

California State Board of Pharmacy

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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor



To: Board Members

Subject: Agenda Item VI. Discussion and Consideration of Proposal Related to Working Conditions

Background

California is not the only state evaluating the issue of workplace conditions with jurisdictions taking various approaches to address the challenge. As the Committee learned some approaches include potential research in workload engineering, adding provisions for anti-retaliatory (whistleblower) protections, and standardizing the CQI process. Some jurisdictions have reporting requirements for unsafe working conditions, some have provisions to ensure sufficient personnel are scheduled to work at all times, some have notification requirements to advise patients that the pharmacy is experiencing significant delays or cannot dispense prescriptions in a timely manner.

Jurisdictions are also considering changes to provisions of the law to address workplace conditions. As an example, pending legislation in Kansas would have established a legislative joint committee to study pharmacy workplace conditions and the impact of such conditions on patient safety. The measure appears to have died in committee.

Prior Committee Discussion

During its September meeting, the Committee reviewed examples from some state provisions, detailed below.

Illinois

Under provisions in Illinois, the department may refuse to issue or renew, or may revoke a license, or take other action (including issuing a fine) with regard to any licensee for any one or combination of the following causes:

- Failing to provide a work environment for all pharmacy personnel that protects the health, safety, and welfare of a patient which includes, but is not limited to, failing to:
 - a. Employ sufficient personnel to prevent fatigue, distraction, or other conditions that interfere with a pharmacist's ability to practice with competency and safety or creates and environment that jeopardizes patient care.
 - b. Provide appropriate opportunities for uninterrupted rest periods and meal breaks.

- c. Provide adequate time for a pharmacist to complete professional duties and responsibilities, to complete professional duties and responsibilities including, but not limited to:
 - i. Drug utilization review
 - ii. Immunization
 - iii. Counseling
 - iv. Verification of the accuracy of a prescription
 - v. All other duties and responsibilities of a pharmacist as specified.
- 2. Introducing or enforcing external factors, such as productivity or production quotas or other programs against pharmacists, student pharmacists or pharmacy technicians, to the extent that they interfere with the ability of those individuals to provide appropriate professional services to the public.

Oklahoma

Oklahoma establishes adequate <u>staffing rules for pharmacists and pharmacies</u>. Specifically, the law provides:

- 1. Adequate staffing to safely fill prescriptions is the responsibility of the pharmacy, the pharmacy manager, and the pharmacist. If conditions exist that could cause prescriptions to be filled in an unsafe manner, each shall take action to correct the problem.
- 2. In order to ensure adequate staffing levels a staffing form shall be available in each pharmacy. A copy of the form, when executed, will be given to the immediate supervisor and a copy must remain in the pharmacy for Board inspection. The form shall include at least the following:
 - a. Date and time inadequate staffing occurred.
 - b. Number of prescriptions filled during the time frame.
 - c. Summary of events.
 - d. Any comments or suggestions.

The forms are not sent to the Board.

- 3. A pharmacist shall complete the staffing report form when:
 - a. A pharmacist is concerned about staff due to specified criteria including inadequate number of support person or excessive workload.
- 4. If the pharmacy manager feels that the situation warrants earlier Board review, the pharmacy manager shall inform the Board.
- 5. Each pharmacy shall review staffing reports and address any issues listed as well as document any corrective action taken or justification for inaction to assure continual self-improvement.
- 6. Each pharmacy shall retain completed staffing reports until reviewed and released by the Board. Such reports requiring further review may be held by the Board and may become part of an investigation file.

7. A registrant, including a pharmacy, a pharmacy manager, or a pharmacist, shall not be subject to discipline by the employing pharmacy for completing a staffing report in could faith.

Source: Okla. Admin. Code § 535:15-3-16 Oklahoma established an <u>inadequate staffing report</u> that can be submitted to the Board by pharmacy personnel.

Vermont

Under provisions of law in Vermont, the Board may impose disciplinary sanctions against drug outlets in a retail chain; unprofessional conduct has occurred at one or more drug outlet's unprofessional conduct is attributable to corporate policies, practices, systems, or procedures, and sanctions are appropriate to protect the public. Vermont recently filed <u>action against Walgreens</u> alleging several violations include including:

- Violation One: 26 V.S.A. § 2053(a)(1) Introducing or enforcing policies and procedures related to the provision of pharmacy services in a manner that results in deviation from safe practice.
- Violation Two: 26 V.S.A. § 2053(a)(2) Unreasonably preventing or restricting a patient's timely access to patient records or essential pharmacy services.
- Violation Three: 26 V.S.A. § 2053(a)(3) Failing to identify and resolve conditions that interfere with a pharmacist's ability to practice with competency and safety or create an environment that jeopardizes patient care, including by failing to provide mandated rest periods.
- Violation Four: 26 V.S.A. § 2053(a) (4) Repeatedly, habitually, or knowingly failing to provide resources appropriate for a pharmacist of reasonable diligence to safely complete professional duties and responsibilities, including: (A) drug utilization review; (B) immunization; (C) counseling; (D) Verification of the accuracy of a prescription; (E) all other duties and responsibilities of a pharmacist under State and federal laws and regulations.
- Violation Seven: 3 V.S.A. § 129a(b)(1) Failure to practice competently by reason of any cause on a single occasion or on multiple occasions may constitute unprofessional conduct, whether actual injury to a client, patient, or customer has occurred. Failure to practice competently includes: (1) performance of unsafe or unacceptable patient or client care.

Virginia

Virginia Law provides that, except in an emergency, a permit holder shall not require a pharmacist to work longer than 12 continuous hours in any workday and shall allow at least six hours of off-time between consecutive shifts. A pharmacist working longer than six continuous hours shall be allowed to take a 30-minute break. Based on an investigation in Virginia, an order was issued against a single CVS store. In this instance the pharmacy license was

reprimanded, a fine of \$346,250 was assessed for the chain, the pharmacy was placed on an indefinite probation for a period of not less than two years subject to terms and conditions. Under conditions of the order the pharmacy has an appeal right to the order.

Source: 18VAC110-20-110. Pharmacy permits generally.

A copy of the order is included in **Attachment 1**.

Summary of Committee's November Discussion and Action

Following review and consideration, and at the direction of the Committee, staff prepared statutory language that could be used to include some of additional provisions into California law. As part of its November meeting, members considered possible several changes to Pharmacy Law detailed below:

- BPC 4113.5 Chain Community Pharmacies: Required Staffing
 - Would establish authority for a pharmacist to close a pharmacy if in their opinion staff at the pharmacy is inadequate to safely fill prescriptions or provide other patient care services.
 - Would establish a minimum staffing floor. Further, would require schedule closures for lunch time for all pharmacy staff where staffing of pharmacist hours does not overlap sufficiently
- BPC 4113 Pharmacist in Charge: Notification to the Board
 - Would provide explicit authority for the PIC to have autonomy to make staffing decisions to ensure sufficient personnel.
 - Would establish authority for the PIC to close a pharmacy under specified conditions based on professional judgement may create an unsafe environment for personnel. In the event the PIC is not available, the pharmacist on duty may close the pharmacy.
- BPC 4301 Unprofessional Conduct
 - Would declare as unprofessional conduct actions or conduct that would subvert or tend to subvert the efforts of a pharmacist, pharmacist-in-charge, pharmacist intern, and pharmacy technician to comply with laws or regulations.
 - Would prohibit pharmacies from establishing policies and procedures related to time guarantees to fill prescriptions.

Committee members generally spoke in support of the provisions and discussed the provisions related to a pharmacist's ability to close the pharmacy and potential impact to patients.

Public comment also appeared supportive of the provisions.

Committee Recommendation: Recommend to the Board pursuit of a statutory proposal to add and amend Business and Professions Code sections 4113.5, 4113, and 4301 consistent with the committee's discussion of the language as presented, with amendment to strike out ",after a reasonable attempt to reach the pharmacist-in-charge," in proposed BPC 4113(d).

Attachment 2 contains a copy of the proposed statutory language as recommended by the Committee.

Attachment 1

BEFORE THE VIRGINIA BOARD OF PHARMACY

IN RE:

CVS PHARMACY #8302

Permit Number:

0201-004432

Case Number:

203229

ORDER

JURISDICTION AND PROCEDURAL HISTORY

Pursuant to Virginia Code §§ 2.2-4020, 2.2-4024(F), and 54.1-2400(11), a panel of the Virginia

Board of Pharmacy ("Board") held a formal administrative hearing on February 7, 2022, in Henrico

County, Virginia, to inquire into evidence that CVS Pharmacy #8302 may have violated certain laws

and regulations governing its permit to conduct a pharmacy in the Commonwealth of Virginia.

Olivia Basseri, Pharmacist in Charge, appeared as the representative of CVS Pharmacy #8302 at

this proceeding. CVS Pharmacy #8302 was also legally represented by the following attorneys from the

Washington, D.C., law firm of Baker & Hostetler, LLP: Elizabeth Scully, Esq., Lee Rosebush, Esq.,

and Marc Wagner, Esq..

NOTICE

By letter dated November 22, 2021, the Board sent a Notice of a Formal Administrative Hearing

("Notice") to CVS Pharmacy #8302 notifying it that a formal administrative hearing would be held on

January 11, 2021. The Notice was sent by certified and first class mail to the legal address of record on

file with the Board, and a copy of the Notice was also mailed to George Parsells, III, Esquire, counsel

for CVS Pharmacy #8302. By letter dated November 31, 2021, the Board notified CVS Pharmacy #8302

that the formal administrative hearing was continued from January 11, 2022, as requested by CVS

Pharmacy #8302 through its counsel, and the Board scheduled the hearing for February 7, 2022. Copies

of the letter were also mailed to George Parsells, III, Esquire, counsel for CVS Pharmacy #8302, and

Brian Johnson, counsel for CVS Pharmacy #8302.

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Upon consideration of the evidence, the Board adopts the following Findings of Fact and Conclusions of Law and issues the Order contained herein.

FINDINGS OF FACT

- 1. On October 7, 2011, the Board issued Permit Number 0201-004432 to CVS Pharmacy #8302 to conduct a pharmacy in the Commonwealth of Virginia. Said permit is scheduled to expire on April 30, 2022. At all times relevant to the allegations herein, said permit was in full force and effect.
- 2. Multiple pharmacists and pharmacy technicians reported to an Inspector from the Virginia Department of Health Professions ("DHP Inspector") that Respondent is routinely understaffed compared to the workload, despite multiple requests for additional staff to be scheduled. Moreover, in or about January and February 2020, prescription volume increased; yet despite this knowledge Respondent cut pharmacy technician staffing hours. Due to the lack of adequate staffing, multiple pharmacists reported that the facility would be so busy that pharmacy staff would barely be able to take a bathroom break during a 12-hour shift. Other pharmacy staff also reported getting home from a shift and realizing that due to the inadequate staffing, pharmacy staff never had time to use the bathroom during their entire shift.
- 3. Multiple pharmacy staff attributed medication dispensing errors to Respondent's facility being understaffed. Specifically:
- a. Multiple pharmacy technicians reported about one occasion, where a pharmacist dispensed an extra 100 Percocet (oxycodone, C-II) tablets when filling a prescription.
- b. A prescription for atorvastatin, a medication used to regulate cholesterol, was dispensed with incorrect instructions to "insert 1 vaginally."

- c. On or about April 2020, a pharmacist dispensed Norco (hydrocodone/acetaminophen, C-II) to a patient instead of Percocet, the medication prescribed to this patient.
- d. A pharmacist reported that "staffing levels contributed to errors" and that "she herself made a few errors in quantity given to a patient because the pharmacy was so slammed." She further reported other errors where prescriptions were entered under the incorrect patient name.
- e. A DHP Inspector reviewed approximately 100 hardcopy prescriptions for the period of November 25, 2019 through January 4, 2020 and 100 hardcopy prescriptions for the period of February 8, 2020 through March 9, 2020, for a total of approximately 200 prescriptions, and discovered a total of 74 medication dispensing errors, for an error rate of approximately 37%. The error types can be described as follows:
- i. The prescriptions with the following numbers had errors, which included prescriptions with the incorrect prescriber location, the wrong prescriber, or incomplete directions: 834925, 834923,834905, 834868, 834856, 834855, 834854, 834830, 834804, 834792, 834791, 834790, 834623, 834616, 834587, 834586, 834585, 834575, 834563, 834486, 834328, 834327, 834316, 834282, 834258, 834019, 818606, 834929, 834927, 807304, 807477, 807753, 808132, 816543, 816557, 816582, 816583, 816619, 816784, 816785, 816786, 816792, 816879, 816908, 816907, 816909, and 816916.
- ii. The prescriptions with the following numbers had errors that put the patients at risk for harm, which included incomplete directions, incorrect prescriber location, the incorrect refill, or the wrong quantity: 818922, 834869, 834858, 834857, 818915, 834649, 834621, 834438, 834426, 834367, 834319, 818270, 834928, 807986, and 816528.

- f. Multiple pharmacy staff reported that the ten phone lines into the pharmacy were "always ringing off the hook" and one reported that patients have reported not being able to get through to the pharmacy over the phone or long wait times.
- g. Multiple pharmacy staff attributed "unsafe" and "stressful" work conditions to the lack of adequate staffing and a corporate focus on numerous burdensome metrics that Respondent expected them to meet, such as prescription turnaround time, quotas for calls to patients asking patients if they want refills, offering to contact doctors to switch to more affordable prescriptions, and promoting various programs at the pharmacy. Multiple pharmacy staff reported that these "metrics affect the ability to dispense prescriptions safely." Multiple pharmacy staff reported feeling stressed or overworked, including one pharmacist who was diagnosed with anxiety and took a medical leave of absence, one pharmacy technician who took a leave of absence because of stress, and another pharmacy technician who was placed on anti-anxiety medication because of the stress of working at Respondent's facility.
- 4. Multiple pharmacists reported being unable to take a 30-minute break when working longer than six continuous hours on a shift. Pharmacists reported that though they were "allowed" by company policy to take a break, they were unable to leave the prescription department because there was little or no pharmacist overlap scheduled and a pharmacist had to be present in the prescription department to verify prescriptions and counsel patients, as needed. One pharmacist reported routinely eating her lunch behind the safe because the facility was too busy to take a designated lunch break.
- 5. Multiple pharmacists reported routinely staying late on shifts to keep the prescription queue from getting too far behind, working for as many as one to three additional hours per shift.
- 6. The pharmacist-in-charge and the pharmacist on duty repeatedly requested additional staffing hours to prevent the pharmacy from falling behind on prescription filling and dispensing and concerns for patient safety; however, the district leader, a pharmacist who does not work at Respondent's

facility, repeatedly denied these requests. If the pharmacy staff scheduled hours beyond what was approved by the district leader, the district leader would contact the pharmacist-in-charge and require her to cut hours to stay within the budgeted staffing hours.

- 7. Between on or about February 8 and March 10, 2020, the pharmacist-in-charge did appear on occasion but never staffed a complete single shift during the four-week period at the Respondent's facility.
- 8. On or about September 9, 2020, a DHP Inspector conducted an inspection of Respondent's facility and found the following deficiencies:
- a. Following the resignation of the former pharmacist-in-charge on or about February 8, 2020, the Board did not receive an application and the associated fee for the incoming pharmacist-in-charge until on or about February 26, 2020, sixteen days later.
- b. The emergency key to the prescription department was kept in a stapled bag in the safe located in the manager's office and was not maintained in an envelope with the pharmacist's signature across the seal.
- c. The biennial inventory was taken on time, but Respondent failed to document if the biennial inventory was taken before or after receipt or distribution of drugs in a 24-hour pharmacy.
- 9. In interviews with the investigator and in testimony, pharmacists and pharmacy technicians testified that pharmacists worked extra hours to keep up with the volume of prescriptions for which they were unpaid.
- 10. A CVS witness testified that they were instituting a revised lunchbreak policy for its employees in the future.

- 11. A pharmacy technician testified that two CVS representatives visited her during the investigation of CVS #8302. She testified that the CVS representatives were "putting words in my mouth despite how much I was trying to explain myself."
- 12. A second pharmacy technician testified that she felt threatened and scared because CVS sent an email stating that employees had to sign the email, which stated the employee was not going to give a statement to the Board of Pharmacy, and the employee was not going to speak to the Board of Pharmacy. At that time, the pharmacy technician had already spoken to the Board of Pharmacy.
- 13. A former pharmacist-in-charge of CVS #8302 testified that she told the CVS district manager that "someone was going to die with these working conditions."
- 14. A pharmacist who worked at CVS #8302 testified that "you go so fast, you just get it done and you are going to hurt somebody. It is just a given. And as a pharmacist, that's your worst fear. Corporate will survive if they kill somebody but is a pharmacist going to?"
 - 15. An expert witness for CVS #8302 testified that medication errors are never "okay".

CONCLUSIONS OF LAW

- 1. Finding of Fact Number 2, 3(a), 3(g) and 3(e)(ii) constitute violations of Virginia Code § 54.1-3316(1) and (13).
- 2. Finding of Fact Number 3(b), 3(c), 3(d), and 3(e)(i) constitute violations of Virginia Code § 54.1-3316(1).
 - 3. Finding of Fact Number 3(f) constitutes a violation of Virginia Code § 54.1-3316(13).
- 4. Finding of Fact Number 4 and 5 constitute violations of Virginia Code § 54.1-3316(7) and 18 VAC 110-20-110(B) of the Regulations Governing the Practice of Pharmacy ("Regulations").
- 5. Finding of Fact Number 6 constitutes a violation of Virginia Code § 54.1-3316(2) and 18 VAC 110-20-25(10) and 18 VAC 110-20-110(C) of the Regulations.

- 6. Finding of Fact Number 7 constitutes a violation of Virginia Code § 54.1-3316(2) and 18 VAC 110-20-25(10) and 18 VAC 110-20-110(G) of the Regulations.
- 7. Finding of Fact Number 8(a) constitutes a violation of Virginia Code § 54.1-3316(2) and 18 VAC 110-20-25(10) and 18 VAC 110-20-110(H) of the Regulations.
- 8. Finding of Fact Number 8(b) constitutes a violation of Virginia Code § 54.1-3316(2) and 18 VAC 110-20-25(10) and 18 VAC 110-20-190(B)(1) of the Regulations.
- 9. Finding of Fact Number 8(c) constitutes a violation of Virginia Code § 54.1-3316(2) and 18 VAC 110-20-25(10) and 18 VAC 110-20-240(A)(4) of the Regulations.

ORDER

Based on the foregoing Findings of Fact and Conclusions of Law, the Virginia Board of Pharmacy hereby ORDERS as follows:

- 1. CVS Pharmacy #8302 is REPRIMANDED.
- 2. CVS Pharmacy #8302 is assessed a MONETARY PENALTY of \$346,250.00. This penalty shall be paid to the Board by certified check or money order made payable to the Treasurer of Virginia within 60 days from the date of entry of this Order. Failure to pay the full monetary penalty by the due date may cause the matter to be sent for collection and constitutes grounds for an administrative proceeding and further discipline.
- 3. CVS Pharmacy #8302 is placed on INDEFINITE PROBATION for a period of not less than two years subject to the following terms and conditions:
- a. The period of probation shall begin on the date that this Order is entered and shall remain in effect until the Board has notified CVS Pharmacy #8302 in writing that it is released from probation.

- b. CVS Pharmacy #8302 shall be subject to quarterly unannounced inspections by an inspector of the Department of Health Professions. The inspections shall be conducted during normal business hours and shall include a review of prescription records and an audit of pharmacy errors. CVS Pharmacy #8302 shall be responsible for the payment of an inspection fee to be paid to the Board within 30 days of each inspection. Any fee not paid in a timely manner will be sent for collection. In the event that any inspection reveals a possible violation of the laws or regulations pertaining to the practice of pharmacy in Virginia or the Virginia Drug Control Act (Virginia Code §§ 54.1-3400 *et seq.*), the Board may notice CVS Pharmacy #8302 to appear for an administrative proceeding.
- c. CVS Pharmacy #8302 shall submit quarterly "Self Reports" which include a reporting of hours worked each week by pharmacists and pharmacy technicians and the number of prescriptions dispensed weekly. Self Reports shall be submitted on a quarterly basis to the Board, with the first report due no later than 60 days from the date of entry of the Order and subsequent reports due the last day of the March, June, September, and December until CVS Pharmacy #8302 is notified, in writing, that the reporting requirement is ended.
- 4. CVS Pharmacy #8302 shall bear any costs associated with the terms and conditions of this Order.
- 5. CVS Pharmacy #8302 shall comply with all laws and regulations governing the practice of pharmacy in the Commonwealth of Virginia. Any violation of the foregoing terms and conditions of this Order or any statute or regulation governing the practice of pharmacy shall constitute grounds for further disciplinary action.
- 6. This Order shall remain in effect until the Board has notified CVS Pharmacy #8302 in writing that it is released from all terms and conditions.

CVS Pharmacy #8302 ORDER Page 9 of 9

7. The Executive Director of the Board is authorized to issue a letter acknowledging satisfactory completion of the foregoing conditions or to refer the matter to a Special Conference Committee for review of CVS Pharmacy #8302's compliance with the foregoing conditions.

Pursuant to Virginia Code § 54.1-2400.2, the signed original of this Order shall remain in the custody of the Department of Health Professions as a public record, and shall be made available for public inspection and copying upon request.

FOR THE BOARD

Caroline D. Juran

Executive Director

Virginia Board of Pharmacy

ENTERED AND MAILED ON:

3/17/2022

NOTICE OF RIGHT TO APPEAL

As provided by Rule 2A:2 of the Supreme Court of Virginia, CVS Pharmacy #8302 has 30 days from the date it is served with this Order in which to appeal this decision by filing a Notice of Appeal with Caroline Juran, Executive Director, Board of Pharmacy, 9960 Mayland Drive, Suite 300, Henrico, Virginia 23233. The service date shall be defined as the date CVS Pharmacy #8302 actually received this decision or the date it was mailed to CVS Pharmacy #8302, whichever occurred first. In the event this decision is served upon it by mail, three days are added to that period.

Attachment 2

Proposed Amendment to BPC 4113.5.

- (a) A community pharmacy shall not require a pharmacist employee to engage in the practice of pharmacy at any time the pharmacy is open to the public, unless either another employee of the pharmacy or, if the pharmacy is located within another establishment, an employee of the establishment within which the pharmacy is located, is made available to assist the pharmacist at all times.
- (b) This section shall not apply to any of the following:
 - (1) A hospital pharmacy, as defined in Section 4029 or 4056.
 - (2) A pharmacy located in a hospital facility, including, but not limited to, a building where outpatient services are provided in accordance with the hospital's license.
 - (3) A pharmacy owned or operated by a federal, state, local, or tribal government entity, including, but not limited to, a correctional pharmacy, a University of California pharmacy, or a pharmacy operated by the State Department of State Hospitals.
 - (4) A pharmacy owned by a person or persons who, collectively, control the majority of the beneficial interest in no more than four pharmacies in California.
 - (5) A pharmacy entirely owned and operated by a health care service plan that exclusively contracts with no more than two medical groups in the state to provide, or arrange for the provision of, professional medical services to the enrollees of the plan.
 - (6) A pharmacy that permits patients to receive medications at a drivethrough window when both of the following conditions are met:
 - (A) A pharmacist is working during the times when patients may receive medication only at the drive-through window.
 - (B) The pharmacist's employer does not require the pharmacist to retrieve items for sale to patients if the items are located outside the pharmacy. These items include, but are not limited to, items for which a prescription is not required.
 - (7) Any other pharmacy from which controlled substances, dangerous drugs, or dangerous devices are not furnished, sold, or dispensed at retail.
- (c) A violation of subdivision (a) is not subject to subdivision (a) of Section 4321.
- (d) The board shall not take action against a pharmacy for a violation of this section if both of the following apply:

- (1) Another employee is unavailable to assist the pharmacist due to reasonably unanticipated circumstances, including, but not limited to, illness, injury, family emergency, or the employee's termination or resignation.
- (2) The pharmacy takes all reasonable action to make another employee available to assist the pharmacist.
- (e) The pharmacist on duty may close a pharmacy if, in their opinion, the staffing at the pharmacy is inadequate to safely fill or dispense prescriptions or provide other patient care services in a safe manner without fear of retaliation.
- (f) A pharmacy is always staffed with at least one clerk or pharmacy technician fully dedicated to performing pharmacy related services. Where staffing of pharmacist hours does not overlap sufficiently, scheduled closures for lunch time for all pharmacy staff shall be established and publicly posted and included on the outgoing phone message.
- (g) This section shall not be construed to permit an employee who is not licensed under this chapter to engage in any act for which a license is required under this chapter.

Proposal to Amend BPC 4113.

- (a) Every pharmacy shall designate a pharmacist-in-charge and, within 30 days thereof, shall notify the board in writing of the identity and license number of that pharmacist and the date he or she was designated.
- (b) The proposed pharmacist-in-charge shall be subject to approval by the board. The board shall not issue or renew a pharmacy license without identification of an approved pharmacist-in-charge for the pharmacy.
- (c) The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy. The pharmacist-in-charge shall have autonomy to make staffing decisions to ensure sufficient personnel are present in the pharmacy to prevent fatigue, distraction or other conditions that may interfere with a pharmacist's ability to practice competently and safely.
- (d) The pharmacist-in-charge shall have the authority to close a pharmacy if workplace hazards, such as unsanitary conditions, temperatures deviate from appropriate drug storage conditions, or other conditions based on their professional judgement may create an unsafe environment for personnel or pharmacy staff. In the event the pharmacist-in-charge is not available, the pharmacist on duty, may close the pharmacy to the reasons previously cited.

- (e) Every pharmacy shall notify the board in writing, on a form designed by the board, within 30 days of the date when a pharmacist-in-charge ceases to act as the pharmacist-in-charge, and shall on the same form propose another pharmacist to take over as the pharmacist-in-charge. The proposed replacement pharmacist-in-charge shall be subject to approval by the board. If disapproved, the pharmacy shall propose another replacement within 15 days of the date of disapproval and shall continue to name proposed replacements until a pharmacist-in-charge is approved by the board.
- (e-f) If a pharmacy is unable, in the exercise of reasonable diligence, to identify within 30 days a permanent replacement pharmacist-in-charge to propose to the board on the notification form, the pharmacy may instead provide on that form the name of any pharmacist who is an employee, officer, or administrator of the pharmacy or the entity that owns the pharmacy and who is actively involved in the management of the pharmacy on a daily basis, to act as the interim pharmacist-in-charge for a period not to exceed 120 days. The pharmacy, or the entity that owns the pharmacy, shall be prepared during normal business hours to provide a representative of the board with the name of the interim pharmacist-in-charge with documentation of the active involvement of the interim pharmacist-in-charge in the daily management of the pharmacy, and with documentation of the pharmacy's good faith efforts prior to naming the interim pharmacist-in-charge to obtain a permanent pharmacist-in-charge. By no later than 120 days following the identification of the interim pharmacistin-charge, the pharmacy shall propose to the board the name of a pharmacist to serve as the permanent pharmacist-in-charge. The proposed permanent pharmacist-in-charge shall be subject to approval by the board. If disapproved, the pharmacy shall propose another replacement within 15 days of the date of disapproval, and shall continue to name proposed replacements until a pharmacist-in-charge is approved by the board.

Proposal to Amend BPC 4301.

The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been issued by mistake. Unprofessional conduct includes, but is not limited to, any of the following:

- (a) Procurement of a license by fraud or misrepresentation.
- (b) Incompetence.
- (c) Gross negligence.
- (d) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153 of the Health and Safety Code.
- (e) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153.5 of the Health and Safety Code. Factors to be considered in determining whether the furnishing of controlled substances is

clearly excessive shall include, but not be limited to, the amount of controlled substances furnished, the previous ordering pattern of the customer (including size and frequency of orders), the type and size of the customer, and where and to whom the customer distributes its product.

- (f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.
- (g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.
- (h) The administering to oneself, of any controlled substance, or the use of any dangerous drug or of alcoholic beverages to the extent or in a manner as to be dangerous or injurious to oneself, to a person holding a license under this chapter, or to any other person or to the public, or to the extent that the use impairs the ability of the person to conduct with safety to the public the practice authorized by the license.
- (i) Except as otherwise authorized by law, knowingly selling, furnishing, giving away, or administering, or offering to sell, furnish, give away, or administer, any controlled substance to an addict.
- (j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.
- (k) The conviction of more than one misdemeanor or any felony involving the use, consumption, or self-administration of any dangerous drug or alcoholic beverage, or any combination of those substances.
- (I) The conviction of a crime substantially related to the qualifications, functions, and duties of a licensee under this chapter. The record of conviction of a violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of a violation of the statutes of this state regulating controlled substances or dangerous drugs shall be conclusive evidence of unprofessional conduct. In all other cases, the record of conviction shall be conclusive evidence only of the fact that the conviction occurred. The board may inquire into the circumstances surrounding the commission of the crime, in order to fix the degree of discipline or, in the case of a conviction not involving controlled substances or dangerous drugs, to determine if the conviction is of an offense substantially related to the qualifications, functions, and duties of a licensee under this chapter. A plea or verdict of guilty or a conviction following a plea of nolo contendere is deemed to be a conviction within the meaning of this provision. The board may take action when the time for appeal has elapsed, or the judgment of conviction has been affirmed on appeal or when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under Section 1203.4 of the Penal Code allowing the person to withdraw his or her plea

of guilty and to enter a plea of not guilty, or setting aside the verdict of guilty, or dismissing the accusation, information, or indictment.

- (m) The cash compromise of a charge of violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code relating to the Medi-Cal program.
- (n) The revocation, suspension, or other discipline by another state of a license to practice pharmacy, operate a pharmacy, or do any other act for which a license is required by this chapter that would be grounds for revocation, suspension, or other discipline under this chapter. Any disciplinary action taken by the board pursuant to this section shall be coterminous with action taken by another state, except that the term of any discipline taken by the board may exceed that of another state, consistent with the board's enforcement guidelines. The evidence of discipline by another state is conclusive proof of unprofessional conduct.
- (o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency.
- (p) Actions or conduct that would have warranted denial of a license.
- (q) Engaging in any conduct that subverts or attempts to subvert an investigation of the board.
- (r) The selling, trading, transferring, or furnishing of drugs obtained pursuant to Section 256b of Title 42 of the United States Code to any person a licensee knows or reasonably should have known, not to be a patient of a covered entity, as defined in paragraph (4) of subsection (a) of Section 256b of Title 42 of the United States Code.
- (s) The clearly excessive furnishing of dangerous drugs by a wholesaler to a pharmacy that primarily or solely dispenses prescription drugs to patients of long-term care facilities. Factors to be considered in determining whether the furnishing of dangerous drugs is clearly excessive shall include, but not be limited to, the amount of dangerous drugs furnished to a pharmacy that primarily or solely dispenses prescription drugs to patients of long-term care facilities, the previous ordering pattern of the pharmacy, and the general patient population to whom the pharmacy distributes the dangerous drugs. That a wholesaler has established, and employs, a tracking system that complies with the requirements of subdivision (b) of Section 4164 shall be considered in determining whether there has been a violation of this subdivision. This provision shall not be interpreted to require a wholesaler to obtain personal medical information or be authorized to permit a wholesaler to have access to personal medical

- information except as otherwise authorized by Section 56 and following of the Civil Code. For purposes of this section, "long-term care facility" has the same meaning given the term in Section 1418 of the Health and Safety Code.
- (t) The acquisition of a nonprescription diabetes test device from a person that the licensee knew or should have known was not the nonprescription diabetes test device's manufacturer or the manufacturer's authorized distributor as identified in Section 4160.5.
- (u) The submission of a reimbursement claim for a nonprescription diabetes test device to a pharmaceutical benefit manager, health insurer, government agency, or other third-party payor when the licensee knew or reasonably should have known that the diabetes test device was not purchased either directly from the manufacturer or from the nonprescription diabetes test device manufacturer's authorized distributors as identified in Section 4160.5.
- (v) Actions or conduct that would subvert or tend to subvert the efforts of a pharmacist to comply with laws and regulations, or exercise professional judgement, including creating or allowing conditions that may interfere with a pharmacist's ability to practice with competency and safety or creating or allowing an environment that may jeopardize patient care.
- (w) Actions or conduct that would subvert or tend to subvert the efforts of a pharmacist-in-charge to comply with laws and regulations, exercise professional judgement, or make determinations about adequate staffing levels to safely fill prescriptions of the pharmacy or provide other patient care services in a safe and competent manner.
- (x) Actions or conduct that would subvert or tend to subvert the efforts of a pharmacist intern or and pharmacy technician to comply with laws or regulations.
- (y) Establishing policies and procedures related to time guarantees to fill prescriptions within a specified time unless such guarantees are required by law or to meet contractual requirements.