

CUMULATIVE UPDATE DECEMBER 2017

(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

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

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

General pharmacy news: the DRUG TOPICS magazine back-issue archive is at <http://drugtopics.modernmedicine.com/past-issues/Drug%20Topics>

Pharmacy Board licensees can 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 is 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 (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). FDA announced in May 2016 that its decision on the proposed rule would not be made until 2017; current FDA Commissioner Scott Gottlieb has stated opposition to that change, and the rule does not appear on the list of rules anticipated for release in 2017 (www.raps.org/Regulatory-Focus/News/2017/08/08/28206/Proposed-and-Final-FDA-Rules-What%E2%80%99s-Left-in-2017/).

For a discussion of the potential impact of such a rule 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*, 570 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).

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).

19 – The 21st Century Cures Act, P.L. 114 – 255, signed in December 2016, made significant changes in the drug approval process (see www.fdalawblog.net/fda_law_blog_hyman_phelps/2016/12/the-president-signs-21st-century-cures-into-law-highlights-of-drug-and-biologic-related-provisions-p.html).

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 §§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/.) 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.”

The FTC has issued two staff reports on drug patent settlement agreements since *Actavis*. The latest, issued in November 2017 reporting on fiscal year 2015, suggests a decline in reverse-payment agreements. Legislation continues to be introduced in Congress to deal with the issue. For details and analysis, see www.fdalawblog.net/fda_law_blog_hyman_phelps/2017/11/ftc-releases-fy-2015-staff-report-on-drug-patent-settlement-agreements-competitive-drugs-act-of-2017.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). 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.

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 states, including California, legalizing and regulating all uses of marijuana, marijuana remains in Schedule I under federal controlled substances law, with possession and sale still 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 (August 12, 2016; <http://bit.ly/2cRXJmr>)).

Five new laws that regulate the medical marijuana industry went into effect in 2016. These laws, among other things, created 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). None of the laws appeared 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)) changed the Bureau’s name to the Bureau of Medical *Cannabis* Regulation, and changed all other medical marijuana references to cannabis as well, but also included 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.

The passage of California Proposition 64, on the November 2016 ballot, provided for marijuana legalization (although under federal law marijuana remains a Schedule I controlled substance). The lengthy initiative measure contained no references to pharmacy (<http://voterguide.sos.ca.gov/en/propositions/64/>). Subsequent legislation passed to implement the initiative (see, e.g., Stats. 2017, ch. 27 (SB 94)) changes nothing in the practice of pharmacy.

30 n. 18 – The most up-to-date information on state laws on medical (and recreational) 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)) added 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 excluded 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 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 2017 law (Stats. 2017, ch. 573 (SB 800), amending §4013(d)) adds designated representatives to this requirement as of 2018.

A new law relevant to applicants for all individual licenses provided 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 provided 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 adopted changes to renewal requirements in section 1702 that require a pharmacist, at the time of renewal, to disclose disciplinary action by any government agency. It simultaneously adopted the same fingerprint submission requirements for pharmacy technicians and designated representatives as for pharmacists, as well as mandated disclosure of disciplinary action by any government agency by pharmacy technicians, designated representatives, nonresident wholesalers, and nonresident pharmacies (§§1702, 1702.1, 1702.2, 1702.5). These changes are effective January 1, 2018. The text is at www.pharmacy.ca.gov/laws_regs/1702_mt.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 were raised to their statutory maximums in 2014. Thereafter, after analyzing its financial needs, the Board sought and obtained statutory authority (ch. 799, 2016 (SB 1039), effective July 1, 2017), for increased fees and fees for new license categories. (The Board has started the process of amending section 1749, its fee regulation, to correspond to the new statutory fees; the text may be found at http://www.pharmacy.ca.gov/laws_regs/1749_1_pt.pdf.) The fee for application and examination as a pharmacist remains \$260 and for issuance of an original pharmacist license \$195. Biennial pharmacist license renewal has increased to \$360. The full list of fees may be found at www.pharmacy.ca.gov/about/fee_schedule.shtml.

50-51 – *Continuing Education* – The Board withdrew the proposed changes to section 1732.2 noted in the text. It has now adopted changes that 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 designated Board and committee meetings (§1732.2). In addition, the proposal requires, for pharmacist license renewal after July 1, 2019,

the completion of a Board-provided CE course in Law and Ethics (§1732.5(b)). The text of the rule is at www.pharmacy.ca.gov/laws_regs/2015_1732_2_mt.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.) As of July 2017 these proposals were still in the early part of the adoption process.

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)).

A 2017 law creates and defines a new category of designated representative, the “designated representative - reverse distributor,” with less stringent requirements for licensure but limited to working for businesses engaged in reverse distribution (Stats. 2017, ch. 598 (SB 752), adding §§4022.6 and 4053.2).

63 – *Pharmacy Ownership* – The Board has drafted proposed amendments to section 1709 that would allow ownership, management, and control of a pharmacy license by a trust. As of July 2017 this proposal was in the early stages of consideration for adoption.

Chapter IV – Licensing Pharmacies

62 – 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 new law passed in 2017 defines, and allows the Board to license, a hospital satellite compounding pharmacy. This area would be separately licensed to perform compounding and would be located outside of the hospital in another physical plant that is regulated as a general acute care hospital. This facility may compound sterile drug products only for administration to registered hospital patients on the premises where it is located. (Stats. 2017, ch. 623 (SB 351), amending §4029 and adding §4127.15.)

Another 2017 law requires Medi-Cal providers to maintain records for ten (rather than three) years, in accordance with federal regulations (Stats. 2017, ch. 511 (AB 1688), amending Welf. & Inst. Code §14124.1).

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 (ADDS)” (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. Registration is required within 30 days of installation, and must be reaffirmed upon annual license renewal; the Board must be notified within 30 days if operation of the system is

discontinued. The Board has been studying the legal landscape as well as the new equipment available for automated drug delivery, and considering whether further changes are necessary for the use of ADDS in a number of new settings (see article in *The Script*, June 2017, available at www.pharmacy.ca.gov/publications/17_jun_script.pdf).

New law effective in 2018 creates an “emergency medical services ADDS” (EMSADDS) for the sole purpose of restocking a secured emergency pharmaceutical supplies container that is used by an emergency medical services agency to provide emergency medical services (such as in an ambulance). This law defines the new type of ADDS, provides the licensure requirements, and creates a new category of licensee, the “licensed designated paramedic,” who can substitute for a pharmacist or medical director as the person restocking the EMSADDS. (Stats. 2017, ch. XX (SB 443), adding §§4034.5, 4119.01, and 4202.5.)

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. A presentation for dispensers is here: www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/UCM453236.pdf.

Pharmacists will be 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.

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 Guidance for Industry on identification of suspect product and notification, which may be found here: www.fda.gov/downloads/drugs/guidances/ucm400470.pdf.

In July 2017, the FDA published a draft guidance extending for an additional year, to November 27, 2018, the deadline for manufacturers, repackagers, and other distributors to place a drug product identifier at the individual package level for each product introduced into interstate commerce. Manufacturers and

distributors cited technical barriers to compliance with the November 2017 deadline (DHHS, FDA. *Product identifier requirements under the Drug Supply Chain Security Act - Compliance Policy; draft guidance for industry; availability*, 82 Fed. Reg. 30868 (July 3, 2017)).

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 forms for wholesalers (as well as hospitals and community pharmacies) were effective on April 20, 2016 The Board has started the process of amending sections 1780-83 to incorporate minimum standards for third-party logistics providers.

A new law effective in 2018 requires wholesalers to notify the Board in writing upon discovery of suspicious orders of controlled substances placed either by a California-licensed pharmacy or wholesaler. Suspicious orders include "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." (Stats. 2017, ch. 548 (AB 401), adding §4169.1.)

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.

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.

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_oa.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.

The Board's regulations concerning the furnishing of prescription medications recommended for people traveling outside the United States went into effect June 8, 2017. The text of new section 1746.5 may be found at www.pharmacy.ca.gov/laws_regs/1746_5_tmt_clean.pdf. The regulations provide for furnishing such medications for conditions not requiring a diagnosis (as defined) or for prophylaxis, and mandate a 10-hour training program and notification to the patient's primary care provider, among other requirements.

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, effective in December 2016; the text of sections 1730, 1730.1, and 1749 is available at www.pharmacy.ca.gov/laws_regs/1730_3rd_mt.pdf. The Board regulation, section 1730.2, concerning programs that will certify applicants to be advanced practice pharmacists, became effective in August 2016 (www.pharmacy.ca.gov/laws_regs/1730_2_oa.pdf). The first licenses for advanced practice pharmacists were issued in February 2017; 169 such licenses were granted as of October 2017.

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 at www.pharmacy.ca.gov/laws_regs/1746_3_mod_15day.pdf. As of July 2017, the Board had in process amendments to section 1746.3, concerning the naloxone fact sheet that must be distributed.

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 is 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)).

Because of a parallel concern about gray and black market nonprescription diabetes test strips, the Legislature adopted an “urgency” statute (which thus went into effect immediately upon its approval on July 31, 2017) to curtail the resale and counterfeiting of these products. The concerns are both with inappropriate profiting from manufacturer and Medicare reimbursements and health risks from counterfeit or improperly-handled products. Manufacturers must make available on their websites and provide to the Board the names of their authorized distributors. The Board may embargo products inspectors believe were not purchased from those distributors. (Stats. 2017, ch. 139 (AB 602), adding §§4025.2, 4084.1, and 4160.5.)

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 transport and disposal of any unwanted prescription drugs. Multiple jurisdictions now 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). The City of Santa Cruz 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 was criticized for its 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). Thereafter it proposed regulations on this subject. The Board has now adopted (effective

June 6, 2017) comprehensive regulations, a new Article 9.1 (sections 1776-1776.6), entitled “Prescription Drug Take-Back Programs,” to provide regulatory oversight for these programs. The text adopted after considerable modifications is available at www.pharmacy.ca.gov/laws_regs/1776_mt3_cln.pdf. Forms to report installation or discontinuance of a collection bin or to report tampering, damage, or theft are available at http://www.pharmacy.ca.gov/licensees/drug_takeback.shtml. A law passed in 2016 limits the liability of those who are authorized to maintain secure drug take-back bins (Stats. 2016, ch. 238 (AB 1229), adopting Civ. Code §1714.24).

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 disposal options for controlled substances collection from ultimate users 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)).

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).

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*, 91 F. Supp. 3d 1 (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. (Bills subsequently introduced in the United States Congress to allow drug importation have 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>). In January 2017 the pharmacist, William Burdine, agreed to surrender his pharmacist and pharmacy licenses to the Pharmacy Board, ending its action against him.

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 increase 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, <http://drugtopics.modernmedicine.com/drug->

[topics/news/modernmedicine/modern-medicine-feature-articles/generic-drug-shortages-show-no-sign?page=full](https://www.fda.gov/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. Its restriction on compounding for office use, included in the FDA's final guidance on the "Prescription Requirement Under Section 503A" (www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm496286.pdf), published December 28, 2016, is quite controversial, with members of Congress joining pharmacy associations in urging that this be allowed in states where it is legal (www.pharmacist.com/article/fda-issues-final-503a-compounding-guidance-prohibiting-office-use; Karla Palmer, "[Letter Signed by 65 Members of Congress Urges FDA to Reconsider "Office Stock" Restrictions for Section 503A Compounders](http://www.fdalawblog.net)," [fdalawblog.net](http://www.fdalawblog.net), posted May 30, 2017).

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)).

The FDA has produced a great deal of guidance, in draft and in final form, on various compounding issues, particularly those raised by the new outsourcing facility law. A list of those guidances may be found at www.fda.gov/drugs/guidancecomplianceregulatoryinformation/guidances/ucm452240.htm. Other information on outsourcing and FDA is at 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), California 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)). The Board began licensing outsourcing facilities that are within or ship products into California on January 1, 2017.

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 statutory authority granted in 2013, the Board adopted changes and additions to numerous sections of its regulations, effective at on January 1, 2017. These included the requirement of a self-assessment. The lengthy text is at www.pharmacy.ca.gov/laws_regs/1735_oaa_clean.pdf.

Some state compounding standards in California statutes were determined to conflict with federal compounding standards. The conflict has been eliminated by passage of a law that repeals section 4127.7 (stats. 2017, ch. 649 (SB 510)). The Board's regulations on compounding environments are now in conformity with those of USP-NF, as required by federal law.

A helpful discussion of the federal and state compounding rules is in the October 2017 edition of *The Script*, at p. 3 (www.pharmacy.ca.gov/publications/17_oct_script.pdf).

156 – Expiration and “Beyond-Use” Dates

The Board voted in July 2017 to pursue an emergency rulemaking to amend regulations related to the establishment of beyond use dates for nonsterile drug preparations and, at the same time, to begin the regular rulemaking process for beyond use dating provisions for nonsterile drugs as well as for additional changes to the rules related to both sterile and nonsterile compounded drug preparations. The text of the amendments to section 1735.2 is at www.pharmacy.ca.gov/laws_regs/1735_2_pet.pdf.

The Board has also clarified that staff in institutional settings may use the wording “do not start after” instead of “exp” on labels, because it is easier for nurses and other institutional staff to understand and provides clearer direction for compliance.

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). Those 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 only 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>).

174 – In July 2017 DEA clarified that an unfilled original electronic prescription for controlled substances (including Schedule IIs) can be forwarded from one DEA-registered retail pharmacy to another.

176 – *The California Form* – The Board issued an alert on November 28, 2017 noting that its inspectors continue to identify noncompliant forms filled by pharmacies. It has responded by educating the licensee and fining the pharmacies and pharmacists involved. Perhaps as a result pharmacies have begun to refuse to fill prescriptions written on noncompliant forms, and the Board has received complaints from patients and prescribers that prescriptions have not been filled as a result. The Board suggests some interim solutions, including familiarizing prescribers as well as dispensers with the required elements of the security form; directing prescribers to reorder compliant forms from a DOJ-licensed security printer; or suggesting prescribers with noncompliant forms consider using e-prescribing for controlled substances. The Board also reminds pharmacists that Schedule III-V controlled substances may be filled and refilled if the pharmacist treats the noncompliant prescription as an oral prescription and then follows the rules for verification of that oral prescription. Schedule II drugs cannot generally be orally prescribed, nor can they be refilled using a California Security Prescription. But, the Board added, “when there is no alternative except to prescribe a Schedule II controlled medication using a noncompliant California Security Form to allow patients to receive their pain medications timely, prescribers and dispensers should communicate about why a noncompliant California Security Form is being used on a temporary basis” (email to PHARM-GENERAL@DCALISTS.CA.GOV, Nov. 28, 2017).

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. At least 42 states are now participating (<https://nabp.pharmacy/forty-two-states-now-participating-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 challenge by the physician to the Medical Board obtaining data from CURES about his patients without a warrant or subpoena in the course of investigating his prescribing practices was held, by the California Supreme Court, not to violate any patient’s right to privacy. Even if there were a significant intrusion on a legally protected privacy interest, the Board’s actions were deemed justified in this particular case (*Lewis v. Superior Court*, 3 Cal. 5th 561 (2017)).

A law effective in 2017 (stats. 2016, ch. 708 (SB 482)) requires 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). (As of December 4, 2017, the state has not certified the database.)

A law effective in 2018 requires the Department of Justice, by October 1, 2018, to make CURES data available to authorized health care providers through health information technology systems that integrate with the CURES database (stats. 2017, ch. 607 (AB 40), amending H&SC §11165.1).

“CURES 2.0” now supersedes the original version of the system, and includes new and improved features, including the ability to assign delegates who can initiate inquiries in the system, daily alerts with information on patients who reach prescribing thresholds, and flagging to allow prescribers to notate patients with treatment contracts.

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)).

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.

The Board sought clarification from its legal counsel of the potential conflicts between CARA and California law on partial filling. Counsel confirmed that the federal law allows partial filling of a Schedule II (providing the prescription is valid and the pharmacist exercises corresponding responsibility) in the circumstances noted in the text (terminal illness, long-term care patients, and when there is inadequate stock), as well as upon request of the patient or practitioner. A new California law effective July 1, 2018 (Stats. 2017, ch. 615 (AB1048)) clarifies the authority to dispense a partial fill of a Schedule II at the request of either the patient or the prescriber (new §4052.10). This law also requires that, as of July 1, 2019, insurers and health care service plans prorate their insured’s out-of-pocket costs when there is a partial fill (new H&SC §4052.1 and Ins. Code §10123.203).

Some policy-makers have been urging use of the partial fill option by prescribers as a way to limit the circulation of opioids, and to aid in the drug abuse epidemic.

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 enacted new section 4073.5 (Stats. 2015, ch. 545 (SB 671)) and allowed 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.

In May 2017 the Board approved the initiation of rulemaking to add section 1717.5, concerning automatic refill programs. It would set standards to assure patient awareness of the automated refills and to allow refunds for prescriptions deemed to be unneeded, after appropriate disenrollment in the program. See attachment 17 at http://www.pharmacy.ca.gov/meetings/agendas/2017/17_jul_bd_viii.pdf.

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 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. That

change in section 1707.5 became effective on July 1, 2017; the text is at www.pharmacy.ca.gov/laws_regs/1707_5_smt.pdf. The Board has posted samples of complying labels at www.pharmacy.ca.gov/licensees/labels.shtml.

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 amended its regulation, section 1744, which lists classes of drugs that cause impairment and require warning labels; it went into effect in April 2017. The text is at www.pharmacy.ca.gov/laws_regs/1744_mt.pdf. Of particular note is the addition to the list of drugs posing substantial risk when taken with alcohol, and requiring warning, of cycloserine and antidiabetic agents including insulin and sulfonylureas (due to risk of hypoglycemia).

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.

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.

206 – *Transfer of a Prescription* – DEA has clarified that an *unfilled* electronic prescription for controlled substances (including Schedule II) can be forwarded from one DEA-registered retail pharmacy to another, even though other forms of transfer are not allowed for *unfilled* prescriptions (only for refills). *The Script* (October 2017), p. 12 (www.pharmacy.ca.gov/publications/17_oct_script.pdf).

209 – *Emergency Provision of Drugs/Public Emergencies* – The Board has used section 4062 several times in recent years, most recently in response to the northern California wildfires, to enable pharmacies to provide prescription medications under emergency circumstances. 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 2017 law modifies the way reimbursement to Medi-Cal pharmacy providers is calculated. It requires the department to base its drug ingredient cost methodology on actual acquisition cost and, for dates of service after April 1, 2017, a dispensing fee based on the pharmacy’s claim volume for the prior year (stats. 2017, ch. 52 (SB97)).

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).

The Legislature passed a law effective in 2018 (stats. 2017, ch. 603 (SB 17)) that focuses on drug price transparency. It sets up reporting requirements about drug cost and volume for health plans and reporting requirements for drug manufacturers with regard to rate increases for drugs with a wholesale acquisition cost of \$40 or more.

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 paper posters available in multiple languages that can be ordered at www.dca.ca.gov/webapps/pharmacy/pubs_request.php.

215-17 – *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 [dot.pharmacy] domain names began in November 2014 (<https://nabp.pharmacy/initiatives/dot-pharmacy/>).

Taking a somewhat different approach to the problem, the U.S. 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>).

Recognizing the potential of electronic communication to improve access to pharmacy services in remote or under-served areas, the Legislature passed new law, effective in 2018, providing for licensure of remote dispensing site pharmacies (Stats. 2017, ch. 548 (AB 401), adding §§4044.6-.7, 4130-35, and adding and amending others). The remote site license needs to be held by the owners of the supervising pharmacy, whose pharmacist-in-charge may also be in charge of the remote site pharmacy. A pharmacy technician will work at the remote site; the limits to that technician's authority are included in the law. The remote site must be connected with its supervising pharmacy site by audio and video communication. The law includes detailed rules for this new type of pharmacy operation.

Chapter XI – Record-Keeping

222 – *The Inventory* – As part of its response to the problem of controlled substance loss and diversion, the Board 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 (see current version of the text at www.pharmacy.ca.gov/laws_regs/1715_65_smt.pdf). The regulation is under review by the Department of Consumer Affairs.

223 – *Maintaining Records on the Premises* – The Board is proposing amendments to section 1707 to allow those cited for a records violation nevertheless to receive a waiver to store records off-site. This proposal is in the early review process.

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* – 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 defined a number of additional behaviors as unprofessional conduct (§1762). 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; a strict liability standard may be applied.

238 – *Improper Filling of Controlled Substance Prescriptions*

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

At the time of publication (2012), while health care and law enforcement professionals, including pharmacy regulators, had long been aware of the diversion and abuse of prescription medications, the issues were just beginning to reach public awareness. A very basic search of the *New York Times* website for the word “opioid” drew 35 articles in 2012, 39 in 2015, and 431 to date in 2017. So while the overall legal framework governing the pharmacy’s controlled substance dispensing responsibilities remains basically unchanged, it is clear that the widespread prescription drug abuse problem has now captured the attention of the public, legislators, and regulators, as well as the health care community. The White House has declared the opioid overdose epidemic (www.nytimes.com/2017/01/06/us/opioid-crisis-epidemic.html) a national emergency, and a commission asked to suggest solutions issued 56 recommendations in its report presented on November 1, 2017 (<https://www.nytimes.com/2017/11/01/health/opioids-trump-commission.html>; click for the [Final Report Draft](#)). It is estimated that 64,000 people died of drug overdoses in the United States in 2016 (www.nytimes.com/2017/11/03/health/deaths-drug-overdose-cdc.html?_r=0). Most relevant to pharmacy are recommendations involving prescription drug monitoring programs, electronic prescribing, and deployment of naloxone.

The federal government has focused enforcement attention on “pill-mill” doctors as well as pharmacies, and major pharmacy chains and wholesalers (including Cardinal Health, Walgreens, and CVS) have also been targets. But “solutions” have not been without critics. When Walgreens, in response to enforcement attention, adopted a “good faith dispensing” policy, requiring its pharmacies to collect additional information before dispensing opioids for chronic pain, the American Medical Association passed a

resolution condemning as inappropriate inquiries from pharmacies to verify the medical rationale behind those prescriptions. Pharmacies have been concerned that the targeting of drug wholesalers for oversupplying painkillers has led to restrictions on supplies to pharmacies, and thus to patients (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 is that it is not trying to limit access to proper prescribing and dispensing, the task of physicians and pharmacies (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>). Considerable controversy has been aroused by a 2016 federal law change that made it easier to distribute quantities of opioids that previously would have triggered DEA investigations (<http://drugtopics.modernmedicine.com/drug-topics/news/pharmacy-community-reacts-60-minutes-washington-post-investigation?GUID=08D9702E-D68B-4E99-9572-691A53031E1A&rememberme=1&ts=19102017>).

State prosecutors in California and elsewhere have filed lawsuits against opioid manufacturers, alleging violations of false advertising and unfair competition laws and causing a public nuisance. The claim 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. So far no such suit has been successful. (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). A lengthy NEW YORKER article explores the responsibility of Purdue Pharma for the opioid crisis (Patrick Radde Keefe, *Empire of Pain*, Oct. 30, 2017, p. 34).

FDA's role has also been discussed; its approval of Zohydro ER was very controversial. Massachusetts even tried, without success, to ban the drug's sale, and then to add regulatory hurdles to dispensing non-abuse-deterrent forms of hydrocodone-only extended release medication. That initiative remains 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). Harder-to-abuse and hard-to-abuse versions of opioids have been approved, as has a drug, Truginiq 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). FDA's website includes an up-to-date timeline of its actions addressing opioid misuse and abuse (www.fda.gov/drugs/drugsafety/informationbydrugclass/ucm338566.htm). FDA has adopted an Opioids Action Plan (www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm484714.htm) which focuses on reversing the abuse epidemic while still allowing for effective and appropriate pain management.

Another federal response was the passage of the Comprehensive Addiction and Recovery Act (CARA) in the summer of 2016, which provides a framework for opioid abuse prevention and treatment. 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 created a federal pain management task force to identify best practices, and required 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. 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). Critics note that Congress did not limit opioid availability and 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).

Pharmacies and pharmacists, of course, are on the front line in dealing with this crisis. It is not an easy place to be, for a number of reasons.

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).

Prescription drug monitoring programs (PDMPs) like CURES appear to be useful, but the ease with which fake identification documents can be obtained can foil that check on 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>).

The 2014 rescheduling by DEA of hydrocodone combination drugs like Vicodin to Schedule II from Schedule III (www.dea.gov/diversion/usdoj/fed_regs/rules/2014/fr0822.htm) was opposed by The National Association of Chain Drug Stores and other health-care groups as ineffective in combating inappropriate opioid use but imposing costs and burdens on patients and providers. Oxycodone itself, opponents noted, was already in Schedule II, but still abused (see www.nacds.org/pdfs/pr/2013/PCF_FDA_hydro.pdf and www.pharmacist.com/hydrocodone-moved-schedule-ii-dea-final-rule).

Pharmacists must meet their corresponding responsibility with respect to these prescriptions, despite difficulties. The Pharmacy Board adopted, in August 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 and pharmacist subject to discipline ([Precedential Decision No. 2013-01](#)). The Board has posted a Corresponding Responsibility brochure online (www.pharmacy.ca.gov/publications/corresponding_responsibility.pdf), as well as a “red flags” video (www.youtube.com/watch?v=jdeQ0GeJjAM&feature=youtu.be). The Board has also proposed (see p. 222, above) enhanced controlled substance inventory requirements.

The difficult 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>). Another development was a Tennessee physician “striking back”: when her prescriptions were refused by pharmacies (while she was under investigation by the local police and the DEA, and after), she sued four pharmacies 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.*, 982 F. Supp. 2d 793 (M.D. Tenn. 2013)). One takeaway is to be careful not to defame a prescriber when refusing to fill a prescription: www.pharmacist.com/refusing-prescription-and-defaming-prescriber.

California has taken actions in response to the opioid overdose problem. A law effective in 2015 (Stats. 2014, ch. 326 (AB 1535), adding §4052.01) allows 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). Usefully, FDA has 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). Pharmacies may also furnish naloxone hydrochloride or other opioid antagonists to school authorities, if they 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 also created a Prescription Opioid Misuse and Overdose Prevention Workgroup (www.cdph.ca.gov/Programs/CCDPHP/DCDIC/SACB/Pages/StatewideOpioidSafetyWorkgroup.aspx) 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 Pharmacy Board participates in this workgroup. The Medical Board of California has created revised guidelines (www.mbc.ca.gov/licensees/prescribing/pain_guidelines.pdf) for prescribing painkillers, intended to lead to better discussions between patients and their providers and pharmacists.

The American Pharmacists Association has created an online resource center on the subject of opioid use, abuse, and misuse (www.pharmacist.com/T/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 and www.pharmacist.com/pharmacies-crosshairs-prescription-drug-crime-and-law-enforcement).

Some insurers are seeking 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)).

Lawsuits by cities and states financially impacted by the consequences of opioid addiction have been targeting the drug companies, making such claims as marketing opioids with false or misleading claims about their risks and benefits, particularly through marketing to doctors, as well as “public nuisance” claims. Plaintiffs include the states of Ohio, Illinois, Mississippi, and West Virginia, counties in New York and California, the City of Everett, WA, and the Cherokee Nation. Some suits have named pharmacy chains as defendants as well. Alana Semuels, *Are Pharmaceutical Companies to Blame for the Opioid Epidemic?* June 2, 2017, www.theatlantic.com/business/archive/2017/06/lawsuit-pharmaceutical-companies-opioids/529020/. This tactic copies that used against the tobacco companies in the 1990’s.

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. See *Emergency Medicine Associates of Jackson v Glover*, 189 So. 3d 1247 (Miss. App. 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.

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 broadened section 1703 (effective July 1, 2017) 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). A 2017 law authorizes the executive officer to issue cease and desist orders for operating a facility without a license (stats. 2017, ch. 573 (SB 800), amending §4316(a)).

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. The proposal has been modified several times; the most recent version of the guidelines is at www.pharmacy.ca.gov/laws_regs/1760_mdg_2.pdf. The regulations are undergoing review by the Department of Consumer Affairs.

Disciplinary action by another state is now a 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).

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 it. The employer may not prohibit its 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).

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’s most recent content outline for the CPJE (adopted in 2015) may be found here: http://www.pharmacy.ca.gov/forms/exam_outline_after0416.pdf.