New Drug Take-Back Rules Include Key Requirements

New regulations adopted by the Board of Pharmacy create a comprehensive framework for pharmacies that choose to provide drug take-back services for the public to safely dispose of unwanted, unused or outdated prescription medications, including controlled substances.

The board added Article 9.1, Prescription Drug Take-Back Services, to Division 17 of Title 16 of the California Code of Regulations (CCR). The new regulations, which took effect June 6, 2017, authorize pharmacies to provide take-back services in the form of on-site collection receptacles and/or mail-back envelopes or packages. Pharmacies that choose to provide collection receptacles must be registered as collectors with the U.S. Drug Enforcement Administration (DEA) and be licensed in good standing with the Board of Pharmacy.

Natomas Pharmacy in Sacramento has established a collection receptacle registered with the DEA for more than a year. It fills up pretty quickly,” pharmacist Parmjit Bains said. “We try to talk to people and go through their items and guide them before they put them in. It’s an opportunity for us to present ourselves and our business.”

Regulations for take-back services are established in CCR sections 1776 through 1776.6. CCR section 1776.1(i) requires pharmacies to notify the board in writing within 30 days of establishing a collection receptacle or ceasing to maintain a receptacle. Pharmacies also must notify the board of collection

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President’s Message
By Amy Gutierrez, PharmD
President, Board of Pharmacy

With a focus on initiatives that will further our consumer protection mandate, the board has taken action on several initiatives that impact this mission. These actions will impact patients who seek care at multiple pharmacy practice settings and are intended to improve access to safe and optimal pharmaceutical care.

Much of the board’s work is done through established committees that are chaired by a board member and focus on active discussions on a variety of critical issues that impact pharmacy practice in California. Each of our committee chairs is actively engaged in leading discussions with committee members and the public and in vetting options to improve pharmacy care throughout our state. This is done in public meetings. (Schedules and information about board and committee meetings can be found here.)

The Enforcement and Compounding Committee is in the process of reviewing current compounding regulations in light of the changing federal regulation landscape. In response to concerns regarding consumer access to compounded nonsterile products within California pharmacies, new emergency regulation language has been approved by the board to allow for the compounding pharmacist to reference published evidence to determine the beyond use date of a compounded nonsterile preparation, aligning the board’s regulation with USP (United States Pharmacopeia). This regulation is currently being vetted through the state’s regulatory process, with the goal of issuing the final regulation before the end of the year. This committee is also engaged in overseeing a pilot project operated by the University of California, San Diego, School of Pharmacy that allows for the use of automation to provide the public with increased access to pick up filled prescriptions from a remote site and is in the process of discussing potential changes to law to facilitate the use of alternate sites for safe prescription retrieval from automated dispensing devices.

The advent of our advanced practice pharmacist regulations has led to 169 licensed APh pharmacist professionals to date who are actively impacting improved patient access to care throughout our state. Recognizing the critical support that pharmacy technicians provide in our pharmacies, the Licensing Committee is in the process of reviewing the role of the pharmacy technician in today’s practice environment, focusing on potential options to further the pharmacist’s ability to utilize his or her advanced training and expertise to improve access to care.

The Legislation and Regulation Committee has had a busy year reviewing the multiple state initiatives focused on pharmacy practice. There are several bills pending the governor’s signature that will impact California pharmacy practice. The next issue of The Script will highlight the approved legislation and explain the pharmacy impact.

Recent public testimony to the board focused on the importance of accurate medication reconciliation during patient transitions of care. Patients who experience a transition of care – whether hospitalization admission/discharge, transfer to a rehabilitation facility or treatment from multiple providers – have the potential for risk due to the accuracy of their active medication list. Key to mitigating this impact is ensuring that a health care professional who is trained on the use of medications is managing the maintenance and review of these medication lists. Pharmacists, with the support of pharmacy technicians, play a key role in ensuring the accuracy of medication lists during transitions of care to safeguard patient safety. The Communication and Public Education Committee is actively working on methods to increase public and professional education and awareness regarding the pivotal role that pharmacists play in regard to ensuring the safety of the medication reconciliation process.

The changing health care environment provides for multiple opportunities to further define California pharmacy practice. We are in the midst of exciting times for the pharmacy profession, and the ongoing discussions taking place now are focused on furthering the board’s mission to promote safe and appropriate access to care across our great state. I encourage you to attend our meetings and join our discussion, as our optimal direction will be a result of active engagement with both the profession and the public.
Compounding Licenses in California: Pharmacies vs. Outsourcing Facilities

Under California law, there are two primary licenses issued by the Board of Pharmacy that permit a facility/premises to engage in compounding: a pharmacy license issued pursuant to California Business and Professions Code section 4110 et seq.; and an outsourcing facility license issued pursuant to California Business and Professions Code section 4129 et seq. This article outlines the different allowances for and restrictions on compounding for each license type under California law.¹

First, recall that under federal and California law, compounds produced in a pharmacy or an outsourcing facility would normally be treated as “new drugs,” and these entities would normally be deemed drug “manufacturers.” (See 21 U.S.C. § 321(p) [defining “new drug” as, inter alia, any drug not previously approved by the FDA]; Cal. Bus. & Prof. Code, § 4033; Cal. Health & Saf. Code, § 109970 [each defining manufacturing to include drug compounding].) This means, in theory, that absent an exception, all pharmacies and outsourcing facilities would have to meet registration and new drug requirements prior to placing any compounded “new drug” into (interstate) commerce (see, e.g., Medical Center Pharmacy v. Mukasey (5th Cir. 2008) 536 F.3d 383, 394-396), and/or that compounding pharmacies and outsourcing facilities in California would have to be identified as manufacturers. (Cal. Health & Saf. Code, § 111615.) That is, the general rule is that compounding is a species of manufacturing.

Federal law includes exemptions from some of the requirements that would otherwise apply to manufacturers for both compounding pharmacies (Section 503A; 21 U.S.C. § 353a) and outsourcing facilities (Section 503B; 21 U.S.C. § 353b). Section 503A (21 U.S.C. § 353a) provides that the adulteration (21 U.S.C. § 351(a)(2)(B)), misbranding (21 U.S.C. § 352(f)(1)), and new drug application (21 U.S.C. § 355) provisions of the federal Food, Drug, and Cosmetic Act (FDCA) will not apply to any compounded drug product “if the drug product is compounded for an identified individual patient based on the reception of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient”; or is compounded “in limited quantities before the receipt of a valid prescription order for such individual patient based on a history of receiving valid prescription orders for the compounding of the drug product, which orders have been generated solely within an established relationship between the compounder, the patient, and the prescriber.” (21 U.S.C. § 353a(a).) There are also limitations on the types of compounds that may be prepared and the methodologies that may be used for compounding. (See 21 U.S.C. § 353a(b).)

Section 503B (21 U.S.C. § 353b) similarly provides that the misbranding (21 U.S.C. § 352(f)(1)), new drug application (21 U.S.C. § 355), and transaction information (21 U.S.C. § 360eee-1) requirements of the FDCA “shall not apply to a drug compounded by or under the direct supervision of a licensed pharmacist in a facility that elects to register as an outsourcing facility” with the FDA for the purposes of compounding sterile drug products and that meets all of the requirements established by the FDA, including compliance with applicable current good manufacturing practices (cGMPs). (See Guidance for Entities Considering Whether to Register as Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act, FDA/CDER, August 2015, ("August 2015 Guidance"), p. 3.) Section 503B outsourcing facilities may not wholesale or use third parties to distribute their products. (Ibid.)

In general terms, therefore, federal law recognizes entities that are primarily engaged in patient-and-prescription-specific compounding (Section 503A facilities) and those that are primarily engaged in non-patient-specific batch compounding (Section 503B facilities). Section 503A facilities are permitted to do some anticipatory compounding “in limited quantities” based on prescription history. (21 U.S.C. § 353a(a).) Conversely, Section 503B facilities are not precluded under federal law from acquiring patient-specific prescriptions (21 U.S.C. § 353b(d)(4)(C)), though all compounding performed in a Section 503B facility must meet cGMPs. (21 U.S.C. § 353b(a)(11); 21 U.S.C. § 351(a)(2)(B); August 2015 Guidance, p. 3.) Most patient-specific compounding will take place in a Section 503A facility (typically co-licensed as a pharmacy), while most batch compounding will take place in a Section 503B facility (typically not).

California law mirrors this general division of license categories between patient-specific and non-patient-specific compounding, with pharmacies focusing on the former and outsourcing facilities being limited to the latter. (Cal. Bus. & Prof. Code, §§ 4110 et seq., 4129 et seq.) For instance, California law also generally requires receipt of a valid patient-specific prescription prior to commencement of compounding a drug preparation. (16 CCR § 1735.2, subd. (a).) California law similarly permits a pharmacy to prepare and store a “limited quantity” of compounded drug preparation prior to receipt of a patient-specific prescription “where and solely in such quantity as is necessary to ensure continuity of care for an identified population of patients of the pharmacy based on a documented history of prescriptions for that patient population.” (16 CCR

¹ This article does not constitute and should not be construed as legal advice. It is not a comprehensive analysis of state or federal law in this subject area, nor does it purport to speak for other agencies, including the California Department of Public Health Food and Drug Branch and the federal Food and Drug Administration (FDA).
Drug Take-Back
Continued from page 1

receptacles annually at time of license renewal and must identify the locations of all receptacles.

In addition, pharmacies must notify the board within 14 days of any:
► Tampering with a receptacle.
► Theft of deposited drugs.
► Tampering, damage or theft of a removed collection receptacle liner.

The board is developing suggested forms that pharmacies can use to notify the board online after installing or discontinuing a collection receptacle or in case of a drug loss from a collection receptacle. The forms will be posted on the board's website when available. Alternatively, pharmacies can submit this information in writing without using the form.

Pharmacies that provide mail-back services for disposing of prescription drugs must provide preaddressed envelopes or packages to allow a consumer to return medications directly to an authorized DEA destruction location. Additional requirements for mail-back services are set out in CCR section 1776.2.

For skilled nursing facilities, pharmacies may provide mail-back envelopes or packages for disposing of a decedent resident's unused prescription drugs. In addition, pharmacies may provide collection receptacles in skilled nursing facilities. Notification and other requirements for take-back services in skilled nursing facilities are set out in CCR section 1776.4.

Additional regulation sections establish specific requirements for other aspects of take-back services, including:
► Locating, securing and operating collection receptacles.
► Using, handling, removing and transporting liners inside collection receptacles.
► Receptacle signage.
► Reverse distributors who accept sealed liners from collection receptacles.
► Record-keeping requirements.

The full text of the new regulations for drug take-back services can be viewed here.

In addition to these regulations adopted by the board, legislation was enacted in 2016 as Civil Code section 1714.24 regarding the obligations of collectors who are authorized by and registered with the DEA to operate a collection receptacle.

As a service to consumers, the board will post and maintain a list of pharmacies that notify the board of collection receptacles. The board also currently hosts website links to the DEA's online search page for public disposal sites for prescription medications and to information about National Prescription Drug Take-Back Day events sponsored by the DEA. The next National Prescription Drug Take-Back Day is Oct. 28, 2017.

Links to these sites and other information about drug take-back services can be found on the Drug Take-Back page at the board's website.

FDA Offers Free CE Courses Online For Pharmacists, Pharmacy Technicians

The U.S. Food and Drug Administration invites pharmacists and pharmacy technicians to participate in free online webinars that provide continuing education credits.

The webinars cover a broad range of FDA drug regulations and medication safety topics. The webinars are sponsored by the FDA Division of Drug Information in the Center for Drug Evaluation and Research (CDER), which is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Information about upcoming webinars may be found online at the FDA Division of Drug Information. The next live webinar, titled “An Overview of FDA Resources,” is scheduled for Oct. 17, 2017.
Travel Medications
Continued from Page 1
diagnosable and self-treatable by
the U.S. Centers for Disease Control
(CDC). Obtaining travel medications
at pharmacies without having to see a
doctor will increase Californians’ access
to care, reduce costs, and benefit public
health and safety.

The board has added section 1746.5,
Pharmacists Furnishing Travel
Medications, to Division 17 of Title 16
of the California Code of Regulations
(CCR). The regulation specifies extensive
training requirements for a pharmacist
who furnishes travel medications:

► An immunization training
  program that meets the
  requirements of Business and
  Professions Code (BPC) section
  4052.8(b)(1).

► A travel medicine training
  program consisting of at least
  10 hours and covering each
  element of the International
  Society of Travel Medicine’s
  Body of Knowledge for the
  Practice of Travel Medicine
  (2012).

► The CDC Yellow Fever Vaccine
  Course.

► Current certification in basic
  life support.

In addition, pharmacists must complete
two hours of continuing education (CE)
training focused on travel medicine
every two years; the training must be
separate from CE in immunizations and
vaccines.

Before furnishing travel medications,
a pharmacist must perform a good
faith evaluation of the patient. The
pharmacist must evaluate the patient’s
travel history, which must include
all the information necessary for a
risk assessment during pre-travel
consultation as identified by the CDC’s
Health Information for International
Travel (commonly known as the Yellow
Book). An example of an appropriate
travel history form is available on the
board’s website.

The regulation requires the pharmacist
to notify the patient’s primary care
provider of furnished drugs or devices
within 14 days. If the patient does
not have a primary care provider, the
pharmacist must give the patient
a written record of the furnished
drugs or devices and advise the
patient to consult with a physician.
The pharmacist also must maintain
a physical or electronic patient
medication record of each furnished
medication that is readily retrievable
during normal operating hours. In
addition, the pharmacist must give the
patient a written document that reflects
the clinical assessment and travel
medication plan.

Information about travel medications,
including links to the text of CCR
section 1746.5 and a travel history form,
is available on the Travel Medications
page at the board’s website.

Board, Committee Meetings Welcome Licensees

Information about all board and committee meetings – including dates, locations,
agendas and packets of background information for agenda items – is available at
the Board of Pharmacy website.

Agendas are posted at least 10 days before each meeting. Background material for
agenda items typically is available to read and download about five days before
each meeting.

For most board meetings, pharmacists and pharmacy technicians who attend
the full-day meeting on the designated date in person may be awarded six CE hours.
No reservation is needed, but signing in and out at the meeting is required. Attendees may earn a maximum of six CE hours
per year by attending the board meeting.

Pharmacists and pharmacy technicians also may earn up to two hours of CE for attending any two different committee
meetings, up to a maximum of four CE hours per year. No reservation is needed, but attendees must arrive at the designated
start of the meeting and must sign in and out.

The last Board of Pharmacy meeting in 2017 is set for Nov. 7-8. Board meetings in 2018 are set for Feb. 6-7, May 2-3, July 24-25,
and Oct. 23-24. When feasible, board meetings are webcast and archived here.

Information about additional board meetings will be posted on the website as they are scheduled. The minutes of board
meetings also are posted online after they are approved at the next board meeting.
There are some important distinctions, however, between federal and California law. As to pharmacies, for instance, California law also contains a second allowance for compounding prior to receipt of a patient-specific prescription NOT recognized in federal law for “prescriber office use.” (See Cal. Bus. & Prof. Code, § 4052, subd. (a)(1); 16 CCR § 1735.2, subd. (c).) A pharmacy may furnish a “reasonable quantity” of compounded drug product to a prescriber for office use where: (1) the compounded preparation was ordered by the prescriber or prescriber’s agent using a purchase order or other documentation received by the pharmacy prior to furnishing that lists the number of patients seen or to be seen in the prescriber’s office for whom the drug is needed or anticipated, and the quantity for each patient that is sufficient for office administration; (2) the compounded preparation is delivered to the prescriber’s office and signed for by the prescriber or the prescriber’s agent; (3) the quantity is sufficient for administration or application to patients solely in the prescriber’s office, or for furnishing of not more than a 120-hour supply for veterinary medical practices, solely to the prescriber’s own veterinary patients seen as part of regular treatment in the prescriber’s office, as fairly estimated by the prescriber and documented on the purchase order or other documentation submitted to the pharmacy prior to furnishing; (4) the pharmacist has a credible basis for concluding the drug furnished is a reasonable quantity for office use considering the intended use of the compounded medication and the nature of the prescriber’s practice; (5) with regard to any individual prescriber, and with regard to all prescribers, the pharmacy is capable of compounding the quantity in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug product; and (6) the amount does not exceed what the pharmacy can reasonably and safely compound.

California law also permits a third scenario for pharmacy compounding NOT recognized under federal law: compounding a drug for parenteral therapy under contract with another pharmacy. (Cal. Bus. & Prof. Code, § 4123.) Under this provision, one pharmacy may enter into a contract with another to compound a drug for parenteral therapy, whereby Pharmacy A (“dispensing pharmacy”) receives the prescription and performs all dispensing functions but contracts with Pharmacy B (“compounding pharmacy”) to prepare the compound. Where such an arrangement is made, the label on the dispensed compound must clearly identify both the compounding pharmacy and the dispensing pharmacy. (16 CCR § 1735.4, subd. (a)(1).) Contract compounding is solely patient-specific compounding, and is not anticipatory compounding. (See Cal. Bus. & Prof. Code, § 4123 (“pursuant to a prescription . . . ”); 16 CCR. § 1735.2, subd. (a).) In other words, Pharmacy B may only begin compounding upon receipt of a patient-specific prescription from Pharmacy A. Also, Pharmacy B may not consider the patients for whom it prepares compounds under contract with Pharmacy A to be its “own patients” for purposes of anticipatory compounding. (16 CCR § 1735.2, subd. (b).) Those patients could only be considered Pharmacy A’s “own patients,” in the event it decided to do its own compounding.

Finally, California also permits a fourth type of pharmacy compounding that has no equivalent under federal law: utilizing a “centralized hospital packaging” license. (Cal. Bus. & Prof. Code, § 4128 et seq.) A specialty license issued to a centralized hospital packaging pharmacy permits it to engage in unit dose packaging and preparation of compounded unit dose drugs for administration to inpatients within its own general acute care hospital AND “one or more general acute care hospitals if the hospitals are under common ownership and located within a 75-mile radius of each other.” (Cal. Bus. & Prof. Code, § 4128, subd. (a).) For inpatients of the general acute care hospital in which it is housed and any general acute care hospitals under common ownership within 75 miles, a licensed centralized hospital packaging pharmacy may prepare unit dose packages for single administration to inpatients from bulk containers, with barcodes for bedside administration; and prepare sterile and non-sterile compounded unit dose drugs for administration to inpatients, again with barcodes for bedside administration.

As to outsourcing facilities, California law more closely conforms to federal law. Indeed, it is a prerequisite for licensure as an outsourcing facility in California that a facility be registered with the FDA as an outsourcing facility. (Cal. Bus. & Prof. Code, §§ 4129 (resident), 4129.2 (nonresident).) However, while federal law simply states that an outsourcing facility is not required to be licensed as a pharmacy (21 U.S.C. § 353b(d)(1)(4)(B)), California law actually prevents a single premises from being issued more than one site license (Cal. Bus. & Prof. Code, § 4107 [exceptions not applicable here]) and specifies that a sterile compounding pharmacy may not be concurrently licensed as an outsourcing facility at the same location. (Cal. Bus. & Prof. Code, § 4129, subd. (b).) In other words, California law prevents co-licensure at a single location. California law also prohibits an outsourcing facility from performing any pharmacy functions, including filling individual patient-specific prescriptions. (Id., subd. (e).) Therefore, a premises that might otherwise qualify for either a pharmacy license or an outsourcing facility license must elect.

2 As such, the board can offer no assurance to any pharmacy relying on this allowance that “prescriber office use” compounding will be tolerated by federal authorities, including the FDA.
3 As such, the board can offer no assurance to any pharmacy relying on this allowance that contract compounding will be tolerated by federal authorities, including the FDA.
4 As such, the board can offer no assurance to any pharmacy relying on this allowance that centralized hospital packaging pharmacy compounding will be tolerated by federal authorities, including the FDA.
State Court Holds Pharmacist “Strictly Liable”

Board Wins Key Ruling in Disciplinary Case

The California State Board of Pharmacy prevailed in a state court of appeal case against a pharmacist who appealed the board’s disciplinary decision affecting his license in Sternberg v. California State Board of Pharmacy (239 Cal. App. 4th 1159 (2015)). The case involved substantial controlled substance losses over a substantial period of time under the pharmacist’s supervision. Most significantly, the court held that a pharmacist-in-charge could be held “strictly liable” for violations of Pharmacy Law by a subordinate even without actual knowledge of the wrongdoing.

Summary of Case

The case involved a pharmacist-in-charge (PIC) of a West Hills, California, community pharmacy of a chain store. An employee of the pharmacy, a pharmacy technician, ordered and then stole, over 216,000 Norco tablets with an estimated retail value of $325,000 and a street value of nearly $1.1 million. The theft took place over a two-year period, from Sept. 1, 2006, through Aug. 31, 2008. The pharmacy’s ordering system allowed anyone with an access code to order from anywhere. The technician was authorized to place orders with the manufacturer and even did so from her home. She had a pattern of ordering six bottles of 500 tablets of Norco at a time; she did this about 85 times over approximately two years.

Although in most cases a pharmacist signed for the delivery, the technician signed for three deliveries herself. Even when the PIC did sign for the delivery, he acknowledged he did not review the contents, counting only the number of bottles received and matching that to the delivery log that was provided, which did not contain the names of the drugs. The PIC’s practice was to then hand the delivery to a technician for further handling. In this case, one particular technician would collect the delivery, go to a far corner of the pharmacy, hide the bottles in the store room, and destroy the invoices. When no pharmacist was on duty (for the pharmacist’s lunch or break), the technician would then take three bottles at a time, place them in her purse and take them out to her car.

The PIC acknowledged that he “never” looked at the invoices as they arrived and did not check them against the drugs received. Invoices were not reviewed regularly by a pharmacist, nor were they audited. Only “occasionally” were the invoices reviewed, typically to look for a specific drug to see if it came in for a particular patient. Review or audit information would have been particularly insightful because the pharmacy did not usually dispense Norco. The pharmacy’s corporate office also failed to notice that it was paying for drugs for which it did not have related sales or income. Eventually, the PIC found a bottle of Norco while looking through the store room, became suspicious and alerted corporate management. The corporate office initiated a loss prevention investigation. The employee was eventually caught on surveillance and arrested with 3,000 stolen Norco tablets.

Disciplinary Action by the Board

Based on these incidents, the board filed an accusation against both the pharmacy and PIC. After considering the record of the case, the board described the scope of the theft as “staggering.” The board found violations of law and cause to discipline the pharmacist on several grounds. Specifically, the board found:

1. The pharmacist violated the law in that, as PIC, his failure to adequately supervise the technician contributed to the pharmacy’s resulting failure to maintain accurate records, even if the drugs were stolen out of his presence and without his knowledge or approval (Bus. & Prof. Code §§ 4300, 4301, subds. (j) and (o), in conjunction with §§ 4005, 4081 and Cal. Code Regs., tit. 16, § 1718).

2. The pharmacist violated the law in that, as PIC, he failed to maintain the records described above or a current inventory for three years, even if the drugs were stolen out of his presence and without his knowledge or approval (Bus. & Prof. Code § 4081(a)).

3. The pharmacist violated the law in that, as PIC, he allowed, through the absence of effective supervision, the technician to sign for and accept delivery of dangerous drugs, even if he was not on duty when the technician did so (Bus. & Prof. Code § 4095.5(a)).

4. The pharmacist violated the law in that, because he was directly responsible for the acts of the technician, and when she violated the law, so did he (Bus. & Prof. Code § 4115(h)).

5. The pharmacist violated the law in that, as PIC, he failed to maintain the pharmacy facility, space, fixtures and equipment so that drugs were “safely and properly prepared maintained and secured,” in this case from diversion or theft (Cal. Code Regs., tit. 16, § 1714(b)).

6. The pharmacist violated the law in that he failed to secure the prescription department and provide effective controls to prevent the technician’s theft, because he failed to provide easily available and effective controls to prevent the theft, such as: a) limiting an employee’s access to the pharmacy’s account code numbers and the location from which orders could be placed, and auditing the orders by checking the invoices against the orders that were placed; b) looking at the invoices being taken out of the delivery container or checking the invoices against the drugs received; c) closing the pharmacy when no pharmacist was present or instituting security measures to ensure adequate supervision;

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New Regulation Delegates Authority To Executive Officer for Certain Functions

The Board of Pharmacy has formally delegated authority to its executive officer to approve non-substantive, regulatory changes without the need for a board vote and to approve prescription label waivers in accordance with Business and Professions Code (BPC) section 4076.5(e).

The board adopted an amendment to Title 16, California Code of Regulations (CCR) section 1703 to give the executive officer authority to approve regulation changes that are deemed to be “without regulatory effect” pursuant to Title 1, CCR section 100. The amendment to CCR section 1703 took effect July 1.

The new regulation also enables the executive officer to approve requests for waivers from requirements for patient-centered, prescription drug labels pursuant to BPC section 4076.5(e). Previously, applicants were required to appear before the Communication and Public Education Committee to request a waiver, which then had to be ratified by the full board.

The goal of amending CCR section 1703 is to improve the efficiency of board operations and thereby improve its ability to protect consumers. Delegating authority to the executive officer for certain functions will shorten the time needed to initiate rulemakings and allow changes to take effect in a more timely manner.

Samples of Changes to Prescription Labels Posted Online

Samples of patient-centered, prescription drug labels that incorporate recent regulatory changes are now posted on the Board of Pharmacy website.

The revised labeling standards are based on a recent amendment to Title 16, California Code of Regulations (CCR) section 1707.5 that slightly changes the requirements for prescription drug container labels. The regulation amendment took effect July 1.

Under the regulation change:

1. In addition to the prior requirement to list the generic name of the drug in the patient-centered area, labels for generic medications must now also state “generic for __________”, with the brand name inserted in the blank. If, however, in the professional judgment of the pharmacist, the brand name is no longer widely used, the patient-centered portion of the label may list only the generic name of the drug.

2. The prior requirement to list the manufacturer’s name in the patient-centered area of the label still exists. However, if it is determined appropriate in the professional judgment of the pharmacist, the manufacturer’s name may now be listed outside the patient-centered area of the label.

The samples can be found on the Prescription Label page at the board’s website. The webpage also has information about translations of directions for use on labels and best practices for making labels accessible to blind, visually impaired or elderly patients.
AB 602 Targets Unlawful Sales Of Nonprescription Diabetes Test Devices

Assembly Bill 602 (Bonta, Chapter 139, Statutes of 2017), which adds provisions regarding sales of nonprescription diabetes test devices to California pharmacy law, was signed into law by Gov. Edmund G. Brown Jr on July 31, 2017, and took effect immediately in order to prevent the sale of such devices that may have been tampered with or improperly stored.

AB 602 generally defines a “nonprescription diabetes test device” as a glucose meter or test strip used in the treatment of prediabetic or diabetic individuals. The law requires pharmacies that dispense these products pursuant to prescriptions to retain records of their acquisition and sale for at least three years.

The law also requires manufacturers of the nonprescription diabetes test devices to post the names of their authorized distributors on the internet and to make the names available to the Board of Pharmacy for posting on the board’s website. Names of authorized distributors are posted online here.

In addition, AB 602 authorizes the board to embargo nonprescription diabetes test devices that were not purchased directly from the manufacturer or an authorized distributor. The law also makes it unprofessional conduct for a licensee to purchase such devices from an unauthorized distributor or to seek reimbursement for such devices that were not purchased from authorized sources.

According to a bill analysis by the Assembly Business and Professions Committee, “In recent years, the acquisition and resale of diabetic test strips has become big business for those participating in the gray and black market. The authorization of the Board to pursue this kind of activity is intended to curtail the resale and counterfeiting of diabetes test strips to turn a profit via manufacturer and Medicare reimbursements.”

Licensees Must Complete Self-Assessment Forms

Licensees are reminded that by July 1 of each odd-numbered year, Title 16 of the California Code of Regulations (CCR) requires that self-assessment forms be completed by all pharmacies (section 1715), compounding pharmacies (section 1735.2(k)) and wholesalers (section 1784).

The regulations require pharmacies, compounding pharmacies and wholesalers to complete current versions of the self-assessment forms. However, the board is in the process of updating the forms through a formal rulemaking to include statutory and regulatory changes that have occurred through 2016.

Therefore, the 2016 draft versions are likely to be a more helpful than the current (required) versions done in 2014. However, either version of the forms may be used to meet the July 1 deadline.

Links to both the required 2014 version and the 2016 draft version of the self-assessment forms can be found at the Board of Pharmacy website here.

Completed self-assessment forms must remain on file at the facility and must be made available to inspectors upon request. They should be submitted to the board only if requested by board staff.

Note that the respective regulations also require pharmacies, compounding pharmacies and wholesalers to complete new self-assessment forms within 30 days whenever:

- A new license is issued.
- There is a change in the pharmacist-in-charge or designated representative-in-charge.
- There is a change in the facility address.

A law that took effect July 1, 2017, requires pharmacists, pharmacy technicians, intern pharmacists and designated representatives to join the Board of Pharmacy email notification list within 60 days of obtaining a license or at the time of license renewal. In addition, licensees must update their information within 60 days of changing their email address.

Signing up is easy! To sign up online for electronic notices from the board, click here.

The board will remind licensees of the email requirements with each renewal application. Under the provisions of the new law – Business and Professions Code section 4013 – email addresses will not be posted on the board’s online verification system.
Drug Supply Chain Security Act Requires Tracking, Tracing

The Drug Quality and Security Act (DQSA) was signed by President Barack Obama on Nov. 27, 2013, and is composed of two titles: The Compounding Quality Act (CQA) and the Drug Supply Chain Security Act (DSCSA).

When signed into effect, the DSCSA created national traceability requirements of pharmaceuticals throughout the supply chain and pre-empted all state requirements that differed from the federal requirements. Additionally, the DSCSA called for the implementation of a new electronic, interoperable system for product tracking over a 10-year period from the date it was signed. The requirements applied to all parties involved in the drug supply chain, such as manufacturers, wholesalers, third-party logistics providers (3PLs), dispensers and repackagers.

Most prescription drugs in their finished dosage forms intended for administration to patients without further manufacturing are included under the DSCSA, such as capsules, tablets, lyophilized products prior to reconstitution, etc. However, certain products are excluded from the DSCSA requirements, including – but not limited to – the blood or blood components intended for transfusion, radioactive drugs or biologics, imaging drugs, certain intravenous products, medical gases, homeopathic drugs and lawfully compounded drugs.

According to section 202 of the DSCSA, a “dispenser” is defined as a retail pharmacy, hospital pharmacy, a group of chain pharmacies under common ownership and control that do not act as a wholesale distributor, or any other person authorized by law to dispense or administer prescription drugs. The section does not include a person who dispenses products to be used in animals.

Whenever a transfer of product occurs between persons in which there is a change of ownership – for example, a transfer between a dispenser and a wholesaler – the requirements outlined in the DSCSA must be followed.

One such requirement of the DSCSA is the exchanging of product tracking and tracing documentation. Product tracking and tracing documentation consists of the following: transaction information (TI), transaction history (TH) and transaction statement (TS).

Transaction information refers to the product description and includes:

- Proprietary or established name or names of the product.
- Strength and dosage form of the product.
- National Drug Code number of the product.
- Container size.
- Number of containers.
- Lot number of the product.
- Date of the transaction.
- Date of the shipment, if more than 24 hours after the date of the transaction.
- Business name and address of the person from whom ownership is being transferred.
- Business name and address of the person to whom ownership is being transferred.

Transaction history is a statement including the transaction information for each prior transaction going back to the manufacturer of the product. Transaction statement is a statement that the entity transferring ownership in a transaction:

- Is authorized as required under the law.
- Received the product from a person that is authorized under the law.
- Received the required transaction information and a transaction statement from the prior owner of the product.
- Did not knowingly ship a suspect or illegitimate product.
- Had systems and processes in place to comply with the verification requirements under the law.
- Did not knowingly provide false transaction information.
- Did not knowingly alter the transaction history.

It is important to note that the product tracking and tracing documentation may be maintained in either paper or electronic formats.

According to the DSCSA, a dispenser shall not accept ownership of a product unless the previous owner provides the necessary tracking and tracing documentation. Each transaction in which the dispenser transfers ownership of a product shall provide the subsequent owner with tracking and tracing documentation. However, the requirements do not apply to sales by a dispenser to another dispenser to fulfill a specific patient need or dispensing directly to a patient. Transaction information, transaction history and transaction statements must be maintained for not less than six years after the transaction.

All those involved in the drug supply chain must be able to respond to any verification requests from the Secretary of Health and Human Services about suspect products. Dispensers shall provide applicable tracking and tracing documentation no later than two business days (or as determined

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d) conducting random checks of the containers that he signed for, the invoices or the orders coming in; or adding loss prevention practices, such as secured equipment for the storage of drugs; e) performing some random audits of drug deliveries that he signed for; conducting audits or review of staff's work, including ordering and unpacking drugs; and actively participating in checking inventory as well as the drugs delivered to the pharmacy (Cal. Code Regs., tit. 16, § 1714(d)).

As a consequence of these violations, the pharmacist's license was subject to a stayed revocation, and he was placed on probation for three years under certain conditions. Prior to this incident, the pharmacist had no history of discipline.

In a prior, separate proceeding, the pharmacy's license was also subject to a stayed revocation, and placed on probation for five years under terms and conditions. In making its decision against the pharmacist, the board acknowledged the culpability of the pharmacy at a corporate level as well.

**California Superior and Appellate Court Decisions**

The pharmacist disagreed with the board's discipline against his license, arguing that because he had no subjective knowledge of the technician's actions, including the theft, he could not be responsible for failing to keep records and inventory about it. He also argued that he had no duty to randomly audit invoices and keep scheduled drugs in a locked area, and that he had no duty to perform a random audit of drug deliveries, check staff work, and participate in checking inventory delivered to the pharmacy.

The pharmacist appealed the board's imposition of discipline to superior court. When the superior court upheld the board's discipline, the pharmacist appealed again, to the court of appeal. The court of appeal concluded that Business and Professions Code section 4081, understood in combination with a pharmacist-in-charge's responsibility for pharmacy compliance (Bus. & Prof. Code, § 4113, subd. (c)) and the board's obligation to protect the public (Bus. & Prof. Code, § 4001.1), did not require “knowledge” to impose discipline for inaccurate inventory or recordkeeping; that imposing “strict liability” was proper in this context; that the PIC's failure to restrict access to the ordering passcode or adequately control or audit telephone ordering formed a sufficient basis to find and discipline him for failure to adequately secure pharmacy facilities and equipment; and that the PIC's failure to control or audit orders, or to implement other procedures such as random audits or checks to avert theft, formed a sufficient basis for the board to find and discipline him for failure to secure the prescription department and to provide effective controls against theft or diversion of dangerous drugs and devises.

It is important to note that “strict liability” does not mean that the consequence of a violation is outright revocation or that there will always be the exact same enforcement consequence for a violation. The board considers each enforcement matter individually and, based on the mitigating and aggravating facts and circumstances, determines how to proceed. Enforcement action is not taken lightly, but it is taken mindfully pursuant to the board's mandate for public protection and, of course, with all due process.

**Conclusion**

The appellate court's ruling and decision are important because they provide guidance to pharmacists-in-charge in carrying out their responsibilities. They also protect the public and assist the board in ensuring pharmacist compliance by ensuring pharmacists and pharmacies are appropriately monitored to prevent risks to the public, including those associated with lost or stolen drugs. This reinforces the board's mission: “The Board of Pharmacy protects and promotes the health and safety of Californians by pursuing the highest quality of a pharmacist's care and the appropriate use of pharmaceuticals through education, communication, licensing, legislation, regulation and enforcement.”

California's 2nd District Court of Appeal, which issued the decision, ordered that the decision be "published," meaning that California trial courts are bound by this decision and it may be referenced or cited by other courts as a persuasive interpretation of the law.

Similarly, the board itself unanimously voted to designate its findings and legal conclusions in the underlying administrative decision (Case No. 3377, Decision After Reconsideration) as precedential pursuant to Government Code section 11425.60. The board is in the process of completing the formal requirements and will post additional information on its website as part of that process.

Information about this case, including a summary and the appellate court's decision, can be found on the board's website here.
DEA Clarifies Rules on Transferring Unfilled Electronic CS Prescriptions

The National Association of Boards of Pharmacy recently released information from the U.S. Drug Enforcement Administration clarifying federal regulations regarding the transfer of unfilled electronic prescriptions for controlled substances.

The information printed below was sent to NABP by Loren T. Miller, associate section chief of the Liaison and Policy Section in the Diversion Control Division at DEA:

The Controlled Substances Act and its implementing regulations outline what can take place regarding prescriptions for controlled substances. In Title 21, Code of Federal Regulations, Section 1306.25 the DEA made a specific exception so that a DEA registered pharmacy can, once it has filled an original prescription for a controlled substance in Schedules III-V, transfer the original prescription information to another DEA registered pharmacy for the purpose of allowing that second pharmacy to then dispense any remaining valid refills still permitted by law and the prescriber’s authorization. With one exception, such an allowance currently does not exist for the forwarding of an unfilled prescription from one DEA registered retail pharmacy so that it may be filled at another DEA registered retail pharmacy.

Prescriptions can take the form of paper (including fax), call-in, or electronic prescription for controlled substances (EPCS). The DEA has addressed the forwarding of an EPCS prescription. The DEA published information in the preamble of the notice of proposed rulemaking (NPRM) on EPCS, 73 FR 36722, and the preamble of the interim final rule (IFR) on EPCS, 75 FR 16235. Note, because this was in the preamble and not in the EPCS regulations, it represents the DEA’s policy. As posted in the preambles of the NPRM and the IFR, an unfilled original EPCS prescription can be forwarded from one DEA registered retail pharmacy to another DEA registered retail pharmacy, and this includes Scheduled II controlled substances.

At the start of 2017, the DEA received inquiries from some pharmacists regarding this issue. The DEA was advised that these pharmacists had received notice from their management that they could not forward original unfilled prescriptions for controlled substances as there was no exception in federal regulation that expressly allowed this activity. The pharmacists were provided with the above information. Although DEA received several inquiries regarding this issue earlier in the year, these have now ceased.

Pharmacists Attend CE Training Co-Sponsored by Board, DEA

More than 160 pharmacists received training on prescription drug abuse and drug diversion at an Aug. 26, 2017, education event co-sponsored by the Board of Pharmacy and the U.S. Drug Enforcement Administration.

Pharmacists also received six hours of CE credit for attending the daylong event hosted by the California Northstate University College of Pharmacy in Elk Grove. At least 150 participants earned an extra CE credit for attending additional training required by the California protocol for providing naloxone.

The event was the second training in 2017 jointly sponsored by the board and DEA. The next training is set for Oct. 21, 2017, at Keck Graduate Institute in Claremont. Registration information is available at the board’s website.
Questions? Ask an Inspector!

The Board of Pharmacy welcomes questions from licensees related to pharmacy laws and regulations.

Note that board staff and inspectors cannot provide legal advice. However, they can identify laws and regulations that may help you find answers to your questions. If you need legal advice, you are advised to contact a lawyer.

You may ask a question by email, fax or phone. Inspectors are available to answer questions by phone on Tuesday and Thursday.

- Email: ask.inspector@dca.ca.gov. Please include your name, organization, phone number and the best time to reach you.
- Fax: (916) 574-8618.
- Phone: (916) 574-7900 from 8 a.m. to 4:30 p.m. Tuesday and Thursday.

Inspectors are often asked questions about key laws and regulations that apply to reporting losses of controlled substance drugs due to loss or theft.

Relevant laws and regulation are:

- **Title 16, California Code of Regulations (CCR) section 1715.6.**
- **California Business and Professions Code (BPC) section 4104(c)(2).**
- **Title 21, Code of Federal Regulations (CFR) section 1301.76(b).**

Federal regulations require that registrants notify the DEA Field Division Office in their area in writing of the theft or significant loss of any controlled substance within one business day of discovery. The registrant must also complete and submit to the Field Division Office in their area DEA Form 106, “Report of Theft or Loss of Controlled Substances.”

A Board of Pharmacy regulation requires a pharmacy to report any loss of a controlled substance to the board within 30 days of discovery.

Business and Professions Code section 4104(c)(2) requires every pharmacy to report any licensee’s admission of theft, diversion or self-use of a dangerous drug to the board within 14 days.

Therefore, any loss of a controlled substance must be reported to the board within 30 days of discovery, while any theft or significant loss of a controlled substance must be reported to the DEA within one business day of discovery. But the loss of any dangerous drug – not limited to controlled substances – due to theft, diversion or self-use by a licensee must be reported to the board within 14 days.

Butler, Veale Reappointed to Board

Gov. Edmund G. Brown Jr. has reappointed Lavanza “Kercheryl” Butler and Deborah Veale as licensee members of the California State Board of Pharmacy.

Ms. Butler was appointed to the board in February 2013 and was reappointed in July 2013.

She has been with the United Food and Commercial Workers International Union Local 770 as a pharmacist, vice president and union representative since 2002. She also was a head pharmacist at Rite Aid Pharmacy for 22 years.

Ms. Butler earned her pharmacy degree in 1975 from Xavier University in New Orleans and is a member of the California Pharmacists Association and the United Food and Commercial Workers Professional Division.

Ms. Veale was appointed to the board in 2010 and reappointed in 2013.

She has been director of payer relations for CVS Pharmacy since 2006. Previously, she served in several positions with Albertsons/Sav-On Drugs. She is a member of the California Pharmacists Association, National Council of Prescription Drug Programs and California Retailers Association.

Ms. Veale also serves on the editorial review committee for the California Pharmacist Journal. She earned her pharmacy degree from the University of Iowa College of Pharmacy.

Terms for both reappointed board members will expire in June 2021.
Oral Chemotherapy Drugs Require Safe Handling, Disposal

By Michael Phan, Thien Huynh, Ani Haroutunyan, Esther Shin, Alexandra Corcoran, Priya Patel, Sun Coco Yang and Siu Fun Wong.

Phan, Huynh, Haroutunyan, Shin, Corcoran and Patel are PharmD candidates at Chapman University School of Pharmacy. Yang is an assistant professor of pharmacy practice, and Wong is a professor of pharmacy practice and an associate dean at Chapman University.

Since its introduction in the 1940s, oral chemotherapy (OC) has been steadily growing in popularity among cancer patients and providers. Approximately 25 percent of novel chemotherapy agents in development are oral agents, and these numbers are expected to continue increasing[1]. This burgeoning development of OCs can be attributed to the unique advantages of OCs over intravenous medications. They are less invasive and allow for self-medication in the home setting, which improves the quality of life of oncology patients[2].

Similar to their intravenous counterpart, OC agents carry the same hazardous risks for carcinogenicity, reproductive toxicity, and genotoxicity[3]. Improper handling in the home setting results in unintentional cross contamination among friends, family and caregivers through contact with clothing, medical equipment or patient excrement. Studies show that OCs are generally misperceived to be less toxic than parenteral chemotherapy medications among patients, caregivers and even healthcare providers[4]. This may contribute to increased risk of cross contamination and improper disposal without adequate education. Improper disposal of non-hazardous medications has brought growing concerns in recent years for its impact on the environment. The hazardous nature of OCs, with the added complexity of their inactivation mechanisms and procedures, heighten their environmental effect[5,6]. Accidental leakage into our environment might not only affect the health of our generation, but also of many future generations.

Emerging evidence from data collected by water treatment centers has revealed an increase of drug contamination in the U.S. water systems[5-7]. Currently, standard wastewater processes are inadequately equipped to filter out medications, especially harmful medications such as OCs[5-7]. Although the documented concentration is miniscule, insufficient filtration methods can cause significant cumulation of medications, increasing long-term exposure risk[5-7].

Currently, USP<800>, ASHP (2006), ASCO (2013) and ONS (2013) provide strict guidelines for handling and disposing of hazardous drugs in the hospital setting. However, when it comes to the home setting, where OCs are primarily being administered, there are still notable gaps. In contrast, institutions in both Canada and Australia have developed robust systems for oral chemotherapy handling[8,9]. Not only do they have guidelines for their patients, but they also provide their patients with the option to return unused or leftover oral chemotherapy for disposal. In Canada, patients are even encouraged to return their empty containers, which may possess the hazardous residues, for safe disposal[10].

In California, the Safe Drug Disposal Ordinance has been established in Alameda County following a Supreme Court ruling, making the local manufacturers financially responsible for the safe collection and disposal of unused medication[10,11].

Exelixis, a drug manufacturer, implemented a mail-back program to dispose of their unused or expired OC medications (Cabometyx/Cometriq). Following Alameda, more cities throughout California have begun to establish similar product stewardship programs to improve safe disposal of medications[10].

In an effort to address this serious public health issue, we intern pharmacists at Chapman University School of Pharmacy (CUSP) have begun an advocacy initiative to assess the current knowledge and practice of handling and disposing of oral anticancer chemotherapy drugs by patients, caregivers, providers, and pharmaceutical industries through survey research. We expect to identify potential barriers that cause gaps in knowledge, practice, and awareness of proper handling and disposal of OCs. Upon completion of our study, we hope to propose a practical solution by formulating an educational and practice model involving all stakeholders.

We recently proposed to a California State Board of Pharmacy committee the addition of a required standardized “hazardous drug” symbol to the OC prescription label that may help to:

1. Promote easy identification of these drugs that require special handling.
2. Remind patients and caregivers of the need for special handling and disposal of these medications, reducing the risks of cross contamination in the home environment and public domain.
3. Serve as a reminder for pharmacists to provide specific counseling and education to patients and/or their caregivers.

Our group will continue to work closely with the board to devise an optimal approach to translate this initiative into practice. We hope this article will serve as our first step to promote awareness and broaden our education effort to our profession.
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References:


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reasonable by the Food and Drug Administration) after receiving the request and may respond in paper or electronic format.

The timeline for the DSCSA is as follows:

► Nov. 27, 2013: DSCSA signed into law by President Obama.
► Jan. 1, 2015: Manufacturers and distributors send and receive tracking and tracing documentation. Suspect and illegitimate product requirements became effective. Trading partners must be authorized.
► July 1, 2015: Dispensers receive tracking and tracing documentation and shall keep documentation for six years.
► Nov. 27, 2015: National standards established for tracking and tracing documentation in paper and electronic format. Guidance documents published by FDA.
► Nov. 27, 2017: Manufacturers shall have all products serialized. (Note: Pending guidance from the FDA could delay this requirement until Nov. 27, 2018.)
► Nov. 27, 2018: Repackers shall have all products serialized.
► Nov. 27, 2019: Wholesale transactions shall only occur with serialized products.
► Nov. 27, 2020: Pharmacy lot-level traceability required. Dispenser transactions shall only occur with serialized products.
► Nov. 27, 2023: Unit-level traceability required.

The board encourages pharmacies and drug distributors to become familiar with these requirements.

Reference:
► Drug Supply Chain Security Act (Public Law 113-54)
Board Honors 50-Year Pharmacists

The Board of Pharmacy honors these registered California pharmacists who have been on active status for at least 50 years. The board gratefully acknowledges their years of contribution to the pharmacy profession.

Pharmacists who recently received a certificate commemorating 50 years of service and were invited to be publicly recognized at a board meeting are:

- Alm, Arthur Walter Jr. Livermore, CA
- Andersen, Alan William Incline Village, NV
- Bertagnolli, Gary L. Winters, CA
- Brodsky, James Michael Villa Park, CA
- Coates, Yolanda Roberta Arcadia, CA
- Crosetti, John Dominic La Jolla, CA
- Delamater, Terry Alfred Bakersfield, CA
- Dickerson, Edwin Graff Pleasanton, CA
- Galanta, Terrie K. Anaheim Hills, CA
- Gosney, Kenneth Lee Carmichael, CA
- Hanna, Claudia Jo Napa, CA
- Hewitson, Louis Francis San Diego, CA
- Jacobsen, James Edward Diamond Bar, CA
- Jue, Richard Kern San Rafael, CA
- Lampshire, Lyle W. Gold River, CA
- Lee, Nancy Lowe Los Altos, CA
- Macmillan, John Kerr Los Angeles, CA
- McLarney, Patrick Joseph Salinas, CA
- McNichol, Lowell Evan Petaluma, CA
- Nelson, Henry Hjalmar Carmichael, CA
- Paper, Michael David Stockton, CA
- Phillips, Roy Bruce Napa, CA
- Quan, Wilbur Lake Elsinore, CA
- Rosenthal, Andrew Sidney San Antonio, TX
- Spolar, Ronald August Meridian, ID
- Takemoto, Gordon Hirokaz Loomis, CA
- Takeuchi, Roy Mamoru Stockton CA
- Toy, Ronald Modesto, CA
- Witherwax, Dennis Clayton Anaheim, CA

Peter B. Perrin
Steve Saylor
Explanation of Disciplinary Terms

**Accusation Filed** – An accusation is the document containing the charges and allegations of violations of the law that is filed when an agency is seeking to discipline a licensee.

**Effective Date of Action** – The date the disciplinary action goes into operation.

**Revocation or Revoked** – The license is canceled as a result of disciplinary action by the board, and the licensee’s right to practice or operate a board-licensed entity is ended.

**Voluntary Surrender** – The licensee has agreed to surrender his or her license, and the right to practice or operate a board-licensed entity is ended. The board may agree to accept the surrender of a license through a “stipulation” or agreement.

**Suspension** - The licensee is prohibited from practicing or operating a board-licensed entity for a specific period of time.

**Suspension/Probation** - The licensee is prohibited from practicing or operating for a specific period of time and the right to practice or operate is contingent with specific terms and conditions during the probationary period.

**PC 23 Order Issued** - The licensee is restricted from practicing or operating by the terms of court issued under the provisions of Penal Code section 23.

**Public Reprimand** – Resulting from a disciplinary action, the licensee is issued a letter of public reprimand.

**Reinstatement of License** – A previously revoked or suspended license is reinstated with or without specified terms and conditions.

**Statement of Issues** – A legal document that details the factual or legal basis for refusing to grant or issue a license.

Disciplinary Actions

**Pharmacy Technician**
Acosta, Philip Anthony, TCH 99539,
Administrative Case AC 5798
Sanger, CA
Through a disciplinary action of the Board, the license is voluntarily surrendered.
View the decision

Blackham, Jodie Lee, TCH 111855,
Administrative Case AC 6048
Tulare, CA
Through a disciplinary action of the Board, the license is revoked and canceled and the right to practice or operate has ended.
Decision effective 4/20/2017.
View the decision

Castillo, Alicia, TCH 130425,
Administrative Case AC 5597
Lancaster, CA
Through a disciplinary action of the Board, the license is revoked and canceled and the right to practice or operate has ended.
Decision effective 6/22/2017.
View the decision

Chavez, Alvaro Saul Cano, TCH 135702,
Administrative Case AC 5705
Chula Vista, CA
Through a disciplinary action of the Board, the license is voluntarily surrendered.
Decision effective 4/14/2017
View the decision

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Escoria, Florentino, TCH 89588, Administrative Case AC 5844
Big Bear City, CA
Through a disciplinary action of the Board, the license is revoked and the revocation is stayed, and the license is placed on probation for five years and is subject to the terms and conditions in the decision.
Decision effective 5/10/2017.
View the decision

Gil, Elizabeth, TCH 76948, Administrative Case AC 5699
Los Angeles, CA
Through a disciplinary action of the Board, the license is subject to a public reprimand.
View the decision

Hamlin, Alyssa Michelle, TCH 124537, Administrative Case 5831
Morgan Hill, CA
Through a disciplinary action of the Board, the license is revoked, the revocation is stayed, and the licensee is placed on probation for three (3) years, suspended from practice, pending certification and is subject to the terms and conditions in the decision.
Decision effective 6/7/2017.
View the decision

Hernandez, Brianna Lina, Applicant, Statement of Issues Case SI 5902
Sacramento, CA
Through a disciplinary action of the Board, the Application for Pharmacy Technician Registration is granted.
Upon satisfaction of all statutory and regulatory requirements, the license is issued, immediately revoked, the revocation stayed, and respondent is placed on probation for five years subject to the terms and conditions in the decision.
Decision effective 4/7/2017.
View the decision

Hernandez, Steven, TCH 145922, Administrative Case AC 6027
Alhambra, CA
Through a disciplinary action of the Board, the license is revoked and canceled and the right to practice or operate has ended.
View the decision

Hoorfar, Rana, TCH 98206, Administrative Case AC 4919
Woodland Hills, CA
Through a disciplinary action of the Board, the license is voluntarily surrendered.
Decision effective 6/7/2017.
View the decision

Howard, Alex Demoye, Applicant, Statement of Issues Case SI 5871
Moreno Valley, CA
The application for pharmacy technician registration is denied.
Decision effective 4/20/2017.
View the decision

Kirksey, Erin Anne, TCH 65835, Administrative Case AC 5815
Hesperia, CA
Through a disciplinary action of the Board, the license is revoked, the revocation is stayed, and the license is placed on probation for three years and is subject to the terms and conditions in the decision.
Decision effective 5/24/2017.
View the decision

Labiak, Brittany Jane, TCH 137467, Administrative Case AC 5970
Whittier, CA
Through a disciplinary action of the Board, the license is revoked and canceled and the right to practice or operate has ended.
Decision effective 6/7/2017.
View the decision

Mendoza, Ezequiel, TCH 105387, Administrative Case AC 5601
Salinas, CA
Through a disciplinary action of the Board, the license is revoked and canceled and the right to practice or operate has ended.
Decision effective 5/17/2017.
View the decision

Mussell, Cheryl Ann, TCH 135012, Administrative Case AC 5709
Quincy, CA
Through a disciplinary action of the Board, the license is revoked and canceled and the right to practice or operate has ended.
Decision effective 6/7/2017.
View the decision

Osuna, Alicia Andrea, TCH 137137, Administrative Case AC 5876
Hemet, CA
Through a disciplinary action of the Board, the license is revoked and canceled and the right to practice or operate has ended.
Decision effective 4/19/2017.
View the decision

Rees, Tracy L., TCH 32511, Administrative Case AC 6057
Hemet, CA
Through a disciplinary action of the Board, the license is revoked and canceled and the right to practice or operate has ended.
View the decision

Richards, Owen Edward, TCH 122058, Administrative Case AC 5821
Sacramento, CA
Through a disciplinary action of the Board, the license is revoked and canceled and the right to practice or operate has ended.
Decision effective 5/24/2017.
View the decision

Rodriguez, Daniel, TCH 53054, Administrative Case AC 5291
Coachella, CA
Through a disciplinary action of the Board, the license is revoked and canceled and the right to practice or operate has ended.
Decision effective 4/7/2017.
View the decision

Romero, Victor Romero, TCH 116284, Administrative Case AC 5907
North Hills, CA
Through a disciplinary action of the Board, the license is revoked and canceled and the right to practice or operate has ended.
Decision effective 6/7/2017.
View the decision

See Disciplinary Actions, Page 19
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Salas, Karla Marilyn, TCH 142791, Administrative Case AC 5763
Corona, CA
Through a disciplinary action of the Board, the license is voluntarily surrendered.
Decision effective 4/26/2017.
View the decision

Saldivar, Desiree Alyse, TCH 124898, Administrative Case AC 5817
Fresno, CA
Through a disciplinary action of the Board, the license is voluntarily surrendered.
Decision effective 4/26/2017.
View the decision

Sanchez, Javier, TCH 139199, Administrative Case AC 5734
Perris, CA
Through a disciplinary action of the Board, the license is voluntarily surrendered.
Decision effective 5/18/2017.
View the decision

Schmidt, Samantha Nicole, TCH 114184, Administrative Case AC 5777
Sacramento, CA
Through a disciplinary action of the Board, the license is voluntarily surrendered.
Decision effective 4/19/2017.
View the decision

Silligman, Kenneth, TCH 11724, Administrative Case AC 5765
Tracy, CA
Through a disciplinary action of the Board, the license is voluntarily surrendered.
Decision effective 5/17/2017.
View the decision

Wendel-Henry, Emerson Everett, TCH 133780, Administrative Case AC 5894
Paradise, CA
Through a disciplinary action of the Board, the license is voluntarily surrendered.
Decision effective 5/17/2017.
View the decision

Woldegabriel, Abel, Applicant, Statement of Issues Case SI 5421
San Leandro, CA
The application for pharmacy technician registration is denied.
Decision effective 4/6/2017.
View the decision

Wong, Jacqueline Cheun Toy, TCH 49473, Administrative Case AC 4884
San Francisco, CA
Through a disciplinary action of the Board, the license is voluntarily surrendered.
Decision effective 4/20/2017.
View the decision

Xiong, Susan, TCH 85081, Administrative Case 5896
Porterville, CA
Through a disciplinary action of the Board, the license is revoked, the revocation is stayed, and the licensee is placed on probation for five (5) years, suspended for thirty (30) days and is subject to the terms and conditions in the decision.
View the decision

Intern Pharmacist

Dixon, Heather Lynn, INT 29781, Administrative Case AC 5846
Pasadena, CA
Through a disciplinary action of the Board, the license is voluntarily surrendered.
Decision effective 6/22/2017.
View the decision

Gomez, Cynthia, INT 21078, Administrative Case AC 5826
Los Angeles, CA
Through a disciplinary action of the Board, the license is voluntarily surrendered.
Decision effective 6/30/2017.
View the decision

Pharmacist

Antranik, Liza, RPH 51006, Administrative Case AC 4919
Chatsworth, CA
Through a disciplinary action of the Board, the license is subject to a public reproval.
Decision effective 6/7/2017.
View the decision

Amano, Dennis Akira, RPH 41015, Administrative Case 5438
Yorba Linda, CA
Through a disciplinary action of the Board, the license is revoked, the revocation is stayed, and the licensee is placed on probation for four (4) years and is subject to the terms and conditions in the decision.
View the decision

Briggs, Marcus Lynn, RPH 45400, Administrative Case 5771
Riverside, CA
Through a disciplinary action of the Board, the license is revoked, the revocation is stayed, and the licensee is placed on probation for five (5) years and is subject to the terms and conditions in the decision.
View the decision

Brody, Wendy Re, RPH 42050, Administrative Case 5286
San Diego, CA
Through a disciplinary action of the Board, the license is revoked, the revocation is stayed, and the licensee is placed on probation for five (5) years and is subject to the terms and conditions in the decision.
Decision effective 4/20/2017.
View the decision

Buehler, Eric B., RPH 31905, Administrative Case AC 5843
San Clemente, CA
Through a disciplinary action of the Board, the license is voluntarily surrendered.
Decision effective 6/7/2017.
View the decision

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Castillo, Gerardo, RPH 68819, Administrative Case AC 6002
Modesto, CA
Through a disciplinary action of the Board, the license is revoked and canceled and the right to practice or operate has ended.
Decision effective 4/19/2017.
View the decision

Castillo, Ismael, RPH 64666, Administrative Case AC 4995
San Bernardino, CA
Through a disciplinary action of the Board, the license is voluntarily surrendered.
View the decision

Chang, Soong, RPH 45540, Administrative Case AC 4981 and 5328
Anaheim Hills, CA
Through a disciplinary action of the Board, the license is revoked, the revocation is stayed, and the licensee is placed on probation for five years, suspended for sixty (60) days and is subject to the terms and conditions in the decision.
Decision effective 4/20/2017.
View the decision

Cheng, Cindy, RPH 50473, Administrative Case AC 5743
Pasadena, CA
The Application for Pharmacist Examination and Licensure is granted. Upon satisfaction of all statutory and regulatory requirements, the license is immediately issued a public reproval.
Decision effective 6/22/2017.
View the decision

Cooley, Steven, RPH 28548, Administrative Case AC 4865
Santa Barbara, CA
Through a disciplinary action of the Board, the license is voluntarily surrendered.
Decision effective 6/30/2017.
View the decision

Darling, Dana D., RPH 40309, Administrative Case 5897
Tulare, CA
Through a disciplinary action of the Board, the license is revoked, the revocation is stayed, and the licensee is placed on probation for five (5) years, suspended from practice, pending determination safe to practice and is subject to the terms and conditions in the decision.
View the decision

Do, Tan, RPH 47372, Administrative Case AC 5315
Mojave, CA
Through a disciplinary action of the Board, the license is revoked and canceled and the right to practice or operate has ended.
Decision effective 4/20/2017.
View the decision

Fon, Anabella Sai-Yan, RPH 35288, Administrative Case AC 5667
Palo Alto, CA
Through a disciplinary action of the Board, the license is subject to a public reproval.
Decision effective 6/22/2017.
View the decision

Gee, James Ying-Ming, RPH 44796, Administrative Case AC 4981 and 5328
Irvine, CA
Through a disciplinary action of the Board, the license is revoked, the revocation is stayed, and the licensee is placed on probation for five and a half years, 120-day suspension and is subject to the terms and conditions in the decision.
Decision effective 4/20/2017.
View the decision

Gonzalez, Mark Anthony, RPH 50523, Administrative Case 5898, Yorba Linda, CA
Through a disciplinary action of the Board, the license is subject to a public reproval.
Decision effective 5/17/2017.
View the decision

Hojjati, Nazleila, RPH 63668, Administrative Case AC 5668
Long Beach, CA
Through a disciplinary action of the Board, the license is revoked and canceled and the right to practice or operate has ended.
View the decision

Imoohi, Gregory, RPH 42948, Administrative Case AC 5037
San Bernardino, CA
Through a disciplinary action of the Board, the license is revoked and canceled and the right to practice or operate has ended.
Decision effective 5/18/2017.
View the decision

Johnson, Eric Stafford, RPH 38375, Administrative Case AC 6011
Corona, CA
Through a disciplinary action of the Board, the license is voluntarily surrendered.
Decision effective 4/26/2017.
View the decision

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Kothary, Viral Shashikant, RPH 53998, Administrative Case AC 5137
Buena Park, CA
Through a disciplinary action of the Board, the license is revoked, the revocation is stayed, and the license is placed on probation for five years and is subject to the terms and conditions in the decision.
Decision effective 6/14/2017. View the decision

Lee, Jennifer Hwa-Young, RPH 35288, Administrative Case AC 5667
San Jose, CA
Through a disciplinary action of the Board, the license is subject to a public reproval.
Decision effective 4/20/2017. View the decision

Lee, Shao-Lun, RPH 48518, Administrative Case 5401
San Jose, CA
Through a disciplinary action of the Board, the license is placed on probation for four years and is subject to the terms and conditions in the decision.
Decision effective 4/20/2017. View the decision

Lenchitsky, Vladimir, RPH 51484, Administrative Case AC 5622
Sherman Oaks, CA
Through a disciplinary action of the Board, the license is subject to a public reproval.
Decision effective 6/12/2017. View the decision

Lin, Clive L., RPH 41552, Administrative Case AC 5487
Bountiful, UT
Through a disciplinary action of the Board, the license is voluntarily surrendered.
Decision effective 6/30/2017. View the decision

Ly, Qui Van, RPH 41386, Administrative Case 5707
Fresno, CA
Through a disciplinary action of the Board, the license is revoked, the revocation is stayed, and the licensee is placed on probation for three (3) years and is subject to the terms and conditions in the decision.
Decision effective 5/17/2017. View the decision

Matsuo, David S., RPH 36383, Administrative Case AC 5667
Los Gatos, CA
Through a disciplinary action of the Board, the license is placed on probation for five (5) years and is subject to the terms and conditions in the decision.
Decision effective 4/20/2017. View the decision

Matsuo, Vivian Choi, RPH 36646, Administrative Case AC 5667
Los Gatos, CA
Through a disciplinary action of the Board, the license is subject to a public reproval.
Decision effective 4/20/2017. View the decision

Nemetalla, Atef Riad, RPH 65460, Administrative Case AC 5687
Huntington, CA
Through a disciplinary action of the Board, the license is subject to a public reproval.
Decision effective 5/5/2017. View the decision

Phan, Anh Ngoc, RPH 42197, Administrative Case AC 5328
Garden Grove, CA
Through a disciplinary action of the Board, the license is voluntarily surrendered.
Decision effective 4/20/2017. View the decision

Quamoh, Yazen, Pharmacist Applicant, Statement of Issues SI 5949
El Cajon, CA
Upon satisfaction of all statutory and regulatory requirements for issuance of a license, a license shall be issued to respondent and immediately revoked; the order of revocation stayed, and respondent is placed on probation for three (3) years probation, and is subject to the terms and conditions in the decision.
Decision effective 6/7/2017. View the decision

Rogers, Thomas Steven, RPH 30137, Administrative Case 5745
Foresthill, CA
Through a disciplinary action of the Board, the license is revoked, the revocation is stayed, and the licensee is placed on probation for five (5) years, suspended from practice, pending certification and is subject to the terms and conditions in the decision.
Decision effective 6/30/2017. View the decision

Schwartz, Stanley, RPH 32928, Administrative Case AC 4873
Cypress, CA
Through a disciplinary action of the Board, the license is voluntarily surrendered.
Decision effective 6/29/2017. View the decision

Sise, Darin, RPH 43429, Administrative Case AC 5533
Modesto, CA
Through a disciplinary action of the Board, the license is subject to a public reproval.
Decision effective 6/29/2017. View the decision

Solomon, George, RPH 49116, Administrative Case AC 5506
West Hollywood, CA
Through a disciplinary action of the Board, the license is revoked the revocation is stayed, and the license is placed on probation for five years and is subject to the terms and conditions in the decision.
Decision effective 4/6/2017. View the decision

Sterling, Michael, RPH 36628, Administrative Case AC 5622
Bell Canyon, CA
Through a disciplinary action of the Board, the license is subject to a public reproval.
Decision effective 6/12/2017. View the decision

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Tran, Kevin Nhathuy, Quang, RPH 56316, Administrative Case AC 5120
Fountain Valley, CA
Through a disciplinary action of the Board, the license is revoked the revocation is stayed, and the license is placed on probation for three years and is subject to the terms and conditions in the decision.
View the decision

Watherby, Michael, RPH 38874, Administrative Case AC 5163
Huntington Beach, CA
Through a disciplinary action of the Board, the license is voluntarily surrendered.
Decision effective 6/30/2017.
View the decision

Wusttig, Angaline Marie, RPH 69944, Administrative Case AC 5534, West Sacramento, CA
Through a disciplinary action of the Board, the license is voluntarily surrendered.
Decision effective 6/30/2017.
View the decision

Zaroshti, Shahriar, RPH 66143, Administrative Case AC 5779
Venice, CA
By Hearing Decision, the accusation is dismissed.
Decision effective 5/10/2017.
View the decision

Facility Licenses

Wholesalers

Alere Home Monitoring, WLS 6079, Administrative Case AC 5785
Walker, Theodore Lloyd, EXC 22009
Livermore, CA
Through a disciplinary action of the Board, the licenses are subject to a public reproval.
Decision effective 5/10/2017.
View the decision

Licensed Sterile Compounding

Innovrx Inc. DBA Med Specialties, LSC 99056, Administrative Case AC 5898, Yorba Linda, CA
Through a disciplinary action of the Board, the license is subject to a public reproval.
Decision effective 5/17/2017.
View the decision

Wellness Pharmacy, Inc., DBA Wellness Pharmacy, NSC 99103, Administrative Case AC 5845
Birmingham, AL
Through a disciplinary action of the Board, the licenses are subject to a public reproval.
Decision effective 6/30/2017.
View the decision

Wickliffe Pharmaceuticals Inc., NSC 99710, Administrative Case AC 5856
Lexington, KY
Through a disciplinary action of the Board, the license is revoked, the revocation is stayed, and the licensee is placed on probation for three years and is subject to the terms and conditions in the decision.
Decision effective 4/20/2017.
View the decision

Pharmacy

1010 Pharmacy, PHY 51478, Administrative Case AC 5668
Los Angeles, CA
Through a disciplinary action of the Board, the license is revoked and canceled and the right to practice or operate has ended.
View the decision

Capitol Park Pharmacy, PHY 50066, Administrative Case AC 4981
Santa Ana, CA
Through a disciplinary action of the Board, the license is voluntarily surrendered.
Decision effective 4/20/2017.
View the decision

CHJ Pharmacare, PHY 45334, Administrative Case AC 5668
Garden Grove, CA
Through a disciplinary action of the Board, the license is revoked and canceled and the right to practice or operate has ended.
View the decision

See Disciplinary Actions, Page 23
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K & Z Inc. DBA Global RX Pharmacy & Compounding, PHY 52535, Administrative Case 5728
Irvine, CA
Through a disciplinary action of the Board, the license is subject to a public reproval.
Decision effective 4/20/2017.
View the decision

Live Oak Pharmacy, PHY 45317, Administrative Case AC 5527
Singh, Ranjit, RPH 46870
Live Oak, CA
Through a disciplinary action of the Board, the licenses are voluntarily surrendered.
View the decision

Los Angeles County/USC Medical Center, PHE 49214, Administrative Case AC 5883
Los Angeles, CA
Through a disciplinary action of the Board, the license is subject to a public reproval.
View the decision

Mojave Pharmacy, PHY 47150, Administrative Case AC 5315
Mojave, CA
Through a disciplinary action of the Board, the license is revoked and canceled and the right to practice or operate has ended.
Decision effective 4/20/2017.
View the decision

Sansum Clinic Pharmacy, Inc., PHY 32685, Administrative Case AC 4865
Santa Barbara, CA
Through a disciplinary action of the Board, the license is voluntarily surrendered.
Decision effective 6/30/2017.
View the decision

Sierra Compounding Pharmacy, PHY 49228, Administrative Case 5534
Auburn, CA
Through a disciplinary action of the Board, the license is subject to a public reproval.
View the decision

Sierra Compounding Pharmacy, PHY 44228, Administrative Case 5667, Los Gatos, CA
Through a disciplinary action of the Board, the license is subject to a public reproval.
Decision effective 4/20/2017.
View the decision

TLC Xpress Pharmacy, PHY 49837, Administrative Case AC 5120
Fountain Valley, CA
Through a disciplinary action of the Board, the license is revoked the revocation is stayed, and the license is placed on probation for three years and is subject to the terms and conditions in the decision.
View the decision

Vons Corporation, DBA Vons Pharmacy 2406, PHY 43000, Administrative Case AC 5554, El Centro, CA
Through a disciplinary action of the Board, the license is subject to a public reproval.
View the decision

West Modesto Pharmacy, PHY 52073, Vicijan, Nada, RPH 41607, Administrative Case AC 5901
Modesto, CA
Through a disciplinary action of the Board, the license is revoked and canceled and the right to practice or operate has ended.
Decision effective 6/7/2017.
View the decision

Wickliffe Pharmaceuticals Inc., NRP 1145, Administrative Case 5856
Lexington, KY
Through a disciplinary action of the Board, the license is revoked, the revocation is stayed, and the licensee is placed on probation for three years and is subject to the terms and conditions in the decision.
Decision effective 4/20/2017.
View the decision

Yorba Park Pharmacy, PHY 45771, Administrative Case AC 5328
Orange, CA
Through a disciplinary action of the Board, the license is voluntarily surrendered.
Decision effective 4/20/2017.
View the decision