt of a DEA registration, that all pharmacists be registered to access the CURES system to obtain controlled substance histories of patients. Among the stated legislative goals for an upgraded system are that it be capable of accepting real-time updates; be accessible in real-time, all the time; and that it interconnect with all national PDMPs (stats. 2013, ch. 400 (SB 809)).

NABP's project PMP InterConnect, intended to allow the states' prescription drug monitoring programs to securely exchange information, is fully operational. Thirty states are now participating ([www.nabp.net/programs/pmp-interconnect/nabp-pmp-interconnect](http://www.nabp.net/programs/pmp-interconnect/nabp-pmp-interconnect)), not including California.

A patient complaint led Medical Board investigators to search the CURES database, resulting in a finding of overprescribing of medications and punishment of the physician. The physician complained that the Board had violated his patients' rights to privacy by "fishing" for information about him. The California Court of Appeal concluded that, on balance, "the CURES statute does not amount to an impermissible

invasion of Dr. Lewis's patients' state constitutional right to privacy, as there are sufficient safeguards to prevent unwarranted public disclosure and unauthorized access to CURES data" (*Lewis v. Superior Court*, 226 Cal. App. 4th 933 (2014)); the California Supreme Court granted a petition for review, but has not yet scheduled oral argument.

A law effective in 2017 (stats. 2016, ch. 708 (SB 482)) will require all health care practitioners (except pharmacists and veterinarians) who prescribe, order, administer, or furnish controlled substances to consult the CURES database to review the patient's controlled substance history before prescribing a CS II, III, or IV for the first time, and then every four months thereafter if the substance remains part of the patient's treatment. There are a number of exceptions (for inpatients, for ER use, and for surgical procedures, at least for limited quantities). This requirement will only become operative six months after the state certifies that the database is ready for statewide use and has adequate staff, user support, and education (H&SC §11165.4).

182-83 – *Receipt of the Prescription* – The requirement that oral or electronically-transmitted controlled substance prescriptions must be reduced to writing (H&SC §11164(b)) can be avoided if the pharmacy has received Board and DOJ approval under section 4071.1 for electronic entry of prescription data from outside (H&SC §11164.5(b)).

Although not required by California law, federal law requires (and thus California pharmacies must comply) that the address and DEA number of the prescriber be on the prescription itself (21 CFR 1306.05(a)).

The Board has published a correction clarifying a prior publication on electronically-transmitted prescriptions (*The Script*, Fall 2015, p. 21, [www.pharmacy.ca.gov/publications/15\\_fall\\_script.pdf](http://www.pharmacy.ca.gov/publications/15_fall_script.pdf)).

187 – *Partial filling* – The Board has amended its regulation on partial filling of Schedule II prescriptions to allow the pharmacist to record the date and amount of each partial fill *either* in a readily retrievable form *or* on the original prescription (§1745(d)), in conformity with a change that DEA had made several years earlier.

The Comprehensive Addiction and Recovery Act (CARA) of 2016 (see description below at p. 245) allows for partial filling of Schedule II prescriptions, in an attempt to limit the quantities of these drugs in circulation to those actually likely to be used by the intended patient. Section 702 of CARA amends section 829, 21 US Code, to allow partial fills if not prohibited by state law, if written and filled in accordance with regulations adopted by the US Attorney General and the state, if requested by the patient or practitioner, and the total quantity dispensed overall does not exceed the quantity prescribed. Remaining portions of the partially-filled prescriptions may be filled within 30 days after the date of the prescription. In emergency situations the remainder may be filled, but within 72 hours after the issuance of the prescription. Presumably DEA will propose regulations to implement this new law.

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 (stats. 2012, ch. 455 (SB 1301), adding §4064.5). The total number of dosage units dispensed may not exceed the total authorized by the prescription. The pharmacist must use professional judgment, must notify the prescriber of the increase in quantity, and may not "substitute" the larger quantity if the prescriber prohibits it.

A law effective in 2017 (stats. 2016, ch. 499 (SB 999)) has as its intent to expand California's existing contraceptive coverage policy by requiring all health care plans to cover a 12-month supply of a prescribed FDA-approved contraceptive. The law cites the effectiveness of such a policy in reducing unintended pregnancies. The law amends section 4064.5, cited above, to limit its applicability to FDA-approved self-administered hormonal contraceptives. At a patient's request, a pharmacist is allowed to

dispense up to a 12-month supply of contraceptives pursuant to a valid prescription that specifies an initial quantity followed by periodic refills. A pharmacist furnishing contraceptives under protocol pursuant to section 4052.3 may, at the patient's request, furnish a 12-month supply at one time (§ 4064.5(f)).

Existing law on generic substitution, based on the “same-ness” (§4073(a)) of the drugs, did not cover generic biologics, also called biogenerics or biosimilars, which are now authorized for FDA approval and being approved for marketing. Generic biologics can be approved on the basis of *biosimilarity*. Biologics firms have lobbied intensely for state laws that include barriers to easy substitution; see discussion at pp. 25-26, above.

A statute effective in 2016 enacts new section 4073.5 (Stats. 2015, ch. 545 (SB 671)) and allows the pharmacist to substitute an interchangeable biologic, but only if the prescriber does not prohibit substitution, which may be done by a checkbox on the prescription. Within five days the pharmacist must enter the name of the biological product substituted, and its manufacturer, into an interoperable electronic records system, PBM system, or pharmacy record, which is presumed to give notice to the prescriber. If the pharmacy does not have access to such a system, communication of the substitution must be made by fax, telephone, email or the like, but is not required at the time of a refill with the same product. The prescriber will not be liable for an act or omission by the pharmacist in selecting, preparing, or dispensing a substituted biologic. No substitution is allowed unless the cost to the patient is the same or less than the cost of the prescribed product. Substitution also must be communicated to the patient. The Pharmacy Board is required to link from its website to the current list of FDA-designated interchangeable biologics. Insurers or health care plans may require prior authorization or other utilization controls with respect to coverage for any biologics.

191 – *The Prescription Label* – The condition or purpose for which the drug is prescribed must be included if it is indicated on the prescription (§4076(a)(10)).

In adopting its patient-centered label requirements effective in 2011, the Board included a mandate that it re-evaluate the requirements by December 2013 to ensure optimal conformity with section 4076.5, which required adoption of labeling changes. As a result of that re-evaluation, the Board proposed two amendments. First, the four items that are required to be clustered into one area of the label that comprises at least 50 percent of the label must be the *only* items in that space. Those items are the patient's name, name and strength of the drug, directions for use, and the condition or purpose for which the drug is prescribed, if indicated on the prescription. Second, those items must be printed in at least a 12-point sans serif typeface, rather than a 10-point typeface. The Board noted that its proposal harmonizes with the USP guidelines, finalized in November 2012, for prescription container labeling and with the National Council for Prescription Drug Programs' April 2013 draft, “Universal Medication Schedule White Paper.” These regulatory changes were adopted effective April 1, 2015.

Upon further consideration, the Board has also proposed to require that the “name of the drug” on the label include, if it is a generic, the statement “generic for \_\_\_\_\_” and the brand name. If, in the professional judgment of the pharmacist, the brand name is no longer widely used, the label may list only the generic name of the drug and, outside of the patient centered area, may list the name of the manufacturer. The Board has approved the regulation, which is awaiting approval by the Department of Consumer Affairs. The text is at [www.pharmacy.ca.gov/laws\\_regs/1707\\_5\\_smt.pdf](http://www.pharmacy.ca.gov/laws_regs/1707_5_smt.pdf).

The question whether to mandate bilingual drug labels has been on the Board's agenda for some time. Legislation the Board sponsored in 2015, effective in 2016 (stats. 2015, ch. 784 (AB 1073)), amends section 4076 to require a pharmacist to use professional judgment to provide patients with directions for use that enhance their understanding of those directions, consistent with the prescriber's instructions (§4076(e)). It adds section 4076.6, providing that, upon request, the dispenser “shall provide translated directions for use, which shall be printed on the prescription container, label, or on a supplemental document.” If translated directions for use are on the container or label, English directions for use shall

also be provided. The English directions can be outside the patient-centered area of the label or, if they cannot be put on the container or label, on a supplemental document. The dispenser may use translations made available by the Board under section 1707.5, and is not required to provide such translations other than in the languages for which the Board has made translated directions available. A dispenser may provide his or her own translated directions for use, including in languages beyond those that the Board has made available or beyond the directions that the Board has translated. The dispenser is responsible for the accuracy of the English-language directions for use provided to the patient. This section does not include veterinarians as dispensers.

## **Chapter X – The Prescription Process: Dispensing and Beyond**

197-201 – *Patient Consultation* – While no substitute for patient consultation, manufacturer-provided patient medication information (PMI) can be very useful. FDA began a pilot study in 2011 of a new one-page PMI document featuring boxes for key topics such as “Uses,” “Important Safety Information,” “How to Take,” “Get emergency help if you have,” and “Possible side effects” (Christine Blank, *New PMI design gets med info to patients in one page*, DRUG TOPICS, Oct. 15, 2012).

While any staff member can communicate to patients about the availability of consultation, it is inappropriate to present consultation as an “offer,” which patients can too easily consider as an optional rather than mandatory service. Patients may refuse consultation, but it should be presented as a standard part of receiving a prescription (see *President’s Message*, THE SCRIPT, Mar. 2012, p. 2). The seriousness of this Board reminder is reflected in later announcements that the Board, with several county district attorney offices, had been conducting undercover investigations about compliance. Lawsuits that followed have led to significant settlements of failure-to-consult and unfair business practices charges (Rite-Aid agreed to pay \$498,250; CVS paid more than \$658,000; as recently as August 2015 Walgreens agreed to pay \$502,200 to settle charges that some of its California pharmacists failed to provide required patient consultations). The Board has, however, discussed the struggle pharmacists have in balancing their workload and providing consultations, in both chain and independent pharmacies, and has expressed interest in whether/how the subject is being taught in pharmacy schools.

198 – Section 4074 has been amended to require written warning labels when a pharmacist, exercising his or her professional judgment, determines that a drug may impair a person’s ability to operate a vehicle or (in a new addition to the law) a vessel (stats. 2013, ch. 304 (AB 1136), adding §4074(b)). The previous language, in section 4074(a), which requires *oral or written* notice of the risk of impairment, remains unchanged, but if a pharmacist decides the warning is necessary the warning label is now mandatory. The Board has pending changes to its regulation, section 1744, which lists classes of drugs that cause impairment requiring warning labels; the text is at [www.pharmacy.ca.gov/laws\\_regs/1744\\_mt.pdf](http://www.pharmacy.ca.gov/laws_regs/1744_mt.pdf). The proposal is currently under review by the Department of Consumer Affairs.

200 – *Suppose the patient ... does not understand English*– In addition to its general “Notice to Consumers,” every pharmacy must have conspicuously posted at or adjacent to each counter where drugs are dispensed a notice containing the words, “Point to your language. Interpreter services will be provided to you upon request at no cost.” This text needs to be repeated in at least 12 languages (Arabic, Armenian, Cambodian, Cantonese, Farsi, Hmong, Korean, Mandarin, Russian, Spanish, Tagalog, and Vietnamese) and positioned so it can be effectively used by the consumer to communicate his or her language needs. While there are alternative means to comply with this regulation, section 1707.6(c), the Board has designed a poster for this purpose: [www.pharmacy.ca.gov/publications/point\\_to\\_your\\_language.pdf](http://www.pharmacy.ca.gov/publications/point_to_your_language.pdf).

See discussion of label translations at p. 191, above.

202 – *To Whom May the Prescription be Delivered?* – As noted above (pp. 134-137), a law effective January 1, 2015, clarifies that it is not unlawful for a person to possess a controlled substance for delivery to the prescription holder (Stats. 2014, ch. 540 (AB 2603), adding H&SC §11350(e)-(f)).

204-06 – *Refills* – see 188-89 – *Filling the Order/Substitution*, above. A law change allows some refills to be for a longer time period/more medication than the original prescription.

209 – *Emergency Provision of Drugs/Public Emergencies* – The Board has used section 4062 several times in recent years to enable pharmacies to provide prescription medications under emergency circumstances in response to wildfires. Section 4110(c), concerning temporary permits for mobile pharmacy, has been amended effective in 2017 (stats. 2016, ch. 484 (SB 1193)), although it appears almost identical to the prior provision.

213-214 – *Medicaid/Financial Pressures on Pharmacy* – The pharmacy profession has lost several lawsuits about Medi-Cal reimbursement rates. In June 2014, the California Supreme Court upheld a lower court ruling that allows health care plans to ignore what pharmacies must pay for drugs when setting reimbursement rates, even though pharmacies complained those reimbursements sometimes are lower than drug costs (Bob Egelko, *Pharmacies lose appeal on Medi-Cal drug reimbursement rates*, SF CHRONICLE, June 11, 2014). A year earlier the Ninth U.S. Circuit Court of Appeals in San Francisco ruled against a challenge to Medi-Cal rates, concluding that regulators do not have to consider drug costs. Pharmacies, physicians, and other providers have challenged cuts in reimbursements (including a 10 percent cut during the recent California fiscal crisis), arguing that cuts discourage providers from serving Medi-Cal patients and have even forced some pharmacies out of business (Mark Lowery, *Pharmacies lose Medi-Cal reimbursement appeal*, DRUG TOPICS, June 18, 2014, <http://drugtopics.modernmedicine.com/drug-topics/content/tags/california-supreme-court/pharmacies-lose-medi-cal-reimbursement-appeal?page=full>).

A law passed in September 2016, and made effective immediately, declares pharmacist services to be a benefit under Medi-Cal and authorizes the State Department of Health Services to establish a fee schedule to compensate such services as furnishing travel medications, naloxone hydrochloride, and self-administered hormonal contraception; initiating and administering immunizations; and providing tobacco cessation counseling and furnishing nicotine replacement therapy, all of which are now within the scope of pharmacy practice in California. The Department's actions have to be approved by the federal Medicaid program. (Stats. 2016, ch. 602 (AB 1114), adding Welf. & Inst. Code § 14132.968.)

Long-term care pharmacists fear that goals of a Medicare short-cycle dispensing policy enacted in 2010 – and profits – are endangered by prescription drug plans switching from payment based on a professional fee to payment tied to the number of days' supply dispensed (Christine Blank, *Push continues for short-cycle dispensing provisions*, DRUG TOPICS, Mar. 5, 2014, <http://drugtopics.modernmedicine.com/drug-topics/content/tags/cms/push-continues-short-cycle-dispensing-provisions?page=full>).

CMS modified its rules to expand availability of medical therapy management services in 2015 (*Medicare Program: Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs*, 79 Fed. Reg. 29844 (May 23, 2014)).

Rapid and steep changes in the prices of some generic drugs have left pharmacies in the position of purchasing drugs for a higher price than reimbursement rates (Jason Poquette, *The Honest Apothecary: "What can we do about skyrocketing generic drug prices?"* DRUG TOPICS, Sept. 30, 2015). Mail-order pharmacies that have focused their business on helping manufacturers protect their products from generic substitution are skirmishing, now in the courts, with pharmacy benefit managers that want to keep costs down (Andrew Pollack, *Irmat, a Mail-Order Pharmacy, Sues OptumRx in Latest Drug-Price Skirmish*, NEW YORK TIMES, Nov. 13, 2015).

214-15 – *Prescription Price Information* – The Board has modified its regulations concerning the notice to consumers. It removed the requirement from section 1707.2 (which it renamed “Duty to Consult”) into a new regulation, section 1707.6. This section mandates the posting of the standard poster provided by the Board, but provides for a video alternative as well as for seeking permission for another format or display methodology. The new poster reflects patient-centered labeling changes (the right to obtain a label printed in a larger font) as well as rules concerning translation service availability (noted above, p. 200). The Board has both paper posters available in multiple languages that can be ordered at [www.dca.ca.gov/webapps/pharmacy/pubs\\_request.php](http://www.dca.ca.gov/webapps/pharmacy/pubs_request.php).

215 – *Internet Practice and Transactions/Telemedicine* – In a statute clarifying that practitioners providing electronic, rather than face-to-face, health care services are subject to their professional practice acts, the Legislature changed references to “telemedicine” to the word “telehealth” (stats. 2012, ch. 782 (AB 1733), amending §4001).

The problem of regulating internet pharmacies that are unlicensed, don’t require legitimate prescriptions, and may be filling prescriptions with counterfeit or adulterated drugs continues unabated (see, e.g., Julia Talsma, *Most Canadian online pharmacies are fraudulent*, DRUG TOPICS, Feb. 10, 2014, <http://drugtopics.modernmedicine.com/drug-topics/content/tags/canadian-pharmacies/most-canadian-online-pharmacies-are-fraudulent?page=full>). The California Board has in recent years investigated in-state pharmacies filling prescriptions for internet website operators, using its power to issue fines of \$25,000 for each invalid prescription. NABP has launched the “.pharmacy” top-level domain name, and it will assure that websites using that name are engaging in legal and ethical pharmacy practice. Registration for .pharmacy domain names began in November 2014 (<https://nabp.pharmacy/initiatives/dot-pharmacy/>).

Taking a somewhat different approach to the problem, the US Department of Justice brought charges against FedEx for “knowingly and intentionally” conspiring to distribute substances from unauthorized pharmacies. UPS settled similar charges to those brought against FedEx for \$40 million in 2014; the investigation against FedEx had been ongoing for a number of years when the indictment came down (*Justice Department Indicts FedEx in a Drug-Shipping Inquiry*, NEW YORK TIMES, July 18, 2014, p. B7). However, the government dropped the charges in the middle of the trial in federal district court in 2016 (Bob Egelko, *Government drops case accusing FedEx of illegal drug deliveries*, SAN FRANCISCO CHRONICLE, June 17, 2016). Google paid \$500 million to settle charges that it sold advertising to Canada-based online pharmacies that were marketing to Americans in violation of U.S. laws (Mark Lowery, *FedEx indicted for assisting illegal pharmacies*, DRUG TOPICS, Jul. 18, 2014, <http://drugtopics.modernmedicine.com/drug-topics/content/tags/fedex/fedex-indicted-assisting-illegal-pharmacies?page=full>).

## **Chapter XI – Record-Keeping**

222 – *The Inventory* – As part of its response to the problem of controlled substance loss and diversion, the Board has proposed the adoption of a new regulation (§ 1715.65) that will 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 additional controlled substance as identified by the Board based on drug loss reports. The Board is continuing to accept comments on the proposal.

225 – *Records of Controlled Substances* – A change in federal law no longer makes DEA registrants *strictly liable* for record-keeping violations; it is now unlawful to refuse or *negligently* fail to make or keep required records (21 USC §842).

## Chapter XII – Practice Pitfalls

232 – *Grounds for Discipline/In General* – New law affirms that the Board retains jurisdiction to take, continue, or decide disciplinary action against a licensee even if the license is expired, cancelled, forfeited, suspended, placed on retired status, or voluntarily surrendered (stats. 2012, ch. 799 (SB 1575), adding §4300.1).

The Board has adopted a regulation (§1762) that defines a number of additional behaviors as unprofessional conduct. These include agreeing to provisions in the settlement of a civil dispute that prohibit the other party from filing a complaint or cooperating with the Board, failing without lawful excuse to provide requested records in a timely fashion or to comply with a court order issued in the enforcement of a subpoena mandating the release of records, or committing any act that requires the licensee to register as a sex offender.

The Board now has authority to issue a letter of admonishment to an applicant for any Board license who has committed a violation of law that the Board feels does not merit denial of the license or require a probationary period, but chooses to acknowledge in this way. By its terms, the law deems this letter of admonishment not to be a disciplinary action (for purposes of licensure or reporting of discipline) (Stats. 2014, ch. 247 (SB960), amending §4315).

232 n. 2 – Gross negligence, cited as a ground for discipline in section 4301.5, is considerably beyond simple negligence. However, another section of the law (§4306.5), effective in 2007, in essence defines as unprofessional conduct various types of pharmacist acts and omissions that could be “simple” rather than “gross” negligence, potentially expanding grounds for discipline significantly. There are no judicial decisions to date on this subject.

235-236 – *Failure to Supervise* – The responsibility of the pharmacist-in-charge for the legal operations of the pharmacy was underscored in a recent decision of the California Court of Appeal upholding discipline of the pharmacist-in-charge related to an employee’s theft of a million dollars’ worth of narcotics (*Sternberg v. California State Board of Pharmacy*, 239 Cal. App. 4th 1159 (2nd Dist. 2015)). Sternberg was pharmacist-in-charge during a two-year period when a pharmacy technician stole at least 216,630 Norco (hydrocodone and acetaminophen) tablets, by ordering the drugs by phone and scheduling deliveries to the pharmacy on her work days. She destroyed the invoices and hid the drugs in the storeroom for later removal; her boyfriend sold them on the street. Sternberg discovered the scheme when looking in the storeroom for other merchandise and noticing a Norco bottle, which he knew the pharmacy did not regularly stock. Drug orders were typically delivered between 12:30 and 1 p.m. Although pharmacy policy, in accordance with the law, was that only a pharmacist could sign for deliveries, the pharmacist-in-charge did not explain how that policy would be enforced or implemented. When he signed for deliveries, he did not look at or check invoices against drugs received, nor were invoices regularly reviewed. The Board concluded that proper supervision of staff and random checks of containers of drugs received may have led to earlier discovery of thefts; furthermore, it appeared no loss prevention practices were in place. Discipline in these circumstances, the court held, was appropriate, whether or not the pharmacist-in-charge had actual knowledge of the violations of law. While such knowledge is necessary for criminal charges, it is not required for disciplinary action.

238 – *Improper Filling of Controlled Substance Prescriptions*

245 – *Meeting Patients’ Needs for Controlled Substances: Pain Management*

While the overall legal framework governing the pharmacy’s controlled substance dispensing responsibilities remains basically unchanged, the widespread prescription drug abuse problem has captured the attention of legislators and regulators, as well as the health care community. Federal enforcement has focused on “pill-mill” doctors as well as pharmacies, investigating and assessing big fines against major pharmacy and wholesaler companies (Cardinal Health, Walgreens, and CVS) and investigating others (see, e.g., Kristina Davis, *Feds step up drug enforcement of pharmacies; San Diego*

pharmacies latest to settle with government over distribution of drugs that can end up on street, SAN DIEGO UNION-TRIBUNE (Nov. 25, 2015); Denny Walsh, *Federal probe looks at volume of hydrocodone sold at Costco pharmacies*, SACRAMENTO BEE, Mar. 19, 2014)). In response Walgreens adopted a “good faith dispensing” policy, requiring its pharmacies to collect additional information before dispensing opioids for chronic pain. That apparently led the American Medical Association to pass a resolution condemning as inappropriate inquiries from pharmacies to verify the medical rationale behind these prescriptions.

Enforcement has not been without issues and criticism. When DEA, several years ago, targeted drug wholesalers for oversupplying painkillers, restrictions on supplies to pharmacies, and thus to patients, followed (Julia Talsma, *Access to painkillers disrupted by unpredictable supply chain*, DRUG TOPICS, Jan. 10, 2014, <http://drugtopics.modernmedicine.com/drug-topics/content/tags/b-douglas-hoey/access-painkillers-disrupted-unpredictable-supply-chain?page=full>). DEA’s position was that proper prescribing and dispensing is the task of physicians and pharmacies, and it is not trying to limit access (Mark Lowery, *DEA official blames pharmacists, doctors for pain-med denials*, DRUG TOPICS, Mar. 10, 2014, <http://drugtopics.modernmedicine.com/drug-topics/content/tags/cardinal-health/dea-official-blames-pharmacists-doctors-pain-med-denials?page=full>).

At the same time prosecutors in California and elsewhere filed lawsuits against the manufacturers of opioids, alleging violations of false advertising and unfair competition laws and causing a public nuisance. The essence of their suits is that marketing has led to the use of opioids for chronic non-cancer pain, whereas before that marketing they were rarely prescribed for that purpose because of their serious side effects and the substantial risk of addiction. Several such suits have been filed but without success. (See, e.g., *People v. Purdue Pharma et al.*, Cal. Super. Ct., Orange Co., May 21, 2014, <http://bit.ly/1oxQGOq>; *Indiana/Kentucky/Ohio Regional Council of Carpenters Welfare Fund et al. v. Cephalon, Inc., et al.*, 2014 U.S. Dist. LEXIS 69526 (E.D. Pa.), May 21, 2014)).

What must pharmacies do to meet their corresponding responsibility with respect to these prescriptions? The Pharmacy Board adopted, on August 5, 2013, a “precedential decision” (a decision in an individual enforcement matter which it designates as containing a significant legal or policy determination of general application that is likely to recur (Govt. Code § 11425.60)) on corresponding responsibility. The lengthy legal decision notes some “red flags” with respect to prescriptions filled by the pharmacy ([www.pharmacy.ca.gov/enforcement/precedential.shtml](http://www.pharmacy.ca.gov/enforcement/precedential.shtml)). The Board has posted a Corresponding Responsibility brochure online ([www.pharmacy.ca.gov/publications/corresponding\\_responsibility.pdf](http://www.pharmacy.ca.gov/publications/corresponding_responsibility.pdf)), as well as a “red flags” video ([www.youtube.com/watch?v=jdeQ0GeJjAM&feature=youtu.be](http://www.youtube.com/watch?v=jdeQ0GeJjAM&feature=youtu.be)). The Board has also proposed (see p. 222, above) enhanced controlled substance inventory requirements. (The flip side of watching out for “red flags” is waving a “white flag” and not filling prescriptions, thus harming legitimate pain patients (Kenneth Baker, *Opioid Rx’s: Are pharmacists waving white flags?* DRUG TOPICS, Aug. 10, 2014, <http://drugtopics.modernmedicine.com/drug-topics/content/tags/controlled-substances/opioids-prescriptions-are-pharmacists-waving-white-fl?page=full>).

While prescription drug monitoring programs (PDMPs) like CURES appear to be useful, the ease with which fake identification documents can be obtained enables drug abuse (Steven Ariens, *The Hundred Years’ War*, DRUG TOPICS, Sept. 15, 2013, <http://drugtopics.modernmedicine.com/drug-topics/content/tags/dea/hundred-years-war?page=full>). And physicians can strike back when their prescriptions are refused, as one did in Tennessee, suing four pharmacies that refused to fill her prescriptions (both while she was under investigation by the local police and the DEA, and after) for intentional interference with business relationships. While the case was dismissed on summary judgment for defendants, legal defense is expensive (*Brown v. CVS Pharmacy, LLC et al.*, 2013 U.S. Dist. LEXIS 146025 (M.D. Tenn.), Oct. 9, 2013). Reminder to be careful not to defame a prescriber when refusing to fill a prescription: [www.pharmacist.com/refusing-prescription-and-defaming-prescriber](http://www.pharmacist.com/refusing-prescription-and-defaming-prescriber).

Keeping track of prescribers has gotten increasingly difficult as more non-physicians write prescriptions; about a third of painkiller prescriptions in 2013 were written by PAs, NPs, and other mid-level practitioners (Mark Lowery, *Non-doctors writing millions of painkiller Rx's*, DRUG TOPICS, Mar. 6, 2014, <http://drugtopics.modernmedicine.com/drug-topics/content/tags/benzodiazepines/non-doctors-writing-millions-painkiller-rxs?page=full>), though many must be in the name of a supervising prescriber (depending upon state law).

FDA's approval of Zohydro ER, in light of the opioid abuse problem, was very controversial; Massachusetts even tried, without success, to ban its sale (Steve LeBlanc, *Judge Blocks Massachusetts Ban On Zohydro*, HUFFINGTON POST, Apr. 15, 2014). Massachusetts regulators then tried to make dispensing non-abuse-deterrent forms of hydrocodone-only extended release medication difficult, adding regulatory hurdles, and that initiative also got tied up in litigation (*Zogenix, Inc. v. Patrick*, 2014 U.S. Dist. LEXIS 120866 (D.Mass.), Aug. 28, 2014; stayed in May 2015 to await a final decision by FDA on the drug's labeling). A harder-to-abuse version of Zohydro was approved by FDA in 2015 (but without abuse-deterrent claim labeling). FDA approved the first hard-to-abuse version, Hysingla ER, in November 2014; the agency has a webpage showing a timeline of its actions addressing opioid misuse and abuse ([www.fda.gov/drugs/drugsafety/informationbydrugclass/ucm338566.htm](http://www.fda.gov/drugs/drugsafety/informationbydrugclass/ucm338566.htm)). Among these are the approval of Tragiciniq ER, which adds naloxone to Oxycontin, so if a tablet is crushed and snorted or injected the naloxone blocks the euphoria, although not if the tablets are swallowed (*F.D.A. Approves Pain Drug Meant to Discourage Abuse*, NEW YORK TIMES, July 24, 2014, p. B2). In 2013 FDA required strengthened safety-label warnings on, and post-marketing studies of, long-acting opioids. It moved further in August 2016, requiring class-wide labeling changes, including patient information, to inform about the risks of certain opioids, particularly when combined with benzodiazepines or alcohol. It is mandating boxed warnings and Medication Guides for about 400 products, and noting the risks of extreme sleepiness, respiratory depression, coma, and death. This is part of FDA's Opioids Action Plan ([www.fda.gov/newsevents/newsroom/factsheets/ucm484714.htm](http://www.fda.gov/newsevents/newsroom/factsheets/ucm484714.htm)), which focuses on reversing the abuse epidemic while still allowing for effective and appropriate pain management.

Pharmacies expressed considerable concern about the 2014 rescheduling by DEA of hydrocodone combination drugs like Vicodin to Schedule II from Schedule III ([www.pharmacy.ca.gov/licensing/rescheduling\\_hydrocodone.shtml](http://www.pharmacy.ca.gov/licensing/rescheduling_hydrocodone.shtml)). The National Association of Chain Drug Stores and other health-care groups opposed this change, arguing that it would not be effective in combating inappropriate opioid use but would impose costs and burdens on patients and providers; it noted that Oxycodone itself was already in Schedule II (see [www.nacds.org/pdfs/pr/2013/PCF\\_FDA\\_hydro.pdf](http://www.nacds.org/pdfs/pr/2013/PCF_FDA_hydro.pdf)).

The California Legislature, responding to the opioid overdose problem, adopted a law effective in 2015 (stats. 2014, ch. 326 (AB 1535), adding §4052.01) allowing pharmacists to furnish naloxone hydrochloride without a prescription, in accordance with standardized procedures or protocols developed by the Pharmacy and Medical Boards (see pp. 108-110, above). FDA has recently approved an Epi-pen-like device to deliver naloxone (Sabrina Tavernese, *Hand-Held Treatment for Overdoses Is Approved*, NEW YORK TIMES, Apr. 4, 2014, p. A13). A law effective in 2017 allows pharmacies to furnish naloxone hydrochloride or other opioid antagonists to school authorities, if it will be used only at a school site, a physician provides a written order specifying the quantity to be furnished, and records are kept by the school authorities for three years. The school authorities are responsible for monitoring the supply and destroying expired product (stats. 2016, ch. 557 (AB 1748), adding §4119.8)). The law also amends the Education Code to provide necessary authority to the schools (Education Code §49414.3).

California has created a [Prescription Opioid Misuse and Overdose Prevention Workgroup](#) to inform healthcare providers, pharmacists, and the public about the overdose epidemic, particularly about the fact that many overdose deaths come from misuse of legal prescription drugs. The Medical Board of California has created revised [guidelines](#) for prescribing painkillers, intended to lead to better discussions

between patients and their providers and pharmacists. The Pharmacy Board participates in this workgroup.

The American Pharmacists Association has created an online resource center on the subject of opioid use, abuse, and misuse ([www.pharmacist.com/opioid-use-abuse-and-misuse-resource-center](http://www.pharmacist.com/opioid-use-abuse-and-misuse-resource-center)). It also has published a series of articles entitled The Challenge of Pain (see [www.pharmacist.com/governments-respond-rx-drug-abuse-pharmacists-and-their-patients-face-challenges](http://www.pharmacist.com/governments-respond-rx-drug-abuse-pharmacists-and-their-patients-face-challenges) and [www.pharmacist.com/pharmacies-crosshairs-prescription-drug-crime-and-law-enforcement](http://www.pharmacist.com/pharmacies-crosshairs-prescription-drug-crime-and-law-enforcement)).

The opioid misuse crisis got Congressional attention in 2016. An almost-unanimous Congress passed, and the President signed, the Comprehensive Addiction and Recovery Act (CARA) in the summer of 2016. The law provides a framework for opioid abuse prevention and treatment, and includes multiple provisions aimed at dealing with the crisis. Some of its provisions involve grants for various purposes, such as funding naloxone-dispensing programs through pharmacies. It seeks to encourage prescribers to co-prescribe naloxone with opioids and states to expand access to naloxone to caregivers of persons at risk. It creates a federal pain management task force to identify best practices, and requires FDA to consult an advisory committee before approving opioids that are not abuse-deterrent. It includes provisions for drug prevention awareness campaigns, addiction prevention and treatment, expansion of drug take-back programs, and the like. Funding, however, was not included in the measure. Of greatest immediate import to pharmacists is the provision allowing partial fills for Schedule II drugs, as noted above at p. 187. Critics note that Congress has not limited the availability of these drugs and has curtailed some DEA enforcement powers (Gardiner Harris and Emmarie Huetteman, *Actions by Congress on Opioids Haven't Included Limiting Them*, NEW YORK Times, May 18, 2016, p. A1, [www.nytimes.com/2016/05/19/us/politics/opioid-dea-addiction.html?\\_r=2#story-continues-1](http://www.nytimes.com/2016/05/19/us/politics/opioid-dea-addiction.html?_r=2#story-continues-1)).

Another federal law passed in 2016 may have indirect impact on pharmacies. The Ensuring Patient Access and Effective Drug Enforcement Act of 2016 primarily deals with enforcement issues and controlled substances ([www.govtrack.us/congress/bills/114/s483/summary](http://www.govtrack.us/congress/bills/114/s483/summary)).

Some insurers have recently taken actions to block high risk patients from getting multiple opioid prescriptions by limiting where they can fill their prescriptions, or by mandating use of a PDMP before filling a prescription for more than 21 doses (Christine Blank, *Insurers restrict high-risk opioid users to select pharmacies*, DRUG TOPICS (July 1, 2016)).

248 – *Fraud, Deceit, and Corruption* – A new law effective in 2017 (stats. 2016, ch. 484 (SB 1193)) will eliminate “gross immorality” as a ground for unprofessional conduct. As noted in footnote 26, that is an open-ended term the meaning of which changes over time with societal attitudes.

250 – *Kickbacks, rebates, and referrals* – The owner of a Los Angeles pharmacy was sentenced to 18 months in prison and ordered to pay \$644,060 in restitution to Medicare for paying illegal cash kickbacks to Medicare beneficiaries to agree to submit their prescriptions to his pharmacy (Mark Lowery, *California pharmacist sentenced for Medicare fraud*, DRUG TOPICS, Aug. 7, 2015, <http://drugtopics.modernmedicine.com/drug-topics/news/california-pharmacist-sentenced-medicare-fraud?page=full>).

260-61 – *Civil Liability* – All licensees of the Pharmacy Board (and the other boards in the Department of Consumer Affairs) are responsible for assuring that there be no provision in any agreement to settle a civil dispute that prohibits the other party from filing a complaint or cooperating with the regulatory board or requires the withdrawal of a complaint (stats. 2012, ch. 561 (AB 2570)). The statute declares any such provision to be void as against public policy and, as noted above (p. 232), the licensee may be disciplined for allowing its inclusion in any settlement agreement. When there has been a settlement of a civil action related to a disciplinary action the Board may not require the licensee to pay any additional sum to the

plaintiff as a condition of the discipline. The purpose of this statute is to preclude the practice of settling a civil suit in a manner that prevents the licensing board from obtaining information that might prevent future harm to the public.

With increasing scope of practice, with increasing recognition of the value of the pharmacist's knowledge, can come increased responsibility, and thus liability for error, as the courts are beginning to recognize. (See Kenneth R. Baker, *Can Pharmacists Be Sued for Doing Their Jobs?* DRUG TOPICS, Feb. 10, 2016, <http://drugtopics.modernmedicine.com/drug-topics/news/can-pharmacists-be-sued-doing-their-jobs>.)

Recent litigation suggests that pharmacists should be extremely wary of – even avoid -- “as directed” instructions. In the case at issue, the prescriber had issued a prescription with the notation “as directed by the pharmacy,” but the pharmacist had omitted the last three words. Essentially no one instructed the patient, resulting in harm. (The case is *Emergency Medicine Associates of Jackson v Glover*, 2016 Miss.App. LEXIS 239 (April 26, 2016), as discussed in David Brushwood, *Pharmacists may be liable when ‘as directed’ causes harm*, PHARMACY TODAY, [http://pharmacytoday.org/article/S1042-0991\(16\)30536-9/abstract](http://pharmacytoday.org/article/S1042-0991(16)30536-9/abstract).)

### **Chapter XIII – The Board of Pharmacy and Other Agencies**

265 – *Board Committees* – The Enforcement Committee is now the Enforcement and Compounding Committee.

*Authority of the Board* – The Board, by regulation, increased all its fees to their statutory maximums effective July 1, 2014 (§1749).

266 – *Continuity of the Board* – The Board's most recent sunset review was successfully completed; its statutes are next scheduled to become inoperative as of January 1, 2021 (stats. 2016, ch. 484 (SB 1193), amending §§4001(f), 4003(e)).

267 – *The Executive Officer* – The Board is working on broadening section 1703 to allow the executive officer also to make changes to Board regulations that are without regulatory effect pursuant to 1 CCR §100 and to approve waivers pursuant to §4076.5(e).

272 – *Disciplinary Action* – The Board decided in 2012 not to proceed with proposed regulations modifying its disciplinary guidelines, but in 2015 it proposed comprehensive modifications to those guidelines and to section 1760, which requires the Board to use its disciplinary guidelines. The review was necessary to incorporate changes in pharmacy law since the last revision (October 2007), to ensure consistency in terminology between the guidelines and pharmacy law, to remove outdated and unnecessary terms and conditions of probation, and to incorporate changes to facilitate implementation of a 2008 statute seeking to ensure rehabilitation of licensees on probation. A summary of the proposed changes is in the initial statement of reasons ([www.pharmacy.ca.gov/laws\\_regs/1760\\_isr.pdf](http://www.pharmacy.ca.gov/laws_regs/1760_isr.pdf)); the proposed text of the disciplinary guidelines is at [http://www.pharmacy.ca.gov/laws\\_regs/1760\\_mdg.pdf](http://www.pharmacy.ca.gov/laws_regs/1760_mdg.pdf). These changes are currently under review by the Department of Consumer Affairs.

Disciplinary action by another state is made the basis for similar action in California, with the Board mandated to act coterminously with the other state's action. California could exceed the other state's disciplinary term consistent with its enforcement guidelines. The new law provides that discipline by another state is conclusive proof of unprofessional conduct. The Board is also required, in order to maximize its resources for protection of the public health and safety, to prioritize its use of investigational

and prosecutorial resources to expeditiously identify and discipline pharmacists presenting the greatest threat of patient harm (stats. 2016, ch. 484 (SB 1193), amending § 4301(n) and adding §4301.1).

## **Chapter XIV – Other Law Relevant To Pharmacy**

282 – *Protecting the Patient’s Right to Privacy/Nature of the Right* – In addition to minors, many young adults are enrolled on a parent’s health insurance plan, as are many adult partners. HIPAA explicitly protects the confidentiality of medical information of dependents insured on another person’s health insurance policy, but California law has not been explicit. A statute effective in 2015 (stats. 2014, ch. 444 (SB138)) prohibits disclosures to the insurance policyholder about other insured individuals under the policy without their consent or knowledge.

285-88 – *Federal Privacy Protection* – California law also imposes recently-strengthened requirements concerning reports of security breaches (see, e.g., Civ. Code §§1798.29, 1798.82).

The federal Department of Health and Human Services issued a final rule on January 17, 2013, revising the privacy, security, and enforcement rules previously issued to implement HIPAA and the HITECH Act (Ned Milenkovich, *CR issues new HITECH regulations*, DRUG TOPICS, Mar. 15, 2013, <http://drugtopics.modernmedicine.com/drug-topics/news/drug-topics/health-system-news/ocr-issues-new-hitech-regulations?page=full>). Requirements to safeguard PHI have been strengthened and to report breaches have been expanded (Fred Gebhart, *New HIPAA requirements coming*, DRUG TOPICS, Aug. 15, 2013, <http://drugtopics.modernmedicine.com/drug-topics/content/tags/hippa/new-hipaa-requirements-coming?page=full>).

290 – *Anti-Discrimination Laws* – A final rule of the US Department of Health and Human Services on Nondiscrimination in Health Programs and Activities includes specific requirements applicable to pharmacies on providing language assistance for people with limited English proficiency. These requirements may go beyond the labeling requirements discussed above, at p. 191 (81 Fed. Reg. 31375 (May 18, 2016); [www.gpo.gov/fdsys/pkg/FR-2016-05-18/pdf/2016-11458.pdf](http://www.gpo.gov/fdsys/pkg/FR-2016-05-18/pdf/2016-11458.pdf)).

## **Chapter XV – Ethics and Law**

The End of Life Option Act, passed in 2015 and effective from January 1, 2016, to January 1, 2026, contains a “conscience clause” relevant to this chapter (p. 297), and relates also to other chapters in the text. In brief, the new statute (Stats. 2015-16 2nd Ex. Session, ch. 1 (ABX2-15)) 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. While physicians may dispense the necessary drugs, a prescription may also be written and filled by a pharmacy. The prescriber must inform the pharmacist of the prescriptions and deliver them personally, by mail or electronically. The pharmacist may dispense the drug to the patient, the attending physician, or a person expressly designated by the patient (with that designation delivered to the pharmacist in writing or verbally), including by delivery service (H&SC §443.5(b)). No health care provider is to be subject to censure, discipline, or any other type of penalty for participating in good faith compliance with this statute or refusing to participate; neither shall there be any civil, criminal, administrative or other type of penalty or liability for participating (H&SC §443.14(b)-(c)).

In addition, the statute specifically provides, “Participation in activities authorized pursuant to this part shall be voluntary” (H&SC §443.14(e)), and refusal may not give rise to any type of sanctions. A health care provider may prohibit its employees and independent contractors (including other health care providers) from participating in activities under this statute while on that provider’s premises or acting on its behalf, but must first give notice of its policy prohibiting participation in order to enforce its policy. It

may not prohibit employees, independent contractors, or other entities from engaging in activities allowed under this statute when acting outside the course and scope of duties for the prohibiting health care provider (H&SC §443.15). Section 443.16 provides additional protection against sanctions for health care providers under this law.

The Board has adopted a policy statement recommending the elimination of tobacco and e-cigarette sales from California pharmacies ([www.pharmacy.ca.gov/about/tobacco.shtml](http://www.pharmacy.ca.gov/about/tobacco.shtml)).

295 – A very worthwhile discussion could – and should – be had of the ethical dilemmas increasingly faced by pharmacists with respect to prescriptions for controlled substances. The legal issues are discussed in Chapter XII – Practice Pitfalls as well as elsewhere in this book. Pharmacists have always had a legal, as well as an ethical, obligation to fill only *legitimate* prescriptions for controlled substances. Laws and regulations can easily place that obligation in the hands of the pharmacist; more difficult is for the pharmacist to fulfill that obligation.

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 (B&PC §733), now also applies to self-administered hormonal contraceptives described in Section 4052.3, as well as emergency contraception (Stats. 2013, ch. 469 (SB 493)).

A Washington State rule requiring pharmacies to promptly fill all lawful prescriptions (with some exceptions) would require emergency contraception prescriptions to be filled. A decades-long challenge in the federal courts, alleging violation of the First Amendment right to freedom of religion, ended in July 2016, when the United States Supreme Court refused to review the 9th Circuit’s decision finding the rule not in violation of the First Amendment. (Three justices of the Supreme Court wrote a dissenting opinion on the refusal to review.) The case is *Stormans, Inc. v. Wiesman*, 794 F. 3d 1064 (9th Cir. 2015), *cert. den.*, 136 S. Ct. 2433 (2016). The rule applies to *pharmacies*, not *pharmacists*.

## **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](http://www.pharmacy.ca.gov/meetings/agendas/2015/15_jun_bd_content_outline.pdf)