

BOARD OF PHARMACY

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Protection of the public shall be the highest priority for the California State Board of Pharmacy in exercising its licensing, regulatory, and disciplinary functions. Whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.

— Business and Professions Code § 4001

The California State Board of Pharmacy is a consumer protection agency within the state Department of Consumer Affairs (DCA). The Board is charged with enforcing the Pharmacy Law, Business and Professions Code section 4000 et seq. The Board's regulations are located in Division 17, Title 16 of the California Code of Regulations (CCR).

The Board of Pharmacy grants licenses and permits to pharmacists, advanced practice pharmacists, pharmacy interns, pharmacy technicians, pharmacies, pharmacy corporations, nonresident pharmacies, wholesale drug facilities, veterinary food-animal drug retailers, out-of-state distributors, clinics, hypodermic needle and syringe distributors, and an extensive array of associated individuals and entities. As of December 31, 2021, there were 141,390 current licensees. In addition, the Board regulates all sales of dangerous drugs, controlled substances, and poisons.

The Board consists of 13 members, six of whom are public members. The Governor appoints four public members. The Senate Rules Committee and the Speaker of the Assembly each appoint one public member. The remaining members are pharmacists appointed by the Governor, five of whom must be active practitioners. Additionally, Business and Professions Code section 4001(c) requires that the membership of the Board include at least one pharmacist representative from each of the following practice settings: an acute care hospital, an independent community

pharmacy, a chain community pharmacy, and long-term health care or skilled nursing facility. Furthermore, the Board must include a pharmacist who is a member of a labor union that represents pharmacists. All Board members are appointed to four-year terms.

In December 2021, Governor Newsom [appointed](#) Kula Koenig of Sacramento as a public member of the Board. Ms. Koenig is the Senior Director of impact at the United Way California Capital Region.

On February 3, 2022, Governor Newsom [appointed](#) Indira J. Cameron-Banks as a public member of the Board. Cameron-Banks has worked as a sole practitioner attorney since 2021, previously served as the Director of the Preventing and Ending Homelessness Project for the Inner City Law Center, and has held several positions at the Department of Justice.

At this writing, the Board has one licensee vacancy for work in long-term health care or a skilled nursing facility. This vacancy is to be appointed by the Governor.

HIGHLIGHTS

Legislature Introduces Bill for Mobile Pharmacy Units

[SB 872 \(Dodd\)](#), as introduced on January 24, 2022, would add to section 4110.5 to the Business and Professions Code regarding mobile pharmacy units. New section 4110.5 would authorize a county or a city to operate a temporary licensed mobile unit to provide prescription medication within its jurisdiction to specified individuals, including those without fixed addresses, in cases of damage or destruction to the pharmacy causing closure. Each mobile unit would have a physician as part of the team to prescribe medications that can be dispensed immediately.

The bill would allow mobile units to dispense prescription medications based on a valid prescription if the county or city meets specific requirements for licensure, staffing, and operations. These requirements would include: (1) The mobile unit is licensed by the Board pursuant to subdivision (b), (2) The mobile unit is staffed by a pharmacist in charge and a pharmacy technician, (3) A licensed pharmacist is on the premises and the mobile unit is under the control and management of a pharmacist while prescription medications are being dispensed, (4) All activities of the pharmacist, including the furnishing of medication by the pharmacist, are consistent with Article 3 (commencing with Section 4050), (5) If a physician is practicing in the mobile unit, all prescribed by the physician meets the requirements of the Medical Practice Act (Chapter 5 (commencing with Section 2000)), (6) The mobile unit does not carry or dispense controlled substances and the Board may license a mobile unit that meets the requirements of this section. This bill would give the Pharmacy Board authorization to license these mobile units.

A violation of the bill's requirements (stated above) in creating the mobile pharmacy units would be a crime. Because of that, the state would reimburse local governments for costs incurred creating their local mobile unit programs.

This bill is important because it would provide pharmacy services to the public in case of destruction to a pharmacy facility. This would create continuity in pharmacy care for California residents in case of a weather disaster, fire, or other causes of damage or destruction of a pharmacy structure. According to the [author](#), this bill creates critical access to potentially life-saving drugs that will improve the lives of the most vulnerable Californians, particularly in unhoused communities.

The bill is currently pending before the Senate Appropriations committee.

Legislature Introduces Bill for Cultural Competency Training Requirements

[AB 2194 \(Ward\)](#), as introduced February 15, 2022, would add sections 4202 and 4231 to the Business and Professions Code to require that one hour of the 30 continuing education hours required for license renewal as a pharmacist or pharmacy technician include a cultural competency course. Specifically, the bill would amend section 4231 to define and set forth the criteria for the cultural competency and humility course with respect to patients who identify as LGBTQIA+, including that the course is from an accreditation agency approved by the Board; that the course cover recognized health disparities faced by Black, Indigenous, and people of color communities; and that the course contains elements showing how sexual identity is directly impacted through intersectionality.

According to a [press release](#) issued by the author, members of the LGBTQ+ community often face barriers when receiving healthcare, including fear, stigma, and discrimination. Ward asserts that consistent training is needed to help pharmacists address the unique needs of the LGBTQ+ community. Ward states, “[w]hen LGBTQ+ individuals have a negative experience seeking healthcare, it discourages them from seeking adequate or even life-saving measures when they need it. AB 2194 will ensure pharmacists are looking out for the well-being of LGBTQ+ individuals by providing culturally competent care.”

According to Ward, California has the highest population of individuals identifying as LGBTQ+ in the United States, with an estimated 2.6 million people identifying as LGBTQ+. AB 2194 will help pharmacists and pharmacist technicians create a trusting relationship with the

LGBTQ+ community. This will make these patients more likely to seek out care, resulting in more positive health outcomes.

Assemblymember Ward states that this bill is important because the healthcare system has historically struggled to fully support underrepresented groups, such as the LGBTQ+ community. Adding a cultural competency requirement for pharmacists and pharmacy technicians will help them better serve and support their LGBTQ+ patients.

On March 29, 2022, the Assembly Business and Professions Committee voted to pass the bill out of committee, and it is now pending before the Assembly Appropriations Committee.

Law Requiring That Most Prescriptions Issued by a Licensed Healthcare Practitioner to a California Pharmacy Must be Submitted Electronically Takes Effect

On January 1, 2022, section 688 of the Business and Professions Code became effective, requiring that all prescriptions issued by a licensed healthcare practitioner to a California pharmacy must be issued electronically unless specified exemptions are met. This requirement includes prescriptions issued by healthcare practitioners in a state other than California that a California pharmacy will fill. The law also requires that as of January 1, 2022, all California pharmacies must have the capability to receive prescriptions electronically. The new provision was added by [AB 2789 \(Wood\) \(Chapter 438, Statutes of 2018\)](#) in an effort to increase the accuracy of patient outcomes for people prescribed medication by licensed healthcare practitioners and curtail the ongoing abuse and misuse of prescriptions for controlled substances and ongoing diversion of prescription medication. [*see* [24:1 CRLR 84–85](#)]

The law does provide for certain exemptions, including cases where the prescription is issued to a patient who has a terminal illness pursuant to section 11159.2 of the Health and Safety Code; cases where the prescription is issued to a patient who resides outside of California; and cases where transmission of an electronic data prescription is not available due to a temporary technological or electrical failure. When such technological or electrical failures occur, however, prescribers must document the reason in the patient's medical record as soon as practicable and within 72 hours of the end of the technological or electrical failure that prevented the electronic data transmission of the prescription.

The Board has been advising its licensees about the law to ensure compliance and clarify the new requirements. In addition to highlighting the impending statutory change in [quarterly newsletters](#), staff compiled a [list](#) of answers to frequently asked questions on its website which specifies requirements for pharmacies, including their capability to receive electronic data transmission prescriptions, whether they are permitted to dispense a prescription medication that does not comply with the new law, transfers of e-prescriptions to other pharmacies, record keeping requirements, telemedicine situations, and out-of-state prescriptions, among other details.

Board Modifies Language of Proposed Regulation Related to Inventory Reconciliation in Response to Public Comments

At its December 2, 2021 [meeting](#), the Board discussed the pending Inventory Reconciliation regulation, which proposes to amend section 1715.65, Title 16 of the CCR, and clarified that the proposed regulation intends to require licensees to complete a full inventory reconciliation for any drug loss, even if only a single controlled substance pill is lost. However, the Board also made an essential distinction, noting that a situation where a single pill is lost would

not require the licensee to submit a reconciliation report to the Board but would still require the licensee to conduct the inventory activities described by the proposed regulation. The Board reasoned that requiring a full inventory reconciliation for any drug loss, even if only a single pill, can be key in helping licensees identify the cause of the loss and ameliorate any pattern of loss before it meets the minimum reporting threshold.

The Board originally published notice of its proposed amendments on September 17, 2021. [\[see 27:1 CRLR 70–72\]](#) During the 45-day comment period, Valley Children’s Hospital submitted a written comment requesting clarification on the meaning of “inventory activities” in subsection (a)(3)(B) of the proposed text as it related to Schedule III-V controlled substances reconciliation. In response, Board staff recommended changes to the regulatory text to define further “inventory activities.” Following these considerations, the Board voted to approve the staff-recommended [modified text](#) and initiate a 15-day comment period from December 3, 2021, to December 18, 2021.

At its January 27–28 [meeting](#), the Board again discussed the pending Inventory Reconciliation regulation and considered comments from stakeholders made during the 15-day comment period. As recorded in the Board’s meeting [materials](#), a commenter submitted a written comment requesting clarification on the minimum criteria to initiate an inventory reconciliation report resulting from a controlled substance loss. Board staff reviewed this comment and recommended clarifying language subsection (a)(3)(A). However, the Board highlighted that there may be some misunderstanding among stakeholders about the requirements of the regulation. The Board encouraged stakeholders to read the text of the proposed regulation and note the difference where inventory reconciliation reporting is required versus inventory activities only. The Board

voted to release a second [modified text](#) and initiate a second 15-day comment period, ending on February 12, 2022.

At its March 16, 2022 meeting, the Board considered comments made regarding the second modified text and voted to adopt it as modified on January 28, 2022. At this writing, according to the Board's website, the regulation is pending review by DCA.

MAJOR PUBLICATIONS

The following reports or studies have been conducted by or about the Board of Pharmacy during this reporting period:

- [California State Board of Pharmacy Strategic Plan 2022–2026](#), Board of Pharmacy, revised March 2022 (covers Board composition, accomplishments, mission and values, goals, and strategic planning process).
- [The Script](#), Board of Pharmacy, March 2022 (describes the Board's major projects in a bi-yearly newsletter; provides a policy statement on proposed revisions to USP General Chapters 795 and 797 concerning the current status of legal requirements for pharmacies compounding drug preparations; makes recommendations to pharmacies to help prevent the ongoing problem of drug diversion; shares an apology letter from a pharmacist in charge (PIC) for dereliction of duties; and lists licensee disciplinary actions).

RULEMAKING

The following is a status update on recent rulemaking proceedings that the Board of Pharmacy has initiated:

- **Pharmacy Technicians:** On January 28, 2022, the Board published [notice of modified text](#) and a 15-day public comment period for its proposal to amend sections 1793.5 and

1793.6, and adopt section 1793.65, Title 16 of the CCR to update the pharmacy technician application form, update the requirements for schools providing training courses for pharmacy technicians, and add pharmacy technician certification programs accredited by the National Commission for Certifying Agencies programs. The Board originally published [notice](#) of its intent to amend these sections on October 22, 2021. [See [27:1 CRLR 80](#)] The [modified text](#) proposes to add a criminal background check on the applicant consistent with the background checks proscribed in section 4202(c) of the Business and Professions Code, information on course training, a requirement that applicants are 18 years or older, and a final exam. In addition, the modified text removes applicant questions about mental health, and removes some about disciplinary action, and status as a third-party wholesaler. The public comment period on the modified text expired on February 12, 2022. According to the Board's website, at this writing, Board staff is preparing the final rulemaking documents for approval by the Office of Administrative Law (OAL).

- **Notice of Temporary Closure:** On January 28, 2022, the Board published [notice of modified text](#) and a 15-day public comment period for its proposal to adopt section 1708.1, Title 16 of the CCR, to require pharmacies to notify the Board of a temporary closure of a licensed facility as soon as any closure exceeds three consecutive calendar days. The Board originally published notice of its intent to adopt this section on October 29, 2021. [see [27:1 CRLR 82](#)]. The modified text would provide an exception for correctional pharmacies and update the text to exclude holidays and routine closures. According to the Board website, at this writing, the proposal is undergoing review by DCA.

- **Address Change Notification:** On January 18, 2022, OAL [approved](#) the Board's

[proposed amendments](#) to section 1704, Title 16 of the CCR, to require all persons who practice to provide a residential and an email address to the Board, if they have one. Practitioners must provide to the Board any changes to either address within 30 days. The Board originally published [notice](#) of its intent to amend this section on September 3, 2021. [[27:1 CRLR 81](#)] The regulation went into effect on April 1, 2022.

- **Administering Vaccines:** On January 25, 2022, OAL [approved](#) the Board's [proposed amendments](#) to amend section 1746.4, Title 16 of the CCR, to provide criteria for Pharmacists Initiating and Administering Vaccines. The criteria include documentation of training and certifications, notifications to primary care doctors, utilization of the immunization registry, and documentation at the pharmacy site. The Board originally published [notice](#) of its intent to amend this section on October 8, 2021. [[27:1 CRLR 74–75](#)] The regulation went into effect on January 25, 2022.

- **Ownership, Management & Control of Business Entities:** On January 11, 2022, OAL [approved](#) the Board's [proposed amendment](#) to section 1709, Title 16 of the CCR to clarify and make specific the standards of pharmacy and ownership disclosure as they relate to pharmacy ownership, management, and control, including through trusts, which is set forth in the [approved regulatory text](#). According to the [Final Statement of Reasons](#), it is not uncommon for an individual who is prohibited from having management and control of a pharmacy to attempt to conceal ownership and continue to profit from and run the pharmacy through the hidden ownership interest vehicle of a trust, while on paper it looks as though someone else owns it. The Final Statement of Reasons further states that Board staff have the duty to protect the public by reviewing the entire trust document to ascertain whether any prohibited person receives a benefit under the trust. The

Board originally published [notice](#) of its proposed rulemaking on July 23, 2021. [*see* [27:1 CRLR 77–78](#)] The new regulation went into effect on April 1, 2022.

- **Reporting Drug Loss:** On February 24, 2022, OAL [approved](#) the Board’s [proposed amendment](#) to section 1715.6, Title 16 of the CCR, to reduce mandatory reporting of loss of controlled substances, which is set forth in the [approved regulatory text](#). According to the [Initial Statement of Reasons](#), the regulation establishes a minimum reporting threshold corresponding to what it deems to be a significant loss, depending on the type and amount of controlled substance lost. The Board originally published [notice](#) of its proposed rulemaking on June 4, 2021. [*see* [27:1 CRLR 69–70](#)] The new regulation went into effect on April 1, 2022.

- **Wholesaler/3PL Self-Assessment Form:** On February 15, 2022, the Board [notice](#) of the availability of [modified text](#) for a 15-day comment period concerning its proposal to amend section 1784, Title 16 of the CCR, related to Wholesaler/3PL Self-Assessment. The Board originally published notice of its proposed rulemaking on September 17, 2021. The proposed regulation aims to provide clarifying language regarding the application of this section, and aims to identify the individual who must complete the self-assessment based on the license type. [*see* [27:1 CRLR 75–76](#)] According to the [Initial Statement of Reasons](#), this regulation will add the requirement for third-party logistics providers to complete the self-assessment, which continues the requirements that were applied previously when these entities were licensed as wholesalers. The 15-day comment period expired on March 2, 2022. At this writing, according to the Board’s website, the regulation is pending review by the DCA.

- **Pharmacy/Hospital Self-Assessment Forms:** On February 15, 2022, the Board [notice](#) of the availability of [modified text](#) for a 15-day comment period concerning its

proposal to amend section 1715, Title 16 of the CCR, related to Pharmacy/Hospital Self-Assessment Forms. The Board originally published notice of its proposed rulemaking on November 12, 2021. [see [27:1 CRLR 82](#)] According to the [Initial Statement of Reasons](#), the proposed regulation aims to specify the requirements of pharmacy self-assessment forms further. At this writing, according to the Board’s website, the regulation is pending DCA review.

- **Inventory Reconciliation:** On February 12, 2022, the Board published [notice](#) of the availability of a [second modified text](#) concerning its proposal to amend section 1715.65, Title 16, of the CCR to address frequent compliance questions the Board receives and address the ongoing diversion of non-Schedule II controlled substances from pharmacies and clinics (see HIGHLIGHTS).

LEGISLATION

- [SB 939 \(Pan\)](#), as amended March 15, 2022, would add Article 3 (commencing with section 127470) to the Health and Safety Code to prohibit a pharmacy benefit manager from discriminating against a covered entity or its pharmacy in connection with dispensing a drug subject to federal drug discount programs. The bill includes legislative findings and declarations that the federal drug discount programs are essential to California’s health care safety net and states the legislature’s intent to ensure continued access to these benefits without discrimination and interference from pharmacy benefit managers, drug manufacturers, and other payers. [S. Floor]
- [SB 1346 \(Becker\)](#), as amended on March 24, 2022, would amend section 150204

According to the author, billions of dollars of unused medication end up in the garbage every year; current requirements on repository programs place unnecessary and cumbersome burdens on participating entities. This bill would provide operational flexibility and increase the number of entities that operate voluntary drug repository programs. *[S. Health]*

- [AB 2265 \(Arambula\)](#), as amended April 6, 2022, would add Article 12.5 (commencing with section 4178) of the Business and Professions Code to require a pharmacist who dispenses a Schedule II or Schedule IIN controlled substance to dispense the drug in a lockable vial paid for by the drug’s manufacturer, include the Code for the lockable vial in any patient notes, and provide the patient with a copy of the Opioid Factsheet for Patients published by the federal Centers for Disease Control and Prevention. This bill would also require the Board to establish reasonable minimum and maximum amounts of reimbursement for costs of the vial, services rendered, and dispensing costs. According to the author, by requiring that highly addictive Schedule II or Schedule IIN medications be dispensed in tamper-proof containers, this bill will help reduce unauthorized access to potentially harmful medications. This bill is similar to [SB 1084 \(Umberg\) \(2020\)](#) and [AB 1430 \(Arambula\) \(2021\)](#), both of which failed to be enacted. *[see [25:2 CRLR 47–48](#); see also [26:1 CRLR 58](#)]* At its April 29–30 [meeting](#), the Board voted unanimously to take an oppose position on this bill, expressing concern that it could impede patient care and medication adherence. Further, the Board noted that it is generally not within the purview of the Board to establish a reimbursement rate for goods and services, and that the Board may not be the appropriate entity to develop such rates or enforce reimbursement. *[A. Appr]*

- [AB 2055 \(Low\)](#), as introduced February 14, 2022, would amend section 208 of and

responsibility for the administration of the Controlled Substance Utilization Review and Evaluation System (CURES) prescription drug monitoring program (PDMP) from the Department of Justice to another department specified by the Governor. According to the author, combating prescription drug abuse should be approached through a health-oriented lens rather than through criminal prosecution, and therefore CURES would be better positioned in a more health-focused department. *[A. PubSafe]*

- [SB 988 \(Hueso\)](#), as introduced February 14, 2022, would repeal section 1649.3 of the Health and Safety Code to remove the requirement that a hospital manages a terminal patient's personal use of medical cannabis in the same manner as Schedule II-IV drugs. On September 28, 2021, Governor Newsom signed into law [SB 311 \(Hueso, Chapter 384, Statutes of 2021\)](#), titled Ryan's Law, granting terminally-ill Californians access to medicinal cannabis in hospitals and certain types of healthcare facilities in the state. *[see [27:1 CRLR 85](#)]* As part of its discussions during its October 20, 2021, Enforcement and Compounding Committee [meeting](#), Board members received public comment and discussed challenges with Ryan Law's requirements that medicinal cannabis complies with provisions related to Schedule II-IV medications and the applicability of provisions of the Board's regulations, including storage, inventory control, acquisition, and the role of the pharmacy in these health facilities. *[see [27:1 CRLR 85](#)]* The author of SB 988 conveys this bill aims to clarify that Ryan's Law does not require medicinal cannabis to be subject to all requirements applicable to Schedule II-IV medications, nor does it require that a pharmacy or pharmacist be involved in the use, storage, management, or dispensing of medicinal cannabis at a health facility. *[S. Appr]*

- [SB 958 \(Limón\)](#), as amended March 31, 2022, would add Article 6.15 (commencing with section 1385.010) to the Health and Safety Code, and add Article 1.6

(commencing with section 10128.5) to the Insurance Code to address certain practices known as “brown bagging” and “white bagging” engaged in by health plans and insurers that restrict patients’ access to medications including high-quality infusion and injection services. According to the author, some plans and insurers have implemented a policy sometimes referred to as “brown-bagging” by which they contract with a vendor to deliver medications to the patient’s home, and the patient brings the medication to the health care provider for administration. Similarly, according to the author, some plans and insurers have adopted policies that are sometimes referred to as “white-bagging,” which require a health care provider to accept delivery from a plan’s or insurer’s vendor of a medication labeled for a specific patient in advance of the patient’s visit. The author states that with “white-bagging” a health care provider is not permitted to give any other medication to the patient, even if the patient’s same-day assessment indicates that a different medication, strength, or dosage is better suited for the patient. The author conveys that this bill would ensure that patients with complex and life-threatening illnesses who need specialty, infused, or injected medications administered by a doctor or nurse, such as chemotherapy, can receive the necessary medication in a safe, timely manner. On February 18, 2021, the Board’s Enforcement and Compounding Committee convened an informational [hearing](#) on “White Bagging,” where the regulated public shared challenges with the practice of white bagging and its adverse impacts on patient care. *[S. Jud]*

- [SB 1365 \(Jones\)](#), as introduced February 18, 2022, would add section 114.6 to the Business and Professions Code to require the Board to publicly post on its website a list of criteria used to evaluate applicants with criminal convictions. This bill would also require DCA to develop a process for each board to verify applicant information and perform background checks on applicants. These processes would require applicants with convictions to provide certified court

documents instead of listing convictions on the application. According to the author, the current process lets DCA Boards and Bureaus have their own autonomy over how they award licensure, which results in a lack of consistency because, at least in part, there is not a regulated definition for “related convictions” or “rehabilitation,” which can create disadvantages for applicants. [*S. PubSafe*]

- [AB 1662 \(Gipson\)](#), as introduced January 18, 2022, would amend section 480 of the Business and Professions Code to allow a prospective applicant for licensure to request a pre-application determination concerning whether they would be disqualified from licensure by the Board based on the information submitted with the request regarding their criminal conviction. This bill would also require the Board to deliver a determination to the prospective applicant. According to the author, this bill would provide notice to people with criminal records applying for a licensed profession on whether their record might disqualify them from receiving an occupational license in the future, before financial and educational investment toward any program. [*A. B&P*]

LITIGATION

- *In re: Purdue Pharma LP, et al., Case No. 19-23649 (RDD) (Bankr. SDNY 2021)*. On March 10, 2022, the United States Bankruptcy Court for the Southern District of New York issued an [order](#) authorizing and approving settlement term sheets. The order requires the Sackler Family of Purdue Pharma to contribute at least \$5.5 billion to opioid abatement trusts if the debtor’s plan is confirmed. After the approval of the states affected by this order, the Sackler Family will pay out money from their personal wealth as well as other trusts. This case is ongoing. [*see 27:1 CRLR 87*]

- ***United States of America v. Walmart Inc. and Wal-Mart Stores East, LP*, Case No: 20-cv-01744 (D. Del. 2020).** On November 19, 2021, the United States District Court for the District of Delaware [granted](#) Walmart Inc. and Wal-Mart Stores East, LP’s (Walmart) [Motion to Stay Pending the Supreme Court’s Decisions in *Ruan* and *Kahn*](#). On December 22, 2020, the United States Department of Justice filed a complaint against Walmart for facilitating opioid misuse and abuse by knowingly and unlawfully filling “thousands upon thousands of invalid controlled-substance prescriptions” in violation of the Controlled Substance Act. [see [25:2 CRLR 64–65](#)] Walmart filed its request for the stay four days after the Supreme Court of the United States announced that it would hear and consolidate cases out of the Tenth and Eleventh Circuits in which federal juries convicted doctors who specialized in pain management of charges related to allegedly prescribing controlled substances in violation of the Controlled Substances Act. According to Walmart’s Motion to Stay, the Supreme Court’s ruling in *Ruan* and *Kahn* will shed light on key issues in Walmart’s case by providing clarity on the circumstances in which a physician alleged to have prescribed controlled substances outside the usual course of professional practice may be convicted under section 841(a)(1) without regard to whether, in good faith, the physician “reasonably believed” or “subjectively intended” that the physician’s prescriptions fall outside that usual course of professional practice. This case is stayed until 14 days after the resolution of *Ruan* and *Kahn*, by which time the parties shall file a joint status report with the district court.

- ***Carl Washington, et al. v. CVS Pharmacy Inc.*, Case No. 21-16162 (9th Cir. 2021).** On January 26, 2022, multiple buyer classes filed an [opening brief](#) with the Ninth Circuit, asking the appellate court to reverse the jury’s finding in a June 2021 trial that [cleared](#) CVS Pharmacy Inc. (CVS) of claims that it overcharged insured drug buyers by more than \$121 million

for generic drugs in violation of consumer protection statutes of California and five other states. [\[see 27:1 CRLR 86–87\]](#) The multiple buyer classes asked the Ninth Circuit for a new trial, claiming that a series of legal errors by the United States District Court for the Northern District of California resulted in substantial juror confusion and prejudice to plaintiffs. For example, the multiple buyer classes claimed that CVS insisted at trial that CVS had complied with industry standards when it did not report discounted cash prices for uninsured customers as usual and customary. By this, the multiple buyer classes claimed that CVS opened the door for plaintiffs to present evidence that numerous major health insurers had filed suits and arbitrations against CVS and other pharmacies for failing to report discounted cash prices as usual and customary pricing. In addition, the multiple class buyers asserted that despite the plaintiffs’ repeated objections, the district court abused its discretion by barring evidence of industry standards as to usual and customary prices. Appellee CVS filed an [answering brief](#) with the Ninth Circuit on March 29, 2022.

- ***Association for Accessible Medicines v. Becerra*, Case No. 2:20-cv-01708 (E.D. Cal. 2020)**. On February 15, 2022, a California federal judge issued an [order](#) that partially reinstated California’s ban on “pay-for-delay” deals, which occur when brand-name pharmaceutical manufacturers settle patent infringement claims against generic pharmaceutical manufacturers by paying them to delay releasing cheaper, generic versions. [AB 824 \(Wood\) \(Chapter 531, Statutes of 2019\)](#) made “pay-for-delay” deals presumptively anticompetitive in violation of California law. The court’s ruling permitted the prohibition pursuant to AB 824 (Wood) on “pay-for-delay” deals entered within California but issued a preliminary injunction on the prohibition of “pay-for-delay” deals made elsewhere that merely impact drug sales in California. The court reasoned that allowing California to prohibit “pay-for-delay” agreements

made outside of California would conflict with the dormant Commerce Clause. This case is ongoing.