California State Board of Pharmacy
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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

Legislation and Regulation Committee
Chair Report

Greg Lippe, Public Member, Chair
Lavanza Butler, Licensee Member, Vice Chair
Ryan Brooks, Public Member
Shirley Kim, Public Member
Seung Oh, Licensee Member
Maria Serpa, Licensee Member

I. Call to Order, Establishment of Quorum, and General Announcements

II. Public Comment for Items Not on the Agenda, Matters for Future Meetings

Note: The committee may not discuss or take action on any matter raised during this public comment section that is not included on this agenda, except to decide whether to place the matter on the agenda of a future meeting. [Government Code sections 11125, 11125.7(a)]

III. Discussion and Consideration of Petition Submitted to the Board for Interpretative Ruling or Policy Statement Regarding Mandatory Reporting Provision of Penal Code Section 11160 and Its Applicability to Community Pharmacists

Background
During the June 18, 2020, the Board received public comment requesting that the Board provide a policy statement or other ruling regarding the provisions of California Penal Code Section 11160 and its applicability to community pharmacists.

Subsequent to the meeting, the Board received a formal request for consideration.

For Committee Discussion and Consideration
During the meeting members will have the opportunity to discuss the formal request and the legal analysis prepared by DCA counsel William Maguire.

In short, the legal analysis concludes that it does not appear that community pharmacists would be considered a mandatory reporter under the provisions of the penal code. As there is no definition for "community pharmacist," anyone evaluating the issue should make an independent assessment of the facts. It is also very important to note that enforcement of Penal Code section 11160 does not reside with the Board. As such, it is recommended that the Board not issue an interpretative ruling nor policy statement on the subject.

Attachment 1 includes a copy of the petition and legal analysis.

IV. Discussion and Consideration of Pharmacy Security Requirements

Background

Beginning on or around May 29, numerous pharmacies in California, and nationwide, were damaged, vandalized, looted, and, in some cases, set on fire due to the recent riots occurring throughout the state of California. The scope of damage ranged significantly and, in some cases, appears to escalate over time. Some pharmacies were targeted on more than one occasion.

On June 1, 2020, the Board released guidance to provide pharmacies with recommendations on actions including:

1. Provisions for identifying losses
2. Provisions to ensure continuity of patient care for consumers
3. Instructions for handle adulterated drugs
4. Provisions for operating from a temporary location
5. Notification requirements
6. Provisions to notify the Board of a discontinuance of business.

Further, the guidance also reminded licensees of the "ask inspector" email and phone number.

Since that time board staff has been in communication with pharmacies who experienced damages and losses, primarily during the period of May 29, 2020 to June 2, 2020. Based on the voluntary reporting of closures, damages and controlled substance losses, as of June 30, the board is aware of 286 pharmacies reporting damage or destruction. The reporting indicates that 98 of the pharmacies sustaining damage were independent pharmacies and five remain closed. Further, the reporting indicates that 187 chain store pharmacies were impacted, with 100 either still closed or the Board was unclear on the status.

A review of the information indicates that some regions of the state were impacted more significantly than others. The below details the highest frequency of reported impact by city.

Ranking	City:	# of Pharmacies, Reported
1	Los Angeles	56
2	San Francisco	38
3	Oakland	26
4	Long Beach	26
5	Sacramento	16
6	Santa Monica	13

7	San Bernardino	12
8	San Leandro	11
9	Van Nuys	10
10	Hayward	8

To fully understand the scope and severity of the damage and destruction as well as to demonstrate what appears to be planned and coordinated efforts on the part of the looters, below is a summary of the types of damage sustained.

- Front and back doors, including iron gates were smashed and pried open.
- Safes and controlled substance cabinets were stolen, pried or smashed open.
- Surveillance videos inside some pharmacies showed groups arriving in cars and trucks with hammers, drills, saws, chains, and bolt cutters. In some cases, there appeared to be coordination between several groups, with each following in close succession.
- Refrigerator doors were left open and fire extinguishers were used leaving retardant throughout pharmacies.
- Two pharmacies were set on fire.

Pharmacies were looted while the pharmacy was open, closed, even after windows and doors were boarded up. Many alarm systems were activated but law enforcement did not respond.

The Board will have a better understanding of the full impact of drugs stolen after drug losses are reported to the Board. In general, it appears both controlled and non-controlled drugs were taken. Most pharmacies reported that the individuals were specifically looking for promethazine with codeine and guaifenesin with codeine. Expired drugs were also stolen, as were drugs in the will call area or those ready for delivery. Waste baskets including waste baskets used for confidential waste were emptied and used to transport drugs out of the pharmacy.

In addition to drugs, prescription records, cash registers and cash, computers, as well as licenses (pharmacy, pharmacist, pharmacy technician and DEA) were also taken in some cases. Over the counter and other front-end products were stolen.

For Committee Discussion and Consideration

During the meeting, members will have the opportunity to discuss these events and determine what, if any, action should be recommended to the Board.

V. Discussion and Consideration of Legislation Impacting the Practice of Pharmacy, the Board's Jurisdiction, or Board Operations

Attachment 2

a. Assembly Bill 2028 (Aguiar-Curry) State Agencies: Meetings
Version: As amended June 4, 2020
Status: Referred to Senate Committee on Governmental Organization
Staff recommendation: Oppose unless amended
Summary: This measure would require state agencies to post meeting materials the same day the information is disseminated to members of the state body, or at least 48 hours in advance of the meeting, whichever is sooner. Under the provisions of the measure, additional flexibility is provided for pending legislation

b. Assembly Bill 2077 (Ting) Hypodermic Needles and Syringes
Version: As amended May 20, 2020
Status: Referred to Senate Committee on Health
Staff Recommendation: Support
Summary: Extends provisions of existing law that authorize a physician or pharmacist to furnish hypodermic needles and syringes for human use to a person eighteen years or older, without a prescription.

c. Assembly Bill 2113 (Low) Refugees, Asylees, and Immigrants: Licensing
Version: As amended May 4, 2020
Status: Referred to Senate
Staff Recommendation: None
Summary: Requires Boards within the DCA to expedite the initial licensure process for an applicant who supplies satisfactory evidence to the Board that the applicant is a refugee, been granted political asylum, or possesses a special immigrant visa.

d. Assembly Bill 2549 (Salas) Department of Consumer Affairs: Temporary Licenses
Version: As amended May 18, 2020
Status: Referred to the Senate
Staff Recommendation: Oppose Unless Amended
Summary: Would require the Board to issue temporary licenses to military spouse and requires the Board to promulgate regulations

e. Assembly Bill 2983 (Holden) Pharmacies: Automatic Refills
Version: As amended June 15, 2020
Status: Referred to the Senate
Staff Recommendation: Support
Summary: Would prohibit a pharmacy from automatically contacting a prescriber to request refill authorization unless the prescriber or patient has expressly authorized such contact.

f. Assembly Bill 3045 (Gray) Department of Consumer Affairs: Boards: Veterans
Version: As introduced February 21, 2020
Status: Referred to the Senate
Staff Recommendation: Oppose unless amended

Summary: Would require Boards within the DCA to issue licenses to an applicant if the applicant meets specified requirements, including that the applicant was honorably discharged from the armed forces, or is married or in a domestic partnership or other legal union with an active duty member.

g. Assembly Bill 3342 (Bauer-Kahan) Child Day Care Facilities: Epinephrine Auto Injectors
Version: As amended May 4, 2020
Status: Referred to Committee on Human Services
Staff Recommendation: Support
Summary: As related to the Board would authorize a pharmacy to furnish epinephrine auto-injectors to the State Department of Health Care Services under the program created pursuant to this bill, subject to similar requirements.

h. Senate Bill 878 (Jones) Department of Consumer Affairs Licensing: Applications
Version: As amended June 18, 2020
Status: Referred to Assembly Committee on Business and Professions
Staff Recommendation: None
Summary: Requires Boards within the DCA to prominently display the current timeframe for processing initial and renewal license applications on its internet website.

i. Senate Bill 1474 (Committee on Business, Professions and Economic Development
Version: As amended May 14, 2020
Status: Referred to Assembly Committee on Business and Professions
Staff Recommendation: Support
Summary: Would extend the operations of several Boards for one year.

Attachment 2 includes a copy of each measure and a bill analysis.

VI. Board Adopted Regulations Approved by the Office of Administrative Law

Attachment 3

a. Proposed Regulation to Amend Title 16 CCR Section 1706.2 Related to Abandonment of Applications

Summary of Regulation: This proposal updates the application abandonment language to include all licensing programs to ensure that all applicants have appropriate notice about the requirements for abandoning an application and reduce the administrative workload associated with the need for frequent amendments when new licensing programs are established.

Status: Board adopted November 6, 2019. Approved by OAL on June 15, 2020. The regulation becomes effective on October 1, 2020.

b. Proposed Regulation to Amend Title 16 CCR Section 1707.2 Related to Duty to Consult

Summary of Regulation: This proposal amends the Board's regulations regarding the duty to provide consultation for mail-order pharmacies.

Status: Board adopted November 6, 2019. Approved by OAL on June 19, 2020. The regulation becomes effective on October 1, 2020.

VII. Discussion and Consideration of Board Adopted Regulations Undergoing Final Review by the Office of Administrative Law

Attachment 4

a. Proposed Regulation to Add Title 16, Section 1714.3, Community Pharmacy Staffing

Summary of Regulation: This proposal will require establish the criteria a pharmacy must meet to identify and ensure a person is assigned to assist the pharmacist as needed when the pharmacist is working as alone in compliance with B&P section 4113.5.

Status: Submitted for review by OAL: June 5, 2020

VIII. Discussion and Consideration of Board Adopted Regulations Undergoing Formal Review by the Department of Consumer Affairs or the Business, Consumer Services and Housing Agency

Attachment 5

a. Proposed Regulation to Amend Title 16, Sections 1769 and 1770, Substantial Relationship and Rehabilitation Criteria

Summary of Regulation: This proposal will increase transparency and clarity to license applicants with respect to rehabilitation criteria the board considers when evaluating an applicant's eligibility for licensure.

Status: Submitted to DCA for Formal Review: May 15, 2020. Submitted to Agency for Formal Review: June 17, 2020.

b. Proposed Regulation to Amend Title 16, Sections 1702, 1702.1, 1702.2, 1702.5, Renewal Requirements

Summary of Regulation: This proposal updates the renewal requirement language to include all licensing programs and reduce the administrative workload associated with the need for frequent amendments when new licensing programs are established.

Status: Submitted to DCA for Formal Review: **May 19, 2020**

c. Proposed Regulation to Amend Title 16, Section 1707, Off-Site Storage

Summary of Regulation: This proposal amends the board's regulations regarding the waiver requirements for off-site storage of records to allow those cited for a records violation to receive a waiver to store records off-site.

Status: Submitted to DCA for Formal Review: June 15, 2020

IX. Discussion and Consideration of Board Approved Regulations Undergoing Public Comment

Attachment 6

a. Proposed Regulations to Amend Title 16 CCR Sections 1780-1783 et seq., Related to Dangerous Drug Distributors and Third-Party Logistics Providers

Summary of Regulation: This proposal establishes the regulatory framework for third-party logistics providers.

Status: Noticed for Public Comment on May 29, 2020. The 45-day public comment period ends on July 13, 2020.

b. Proposed Regulations to Amend Title 16 CCR Section 1711 Related to Quality Assurance Programs for ADDS, Section 1713 Related to Use of Receipt and Delivery of Prescriptions and Prescription Medications, and Add Section 1715.1 Related to ADDS Self-Assessment Form 17M-112

Summary of Regulation: This proposal will require submission of quality assurance records to the Board, update the Board regulations with respect to the use of an APDS, and identify the specific requirements for the annual completion of the ADDS self-assessment form.

Status: Noticed for Public Comment on July 3, 2020. The 45-day public comment period ends on August 17, 2020.

X. Discussion and Consideration of Board Approved Regulations Undergoing Pre-Notice Review by the Department of Consumer Affairs or the Business, Consumer Services and Housing Agency

Attachment 7

Provided below is a summary of each of the regulations currently undergoing pre-notice review. As there are many steps included in the pre-review process, the status is detailed below. Members have previously requested that regulations without action for over 30 days be highlighted. As such, regulations with inactivity for over 30 days are indicated below in **red**. The full timelines for each of the regulation are included in **Attachment 6**.

- **Regulations under Pre-Notice review by the Business, Consumer Services and Housing Agency**

a. Proposed Regulations to Add Title 16 CCR Sections 1717.5 Related to Automatic Refill Programs

Summary of Regulation: This proposal establishes regulatory requirements for automated refill programs.

Status: Approved by DCA and Submitted to Agency for Formal Review: January 9, 2020

- **Regulations under Pre-Notice review by DCA Legal or DCA Budget Office**

b. Proposed Regulations to Amend Title 16 CCR Section 1715 to Update Self-Assessment Forms 17M-13 and 17M-14

Summary of Regulation: This proposal updates the Self-Assessment forms 17M-13 (rev. 10/16) and 17M-14 (rev. 10/16) as incorporated by reference in Title 16 CCR section 1715. Additionally, this regulation updates section 1715 with clarifying language as to the completion and certification requirements of the self-assessment forms.

Status: Submitted to DCA for Pre-Notice Review: December 26, 2018

The Board approved self-assessment forms can be found on the Board's website: https://www.pharmacy.ca.gov/licensees/facility/self_assess.shtml

c. Proposed Regulations to Amend Title 16 CCR Section 1784 to Update the Wholesaler/3PL Self-Assessment Form 17M-26

Summary of Regulation: This proposal updates the Self-Assessment form 17M-26 (rev. 10/16) as incorporated by reference in Title 16 CCR section 1784. Additionally, this regulation updates section 1784 with clarifying language as to the completion and certification requirements of the self-assessment form.

Status: Submitted to DCA for Pre-Notice Review: December 26, 2018

The Board approved self-assessment forms can be found on the Board's website: https://www.pharmacy.ca.gov/licensees/facility/self_assess.shtml

d. Proposed Permanent Regulation to Add Title 16 CCR Section 1747 Related to Independent HIV Preexposure and Postexposure Prophylaxis Furnishing

Summary of Regulation: This proposal, on an permanent basis, establishes the criteria for training programs to meet in order to be offered to pharmacists so that the

pharmacists may independently initiate and furnish preexposure and postexposure prophylaxis.

Status: **Submitted to DCA for Pre-Notice Review: February 7, 2020**

e. Proposed Regulation to Amend Title 16 CCR Section 1715.65 Related to Inventory Reconciliation

Summary of Regulation: This proposal amends and clarifies the requirements for the completion of the inventory reconciliation report.

Status: **Submitted to DCA for Pre-Notice Review: May 11, 2020**

f. Proposed Regulation to Amend Title 16 CCR Section 1715.6 Related to Drug Losses

Summary of Regulation: This proposal amends the drug loss reporting requirements to further define when drug losses must be reported to increase clarity for the regulated public.

Status: Submitted to DCA for Pre-Notice Review: June 3, 2020

XI. Discussion and Consideration of Board Approved Text to Initiate Rulemaking –Staff Drafting Documents for Pre-Notice Review by the Department of Consumer Affairs and the Business, Consumer Services and Housing Agency

Attachment 8

a. Proposed Regulations to Amend Title 16 CCR Section 1793.5 Related to the Pharmacy Technician Application, Section 1793.6 Related to the Pharmacy Technician Training Requirements, and Section 1793.65 Related to the Pharmacy Technician Certification Programs

Summary of Regulation:
This proposal establishes the training requirements and certification programs and updates the application for licensure for pharmacy technicians.

Status: **Returned to the board: December 12, 2019. Board staff is working on amendments to the package to integrate AB 2138 and the substantial relationship/rehabilitation criteria.**

b. Proposed Regulation to Amend Title 16 CCR Section 1709 Related to Pharmacy Ownership, Management, and Control, Including Through Trusts

Summary of Regulation: This proposal amends the board's regulations regarding ownership to include provisions relating to trust ownership of pharmacies.

Status: **Returned to the board: April 22, 2020. Board staff is reviewing the legal recommendations offered by DCA to determine a course of action.**

XII. Future Committee Meeting Dates

The committee will meet on the following dates:

- October 27, 2020

Attachment 1

PETITION FOR INTERPRETATIVE RULING OR POLICY STATEMENT SUBMITTED TO THE CALIFORNIA STATE BOARD OF PHARMACY

RE: Clarifying Community Pharmacist Non-Coverage Under California Domestic Violence Mandatory Reporting Provision (Cal. Pen. Code §11160)

To Whom It May Concern at the California State Board of Pharmacy,

My name is Saikrishna Upadhyayula, and I am a Doctor of Pharmacy and Registered Pharmacist. I am also a newly graduated J.D. from the University of California, Irvine (UCI) School of Law, where, to date, I have spent over a year representing and advocating for victims of domestic violence through the UCI Domestic Violence Clinic.

For the reasons stated below, I am writing to petition the Board of Pharmacy for an interpretative ruling or agency policy statement clarifying that community-based pharmacists are *not* covered practitioners under California's domestic violence mandatory reporting provision codified in California Penal Code Section 11160 for purposes of Board enforcement actions.

Domestic violence is a critical healthcare issue, with long-lived medical and social consequences for affected individuals. However, research shows that mandatory reporting obligations—actual or perceived—deter vulnerable victims of domestic violence from accessing care services and resources in common clinical venues. Statutory analysis reveals that community pharmacists are not subject to these mandatory reporting obligations and are well-poised to screen for domestic violence in appropriate cases, promoting health and safety while preserving autonomy for needful patients.

However, there is confusion on this issue among pharmacists and patients alike, chilling both parties from collaborating to reduce the impact of domestic violence in our communities. The matter is increasingly urgent in light of numerous reports indicating a surge in domestic abuse during the community lockdowns implemented to curb the spread of COVID-19.

As evidence of the unmet need for community-based domestic violence screenings increases, Board clarification on this issue is essential and in the public interest.

Domestic Violence is a Primary Health Concern

Through working with victims of domestic violence, I have come to appreciate—as both a pharmacist and an advocate—that violence by intimate partners is a pressing primary health concern. Domestic, or "intimate partner," violence may include physical violence as well sexual, emotional, or social abuse by a partner in a dating or other domestic relationship.[1] In California, one in three women and one in four men experience some form of intimate partner violence in their lifetimes.[2] The direct effects of intimate partner violence are millions of physical injuries and innumerable mental and emotional traumas. As a result of the sexual and psychological coercion that

[1] Domestic Violence Prevention Act, CAL. FAM. CODE § 6203 (Deering 2016); CAL. FAM. CODE § 6320 (Deering 2014).
[2] *Domestic Violence in California*, NATIONAL COALITION AGAINST DOMESTIC VIOLENCE, https://assets.speakcdn.com/assets/2497/california_2019.pdf (referencing CDC data on the lifetime prevalence of rape, physical violence, and/or stalking by an intimate partner by state of residence).

characterizes intimate partner violence, victims experience higher rates of STD transmission and poorer management of conditions such as HIV. Female victims are at increased risk for obstetrics and gynecological pathologies, including cervical cancer in the absence of informed preventative care.[3]

Furthermore, numerous validated studies have shown that individuals who experienced intimate partner violence are significantly more likely to suffer from chronic conditions such as diabetes, hypertension, asthma, insomnia, depression, and chronic pain.[4] Intimate partner violence victims are also significantly more likely to suffer from multiple chronic conditions and substance abuse disorders, including Opioid Use Disorder (OUD), than individuals who never suffered abuse, and studies show the downstream effects of intimate partner violence can have medical and social consequences emanating over generations.[5, 6]

Injuries, mental health effects, and chronic metabolic pathologies resulting from intimate partner violence cost California billions of dollars a year.[7] But, there is something we can do. The Centers for Disease Control and Prevention (CDC), Institute of Medicine (IOM), experts at the U.S. Department of Health and Human Services (HHS), and most major medical organizations and associations agree that screening is the most effective method of preventing and reducing the impact of intimate partner violence.[8, 9]

Mandatory Reporting Laws Undermine Care for Domestic Violence Victims

However, a growing body of literature reveals that the potential benefits of intimate partner violence screening are, in many cases, undermined by mandatory reporting laws. A large-scale study conducted by the National Domestic Violence Hotline surveying nearly four-thousand domestic violence survivors and help-seekers found that mandatory reporting policies directly and detrimentally impacted respondent decisions to share critical information with providers or to seek out care at all.[10] For those with direct experience of mandated reports, 50% said the report made things much worse. Only 3% reported that mandatory intervention made things much better.[11] Qualitative responses by survivors shed some light on why this might be: many survivors reported

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[3] Alexis Jetter, *A Hidden Cause of Chronic Illness*, MORE MAGAZINE (Nov. 2013), https://dartcenter.org/content/hidden-cause-chronic-illness.
[4] Gina Dillon et al., *Mental and Physical Health and Intimate Partner Violence against Women: A Review of the Literature*, INTERNATIONAL JOURNAL OF FAMILY MEDICINE, Jan. 2013. doi:10.1155/2013/313909.
[5] *Verizon Foundation and MORE Magazine Survey: Exploring the Relationship Between Domestic Violence and Chronic Health Conditions*, VERIZON FOUNDATION (summarized at http://www.ncdsv.org/Verizon-More_Exploring-the-Relationship-between-DV-and-Chronic-Health-Conditions-survey-summary_10-2013.pdf).
[6] Jetter, *supra* note 3.
[7] CENTERS FOR DISEASE CONTROL AND PREVENTION, COSTS OF INTIMATE PARTNER VIOLENCE AGAINST WOMEN IN THE UNITED STATES (Mar. 2003), https://www.cdc.gov/violenceprevention/pdf/ipvbook-a.pdf.
[8] Anyssa Garza, *Domestic Violence: The Power of Screening,* PHARMACY TIMES (June 14, 2017), https://www.pharmacytimes.com/publications/issue/2017/june2017/domestic-violence.
[9] OFFICE OF HUMAN SERVICES POLICY, OFFICE OF THE ASSISTANT SECRETARY FOR PLANNING AND EVALUATION, U.S. DEP'T. OF HEALTH AND HUMAN SERVICES, ASPE POLICY BRIEF: SCREENING FOR DOMESTIC VIOLENCE IN HEALTH CARE SETTINGS (AUG. 2013); *see also* Garza, *supra* note 8.
[10] Carrie Lippy et al., *There's No One I Can Trust – The Impact of Mandatory Reporting on the Help-Seeking and Wellbeing of Domestic Violence Survivors*, NATIONAL LGBTQ DV CAPACITY BUILDING LEARNING CENTER (2016) (accessible at http://www.ncdsv.org/Natl-LGBTQ-DV-CBLC_There%27s+No+One+I+Can+Trust_2016.pdf) at 4.
[11] *Id.* at 10.

unintended consequences and hardships as a result of involuntary engagement with the criminal justice system.[12] In many cases, police involvement against the survivor's wishes results in social and economic disenfranchisement of the survivor, causing further encumbrance of state resources. In light of these dynamics, many prominent stakeholders such as the American Medical Association (AMA) have come out against mandatory reporting laws for adult survivors.[13]

In particular, mandatory reporting policies may deter socially and legally vulnerable patients from accessing medical care in common clinical venues where treatment by a covered provider could trigger police involvement. Accordingly, those patients are likely to first turn to community resources and products for self-care.

With our training and accessibility, pharmacists can help. Community pharmacists are the most accessible doctorate-level healthcare practitioners in the country, and well-poised to screen for domestic violence, identify signs of abuse earlier than other professionals, and provide counseling and referral resources without compromising patient autonomy. Pharmacists are clinically savvy and trained to conduct health screenings, manage medication therapy for chronic metabolic conditions and pain, and provide vaccinations—including for diseases like HPV which may result from sexual coercion in an intimate partnership.

Community Pharmacists Are Not Statutorily Mandated Reporters for Domestic Violence

Most importantly, community pharmacists are not domestic violence mandatory reporters as defined in California Penal Code Section 11160, titled "Injuries required to be reported; Method of reporting; Team reports; Internal procedures."[14] The section provides in part:

> **(a)** A health practitioner, as defined in subdivision (a) of Section 11162.5, employed by a health facility, clinic, physician's office, local or state public health department, local government agency, or a clinic or other type of facility operated by a local or state public health department who, in the health practitioner's professional capacity or within the scope of the health practitioner's employment, provides medical services for a physical condition to a patient whom the health practitioner knows or reasonably suspects is a person described as follows, shall immediately make a report in accordance with subdivision (b):
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> . . .
>
> **(2)** A person suffering from any wound or other physical injury inflicted upon the person where the injury is the result of assaultive or abusive conduct.

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[12] *See* Richard Wexler, *Domestic Violence Survivors Say Mandatory Reporting Laws Made Their Lives Worse*, YOUTH TODAY (July 26, 2017), https://youthtoday.org/2017/07/domestic-violence-survivors-say-mandatory-reporting-laws-made-their-lives-worse/.

[13] Family and Intimate Partner Violence H-515.965, AMERICAN MEDICAL ASSOCIATION (2019) ("With respect to issues of reporting . . . our AMA oppose the adoption of mandatory reporting laws for physicians treating competent, non-elderly adult survivors of intimate partner violence if the required reports identify survivors [such as Cal. Pen. Code § 11160(b)(4), which states that "[t]he report shall include . . . (A) The name of the injured person . . ."]. Such laws violate basic tenets of medical ethics.") (accessible at https://policysearch.ama-assn.org/policyfinder/detail/H-515.965?uri=%2FAMADoc%2FHOD.xml-0-4664.xml).

[14] CAL. PEN. CODE § 11160 (Deering 2019).

While community pharmacists may be considered "health practitioners" as defined in California Penal Code Section 11165.7(a)(21) (". . . any [ ] person who is currently licensed under Division 2 . . . of the Business and Professions Code."), they are not employed in any of the statutorily enumerated venues (i.e. "heath facility, clinic, physician's office . . .") according to the legal definitions of those venues.[15, 16] Moreover, community pharmacists—even those who have achieved Advanced Practice designations—do not provide "medical services" for physical conditions (i.e. injuries) within their scopes of employment or professional capacities. Scope of practice reservations by physicians, nurses, and other applicable practitioners certified under the Medicine Arts specifically distinguish medical services from pharmacists' provision of "health care services" and engagement in "patient care activities," limiting such activities to functions like "furnishing," "dispensing," "interpreting," and "monitoring" on behalf of patients.[17, 18] At most, pharmacists may "administer" preventative medications such as vaccinations, which are considered prophylactic measures rather than "treatments" under the sole purview of medical practitioners.

The fact that community pharmacists are not covered practitioners under the domestic violence mandatory reporting provision provides a tremendous opportunity for us to screen against intimate partner violence and provide support in a manner that encourages patient candor while promoting safety and autonomy.

Board Clarification is in the Public Interest

However, there is a need for clarification and communication of this fact by the California State Board of Pharmacy. Pharmacists referring to the Board of Pharmacy-compiled Law Book for guidance on mandatory reporting obligations only encounter the following language nested under Sections 1746 and 1746.1 of Title 16 of the California Code of Regulations, regarding a pharmacist furnishing hormonal contraception:

> "The pharmacist shall comply with all state mandatory reporting laws, including sexual abuse laws."[19]

Pharmacists reading this language (which very likely refers to healthcare practitioners' obligations under child abuse reporting laws) may conflate "sexual abuse" with the more expansive statutory definition of domestic violence. As a result, pharmacists may be misled into believing that they are required to report suspicions of intimate partner physical abuse or coercion.

As the most accessible healthcare providers in the country, community pharmacists have a stake in the public health landscape of intimate partner violence and in the wellbeing of their respective communities. Moreover, according to exploratory surveys on the issue, community pharmacists

[15] CAL. PEN. CODE § 11162.5(b) (stating that "Clinic" is limited to include any clinic specified in Sections 1204 and 1204.3 of the Health and Safety Code).
[16] CAL. PEN. CODE § 11162.5(c) (stating that "Health facility" has the meaning provided in Section 1250 of the Health and Safety Code).
[17] *See* CAL. BUS. & PROF. CODE § 4050 (regarding "[p]harmacy as a profession").
[18] *See* CAL. BUS. & PROF. CODE § 2052, (regarding "[p]ractice without [a medical] certificate").
[19] Emergency Contraception, 16 C.C.R. § 1746(b)(5) (2013); *see also* 2020 LAWBOOK FOR PHARMACY, CAL. STATE BOARD OF PHARMACY (2020) at 451.

want to provide screening services to appropriate patients and learn more about intimate partner violence as a healthcare issue directly related to patient outcomes.[20]

However, in California, community pharmacists are reluctant to engage in this important, survivor-centric screening for fear of possible Board enforcement actions and, collaterally, inappropriate criminal scrutiny for failure to report.[21] Similarly, victims of intimate partner violence who may benefit from resource counseling and safety planning by a community pharmacist do not know the scope of a pharmacist's reporting obligations.

It is in the public interest to resolve this uncertainty as soon as possible through an interpretative rule or agency policy statement advising licensees and the public that pharmacists are not domestic violence mandatory reporters under California Penal Code Section 11160.

This clarification would be particularly timely, as the California legislature recently recognized pharmacists' clinical acumen and role in outpatient preventative care by authorizing qualified community pharmacists to independently furnish hormonal contraceptives and pre-exposure HIV prophylactics. Reproductive autonomy through contraception and HIV status or exposure are issues highly relevant to the dynamics of intimate partner violence. These burgeoning modes of patient interface could provide high-yield screening opportunities for pharmacists without the chill of mandatory reporting laws bearing on the incidental finding of an injury.

Board Clarification is Urgent in Light of COVID-19

The need for Board clarification is made even more immediate due to numerous reports indicating an alarming increase in domestic violence due to the social isolation and stressors associated with COVID-19.[22, 23] In light of these dangerous circumstances, experts at the American Psychological Association have called for health-care providers such as pharmacists to "be on the lookout for patients potentially in crisis."[24] This call is aptly issued, as community pharmacies are among the only healthcare venues still readily accessible to individuals suffering abuse, and pharmacists remain on the front lines, ready to assist community members in these turbulent times.

A powerful analogy and acknowledgment of pharmacists' essential role in community health may be found in an HHS guidance issued on April 8, 2020, regarding its reasoning for authorizing pharmacists to provide COVID-19 testing:

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[20] Marie Barnard et al., *Community Pharmacists' Awareness of Intimate Partner Violence: An Exploratory Study*, INOV. PHARM., 2013;4(1): Article 106 (accessible at http://pubs.lib.umn.edu/innovations/vol4/iss1/7).

[21] Anecdotally, an experienced community pharmacist and educator at a prominent California pharmacy school stated that he "would not [conduct domestic violence screenings] without clarification from the Board of Pharmacy," and nor would he advise other pharmacists to do so.

[22] Sarah Fielding, *In quarantine with an abuser: surge in domestic violence reports linked to coronavirus*, THE GUARDIAN (April 3, 2020), https://www.theguardian.com/us-news/2020/apr/03/coronavirus-quarantine-abuse-domestic-violence.

[23] Mélissa Godin, *As Cities Around the World Go on Lockdown, Victims of Domestic Violence Look for a Way Out*, TIME (March 18, 2020), https://time.com/5803887/coronavirus-domestic-violence-victims/.

[24] Ashley Abramson, *How COVID-19 may increase domestic violence and child abuse*, AMERICAN PSYCHOLOGICAL ASSOCIATION (April 8, 2020), https://www.apa.org/topics/covid-19/domestic-violence-child-abuse (also noting that "[i]n several European countries, those in abusive situations are being told by the government to report the abuse to their local pharmacist, using the code word "mask 19" if they can't speak openly.").

> Pharmacists, in partnership with other healthcare providers, are well positioned to aid COVID-19 testing expansion. Pharmacists are trusted healthcare professionals with established relationships with their patients. The vast majority of Americans live close to a retail or independent community-based pharmacy. That proximity reduces travel to testing locations, which is an important mitigation measure. Pharmacists also have strong relationships with medical providers and hospitals to appropriately refer patients when necessary.[25]

Each of HHS's rationales empowering pharmacists to the critical task of testing for COVID-19 applies persuasively to screening on behalf of domestic violence victims: Pharmacists are poised; pharmacists are qualified and credible; pharmacists are accessible; and pharmacists generate strong relationships with other service providers in the community to appropriately refer patients when necessary.

Patients who brave a trip to their local pharmacy at the risk of exposure to COVID-19 should not be further deterred from approaching a pharmacist for domestic violence resources out of fear of mandated reporting. As the aforementioned research shows, victims of domestic violence have a legitimate fear of social and economic disenfranchisement as a result of untimely, involuntary police involvement—disenfranchisement they may be unable to bear on top of what has already been meted by the COVID-19 crisis.

Conclusion

When I graduated from pharmacy school, I took an oath to "consider the welfare of humanity and relief of suffering my primary concerns," and to "embrace and advocate changes that improve patient care."[26] I am submitting this petition pursuant to that oath. Pharmacists are not domestic violence mandatory reporters and should not be construed as such in the future. Providing clarity on this issue serves the public interest by informing pharmacists and needful patients of a pharmacist's ability to provide survivor-centric care in the community setting.

Thank you,

Saikrishna Upadhyayula, PharmD, RPh, JD

Support for this petition is provided on the following page.

[25] U.S. DEP'T OF HEALTH & HUMAN SERVICES, OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH, GUIDANCE FOR LICENSED PHARMACISTS, COVID-19 TESTING, AND IMMUNITY UNDER THE PREP ACT (April 8, 2020), https://www.hhs.gov/sites/default/files/authorizing-licensed-pharmacists-to-order-and-administer-covid-19-tests.pdf.
[26] *Oath of a Pharmacist*, AMERICAN PHARMACISTS ASSOCIATION, https://www.pharmacist.com/oath-pharmacist.

This petition is joined by:

Susie H. Park, PharmD, BCPP, FCSHP, APh

Steven Chen, PharmD, FASHP, FCSHP, FNAP

Ramesh Upadhyayula, RPh, APh

Katherine Fukunaga, PharmD, RPh

San Quach, PharmD, RPh

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Paramjjit Randhawa, RPh

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Poonam Gupta, PharmD, RPh

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Daniel J. Link, PharmD, RPh

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STATE OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY • GAVIN NEWSOM, GOVERNOR

LEGAL AFFAIRS DIVISION
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MEMORANDUM

DATE	July 1, 2020
TO	Anne Sodergren, Executive Officer **California State Pharmacy Board**
FROM	Will Maguire, Attorney I Legal Affairs Division **Department of Consumer Affairs**
SUBJECT	Mandatory Reporting by Community Pharmacies under Penal Code section 11160

Question Presented

The California State Board of Pharmacy (Board) has been asked whether community pharmacists are health practitioners included under California's domestic violence mandatory reporting provision codified in California Penal Code section 11160 for purposes of Board enforcement actions.

Short Answer

Because there is no single definition of a "community pharmacist," a pharmacist needs to make an individualized, fact-based determination as to whether they meet the elements of a "health practitioner" subject to Penal Code section 11160. In short, if a pharmacist is not "employed by a health facility, clinic, physician's office, local or state public health department, local government agency, or a clinic or other type of facility operated by a local or state public health department," that pharmacist would not be subject to mandatory reporting under Penal Code section 11160. The Board is not the agency, however, that enforces the Penal Code. A violation of Penal Code section 11160 is punishable as a misdemeanor. If a community pharmacist is convicted for violation of the Penal Code, the conviction could be considered "unprofessional conduct" and a basis for enforcement action by the Board. Accordingly, the Board need not, and should not, issue an interpretative ruling or policy statement on this subject.

Background

The Board received a "Petition for Interpretative Ruling or Policy Statement" (Request) from Saikrishna Upadhyayula, PharmD, RPh, JD, et al. It asked the Board to state whether Penal Code section 11160 applies to "community pharmacists" and/or "community-based pharmacists" for purposes of Board enforcement action. The Request's concerns are that by imposing a mandatory reporting requirement on community pharmacists, it could have a chilling effect on potential victims of domestic violence from seeking treatment or contacting a pharmacist. The Request posits that if a victim knows that a pharmacist is not a mandatory reporter the victim will be more comfortable seeking treatment, care, or counseling from the pharmacist.

Analysis

Penal Code section 11160 requires the reporting of specified injuries resulting from suspected abuse to local law enforcement and provides in relevant part:

> (a) A health practitioner, as defined in subdivision (a) of Section 11162.5, employed by a health facility, clinic, physician's office, local or state public health department, local government agency, or a clinic or other type of facility operated by a local or state public health department who, in the health practitioner's professional capacity or within the scope of the health practitioner's employment, provides medical services for a physical condition to a patient whom the health practitioner knows or reasonably suspects is a person described as follows, shall immediately make a report in accordance with subdivision (b):
>
> > (1) A person suffering from any wound or other physical injury inflicted by the person's own act or inflicted by another where the injury is by means of a firearm.
> >
> > (2) A person suffering from any wound or other physical injury inflicted upon the person where the injury is the result of assaultive or abusive conduct.

Violation of Penal Code section 11160 is a misdemeanor, punishable by imprisonment in a county jail not exceeding six months, or by a fine not exceeding one thousand dollars ($1,000), or by both that fine and imprisonment. (Pen. Code, § 11162.)

According to the Pharmacy Law of the Business and Professions Code:

> 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:
>
> > …(l) The conviction of a crime substantially related to the qualifications, functions, and duties of a licensee under this chapter...

(Bus. & Prof. Code, § 4301, subd. (l).)

The Request specifically asks the Board to clarify whether "community pharmacists" are mandatory reporters under Penal Code section 11160. "Community pharmacy" is not specifically defined by the Pharmacy Law.[1] For purposes of discussion, this memorandum presumes the Request is referring generally to "retail pharmacies," such as Walgreens, CVS, or a local independently owned pharmacy that are not affiliated with any other health care or governmental entity.

The Penal Code requires a health practitioner, to be a mandatory reporter of physical injury by means of a firearm or assaultive or abusive conduct if the health practitioner is:

---

[1] The only two relevant references to "community pharmacy" are Business and Professions Code sections 4001 and 4113.5.

Section 4001 describes the makeup of the Board and defines "chain community pharmacy" and "independent community pharmacy" for purposes of that subdivision only, not for the entire Pharmacy Law. (Bus. & Prof. Code, § 4001, subd. (c).) This section defines "independent community pharmacies" as a "pharmacy owned by a person or entity who owns no more than four pharmacies in California" and "chains community pharmacies" as a chain of 75 or more stores in California under the same ownership. (Id.) These definitions, whose meaning is limited to this subdivision, only tell us about the makeup of the Board membership. They also leave an undefined gap of pharmacies with between five and 74 stores.

Business and Professions Code section 4113.5 states 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." This describes the staffing levels at a community pharmacy and provides a list of types of pharmacies to which Section 4113.5 does not apply but does not define what a community pharmacy is.

1) employed by a health facility, clinic, physician's office, local or state public health department, local government agency, or a clinic or other type of facility operated by a local or state public health department;
2) acting in their professional capacity or within their scope of employment; and
3) providing medical services for a physical condition.

(Pen. Code, § 11160, subd. (a).)

As a preliminary matter, it is necessary to determine if pharmacists generally are "health practitioners" under Penal Code section 11160. Indeed, Penal Code section 11160 applies to health practitioners, as defined in subdivision (a) of Penal Code section 11162.5. Section 11162.5, subdivision (a) states that "[h]ealth practitioner" has the same meaning as provided in paragraphs (21) to (28), inclusive, of subdivision (a) of section 11165.7. Penal Code section 11165.7, subdivision (a)(21) includes "[a] physician and surgeon, psychiatrist, psychologist, dentist, resident, intern, podiatrist, chiropractor, licensed nurse, dental hygienist, optometrist, marriage and family therapist, clinical social worker, professional clinical counselor, **or any other person who is currently licensed under Division 2 (commencing with Section 500) of the Business and Professions Code.**" (Emphasis added.) Business & Professions Code, Division 2, Healing Arts, includes pharmacists in Chapter 9 (the "Pharmacy Law".) Therefore, pharmacists are subject to mandatory reporting under Penal Code section 11160, if they meet all three numbered elements above.

1) **Employed by a health facility, clinic, physician's office, local or state public health department, local government agency, or a clinic or other type of facility operated by a local or state public health department**

The first element is "employed by a health facility, clinic, physician's office, local or state public health department, local government agency, or a clinic or other type of facility operated by a local or state public health department." This element is highly fact-specific and likely determinative of the question in the Request. However, without more facts to indicate that all so-called "community pharmacists" practice exclusively in settings outside of those enumerated by this element, the Board cannot say definitively that all so-called "community pharmacists" are exempt. For example, a pharmacist could

practice part-time in a so-called "community pharmacy" and part-time in a facility operated by a local public health department. Instead, it is important to scrutinize the practice setting of each pharmacist.

To conduct this scrutiny, the analysis looks to the definitions of the various practice settings enumerated. Within this Article of the Penal Code, "health facility" is defined as "a facility, place, or building that is organized, maintained, and operated for the diagnosis, care, prevention, and treatment of human illness, physical or mental, including convalescence and rehabilitation and including care during and after pregnancy, or for any one or more of these purposes, for one or more persons, to which the persons are admitted for a 24-hour stay or longer, and includes the following types:…" (Health & Saf. Code, § 1250, as cited to by Penal Code, § 11162.5, subd. (c).) "Clinic" is limited to include any clinic specified in Sections 1204 and 1204.3 of the Health and Safety Code. Those two sections of the Health and Safety Code include "primary care and specialty care clinics." (Health & Saf. Code, § 1204.) Among the types of specialty care clinics are "community clinics." (Health & Saf. Code, § 1204, subd. (a).) Therefore, if a pharmacist does not work in one of these enumerated settings, they are likely not subject to mandatory reporting by Penal Code section 11160.

2) <u>Acting in their professional capacity or within their scope of employment</u>

The second element is "acting in their professional capacity or within their scope of employment." As long as the pharmacist is acting within their scope of practice, at their place of business, it is likely this element is met for purposes of that pharmacist being subject to the mandatory reporting requirement of Penal Code section 11160.

3) <u>Providing medical services for a physical condition</u>

The third element is "providing medical services for a physical condition." The Request argues that pharmacists do not "provide medical services." (Request, p. 4.) Neither the Business and Professions Code nor the Penal Code define "medical services." The Medical Practice Act, within the Business and Professions Code, prohibits the unlicensed practice of medicine. (See Bus. & Prof. Code, § 2052, subd. (a).) This prohibition does not refer to "medical services" specifically. So, it is reasonable to probe further as to whether "provide medical services" means something other than "practice medicine."

Otherwise, based on the above prohibition, it would be impossible for anyone but a "physician and surgeon" to "provide medical services" and thereby meet the third element of Penal Code section 11160. This result is absurd and contrary to the plain language of section 11160. In fact, the very language of

Penal Code section 11160 contemplates that it applies to a whole host of "health practitioners" beyond physicians and surgeons. If the Legislature intended for Section 11160 to only apply to physicians and surgeons, it would have stated that only "physician and surgeons" were subject to mandatory reporting. Instead, as stated above, section 11160 applies to "health practitioners" who meet the remaining elements.

As stated above, "health practitioner" has the same meaning as provided in paragraphs (21) to (28), inclusive, of subdivision (a) of Penal Code section 11165.7. Paragraph 21 of section 11165.7 includes a "physician and surgeon, psychiatrist, psychologist, dentist, resident, intern, podiatrist, chiropractor, licensed nurse, dental hygienist, optometrist, marriage and family therapist, clinical social worker, professional clinical counselor, or any other person who is currently licensed under Division 2 (commencing with Section 500) of the Business and Professions Code [including pharmacists]." Paragraph 22 includes an "emergency medical technician I or II, paramedic…." Paragraph 23 includes a "psychological assistant …" Paragraph 24 includes a "marriage and family therapist trainee…" Paragraph 25 includes an "unlicensed associate marriage and family therapist…" Paragraph 26 includes a "state or county public health employee who treats a minor for venereal disease or any other condition." The vast majority of these professionals, included as "health practitioners" by Penal Code section 11160, do not provide "medical services" akin to a physician and surgeon.

In addition, the Pharmacy Law permits pharmacists to, among other things, administer drugs and immunizations, perform procedures or functions, and provide patient consultation, education, and training. (Bus. & Prof. Code, § 4052.) Because of the Legislature's expansive inclusion of procedures pharmacists may perform, the Board can take an expansive view of the "providing medical services" element of Penal Code section 11160. If a pharmacist is administering, performing procedures, consulting, or providing similar, authorized services to a patient regarding a health problem, that is likely "providing medical services" within the intended meaning of the final element in Penal Code section 11160.

Conclusion

Presuming that pharmacists who work in retail pharmacies are not employed by a health facility, clinic, physician's office, local or state public health department, local government agency, or a clinic or other type of facility operated by a local or state public health department, it is likely that Penal Code section 11160 does not apply to so called "community pharmacists" or "retail pharmacists." However, the Penal

Code is enforced by local district attorneys, not the Board. Therefore, if a district attorney determines that section 11160 does apply to these pharmacists, these pharmacists could still be prosecuted under the Penal Code. Then, if these pharmacists are convicted for violation of the Penal Code, it could be considered "unprofessional conduct," which is cause for enforcement action by the Board. Accordingly, the Board need not, and should not, issue an interpretative ruling or policy statement on this subject.

Attachment 2

AMENDED IN ASSEMBLY JUNE 4, 2020

CALIFORNIA LEGISLATURE—2019–20 REGULAR SESSION

ASSEMBLY BILL No. 2028

Introduced by Assembly Member Aguiar-Curry
(Coauthor: Assembly Member Gonzalez)

January 30, 2020

An act to amend Sections 11125 and 11125.7 of the Government Code, relating to public meetings.

LEGISLATIVE COUNSEL'S DIGEST

AB 2028, as amended, Aguiar-Curry. State agencies: meetings.

Existing law, the Bagley-Keene Open Meeting Act, requires that all meetings of a state body, as defined, be open and public, and that all persons be permitted to attend any meeting of a state body, except as otherwise provided in that act. Existing law requires the state body to provide notice of its meeting, including specified information and a specific agenda of the meeting, as provided, to any person who requests that notice in writing and to make that notice available on the internet at least 10 days in advance of the meeting.

This bill would, except for closed sessions, require that this notice include all writings or materials provided for the noticed meeting to a member of the state body by staff of a state agency, board, or commission, or another member of the state body, that are in connection with a matter subject to discussion or consideration at the meeting. The bill would require these writings and materials to be made available on the internet *website, and to people who so request in writing, on the same day as they are provided to members of the state body or* at least ~~10 days~~ *48 hours* in advance of the ~~meeting.~~ *meeting, whichever is earlier.* The bill would provide that a state body may only distribute or

discuss these writings or materials at a meeting of the state body if it has complied with these requirements. *The bill would except writings or materials relating to matters to be discussed in a closed session from its requirements and would authorize a state body to post and provide additional time-sensitive materials related to certain active legislation, as specified, as they become available, after the prescribed deadlines. The bill would specify that its provisions do not authorize a state body to remove writings and materials from an internet website.*

Existing law requires that a state body provide an opportunity for members of the public to directly address the body on each agenda item. Existing law exempts from this requirement, among other things, an agenda item that has already been considered by a committee composed exclusively of members of the state body at a public meeting where members of the public were afforded an opportunity to address the committee on the item.

This bill would delete this exception, thereby making the requirement to provide an opportunity to address the state body applicable to an agenda item for which the public had an opportunity to address it at a public meeting of a committee of the state body.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. The Legislature finds and declares the following:

(a) The Bagley-Keene Open Meeting Act (Article 9 (commencing with Section 11120) of Chapter 1 of Part 1 of Division 3 of Title 2 of the Government Code) (hereafter "Bagley-Keene") was intended to implement Section 3 of Article I of the California Constitution, which states in part, "The people have the right of access to information concerning the conduct of the people's business, and, therefore, the meetings of public bodies and the writings of public officials and agencies shall be open to public scrutiny."

(b) Bagley-Keene was written to protect public meetings and public notice and to ensure the transparency of actions taken by state agencies, boards, and commissions.

(c) Californians have the right to participate in state body deliberations. This includes the public's ability to comment on all agenda items discussed at a meeting of the state body, regardless

of whether an item has been discussed previously in a committee of the state body.

(d) The purpose of public notice is so that state bodies give the public adequate time for review of the substance of a state body meeting and for comment.

(e) Public notice must also include any writings or materials provided by a state body's staff or by a member of the state body to other members of the state body for a noticed meeting of the body held at least 10 days prior to the meeting.

(f) Bagley-Keene affirms these rights by stating in Section 11120 of the Government Code, "The people of this state do not yield their sovereignty to the agencies which serve them. The people, in delegating authority, do not give their public servants the right to decide what is good for the people to know and what is not good for them to know. The people insist on remaining informed so that they may retain control over the instruments they have created."

SEC. 2. Section 11125 of the Government Code is amended to read:

11125. (a) The state body shall provide notice of its meeting to any person who requests that notice in writing. Notice shall be given and also made available on the internet *website* at least 10 days in advance of the meeting, and shall include the name, address, and telephone number of any person who can provide further information prior to the meeting, but need not include a list of witnesses expected to appear at the meeting. The written notice shall additionally include the address of the internet website where notices required by this article are made available.

(b) The notice of a meeting of a body that is a state body shall include a specific agenda for the meeting, containing a brief description of the items of business to be transacted or discussed in either open or closed session. A brief general description of an item generally need not exceed 20 words. A description of an item to be transacted or discussed in closed session shall include a citation of the specific statutory authority under which a closed session is being held. No item shall be added to the agenda subsequent to the provision of this notice, unless otherwise permitted by this article.

(c) (1) Except as otherwise provided in paragraph (4), any notice provided pursuant to subdivision (a) shall include all writings or materials provided for the noticed meeting to a member

of the state body by the staff of a state agency, board, or commission, or another member of the state body, that are in connection with a matter subject to discussion or consideration at the meeting.

(2) The writings or materials described in paragraph (1) shall be made available on the internet ~~at least 10 days in advance of the meeting,~~ *website,* and to any person who requests ~~that notice in writing.~~ *the writings or materials in writing, on the same day as the dissemination of the writings and materials to members of the state body, or at least 48 hours in advance of the meeting, whichever is earlier.*

(3) A state body may distribute or discuss writings or materials described in paragraph (1) at a meeting of the state body only if it has complied with this subdivision.

(4) This subdivision does not apply to writings or materials prepared for a matter to be discussed in a closed session of the state body.

(5) If the writings or materials described in paragraph (1) on an agenda for discussion at a meeting of the state body are related to legislation that is before the Legislature in a current legislative session, a state body is entitled to post online, and shall provide upon request, additional materials related to that active legislation with additional time-sensitive information as it becomes available after the deadlines in this subdivision. The state body shall make clear what date the new or changed writings or materials are posted and, when applicable, what changes have been made in materials already posted.

(6) This subdivision does not authorize state bodies to remove any of the writings or materials described in paragraph (1) from the internet website.

(d) Notice of a meeting of a state body that complies with this section shall also constitute notice of a meeting of an advisory body of that state body, provided that the business to be discussed by the advisory body is covered by the notice of the meeting of the state body, provided that the specific time and place of the advisory body's meeting is announced during the open and public state body's meeting, and provided that the advisory body's meeting is conducted within a reasonable time of, and nearby, the meeting of the state body.

(e) A person may request, and shall be provided, notice pursuant to subdivision (a) for all meetings of a state body or for a specific meeting or meetings. In addition, at the state body's discretion, a person may request, and may be provided, notice of only those meetings of a state body at which a particular subject or subjects specified in the request will be discussed.

(f) A request for notice of more than one meeting of a state body shall be subject to the provisions of Section 14911.

(g) The notice shall be made available in appropriate alternative formats, as required by Section 202 of the Americans with Disabilities Act of 1990 (42 U.S.C. Sec. 12132), and the federal rules and regulations adopted in implementation thereof, upon request by any person with a disability. The notice shall include information regarding how, to whom, and by when a request for any disability-related modification or accommodation, including auxiliary aids or services may be made by a person with a disability who requires these aids or services in order to participate in the public meeting.

SEC. 3. Section 11125.7 of the Government Code is amended to read:

11125.7. (a) Except as otherwise provided in this section, the state body shall provide an opportunity for members of the public to directly address the state body on each agenda item before or during the state body's discussion or consideration of the item. Every notice for a special meeting at which action is proposed to be taken on an item shall provide an opportunity for members of the public to directly address the state body concerning that item prior to action on the item. In addition, the notice requirement of Section 11125 shall not preclude the acceptance of testimony at meetings, other than emergency meetings, from members of the public if no action is taken by the state body at the same meeting on matters brought before the body by members of the public.

(b) The state body may adopt reasonable regulations to ensure that the intent of subdivision (a) is carried out, including, but not limited to, regulations limiting the total amount of time allocated for public comment on particular issues and for each individual speaker.

(c) (1) Notwithstanding subdivision (b), when a state body limits time for public comment the state body shall provide at least twice the allotted time to a member of the public who utilizes a

translator to ensure that non-English speakers receive the same opportunity to directly address the state body.

(2) Paragraph (1) shall not apply if the state body utilizes simultaneous translation equipment in a manner that allows the state body to hear the translated public testimony simultaneously.

(d) The state body shall not prohibit public criticism of the policies, programs, or services of the state body, or of the acts or omissions of the state body. Nothing in this subdivision shall confer any privilege or protection for expression beyond that otherwise provided by law.

(e) This section is not applicable to any of the following:

(1) Closed sessions held pursuant to Section 11126.

(2) Decisions regarding proceedings held pursuant to Chapter 5 (commencing with Section 11500), relating to administrative adjudication, or to the conduct of those proceedings.

(3) Hearings conducted by the California Victim Compensation Board pursuant to Sections 13963 and 13963.1.

(4) Agenda items that involve decisions of the Public Utilities Commission regarding adjudicatory hearings held pursuant to Chapter 9 (commencing with Section 1701) of Part 1 of Division 1 of the Public Utilities Code. For all other agenda items, the commission shall provide members of the public, other than those who have already participated in the proceedings underlying the agenda item, an opportunity to directly address the commission before or during the commission's consideration of the item.

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CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

Bill Number:	**AB 2028**
Current Version:	**As Amended June 4, 2020**
Author:	**Aguiar-Curry**
Topic:	**State Agencies: meetings**
Staff Recommendation:	**Oppose**

Affected Sections: Amend Government Code Sections 11125 and 11127.5

Status: Referred to Senate Committee on Governmental Organization

EXISTING LAW:
The Bagley-Keene Open Meeting Act of 1967 (Bagley-Keene Act) generally requires that all meetings of a "state body" be open and public and that all persons be permitted to attend and participate in any meeting of a state body.

The Bagley-Keene Act generally requires state bodies to publicly notice their meetings, prepare agendas, accept testimony, and conduct their meetings in public, unless specifically authorized to meet in closed session.

MEASURE SUMMARY:
The bill would amend the provisions of the Bagley-Keene Open Meeting Act to require writings and materials to be made available on the internet website, and to people who so request in writing, on the same day as they are provided to members of the state body, or at least 48 hours in advance of the meeting, whichever is earlier. The bill would provide that a state body may only distribute or discuss these writings or materials at a meeting of the state body if it has complied with these requirements. The bill would except writings or materials relating to matters to be discussed in a closed session from its requirements and would authorize a state body to post and provide additional time-sensitive materials related to certain active legislation, as specified, as they become available, after the prescribed deadlines. The bill would specify that its provisions do not authorize a state body to remove writings and materials from an internet website.

Further, this bill would specify that a state body must provide an opportunity for public comment during a board meeting on an agenda item, even in situations where members of the public were afforded the opportunity to address the item at a public meeting of a committee of the state body.

STAFF COMMENTS:
This measure seeks to ensure transparency and public participation in public meetings. The Board values transparency as reflected in its Strategic Plan and routinely provides opportunities for public comment both before and throughout Board and Committee meetings.

Staff have identified several technical challenges with the measure that could negatively impact full consideration of information by the Board and inadvertently impede public comment.

1. There are documents and materials that cannot be made ADA accessible. If a document is not ADA accessible, the Board cannot post it on its website.
2. The file size for Board materials many times exceeds file size limitations making it difficult to comply with the requirements to provide the information via email. The volume of materials provided to members is significant. Requiring the Board to provide paper copies and mailing at that same time materials are released to members would delay the release and posting of materials due to resource limitations. The measure appears to provide that the meeting materials must be provided on the same day, however differing delivery methods, electronic versus paper, makes this very problematic.
3. Regulation comment periods may end near or immediately before a Board meeting. Compiling the comments, making them ADA accessible and providing them at least 48 hours in advance may not always be possible.
4. It is fairly common for the Board to receive written comments after publicly posting meeting materials. When time permits, these comments are provided to members and posted on the website; however, depending on the timing of the receipt of the comments, it may be impossible to meet the requirement to provide at the same time or within 48 hours of the meeting.
5. The measure also does not appear to recognize that there are times when information is disseminated during a meeting e.g., statistical information, supplemental materials, etc. It is unclear if the measure would preclude this practice moving forward.
6. The measure would prohibit the Board from removing materials from the website. This is problematic for several reasons including, if a mistake is made and the wrong information is posted, the Board would be prohibited from fixing the error.
7. It would appear the measure does not contemplate emergency board meetings, which only require 48 hours' notice. Should the provisions of the measure apply to emergency board meetings, from a practical stand point, the Board would never be able to avail itself of the emergency meeting provisions.

COMMITTEE DISCUSSION:
The committee has not discussed the bill.

FISCAL IMPACT ON THE BOARD:
This bill could have significant fiscal impact should the Board receive a significant number of individuals that request paper copies of meeting materials. These costs would include staff resource time, materials, and postage.

AMENDED IN ASSEMBLY MAY 20, 2020

CALIFORNIA LEGISLATURE—2019–20 REGULAR SESSION

ASSEMBLY BILL No. 2077

Introduced by Assembly Member Ting

February 5, 2020

An act to amend Section 4145.5 of, and to repeal Sections 4142 and 4326 of, the Business and Professions Code, and to amend Section 11364 of, and to repeal Section 121285 of, the Health and Safety Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

AB 2077, as amended, Ting. Hypodermic needles and syringes.

Existing law prohibits, except as specified, the sale of a hypodermic needle or syringe at retail except upon the ~~proscription~~ *prescription* of a physician, dentist, veterinarian, podiatrist, or naturopathic doctor.

This bill would repeal that provision.

Existing law, until January 1, 2021, authorizes a physician or pharmacist to, without a prescription or permit, ~~to~~ furnish hypodermic needles and syringes for human use to a person 18 years of age or older, and authorizes a person 18 years of age or older to, without a prescription or license, obtain hypodermic needles and syringes solely for personal use from a physician or pharmacist, as a public health measure, as specified.

This bill would ~~delete the January 1, 2021, termination date, thereby extending~~ *extend* this authority ~~indefinitely~~ *until January 1, 2026,* and would make other conforming changes.

Existing law makes it a misdemeanor for a person to obtain a hypodermic needle or hypodermic syringe by a false or fraudulent representation or design or by a forged or fictitious name. Existing law

also makes it a misdemeanor for a person who has obtained a hypodermic needle or hypodermic syringe from any person to whom a permit has been issued ~~who uses, or permits or causes,~~ *to use, or permit or cause,* directly or indirectly, the hypodermic needle or hypodermic syringe to be used for any purpose other than that for which it was obtained.

This bill would repeal those provisions and make other conforming changes.

Existing law establishes the Disease Prevention Demonstration Project, a collaboration between pharmacies and local and state health officials for the purpose of evaluating the long-term desirability of allowing licensed pharmacists to furnish or sell nonprescription hypodermic needles or hypodermic syringes to prevent the spread of bloodborne pathogens.

This bill would repeal those provisions.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 4142 of the Business and Professions Code is repealed.

SEC. 2. Section 4145.5 of the Business and Professions Code is amended to read:

4145.5. (a) Notwithstanding any other provision of law, a pharmacist or physician may, without a prescription or a permit, furnish hypodermic needles and syringes for human use, and a person may, without a prescription or license, obtain hypodermic needles and syringes from a pharmacist or physician for human use, if the furnisher has previously been provided a prescription or other proof of a legitimate medical need requiring a hypodermic needle or syringe to administer a medicine or treatment.

(b) Notwithstanding any other provision of law, *and until January 1, 2026,* as a public health measure intended to prevent the transmission of HIV, viral hepatitis, and other bloodborne diseases among persons who use syringes and hypodermic needles, and to prevent subsequent infection of sexual partners, newborn children, or other persons, a physician or pharmacist may, without a prescription or a permit, furnish hypodermic needles and syringes for human use to a person 18 years of age or older, and a person

18 years of age or older may, without a prescription or license, obtain hypodermic needles and syringes solely for personal use from a physician or pharmacist.

(c) Notwithstanding any other provision of law, a pharmacist, veterinarian, or person licensed pursuant to Section 4141 may, without a prescription or license, furnish hypodermic needles and syringes for use on animals, and a person may, without a prescription or license, obtain hypodermic needles and syringes from a pharmacist, veterinarian, or person licensed pursuant to Section 4141 for use on animals.

(d) A pharmacy that furnishes nonprescription hypodermic needles and syringes shall store hypodermic needles and syringes in a manner that ensures that they are available only to authorized personnel, and are not accessible to other persons.

(e) In order to provide for the safe disposal of hypodermic needles and syringes, a pharmacy or hypodermic needle and syringe exchange program that furnishes nonprescription hypodermic needles and syringes shall counsel consumers on safe disposal and provide consumers with one or more of the following disposal options:

(1) It shall establish an onsite, safe, hypodermic needle and syringe collection and disposal program that meets applicable state and federal standards for collection and disposal of medical sharps waste.

(2) It shall furnish, or make available, mail-back sharps containers authorized by the United States Postal Service that meet applicable state and federal requirements for the transport of medical sharps waste, and shall provide tracking forms to verify destruction at a certified disposal facility.

(3) It shall furnish, or make available, a sharps container that meets applicable state and federal standards for collection and disposal of medical sharps waste.

(f) ~~A~~ *Until January 1, 2026, a* pharmacy that furnishes nonprescription syringes shall provide written information or verbal counseling to consumers at the time of furnishing or sale of nonprescription hypodermic needles or syringes on how to do the following:

(1) Access drug treatment.

(2) Access testing and treatment for HIV and hepatitis C.

(3) Safely dispose of sharps waste.

SEC. 3. Section 4326 of the Business and Professions Code is repealed.

SEC. 4. Section 11364 of the Health and Safety Code is amended to read:

11364. (a) It is unlawful to possess an opium pipe or any device, contrivance, instrument, or paraphernalia used for unlawfully injecting or smoking (1) a controlled substance specified in subdivision (b), (c), or (e) or paragraph (1) of subdivision (f) of Section 11054, specified in paragraph (14), (15), or (20) of subdivision (d) of Section 11054, specified in subdivision (b) or (c) of Section 11055, or specified in paragraph (2) of subdivision (d) of Section 11055, or (2) a controlled substance that is a narcotic drug classified in Schedule III, IV, or V.

(b) This section shall not apply to hypodermic needles or syringes that have been containerized for safe disposal in a container that meets state and federal standards for disposal of sharps waste.

(c) ~~As~~ *Until January 1, 2026, as* a public health measure intended to prevent the transmission of HIV, viral hepatitis, and other bloodborne diseases among persons who use syringes and hypodermic needles, and to prevent subsequent infection of sexual partners, newborn children, or other persons, this section shall not apply to the possession solely for personal use of hypodermic needles or syringes.

SEC. 5. Section 121285 of the Health and Safety Code is repealed.

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CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

Bill Number:	**AB 2077**
Current Version:	**As Amended May 20, 2020**
Author:	**Ting**
Topic:	**Hypodermic needles and syringe**
Staff Recommendation:	**Support**

Affected Sections: Amend Business and Professions Code (BPC) section 4145.5, repeal BPC sections 4142 and 4326, amend Health and Safety Code (HSC) section 11364, repeal HSC 121285

Status: Referred to Senate Committee on Health

Existing Law:
BPC 4142 provides that in general, no hypodermic needle or syringe may be sold without a prescription.

BPC 4145.5 provides some exceptions to BPC 4142, including authority for a pharmacy to furnish hypodermic needs and syringes for human use without a prescription under specified conditions, including knowledge that such furnishing is for a legitimate medical use. This section provides, that as a public health measure, such furnishing must also occur to prevent the transition of specified conditions, until January 1, 2021. Further, the section provides that as such a condition of furnishing, a pharmacy must also provide information on access to drug treatment, access to testing information, and information on safely disposing of sharps waste.

BPC 4326 provides that a person who obtains a hypodermic needle or syringe without a prescription is guilty of a misdemeanor and establish penalties.

Measure Summary:
This bill extends, until January 1, 2026, the sunset date of current law that allows the retail sale or furnishing of a hypodermic needle or syringe to a person 18 years of age or older without a prescription.

It also deletes provisions that describe the pilot project that originally allowed for the sale of syringes at pharmacies and eliminates the crime and penalty associated with obtaining a hypodermic needle or syringe without a prescription.

Staff Comments:
The Board has historically supported similar public health measures, including AB 1743 (Ting, Chapter 331, Statutes 2014), which previously extended the sunset provisions of this measure to January 1, 2021.

Committee Discussion:
The committee has not discussed the bill.

FISCAL IMPACT ON THE BOARD:
As amended, any fiscal impact would be minor and absorbable.

AMENDED IN ASSEMBLY MAY 4, 2020

CALIFORNIA LEGISLATURE—2019–20 REGULAR SESSION

ASSEMBLY BILL No. 2113

Introduced by Assembly Member Low
(Coauthors: Assembly Members Carrillo, *Chiu,* Medina, ~~and Blanca Rubio)~~ *Blanca Rubio, and Gonzalez)*

February 6, 2020

An act to add Section 135.4 to the Business and Professions Code, relating to professions and vocations.

LEGISLATIVE COUNSEL'S DIGEST

AB 2113, as amended, Low. Refugees, asylees, and immigrants: professional licensing.

Existing law provides for the licensure and regulation of various professions and vocations by boards within the Department of Consumer Affairs. Existing law prohibits an entity within the department from denying licensure to an applicant based upon their citizenship or immigration status.

This bill, notwithstanding any other law, would require a board within the department to expedite, and authorize it to assist, the initial licensure process for an applicant who supplies satisfactory evidence to the board that they are a refugee, have been granted political asylum, or have a special immigrant visa, as specified. The bill would authorize a board to adopt regulations necessary to administer these provisions.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 135.4 is added to the Business and Professions Code, to read:

135.4. (a) Notwithstanding any other law, a board within the department shall expedite, and may assist, the initial licensure process for an applicant who supplies satisfactory evidence to the board that they have been admitted to the United States as a refugee under Section 1157 of Title 8 of the United States Code, have been granted political asylum by the Secretary of Homeland Security or the Attorney General of the United States pursuant to Section 1158 of Title 8 of the United States Code, or they have a special immigrant visa (SIV) that has been granted a status under Section 1244 of Public Law 110-181, under Public Law 109-163, or under Section 602(b) of Title VI of Division F of Public Law 111-8.

(b) Nothing in this section shall be construed as changing existing licensure requirements. A person applying for expedited licensure under subdivision (a) shall meet all applicable statutory and regulatory licensure requirements.

~~(b)~~

(c) A board may adopt regulations necessary to administer this section.

REVISIONS:

Heading—Lines 2 and 3.

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CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

Bill Number:	**AB 2113**
Current Version:	**As Amended May 4, 2020**
Author:	**Low**
Topic:	**Refugees, asylees, and immigrants: professional licensing**
Staff Recommendation:	**None**

Affected Sections: Add Business and Professions Code section 135.4

Status: Referred to the Senate

Existing Law:
Existing law establishes the requirements for licensure. Further, under existing law, the Board is required to expedite the application for 1. an applicant that was honorably discharged from the armed forces or 2. an applicant that is either the spouse, domestic partner, or in another legal union with an active duty member of the armed forces, as specified.

Measure Summary:
This bill would require a board within the department to expedite, and authorize it to assist, the initial licensure process for an applicant who supplies satisfactory evidence to the board that they are a refugee, have been granted political asylum, or have a special immigrant visa, as specified. The bill would authorize a board to adopt regulations necessary to administer these provisions.

Staff Comments:
As currently written, there is no definition of what documentation should be deemed efficient to support the immigration status. Additionally, there is no definition of how long "expedite" would be and also no definition of what is meant by how to "assist" the applicant. Consistent with the provisions of the measure, regulations would most likely be necessary to provide clarification.

Staff notes that expediting such applications, without supplemental resources, could impact current processing times for other applicants.

Committee Discussion:
The committee has not discussed the bill.

FISCAL IMPACT ON THE BOARD:

From an implementation standpoint, the Board will need to promulgate the regulations to provide clarity on the provisions of the measure as well as changes to update any application forms that are incorporated by reference within our regulations. The resources identified could be shared to also meeting the requirements of AB 2549.

AMENDED IN ASSEMBLY MAY 18, 2020

AMENDED IN ASSEMBLY MARCH 12, 2020

CALIFORNIA LEGISLATURE—2019–20 REGULAR SESSION

ASSEMBLY BILL No. 2549

Introduced by Assembly Member Salas
(Coauthor: Assembly Member Gonzalez)

February 19, 2020

An act to amend Sections 115.6 and 5132 of the Business and Professions Code, relating to professions and vocations, and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

AB 2549, as amended, Salas. Department of Consumer Affairs: temporary licenses.

Under existing law, the Department of Consumer Affairs, which is under the control of the Director of Consumer Affairs, is comprised of various boards, as defined, that license and regulate various professions and vocations. Existing law requires a board within the department to issue, after appropriate investigation, certain types of temporary licenses to an applicant if the applicant meets specified requirements, including that the applicant supplies evidence satisfactory to the board that the applicant is married to, or in a domestic partnership or other legal union with, an active duty member of the Armed Forces of the United States who is assigned to a duty station in this state under official active duty military orders and the applicant holds a current, active, and unrestricted license that confers upon the applicant the authority to practice, in another state, district, or territory of the United States, the profession or vocation for which the applicant seeks a temporary license from the

board. Existing law authorizes a board to adopt regulations necessary to administer these provisions.

This bill would expand that requirement to issue temporary licenses to include licenses issued by the Veterinary Medical Board, the Dental Board of California, the Dental Hygiene Board of California, the California State Board of Pharmacy, the State Board of Barbering and Cosmetology, the Board of Psychology, the California Board of Occupational Therapy, the Physical Therapy Board of California, and the California Board of Accountancy. The bill would require a board to issue a temporary license within 30 days of receiving the required documentation. The bill would specifically direct revenues from fees for temporary licenses issued by the California Board of Accountancy to be credited to the Accountancy Fund, a continuously appropriated fund. By establishing a new source of revenue for a continuously appropriated fund, the bill would make an appropriation. ~~The bill would require a temporary license to be converted to a standard license if, within 12 months of issuance, the applicant demonstrates having met all of the requirements for a standard license or submits documents demonstrating that the requirements to obtain the out-of-state license were substantially equivalent to the requirements for a standard license as determined by the board in order to protect the public.~~ The bill would require a board to ~~adopt~~ *submit to the department for approval draft* regulations necessary to administer these provisions ~~and to publish regulations on its internet website and in application materials~~ by January 1, 2022. *The bill would exempt from these provisions a board that has a process in place by which an out-of-state licensed applicant in good standing who is married to, or in a domestic partnership or other legal union with, an active duty member of the Armed Forces of the United States is able to receive expedited, temporary authorization to practice while meeting state-specific requirements for a period of at least one year.*

Vote: majority. Appropriation: yes. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 115.6 of the Business and Professions Code is amended to read:

115.6. (a) ~~A~~ *Except as provided in subdivision (h), a* board within the department shall, after appropriate investigation, issue

the following eligible temporary licenses to an applicant within 30 days of receiving the required documentation pursuant to meeting the requirements set forth in subdivision (c):

(1) Registered nurse license by the Board of Registered Nursing.

(2) Vocational nurse license issued by the Board of Vocational Nursing and Psychiatric Technicians of the State of California.

(3) Psychiatric technician license issued by the Board of Vocational Nursing and Psychiatric Technicians of the State of California.

(4) Speech-language pathologist license issued by the Speech-Language Pathology and Audiology and Hearing Aid Dispensers Board.

(5) Audiologist license issued by the Speech-Language Pathology and Audiology and Hearing Aid Dispensers Board.

(6) All licenses issued by the Veterinary Medical Board.

(7) All licenses issued by the Board for Professional Engineers, Land Surveyors, and Geologists.

(8) All licenses issued by the Medical Board of California.

(9) All licenses issued by the Podiatric Medical Board of California.

(10) All licenses issued by the Dental Board of California.

(11) All licenses issued by the Dental Hygiene Board of California.

(12) All licenses issued by the California State Board of Pharmacy.

(13) All licenses issued by the State Board of Barbering and Cosmetology.

(14) All licenses issued by the Board of Psychology.

(15) All licenses issued by the California Board of Occupational Therapy.

(16) All licenses issued by the Physical Therapy Board of California.

(17) All licenses issued by the California Board of Accountancy. Revenues from fees for temporary licenses issued under this paragraph shall be credited to the Accountancy Fund in accordance with Section 5132.

(b) The board may conduct an investigation of an applicant for purposes of denying or revoking a temporary license issued pursuant to this section. This investigation may include a criminal background check.

(c) An applicant seeking a temporary license pursuant to this section shall meet the following requirements:

(1) The applicant shall supply evidence satisfactory to the board that the applicant is married to, or in a domestic partnership or other legal union with, an active duty member of the Armed Forces of the United States who is assigned to a duty station in this state under official active duty military orders.

(2) The applicant shall hold a current, active, and unrestricted license that confers upon the applicant the authority to practice, in another state, district, or territory of the United States, the profession or vocation for which the applicant seeks a temporary license from the board.

(3) The applicant shall submit an application to the board that shall include a signed affidavit attesting to the fact that the applicant meets all of the requirements for the temporary license and that the information submitted in the application is accurate, to the best of the applicant's knowledge. The application shall also include written verification from the applicant's original licensing jurisdiction stating that the applicant's license is in good standing in that jurisdiction.

(4) The applicant shall not have committed an act in any jurisdiction that would have constituted grounds for denial, suspension, or revocation of the license under this code at the time the act was committed. A violation of this paragraph may be grounds for the denial or revocation of a temporary license issued by the board.

(5) The applicant shall not have been disciplined by a licensing entity in another jurisdiction and shall not be the subject of an unresolved complaint, review procedure, or disciplinary proceeding conducted by a licensing entity in another jurisdiction.

(6) The applicant shall, upon request by a board, furnish a full set of fingerprints for purposes of conducting a criminal background check.

(d) A temporary license issued pursuant to this section may be immediately terminated upon a finding that the temporary licenseholder failed to meet any of the requirements described in subdivision (c) or provided substantively inaccurate information that would affect the person's eligibility for temporary licensure. Upon termination of the temporary license, the board shall issue a notice of termination that shall require the temporary

licenseholder to immediately cease the practice of the licensed profession upon receipt.

(e) An applicant seeking a temporary license as a civil engineer, geotechnical engineer, structural engineer, land surveyor, professional geologist, professional geophysicist, certified engineering geologist, or certified hydrogeologist pursuant to this section shall successfully pass the appropriate California-specific examination or examinations required for licensure in those respective professions by the Board for Professional Engineers, Land Surveyors, and Geologists.

(f) A temporary license issued pursuant to this section shall expire 12 months after issuance, upon issuance of an expedited license pursuant to Section 115.5, a license by endorsement, or upon denial of the application for expedited licensure by the board, whichever occurs first.

~~(g) A temporary license issued pursuant to this section shall be converted to a standard license if, within 12 months of issuance, the applicant demonstrates having met all of the requirements for a standard license or submits documents demonstrating that the requirements to obtain the out-of-state license were substantially equivalent to the requirements for a standard license as determined by the board in order to protect the public.~~

~~(h)~~

(g) A board shall ~~adopt~~ *submit to the department for approval draft* regulations necessary to administer this section ~~and shall publish these regulations on its internet website and in application materials~~ by January 1, 2022. *These regulations shall be adopted pursuant to the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code).*

(h) This section shall not apply to a board that has a process in place by which an out-of-state licensed applicant in good standing who is married to, or in a domestic partnership or other legal union with, an active duty member of the Armed Forces of the United States is able to receive expedited, temporary authorization to practice while meeting state-specific requirements for a period of at least one year.

SEC. 2. Section 5132 of the Business and Professions Code is amended to read:

5132. (a) All moneys received by the board under this chapter from any source and for any purpose and from a temporary license issued under Section 115.6 shall be accounted for and reported monthly by the board to the Controller and at the same time the moneys shall be remitted to the State Treasury to the credit of the Accountancy Fund.

(b) The secretary-treasurer of the board shall, from time to time, but not less than once each fiscal year, prepare or have prepared on their behalf, a financial report of the Accountancy Fund that contains information that the board determines is necessary for the purposes for which the board was established.

(c) The report of the Accountancy Fund, which shall be published pursuant to Section 5008, shall include the revenues and the related costs from examination, initial licensing, license renewal, citation and fine authority, and cost recovery from enforcement actions and case settlements.

REVISIONS:

Heading—Line 2.

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CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

Bill Number:	**AB 2549**
Current Version:	**As Amended May 18, 2020**
Author:	**Salas**
Topic:	**Department of Consumer Affairs, temporary license**
Staff Recommendation:	**Oppose Unless Amended**

Affected Sections: Amend Business and Professions Code section 115.6

Status: Referred to Senate Rules Committee

Existing Law:
Existing law establishes the requirements for licensure. Further, under existing law, the Board is required to expedite the application for 1. an applicant that was honorably discharged from the armed forces or 2. an applicant that is either the spouse, domestic partner, or in another legal union with an active duty member of the armed forces, as specified.

Measure Summary:
This measure would add the Board, to the existing the list of boards under the Department of Consumer Affairs (DCA) that are required to issue temporary licenses to military spouses, requires boards under the requirement to promulgate regulations, as specified, and makes other technical changes. The temporary license would expire within 12 months after issuance, unless a permanent license is issued, or the application is subsequently denied

Staff Comments:
Consistent with existing provisions of law, the Board expedites such applications. Under the provisions of this measure, the Board would be required to issue a temporary license to such applicants within 30 days after receiving the required documentation. The measure includes that the Board conduct an appropriate investigation, however it appears to waive an examination requirement for purposes of issuing a temporary license.

Staff notes, that legal requirements and practice standards for pharmacists vary between jurisdictions and suggests it may be appropriate to specify that passing the CPJE must be a requirement prior to issuing a temporary pharmacist license. Such a requirement would be consistent with the Board's consumer protection

mandate. A similar provision currently exists for several license types regulated by the Board of Professional Engineers, Land Surveyors, and Geologists.

Under existing law the Board has the authority to issue temporary licenses for facilities (pharmacies, wholesalers, etc.) for a period of up to 180 days when it is determined such action is necessary to protect public safety.

Committee Discussion:

The committee has not discussed the bill.

FISCAL IMPACT ON THE BOARD:

From an implementation standpoint, the Board will need to promulgate the required regulations as well as pursue a regulation changes to update any application forms that are incorporated by reference within our regulations. To fully implement the provisions of this measure, I believe we would require an AGPA for a two-year limited capacity to implement. Such activities would include development and promulgation the regulations, updating application forms, developing internal processes, partnering with OIS on programming changes and testing, developing education and outreach materials, etc. Depending on the workload generated, it is possible that the position may need to be permanent if the resulting impact and expansion of the provisions consistent with the policy is realized. This resource could be shared with the resource needs identified in AB 2113.

AMENDED IN ASSEMBLY JUNE 15, 2020

AMENDED IN ASSEMBLY MAY 11, 2020

AMENDED IN ASSEMBLY MARCH 12, 2020

CALIFORNIA LEGISLATURE—2019–20 REGULAR SESSION

ASSEMBLY BILL No. 2983

Introduced by Assembly Member Holden

February 21, 2020

An act to add Section 4063.5 to the Business and Professions Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

AB 2983, as amended, Holden. Pharmacies: automatic refills.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacists and pharmacies by the California State Board of Pharmacy, and makes a willful violation of those provisions a misdemeanor. Existing law prohibits a prescription for any dangerous drug or dangerous device to be refilled except upon authorization of the prescriber.

This bill ~~would~~ *would, commencing January 1, 2022,* prohibit a pharmacy from ~~automatically contacting~~ *using an automated computer system to contact* a prescriber to authorize a prescription for any dangerous drug or device to be refilled for more than a ~~7-day~~ *30-day* supply unless the prescriber or patient has ~~expressly~~ authorized the ~~pharmacy to automatically contact the prescriber to refill that prescription.~~ *pharmacy to do so.* The bill would ~~require a pharmacy to obtain separate written authorization for each prescription and would~~ prohibit a pharmacy from requesting more than the number of refills authorized in the original prescription. ~~The bill would require the~~

~~pharmacy to retain a record of the authorization for at least 3 years.~~ The bill would exempt certain pharmacies owned or operated by a nonprofit health care service plan, as specified. Because the bill would expand the scope of a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 4063.5 is added to the Business and Professions Code, to read:

4063.5. (a) A pharmacy shall not ~~automatically~~ *use an automated computer system to* contact a prescriber to authorize a prescription for any dangerous drug or device to be refilled for more than a ~~seven-day~~ *30-day* supply unless the prescriber or patient has ~~expressly~~ authorized the pharmacy to ~~automatically contact the prescriber to refill that prescription. The pharmacy shall obtain separate written authorization to automatically contact the prescriber for each prescription and~~ *do so. A pharmacy* shall not request more than the number of refills authorized in the original prescription. ~~The pharmacy shall retain a record of the authorization for at least three years.~~

(b) This section shall not apply to a pharmacy owned or operated by a nonprofit health care service plan with at least 3,500,000 enrollees that provides health care services to enrollees in a specific geographic area through a mutually exclusive contract with a single medical group.

(c) This section shall become operative on January 1, 2022.

SEC. 2. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of

the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

Bill Number:	**AB 2983**
Current Version:	**As Amended June 15, 2020**
Author:	**Holden**
Topic:	**Pharmacies: automatic refills**
Staff Recommendation:	**Support**

Affected Sections: Add Business and Professions Code section 4063.5

Status: Referred to Senate Rules Committee

Existing Law:
Existing law provides for the regulation of the practice of pharmacy by the Board. As included in Pharmacy Law, various provisions establish the authorities for the pharmacies to operate and obligations that must be fulfilled.

Regulations promulgated by the Board in Title 16, California Code of Regulations, further define the authorities and obligations. As an example, BPC section 4125 requires all pharmacies to establish a quality assurance to document medication errors as specified. CCR section 1711 establishes the clarity and specificity to the general requirements of BPC section 4125.

Measure Summary:
As amended, this measure, effective January 1, 2022, would prohibit a pharmacy from using an automated computer system to contact a prescriber to authorize a prescription for any dangerous drug or device to be refilled for more than a 30-day supply unless the prescriber or patient has authorized the pharmacy to do so. The bill would prohibit a pharmacy from requesting more than the number of refills authorized in the original prescription. The bill would exempt certain pharmacies owned or operated by a nonprofit health care service plan, as specified. Because the bill would expand the scope of a crime, the bill would impose a state-mandated local program.

Staff Comments:
Staff notes that the Board has pending regulations that would prevent a pharmacy from automatically enrolling an individual into an auto refill program. As detailed in the Board's Initial Statement of Reasons, some areas of concern identified in current programs indicate that:

> Auto-refill programs can cause harm to patients if they are not operated properly. If a patient's prescription has been discontinued by the prescriber but the pharmacy continues to automatically refill the prescription, the patient may take a medication that is not needed or could adversely interact with a newly prescribed medication.
>
> Another problematic situation may arise when a patient is enrolled without consent in an auto-refill program at Pharmacy A and decides to switch to Pharmacy B. If Pharmacy A has already filled the prescription and billed the insurance for the auto-refill, Pharmacy B would not be able to fill the prescription. This could cause a delay in therapy for the patient while insurance and billing issues are resolved.
>
> An additional problem can occur when the patient receives a duplicate prescription if the patient that is enrolled without consent in an auto-refill program, which includes one prescription medication and then receives another prescription for the same or similar medication (e.g. differing dosages). In such a case, the patient may take the same medication twice without knowing it.
>
> When patients are automatically refilled prescriptions they no longer take, there is an increase in the amount of unused pharmaceutical waste that must be disposed. The state's environment is negatively impacted by an increase of unused pharmaceutical waste. This regulatory proposal may reduce the amount of unused or unneeded pharmaceutical waste that requires appropriate and costly disposal (e.g., incineration).

This measure appears to stem in part from a New York Times article published earlier this year that indicated that prescribers are inundated with numerous requests from pharmacies for refills on behalf of patients whom the pharmacists believe do not warrant additional medication. The article describes how these activities are a nuisance for busy prescribers. It also discusses concerns regarding medication errors for patients who ultimately receive and take medication they wrongly assume they need because of the prescription refill. Although staff cannot validate the information from the New York Times article itself, staff notes an increase in the number of complaints received by prescribers seeking investigation by the Board stemming from the current automated refill requests being used by some pharmacies.

Staff notes concern that some auto-refill programs which include automatically generated refill requests can cause harm to patients if they are not operated properly. If pharmacies send automatically generated refill requests to prescribers for medications that the patient is no longer taking, it creates problems for prescribers and public risk for consumers, who often assume that if the pharmacy filled the prescription then the prescriber intended for the patient to take the medication. Prescribers have complained that this practice of

automatic refill requests wastes valuable time as office staff must research each refill request and reach out to their patients to verify if the patient actually requested or needs the medication.

Additionally, staff has received complaints that pharmacies with these programs often continue to fax automatic refill requests after the prescriber has determined the patient no longer needs the medication and has denied the refill.

Committee Discussion:
The committee has not discussed the bill.

FISCAL IMPACT ON THE BOARD:
Staff do not anticipate any significant fiscal impact to the Board. Any minor impact could be absorbed within existing resources.

ASSEMBLY BILL No. 3045

Introduced by Assembly ~~Member Gray~~ *Members Gray and Patterson*
(Principal coauthor: Assembly Member Gallagher)
(Coauthors: Assembly Members Fong, Gipson, Grayson, and Obernolte)

February 21, 2020

An act to add Section 115.7 to the Business and Professions Code, relating to professions and vocations, and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

AB 3045, as introduced, Gray. Department of Consumer Affairs: boards: veterans: military spouses: licenses.

Under existing law, the Department of Consumer Affairs, under the control of the Director of Consumer Affairs, is comprised of various boards that license and regulate various professions and vocations. Existing law requires an applicant seeking a license from a board within the department to meet specified requirements and to pay certain licensing fees. Existing law requires a board within the department to issue, after appropriate investigation, certain types of temporary licenses to an applicant if the applicant meets specified requirements, including that the applicant supplies evidence satisfactory to the board that the applicant is married to, or in a domestic partnership or other legal union with, an active duty member of the Armed Forces of the United States who is assigned to a duty station in this state under official active duty military orders and the applicant holds a current, active, and unrestricted license that confers upon the applicant the authority to practice, in another state, district, or territory of the United States, the profession

or vocation for which the applicant seeks a temporary license from the board. Existing law requires these temporary licenses to expire 12 months after issuance. Under existing law, some of the funds within the jurisdiction of a board consist of revenue from fees that are continuously appropriated.

This bill would require boards not subject to the temporary licensing provisions described above to issue licenses to an applicant if the applicant meets specified requirements, including that the applicant supplies evidence satisfactory to the board that the applicant is an honorably discharged veteran of the Armed Forces of the United States or is married to, or in a domestic partnership or other legal union with, an active duty member of the Armed Forces of the United States, as provided. The bill would require an application for a license to include a signed affidavit attesting to the fact that the applicant meets all requirements for a license. By expanding the scope of the crime of perjury, the bill would impose a state-mandated local program. The bill's expansion of the requirement to issue licenses would result in revenues from fees for certain licenses being deposited into continuously appropriated funds. By establishing a new source of revenue for those continuously appropriated funds, the bill would make an appropriation.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: yes. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 115.7 is added to the Business and Professions Code, to read:

115.7. (a) A board not specified in subdivision (a) of Section 115.6 shall, after appropriate investigation, issue a license to an applicant if the applicant meets all of the following requirements:

(1) The applicant shall supply evidence satisfactory to the board that the applicant is an honorably discharged veteran of the Armed Forces of the United States or is married to, or in a domestic partnership or other legal union with, an active duty member of

the Armed Forces of the United States who is assigned to a duty station in this state under official active duty military orders.

(2) The applicant shall hold a current, active, and unrestricted license that confers upon the applicant the authority to practice, in another state, district, or territory of the United States, the profession or vocation for which the applicant seeks a license from the board.

(3) The applicant shall submit an application to the board that shall include a signed affidavit attesting to the fact that the applicant meets all of the requirements for the license and that the information submitted in the application is accurate, to the best of the applicant's knowledge. The application shall also include written verification from the applicant's original licensing jurisdiction stating that the applicant's license is in good standing in that jurisdiction.

(4) The applicant shall not have committed an act in any jurisdiction that would have constituted grounds for denial, suspension, or revocation of the license under this code at the time the act was committed. A violation of this paragraph may be grounds for the denial or revocation of a license issued by the board.

(5) The applicant shall not have been disciplined by a licensing entity in another jurisdiction and shall not be the subject of an unresolved complaint, review procedure, or disciplinary proceeding conducted by a licensing entity in another jurisdiction.

(6) The applicant shall, upon request by a board, furnish a full set of fingerprints for purposes of conducting a criminal background check.

(b) A board may adopt regulations necessary to administer this section.

SEC. 2. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

REVISIONS:
Heading—Lines 1 and 2.

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CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

Bill Number:	**AB 3045**
Current Version:	**As Introduced February 21, 2020**
Author:	**Gray and Patterson**
Topic:	**Department of Consumer Affairs: Boards: Veterans: Military Spouses: Licenses**
Staff Recommendation:	**Oppose unless amended**

Affected Sections: Add Business and Professions Code section 115.7

Status: Referred to Senate Rules Committee

Existing Law:
Existing law establishes the requirements for licensure. Further, under existing law, the Board is required to expedite the application for 1. an applicant that was honorably discharged from the armed forces or 2. an applicant that is either the spouse, domestic partner, or in another legal union with an active duty member of the armed forces, as specified.

Measure Summary:
This bill would require boards not subject to the temporary licensing provisions (including the Board) to issue a license to an applicant if the applicant meets specified requirements, including that the applicant supplies evidence satisfactory to the board that the applicant is an honorably discharged veteran of the Armed Forces of the United States or is married to, or in a domestic partnership or other legal union with, an active duty member of the Armed Forces of the United States, as provided. The bill would require an application for a license to include a signed affidavit attesting to the fact that the applicant meets all requirements for a license.

Staff Comments:
The Board has a history of supporting measures that assist members of the armed forces, spouses, and veterans in obtaining licensure. Staff however notes concerns that under the provisions of this bill, the Board would be precluded from ensuring minimum competency for practice in California. Provisions of pharmacy law, standards of practice and licensure requirements vary across jurisdictions. Without an opportunity to fully assess a candidate's eligibility for licensure consumers could be at risk. On balance, expedited application processing that prioritizes processing for such individuals, but that affords the Board the opportunity to assess for minimum competency for California appears to be more consistent with the Board's consumer protection mandate.

Committee Discussion:
The committee has not discussed the bill.

Fiscal Impact on the Board:
The costs for this measure are unknown, however potential costs could include an increase in investigations and other enforcement related costs resulting from the Board issuing licenses to individuals that may not otherwise qualify for licensure.

AMENDED IN ASSEMBLY MAY 4, 2020

CALIFORNIA LEGISLATURE—2019–20 REGULAR SESSION

ASSEMBLY BILL No. 3342

Introduced by Assembly Member Bauer-Kahan

February 21, 2020

An act to ~~amend Section 25914.2 of the Health and Safety Code, relating to hazardous substances.~~ *add Section 4119.25 to the Business and Professions Code, and to add Section 1596.7985 to the Health and Safety Code, relating to care facilities.*

LEGISLATIVE COUNSEL'S DIGEST

AB 3342, as amended, Bauer-Kahan. ~~Asbestos and hazardous substance removal.~~ *Child daycare facilities: emergency epinephrine auto-injectors.*

Existing law, the California Child Day Care Facilities Act, provides for the licensure and regulation of daycare centers, as defined, and family daycare homes, as defined, by the State Department of Social Services. A violation of the act is a crime. Existing law declares the intent of the Legislature to encourage any person who provides childcare in a licensed child daycare facility to have certain elementary health care training, including cardiopulmonary resuscitation and pediatric first aid. Existing law authorizes licensees and staff of a child daycare facility to perform blood glucose testing and administer inhaled medication to a child if specified requirements are met.

Existing law requires school districts, county offices of education, and charter schools to provide emergency epinephrine auto-injectors, as defined, to school nurses and trained personnel who have volunteered to use epinephrine auto-injectors under emergency circumstances, as specified, and authorizes school nurses and trained personnel to use

epinephrine auto-injectors to provide emergency medical aid to persons suffering, or reasonably believed to be suffering, from an anaphylactic reaction.

This bill would require the State Department of Social Services by January 1, 2025, to establish a program to authorize child daycare facilities to keep emergency epinephrine auto-injectors onsite to be administered by trained, volunteer personnel to provide emergency medical aid to a person who is suffering, or reasonably believed to be suffering, from an anaphylactic reaction. The bill would require the department to develop a training program for the participating personnel, which would include components, including, but not limited to, techniques for recognizing symptoms of anaphylaxis and emergency followup procedures.

Existing law authorizes a pharmacy to furnish epinephrine auto-injectors to a school district, county office of education, or charter school if certain requirements are met.

This bill would authorize a pharmacy to furnish epinephrine auto-injectors to the State Department of Health Care Services under the program created pursuant to this bill, subject to similar requirements.

~~Existing law regulates the removal of asbestos and hazardous substances, as defined, under contracts for work performed on behalf of the public and private entities and persons. Existing law requires, when the presence of asbestos or hazardous substances is not disclosed in the bid or contract documents, that all asbestos-related work and hazardous substance removal be performed pursuant to a separate contract from any other work performed. Existing law further requires a contractor who encounters materials the contractor believes to be asbestos or a hazardous substance to stop work on the affected area and report the condition, as specified.~~

~~This bill would make technical, nonsubstantive changes to those provisions.~~

Vote: majority. Appropriation: no. Fiscal committee: ~~no~~ *yes*. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 4119.25 is added to the Business and Professions Code, to read:

4119.25. (a) Notwithstanding any other law, a pharmacy may furnish epinephrine auto-injectors to the State Department of Social Services only if the following conditions are met:

(1) The epinephrine auto-injectors are furnished exclusively for use at a child daycare facility participating in the program created by the department pursuant to Section 1596.7985 of the Health and Safety Code.

(2) A physician and surgeon provides a written order that specifies the quantity of epinephrine auto-injectors to be furnished.

(b) Records regarding the acquisition and disposition of epinephrine auto-injectors furnished pursuant to subdivision (a) shall be maintained by the State Department of Social Services for a period of three years from the date the records were created. The department shall be responsible for monitoring the supply of epinephrine auto-injectors and ensuring the destruction of expired epinephrine auto-injectors.

SEC. 2. Section 1596.7985 is added to the Health and Safety Code, to read:

1596.7985. (a) By January 1, 2025, the department shall establish a program to authorize child daycare facilities to keep emergency epinephrine auto-injectors onsite to be administered by trained personnel to provide emergency medical aid to persons suffering, or reasonably believed to be suffering, from an anaphylactic reaction. The program shall include training requirements for those employees who volunteer to participate in the program.

(b) For purposes of this section, the following terms have the following meanings:

(1) "Anaphylaxis" means a potentially life-threatening hypersensitivity to a substance.

(A) Symptoms of anaphylaxis may include shortness of breath, wheezing, difficulty breathing, difficulty talking or swallowing, hives, itching, swelling, shock, or asthma.

(B) Causes of anaphylaxis may include, but are not limited to, an insect sting, food allergy, drug reaction, and exercise.

(2) "Epinephrine auto-injector" means a disposable delivery device designed for the automatic injection of a premeasured dose of epinephrine into the human body to prevent or treat a life-threatening allergic reaction. "Epinephrine auto-injector" includes a junior epinephrine auto-injector.

(3) "Volunteer" or "trained personnel" means an employee with a current certificate in pediatric first aid who has volunteered to administer an epinephrine auto-injector to a person who is suffering, or reasonably believed to be suffering, from anaphylaxis, has been designated by a daycare facility, and has received training pursuant to subdivision (c).

(c) (1) The department shall develop, or contract for the development of, a training program for purposes of this section and shall ensure that an individual described in paragraph (3) of subdivision (b) successfully completes that program. The training program shall address, at a minimum, all of the following:

(A) Techniques for recognizing symptoms of anaphylaxis.

(B) Standards and procedures for the storage, restocking, and emergency use of epinephrine auto-injectors.

(C) Emergency followup procedures, including calling the emergency 911 telephone number and contacting, if possible, the child's parent and physician.

(D) Recommendations on the necessity of instruction and certification in cardiopulmonary resuscitation.

(E) Written materials covering the information required under this subdivision.

(2) The training developed pursuant to this subdivision shall be consistent with the most recent Voluntary Guidelines for Managing Food Allergies In Schools and Early Care and Education Programs published by the federal Centers for Disease Control and Prevention and the most recent guidelines for medication administration issued by the department.

~~SECTION 1. Section 25914.2 of the Health and Safety Code is amended to read:~~

~~25914.2. (a) All asbestos-related work and hazardous substance removal shall be performed pursuant to a contract separate from any other work to be performed, when the presence of asbestos or hazardous substances is not disclosed in the bid or contract documents.~~

~~(b) Asbestos-related and hazardous substance removal work that is disclosed in the bid or contract documents shall not require a separate contract from any other work to be performed.~~

~~(c) If a contractor encounters on the site materials the contractor reasonably believes to be asbestos or a hazardous substance, and the asbestos or hazardous substance has not been rendered~~

~~harmless, the contractor may continue work in unaffected areas reasonably believed safe, and shall immediately cease work on the area affected and report the condition to the owner, or the owner's representative, or architect in writing.~~

~~(d) With regard to a public entity, if an emergency condition arises, as defined in Section 10122 or 22035 of the Public Contract Code, then all asbestos-related and hazardous substance removal shall be contracted and performed pursuant to Section 10122 or 22035 of the Public Contract Code, respectively. Contractors performing the work shall have all registration and certificates required pursuant to the Labor Code and the Business and Professions Code.~~

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CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

Bill Number:	**AB 3342**
Current Version:	**As Amended May 4, 2020**
Author:	**Bauer-Kahan**
Topic:	**Child daycare facilities: emergency epinephrine auto-injectors**
Staff Recommendation:	**Support**

Affected Sections: Add BPC Section 4119.25 and to add Section 1596.7985 to the Health and Safety Code

Status: Referred to Assembly Human Services Committee

Existing Law:
BPC section 4119.2 provides the authority for a pharmacy to furnish epinephrine auto-injectors to a school district, county office of education, or charter school pursuant to Section 49414 of the Education Code under specified conditions.

BPC section 4119.3 provides that a pharmacy may dispense epinephrine auto-injectors to a prehospital emergency medical care person or lay rescuer for the purpose of rendering emergency care, as specified.

BPC section 4119.4 provides that a pharmacy may furnish epinephrine auto-injectors to an authorized entity, for the purpose of rendering emergency care, as specified.

Measure Summary:
As related to the Board, the measure would authorize a pharmacy to furnish epinephrine auto-injectors to the State Department of Health Care Services under the program created pursuant to this bill, subject to similar requirements.

Staff Comments:
The Board has a history of supporting similar measures, including AB 1386 (Chapter 374, Statutes of 2016) which added the provisions of BPC 4119.4.

Committee Discussion:
The committee has not discussed the bill.

Fiscal Impact on the Board:
Board staff do not anticipate any significant fiscal impact. Any minor impact could be absorbed within existing resources.

AMENDED IN SENATE JUNE 18, 2020

SENATE BILL No. 878

Introduced by Senator Jones

January 22, 2020

An act to add Section 139.5 to the Business and Professions Code, relating to professions and vocations.

LEGISLATIVE COUNSEL'S DIGEST

SB 878, as amended, Jones. Department of Consumer ~~Affairs Licensing: applications: wait times.~~ *Affairs: license: application: processing timeframes.*

Existing law provides for the licensure and regulation of various professions and vocations by boards within the Department of Consumer Affairs.

This ~~bill~~ *bill, beginning July 1, 2021,* would require each board within the department that issues ~~licenses~~ *licenses, on at least a quarterly basis,* to prominently display *on its internet website either* the current ~~timeframe~~ *average timeframes* for processing initial and renewal license applications ~~on its internet website, as provided.~~ *or the combined current average timeframe for processing both initial and renewal license applications. The bill would also require each board to prominently display on its internet website either the current average timeframes for processing each license type that the board administers or the combined current average timeframe for processing all license types that the board administers.*

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 139.5 is added to the Business and Professions Code, to read:

139.5. ~~Each~~ *Beginning July 1, 2021, each* board, as defined in ~~section~~ *Section* 22, within the department that issues a license shall do both of the~~ following:~~ *following on at least a quarterly basis:*

(a) Prominently display~~ the~~ *on its internet website one of the following:*

(1) The current~~ timeframe~~ *average timeframes* for processing initial and renewal license~~ applications on its internet website.~~ *applications.*

(2) The combined current average timeframe for processing both initial and renewal license applications.

(b) ~~With respect to the information displayed on the website, specify the~~ *Prominently display on its internet website one of the following:*

(1) The current average~~ timeframe~~ *timeframes* for *processing* each license~~ category.~~ *type that the board administers.*

(2) The combined current average timeframe for processing all license types that the board administers.

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CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

Bill Number:	**SB 878**
Current Version:	**As Amended June 18, 2020**
Author:	**Jones**
Topic:	**Department of Consumer Affairs: License: Application: Processing Timeframes**
Staff Recommendation:	**None**

Affected Sections: Add Business and Professions Code section 115.7

Status: Referred to Assembly Committee on Business and Professions

Existing Law:
Existing law provides for the licensure and regulation of various professions and vocations by boards within the Department of Consumer Affairs.

Measure Summary:
As amended, this measure would require each board within the department that issues licenses, on at least a quarterly basis, to prominently display on its internet website either the current average timeframes for processing initial and renewal license applications or the combined current average timeframe for processing both initial and renewal license applications. The bill would also require each board to prominently display on its internet website either the current average timeframes for processing each license type that the board administers or the combined current average timeframe for processing all license types that the board administers.

Staff Comments:
Staff notes that application processing times are reported on a quarterly basis to the Licensing Committee and Board as part of the licensing statistics provided in meeting materials. A reporting system for renewal processing information could similarly be developed.

Committee Discussion:
The committee has not discussed the bill.

FISCAL IMPACT ON THE BOARD:
Staff anticipates minor fiscal impact that could be absorbed within existing resources.

AMENDED IN SENATE JUNE 18, 2020

AMENDED IN SENATE MAY 14, 2020

SENATE BILL No. 1474

Introduced by Committee on Business, Professions and Economic Development (Senators Glazer (Chair), Archuleta, Chang, Dodd, Galgiani, Hill, Leyva, Pan, and Wilk)

(Principal coauthor: Assembly Member Low)

March 16, 2020

An act to amend Sections 27, 101, 125.9, 130, 144, 200.1, 205, 494.5, 1913, 1917, 1917.1, 1922, 2065, 2113, 2135.5, 2460, 2841, *2847.1, 2847.3,* 2920, 2933, 3504, 3512, 4001, 4003, 4501, 4503, *4604,* 4621, 4800, 4804.5, 4990, 4990.04, 5600.4, 7000, 7000.5, 7000.6, 7011.4, 7011.5, 7011.8, 7015, 7017.3, 7028.7, 7030, 7031, 7058.7, 7071.4, 7080.5, 7085.5, 7099.2, 7123.5, 7135, 7136, 7137, 7137.5, 7138, 7139.1, 7139.2, 7145.5, 7159, 7170, 7303, 8516, 10050, 11301, 16100, and 19164 of, and to add Sections 5650.5 and 7099.9 to, the Business and Professions Code, and to amend Section 94950 of the Education Code, relating to business and professions, and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

SB 1474, as amended, Committee on Business, Professions and Economic Development. Business and professions.

(1) Existing law, the Contractors' State License Law, provides for the licensure and regulation of contractors by the Contractors' State License Board in the Department of Consumer Affairs. Existing law requires fees and penalties received pursuant to the law to be deposited in the Contractors' License Fund, a continuously appropriated fund,

~~SEC. 23.~~

SEC. 25. Section 4001 of the Business and Professions Code is amended to read:

4001. (a) There is in the Department of Consumer Affairs a California State Board of Pharmacy in which the administration and enforcement of this chapter is vested. The board consists of 13 members.

(b) The Governor shall appoint seven competent pharmacists who reside in different parts of the state to serve as members of the board. The Governor shall appoint four public members, and the Senate Committee on Rules and the Speaker of the Assembly shall each appoint a public member who shall not be a licensee of the board, any other board under this division, or any board referred to in Section 1000 or 3600.

(c) At least five of the seven pharmacist appointees to the board shall be pharmacists who are actively engaged in the practice of pharmacy. Additionally, the membership of the board shall 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 a long-term health care or skilled nursing facility. The pharmacist appointees shall also include a pharmacist who is a member of a labor union that represents pharmacists. For the purposes of this subdivision, a "chain community pharmacy" means a chain of 75 or more stores in California under the same ownership, and an "independent community pharmacy" means a pharmacy owned by a person or entity who owns no more than four pharmacies in California.

(d) Members of the board shall be appointed for a term of four years. No person shall serve as a member of the board for more than two consecutive terms. Each member shall hold office until the appointment and qualification of their successor or until one year shall have elapsed since the expiration of the term for which the member was appointed, whichever first occurs. Vacancies occurring shall be filled by appointment for the unexpired term.

(e) Each member of the board shall receive a per diem and expenses as provided in Section 103.

(f) This section shall remain in effect only until January 1, 2022, and as of that date is repealed. Notwithstanding any other law, the repeal of this section renders the board subject to review by the appropriate policy committees of the Legislature.

~~SEC. 24.~~

SEC. 26. Section 4003 of the Business and Professions Code is amended to read:

4003. (a) The board, with the approval of the director, may appoint a person exempt from civil service who shall be designated as an executive officer and who shall exercise the powers and perform the duties delegated by the board and vested in them by this chapter. The executive officer may or may not be a member of the board as the board may determine.

(b) The executive officer shall receive the compensation as established by the board with the approval of the Director of Finance. The executive officer shall also be entitled to travel and other expenses necessary in the performance of their duties.

(c) The executive officer shall maintain and update in a timely fashion records containing the names, titles, qualifications, and places of business of all persons subject to this chapter.

(d) The executive officer shall give receipts for all money received by them and pay it to the department, taking its receipt therefor. Besides the duties required by this chapter, the executive officer shall perform other duties pertaining to the office as may be required of them by the board.

(e) This section shall remain in effect only until January 1, 2022, and as of that date is repealed.

~~SEC. 25.~~

SEC. 27. Section 4501 of the Business and Professions Code is amended to read:

4501. (a) "Board," as used in this chapter, means the Board of Vocational Nursing and Psychiatric Technicians of the State of California.

(b) This section shall remain in effect only until January 1, 2022, and as of that date is repealed.

~~SEC. 26.~~

SEC. 28. Section 4503 of the Business and Professions Code is amended to read:

4503. (a) The board shall administer and enforce this chapter.

(b) This section shall remain in effect only until January 1, 2022, and as of that date is repealed.

SEC. 29. Section 4604 of the Business and Professions Code is amended to read:

CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

Bill Number:	**SB 1474**
Current Version:	**As Amended June 18, 2020**
Author:	**Committee on Business, Professions and Economic Development**
Topic:	**Business and Professions**
Staff Recommendation:	**Support**

Affected Sections: As related to the Board, Amends Business and Professions Code sections 4001 and 4003

Status: Referred to the Assembly

Existing Law:
Existing law BPC section 4001 establishes the California State Board of Pharmacy and provides for the membership constitution. Further this section provides a sunset date of January 1, 2021.

Further BPC section 4003 established the authority for the Board, with the approval of the DCA Director, to appoint a person designated as the Executive Officer. This section also provides a sunset date of January 1, 2021.

Measure Summary:
This measure would extend the operations of the Board and the Executive Officer through January 1, 2022.

Staff Comments:
In December 2019, the Board submitted its Sunset Review Report in anticipation of review by oversight committees this year. Due to the COVID-19 Pandemic and the unprecedented nature of the 2020 Legislative Session, oversight review was postponed. The extension provided in this measure will allow for the Board to be evaluated via the comprehensive Sunset Review Process next year.

Committee Discussion:
The committee has not discussed the bill.

FISCAL IMPACT ON THE BOARD:
Staff anticipates minor fiscal impact that could be absorbed within existing resources.

Attachment 3

Regulation Timeline

VI. Board Adopted Regulations Approved by the Office of Administrative Law

a. Proposed Regulations to Amend Title 16 CCR Section 1706.2 Related to Abandonment of Applications

Timeline:
Approved by Board: February 6, 2018
Submitted to DCA for Pre-Notice Review: July 2, 2018
Formal DCA Pre-Notice Review began: August 3, 2018
45-Day Comment Period: August 30, 2019 to October 14, 2019
Adopted by the Board: November 6, 2019
Submitted to DCA for Formal Review: December 11, 2019
Submitted to OAL for Final Review: March 3, 2020
Approved by OAL: June 15, 2020
Effective Date of Regulation: October 1, 2020

b. Proposed Regulations to Amend Title 16 CCR Section 1707.2 Related to Mail-Order Pharmacy Consultation

Timeline:
Approved by Board: May 2, 2018
Submitted to DCA for Pre-Notice Review: July 23, 2018
Returned to the Board on: August 23, 2018
Re-submitted to DCA for Pre-Notice Review: September 14, 2018
Formal DCA Pre-Notice Review began: October 1, 2018
45-Day Comment Period: August 16, 2019 to September 30, 2019
Adopted by the Board: November 6, 2019
Submitted to DCA for Formal Review: December 17, 2019
Submitted to OAL for Final Review: March 6, 2020
Approved by OAL: June 15, 2020
Effective Date of Regulation: October 1, 2020

Abandonment of Applications
16 CCR § 1706.2

Title 16. Board of Pharmacy
Order of Adoption

Amend section 1706.2 in Article 1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1706.2. Abandonment of Application Files.

(a) An applicant for a premises license ~~to conduct a pharmacy, non-resident pharmacy, sterile injectable compounding pharmacy, wholesaler, out-of-state distributor, clinic, veterinary food-animal drug retailer, or to furnish hypodermic needles and syringes~~ who fails to complete all application requirements within 60 days after being notified by the board of deficiencies in his, her or its file, may be deemed to have abandoned the application and may be required to file a new application and meet all of the requirements in effect at the time of reapplication.

(b) An applicant for ~~a pharmacy technician license or a designated representative license~~ an individual license not included in subdivision (c), (d), or (e) who fails to complete all application requirements within 60 days after being notified by the board of deficiencies in his or her file, may be deemed to have abandoned the application and may be required to file a new application and meet all of the requirements which are in effect at the time of reapplication.

(c) An applicant who fails to pay the fee for licensure as a pharmacist required by subdivision (f)(1) of section 1749 of this Division within 12 months after being notified by the board of his or her eligibility shall be deemed to have abandoned the application and must file a new application and be in compliance with the requirements in effect at the time of reapplication.

(d) An applicant to take the pharmacist licensure examinations who fails to take the examinations within 12 months of being deemed eligible, shall be deemed to have abandoned the application and must file a new application in compliance with all of the requirements in effect at the time of reapplication.

(e) An applicant for an intern pharmacist license who fails to complete all application requirements within one year after being notified by the board of deficiencies in his or her file, may be deemed to have abandoned the application and may be required to file a new application and meet all of the requirements which are in effect at the time of reapplication.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4022.5, 4029, 4030, 4034, 4034.5, 4037, 4041, ~~4042,~~ 4043, 4044.3, 4045, 4053, 4110, 4112, 4115, 4120, 4127.1, 4127.15, 4141, 4160, 4161, 4180, 4190, 4200, 4201, 4202, 4202.5, 4203, 4203.5, 4204, 4205, ~~and~~ 4208, and 4210, Business and Professions Code.

Mail-Order Pharmacy Consultation
16 CCR § 1707.2

Title 16. Board of Pharmacy
Order of Adoption

Amend section 1707.2 in Article 2 of Division 17 of Title 16 California Code of Regulations to read as follows:

§ 1707.2. Duty to Consult

(a) A pharmacist shall provide oral consultation to his or her patient or the patient's agent in all ~~care~~ settings:

(1) upon request; ~~or~~

(2) whenever the pharmacist deems it warranted in the exercise of his or her professional judgment;~~.~~

~~(b) (1) In addition to the obligation to consult set forth in subsection (a), a pharmacist shall provide oral consultation to his or her patient or the patient's agent in any care setting in which the patient or agent is present:~~

(3~~A~~) whenever the prescription drug has not previously been dispensed to a patient; or

(4~~B~~) whenever a prescription drug not previously dispensed to a patient in the same dosage form, strength, or with the same written directions, is dispensed by the pharmacy.

(b)(1~~2~~) When the patient or patient's agent is not present (including, but not limited to, a prescription drug that was shipped by mail or delivery), a pharmacy shall ensure that ~~the patient receives written notice~~:

(A) the patient receives written notice of his or her right to request consultation; ~~and~~

(B) the patient receives written notice of ~~a~~ the hours of availability and the telephone number from which the patient may obtain oral consultation from a pharmacist who has ready access to the patient's record~~.~~; and

(C) a pharmacist shall be available (i) to speak to the patient or patient's agent during any regular hours of operation, within an average of ten (10) minutes or less, unless a return call is scheduled to occur within one business hour, (ii) for no less than six days per week, and (iii) for a minimum of 40 hours per week.

(2~~3~~) A pharmacist is not required by this subsection to provide oral consultation to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code, or to an inmate of an adult correctional facility or a juvenile detention facility, except upon the patient's discharge. A pharmacist is not obligated to consult about discharge medications if a health facility licensed pursuant to subdivision (a) or (b) of Health and Safety Code Section 1250 has implemented a written policy about discharge medications

which meets the requirements of Business and Professions Code Section 4074.

(c) When oral consultation is provided, it shall include at least the following:

(1) directions for use and storage and the importance of compliance with directions; and

(2) precautions and relevant warnings, including common severe side or adverse effects or interactions that may be encountered.

(d) Whenever a pharmacist deems it warranted in the exercise of his or her professional judgment, oral consultation shall also include:

(1) the name and description of the medication;

(2) the route of administration, dosage form, dosage, and duration of drug therapy;

(3) any special directions for use and storage;

(4) precautions for preparation and administration by the patient, including techniques for self-monitoring drug therapy;

(5) prescription refill information;

(6) therapeutic contraindications, avoidance of common severe side or adverse effects or known interactions, including serious potential interactions with known nonprescription medications and therapeutic contraindications and the action required if such side or adverse effects or interactions or therapeutic contraindications are present or occur;

(7) action to be taken in the event of a missed dose.

(e) Notwithstanding the requirements set forth in subsection (a) and (b), a pharmacist is not required to provide oral consultation when a patient or the patient's agent refuses such consultation.

Note: Authority cited: Sections 4005, 4076 and ~~4122~~4112, Business and Professions Code. Reference: Sections 4005, 4076 and ~~4122~~4112, Business and Professions Code.

Attachment 4

Regulation Timeline

VII. Discussion and Consideration of Board Adopted Regulations Undergoing Final Review by the Office of Administrative Law

a. Proposed Regulations to Add Title 16 CCR Section 1714.3 Related to Community Pharmacy Staffing

Timeline:
Approved by Board: July 25, 2019
Submitted to DCA for Pre-Notice Review: August 26, 2019
Formal DCA Pre-Notice Review began: December 13, 2019
45-Day Comment Period: February 28, 2020 to April 30, 2020
Adopted by the Board: May 7, 2020
Submitted to DCA for Formal Review: May 14, 2020
Submitted to OAL for Final Review: June 5, 2020
OAL decision due by July 20, 2020

Community Pharmacy Staffing
16 CCR § 1714.3

Title 16. Board of Pharmacy
Proposed Regulation

Add section 1714.3 to Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

Section 1714.3. Community Pharmacy Staffing

This section applies to a community pharmacy that is required to comply with Business and Professions Code section 4113.5.

(a) When a pharmacy is open to the public and a pharmacist is working without another pharmacy employee, the pharmacy must make another person available to assist a pharmacist. The pharmacy must:

(1) Designate the names of one or more persons who will be available to assist the pharmacist;

(2) Determine that each designated person is able, at a minimum, to perform the duties of non-licensed pharmacy personnel as specified in section 1793.3;

(3) Determine that each designated person qualifies to access to controlled substances by conducting a background check on each person that is consistent with federal requirements for pharmacy employees with such access;

(4) Ensure that a designated person responds and is able to assist the pharmacist within five minutes after the pharmacist's request.

(b) A pharmacy must have and maintain policies and procedures that addresses the following:

(1) The required criteria and training for a designated person, which shall be consistent with subdivison (a).

(2) The process for the pharmacist to request assistance and to document the response time between the request and arrival of the designated person at the pharmacy.

(3) All impacted pharmacy employees and designated persons must read and sign a copy of the policies and procedures required by this section.

(c) The pharmacy must maintain the policies and procedures in the pharmacy premises in a readily retrievable format.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, 4007, 4029, 4036, 4037, 4056, 4110, and 4113.5, Business and Professions Code.

Attachment 5

Regulation Timeline

VIII. Discussion and Consideration of Board Adopted Regulations Undergoing Formal Review by the Department of Consumer Affairs or the Business, Consumer Services and Housing Agency

a. Proposed Regulations to Amend Title 16 CCR Sections 1769 and 1770 Related to Criminal Conviction Substantial Relationship and Rehabilitation Criteria

Timeline:
Approved by Board: May 6, 2019
Submitted to DCA for Pre-Notice Review: May 31, 2019
Formal DCA Pre-Notice Review began: December 5, 2020
45-Day Comment Period: March 13, 2019 to April 27, 2019
Adopted by the Board: May 7, 2019
Submitted to DCA for Formal Review: May 15, 2019

b. Proposed Regulations to Amend Title 16 CCR Sections 1702, 1702.1, 1702.2, and 1702.5 Related to Renewal Requirements

Timeline:
Approved by Board: May 2, 2018
Submitted to DCA for Pre-Notice Review: July 12, 2018
Returned to the board: September 6, 2018
Re-submitted to DCA for Pre-Notice Review: September 18, 2018
Returned to the board: September 28, 2018
Re-submitted to DCA for Pre-Notice Review: October 4, 2018
Formal DCA Pre-Notice Review began: October 16, 2018
Returned to the Board on: July 23, 2019
Re-submitted to DCA for Formal Pre-Notice Review: December 18, 2019
45-Day Comment Period: February 7, 2020 to March 23, 2020
Adopted by the Board: May 7, 2020
Submitted to DCA for Formal Review: May 19, 2020

c. Proposed Regulations to Amend Title 16 CCR Section 1707 Related to Offsite Storage

Timeline:
Approved by Board: January 24, 2017
Submitted to DCA for Pre-Notice Review: April 27, 2017
Returned to the board: January 18, 2018
Re-submitted to DCA for Pre-Notice Review: June 25, 2018
Returned to the board: July 3, 2018
Re-submitted to DCA for Pre-Notice Review: July 13, 2018
Formal DCA Pre-Notice Review began: August 20, 2018

Returned to the board: March 19, 2019
Re-submitted to DCA for Formal Pre-Notice Review: April 9, 2019
45-Day Comment Period: February 7, 2020 to March 23, 2020
15-Day Comment Period: May 19, 2020 to June 3, 2020 (No Negative Comments)
Adopted by the EO per Delegation: May 7, 2020
Submitted to DCA for Formal Review: June 3, 2020

Criminal Conviction Substantial Relationship and Rehabilitation Criteria 16 CCR §§ 1769 and 1770

Title 16. Board of Pharmacy
Proposed Regulation

Proposed changes to the current regulation language are shown by strikethrough for deleted language and underline for added language.

Amend section 1769 of Article 8 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

(a) In addition to any other requirements for licensure, when considering the approval of an application, the board or its designee may require an applicant to be examined by one or more physicians and surgeons or psychologists designated by the board if it appears that the applicant may be unable to safely practice due to mental illness or physical illness affecting competency. An applicant's failure to comply with the examination requirement shall render his or her application incomplete. The board shall pay the full cost of such examination. The board shall seek that the evaluation be conducted within 60 days of the date the applicant is advised that an examination is required. The board shall receive the examiner's evaluation within 60 days of the date the examination is completed. The report of the examiner shall be made available to the applicant.

If after receiving the report of the evaluation, the board determines that the applicant is unable to safely practice, the board may deny the application.

(b) When considering the denial of a facility or personal license under Section 480 of the Business and Professions Code on the grounds that the applicant was convicted of a crime, the board shall consider whether the applicant made a showing of rehabilitation and is presently eligible for a license, if the applicant completed the criminal sentence at issue without a violation of parole or probation. In making this determination, the board shall consider the following criteria:~~, the board, in evaluating the rehabilitation of the applicant and his present eligibility for licensing or registration, will consider the following criteria:~~

(1) The nature and gravity of the crime(s).

(2) The length(s) of the applicable parole or probation period(s).

(3) The extent to which the applicable parole or probation period was shortened or lengthened, and the reason(s) the period was modified.

(4) The terms or conditions of parole or probation and the extent to which they bear on the applicant's rehabilitation.

(5) The extent to which the terms or conditions of parole or probation were modified, and the reason(s) for modification.

(c) If subdivision (b) is inapplicable, or the board determines that the applicant did not make the showing of rehabilitation based on the criteria in subdivision (b), the board shall apply the following criteria in evaluating an applicant's rehabilitation. The board shall find that the

applicant made a showing of rehabilitation and is presently eligible for a license if, after considering the following criteria, the board finds that the applicant is rehabilitated:

(1) The nature and severity of the act(s) or ~~offense(s)~~crimes(s) under consideration as grounds for denial.

(2) Evidence of any act(s) or crime(s) committed subsequent to the act(s) or crime(s) under consideration as grounds for denial under Section 480 of the Business and Professions Code.

(3) The time that has elapsed since commission of the act(s) or crime(s) referred to in subdivision (1) or (2).

(4) Whether the applicant has complied with any terms of parole, probation, restitution or any other sanctions lawfully imposed against the applicant.

(5) The criteria in subdivision (b)(1)-(5), as applicable.

~~(5)~~(6) Evidence, if any, of rehabilitation submitted by the applicant.

~~(c)~~(d) When considering the suspension or revocation of a facility or a personal license on the ground that the licensee or the registrant has been convicted of a crime, the board, in evaluating the rehabilitation of such person and his present eligibility for a license will consider the following criteria:

(1) Nature and severity of the act(s) or offense(s).

(2) Total criminal record.

(3) The time that has elapsed since commission of the act(s) or offense(s).

(4) Whether the licensee has complied with all terms of parole, probation, restitution or any other sanctions lawfully imposed against the licensee.

(5) Evidence, if any, of rehabilitation submitted by the licensee.

Note: Authority cited: Sections 482 and 4005, Business and Professions Code. Reference: Sections 480, 481, 482, 488, 493, 4030, 4200 and 4400, Business and Professions Code.

Amend section 1770 of Article 8 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

(a) For the purpose of denial, suspension, or revocation of a personal or facility license pursuant to Section 141 or Division 1.5 (commencing with Section 475) of the Business and Professions Code, a crime, professional misconduct, or act shall be considered substantially related to the qualifications, functions or duties of a licensee or registrant if to a substantial degree it evidences present or potential unfitness of a licensee or registrant to perform the functions authorized by ~~his~~the license or registration in a manner consistent with the public health, safety, or welfare.

(b) In making the substantial relationship determination required under subdivision (a) for a crime, the board shall consider the following criteria:

(1) The nature and gravity of the offense;

(2) The number of years elapsed since the date of the offense; and

(3) The nature and duties of the profession or occupation the person may perform with the license type sought or held.

(c) For purposes of subdivision (a), substantially related crimes, professional misconduct, or acts shall include, but are not limited to, those which:

(1) Violate or attempt to violate, directly or indirectly, or to aid, abet or conspire to violate, any provision of law of this state, or any other jurisdiction, governing the practice of pharmacy.

(2) Violate or attempt to violate, directly or indirectly, or to aid, abet or conspire to violate, any provision of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of a violation of any law of this state, or any other jurisdiction, relating to controlled substances or dangerous drugs.

(3) Violate or attempt to violate, directly or indirectly, or to aid, abet or conspire to violate, any provision of law of this state, or any other jurisdiction, relating to government provided or government supported healthcare.

(4) Involve dishonesty, fraud, deceit, or corruption related to money, items, documents, or personal information.

(5) Involve a conviction for driving under the influence of drugs or alcohol.

Note: Authority cited: Sections 481, 493, and 4005, Business and Professions Code. Reference: Sections 141, 480, 481, 490, 493, 4300, 4301, 4301.5, and 4309, Business and Professions Code.

Renewal Requirements 16 CCR §§ 1702, 1702.1, 1702.2, 1702.5

Title 16. Board of Pharmacy
Proposed Text

Proposed changes to the current regulation language are shown by strikethrough for deleted language and underline for added language.

Amend section 1702 in Article 1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1702. Pharmacist Renewal Requirements.

(a) A pharmacist applicant for renewal who has not previously submitted fingerprints as a condition of licensure or for whom an electronic record of the licensee's fingerprints does not exist in the Department of Justice's criminal offender record identification database shall successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice by the licensee's or registrant's renewal date.
   (1) A pharmacist ~~s~~ shall retain for at least three years as evidence of having complied with subdivision (a) either a receipt showing that he or she has electronically transmitted his or her fingerprint images to the Department of Justice or, for those who did not use an electronic fingerprinting system, a receipt evidencing that his or her fingerprints were recorded and submitted to the board.
   (2) A pharmacist applicant for renewal shall pay the actual cost of compliance with subdivision (a).
   (3) As a condition of petitioning the board for reinstatement of a revoked or surrendered license, or for restoration of a retired license, an applicant shall comply with subdivision (a).
   (4) The board may waive the requirements of this section for licensees who are actively serving in the United States military. The board may not return a license to active status until the licensee has complied with subdivision (a).

(b) As a condition of renewal, a pharmacist applicant shall disclose on the renewal form whether he or she has been convicted, as defined in Section 490 of the Business and Professions Code, of any violation of the law in this or any other state, the United States, or other country, since his or her last renewal. Traffic infractions not involving alcohol, dangerous drugs, or controlled substances do not need to be disclosed.

(c) As a condition of renewal, a pharmacist applicant shall disclose on the renewal form any disciplinary action against any license issued to the applicant by a government agency. For the purposes of this section, “disciplinary action” means an adverse licensure or certification action that resulted in a restriction or penalty being placed on the license, such as revocation, suspension, probation or public reprimand or reproval.

(d) As a condition of renewal, a pharmacist applicant shall disclose whether he or she has complied with any continuing education requirements to renew his or her pharmacist or advanced pharmacist license as required by section 1732.2.

(e) Failure to provide all of the information required by this section renders an application for renewal incomplete and the board shall not renew the license and shall issue the applicant an inactive pharmacist license. An inactive pharmacist license issued pursuant to this section may only be reactivated after compliance is confirmed for all licensure renewal requirements.

Note: Authority cited: Sections 4001.1 and 4005, Business and Professions Code. Reference: Sections 141, 490, 4036, 4200.5, 4207, 4231, 4300, 4301, 4301.5, 4311 and 4400, Business and Professions Code; and Sections 11105(b)(10) and 11105(e), Penal Code.

Amend section 1702.1 in Article 1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1702.1. ~~Pharmacy Technician~~ Renewal Requirements for Individual Licensees Other Than Pharmacists.

This section applies to the renewal of any license held by an individual other than a license as a pharmacist or an advanced practice pharmacist.

(a) An individual licensee ~~pharmacy technician~~ applying ~~icant~~ for renewal who has not previously submitted fingerprints as a condition of licensure or for whom an electronic record of the licensee's fingerprints does not exist in the Department of Justice's criminal offender record identification database shall successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice by the licensee's or registrant's renewal date that occurs on or after January 1, 2018.

(1) The individual ~~A pharmacy technician~~ shall retain for at least three years as evidence of having complied with subdivision (a) either a receipt showing that he or she has electronically transmitted his or her fingerprint images to the Department of Justice or, for those who did not use an electronic fingerprinting system, a receipt evidencing that his or her fingerprints were recorded and submitted to the board.

(2) The individual ~~A pharmacy technician~~ applicant for renewal shall pay the actual cost of compliance with subdivision (a).

(3) As a condition of petitioning the board for reinstatement of a revoked or surrendered license an applicant shall comply with subdivision (a).

(4) The board may waive the requirements of this section for licensees who are actively serving in the United States military. The board may not return a license to active status until the licensee has complied with subdivision (a).

(b) As a condition of renewal, ~~a pharmacy technician applicant~~ the individual shall disclose on the renewal form whether he or she has been convicted, as defined in Section 490 of the Business and Professions Code, of any violation of the law in this or any other state, the United States, or other country, since his or her last renewal. Traffic infractions not involving alcohol, dangerous drugs, or controlled substances do not need to be disclosed.

(c) As a condition of renewal, ~~a pharmacy technician applicant~~ the individual shall disclose on the renewal form any disciplinary action against any license issued to the applicant by a government agency. For the purposes of this section, “disciplinary action” means an adverse licensure or certification action that resulted in a restriction or penalty against the license or certification such as revocation, suspension, probation or public reprimand or reproval.

(d) Failure to provide all of the information required by this section renders an application for renewal incomplete and the board shall not renew the license until the licensee demonstrates compliance with all requirements.

Note: Authority cited: Sections 4001.1 and 4005, Business and Professions Code. Reference: Sections 141, 490, 4022.5, 4022.6, 4022.7, 4038, 4115, 4202, 4207, 4300, 4301 and 4400, Business and Professions Code; and Sections 11105(b)(10) and 11105(e), Penal Code.

Repeal section 1702.2 in Article 1 of Division 17 of Title 16 of the California Code of Regulations.

~~1702.2. Designated Representative Renewal Requirements.~~

~~(a) A designated representative applicant for renewal who has not previously submitted fingerprints as a condition of licensure or for whom an electronic record of the licensee's fingerprints does not exist in the Department of Justice's criminal offender record identification database shall successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice by the licensee's or registrant's renewal date that occurs on or after January 1, 2018.~~

~~(1) A designated representative shall retain for at least three years as evidence of having complied with subdivision (a) either a receipt showing that he or she has electronically transmitted his or her fingerprint images to the Department of Justice or, for those who did not use an electronic fingerprinting system, a receipt evidencing that his or her fingerprints were recorded and submitted to the board.~~

~~(2) A designated representative applicant for renewal shall pay the actual cost of compliance with subdivision (a).~~

~~(3) As a condition of petitioning the board for reinstatement of a revoked or surrendered license an applicant shall comply with subdivision (a).~~

~~(4) The board may waive the requirements of this section for licensees who are actively serving in the United States military. The board may not return a license to active status until the licensee has complied with subdivision (a).~~

~~(b) As a condition of renewal, a designated representative applicant shall disclose on the renewal form whether he or she has been convicted, as defined in Section 490 of the Business and Professions Code, of any violation of the law in this or any other state, the United States, or other country, since his or her last renewal. Traffic infractions not involving alcohol, dangerous drugs, or controlled substances do not need to be disclosed.~~

~~(c) As a condition of renewal, a designated representative applicant shall disclose on the renewal form any disciplinary action against any license issued to the applicant by a government agency. For the purposes of this section, "disciplinary action" means an adverse licensure or certification action that resulted in a restriction or penalty against the license or certification such as revocation, suspension, probation or public reprimand or reproval.~~

~~(d) Failure to provide all of the information required by this section renders an application for renewal incomplete and the board shall not renew the license until the licensee demonstrates compliance with all requirements.~~

~~Note: Authority cited: Sections 4001.1 and 4005, Business and Professions Code. Reference: Sections 141, 490, 4022.5, 4022.7, 4053, 4207, 4300, 4301 and 4400, Business and Professions Code; and Sections 11105(b)(10) and 11105(e), Penal Code.~~

Offsite Storage
16 CCR § 1707

Title 16. Board of Pharmacy
Modified Text

Proposed changes to the current regulation language are shown by strikethrough for deleted language and underline for added language.

Proposed changes to the initial proposed text are shown by double underline for added language.

Proposal to Amend § 1707 in Article 2 of Division 17 of Title 16 of the California Code of Regulations to read:

§ 1707. Waiver Requirements for Off-Site Storage of Records

(a) Pursuant to subdivision (e) of Section 4105 of the Business and Professions Code and subdivision (c) of Section 4333 of the Business and Professions Code, a waiver ~~shall~~ may, on a case-by-case basis, be granted to any entity licensed by the board for ~~off-site~~ storage of the records outside the licensed area of the pharmacy described in subdivisions (a), (b) and (c) of Section 4105 of the Business and Professions Code ~~unless the applicant has, within the preceding five years, failed to produce records pursuant to Section 4081 of the Business and Professions Code or has falsified records covered by Section 4081 of the Business and Professions Code~~. The board may consider space limitations within the pharmacy, cost, previous compliance with records requirements, ease of access to records stored outside of the licensed area, and any other factor presented by the licensee in making its determination.

(b) An entity that is granted a waiver pursuant to subdivision (a) shall:
   (1) maintain the storage area so that the records are secure, including from unauthorized access; and
   (2) be able to produce the records within two business days upon the request of the board or an authorized officer of the law.

(c) In the event that a licensee fails to comply with the conditions set forth in subdivision (b), the board may cancel the waiver without a hearing. Upon notification by the board of cancellation of the waiver, the licensee shall maintain all records at the licensed premises.

(d) A licensee whose waiver has been cancelled pursuant to the provisions set forth in subsection (c) may reapply to the board when compliance with the conditions set forth in subsection (b) can be confirmed by the board.

(e) Notwithstanding any waiver granted pursuant to subdivision (a), all prescription records for non controlled substances shall be maintained on the licensed premises for a period of one year from the date of dispensing.

(f) Notwithstanding any waiver granted pursuant to subdivision (a), all prescription records for controlled substances shall be maintained on the licensed premises for a period of two years from the date of dispensing.

(g) Notwithstanding the requirements of this section, any entity licensed by the board may store the records described in subdivisions (a), (b) and (c) of Section 4105 of the Business and Professions Code in a storage area at the same address or adjoining the licensed premises without obtaining a waiver from the board if the following conditions are met:
   (1) The records are readily accessible to the pharmacist-in-charge (or other pharmacist on duty, or designated representative) and upon request to the board or any authorized officer of the law.
   (2) The storage area is maintained so that the records are secure and so that the confidentiality of any patient-related information is maintained.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4081, 4105 and 4333, Business and Professions Code.

Attachment 6

Regulation Timelines

IX. Discussion and Consideration of Board Approved Regulations Undergoing Public Comment

a. Proposed Regulations to Amend Title 16 CCR Sections 1780-1783 et seq., Related to Dangerous Drug Distributors and Third-Party Logistics Providers

Timeline:
Approved by board: October 26, 2016
Submitted to DCA for Pre-Notice Review: February 9, 2017
Returned to the board on: February 28, 2017
Re-submitted to DCA for Pre-Notice Review: October 25, 2017
Returned to the board on: March 26, 2018
Re-submitted to DCA for Pre-Notice Review: June 28, 2018
Returned to the board on: August 28, 2018
Re-submitted to DCA for Pre-Notice Review: September 6, 2018
Returned to the board on: October 30, 2018
Re-submitted to DCA for Pre-Notice Review: December 20, 2018
Under review by DCA Budget Office: December 13, 2019
Submitted to DCA for Formal Review: December 13, 2019
45-Day Comment Period: May 29, 2020 to July 13, 2020

b. Proposed Regulation to Amend Title 16 CCR Section 1711 Related to Quality Assurance Programs for ADDS, Section 1713 Related to Use of an APDS, and Add Section 1715.1 Related to the ADDS Self-Assessment Forms 17M-112

Timeline:
Approved by Board: January 30, 2019
Submitted to DCA for Pre-Notice Review: April 30, 2019
Under review by DCA Budget Office: December 31, 2019
Submitted to DCA for Formal Review: December 23, 2019
45-Day Comment Period: July 3, 2020 to August 17, 2020

Third-Party Logistics Providers and Dangerous Drug Distributors
16 CCR §§ 1780-1783

Title 16. Board of Pharmacy

Proposed Language

To Amend Article 10 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

Article 10. ~~Wholesalers~~ Dangerous Drug Distributors

To Amend Section 1780 of Article 10 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1780. Minimum Standards for Wholesalers and Third-Party Logistics Providers.
The following minimum standards shall apply to all wholesale and third-party logistics provider establishments for which permits have been issued by the Board:

(a) A wholesaler and a third-party logistics provider shall store dangerous drugs in a secured and lockable area.

(b) All wholesaler and third-party logistics provider premises, fixtures and equipment therein shall be maintained in a clean and orderly condition. Wholesale and third-party logistics provider premises shall be well ventilated, free from rodents and insects, and adequately lighted. Plumbing shall be in good repair. Temperature and humidity monitoring shall be conducted to assure compliance with the standards set forth in the latest edition of the United States Pharmacopeia ~~Standards (1990, 22nd Revision)~~.

(c) Entry into areas where prescription drugs are held shall be limited to authorized personnel.
  (1) All facilities shall be equipped with an alarm system to detect entry after hours.
  (2) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.
  (3) The outside perimeter of the ~~wholesaler~~ premises shall be well-lighted.

(d) All materials must be examined upon receipt and ~~or~~ before shipment.
  (1) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.
  (2) Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.

(e) The following procedures must be followed for handling returned, damaged and outdated prescription drugs.
  (1) Prescription drugs that are outdated, damaged, deteriorated, misbranded or adulterated shall be placed in a quarantine area and physically separated from other drugs until they are destroyed or returned to their supplier.
  (2) Any prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be placed in a quarantine area and physically separated from other prescription drugs until they are either destroyed or returned to the supplier.

(3) If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality or purity, the drug shall be destroyed or returned to the supplier unless testing or other investigation proves that the drug meets the standards set forth in the latest edition of the ~~appropriate~~ United States Pharmacopeia ~~Standards (1990, 22nd Revision)~~.

(f) Policies and procedures must be written and made available upon request by the board.

(1) Each ~~W~~ wholesaler and third-party logistics provider ~~drug distributors~~ shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, for correcting all errors and inaccuracies in inventories, and for maintaining records to document proper storage.

(2) The records required by paragraph (1) shall be in accordance with Title 21, Code of Federal Regulations, Section 205.50(g). These records shall be maintained for three years after disposition of the drugs.

(3) Each ~~W~~ wholesaler and third-party logistics provider ~~drug distributors~~ shall establish and maintain lists of officers, directors, managers and other persons in charge of ~~wholesale~~ drug distribution, storage and handling, including a description of their duties and a summary of their qualifications.

(4) Each wholesaler and third-party logistics provider shall provide adequate training and experience to assure compliance with licensing requirements by all personnel.

(g) The board shall require an applicant for a licensed premise or for renewal of that license to certify that it meets the requirements of this section at the time of licensure or renewal.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4025, 4043, 4045, 4051, 4053, 4053.1, 4054, 4059, 4120, 4160, 4161, 4161.5 ~~and~~ 4304, and 4342 of the Business and Professions Code; Sections 109985 and 111280 of the Health and Safety Code; Section 321 of Title 21, U.S. Code; and Section 205.50 of Title 21, Code of Federal Regulations.

To Amend Section 1781 of Article 10 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1781. ~~Exemption Certificate~~ Pharmacist or Designated Representative on Premises and In Control.

(a) A registered pharmacist, or a designated representative certified in accordance with Section 4053 ~~or 4054~~ of the Business and Professions Code, shall be present and in control of a manufacturer's, or wholesaler's licensed premises during the conduct of business.

(b) A designated representative – 3PL certified in accordance with Section 4053.1 of the Business and Professions Code, shall be present and in control of a third-party logistics provider's licensed premises during the conduct of business.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4022.5, 4022.7, 4053, 4053.1, 4160, and 4161 ~~4054~~, Business and Professions Code.

To Amend Section 1782 of Article 10 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1782. Reporting Sales of Drugs Subject to Abuse.

~~All~~ Each manufacturer~~s~~, ~~and~~ wholesaler~~s~~, and third-party logistics provider shall report to the Board or its designee, up to twelve (12) times a year, all sales of dangerous drugs subject to abuse as designated by the Board for reporting, in excess of amounts to be determined by the Board from time to time. Reports shall be made within thirty (30) days of the request in the form specified by the Board.

Note: Authority cited: Section 4005, Business and Professions Code~~; and Section 26692, Health and Safety Code~~. Reference: Sections 4053.1, 4081, 4164, 4165, and 4332, Business and Professions Code~~; and Section 26692, Health and Safety Code~~.

To Amend Section 1786 of Article 10 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1783. Manufacturer, ~~or~~ Wholesaler, or Third-Party Logistics Provider Furnishing Drugs and Devices.

(a) A manufacturer, ~~or~~ wholesaler, or third-party logistics provider shall furnish dangerous drugs or devices only to an authorized person; prior to furnishing dangerous drugs and devices to a person not known to the furnisher, the manufacturer, ~~or~~ wholesaler, or third-party logistics provider shall contact the board or, if the person is licensed or registered by another government entity, that entity, to confirm the recipient is an authorized person.

(b) "Authorized person" means a person to whom the board has issued a permit which enables the permit holder to purchase dangerous drugs or devices for use within the scope of its permit. "Authorized person" also means any person in this state or in another jurisdiction within the United States to the extent such furnishing is authorized by the law of this state, any applicable federal law, and the law of the jurisdiction in which that person is located. The manufacturer, ~~or~~ wholesaler, or third-party logistics provider furnishing to such person shall, prior to furnishing the dangerous drugs and devices, establish the intended recipient is legally authorized to receive the dangerous drugs or devices.

(c) Dangerous drugs or devices furnished by a manufacturer, ~~or~~ wholesaler, or third-party logistics provider shall be delivered only to the premises listed on the permit; provided that a manufacturer, ~~or~~ wholesaler, or third-party logistics provider may furnish drugs to an authorized person or an agent of that person at the premises of the manufacturer, ~~or~~ wholesaler, or third-party logistics provider if (1) the identity and authorization of the recipient is properly established and (2) this method of receipt is employed only to meet the immediate needs of a particular patient of the authorized person. Dangerous drugs or devices may be furnished to a hospital pharmacy receiving area provided that a pharmacist or authorized receiving personnel signs, at the time of delivery, a receipt showing the type and quantity of the dangerous drugs or devices so received. Any discrepancy between the receipt and the type and quantity of dangerous drugs and devices actually received shall be reported to the delivering manufacturer, ~~or~~ wholesaler, or third-party logistics provider by the next business day after the delivery to the pharmacy receiving area.

(d) A manufacturer, ~~or~~ wholesaler, or third-party logistics provider shall not accept payment for or allow the use of an entity's credit to establish an account for the purchase of dangerous

drugs or devices from any person other than: (1) the owner(s) of record, chief executive officer, or chief financial officer listed on the p~~m~~ermit for the authorized person; and (2) on an account bearing the name of the permittee.

(e) All records of dangerous drugs or devices furnished by a manufacturer, ~~or~~ wholesaler, or third-party logistics provider to an authorized person shall be preserved by the authorized person for at least three years from the date of making and shall, at all times during business hours, be open to inspection by authorized officers of the law at the licensed premises. The manufacturer, ~~or~~ wholesaler, or third-party logistics provider shall also maintain all records of dangerous drugs or devices furnished pursuant to this section for at least three years from the date of making and shall, at all times during business hours, keep them open to inspection by authorized officers of the law at the premises from which the dangerous drugs or devices were furnished.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4025, 4043, 4053.1, 4059, 4059.5, 4080, 4081, 4105, 4120, 4160, 4161, 4163, 4165 and 4304, Business and Professions Code; and Section 11209, Health and Safety Code.

Automated Drug Delivery Systems (ADDS) 16 CCR §§ 1711, 1713, and 1715.1

Title 16. Board of Pharmacy
Proposed DRAFT Regulation

Proposal to amend §17## of Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 17##. Self-Assessment of an Automated Drug Delivery System by Pharmacist-in-Charge.

(a) The pharmacist-in-charge of each automated drug delivery system as defined under section 4119.11, 4187.5 or section 4427.3 of the Business and Professions Code shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. The assessment shall be performed annually before July 1 of every year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

(b) In addition to the self-assessment required in subdivision (a) of this section, the pharmacist-in-charge shall complete a self-assessment within 30 days whenever:

(1) A new automated drug delivery system permit has been issued, or

(2) There is a change in the pharmacist-in-charge, and he or she becomes the new pharmacist-in-charge of an automated drug delivery system, or

(3) There is a change in the licensed location of an automated drug delivery system to a new address.

(c) A pharmacist-in-charge of an automated drug delivery system shall assess the system's compliance with current laws and regulations by using the components of Form ##X-## (Rev 12/18) entitled "Automated Drug Delivery System Self-Assessment". Form ##X-## shall be used for all automated drug delivery systems and is hereby incorporated by reference.

(1) The pharmacist-in-charge shall provide identifying information about the underlying operating pharmacy including:

(A) Name and any license number(s) of the underlying pharmacy and their expiration date(s);

(B) Address, phone number, and website address, if applicable, of the underlying pharmacy;

(C) DEA registration number, expiration date and date of most recent DEA inventory;

(D) Hours of operation of the pharmacy; and

(3) The pharmacist-in-charge shall respond “yes”, “no” or “not applicable” (N/A) about whether the automated drug delivery system is, at the time of the self-assessment, in compliance with laws and regulations that apply to that pharmacy setting.

(4) For each “no” response, the pharmacist-in-charge shall provide a written corrective action or action plan to come into compliance with the law.

(5) The pharmacist-in-charge shall initial each page of the self-assessment with original handwritten initials in ink on the self-assessment form.

(6) The pharmacist-in-charge shall certify on the last page of the self-assessment that he or she has completed the self-assessment of the automated drug delivery system of which he or she is the pharmacist-in-charge. The pharmacist-in-charge shall also certify a timeframe within which any deficiency identified within the self-assessment will be corrected and acknowledge that all responses are subject to verification by the Board of Pharmacy. The certification shall be made under penalty of perjury of the laws of the State of California that the information provided in the self-assessment form is true and correct with an original handwritten signature in ink on the self-assessment form.

(7) The automated drug delivery system owner shall certify on the final page of the self-assessment that he or she has read and reviewed the completed self-assessment and acknowledges that failure to correct any deficiency identified in the self-assessment could result in the revocation of the automated dispensing system’s license issued by the board. This certification shall be made under penalty of perjury of the laws of the State of California with an original handwritten signature in ink on the self-assessment form.

(d) Each self-assessment shall be completed in its entirety and kept on file in the underlying pharmacy for three years after it is performed.

(e) Any identified areas of noncompliance shall be corrected as specified in the assessment. An automated drug delivery system shall correct any non-compliance as specified in the assessment.

Note: Authority cited: Sections 4119.11 and 4427.7, Business and Professions Code. Reference: Sections 4001.1, 4008, 4017.3, 4021, 4022, 4036, 4037, 4038, 4040, 4050, 4051, 4052, 4059, 4070, 4076, 4081, 4101, 4105, 4107, 4113, 4119.1, 4125, 4126, 4180, 4186, 4305, 4330, 4332, 4333, and 4333, 4400, 4427, 4427.1, 4427.2 4427.3, 4427.4, and 4427.5 Business and Professions Code.

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

AUTOMATED DRUG DELIVERY SYSTEM SELF-ASSESSMENT

Business and Professions Code (BPC) section 4427.7(a) requires the pharmacy holding an automated drug delivery system (ADDS) license complete an annual self-assessment, performed pursuant to section 1715.1 of Title 16 of the California Code of Regulations, evaluating the pharmacy's compliance with pharmacy law relating to the use of the ADDS. The assessment shall be performed annually **before July 1 of every year** by the pharmacist-in-charge of each pharmacy under section 4029 (Hospital Pharmacy) or section 4037 (Pharmacy). The pharmacist-in-charge must also complete a self-assessment within 30 days whenever; (1) a new automated drug delivery system permit has been issued, or (2) there is a change in the pharmacist-in-charge and becomes the new pharmacist-in-charge of an automated drug delivery system, or (3) there is a change in the licensed location of an automated drug delivery system to a new address. The primary purpose of the self-assessment is to promote compliance through self-examination and education. All information regarding operation, maintenance, compliance, error, omissions, or complaints pertaining to the ADDS shall be included in the Self-Assessment.

All references to Business and Professions Code (BPC) are to Chapter 9, Division 2; California Code of Regulations (CCR) are to Title 16; and Code of Federal Regulations (21 CFR) to Title 21 unless otherwise noted.

The self-assessment must be completed and retained in the pharmacy for three (3) years after performed.

Please mark the appropriate box for each item. If "NO", enter an explanation and timeframe when the deficiency will be completed on the "CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE" lines at the end of the section. If more space is needed, you may add additional sheets.

Pharmacy Name: _____
Address: _____
City: _____
Phone: _____
Fax number: _____
Website: _____
Pharmacy License #: _____
Expiration Date: _____
DEA Registration #: _____
DEA Expiration Date: _____
DEA Inventory Date: _____
Last C2 Inventory Reconciliation Date (CCR 1715.65(c)): _____
Pharmacy Hours: M-F: _____ **Saturday**_____ **Sunday**_____

PIC: _____**RPH#**_____
ADDS License #: _____
ADDS Expiration Date:_____
ADDS Address: _____
City: _____
ADDS Hours: **M-F:** _____**Saturday**_____ **Sunday**_____
Please explain if the ADDS hours are different than the pharmacy:
_____

FOR ALL TYPES OF ADDS: COMPLETE SECTIONS 1, 2 AND 3

SECTION 1: DEFINITIONS/TYPE OF ADDS DEVICE USED

An **ADDS – "Automated drug delivery system**," a mechanical system that performs operations or activities other than compounding or administration, relative to storage, dispensing, or distribution of drugs. An ADDS, shall collect, control and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability. [BPC 4119.11(b)(1), 4017.3(a)]

IDENTIFY THE TYPE OF ADDS DEVICE USED

Yes No N/A

☐☐☐ 1.1. The pharmacy uses an **APDS – "Automated PATIENT dispensing system**," an ADDS for storage and dispensing of prescribed drugs directly to the patients pursuant to prior authorization by a pharmacist. [BPC 4119.11(b)(2), 4017.3(c)]

☐☐☐ 1.2 The pharmacy uses an **AUDS – "Automated UNIT DOSE system**," an ADDS for the storage and retrieval of unit dose drugs for administration to patient by persons authorized to perform these functions. [BPC 4119.11(b)(3), 4017.3(b)]

SECTION 2: LOCATION OF DEVICES

Yes No N/A

☐☐☐ 2.1 Provides pharmacy services to the patient of **covered entities**, as defined, that are eligible for discount drug programs under federal law as specified through the use of an APDS as defined. The APDS need not be at the same location as the underlying operating pharmacy if all the specific conditions are met. "Covered entity" as defined by Section 256b of Title 42 of United Sates Code. [BPC 4119.11(a)-(a)(11)]

☐☐☐ 2.2 Provides pharmacy services through an ADDS **adjacent to the secured pharmacy area** of the pharmacy holding the ADDS license. [BPC 4427.3(b)(1)]

☐☐☐ 2.3 Provides pharmacy services through an ADDS in **a health facility** licensed pursuant to Section 1250 of the Health and Safety Code (Long Term Care (LTC)) that complies with Section 1261.6 of the Health and Safety Code. [BPC 4427.3(b)(2)]

Yes No N/A

☐☐☐ 2.4 Provides pharmacy services through **a clinic** licensed pursuant to Section 1204 or 1204.1 of the Health and Safety Code, or Section 4180 or 4190 of Business and Professions Code. [BPC 4427.3(b)3)]

☐☐☐ 2.5 Provides pharmacy services through a **correctional clinic**. [BPC 4187.1, 4427.3(b)(4)]

☐☐☐ 2.6 Provides pharmacy services through a **medical office**. [BPC 4427.3(b)(5), 4427.6(j)]

☐☐☐ 2.7 **AUDS operated by a licensed hospital pharmacy**, as defined in Section 4029, and is used solely to provide doses administered to patients while in a licensed general acute care hospital facility or a licensed acute psychiatric hospital facility, as defined in subdivision (a) and (b) of Section 1250 of the Health and Safety Code, shall be exempt from the requirement of obtaining an ADDS license, if the licensed hospital pharmacy owns or leases the AUDS and owns the dangerous drugs and dangerous devices in the AUDS. The AUDS shall comply with all other requirements for an ADDS in Article 25. The licensed hospital pharmacy shall maintain a list of the locations of each AUDS it operates and shall make the list available to the board upon request. [BPC4427.2(i)]

Note: An ADDS license is not required for technology, installed **within the secured licensed premises area of a pharmacy,** used in the selecting, counting, packaging, and labeling of dangerous drugs and dangerous devices. [BPC 4427.2(j)]

SECTION 3: GENERAL REQUIREMENTS FOR ALL TYPES OF ADDS

(Answer N/A if licensure not required)

Yes No N/A

☐☐☐ 3.1 The ADDS is installed, leased, owned, or operated in California and is licensed by the board. [BPC 4427.2(a), 4427.4(a)]

☐☐☐ 3.2 The ADDS license was issued to a holder of a current, valid, and active pharmacy license of a pharmacy located and licensed in California. [BPC 4427.2(b)]

☐☐☐ 3.3 Each ADDS has a separate license. [BPC 4427.2(c)]

☐☐☐ 3.4 The licensed ADDS meets the following conditions: [BPC 4427.2(d)]

- Use of the ADDS is consistent with legal requirements.
- The proposed location for installation of the ADDS met the requirements of Section 4427.3 and the ADDS is secure from access and removal by unauthorized individuals.
- The pharmacy's policies and procedures related to the ADDS include appropriate security measures and monitoring of the inventory to prevent theft and diversion.
- The pharmacy's policy and procedures included provisions for reporting to the board drug losses from the ADDS inventory, as required by law.

Yes No N/A

☐☐☐ 3.5 A prelicensure inspection was conducted within 30 days of a completed application for the ADDS license at the proposed location(s). [BPC 4427.2(e)]
List date(s) of pre-license inspection(s):

_____
_____
_____

☐☐☐ 3.6 The pharmacy is aware a relocation of an ADDS shall require a new application for licensure. [BPC 4427.2(e)]

☐☐☐ 3.7. The pharmacy is aware a replacement of an ADDS shall require notification to the board within 30 days. [BPC 4427.2(e)]

☐☐☐ 3.8 The pharmacy is aware the ADDS license will be canceled by operation of law if the underlying pharmacy license is not current, valid, and active. Upon reissuance or reinstatement of the underlying pharmacy license, a new application for an ADDS license is submitted to the board. [BPC 4427.2(f)]

☐☐☐ 3.9 The pharmacy is aware the holder of an ADDS license will advise the board in writing within 30 days if use of an ADDS is discontinued. [BPC 4427.2(g)]

☐☐☐ 3.10 The ADDS license(s) was/were renewed annually, and the renewal date is the same as the underlying pharmacy license. [BPC 4427.2(h)]

☐☐☐ 3.11 The ADDS is placed and operated inside an enclosed building, with a premises address, at a location approved by the board. [BPC 4427.3(a)]

☐☐☐ 3.12 Prior to installation, the pharmacy holding the ADDS license and the location where the ADDS is placed pursuant to subdivision (b) of Business and Professions Code section 4427.3, jointly developed and implemented written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the ADDS, as well as quality, potency, and purity of the drugs and devices. The policies and procedures are maintained at the location of the ADDS and at the pharmacy holding the ADDS license. [BPC 4427.3(c)]

☐☐☐ 3.13 Each ADDS is operated under the supervision of the pharmacy holding the ADDS license. [BPC 4427.4(b)]

☐☐☐ 3.14 The ADDS is considered an extension and part of the pharmacy holding the ADDS license, regardless of the ADDS location, and is subject to inspection pursuant to BPC 4008. [BPC 4427.4(c)]

Yes No N/A

☐☐☐ 3.15 Drugs and devices stored in an ADDS will be deemed part of the inventory and the responsibility of the pharmacy holding the ADDS license, and the drugs and devices dispensed from the ADDS shall be considered to have been dispensed by the pharmacy. [BPC 4427.4(d)]

☐☐☐ 3.16 The stocking and restocking of an ADDS is performed by a pharmacist, or by a pharmacy technician or intern pharmacist under the supervision of a pharmacist, except for an ADDS located in a health facility pursuant to HSC 1250, where the stocking and restocking of the ADDS may be performed in compliance with HSC 1261.6. [BPC 4427.4(e)(1)]

☐☐☐ 3.17 Access to the ADDS is controlled and tracked using an identification or password system or biosensor. [BPC 4427.4(e)(2)]

☐☐☐ 3.18 The ADDS makes a complete and accurate record of all transactions including all users accessing the system and all drugs added to, or removed from, the system. [BPC 4427.4(e)(3)]

☐☐☐ 3.19 Are drugs or devices not immediately transferred into an ADDS upon arrival at the ADDS location, stored for no longer than 48 hours in a secured room within the ADDS location approved by the board under Section 4427.3 and upon retrieval of the dangerous drugs and devices from the secured storage is an inventory taken to detect any losses or overages? [BPC 4427.4(f)]

☐☐☐ 3.20 Prior to installation, and annually thereafter, the pharmacy holding the ADDS license provides training on the operation and use of the ADDS to the pharmacy personnel and to personnel using the ADDS at the location where the ADDS is placed pursuant to BPC 4427.3(b). [BPC 4427.5]

☐☐☐ 3.21 The pharmacy complies with all recordkeeping and quality assurance requirements established in pharmacy law and regulations, and maintains records within the licensed pharmacy holding the ADDS license and separate from other pharmacy records. [BPC 4427.7(b)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

_____
_____
_____
_____
_____
_____
_____

CHECK OFF THE TYPE OF ADDS USED BY THE PHARMACY AND COMPLETE THE FOLLOWING SECTION(S) AS IT APPLIES TO THE TYPE OF ADDS THE PHARMACY IS USING.

Please Note: The Pharmacist-in-Charge of the pharmacy and the owner of the ADDS shall sign the Certification Acknowledgment on page 33 after completing the assessment.

- ☐ SECTION 4 – APDS used to provide pharmacy service to covered entities and medical professionals contracted with a covered entity.
- ☐ SECTION 5 – ADDS adjacent to the secured pharmacy area and Medical Offices.
- ☐ SECTION 6 – ADDS in a health facility pursuant to HSC 1250 (LTC).
- ☐ SECTION 7 – APDS through a clinic pursuant to HSC 1204 or 1204.1 or BPC 4180 or 4190.
- ☐ SECTION 8 – ADDS operated by a correctional clinic.

SECTION 4: APDS USED TO PROVIDE PHARMACY SERVICES TO COVERED ENTITIES AND MEDICAL PROFESSIONALS CONTRACTED WITH A COVERED ENTITY

A. GENERAL REQUIREMENTS

Yes No N/A

☐☐☐ 4.1 Covered Entity May Contract with Pharmacy to Provide Services- The operating pharmacy providing pharmacy services to the patients of the covered entity, including, unless prohibited by any other law, patients enrolled in the Medi-Cal program, shall be under contract with the covered entity as described in BPC Section 4126 to provide those pharmacy services through the use of the APDS. [BPC 4119.11(a)(2)]

☐☐☐ 4.2 Contracts between the covered entities and the pharmacy shall comply with the guidelines published by the Health Resources and Services Administration and are available for inspection by Board during normal business hours. [BPC 4126(a)]

☐☐☐ 4.3 Drugs purchased and received pursuant to Section 256b of Title 42 USC shall be segregated from the pharmacy's other drug stock by physical or electronic means. [BPC 4126(b)]

☐☐☐ 4.4 All records of acquisition and disposition of these drugs shall be readily retrievable in a form separate from the pharmacy's other records. [BPC 4126(b)]

☐☐☐ 4.5 The drugs shall be returned to the distributor from which the drugs were obtained if drugs to be dispensed to patient of a covered entity pursuant to section 256b of Title 42USC cannot be distributed because of a change in circumstances of the covered entity or the pharmacy. [BPC 4126(c)]

☐☐☐ 4.6 A licensee that participates in a contract to dispense preferentially priced drugs pursuant to this section shall not have both a pharmacy and a wholesaler license. [BPC 4126(d)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

_____

_____

_____

_____

B. UNDERLYING OPERATING PHARMACY

Yes No N/A

☐☐☐ 4.7 The operating pharmacy has obtained a license from the Board to operate the APDS which includes the address of the APDS location and the identity of the covered entity or affiliated site. [BPC 4119.11(a)(1)]

☐☐☐ 4.8 A separate license was obtained for each APDS location and has been renewed annually concurrent with the pharmacy license. (Note: The Board may issue a license for operation of an APDS at an address for which the Board has issued another site license.) [BPC 4119.11(a)(1), 4119.11(a)(8), 4107]

☐☐☐ 4.9 A prelicensure inspection of the proposed APDS location was conducted by the Board within 30 days after Board receipt of the APDS application before Board approval. [BPC 4119.11(a)(9)]

Date of Inspection: _____

☐☐☐ 4.10 The pharmacy will submit a new APDS licensure application for Board approval if the current APDS is relocated. [BPC 4119.11(a)(9)]

☐☐☐ 4.11 The pharmacy will notify the Board within 30 days of replacement of an APDS or discontinuing an APDS. [BPC 4119.11(a)(9), 4119.11(a)(11)]

☐☐☐ 4.12 A new APDS licensure application will be submitted if original APDS is cancelled due to the underlying operating pharmacy's permit being cancelled, not current, not valid, or inactive. (Once cancelled, a new APDS license can only be issued if the underlying pharmacy's permit is reissued or reinstated.) [BPC 4119.11(a)(10)]

☐☐☐ 4.13 The pharmacy does not have more than 15 APDS licenses for one underlying operating pharmacy under this section. [BPC 4119.11(d)(10)] List of current APDS licenses:

1._____ 2. _____

3._____ 4. _____

5._____6. _____

7._____8. _____

9._____10._____

11. _____ 12._____

13._____14. _____

15. _____

Yes No N/A

☐☐☐ 4.14 The operating pharmacy will maintain the written APDS policies and procedures for 3 years after the last date of use for that APDS. [BPC 4119.11(d)(11)]

☐☐☐ 4.15 The operating pharmacy of an APDS has completed an annual Self-Assessment pursuant to CCR 1715 or BPC 4427.7(a) evaluating the pharmacy's compliance with pharmacy law relating to the use of the APDS. [BPC 4119.11(i)]

Date of Last Self-Assessment: _____

☐☐☐ 4.16 The operating pharmacy has complied with all recordkeeping and quality assurance requirements pursuant to BPC 4119.11 and those records will be maintain within the pharmacy holding the APDS and separately from the other pharmacy records. [BPC 4119.11(j)]

☐☐☐ 4.17 The pharmacy is aware that the drugs stored in an APDS are a part of the operating pharmacy's drug inventory and the drugs dispensed by the APDS shall be considered to have been dispensed by that pharmacy. [BPC 4119.11(a)(3)]

☐☐☐ 4.18 The underlying operating pharmacy is solely responsible for:

- The security of the APDS. [BPC 4119.11(a)(5)]
- The operation of the APDS. [BPC 4119.11(a)(5)]
- The maintenance of the APDS. [BPC 4119.11(a)(5)]
- The training regarding the operation and use of the APDS for both the pharmacy and covered entity personnel using system. [BPC 4119.11(a)(6)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

_____

_____

_____

_____

C. PHARMACIST RESPONSIBILITIES

Yes No N/A

☐☐☐ 4.19 The operation of the APDS is under the supervision of a licensed pharmacist acting on behalf of the operating pharmacy. [BPC 4119.11(a)(7)]. Note: The pharmacist need not be physically present at the site of the APDS and may supervise the system electronically.

☐☐☐ 4.20 The pharmacist performs the stocking of the APDS or if the APDS utilizes removable pockets, cards, drawers, similar technology, or unit of use or single dose containers are used, the stocking of the APDS may be done outside of the facility if the following conditions are met: [BPC 4119.11(g)]

☐☐☐ 4.20.1 A pharmacist, intern pharmacist or pharmacy technician working under the supervision of the pharmacist may place drugs into the removeable pockets, cards, drawers, similar technology, or unit of use or single dose containers. [BPC 4119.11(g)(1)]

☐☐☐ 4.20.2 Transportation of removeable pockets, cards, drawers or similar technology or unit of use or single dose container between the pharmacy and the facility are in a tamper-evident container. [BPC 4119.11(g)(2]

☐☐☐ 4.20.3 There are policies and procedures to ensure the removeable pockets, cards, drawers, similar technology, or unit of use or single dose containers are properly placed into the APDS. [BPC 4119.11(g)(3)]

☐☐☐ 4.21 The pharmacist conducts a monthly review of the APDS including a physical inspection of the drugs contained within, operation, maintenance, and cleanliness of the APDS, and a review of all transaction records in order to verify the security and accountability of the APDS. [BPC 4119.11(h)]

Date of Last Review: _____

☐☐☐ 4.22 The Pharmacist-in-charge of the offsite ADDS/APDS has ensured the following: [CCR 1715.65(h)]

- All controlled substances added to the ADDS/APDS are accounted for;
- Access to ADDS/APDS is limited to authorized facility personnel;
- An ongoing evaluation of discrepancies or unusual access associated with controlled substance is performed; and
- Confirmed losses of controlled substances are reported to the Board.

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

_____

_____

_____

_____

D. DEVICE REQUIREMENTS

Yes No N/A

☐☐☐ 4.23 Access to the APDS is controlled and tracked using an identification or password system or biosensor. Systems tracked via password shall include a camera that records a picture of the individual accessing the APDS and the picture must be maintained for a minimum of 180 days. [BPC 4119.11(e)]

☐☐☐ 4.24 The APDS makes complete and accurate records of all transactions including users accessing system and drugs added and removed from the APDS. [BPC 4119.11(f)]

☐☐☐ 4.25 The APDS will collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of APDS. [BPC 4119.11(c)(1)]

☐☐☐ 4.26 The APDS will maintain transaction information in a readily available in downloadable format for review and inspection by authorized individuals for a minimum of 3 years. [BPC 4119.11(c)(2)]

☐☐☐ 4.27 The APDS may dispense medications **DIRECTLY** to the patient if **all** the following are met: [BPC 4119.11(d)]

☐☐☐ 4.27.1 The pharmacy has developed and implemented written policies and procedures with respect to all the following and the policies are reviewed annually: [BPC 4119.11(d)(1) – (d)(1)(F)]

- Maintaining the security of the APDS and dangerous drug and devices within the APDS
- Determine and apply inclusion criteria regarding which drugs, devices are appropriate for placement in the APDS and for which patients.
- Ensuring patients are aware that consultation with a pharmacist is available for any prescription medication including those delivered via APDS
- Describing assignment of responsibilities and training of pharmacy personnel and other personnel using the APDS at that location regarding maintenance and filling procedures for the APDS.
- Orienting patients on use of APDS and notifying patients when expected medications are not available in the APDS. The pharmacy must ensure the use of the APDS does not interfere with the delivery of drugs and devices.
- Ensuring the delivery of drugs and devices to patients expecting medications from the APDS in the event the APDS is disabled or malfunctions.

Date of Last Policy Review: _____

☐☐☐ 4.27.2 The APDS may only be used for patients who have signed a written consent demonstrating their informed consent to receive prescribed drug and devices from the APDS. Attach a copy of the consent form to the back of the self-assessment. [BPC 4119.11(d)(2)]

Yes No N/A

☐☐☐ 4.27.3 The device shall have a means to identify each patient and only release the identified patient's drugs and devices to the patient or the patient's agent. [BPC 4119.11(d)(3)]

☐☐☐ 4.27.4 The pharmacist has performed all clinical services as part of the dispensing process including but not limited to drug utilization review and consultation. [BPC 4119.11(d)(4)]

☐☐☐ 4.27.5 Drugs are dispensed from the APDS only upon authorization from the pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potentials contraindication and adverse drug reactions. [BPC 4119.11(d)(5)]

☐☐☐ 4.27.6 The pharmacist shall consult patients for the first time on all prescribed drugs and devices dispensed from the APDS. The consultation shall be provided by a Board licensed pharmacist via telecommunication link that has two-way audio and video capabilities. [BPC 4119.11(d)(6)]

☐☐☐ 4.27.7 The APDS shall prominently post a notice that provides the name, address and telephone number of the pharmacy [BPC 4119.11(d)(7)]

☐☐☐ 4.27.8 The prescription labels on all drugs dispensed via APDS shall comply with BPC 4076 and CCR 1707.5. [BPC 4119.11(d)(8)]

☐☐☐ 4.27.9 Any complaint, error or omission involving the APDS shall be reviewed as a part of the pharmacy's quality assurance program pursuant to BPC 4125. [BPC 4119.11(d)(9)]

☐☐☐ 4.28 The federal warning label prohibiting transfer of controlled substances is on the prescription container. [21 CFR 290.5]

☐☐☐ 4.29 Prescriptions are dispensed in a new and child-resistant container, or senior-adult ease-of-opening tested container, or in a non-complying package only pursuant to the prescriber or when requested by the purchaser. [15 USC 1473(b), 16 CFR 1700.15, CCR 1717]

☐☐☐ 4.30 Patient package inserts are dispensed with all estrogen medications. [21 CFR 310.515]

☐☐☐ 4.31 The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57(c).

☐☐☐ 4.32 Medication guides are provided on required medications. (21 CFR 208.1)

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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E. RECORD KEEPING REQUIREMENTS

Yes No N/A

☐☐☐ 4.33 The operating pharmacy has complied with all recordkeeping and quality assurance requirements pursuant to BPC 4119.11 and those records shall be maintain within the pharmacy holding the APDS and separately from the other pharmacy records. [BPC 4119.11(j)]

☐☐☐ 4.34 The operating pharmacy will maintain records of acquisition and disposition of dangerous drugs stored in the APDS separate from other pharmacy records. [BPC 4119.11(a)(4)]

☐☐☐ 4.35 Any records maintained electronically must be maintained so that the pharmacist-in-charge, or the pharmacist on duty if the pharmacist-in-charge is not on duty, must, at all times during which the licensed premises are open for business, be able to produce a hardcopy and electronic copy of all records of acquisition and disposition or other drug or dispensing-related records maintained electronically. [BPC 4105(d)(1)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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F. POLICIES AND PROCEDURES

Yes No N/A

☐☐☐ 4.36 The pharmacy has developed and implemented written policies and procedures with respect to all the following and the policies are reviewed annually:

- Maintaining the security of the APDS and dangerous drug and devices within the APDS
- Determine and apply inclusion criteria regarding which drugs, devices are appropriate for placement in the APDS and for which patients.
- Ensuring patients are aware that consultation with a pharmacist is available for any prescription medication including those delivered via APDS
- Describing assignment of responsibilities and training of pharmacy personnel and other personnel using the APDS at that location regarding maintenance and filling procedures for the APDS.
- Orienting patients on use of APDS and notifying patients when expected medications are not available in the APDS. The pharmacy must ensure the use of the APDS does not interfere with the delivery of drugs and devices.
- Ensuring the delivery of drugs and devices to patients expecting medications from the APDS in the event the APDS is disabled or malfunctions.

Date of Last Policy Review: _____

Yes No N/A

☐☐☐ 4.37 The pharmacy has policies and procedures for security measures and monitoring of the inventory to prevent theft and diversion. [BPC 4105.5(c)(2)]

☐☐☐ 4.38 The pharmacy reports drug losses as required by law. [BPC 4104, 4105.5(c), CCR 1715.6, 21 CFR 1301.76]

Last Reported Drug Loss: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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SECTION 5: ADDS ADJACENT TO THE SECURED PHARMACY AREA AND IN MEDICAL OFFICES.

A. GENERAL REQUIREMENTS

Yes No N/A

☐☐☐ 5.1 The pharmacy maintains the APDS policies and procedures for 3 years after the last date of use for that APDS. [BPC 4427.6(l)]

☐☐☐ 5.2 The pharmacy developed and implemented, and reviewed annually the APDS policy and procedures pertaining to the APDS, including: [BPC 4427.6(a)]

- Maintaining the security of the APDS and the dangerous drugs and devices within the APDS.
- Determining and applying inclusion criteria regarding which drugs and devices are appropriate for placement in the APDS and for which patients.
- Ensuring patients are aware consultation with a pharmacist is available for any prescription medications, including those delivered via the APDS.
- Describing assignment of responsibilities to, and training of, pharmacy personnel and other personnel using the APDS at the location where the APDS is placed, regarding maintenance and filing procedures for the APDS.
- Orienting participating patients on the use of the APDS, notifying patients when expected prescription medications are not available in the APDS, and ensuring patient use of the APDS does not interfere with delivery of drugs and devices.
- Ensuring delivery of drugs and devices to patients expecting to receive them from the APDS in the event the APDS is disabled or malfunctions.

Yes No N/A

☐☐☐ 5.3 The pharmacy does not have more than 15 APDS licenses for one underlying operating pharmacy under this section. [BPC 4427.6(k)] List of current APDS licenses:

1._____2. _____

3._____ 4. _____

5._____6. _____

7._____8. _____

9._____10._____

11. _____ 12._____

13._____14. _____

15. _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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B. PHARMACIST RESPONSIBILITIES:

Yes No N/A

☐☐☐ 5.4 A pharmacist licensed by the board performs all clinical services conducted as part of the dispensing process, including but not limited to, drug utilization review and consultation. [BPC 4427.6(d)]

☐☐☐ 5.5 Drugs are dispensed from the APDS only upon authorization from the pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions. [BPC 4427.6(e)]

☐☐☐ 5.6 The pharmacist shall consult patients for the first time on all prescribed drugs and devices dispensed from the APDS. The consultation shall be provided by a Board licensed pharmacist via telecommunication link that has two-way audio and video capabilities. [BPC 4427.6(f)]

Yes No N/A

☐☐☐ 5.7 The Pharmacist-in-charge of the offsite ADDS/APDS has ensured the following: [CCR 1715.65(h)]

- All controlled substances added to the ADDS/APDS are accounted for;
- Access to ADDS/APDS is limited to authorized facility personnel;
- An ongoing evaluation of discrepancies or unusual access associated with controlled substance is performed; and
- Confirmed losses of controlled substances are reported to the Board.

☐☐☐ 5.8. The pharmacy operating the APDS has completed an annual Self-Assessment pursuant to CCR 1715 evaluating the pharmacy's compliance with pharmacy law relating to the use of the APDS. [BPC 4427.7(a)]

Date of Last Self-Assessment: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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C. DEVICE REQUIREMENTS:

Yes No N/A

☐☐☐ 5.9 The stocking of the APDS is performed by a pharmacist, or by a pharmacy technician or intern pharmacist under the supervision of a pharmacist, except for an APDS located in a health facility pursuant to HSC 1250, where the stocking and restocking of the APDS may be performed in compliance with HSC 1261.6. [BPC 4427.4(e)(1)]

☐☐☐ 5.10 Access to the APDS is controlled and tracked using an identification or password system or biosensor. [BPC 4427.4(e)(2)]

☐☐☐ 5.11 The ADDS makes a complete and accurate record of all transactions including all users accessing the system and all drugs added to, or removed from, the system. [BPC 4427.4(e)(3)]

☐☐☐ 5.12 Drugs and devices not immediately transferred into an APDS upon arrival at the APDS location are stored for no longer than 48 hours in a secured room within the APDS location. Upon retrieval of these drugs and devices from secured storage, an inventory is taken to detect any losses or overages. [BPC 4427.4(f)]

☐☐☐ 5.13 Drugs stored in the APDS are part of the inventory of the operating pharmacy and drugs dispensed by the APDS shall be considered to have been dispensed by the pharmacy. [BPC 4427.4(d)]

Yes No N/A

☐☐☐ 5.14 The APDS may only be used for patients who have signed a written consent demonstrating their informed consent to receive prescribed drug and devices from the APDS. Attach a copy of the consent form to the back of the self-assessment. [BPC 4427.6(b)]

☐☐☐ 5.15 The APDS has a means to identify each patient and only release the identified patient's drugs and devices to the patient or the patient's agent. [BPC 4427.6(c)]

☐☐☐ 5.16 The APDS has a notice, prominently posted on the APDS, which provides the name, address, and phone number of the pharmacy. [BPC 4427.6(g)]

☐☐☐ 5.17 Any incident involving the APDS where a complaint, error, or omission occurred is reviewed as part of the pharmacy's quality assurance program pursuant to BPC 4125. [BPC 4427.6(i)]

☐☐☐ 5.18 If the APDS is located and operated in a medical office or other location where patients are regularly seen for purposes of diagnosis and treatment, the APDS is only used to dispense dangerous drugs and dangerous devices to patients of the practice. [BPC 4427.6(j)]

☐☐☐ 5.19 The labels on all drugs and devices dispensed by the APDS comply with Section 4076 and with Section 1707.5 of Title 16 of the California Code of Regulations. [BPC 4427.6(h)]

☐☐☐ 5.20 The federal warning label prohibiting transfer of controlled substances is on the prescription container. [21 CFR 290.5]

☐☐☐ 5.21 Prescriptions are dispensed in a new and child-resistant container, or senior-adult ease-of-opening tested container, or in a non-complying package only pursuant to the prescriber or when requested by the purchaser. [15 USC 1473[b], 16 CFR 1700.15, CCR 1717]

☐☐☐ 5.22 Patient package inserts are dispensed with all estrogen medications. [21 CFR 310.515]

☐☐☐ 5.23 The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57(c).

☐☐☐ 5.24 Medication guides are provided on required medications. [21 CFR 208.1]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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D. RECORD KEEPING REQUIREMENTS

Yes No N/A

☐☐☐ 5.25 The operating pharmacy has complied with all recordkeeping and quality assurance requirements pursuant to BPC 4427.6 and those records shall be maintain within the pharmacy holding the APDS and separately from the other pharmacy records. [BPC 4427.7(b)]

☐☐☐ 5.26 The operating pharmacy will maintain records of acquisition and disposition of dangerous drugs stored in the APDS separate from other pharmacy records. [BPC 4119.11(a)(4)]

☐☐☐ 5.27 Any records maintained electronically must be maintained so that the pharmacist-in-charge, or the pharmacist on duty if the pharmacist-in-charge is not on duty, must, at all times during which the licensed premises are open for business, be able to produce a hardcopy and electronic copy of all records of acquisition and disposition or other drug or dispensing-related records maintained electronically. [BPC 4105(d)(1)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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E. POLICIES AND PROCEDURES

Yes No N/A

☐☐☐ 5.28 The pharmacy has developed and implemented written policies and procedures with respect to all the following and the policies are reviewed annually: [4427.6(a) – 4427.6(a)(6)]

- Maintaining the security of the APDS and dangerous drug and devices within the APDS
- Determine and apply inclusion criteria regarding which drugs, devices are appropriate for placement in the APDS and for which patients.
- Ensuring patients are aware that consultation with a pharmacist is available for any prescription medication including those delivered via APDS
- Describing assignment of responsibilities and training of pharmacy personnel and other personnel using the APDS at that location regarding maintenance and filling procedures for the APDS.
- Orienting patients on use of APDS and notifying patients when expected medications are not available in the APDS. The pharmacy must ensure the use of the APDS does not interfere with the delivery of drugs and devices.
- Ensuring the delivery of drugs and devices to patients expecting medications from the APDS in the event the APDS is disabled or malfunctions.

Date of Last Policy Review: _____

Yes No N/A

☐☐☐ 5.29 The pharmacy reports drug losses as required by law. [BPC 4104, 4105.5(c), CCR 1715.6, 21 CFR 1301.76]

Last Reported Drug Loss: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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SECTION 6: ADDS IN A HEALTH FACILITY PURSUANT TO HSC 1250 – LONG TERM CARE FACILITIES

A. GENERAL REQUIREMENTS

For purposes of this section, "FACILITY" means a health facility licensed pursuant to subdivision (c), (d), or (k) of Section 1250 of the Health and Safety Code that has an ADDS provided by a pharmacy. [HSC 1261.6(a)(2)]

For purposes of this section, "PHARMACY SERVICES" means the provision of both routine and emergency drugs and biologicals to meet the needs of the patient, as prescribed by a physician. [HSC 1261.6 (a)(3)]

Yes No N/A

☐☐☐ 6.1 The facility and the pharmacy has developed and implemented written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the ADDS as well as quality, potency, and purity of the stored drugs and devices. [BPC 4427.3(c), HSC 1261.6 (d)(1)]

☐☐☐ 6.2 The ADDS policies and procedures define access to the ADDS and limits to access to equipment and drugs. [HSC 1261.6 (d)(1)]

☐☐☐ 6.3 All ADDS policies and procedures are maintained at the pharmacy and the location where the ADDS is being used. [HSC 1261.6(d)(2), BPC 4427.3(c)]

☐☐☐ 6.4 The pharmacy is responsible for review of drugs contained within the ADDS and the operation and maintenance of the ADDS. [HSC 1261.6(h)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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B. PHARMACIST RESPONSIBILITIES:

Yes No N/A

☐☐☐ 6.5 The stocking of the ADDS is performed by a pharmacist or if the ADDS utilizes removable pockets, cards, drawers, similar technology, or unit of use or single dose containers are used, the stocking system may be done outside the facility and be delivered to the facility if the following conditions are met: [HSC 1261.6 (g)]

☐☐☐ 6.5.1 The task of placing drugs into the removeable pockets, cards, drawers, or unit or use or single dose containers is performed by a pharmacist, or by an intern pharmacist or a pharmacy technician under the direct supervision of a pharmacist. [HSC 1261.6 (g)(1)]

☐☐☐ 6.5.2 The removable pockets, cards, drawers, or unit of use or single dose containers are transported between the pharmacy and the facility in a secure tamper-evident container. [HSC 1261.6 (g)(2)]

☐☐☐ 6.5.3 The facility, in conjunction with the pharmacy, has developed policies and procedures to ensure that the removable pockets, cards, drawers, or unit of use or single dose containers are properly placed into the ADDS. [HSC 1261.6(g)(3)]

☐☐☐ 6.6 Individualized and specific access to the ADDS is limited to facility and contract personnel authorized by law to administer drugs. [HSC 1261.6 (c)]

☐☐☐ 6.7 A pharmacist reviews and approves all orders prior to a drug being removed from the ADDS for administration to a patient. The pharmacist reviews the prescriber's orders and the patient's profile for potential contraindications and adverse drug reactions. [HSC 1261.6 (f)(2)]

☐☐☐ 6.8 The review of the drugs contained within the ADDS and the operation and maintenance of the ADDS is conducted, on a monthly basis, by a pharmacist. The review includes a physical inspection of the ADDS for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system. [HSC 1261.6 (h)]

Date of Last Review: _____

☐☐☐ 6.9 The Pharmacist-in-charge of the offsite ADDS has ensured the following: [CCR 1715.65(h)]

- All controlled substances added to the ADDS are accounted for;
- Access to ADDS is limited to authorized facility personnel;
- An ongoing evaluation of discrepancies or unusual access associated with controlled substance is performed; and
- Confirmed losses of controlled substances are reported to the Board.

Yes No N/A

☐☐☐ 6.10 The pharmacy operating the ADDS has completed an annual Self-Assessment pursuant to BPC4427.7(a) evaluating the pharmacy's compliance with pharmacy law relating to the use of the APDS (BPC 4427.7(a)).

Date of Last Self-Assessment: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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C. DEVICE REQUIREMENTS:

Yes No N/A

☐☐☐ 6.11 The stocking and restocking of the ADDS is performed in compliance with Section 1261.6 of the Health and Safety Code. [BPC 4427.4(e)(1)]

☐☐☐ 6.12 Drugs and devices not immediately transferred into an ADDS upon arrival at the ADDS location are stored for no longer than 48 hours in a secured room within the ADDS location. Upon retrieval of these drugs and devices from secured storage, an inventory is taken to detect any losses or overages. [BPC 4427.4(f)]

☐☐☐ 6.13 Transaction information from the ADDS will be made readily available in a written format for review and inspection by individuals authorized by law and maintained in the facility for a minimum of three years. [HSC 1261.6(b)]

☐☐☐ 6.14 The information required by BPC Section 4076 and HSC 111480 is readily available at the time of drug administration if unit dose packaging or unit of use packaging is used. Unit dose packaging, for purposes of this section, includes blister pack cards. [HSC 1261.6(i)]

When the ADDS is used as an emergency pharmaceutical supplies container, drugs removed from the ADDS are limited to the following [HSC 1261.6(e)]:

Yes No N/A

☐☐☐ 6.15 A new drug order given by a prescriber for a patient of the facility for administration prior to the next scheduled delivery from the pharmacy, or 72 hours, whichever is less. The drug is retrieved only upon the authorization of a pharmacist and after the pharmacist has reviewed the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions. [HSC 1261.6(e)(1)]

☐☐☐ 6.16 Drugs that a prescriber has ordered for a patient on an as-needed basis, if the utilization and retrieval of those drugs are subject to ongoing review by a pharmacist. [HSC 1261.6(e)(2)]

☐☐☐ 6.17 Drugs designed by the patient care policy committee or pharmaceutical service committee of the facility as emergency drugs or acute onset drugs. These drugs are retrieved from the

ADDS pursuant to the order of a prescriber for emergency or immediate administration to a patient of the facility and reviewed by a pharmacist within 48 hours. [HSC 1261.6(e)(3)]

When the ADDS is used to provide pharmacy services pursuant to BPC 4017.3, the ADDS is subject to the following requirements [HSC 1261.6 (f)]:

Yes No N/A

☐☐☐ 6.18 Drugs removed from the ADDS for administration to a patient are in properly labeled units of administration containers or packages. [HSC 1261.6(f)(1)]

☐☐☐ 6.19 A pharmacist reviews and approves all orders prior to a drug being removed from the ADDS for administration to a patient. The pharmacist reviews the prescriber's orders and the patient's profile for potential contraindications and adverse drug reactions. [HSC 1261.6 (f)(2)]

☐☐☐ 6.20 The pharmacy controls access to the drugs stored in the ADDS. [HSC 1261.6 (f)(3)]

☐☐☐ 6.21 Access to the ADDS is controlled and tracked using an identification or password system or biosensor. [BPC 4427.4(e)(2), HSC 1261.6(f)(4)]

☐☐☐ 6.22 The ADDS makes a complete and accurate record of all transactions that includes all users accessing the system and all drugs added to, or removed from, the system. [BPC 4427.4(e)(3), HSC 1261.6(f)(5)]

☐☐☐ 6.23 After the pharmacist reviews the prescriber's order, access by licensed personnel to the ADDS is limited only to drugs ordered by the prescriber and reviewed by the pharmacist and that are specific to the patient. [HSC 1261.6(f)(6)]

☐☐☐ 6.24 When the prescriber's order requires a dosage variation of the same drug, licensed personnel only have access to the drug ordered for that scheduled time of administration. [HSC 1261.6 (f)(6)]

☐☐☐ 6.25 If the ADDS allow licensed personnel to have access to multiple drugs and are not patient specific in their design, the ADDS has electronic and mechanical safeguards in place to ensure that the drugs delivered to the patient are specific to that patient (HSC 1261.6 (f)(7)).

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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D. RECORD KEEPING REQUIREMENTS

Yes No N/A

☐☐☐ 6.26 The pharmacy complies with all recordkeeping and quality assurance requirements, established in pharmacy law and regulation, and maintains those records within the licensed pharmacy holding the ADDS license and separate from the other pharmacy records. [BPC 4427.7 (b)]

☐☐☐ 6.27 Transaction information from the ADDS will be made readily available in a written format for review and inspection by individuals authorized by law and maintained in the facility for a minimum of three years. [HSC 1261.6(b)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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E. POLICIES AND PROCEDURES

Yes No N/A

☐☐☐ 6.28 The facility and the pharmacy has developed and implemented written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the ADDS as well as quality, potency, and purity of the stored drugs and devices. [BPC 4427.3(c), HSC 1261.6(d)(1)]

☐☐☐ 6.29 The ADDS policies and procedures define access to the ADDS and limits to access to equipment and drugs. [HSC 1261.6(d)(1)]

☐☐☐ 6.30 All ADDS policies and procedures are maintained at the pharmacy and the location where the ADDS is being used. [HSC 1261.6(d)(2), BPC 4427.3(c)]

☐☐☐ 6.31 The facility, in conjunction with the pharmacy, has developed policies and procedures to ensure that the removable pockets, cards, drawers, or unit of use or single dose containers are properly placed into the ADDS. [HSC 1261.6(g)(3)]

☐☐☐ 6.32 The pharmacy has policies and procedures that include appropriate security measures and monitoring of the inventory to prevent theft and diversion. [BPC 4427.2(d)(3)]

☐☐☐ 6.33 The pharmacy's policies and procedures include provisions for reporting to the board drug losses from the ADDS inventory, as required by law. [BPC 4104, 4427.2(d)(4), CCR 1715.6, 21 CFR 1301.76]

Last Reported Drug Loss: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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SECTION 7: APDS THROUGH A CLINIC PURSUANT TO HSC 1204 OR 1204.1 OR BPC 4180 OR 4190

A. GENERAL REQUIREMENTS

Yes No N/A

☐☐☐ 7.1 The ADDS is located inside an enclosed building with a premises address, at a location approved by the Board [BPC 4427.3 (a)]. The clinic has a current Board of Pharmacy Clinic license pursuant to BPC 4180 or BPC 4190? or the clinic is licensed pursuant to HSC 1204 or 1204.1. [BPC 4427.3(b)(3)]

License number: _____Expiration Date: _____

☐☐☐ 7.2 The clinic has developed and implemented written policies and procedures that ensure the safety, accuracy, accountability, security and patient confidentiality. Additionally, the policies and procedures shall ensure the maintenance of the quality, potency and purity of the drugs. **The policies and procedures shall be maintained at the location where the ADDS is being used.** [BPC 4186(a)]

☐☐☐ 7.3 Drugs removed from the ADDS shall be provided to the patient by a health professional licensed pursuant to BPC 4186(b).

☐☐☐ 7.4 The clinic is responsible for the review of the drugs contained within, and the operation and maintenance of, the ADDS. [BPC 4186(d)]

☐☐☐ 7.5 Drugs dispensed from the clinic ADDS shall comply with labeling requirements in BPC 4076 with CCR 1707.5. [BPC 4186(g), 4426.7(h)]

☐☐☐ 7.6 The clinic shall keep records of the kind and amounts of drugs purchased, administered, and dispensed and the records shall be available and maintained for a minimum of three years for inspection by all authorized personnel. [BPC 4180(a)(2)]

☐☐☐ 7.7 The proposed ADDS installation location meets the requirement of BPC 4427.3 and the ADDS is secure from access and removal by unauthorized individuals. [BPC 4427.2(d)(2)]

☐☐☐ 7.8 The clinics licensed under BPC 4180 or BPC 4190 perform periodic inventory and inventory reconciliation functions to detect and prevent the loss of controlled substances. [CCR 1715.65(a)]

Yes No N/A

☐☐☐ 7.9 The clinic shall compile an inventory reconciliation report of all **federal Schedule ll controlled substance** at least every three months. [CCR 1715.65(c)] The compilation requires:

- A physical count (not estimate) of all quantities of all **federal Schedule ll controlled substances.**
- A review of all acquisition and disposition records of **federal Schedule ll controlled substances** since that last inventory reconciliation report:

Date of last inventory_____

- A comparison of (1) and (2) to determine if there are any variances.
- All records used to compile each inventory reconciliation report shall be maintained at clinic for 3 years in a readily retrievable form.
- Possible causes of overages shall be identified in writing and incorporated into the inventory reconciliation report.

☐☐☐ 7.10 The clinic shall report in writing identified drug losses and known cause to the Board within 30 days of discovery. Cases of the loss is due to theft, diversion or self-use shall be reported to the Board within 14 days of discovery. If the clinic is unable to identify the cause of loss, further investigation shall be undertaken to identify the cause and actions necessary to prevent additional losses of controlled substances. [CCR 1715.65(d)]

☐☐☐ 7.11 The individuals performing the inventory AND the clinic professional director shall date and sign the inventory reconciliation reports. The reports shall be readily retrievable at the clinic for 3 years. [CCR 1715.65(e)]

☐☐☐ 7.12 Any incident involving the APDS where a complaint, error, or omission has occurred is reviewed as part of the pharmacy's quality assurance program pursuant to BPC 4125. [BPC 4427.6(i)]

☐☐☐ 7.13 The federal warning label prohibiting transfer of controlled substances is on the prescription container. [21 CFR 290.5]

☐☐☐ 7.14 Prescriptions are dispensed in a new and child-resistant container, or senior-adult ease-of-opening tested container, or in a non-complying package only pursuant to the prescriber or when requested by the purchaser. [15 USC 1473(b), 16 CFR 1700.15, CCR 1717]

☐☐☐ 7.15 Patient package inserts are dispensed with all estrogen medications. [21 CFR 310.515]

☐☐☐ 7.16 The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57(c).

☐☐☐ 7.17 Medication guides are provided on required medications. [21 CFR 208.1]

Yes No N/A

☐☐☐ 7.18 Is the APDS located and operated only used to dispense dangerous drugs and dangerous devices to patients of the clinic? [BPC 4427.6j)]

☐☐☐ 7.19 Does the pharmacy have no more than 15 ADDS licensed as APDS units? [BPC 4427.6(k)]
List of current APDS licenses:

1._____ 2. _____

3._____ 4. _____

5._____6. _____

7._____8. _____

9._____10._____

11. _____ 12._____

13._____14. _____

15. _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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B. PHARMACIST RESPONSIBILITY

Yes No N/A

☐☐☐ 7.20 The pharmacist performs the stocking of the ADDS. [BPC 4186(c)]

☐☐☐ 7.21 Drugs are removed from the ADDS system only upon the authorization of the pharmacist after the pharmacist has reviewed the prescription and patient profile for potential contraindications and adverse drug reactions. [BPC 4186(b)]

☐☐☐ 7.22 The pharmacist shall conduct a review on a monthly basis including a physical inspection of the drugs in the ADDS for cleanliness and a review of all transaction records in order to verify the security and accountability of the ADDS. [BPC 4186(d)]

Date of Last Review: _____

Yes No N/A

☐☐☐ 7.23 The pharmacist licensed by the board performs all clinical services conducted as part of the dispensing process, including, but not limited to, drug utilization review and consultation. [BPC 4427.6(d)]

☐☐☐ 7.24 Drugs are dispensed from the APDS after the pharmacist has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions. [BPC 4427.6(e)]

☐☐☐ 7.25 All prescribed drugs and devices dispensed to the patient from an APDS for the first time shall be accompanied by a consultation conducted by a pharmacist licensed by the board via telecommunication link with a two-way audio and video. [BPC 4427.6(f)]

☐☐☐ 7.26 The APDS has a notice, prominently posted on the APDS, with the name, address, and phone number of the pharmacy holding the ADDS license for the APDS. [BPC 4427.6(g)]

☐☐☐ 7.27 The pharmacist shall provide patient consultation pursuant to CCR 1707.2 via a two-way audio and video telecommunication link for drugs dispensed by the clinic ADDS. [BPC 4186(e)]

☐☐☐ 7.28 The pharmacist operating the ADDS shall be located in California. [BPC 4186(f)]

☐☐☐ 7.29 The clinic consultant pharmacist shall review all inventory and inventory reconciliation reports taken and establish and maintain secure methods to prevent losses of controlled substances. The clinic shall develop written policies and procedures for performing the inventory reconciliation reports. (CCR 1715.65(b))

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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C. POLICIES AND PROCEDURES

Yes No N/A

☐☐☐ 7.32 The pharmacy has developed and implemented, and reviewed annually, written policies and procedures pertaining to the APDS, including all the following: [BPC 4427.6(a)]

- Maintaining the security of the APDS and dangerous drugs and dangerous devices within the APDS.
- Determining and applying inclusion criteria regarding which drugs and devices are appropriate for placement in the APDS and for which patients.
- Ensuring patients are aware consultation with a pharmacist is available for any prescription medication, including those delivered via the APDS.
- Describing assignments of responsibilities to, and training of, pharmacy personnel, and other personnel using the APDS at the location where the APDS is placed pursuant to

subdivision (b) of Section 4427.3, regarding maintenance and filing procedures for the APDS.

- Orienting participating patients on the use of the APDS, notifying patient when expected prescription medications are not available in the APDS, and ensuring the patient use of the APDS does not interfere with delivery of drugs and devices.
- Ensuring delivery of drugs and devices to patients expecting to receive them from the APDS in the event the APDS is disabled or malfunctions.

Date of Last Policy Review: _____

Yes No N/A

☐☐☐ 7.33 Is the APDS only used for patients who have signed a written consent form demonstrating their informed consent to receive prescribed drugs and devices from an APDS, and whose use of the APDS meets inclusion criteria established by policies and procedures. [BPC 4427.6(b)]

☐☐☐ 7.34 The APDS shall have a means of identifying each patient and only release the identified patient's drugs and devices to the patient or patient's agent. [BPC 4427.6(c)]

☐☐☐ 7.35 The pharmacy holding the ADDS license for an APDS maintains its policies and procedures for three (3) years after the last date of use of an APDS. [BPC 4427.6(l)]

☐☐☐ 7.36 Does the pharmacy maintain all recordkeeping and quality assurance requirements established in pharmacy law and regulations, and maintain these records within the licensed pharmacy holding the ADDS license and separate from other pharmacy records. [BPC 4427.7(b)]

SECTION 8: ADDS OPERATED BY A CORRECTIONAL CLINIC

A. GENERAL REQUIREMENTS

Yes No N/A

☐☐☐ 8.1 The pharmacy uses an "automated drug delivery system" used in a correctional clinic, meaning a mechanical system controlled remotely by a pharmacist that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of prepackaged dangerous drugs or dangerous devices. An automated drug delivery system shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability. [BPC 4187.5(h)]

☐☐☐ 8.2 The ADDS is located in a "correctional clinic," a primary care clinic, as referred to in subdivision (b) of Section 1206 of the Health and Safety Conde, conducted, maintained, or operated by the state to provide health care eligible patients of the Department of Corrections and Rehabilitation (BPC 4187).

Yes No N/A

☐☐☐ 8.3 The correctional clinic licensed by the board obtains the drugs from a licensed correctional pharmacy, the Department of Correction and Rehabilitation's Central Fill Pharmacy, or from another correctional clinic licensed by the board within the same institution for the administration or dispensing of drugs or devices to patients eligible for care at the correctional facility if under either: [BPC 4187.1(a)]

- The directions of a physician and surgeon, dentist, or other person lawfully authorized to prescribe.
- An approved protocol as identified within the statewide Inmate Medical Services Policies and Procedures.

☐☐☐ 8.4 The dispensing or administering of drugs in the correctional clinic is performed pursuant to a chart order, as defined in Section 4019, a valid prescription consistent with chapter 9 division 2 of the Business and Professions Code, or pursuant to an approved protocol as identified within the statewide Inmate Medical Services Policies and Procedures. [BPC 4187.1(b)]

☐☐☐ 8.5 Medications dispensed to patients that are kept on the patient's person for use shall meet the labeling requirements of Section 4076 and all record keeping requirements of chapter 9 division 2 of the Business and Professions Code. [BPC 4187.1(b)]

☐☐☐ 8.6 The correctional clinic keeps records of the kind and amounts of drugs acquired, administered, transferred, and dispensed. The records must be readily available and maintained for a minimum of three years for inspection by all properly authorized personnel. [BPC 4187.1(c)]

☐☐☐ 8.7 The correctional clinic has obtained a license from the board. [BPC 4187.1(d)(1)]

☐☐☐ 8.8 A separate license was obtained for each correctional clinic location where an APDS is located and is not to be transferrable. [BPC 4187.1(d)(2)]

☐☐☐ 8.9 The correctional clinic's location and address is identified by the correctional institution and building within the correctional institution. [BPC 4187.1(d)(3)]

☐☐☐ 8.10 The correctional clinic will notify the board in advance of any change in the clinic's address on a form furnished by the board. [BPC 4187.1(d)(4)]

☐☐☐ 8.11 The ADDS is secured from access and removal by unauthorized individuals. [BPC 4427.2(d)(2)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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B. POLICIES AND PROCEDURES

Yes No N/A

☐☐☐ 8.12 The policies and procedures to implement the laws and regulations of this article within the correctional clinic was developed and approved by the statewide Correctional Pharmacy and Therapeutics Committee referenced in Section 5024.2 of the Penal Code. [BPC 4187.2(a)]

☐☐☐ 8.13 Prior to the issuance of the correctional clinic license by the board, an acknowledgment of the policies and procedures was signed by the correctional facility pharmacist-in-charge servicing the institution, the pharmacist-in-charge for the California Department of Correction and Rehabilitation's Central Fill Pharmacy, and the correctional clinic's chief medical executive, supervising dentist, chief nurse executive, and chief executive officer. [BPC 4187.2(a)]

☐☐☐ 8.14 The chief executive officer is responsible for the safe, orderly and lawful provision of pharmacy services. [BPC 4187.2(b)(1)]

☐☐☐ 8.15 The pharmacist-in-charge of the correctional facility shall implement the policies and procedures developed and approved by the statewide Correctional Pharmacy and Therapeutics Committee referenced in Section 5042.2 of the Penal Code and the statewide Inmate Medical Services Policies and Procedures in conjunction with the chief executive officer, the chief medical executive, the supervising dentist, and the chief nurse executive. [BPC 4187.2(b)(1)]

☐☐☐ 8.16 The licensed correctional clinic will notify the board within 30 days of any change in the chief executive officer on a form furnished by the board. [BPC 4187.2(b)(2)]

☐☐☐ 8.17 Schedule II, III, IV or V controlled substances may be administered by health care staff of the licensed correctional clinic lawfully authorized to administer pursuant to a chart order, as defined in Section 4019, a valid prescription consistent with chapter 9 division 2 of the Business and Professions Code, or pursuant to an approved protocol as identified within the statewide Inmate Medical Services Policies and Procedures. [BPC 4187.3]

☐☐☐ 8.18 The ADDS located in a licensed correctional clinic has implemented the statewide Correctional Pharmacy and Therapeutics Committee's policies and procedures and the statewide Inmate Medical Services Policies and Procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of drugs. [BPC 4187.5(a)]

☐☐☐ 8.19 All policies and procedures are maintained either in an electronic form or paper form at the location where the automated drug system is being used. [BPC 4187.5(a)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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C. PHARMACIST RESPONSIBILITIES

Yes No N/A

☐☐☐ 8.20 A correctional facility pharmacist inspects the clinic at least quarterly. [BPC 4187.2(c)]

☐☐☐ 8.21 Drugs removed from the automated drug delivery system is removed upon authorization by a pharmacist after the pharmacist has reviewed the prescription and the patient profile for potential contraindications and adverse drug reactions. If the correctional pharmacy is closed, and if, the prescriber's professional judgment, a delay in therapy may cause patient harm, the medication may be removed from the automated drug delivery system and administered or furnished to the patient under the direction of the prescriber. Where the drug is otherwise unavailable, a medication may be removed and administered or furnished to the patient pursuant to an approved protocol as identified within the statewide Inmate Medical Services Policies and Procedures. Any removal of the medication from an automated drug delivery system is documented and provided to the correctional pharmacy when it reopens. [BPC 4187.5(b)]

☐☐☐ 8.22 The review is conducted on a monthly basis by a pharmacist and shall include a physical inspection of the drugs in the automated drug delivery system, an inspection of the automated drug delivery system machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system. [BPC 4187.5(e)]

Date of Last Review: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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D. DEVICE REQUIREMENT

Yes No N/A

☐☐☐ 8.23 Drugs removed from the ADDS is provided to the patient by a health professional licensed pursuant to division 2 of the Business and Professions Code who is lawfully authorized to perform the task. [BPC 4187.5(c)]

☐☐☐ 8.24 The review of the drugs contained within, and the operation and maintenance of, the ADDS shall be the responsibility of the correctional clinic. [BPC 4187.5(e)]

☐☐☐ 8.25 The ADDS is operated by a licensed correctional pharmacy. Any drugs within the ADDS are considered owned by the licensed correctional pharmacy until they are dispensed from the ADDS. [BPC 4187.5(f)]

☐☐☐ 8.26 Drugs from the ADDS in the correctional clinic are removed by a person lawfully authorized to administer or dispense the drugs. [BPC 4187.5(g)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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E. RECORD KEEPING REQUIREMENTS

Yes No N/A

☐☐☐ 8.27 All records of manufacture and of sale, acquisition, receipt, shipment, or disposition of dangerous drugs or dangerous devices, at all times during business hours, are open for inspection by authorized officer of the law and is preserved for at least three years from the date of making. A current inventory is kept by the licensed correctional clinic. [BPC 4081(a)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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CERTIFICATION ACKNOWLEDGMENT

PHARMACIST-IN-CHARGE CERTIFICATION:

I, (please print)_____, RPH #_____ hereby certify that I have completed the self-assessment of this automated drug delivery system of which I am the pharmacist-in-charge. Any deficiency identified herein will be corrected. I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury of the laws of the State of California that the information that I have provided in this self- assessment form is true and correct.

Signature _____Date _____
(Pharmacist-in-Charge)

ACKNOWLEDGEMENT BY OWNER OF ADDS:

I, (please print)_____, hereby certify under penalty of perjury of the laws of the State of California that I have read and reviewed this completed self-assessment. I understand that failure to correct any deficiency identified in this self-assessment could result in the revocation of the pharmacy's license issued by the California State Board of Pharmacy.

Signature _____Date _____

CERTIFICATION OF COMPLETED ACTION PLAN

PHARMACIST-IN-CHARGE CERTIFICATION:

I, (please print)_____, RPH #_____ hereby certify that I have completed deficiencies identified in the self-assessment of this automated drug delivery system of which I am the pharmacist-in-charge. I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury of the laws of the State of California that the information that I have provided in this self- assessment form is true and correct.

Signature _____Date _____
(Pharmacist-in-Charge)

ACKNOWLEDGEMENT BY OWNER OF ADDS:

I, (please print)_____, hereby certify under penalty of perjury of the laws of the State of California that I have read and reviewed this completed self-assessment. I understand that failure to correct any deficiency identified in this self-assessment could result in the revocation of the pharmacy's license issued by the California State Board of Pharmacy.

Signature _____Date _____

Attachment 7

Regulation Timeline

X. Discussion and Consideration of Board Approved Regulations Undergoing Pre-Notice Review by the Department of Consumer Affairs or the Business, Consumer Services and Housing Agency

- Regulations under Pre-Notice review by the Business, Consumer Services and Housing Agency

a. Proposed Regulations to Add Title 16 CCR Sections 1717.5 Related to Automatic Refill Programs

Timeline:
Approved by Board: May 3, 2017
Submitted to DCA for Pre-Notice Review: November 7, 2017
Returned to the Board on: March 26, 2018
Re-submitted to DCA for Pre-Notice Review: June 29, 2018
Returned to the Board on: August 20, 2018
Re-submitted to DCA for Pre-Notice Review: September 20, 2018
Submitted to Agency for Pre-Notice Review: January 9, 2020

- Regulations under Pre-Notice review by DCA Legal or DCA Budget Office

b. Proposed Regulations to Amend Title 16 CCR Section 1715 to Update Self-Assessment Forms 17M-13 and 17M-14

Timeline:
Approved by Board: November 8, 2017
Submitted to DCA for Pre-Notice Review: February 2, 2018
Returned to the Board on: April 17, 2018
Re-submitted to DCA for Pre-Notice Review: July 23, 2018
Returned to the Board on: November 13, 2018
Re-submitted to DCA for Pre-Notice Review: December 24, 2018

c. Proposed Regulations to Amend Title 16 CCR Section 1784 to Update the Wholesaler/3PL Self-Assessment Form 17M-26

Timeline:
Approved by Board: November 8, 2017
Submitted to DCA for Pre-Notice Review: December 26, 2018

d. Proposed Permanent Regulation to Add Title 16 CCR Section 1747 Related to Independent HIV Preexposure and Postexposure Prophylaxis Furnishing

Timeline:
Approved by Board: January 29, 2020
Submitted to DCA for Pre-Notice Review: February 7, 2020

e. Proposed Regulation to Amend Title 16 CCR Section 1715.65 Related to Inventory Reconciliation

Timeline:
Approved by Board: January 29, 2020
Submitted to DCA for Pre-Notice Review: May 11, 2020

f. Proposed Regulation to Amend Title 16 CCR Section 1715.6 Related to Drug Losses

Timeline:
Approved by Board: January 29, 2020
Submitted to DCA for Pre-Notice Review: June 3, 2020

Automatic Refill Programs

16 CCR § 1717.5

Title 16. BOARD OF PHARMACY
Proposed Text

Proposal to add § 1717.5 in Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1717.5. Automatic Refill Programs.

(a) A pharmacy may offer a program to automatically refill prescription medications provided the pharmacy complies with this section.

(1) Written notice regarding the program shall be given to the patient or patient's agent. Such notice shall include instructions about how to withdraw a prescription medication from the program.

(2) The patient or patient's agent shall enroll by written, online or electronic consent to participate in the program.

(3) The pharmacy shall keep a copy of the written consent to enroll on file for one year from date of dispensing.

(4) The pharmacy shall have written policies and procedures in place that outline specifics of the program. The policies and procedures shall specify the medications that may be refilled through the program.

(5) The patient or patient's agent shall have the option to withdraw from the program at any time.

(6) The pharmacy shall complete a drug regimen review for each prescription refilled through the program.

(7) Each time a prescription is refilled through the program, the pharmacy shall provide a written notification to the patient or patient's agent confirming that the prescription medication is enrolled in the program.

(8) The pharmacy shall provide a full refund to the patient, patient's agent, or payer for any prescription medication in the program reported as unneeded or unnecessary, if the pharmacy had been notified of withdrawal or disenrollment from the program.

(9) A pharmacy shall make available any written notification required by this section in alternate languages as required by state or federal law.

(b) A health care facility licensed pursuant to Health and Safety Code section 1250 that automatically refills prescription medications for its patients need not comply with the provisions of this section.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4001.1, 4005, 4063 and 4076.6, Business and Professions Code and Section 1250, Health and Safety Code.

Self-Assessment Forms
16 CCR § 1715
17M – 13
17M – 14

Title 16. Board of Pharmacy
Proposed Regulation

Proposal to amend §1715 of Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1715. Self-Assessment of a Pharmacy by the Pharmacist-in-Charge.

(a) The pharmacist-in-charge of each pharmacy as defined under section 4029 or section 4037 of the Business and Professions Code shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

(b) In addition to the self-assessment required in subdivision (a) of this section, the pharmacist-in-charge shall complete a self-assessment within 30 days whenever:

(1) A new pharmacy permit has been issued, or

(2) There is a change in the pharmacist-in-charge, and he or she becomes the new pharmacist-in-charge of a pharmacy.

(3) There is a change in the licensed location of a pharmacy to a new address.

(c) A pharmacist-in-charge of a community pharmacy shall use ~~The~~ the components of this assessment ~~shall be~~ on Form 17M-13 (Rev. 10/~~14~~ 16) entitled "Community Pharmacy Self-Assessment/Hospital Outpatient Pharmacy Self-Assessment." Form 17M-13 shall be used for all pharmacies serving retail or outpatient consumers. A pharmacist-in-charge of a hospital pharmacy serving inpatient consumers, shall use the components of this assessment ~~and~~ on Form 17M-14 (Rev. 10/~~14~~ 16) entitled "Hospital Pharmacy Self-Assessment." ~~which are~~ Both forms are hereby incorporated by reference ~~to evaluate compliance with federal and state laws and regulations~~.

(1) The pharmacist-in-charge shall provide identifying information about the pharmacy including

(A) Name and license number of the pharmacy

(B) Address, phone number, and website address, if applicable, of the pharmacy

(C) DEA registration number, expiration date and date of most recent DEA inventory

(D) Hours of operation of the pharmacy

(2) The pharmacist-in-charge shall list the name of each licensed staff person working in the pharmacy, the person's license type and number, and the expiration date for each license.

(3) The pharmacist-in-charge shall respond "yes", "no" or "not applicable" (N/A) about whether the pharmacy is, at the time of the self-assessment, in compliance with each of the requirements that apply to that pharmacy setting.

(4) For each "no" response, the pharmacist-in-charge shall provide a written corrective action or action plan to come into compliance with the law.

(5) The pharmacist-in-charge shall initial each page of the self-assessment form.

(6) The pharmacist-in-charge shall provide a certification on the final page of the self-assessment that affirms he or she has completed the self-assessment of the pharmacy of which he or she is the pharmacist-in-charge. The certification shall also provide a timeframe within which any deficiency identified within the self-assessment will be corrected and that all responses are subject to verification by the Board of Pharmacy. The certification shall be made under penalty of perjury of the laws of the State of California that the information provided in the self-assessment form is true and correct.

(7) The pharmacy owner or hospital administrator shall provide a certification on the final page of the self-assessment that affirms that he or she has read and reviewed the completed self-assessment and that failure to correct any deficiency identified in the self-assessment could result in the revocation of the pharmacy's license issued by the board. This certification shall be made under penalty of perjury of the laws of the State of California.

(d) Each self-assessment shall be completed in its entirety and kept on file in the pharmacy for three years after it is performed.

(e) Any identified areas of noncompliance shall be corrected as specified in the certification.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4019, 4021, 4022, 4029, 4030, 4036, 4037, 4038, 4040, 4050, 4051, 4052, 4059, 4070, 4081, 4101, 4105, 4110, 4113, 4115, 4119, 4120, 4127, 4201, 4301, 4305, 4330, 4332 and 4333, Business and Professions Code.

Self-Assessment Form
16 CCR § 1784
17M – 26

Proposal to Amend 16 CCR Amend § 1784

§ 1784. Self-Assessment of a Wholesaler/Third Party Logistics Provider by the Designated Representative-In- Charge or Responsible Manager.

(a) ~~The designated representative-in-charge of~~ Eeach wholesaler and third-party logistics provider, as defined under section 4160 of the Business and Professions Code, shall complete a self-assessment of ~~the wholesaler's~~ its compliance with federal and state pharmacy law. The assessment shall be performed by the designated representative-in-charge of the wholesaler, or by the responsible manager of the third-party logistics provider, before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

(b) In addition to the self-assessment required in subdivision (a) of this section, the designated representative-in-charge or responsible manager shall complete a self-assessment within 30 days whenever:

(1) A new ~~wholesaler permit~~ license is issued, ~~or~~

(2) There is a change in the designated representative-in-charge or responsible manager. The new designated representative-in-charge of a wholesaler or responsible manager of a third-party logistics provider is responsible for compliance with this subdivision.

(3) There is a change in the licensed location of a wholesaler or third-party logistics provider to a new address.

(c) ~~The components of this assessment shall be on Form 17M-26 (Rev. 10/14) entitled "Wholesaler Dangerous Drugs & Dangerous Devices Self-Assessment" which is hereby incorporated by reference to evaluate compliance with federal and state laws and regulations~~. Each wholesaler and third-party logistics provider conducting business in California, through its designated representative-in-charge or responsible manager, shall complete "Wholesaler/Third Party Logistics Provider Self-Assessment," Form 17M-26 (Rev. 10/17) which is hereby incorporated by reference. The form shall include the information required by this section.

(1) The designated representative-in-charge or responsible manager shall provide identifying information about the wholesaler or third-party logistics provider including:

(A) Name and license number of the premises;

(B) Address, phone number, website address, if applicable, and type of ownership;

(C) DEA registration number and expiration date and date of most recent DEA; inventory;

(D) Verified-Accredited Wholesale Distributor accreditation number and expiration date, if applicable; and

(E) Hours of operation of the licensee.

(2) The designated representative-in-charge or responsible manager shall list the name of each Board-licensed staff person currently employed by the licensee in the facility at the time the self-assessment is completed, the person's license type and number, and the expiration date for each license.

(3) The designated representative-in-charge or responsible manager shall respond "yes", "no" or "not applicable" (N/A) about whether the licensed premises is, at the time of the self-assessment, in compliance with each of the requirements.

(4) For each "no" response, the designated representative-in-charge or responsible manager shall provide a corrective action or action plan to come into compliance with the law.

(5) The designated representative-in-charge or responsible manager shall initial each page of the self-assessment form.

(6) The designated representative-in-charge or responsible manager shall certify, under penalty of perjury, on the final page of the self-assessment that:

(A) He or she has completed the self-assessment of the licensed premises for which he or she is responsible;

(B) Any deficiency identified within the self-assessment will be corrected and the timeframe for correction;

(C) He or she understands that all responses are subject to verification by the Board of Pharmacy; and

(D) The information provided in the self-assessment form is true and correct.

(7) The licensed premises owner, partner or corporate officer shall certify on the final page of the self-assessment that he or she has read and reviewed the completed self-assessment and understands that failure to correct any deficiency identified in the self-assessment

could result in the revocation of the license issued by the board. This certification shall be made under penalty of perjury of the laws of the State of California.

(d) Each self-assessment shall be kept on file in the licensed ~~wholesale~~ premises for three years after it is completed.

(e) The wholesaler or third-party logistics provider is jointly responsible with the designated representative-in-charge or responsible manager, respectively, for compliance with this section.

(f) Any identified areas of noncompliance shall be corrected as specified in the certification.

Authority: Business and Professions Code §4005. Reference: Business and Professions Code §4022.5, §4043, §4053, §4044.5, §4045, §4059, §4120, §4160, §4161, §4201, §4301 and §4305.5.

Independent HIV Preexposure and Postexposure Prophylaxis Furnishing
16 CCR § 1747 (Permanent)

Title 16. Board of Pharmacy
Proposed Text

Proposal to Add Section 1747 to Title 16 of the California Code of Regulations, to read as follows:

§ 1747. Independent HIV Preexposure and Postexposure Prophylaxis Furnishing.

(a) Prior to independently initiating and furnishing HIV preexposure and/or postexposure prophylaxis to a patient pursuant to Business and Professions Code sections 4052.02 and 4052.03, a pharmacist shall successfully complete a training program approved by the board or provided by a provider accredited by an approved accreditation agency that satisfies the following criteria:

(1) Each training program shall be specific to the use of HIV preexposure and postexposure prophylaxis, and include at least 1.5 hours of instruction covering, at a minimum, the following areas:

(A) HIV preexposure and postexposure prophylaxis pharmacology.

(B) Requirements for independently initiating and furnishing HIV preexposure and postexposure prophylaxis contained in Business and Professions Code sections 4052.02 and 4052.03.

(C) Patient counseling information and appropriate counseling techniques, including at least, counseling on sexually transmitted diseases and sexual health.

(D) Patient referral resources and supplemental resources for pharmacists.

(E) Financial assistance programs for preexposure and postexposure prophylaxis, including the Office of AIDS' PrEP Assistance Program (PrEP-AP).

(F) Clinical eligibility recommendations provided in the federal Centers for Disease Control and Prevention (CDC) guidelines defined in Business and Professions Code sections 4052.02(c) and 4052.03(c).

(2) The training program shall require the passing of an assessment with a score of 70% or higher to receive documentation of successful completion of the training program.

(b) A pharmacist who independently initiates or furnishes HIV preexposure and/or postexposure prophylaxis pursuant to Business and Professions Code sections 4052.02 and 4052.03 shall maintain documentation of their successful completion of the training program for a period of four (4) years. Documentation maintained pursuant to this subdivision must be made available upon request of the board.

Note: Authority cited: Sections 4005, 4052.02, and 4052.03, Business and Professions Code. Reference: Sections 4052, 4052.02, and 4052.03, Business and Professions Code; Section 120972, Health and Safety Code.

Inventory Reconciliation

16 CCR § 1715.65

Title 16. Board of Pharmacy
Proposed Text

Proposed changes to the current regulation language are shown by strikethrough for deleted language and underline for added language.

Amend Section 1715.65 to Title 16 of the California Code of Regulations, to read as follows:

§ 1715.65. Inventory Activities and Inventory Reconciliation Reports of Controlled Substances.

(a) Every pharmacy, and every clinic licensed under sections 4180 or 4190 of the Business and Professions Code, shall perform periodic inventory activities and prepare inventory reconciliation ~~functions~~ reports to detect and prevent the loss of federal controlled substances. Except as provided in subdivisions (f) and (g), inventory reconciliation reports shall be prepared on the following ongoing basis:
(1) For federal Schedule II controlled substances, at least once every three months.
(2) For products containing the following substances in the following strengths per tablet, capsule, other unit, or specified volume, at least once every 12 months:
(A) Alprazolam, 1 milligram/unit.
(B) Alprazolam, 2 milligrams/unit.
(C) Tramadol, 50 milligrams/unit.
(D) Promethazine/codeine, 6.25 milligrams of promethazine and 10 milligrams of codeine per 5 milliliters of product.
(3)(A) For any controlled substance not covered by paragraph (1) or (2), no later than three months after any loss of that controlled substance is discovered either by the inventory activities required by subparagraph (B), or in any other manner. The report shall cover the period from the last physical count of the controlled substance before the loss was discovered through the date of discovery.
(B) Inventory activities for each controlled substance not covered by paragraph (1) or (2) shall be performed at least once every two years from the performance of the last inventory activities. For purposes of this section, "inventory activities" means inventory and all other functions necessary to identify losses of the controlled substance.

(b) The pharmacist-in-charge of a pharmacy or ~~consultant~~ consulting pharmacist for a clinic shall review all inventory activities performed and inventory reconciliation reports ~~taken~~ prepared pursuant to this section, and establish and maintain secure methods to prevent losses of federal controlled ~~drugs~~ substances. Written policies and procedures shall be developed for performing the inventory activities and preparing the inventory reconciliation reports required by this section.

(c) ~~A pharmacy or clinic shall compile an~~ An inventory reconciliation report ~~of all federal Schedule II controlled substances at least every three months. This compilation~~ prepared pursuant to this section shall ~~require~~ include all of the following:

(1) A physical count, not an estimate, of all quantities of ~~federal Schedule II~~ each federal controlled ~~substances~~ substance covered by the report that the pharmacy or clinic has in inventory, except as provided in subdivision (h). The biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories under this section in the year where the federal biennial inventory is performed, provided the biennial inventory was taken no more than three months from the last inventory required by this section. An individual who performs the inventory required by this paragraph shall sign and date the inventory or the report in which it is included as provided in subdivision (e)(1);

(2) A review of all acquisitions and dispositions of each federal ~~Schedule II~~ controlled ~~substances~~ substance covered by the report since the last inventory reconciliation report covering that controlled substance;

(3) A comparison of (1) and (2) to determine if there are any variances;

(4) ~~All~~ Identification of all records used to compile ~~each inventory reconciliation~~ the report, which shall be maintained in the pharmacy or clinic ~~for at least three years in a readily retrievable form~~ pursuant to subdivision (e)(2); ~~and~~

(5) Identification of each individual involved in preparing the report; and

~~(5)~~ (6) Possible causes of overages ~~shall be identified in writing and incorporated into the inventory reconciliation report~~.

(d) A pharmacy or clinic shall report in writing identified losses and known causes to the board within 30 days of discovery unless the cause of the loss is theft, diversion, or self-use in which case the report shall be made within 14 days of discovery. If the pharmacy or clinic is unable to identify the cause of the loss, further investigation shall be undertaken to identify the cause and actions necessary to prevent additional losses of federal controlled substances.

(e)(1) ~~The~~ An inventory reconciliation report shall be dated and signed by ~~the individual(s) performing the inventory, and countersigned by~~ the pharmacist-in-charge or professional director (if a clinic) ~~and~~, in addition to any signature required by subdivision (c)(1). An individual may use a digital or electronic signature or biometric identifier in lieu of a physical signature under this section if, in addition, the individual physically signs a printed statement confirming the accuracy of the inventory or report. The signature shall be dated, and the signed and dated statement shall be retained on file pursuant to paragraph (2).

(2) The report, and all records used to compile the report, shall be readily retrievable in the pharmacy or clinic for three years. ~~A countersignature is not required if the pharmacist-in-charge or professional director personally completed the inventory reconciliation report.~~

(f) A new pharmacist-in-charge of a pharmacy shall complete an inventory reconciliation report ~~as identified in subdivision (c)~~ for all federal controlled substances described in paragraphs (1) and (2) of subdivision (a) within 30 days of becoming pharmacist-in-charge. Whenever possible an outgoing pharmacist-in-charge should also complete an inventory reconciliation report ~~as required in subdivision (c)~~ for those controlled substances.

(g) ~~For~~ Notwithstanding the periodic reporting requirements specified in paragraphs (1) and (2) of subdivision (a), inpatient hospital pharmacies~~,~~ shall prepare an inventory reconciliation

report or reports covering the federal controlled substances described in paragraphs (1) and (2) of subdivision (a) on a ~~separate~~ quarterly ~~inventory reconciliation report shall be required for federal Schedule II~~ basis. The report or reports shall include controlled substances stored within the pharmacy ~~and for~~, within each pharmacy satellite location, and within each drug storage area in the hospital under the pharmacy's control.

(h) ~~The pharmacist in charge of~~ If an inpatient hospital pharmacy ~~or of a pharmacy servicing onsite or offsite~~ uses an automated drug delivery ~~systems~~ system (ADDS), inventory in the ADDS may be accounted for under subdivision (c)(1) using means other than a physical count. ~~shall ensure that:~~

~~(1) All controlled substances added to an automated drug delivery system are accounted for;~~

~~(2) Access to automated drug delivery systems is limited to authorized facility personnel;~~

~~(3) An ongoing evaluation of discrepancies or unusual access associated with controlled substances is performed; and~~

~~(4) Confirmed losses of controlled substances are reported to the board.~~

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4008, 4037, 4080, 4081, 4101, 4104, 4105, 4105.5, 4110, 4113, 4119.1, 4180, 4181, 4182, 4186, 4190, 4191, 4192 and 4332, Business and Professions Code; and Section 1261.6, Health and Safety Code.

Drug Losses
16 CCR § 1715.6

§ 1715.6. Reporting Drug Loss.

(a) The owner shall submit ~~report~~ to the Board a report containing the information in subdivision (b) ~~within~~ no later than thirty (30) days after the date of discovery of the following:

(1) ~~any~~ Any loss of ~~the~~ a controlled substance~~s, including their~~ in one of the following categories that causes the aggregate amount of unreported losses discovered in that category on or after the same day of the previous year to equal or exceed:

(A) For tablets, capsules, or other oral medication, 99 dosage units.

(B) For single-dose injectable medications, lozenges, film, suppositories, or patches, 10 dosage units.

(C) For injectable multi-dose medications, medications administered by continuous infusion, or any other multi-dose unit not described in subparagraph (A), two or more multi-dose vials, infusion bags, or other containers.

(2) Any loss of a controlled substance, regardless of the amount, attributed to employee theft.

(3) Any other ~~substantial~~ significant loss as determined by the pharmacist-in-charge.

(b) All reports under this section shall specify the identity, amount~~s~~ and strength~~s~~ of each controlled substance lost, and date of discovery of the loss, for all losses that have made the report necessary.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4081 and 4332, Business and Professions Code.

Attachment 8

Regulation Timelines

XI. Discussion and Consideration of Board Approved Text to Initiate Rulemaking – Board Staff Drafting Rulemaking Documents for Pre-Notice Review by the Department of Consumer Affairs and the Business, Consumer Services and Housing Agency

a. Proposed Regulations to Amend Title 16 CCR Section 1793.5 Related to the Pharmacy Technician Application, Section 1793.6 Related to the Pharmacy Technician Training Requirements and Section 1793.65 Related to the Pharmacy Technician Certification Programs

Timeline:
Approved by Board: October 26, 2016
Submitted to DCA for Pre-Notice Review: January 23, 2017
Returned to the Board: March 28, 2017
Re-submitted to DCA for Pre-Notice Review: August 21, 2017
Returned to the Board: February 24, 2018
Modified language approved by Board: March 27, 2018
Re-submitted to DCA for Pre-Notice Review: July 11, 2018
Returned to the Board: August 20, 2018
Re-submitted to DCA for Pre-Notice Review: October 26, 2018
Returned to the Board: December 13, 2019

b. Proposed Regulations to Amend Title 16 CCR Section 1709 Related to Pharmacy Ownership, Management, and Control, Including Through Trusts

Timeline:
Approved by Board: October 26, 2016
Submitted to DCA for Pre-Notice Review: January 26, 2017
Returned to the board on: March 28, 2017
Re-submitted to DCA for Pre-Notice Review: May 24, 2018
Returned to the board: August 6, 2018
Re-submitted to DCA for Pre-Notice Review: August 16, 2018
Returned to the board: November 2, 2018
Re-submitted to DCA for Pre-Notice Review: December 20, 2018
Returned to the board: January 3, 2020
Re-submitted to DCA for Pre-Notice Review: January 14, 2020
Returned to the Board: April 22, 2020

Pharmacy Technician

16 CCR § 1793.5, 1793.6, and 1793.65

Title 16. Board of Pharmacy
Proposed Regulation Text

Proposal to amend §1793.5 of Article 11 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1793.5. Pharmacy Technician Application.

The "Pharmacy Technician Application" (Form 17A-5 (Rev. ~~10/15~~ 7/2018)), incorporated by reference herein, required by this section is available from the Board of Pharmacy upon request.
(a) Each application for a pharmacy technician license shall include:
(1) Information sufficient to identify the applicant.
(2) A description of the applicant's qualifications and supporting documentation for those qualifications.
(3) A criminal background check that will require submission of fingerprints in a manner specified by the board and the fee authorized in Penal Code section 11105(e).
(4) A sealed, original Self-Query from the National Practitioner Data Bank (NPDB) dated no earlier than 60 days of the date an application is submitted to the board.
(b) The applicant shall sign the application under penalty of perjury and shall submit it to the Board of Pharmacy.
(c) The board shall notify the applicant within 30 days if an application is deficient; and what is needed to correct the deficiency. Once the application is complete, and upon completion of any investigation conducted pursuant to section 4207 of the Business and Professions Code, the board will notify the applicant within 60 days of a license decision.
(d) Before expiration of a pharmacy technician license, a pharmacy technician must renew that license by payment of the fee specified in subdivision (r) of section 4400 of the Business and Professions Code.

Note: Authority cited: Sections ~~163.5,~~ 4005, ~~4007, 4038,~~ 4115, and 4202, ~~4207 and 4400,~~ Business and Professions Code. Reference: Sections 144, 144.5, 163.5, 4005, 4007, 4038, 4115, 4202, 4207, 4400 and 4402~~ and 4400~~, Business and Professions Code; and Section 11105, Penal Code.

Proposal to amend §1793.6 of Article 11 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1793.6. Training Courses Specified by the Board.

A course of training that meets the requirements of Business and Professions Code section 4202 (a)(2) is:
(a) Any pharmacy technician training program accredited by the American Society of Health--System Pharmacists,
(b) Any pharmacy technician training program provided by a branch of the federal armed services for which the applicant possesses a certificate of completion, or
(c) (1) Any other course that provides a training period of at least 240 hours of instruction covering at least the following:
(~~1~~ A) Knowledge and understanding of different pharmacy practice settings.

(~~2~~ B) Knowledge and understanding of the duties and responsibilities of a pharmacy technician in relationship to other pharmacy personnel and knowledge of standards and ethics, laws and regulations governing the practice of pharmacy.
(~~3~~ C) Knowledge and ability to identify and employ pharmaceutical and medical terms, abbreviations and symbols commonly used in prescribing, dispensing and record keeping of medications.
(~~4~~ D) Knowledge of and the ability to carry out calculations required for common dosage determination, employing both the metric and apothecary systems.
(~~5~~ E) Knowledge and understanding of the identification of drugs, drug dosages, routes of administration, dosage forms and storage requirements.
(~~6~~ F) Knowledge of and ability to perform the manipulative and record-keeping functions involved in and related to dispensing prescriptions.
(~~7~~ G) Knowledge of and ability to perform procedures and techniques relating to manufacturing, packaging, and labeling of drug products.
(2) In addition to the content of coursework specified in subdivision (c)(1), the course of training must also satisfy all of the following:
(A) Prior to admission to the course of training, an administrator or instructor must conduct a criminal background check and counsel applicants to the program about the negative impact to securing licensure if the background check reveals criminal history.
(B) Administer at least one drug screening to each student to evaluate use of illicit drugs or use of drugs without a prescription. The results of any screen shall be considered as part of the evaluation criteria to determine (1) acceptance into the course of training, or (2) appropriateness for continuation in the course of training. An administrator or instructor shall counsel students about the negative impact of a positive drug screen on eligibility for licensure.
(C) Require students to be at least 18 years of age prior to the beginning of instruction.
(D) Require a final examination that demonstrates students' understanding and ability to perform or apply each subject area identified in subsection (1) above.

Authority cited: Sections 4005, ~~4007, 4038, 4115,~~ and 4202, Business and Professions Code. Reference: Sections 4005, 4007, 4038, 4115, 4115.5, and 4202, Business and Professions Code.

Proposal to add §1793.65 of Article 11 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1793.65 Pharmacy Technician Certification Programs Approved by the Board.

(a) Pursuant to Business and Professions Code section 4202(a)(4), the board approves the pharmacy technician certification program offered by:
(1) The Pharmacy Technician Certification Board, and
(2) The National Healthcareer Association.
(b) Approval of these programs is valid through December 31, 2021.

Note: Authority cited: Business and Professions Code Sections 4005 and 4202. Reference: Business and Professions Code Sections 4038 and 4202.

Attachment 6: Board Approved Regulations Undergoing Pre-Notice Review by the Department of Consumer Affairs or the Business, Consumer Services and Housing Agency

A hardcopy of the proposed pharmacy technician application will be made available at the meeting or upon request. Requests may be emailed to Debbie.Damoth@dca.ca.gov.

Pharmacy Ownership, Management, and Control, Including Through Trusts
16 CCR § 1709

Title 16. Board of Pharmacy
Proposed Text

To Amend Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1709. ~~Names of Owners and Pharmacist In Charge~~ Disclosure and Notification Requirements

(a) Each ~~permit~~ license issued by the board to operate a pharmacy shall reflect ~~show~~ the name and address of the pharmacy, the form of ownership ~~(individual, partnership or corporation)~~ and the pharmacist-in-charge. Each pharmacy shall, in its initial application and on the annual renewal form, report the name of the pharmacist-in-charge, the names of all owners and the names of the corporate officers (if a corporation). Any changes in the pharmacist-in-charge, or the owners, or corporate officers shall be reported to the ~~B~~board within 30 days.

(b) Any transfer, in a single transaction or in a series of transactions, of 10 percent or more of the beneficial interest in a business entity licensed by the board to a person or entity who did not hold a beneficial interest at the time the original ~~permit~~ license was issued, shall require written notification to the board within 30 days.

(c) A license issued by the board shall not be transferred from one owner to another. The following shall constitute a change of ownership ~~transfer of permit~~ and shall require a new application for ~~a change of ownership~~ licensure:

(1) any transfer of a beneficial interest in a business entity licensed by the board, in a single transaction or in a series of transactions, to any person or entity, which transfer results in the transferee's holding 50% or more of the beneficial interest in that license. A change of ownership application shall be filed with the board in advance of the proposed transaction taking place.

(d) If any beneficial interest of the pharmacy is held in trust, the applicant, licensee, or any person with management or control of the pharmacy, shall do the following:

(1) In addition to the requirements in subdivision (a), as part of their application and annual renewal, report the name of any other person in any position with management or control of the pharmacy.

(2) As part of the application, disclose the full name of the trust, and provide to the board a complete copy of, and any amendments to the trust document. A trust document and any related amendments shall be considered confidential financial documents by the board.

(3) As part of the renewal, provide to the board a complete copy of any amendments to the trust document made after submission of the original application.

(4) Include in the application and the annual renewal, the name, address and contact information for each grantor, settlor, trustee, and trust protector, as applicable.

(5) The application and annual renewal shall also include the name, address, and contact information for each named beneficiary of the trust, who is age 18 or older.

(6) Notify the board in writing within 30 days of all the following:

(A) A change in trustee, protector or any other person with management or control of the pharmacy.

(B) Any change in the beneficiaries of the trust, where the beneficiary is age 18 or older.

(C) The revocation of the trust.

(D) The dissolution of the trust.

(E) Any amendment to the trust since the original application.

(F) Any change in the character of the trust, including, but not limited to, the trust changing from revocable to irrevocable.

(e) An application may be denied, or a license may be suspended or revoked based on the failure of any individual required to be disclosed to the board to qualify pursuant to the provisions of sections 4302, 4307 and 4308 of the Business and Professions Code.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4035, 4058, 4110, 4111, 4112, 4113, 4120, ~~4124~~, ~~4130~~, ~~4133~~, ~~4141~~, ~~4149~~, ~~4160~~, ~~4161~~, ~~4196~~, 4201, 4302, ~~4304,~~ 4305, 4307, 4308, and 4330, Business and Professions Code.