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LICENSING COMMITTEE REPORT

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During the meeting members will received a summary of the Committee's work at its January 24, 2023, Committee Meeting.

a. Discussion and Consideration of Possible State Protocol Consistent with Provisions of Business and Professions Code Section 4052.01 as amended in Senate Bill 1259 (Chapter 245, Statutes of 2022) Including Proposed Amendment to Title 16, California Code of Regulations Section 1746.3

Relevant Law

Effective January 1, 2023, amendments to <u>Business and Professions Code</u> <u>section 4052.01</u> will provide the authority for a pharmacist to furnish federal Food Drug and Administration approved opioid antagonist in accordance with standardized procedures or protocols developed and approved by the Board and the Medical Board of California, in consultation with the California Society of Addiction Medicine, the California Pharmacists Association, and other appropriate entities. The section further details areas that must be included in the standardized procedures.

<u>California Code of Regulations Section 1746.3</u> establishes the requirements of the standardized procedures established for a pharmacist to furnish naloxone hydrochloride pursuant to section 4052.01.

Background

In 2014, pharmacists were granted authority to furnish naloxone hydrochloride in accordance with standardized procedures established. Following enactment of the statute, the Board, as required in the statute, developed the regulation necessary to implement the statute.

Subsequent to these authorities, additional access points have been established for patients to access naloxone hydrochloride, including authority

for pharmacies to furnish naloxone hydrochloride to law enforcement agencies and to school districts, county office of education, or charter schools under specified conditions.

The California Department of Public Health issued a <u>standing order</u> that allows libraries and other community organizations that are currently working with a physician to obtain and distribute naloxone to a person at risk of an opioid-related overdose or to a family member, friend, or other person in a position to assist; and allow for the administration of the naloxone.

In April 2021, the <u>FDA</u> announced its approval of higher dose of naloxone hydrochloride nasal spray. The FDA has approved naloxone hydrochloride nasal spray products in 2mg, 4 mg and 8 mg naloxone nasal spray products and noted that naloxone is a medicine that can be administered by individuals with or without medical training to help reduce opioid overdose deaths.

As products are approved by the FDA, it appears appropriate to evaluate the Board's current regulation to establish flexibility in the regulation for the furnishing of additional opioid antagonists approved by the FDA.

As discussed during the October 2022 Meeting, staff worked with Dr. James Gasper, PharmD., Psychiatric and Substance Use Disorder Pharmacist, developing draft of revisions to California Code of Regulations section 1746.3. As required in the statute, on November 18, 2022, the draft regulation language was provided to California Society of Addiction Medicine (CSAM), the Medical Board of California and the California Pharmacists Association. Comments received thus far from CSAM and the Medical Board did not identify any concerns with the language. CSAM offered one specific comment, provided below:

 Suggest consideration of moving the 2b statement for overdose reversal earlier.

Comments have not been received from the California Pharmacists Association.

<u>Summary of Committee Discussion and Action</u>

During the meeting members reviewed a summary of the proposed changes detailed below:

1. "Naloxone hydrochloride: is replaced with the generic term "opioid antagonist"

- 2. Training requirement is updated to allow for completion of training completed in a Board recognized school of pharmacy.
- 3. Removes the screening criteria. Any individual seeking an opioid antagonist should have access, similar to the expansion of such products in schools and libraries.
- 4. Product selection should be determined by the pharmacist using professional judgement and not limited to specified forms of an FDA approved product form.
- 5. Labeling requirements should be consistent with other prescription medications dispensed. The Board should no longer be posting sample labels.
- 6. Fact sheets are not necessary as the FDA approved medication guide will provide the necessary information.
- 7. Notification requirements have been updated to only require notification at the request of the patient.
- 8. Documentation and privacy requirements should be consistent with any other product dispensed by the pharmacy.

Members spoke in support of the proposed regulation text. Further, public comment also suggested support for the proposed changes.

Committee Recommendation: Recommend initiation of a rulemaking to amend CCR section 1746.3 as proposed to be amended. Authorize the executive officer to further refine the language consistent with the policy discussions, including those of the Medical Board of California, and as may be required by control agencies (DCA or Agency) and to make any non-substantive changes prior to initiation of the rulemaking. Further, if no adverse comments are received during the 45-day comment period and no hearing is requested, authorize the executive officer to take all steps necessary to complete the rulemaking and adopt the proposed regulation at section 1746.3 as noticed for public comment.

Attachment 1 includes a copy of the proposed language.

Should members voted in support of the Committee's recommendation, Executive Officer Sodergren will present the proposed regulation changes to the Medical Board of California during is February 9-10, 2023, Board Meeting.

b. Discussion and Consideration of Possible State Protocol to Facilitate Pharmacist Provided Medication-Assisted Treatment Pursuant to Business and Professions Code section 4052(a)(14), Including Proposed Addition of Title 16, California Code of Regulations Section 1746.6

Relevant Law

BPC section 4052(a)(14) establishes authority for a pharmacist to provide medication-assisted treatment pursuant to a state protocol, to the extend authorized by federal law.

Background

Medication-assisted treatment (MAT) is used to treat substance use disorders as well as sustain recovery and prevent overdose. Medications used in MAT are approved by the Food and Drug Administration and MAT programs are clinically driven and tailored to meet each patient's needs. As published by SAMSHA, "Research shows that a combination of medication and therapy can successfully treat these disorders, and for some people struggling with addiction, MAT can help sustain recovery. MAT is also used to prevent or reduce opioid overdose."

In 2021, as part of the Board's sunset measure, pharmacist authority was expanded to allow pharmacists authority to provide MAT pursuant to a state protocol.

More recently, President Biden signed legislation to expand access to MAT. Recently SAMHSA has published information about the removal of the DATA Waiver (X-Waiver) Requirement. Information published includes that all practitioners who have a current DEA registration that includes Schedule III authority, may now prescribe buprenorphine for Opioid Use Disorder in their practice site if permitted by applicable state law and SAMHSA encourages them to do so.

Summary of Committee Discussion and Action

During the meeting members will have the first opportunity to review a draft protocol developed to facilitate implementation of the MAT authority. The protocol was developed in consultation with experts in the field including:

- Dr. James Gasper, BCPP, Psychiatric and Substance Use Disorder Pharmacist, California Department of Health Care Services
- 2. Dr. Talia Puzantian, BCPP, Professor of Clinical Sciences, KGI School of Pharmacy and Health Sciences
- 3. Dr. Michelle Geier, BCPP, Psychiatric Pharmacy Supervisor, San Francisco Department of Public Health, Behavioral Health Services

Members generally spoke in support of the draft proposal. Members discussed the provisions related to requiring a confidential patient care area and whether the requirements should require a private patient care area. Member updated the language to require a "private patient care area"; however, expressed concern that if such a requirement creates a barrier, it

may be appropriate to change the language to a "confidential patient care area"

Public comment spoke in support of the draft regulation but expressed concern with the change in the language to require a private patient care area.

Committee Recommendation: Recommend initiation of a rulemaking to add CCR section 1746.6 as proposed. Authorize the executive officer to further refine the language consistent with the policy discussions and as may be required by control agencies (DCA or Agency) and to make any non-substantive changes prior to initiation of the rulemaking. Further, if no adverse comments are received during the 45-day comment period and no hearing is requested, authorize the executive officer to take all steps necessary to complete the rulemaking and adopt the proposed regulation at section 1746.6 as noticed for public comment.

Attachment 2 includes a copy of the proposed language.

c. Discussion and Consideration of Pharmacist Provided HIV Preexposure and Postexposure Prophylaxis, Including Presentations

Relevant Law

<u>BPC 4052</u> generally establishes the scope of practice for pharmacists. Included in the provisions are:

- Authority to initiate, adjust, or discontinue drug therapy for a patient under a collaborative practice agreement with any health care provide with prescriptive authority.
- Authority to perform procedures or functions in a licensed health care facility as authorized in Section 4052.1.
- Authority to perform procedures or functions as part of the care provided by a health care facility, a licensed clinic in which there is physician oversight, and others as specified and as authorized in Section 4052.2.
- Furnish medications as described including HIV preexposure prophylaxis as authorized in Section 4052.02 and HIV postexposure prophylaxis as authorized in Section 4052.03.
- Initiate, adjust, or discontinue drug therapy for a patient under a collaborative practice agreement as specified.

BPC <u>4052.02</u> further defines the provisions for pharmacist authority related to initiating and furnishing HIV preexposure prophylaxis as defined. As required by this section, prior to furnishing preexposure prophylaxis a pharmacist must complete specified training. The section explicitly provides that a pharmacist

shall furnish at least a 30-day supply, and up to a 60-day supply under specified conditions, including:

- 1. The patient is HIV negative.
- 2. The patient does not report any signs or symptoms of acute HIV infection.
- 3. The patient does not report taking any contraindicated medications.
- 4. The pharmacist provides counseling to the patient on the ongoing use of preexposure prophylaxis and the importance of timely testing and treatment as applicable for HIV, renal function, hepatitis B, hepatitis C, sexually transmitted diseases, and pregnancy.
- 5. The pharmacist maintains records.
- 6. The pharmacist does not furnish more than a 60-day supply as specified.
- 7. The pharmacist notifies the patient's primary care providers or meets other requirements.

BPC <u>4052.03</u> further defines the provisions for pharmacist authority related to initiating and furnishing HIV postexposure prophylaxis under specified conditions including completion of specified training and the following conditions:

- 1. The pharmacist screens the patient and determines exposure occurred within the previous 72 hours and the patient meets clinical guidelines established by the CDC.
- 2. The pharmacist either provides testing, or determines the patient is willing to undergoing testing.
- 3. The pharmacist provides mandatory consultation.
- 4. The pharmacist notifies the patient's primary care provider or meets other requirements.

CCR Section $\underline{1747}$ establishes the mandatory elements of a training to meet the requirements of Sections $\underline{4052.02}$ and $\underline{4052.03}$.

Background

Senate Bill 159 (Chapter 532, Statutes of 2019) established authorization for pharmacists to furnish preexposure and post exposure HIV prophylaxis (PrEP and PEP) as generally described above. This legislation sought to expand access to life saving HIV prevention medications.

As required by the statute, the Board's emergency regulations became effective April 30, 2020, with permanent regulations becoming effective June 8, 2021.

Following implementation of the regulation the Board and several other entities developed training programs that could be completed to meet the requirements of the statute and regulation.

As part of the October 2022 meeting, members received a presentation on research underway on pharmacists—furnished HIV prevention. The Board will receive a presentation on the outcome of the research when available.

In addition to providing HIV PrEP and PEP under the provisions established in Senate Bill 159, pharmacist may also provide such services under a collaborative practice agreement as well through traditional pharmacist dispensing.

Summary of Presentations and Committee Discussion

During the meeting members received presentations on pharmacist-driven models used to expand access to HIV PrEP and PEP.

- Presenters include Dr. Maria Lopez, AAHIVP, President, Clinical Pharmacy Services, Residency Program Director, Mission Wellness Pharmacy.
- Dr. Clint Hopkins, APh, CEO Pucci's Pharmacy / Pucci's LTC Pharmacy

Both presentations described the models used for providing HIV PrEP and PEP services and the barriers to care. Common themes arose including reimbursement challenges that exist for both insured and uninsured patients as well as the 60-day limit on furnishing PrEP. Members were advised of approaches taken in other states including Colorado and Nevada that appear to have mandated laboratory reimbursement.

Following the presentations, members highlighted the unique access point pharmacists provide to expand care for patients. Members noted there appears to be actions the Board can take to remove barriers to care while noting that actions must also be taking by others including payors to fully actualize expanded access to care. Members indicated it may be appropriate to convene a dedicated meeting to discuss the challenges experienced with reimbursements.

The presentation slides are included in **Attachment 3**.

d. Discussion, Consideration and Possible Action on Discontinuance of Business by a Pharmacy and Potential Changes to Title 16, California Code of Regulations Section 1708.2

Relevant Law

<u>BPC 4333</u> generally provides in part that all prescriptions filled by a pharmacy and all other records required shall be maintained on the premises and available for inspection. Further, in cases where the pharmacy discontinues business, these records shall be maintained in a board-licensed facility for at least three years.

<u>CCR Section 1708.2</u> requires any permit holder to contact the Board prior to transferring or selling any dangerous drugs, devices, or hypodermic inventory as a result of a termination of business or bankruptcy proceedings and shall follow official instructions given by the Board applicable to the transaction.

<u>Background</u>

The Board's current <u>discontinuance of business</u> provisions require a licensee to notify the Board and provide specified information; however, there are no provisions established to establish conditions for continuity of patient care. Related to this, at times staff receive complaints from consumers and policy makers in two general areas:

- A pharmacy has closed, and a patient cannot receive a refill because they are unable to contact the pharmacy to request a prescription transfer.
- 2. A pharmacy has closed and transferred patient prescription refills to another pharmacy not of the patient's choosing.

In both such scenarios, patient care is impeded and patients many times are required to seek a new prescription from their prescriber.

The Board's Disciplinary Guidelines establish requirements for continuity of patient care in the event a premises license is surrendered or revoked, yet no similar requirements exist for licenses discontinuing business. Specifically, the guidelines provide:

Respondent shall also, by the effective date of this decision, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five (5) days of its provision to the pharmacy's ongoing patients, Respondent shall provide a copy of the written notice to the board. For the purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty days.

Prior Committee Discussion

As part of its last meeting members considered the Board's current discontinuance of business requirements as well as several policy questions detailed below.

- 1. Should the Board consider establishing requirements to facilitate continuity of patient care in the event of a pharmacy closure?
- 2. Should the Board consider establishing a timeframe within which notification to patients is required in advance of a pharmacy closure?
- 3. Should the Board consider specifying some of the elements of such a notification i.e., the process to request a prescription transfer, where pharmacy records will be transferred to and maintained, or any other options the patient does or should be able to provide input?
- 4. Should the Board be provided with a copy of the notification?
- 5. Should the Board provide expectations on prescriptions remaining in the will call area and provisions for reversing billing, etc.
- 6. There are some pharmacy transactions where a pharmacy sells a portion of its business to another pharmacy, e.g., sells the portion of the pharmacy operations related to prescription dispensing but maintains the compounding portion of the business. In such an instance should the Board establish notification requirements to patients in advance of the transaction to ensure patients are aware of the transition in care?

After consideration of the issue and policy questions, members determined changes to the current discontinuance of business requirements was appropriate and requested that staff develop proposed regulation language.

Summary of Committee Discussion and Action

During the meeting members reviewed the draft regulation language. Proposed changes include:

- Establish a requirement that the pharmacy provide a written notice in advance of the closure that includes specified information include including:
 - a. The name of the patient or representative
 - b. The name and address of the pharmacy closing
 - c. The name of the pharmacy where patient records will be transferred
 - d. Information on how to request a prescription transfer prior to closure of the pharmacy
- 2. Establish a requirement that all prescriptions for which reimbursement was sought that are not picked up by the patients must be reversed.
- 3. The Board must be provided a copy of the notice.
- 4. Requires the pharmacist-in-charge (PIC) or the owner to certify compliance as specified.

Members also considered a few additional policy questions.

- 1. The time frame within which the notice must be provided to impacted patients.
 - After consideration members determined notice should be provided at least 30 days in advance.
- 2. The parameters defining the patients that must receive the notice (i.e., patients that received a prescription filled within the last 365 days.)
 - Members considered the appropriate period of time. Members noted that some patients live part time in different areas. As such members determined that any patient that has received a patient within the past year should receive the notice.
- 3. Does the committee wish to specify the type of written notice (e.g. via email, written correspondence, etc.) is acceptable or does the committee believe any form of written communication is sufficient?
 - Members determined that notification should not be make too complicated but would most likely be made in writing.

Public comment spoke in support of providing flexibility within the provisions of providing written notice. Public comment also asked the Board to describe what it intends to do with the notification it receives.

Committee Recommendation: Recommend initiation of a rulemaking to amend CCR section 1708.2 as proposed and further refined by the Committee. Authorize the executive officer to further refine the language consistent with the policy discussions and as may be required by control agencies (DCA or Agency) and to make any non-substantive changes prior to initiation of the rulemaking. Further, if no adverse comments are received during the 45-day comment period and no hearing is requested, authorize the executive officer to take all steps necessary to complete the rulemaking and adopt the proposed regulation at section 1708.2 as noticed for public comment.

Attachment 4 includes a copy of the proposed amendments to CCR section 1708.2.

e. Discussion and Consideration of Legal Requirements for Nonresident Pharmacies Including Possible Statutory Change to Require Licensure by the Pharmacist-in-Charge

Relevant Law

BPC Section 4112 provides that any pharmacy located outside this state that provides services into California shall be considered a nonresident pharmacy. Further this section requires licensure as a nonresident pharmacy. The section also established required disclosure of specified information. Subsection (g) provides that a nonresident pharmacy shall not allow a pharmacist whose license has been revoked by the board to provide pharmacy-related services to a person residing in California.

Background

As part of the application process, the nonresident pharmacy is required to provide the name of the designated pharmacist-in-charge. Under current law, the PIC is not required to hold a license in California.

The National Associations of Boards of Pharmacy Model Rules include that, "The 'Practice of Pharmacy in this State' includes shipping Prescription Drugs into this State from another jurisdiction. However, this is not meant to be construed as a licensure requirement for every Pharmacist that is employed at a Nonresident Pharmacy unless they are specifically engaged in the Practice of Pharmacy and provide services to residents in this state."

States have varying provisions related to the licensure requirements for pharmacists providing services into their respective jurisdictions. As an example:

- Oregon law provides that every non-resident pharmacy shall designate an Oregon licensed Pharmacist-in-Charge, who shall be responsible for all pharmacy services provided to residents in Oregon, and to provide supervision and control in the pharmacy.
- <u>Massachusetts</u> is developing regulations to regulate nonresident pharmacies. As part of the proposed rules the nonresident pharmacy will be required to designate a pharmacist that holds a Massachusetts pharmacist license.
- <u>lowa</u> provides that every nonresident pharmacy is required to have a PIC who is either currently licensed to practice pharmacy in lowa or who is registered with the Board. If the PIC is not currently licensed to practice pharmacy in lowa and is not registered with the Board, the PIC must apply for registration as a nonresident PIC. As part of the registration process, the PIC must complete the Board's training module, "lowa Pharmacy Law Bootcamp: Education for lowa Nonresident Pharmacists," prior to submission of the application.

- Maryland provides that a nonresident pharmacy shall have a
 pharmacist on staff licensed by the Maryland Board of Pharmacy who is
 designated as the pharmacist responsible for providing pharmaceutical
 services to patients in the state.
- <u>Virginia</u> requires a nonresident pharmacy to designate a pharmacist in charge who is licensed as a pharmacist in Virginia and is responsible for the pharmacy's compliance.

Over the years the Board has disciplined nonresident pharmacies for violations of California Law. As an example, the Board disciplined <u>Walgreens</u>, including two nonresident pharmacy permits. At times, these nonresident pharmacies have argued that their actions were in accordance with the pharmacy law of the state the pharmacy is located within. The Board has also issued citations against nonresident pharmacies, as an example <u>ESI Mail Pharmacy, Inc.</u>, for violations of California law.

Prior Committee Discussion

During its October meeting the Committee noted the Board's efforts to strengthen the requirements for a PIC, to ensure pharmacists appointed as a PIC in California have a full understanding of the requirements of a PIC and to empower such individuals to exercise control over the pharmacy operations. Members also considered if changes were appropriate to the current regulation of nonresident pharmacies is appropriate to ensure that Californians who received prescription drugs from nonresident pharmacies have protections that are similar to those received by resident pharmacies in California.

Members spoke in support of establishing a requirement for a California licensed pharmacist to be the PIC of a nonresident pharmacy providing services to California patients. Members noted some potential challenges with gaps in care if a nonresident pharmacy does not have such an individual to serve in such a capacity as well as the need for a transition period to allow for nonresident pharmacies to achieve compliance.

<u>Summary of Committee Discussion and Action</u>

During the meeting members considered draft statutory language to establish a requirement for PIC of a nonresident pharmacy to be licensed in California.

Members spoke in support of the draft language.

Public comment included concerns with the proposal indicating that the requirement could have negative consequences including that it could result in negative impacts to patients. The Committee also received public comment in support of the proposal.

Committee Recommendation: Recommend sponsorship of changes to Business and Professions Code section 4112 related to legal requirements for nonresident pharmacies to require licensure by the pharmacist-in-charge consistent with the language presented.

Attachment 5 includes a copy of the draft statutory language.

f. Discussion, Consideration and Possible Action on Continuing Education Requirements for Pharmacist and Pharmacy Technicians, Including Development of Regulation Language to Facilitate Implementation of Recently Enacted Legislation

Relevant Law

<u>BPC section 4202</u> establishes the licensure requirements for a pharmacy technician. As recently amended, this section will require a pharmacy technician to complete one hour of continuing education in cultural competency during the preceding renewal.

<u>BPC section 4231</u> establishes the renewal requirements for pharmacists. As recently amended, this section will require pharmacists to complete at least one hour of continuing education in a cultural competency course as part of the required CE for each renewal cycle.

<u>CCR Section 1732.5</u> further defines the continuing education renewal requirements for pharmacists.

Background

Assembly Bill 2194 (Ward, Chapter 958, Statutes of 2022) requires, effective January 1, 2024, pharmacists and pharmacy technicians must complete at least one-hour course in cultural competency during the two years preceding the renewal application period. Further, the provisions of the measure prohibit the Board from renewing a pharmacist or pharmacy technician license unless the individual has completed the course.

Prior Discussion

As part of the October 2022 Enforcement and Compounding Committee Meeting members discussed implementation of AB 2194 and recommended that implementation be spearheaded by the Licensing Committee. Members noted the need to amend existing regulation CCR 1732.5 to update the renewal requirements for pharmacists and the need to establish new regulation to define the renewal requirements for pharmacy technicians.

During this discussion, it was noted that the Board's prior action to consolidate all CE related requirements for pharmacists into a single regulation was previously initiated, but subsequently placed on hold in part because of the pending changes in AB 2194.

Summary of Committee Discussion and Action

During the meeting members reviewed the draft regulation language proposing amendments 1732.5 to implement the provisions of AB 2194 for pharmacists to complete a course on cultural competency as well as consolidate the various CE requirements for pharmacists performing specified functions.

The Committee also considered the proposed language establishing new regulations defining the continuing education requirements for pharmacy technicians that mirror the process used for pharmacist renewal.

Members generally spoke in support to of the language but requested that staff confirm if language was sufficiently specific to ensure the course covered the required content.

Public comment spoke in support leaving the proposed language as presented.

Committee Recommendation: Recommend initiation of a rulemaking to amend CCR section 1732.5 and add section 1732.8 as proposed and further refined by the Committee. Authorize the executive officer to further refine the language consistent with the policy discussions and as may be required by control agencies (DCA or Agency) and to make any non-substantive changes prior to initiation of the rulemaking. Further, if no adverse comments are received during the 45-day comment period and no hearing is requested, authorize the executive officer to take all steps necessary to complete the rulemaking and adopt the proposed regulation at sections 1732.5 and 1732.8 as noticed for public comment.

Attachment 6 includes a copy of the proposed amendments to CCR section 1732.5 and addition of CCR 1732.8 with clarifying language to highlight to licensees that specified areas of content must be included.

g. Discussion and Consideration of Business and Professions Code section 4111 <u>Relevant Law</u>

<u>BPC Section 4111</u> provides that the Board shall not issue or renew a license to conduct a pharmacy to:

1. An individual authorized to prescribe

- 2. A person who shares a community or other financial interest with a prescriber.
- 3. Any corporation that is controlled by, or in which 10 percent or more of the stock is owned by a person or persons prohibited from pharmacy ownership.

This section further specifies that the Board may require any information reasonably necessary for the enforcement of this section.

Background

California is a community property state. This means that generally property acquired by either spouse during a marriage is presumed to be equally owned by both spouses. There are some exceptions, such as prenuptial agreements, where property acquired may not be community property depending on the agreement of the parties to a valid prenuptial agreement. However, the existence of a prenuptial agreement in and of itself may or may not remedy the financial interest that each spouse has in the other's businesses. For example, the money earned by one spouse in their pharmacy would likely be used to support the home, family, or lifestyle of the couple. Therefore, while there may be no specific community property interest as defined in the Family Code, there may still be a community or financial interest that would apply under this code section.

As part of the application process for a pharmacy, the Board requires disclosure of ownership information. To confirm compliance with the above provisions, the Board requests information specifically related to officers and owners of individuals authorized to prescribe in California.

Historically as part of the application process, if an applicant disclosed a familial relationship with a prescriber, the Board would inquire about the nature of the relationship to confirm compliance with Pharmacy Law prior to making a licensing decision. For a number of years, the Board accepted representations from the applicant that the prescriber did not have any financial or community interest in the pharmacy. Unfortunately, this was something of a shallow view of the law and failed to take into account the realities of family life, the requirement of the Family Code that spouses owe a duty of care towards each other, and the conflicts of interest that the statute was designed to protect.

As the Board's application and assessment process evolved, most notably in response to changes in the ownership assessment process, Board staff began looking deeper into the financial arrangements between the applicant spouse and the prescriber spouse and came to the realization and understanding that the pre- or post-nuptial agreements would not necessarily resolve the issue of having a community or financial interest in the pharmacy.

The sole focus on the financial aspects of the property does not take into account policy considerations such as financial incentives for a prescriber to direct prescriptions to their spouses' pharmacy, or pharmacists exercising their duty of corresponding responsibility and whether that duty would be impacted when reviewing a prescription written by a pharmacist's spouse of the spouse's practice group.

Prior Committee Discussion

During the July 2022 Committee Meeting, members discussed the issue of prohibited ownership related a prescriber's spouse. Following discussions and consideration of possible statutory changes, BPC section 4111 could be made that would continue to meet the legislative intent intact, while creating flexibility for an otherwise authorized individual to own or operate a pharmacy. Members noted agreement with the proposed language and noted support if such a change was pursued.

During that meeting, public comment suggested that the Committee consider further expanding authority for pharmacists that furnish medications be allowed to owner a pharmacy.

<u>Summary of Committee Discussion</u> and Action

During the meeting members considered draft language prepared by staff to further amend BPC section 4111 to expand pharmacist ownership provisions. As drafted, the proposal would expand provisions to allow a pharmacist that is authorized to issue a drug order under specified conditions.

Committee Recommendation: Recommend sponsorship of changes to Business and Professions Code section 4111 related to ownership prohibitions consistent with the language presented.

Attachment 7 includes the draft statutory language approved by the Committee.

h. Discussion and Consideration of Provisions for Remote Processing

Relevant Law

<u>BPC 4071.1, subdivision (a)</u> permits a pharmacist (or a prescriber or prescriber's agent) to "electronically enter a prescription or an order, as defined in <u>Section 4019</u>, into a pharmacy's or hospital's computer from any location outside of the pharmacy or hospital with the permission of the pharmacy or hospital." This is known as "remote order entry."

<u>Background</u>

As part of the Board's response to the COVID-19 public health emergency and the initial need for social distancing, a "Remote Processing Waiver" was approved by the Board. This waiver is scheduled to expire May 28, 2023. Under the provisions of the waiver, legal authorization for remote processing was expanded to allow for greater flexibility under pandemic conditions. "Remote Processing" is defined to mean the entering of an order or prescription into a computer from outside of the pharmacy or hospital for a licensed pharmacy. The Waiver says that, in addition to the provisions of BPC section 4071.1, pharmacists performing remote processing may also receive, interpret, evaluate, clarify, and approve medication orders and prescriptions, including medication orders and prescriptions for controlled substances classified in Schedule II, III, IV or V. Under the Waiver, remote processing may also include order entry, other data entry, performing prospective drug utilization review, interpreting clinical data, insurance processing, performing therapeutic interventions, providing drug information services, and authorizing release of medication for administration. The Waiver does not permit dispensing of a drug or final product verification by remote processing. Further, the Waiver expands the provisions of section 4071.1 to allow for remote processing by pharmacy technicians and pharmacy interns to include nondiscretionary tasks, including prescription or order entry, other data entry, and insurance processing of prescriptions and medication orders for which supervision by a pharmacist is provided using remote supervision via technology that, at a minimum, ensures a pharmacist is (1) readily available to answer questions of a pharmacy intern or pharmacy technician; and (2) verify the work performed by the pharmacy intern or pharmacy technician.

There are certain limitations and qualifiers regarding the Waiver, including that a pharmacist, pharmacy technician, or pharmacist intern relying on the Waiver must be licensed in California, and must be engaged in processing medication orders or prescriptions from a remote site or on the premises of a California-licensed pharmacy. The pharmacy must have authorized remote processing and must have appropriate policies and procedures as well as adequate training on those policies and procedures.

Last year the Board voted to sponsor legislation to make certain provisions of the remote processing waiver permanent. The Board sponsored legislation, but the legislation did not move because of significant opposition.

During the October 2022 Board meeting, members received public comment requesting that the Board schedule discussion on the issue.

<u>Summary of Committee Discussion and Action</u>

During the meeting members considered the issue and a number of policy questions. Below is a brief summary of the discussion is provided below

identified under the subheading. It is recommended that during the meeting the Board provide general guidance to members on some larger policy questions.

- 1. Does the Board believe permanent changes to the Board current remote processing provisions are appropriate?
- Given federal requirements for hospital pharmacy patient care should the Board prioritize a legislative solution for inpatients and request that the Licensing Committee continue its policy discussion on possible expansion for outpatient prescriptions. **Note**: The last day for a bill to be introduced for the session is February 17, 2023.
- 3. Does the Board wish to provide policy direction to the Committee on specific elements it believes must be included in any proposal related to expanding current remote processing provisions for outpatient prescription processing (including mail order, specialty, etc.)?

Attachment 8 includes possible statutory language or consideration should members believe the answers to question 1 and 2 above are affirmative. Also, included in the attachment are comments received in advance of the Licensing Committee.

Policy Questions Considered and Summary of Discussion

1. After May 28, 2023, is there any continuing need for expanded remote processing authority? Should the law revert to the allowance under BPC section 4071.1, subdivision (a), only for "remote order entry" by pharmacists (and prescribers and their agents)? Is even that authority for pharmacist "remote order entry" still necessary? Should this answer depend on the type of prescription, outpatient versus inpatient?

Members noted the need in hospitals where CMS requirements provided that nonemergency orders must be reviewed by a pharmacist prior to administration and concerns with negative impacts on patient care for hospitals that do not have a pharmacist onsite at all times, including in critical access hospitals. Members also questioned if the workload in community pharmacy still necessitates provisions for remote work.

Public comment spoke in support of a permanent solution noting benefits to pharmacists, including for some pharmacists with health and mobility issues. Commenters representing hospital pharmacies, noted the unique requirements for hospitals and the need to meet federal requirements, noting that inaction now could delay patient care for patients in hospitals.

Public comment was received from several individuals who indicated that they may lose their employment if provisions end because they work in Northern California, but the pharmacy is located in Southern California.

Public comment was also received in opposition to provisions that would allow for remote procession from unlicensed locations.

2. What use was being made of the "remote order entry" provision prior to the Waiver, and the pandemic that prompted the Waiver? What do the stakeholders anticipate being the need for remote order entry or remote processing going forward? Is there something beyond what is already permitted by BPC section 4071.1 that will be required?

Members noted that it appears that some licensees were operating outside of the provisions of the law in advance of the waiver.

Members comments that opportunities from the pandemic have provided an opportunity to learn about remote processing.

Members expressed concern with security including potential for individuals accessing protected health care information from an unsecure network or in a public place. Members noted some concerns with allowing remote processing from unlicensed sites and potential concerns with adherence to labor laws.

- 3. Have operations under the Waiver revealed benefits to expanded remote processing authority that are worth carrying forward into a post-pandemic regulatory environment?
 - o Is it desirable to permit pharmacists to also remotely receive, interpret, evaluate, clarify, and approve medication orders and prescriptions, including medication orders and prescriptions for controlled substances classified in Schedule II, III, IV or V?
 - o Is it desirable to permit pharmacists to remotely perform tasks like order entry, other data entry, prospective drug utilization review, interpreting clinical data, insurance processing, performing therapeutic interventions, providing drug information services, and authorizing release of medication for administration?

- Is it desirable to permit pharmacy technicians and pharmacist interns to remotely perform nondiscretionary tasks, including prescription or order entry, other data entry, and insurance processing of prescriptions and medication orders under supervision by a pharmacist that is also remote, using technology that ensures a pharmacist is (1) readily available to answer questions of a pharmacy technician or pharmacist intern; and (2) verifies the work performed by the pharmacy technician or pharmacist intern.
- Are there other functions that pharmacists or other pharmacy staff should be allowed to perform remotely or from a nonpharmacy location?
- What does the data reveal about the use to which the Waiver has been put? What can the stakeholders share about perceived benefits and risks of remote processing? What are the technology solutions that best facilitate remote processing? Have there been advances in technology as a result of expanded authority under the Waiver?

Members noted the need to address a solution for hospitals and commented that based on information received, pharmacist report gaining a better work life balance through provisions of remote work. Members noted some disciplinary cases involving remote work medication errors stemming from the bifurcation of the dispensing process. Members discussed potential benefits of redirection of some workload to slower pharmacies to alleviate workload challenges, increasing accessibility of work and the ability to work without distractions. Members indicated that there may need to be a different decision for controlled versus noncontrolled substances. Members determined it appropriate to prioritize discussion for pharmacists.

Public comment discussed provisions for technology including use of VPN, encryption and multifactor authentication. Some public comments also indicated that remote processing was only performed from home on desktop computers (as opposed to laptops) with a hardwire connection. Other public comment indicated that access was limited to electronic records, with no paper records being used at remote locations.

- 4. If so, in a post-pandemic regulatory environment, under what circumstances should these additional tasks and functions be permitted? Should it be limited only to pharmacists, as is remote order entry under BPC section 4071.1?
 - There did not appear to be support from members to consider expansion beyond the functions contemplated in the waiver.
- 5. Should the pharmacist-in-charge be required to authorize or decline use of remote functions for the pharmacy? Should the pharmacist-in-charge be required to declare that remote processing functions are necessary and advisable for the pharmacy's practice, prior to their use?
 - Members agreed that the PIC should have autonomy to determine if remote processing is allowed.
- 6. Can a subsequent pharmacist-in-charge make a contrary determination/declaration?
 - Members appeared to agree that a new PIC should have autonomy to change a determine made by a predecessor.
- 7. Should pharmacy staff members be required to consent to performing remote functions?
 - Members noted that consent should be required and commented that as part of the consent, provisions specific to safety, privacy, HIPAA and other provisions should be detailed out.
- 8. Should remote order entry and remote processing functions be authorized only for California-licensed pharmacists (or pharmacy technicians and pharmacist interns), and only in connection with California-licensed pharmacies, as per the Waiver? Should it be limited to pharmacy staff also located (not just licensed) in California? Should it apply outside of California? Or should it be left to the states in which out-of-state pharmacies and pharmacy staff are located to decide whether or under what conditions remote order entry/remote processing will be permitted? Should California law specify that non-resident pharmacies must be guided by home state law?
 - Members agreed that provisions should be limited to California licensed pharmacists, working in California, for California licensed pharmacies.

- 9. If it is not so limited, is there any perceived risk if these remote order entry/remote processing functions are performed in out-of-state or even out-of-country locations?
 - Members again noted that remote provisions, must be limited to California only.
- 10. Should there be any "brick and mortar" requirements for remote order entry/remote processing authority? For instance, should these remote functions be allowed at home sites or other sites not licensed by the Board, or should they only be permitted at call centers that are licensed by the Board for this purpose, or are at least registered with the Board for tracking purposes?
 - Members did not reach a conclusion on this issue but appeared to feel comfortable with "brick and mortar" authority, but uncertain about other locations.
- 11. If remote functions are permitted in home or unlicensed sites, should the law specify that those locations are subject to Board inspection? Would this provoke potential legal challenges?
 - Members noted the need to inspector locations where remote processing would be allowed but that it could be challenging.
- 12. If remote functions are allowed in homes or other unlicensed sites, what should be the record-keeping requirements applicable to the homes or unlicensed sites, versus the pharmacy?
 - Members noted the need for pharmacy records to include an audit trail of all individuals that access the record and perform the functions. Members discussed the use of biometrics to identify personnel. Members noted that remote functions should be limited to only access to electronic records and that pharmacies should be required to maintain a list of the prescriptions involving remoting processing each day.
- 13. Again, should the law specify that any remote site must be located in California?

Member reiterated that the remote site must be located in California.

14. Should there be any limit on the number of pharmacies for which any pharmacist, pharmacy technician, or pharmacist intern can perform functions remotely? Should there be a limit on the number of remote transactions that any pharmacy staff member can perform in a day? Should there be a limit on the geographical distance between the remote site and the pharmacy? Is it acceptable for a pharmacy staff member to work exclusively in a remote location, and to never be required to enter the pharmacy premises? Or should there be a requirement of some level of in-person work in a pharmacy, to balance remote work and prevent atrophy of skills?

Members did not appear to believe there should be a limit on the amount of work that could be done safely noting that it would be determined by each pharmacist's ability. Further geographical considerations do not appear appropriate if PHY is not allowed.

15. Are there any perceived risks or problems with a pharmacy staff member in San Diego remotely processing prescriptions or orders for pharmacy patients located in Eureka? Or with a pharmacy staff member remotely processing above a certain threshold number of prescriptions or orders in a day? What about employees exclusively working remotely, and never in a pharmacy?

After considering the questions members noted that the PIC should make the decisions describing under what conditions remote processing would be allowed at the specific pharmacy.

Public comment was received from pharmacist currently working in Northern California that are concerned that about losing their jobs because the pharmacy is located in Southern California. Other public comment suggested there should not be arbitrary distances established.

16. How should the pharmacy be required to track and trace prescription and order processing that is performed remotely, or by a mixture of remote and in-pharmacy staff? What kind of digital audit trail demonstrating the contributions of each pharmacy staff member will be maintained? How will the pharmacy ensure that pharmacy staff members are digitally positively identified, verified, and registered with regard to each processing function performed? How will those systems

integrate functions performed remotely with those performed inpharmacy?

Members did not define a specific type of technology that should be used.

17. What sort of requirements should be written into law for ensuring secure transmissions and maintenance of security and privacy of sensitive information?

Members discussed the need to meet or exceed best practices related to security.

18. What sort of records should the Board require that pharmacies produce regarding prescription and order processing that is entirely or partially performed remotely? Should the burden be on pharmacies that utilize remote processing functions to provide the Board with complete data on the pharmacy staff involved in each transaction? How should that be accomplished?

Members noted that the Board must have access to records and requested that staff work with the Office of the Attorney General to determine what, if any, changes would be necessary.

19. Should the pharmacy license or the license of the pharmacist-in-charge be subject to discipline, along with the licenses of the pharmacy staff members involved, in the event of misconduct that is associated with performance of remote processing functions?

Members noted that the PIC should be responsible if they had input into the decisions. Members commented on the need for mutual responsibility and accountability to prevent abuse.

20. Should remote processing sites be licensed by the Board, using a license affiliated with the pharmacy license, as with an automated drug delivery system? Or should the pharmacy be required to otherwise identify and register all remote processing sites with the Board?

Members noted that at a minimum the pharmacy should be required to notify the Board of the locations where remote processing occurs, including any changes.

21. Board investigators have seen instances of pharmacies employing call centers to market directly to patients or prescribers, to cold-call patients, and even to run test prescriptions for patients to test reimbursement, which may result in denials for patients at other pharmacies. If the Board authorizes remote order entry and/or remote processing, how does the Board prevent abuse?

Members noted that the scenario described is a primary cause of hesitation with changing the law in the outpatient setting. Members noted enforcement cases involving fraud and the need to solicit additional work from field staff to identify conditions to safeguard against these illegal activities.

Members expressed significant concerns with any final verification being performed from a remote location and that provisions to allow for remote processing could result in reduced staffing at community pharmacies. Members noted the need to consider the issue without diminishing the consumer protection. The committee noted the need to continue its consideration of the issue.

Attachment 1

16 CCR § 1746.3

§ 1746.3. Protocol for Pharmacists Furnishing <u>Opioid Antagonists</u> Naloxone Hydrochloride.

A pharmacist furnishing an <u>opioid antagonist</u> naloxone hydrochloride pursuant to section 4052.01 of the Business and Professions Code shall satisfy the requirements of this section.

- (a) As used in this section:
- (1) "Opioid" means naturally derived opiates as well as synthetic and semisynthetic opioids.
- (2) "Recipient" means the person to whom naloxone hydrochloride an opioid antagonist is furnished.
- (b) Training. Prior to furnishing naloxone hydrochloride an opioid antagonist, pharmacists who use this protocol must have successfully completed a minimum of one hour of an approved continuing education program or equivalent-based training program completed in a board recognized school of pharmacy specific to the use of opioid antagonists for overdose reversal. naloxone hydrochloride such products including in all routes of administration recognized in subsection (c)(4) of this protocol, or an equivalent curriculum based training program completed in a board recognized school of pharmacy.
- (c) Protocol for Pharmacists Furnishing <u>Opioid Antagonists</u> Naloxone Hydrochloride.

Before providing <u>an opioid antagonist</u> naloxone hydrochloride, the pharmacist shall:

- (1) Screen the potential recipient by asking the following questions: <u>Make a reasonable inquiry to determine:</u>
- (A) Whether the potential recipient currently uses or has a history of using illicit or prescription opioids. (If the recipient answers yes, the pharmacist may skip screening question B.);
- (B) Whether the potential recipient is in contact with anyone who uses or has a history of using illicit or prescription opioids. (If the recipient answers yes, the pharmacist may continue.);
- (C) Whether the person to whom the naloxone hydrochloride would be administered has a known hypersensitivity to naloxone. (If the recipient answers yes, the pharmacist may not provide naloxone. If the recipient responds no, the pharmacist may continue.)

The screening questions shall be made available on the Board of Pharmacy's website in alternate languages for patients whose primary language is not English.

- (21) Provide the recipient training in opioid overdose prevention, recognition, response, and administration of the <u>opioid antagonist</u> antidote naloxone.
- (32) When an opioid antagonist naloxone hydrochloride is furnished:
- (A) The pharmacist shall provide the recipient with appropriate counseling and information on the product furnished, including dosing, effectiveness, adverse

- effects, storage conditions, shelf-life, and safety. The recipient is not permitted to waive the required consultation.
- (B) The pharmacist shall provide the recipient with any informational resources on hand and/or referrals to appropriate resources if the recipient indicates interest in addiction treatment, recovery services, or medication disposal resources at this time.
- (C) The pharmacist shall answer any questions the recipient may have regarding naloxone hydrochloride the opioid antagonist.
- (43) Product Selection: A pharmacist shall advise the recipient on how to choose the route of administration based on the formulation available, how well it can likely be administered, the setting, and local context. A pharmacist may supply naloxone hydrochloride as an intramuscular injection, intranasal spray, auto-injector or in another FDA-approved product form. A pharmacist may also recommend optional items when appropriate, including alcohol pads, rescue breathing masks, and rubber gloves.
- (54) Labeling: A pharmacist shall label the naloxone hydrochloride product consistent with law and regulations. The patient shall also receive the FDA approved medication guide. Labels shall include an expiration date for the naloxone hydrochloride furnished. An example of appropriate labeling is available on the Board of Pharmacy's website.
- (6) Fact Sheet: The pharmacist shall provide the recipient a copy of the current naloxone fact sheet approved by the Board of Pharmacy or a fact sheet approved by the executive officer. The executive officer may only approve a fact sheet that has all the elements and information that are contained in the current board-approved fact sheet. The board-approved fact sheet shall be made available on the Board of Pharmacy's website in alternate languages for patients whose primary language is not English. Fact sheets in alternate languages must be the current naloxone fact sheet approved by the Board of Pharmacy.
- (7<u>5</u>) Notifications: If the recipient of the naloxone hydrochloride is also the person to whom the naloxone hydrochloride would be administered, then the naloxone recipient is considered a patient for purposes of this protocol and notification may be required under this section.
- If the patient gives verbal or written consent, then the pharmacist shall notify the patient's primary care provider of any drug(s) and/or device(s) furnished, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the patient and that primary care provider.
- If the patient does not have a primary care provider, or chooses not to give notification consent, then the pharmacist shall provide a written record of the drug(s) and/or device(s) furnished and advise the patient to consult an appropriate health care provider of the patient's choice. At the request of the patient, a pharmacist shall notify to the identified primary care provider of the product furnished or enter appropriate information in a shared patient record

system as permitted by the primary care provider. If the patient does not have or does not identify a primary care provider, the pharmacist shall provide the recipient a written record of the drug furnished along with a recommendation to consult with an appropriate health care provider of the patient's choice.

(8) Documentation: Each naloxone hydrochloride A product furnished by a pharmacist pursuant to this protocol shall be documented in the pharmacy's a medication record for the naloxone recipient, and securely stored within the originating pharmacy or health care facility for a period of at least three years from the date of dispense in compliance with. The medication record shall be maintained in an automated data or manual record mode such that the required information under title 16, sections 1707.1 and 1717 of the California Code of Regulations is readily retrievable during the pharmacy or facility's normal operating hours.

(9) Privacy: All pharmacists furnishing naloxone hydrochloride in a pharmacy or health care facility shall operate under the pharmacy or facility's policies and procedures to ensure that recipient confidentiality and privacy are maintained.

Credits

NOTE: Authority cited: Section 4052.01, Business and Professions Code.

Reference: Section 4052.01, Business and Professions Code.

Attachment 2

Proposal to Add CCR Section 1746.6 Pharmacist Provided Medication-Assisted Treatment

- (a) A pharmacist may initiate, modify, administer, or discontinue medication-assisted treatment pursuant to Section 4052(a)(14) consistent with all relevant provisions of federal law and shall satisfy the requirements of this section.
 - a. The pharmacist possesses appropriate education and training to provide such treatment consistent with the established standard of care used by other health care practitioners providing medication-assisted treatment including nationally accepted guidelines.
 - b. The pharmacist must ensure a private patient care area is used to provide the services. The patient may not waive consultation.
 - c. Assessment of the substance use disorder is performed including physical and laboratory examinations for signs and symptoms of substance use disorder. Initial assessment may be waived if the patient is referred to the pharmacist for treatment following diagnosis by another health care provider.
 - d. Development of a treatment plan for substance use disorder including referral to medical services, case management, psychosocial services, substance use counseling, and residential treatment is provided as indicated.
 - e. Documentation of the pharmacist's assessment, clinical findings, plan of care, and medications dispensed and administered will be documented in a patient record system and shared with a patient's primary care provider or other prescriber, if one is identified.
 - f. A pharmacist performing the functions authorized in this section shall do so in collaboration with other health care providers.
- (b) For purposes of this section medication assisted treatment includes any medication used to treat a substance use disorder.

Attachment 3

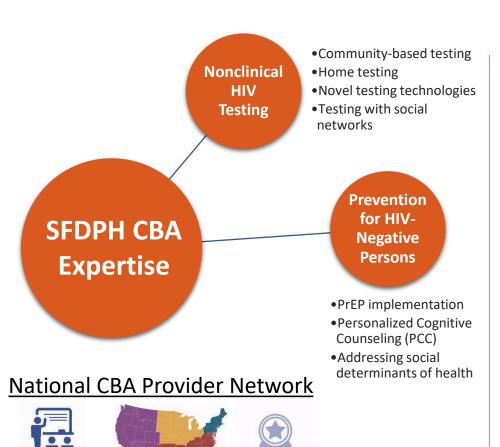
Pharmacy PrEP

Maria Lopez, PharmD Mission Wellness Pharmacy Consultant SFDPH CBA, Center for Learning and Innovation HIV PrEP Advisory Chair, American Pharmacists Association

Disclaimer:

Any comments provided during this presentation are not opinions, nor recommendations on behalf of getSFCBA or the American Pharmacists Association

SFDPH CBA Program



SFDPH, Center for Learning and Innovation

Visit: www.getSFcba.org

Email: get.SFcba@sfdph.org

Call: 628.217.6226

CBA does not provide policy recommendations

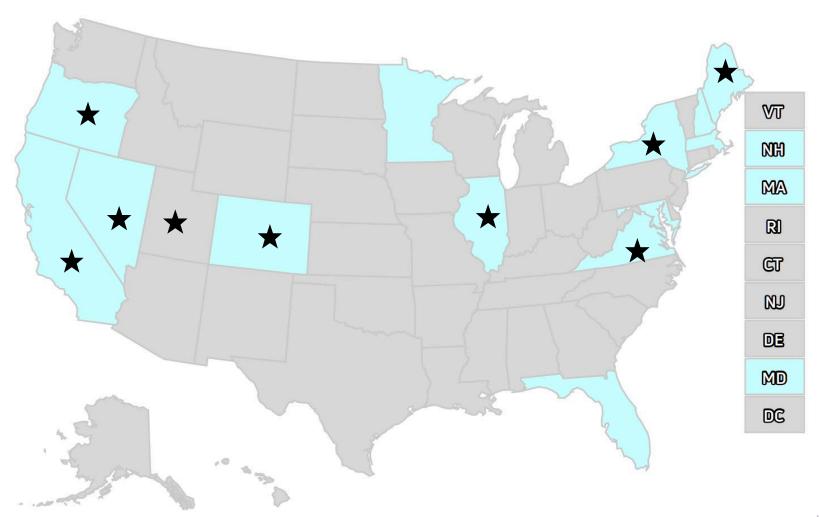
Agenda

National Overview of Legislation Summary of CA Program Barriers to SB159

Pharmacy HIV Testing and PrEP Services

Pharmacy PrEP	Location	Pharmacy Services	Additional Information
VDPH in collaboration with a chain pharmacy	Virginia	• HIV POC rapid testing • Walk-in services	 32 locations Performed 3630 tests 6/14-9/16 Reported 0.8% positivity rate 46% had never been tested
Kelly-Ross Pharmacy "One-Step PrEP" CPA with a private physician	Seattle, Washington	PrEP assessment and initiationPharmacist-run HIV PrEP clinic	 •3/15/-3/16 • 57/251 (=23%) reported having a PCP •3/15-3/2018 •714 patients evaluated •90% had a PDC > 80 •Payment mandated in WA

PrEP Legislation

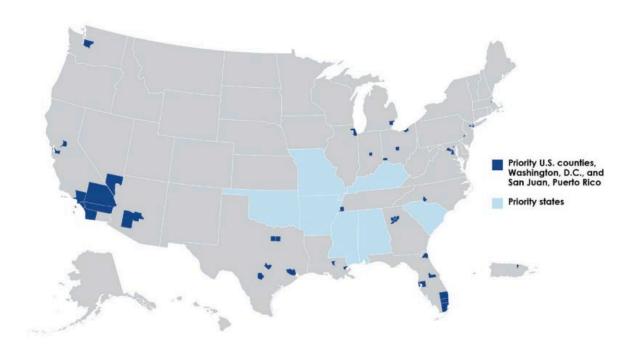


Pharmacists PrEP & PEP authority at a Glance

States with Restricted quantities			
State	Year	Notes	
CA SB159	2019	60 days of PrEP, 30 days of PEP. Mandates reimbursement from Medicaid at 85% rate, does not address private insurances or ADAP	
ME LD1115	2021	2 months of PrEP and 1 month of PEP	
OR HB2958	2021	Up to 30 days of PrEP	

Unrestricted Quantities			
State	Year	Notes	
CO HB1061	2020	All services, including laboratory reimbursed at 100%	
NV SB325	2021	All services, including laboratory reimbursed at 100%	
Utah HB0178	2021	100% reimbursed for services, still working out laboratory	
VA HB2079	2021	Requires reimbursement at 100%, unclear if laboratory reimbursed	
IL H4430	2022	All services, reimbursed at 85%; requires standing order	

CDC: 57 Priority Jurisdictions



California

- Alameda
- Los Angeles
- Orange County
- Riverside County
- Sacramento County
- San Bernadino County
- San Diego County
- San Francisco County

4,396 Californians newly diagnosed with HIV in 2019

Priority Communities

- Gay and bisexual men of all races and ethnicities
- Black/African Americans
- Hispanic/Latinos
- Persons who inject drugs (PWID)
- Transgender individuals

PWID account for 10% of new infections

By Gender

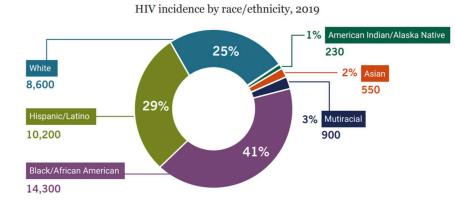
- Men (81%)
- Women (19%)

Among Men - Gay, Bisexual and other men who have sex with men account for 70 % of infections

Trans Individuals
62% Black trans women
35% Hispanic/Latina trans women
17% White trans women

By Race (All Genders)

- Blacks/African Americans
- Hispanic/Latino



Pharmacist PrEP Collaborative Practice Agreement with the San Francisco Department of Public Health

- SFDPH Physician of Record oversees program. SFDPH provides supervision
- Phlebotomist or nurse draws blood
- Pharmacist sees patients
- Pharmacy Technician or peer counselor assists with benefits navigation
- Program has received limited grant funding

Published findings:

- •Between April 2018-March 2019, 51 patients initiated on PrEP and 6 patients received PEP
- •60% utilized navigation assistance
- •47% of patients identified as Hispanic/Latino and 10% identified as Black/African American

PrEP Visit Workflow

- Initial appointments 45-60 minutes, follow up visits 30 minutes
- Visit includes complete medical, social, financial assessment, and labs (HIV, STI, HCV, HBV screening, serum creatinine)

 Patient completes intake questionnaire, insurance verification and benefits navigation

Pharmacist Visit

- Pharmacist interviews patient, orders labs as appropriate
- Patient is given PrEP or PEP

- Follow up appointments for ongoing (or initial PrEP, if starting PEP)
- Monitor refills

Intake

Follow Up

Barriers and Facilitators: Mission Wellness Program

Barriers

- Implementation of CPA
- Lack of funding infrastructure, unable to bill for pharmacists initiated services

Facilitators

- CPA permits ongoing PrEP.
- Referrals in place and collaboration for follow up
- Ease of laboratory tests access, supplied by DPH

SB159 Barriers

- 60 day limitation
- Financial: Payment in CA for services is limited
 - Necessary in order to support testing, staffing, education,
- Education for pharmacists and awareness to patients
- SB159 intent is for pharmacists to follow best practice guidelines and guidance from the CDC; however language has been a barrier and should be more flexible. For example current language:
 - Defines guidelines; CDC publishes additional updates more often than "the Guidelines." Should include language that permits other CDC guidance documents
 - Utilizes prescriptive legislation: PrEP and PEP medications, tests, counseling, etc.,

Prep Basics



PrEP is safe and can reduce your risk of HIV by more than 99%.



It takes at least 1 week on PrEP before you'll be protected for anal sex, and 3 weeks for vaginal sex.



Take 1 pill once a day. Finding a routine is essential.



Get tested for HIV and STIs every 3 months.



Tell your provider if you plan to stop (or restart) PrEP.

EL DEPARTAMENTO DE SALUD PUBLICA DE SAN FRANCISCO

Lo Esencial de PrEP



PrEP es seguro y puede reducir el riesgo de infección de VIH a más de 99%.



Se necesita tomar PrEP por una semana antes de tener sexo anal y tres semanas antes de tener sexo vaginal para ser protegido/a contra el VIH.



Toma una pastilla una vez al día, estableciendo una rutina es importante.



Hazte la prueba del VIH, de las infecciones de transmisión sexual y la función renal cada 3 meses.



Habla con tu doctor si estás pensando en dejar de tomar (o reiniciar) PrEP.



SB159

California Pharmacists Initiation of PrEP and PEP in a pharmacy

In 2019, California passed SB159 legislation to allow pharmacists to initiate important HIV prevention medications to reduce HIV risk and incidence.



SB159 KEY HIGHLIGHTS

- Allows pharmacists to independently initiate and furnish PrEP for up to 60 days and PEP for 30 days.
- Mandates Medi-Cal (California Medicaid Program) to reimburse pharmacist services for PrEP and PEP.
- Prohibits Prior Authorizations on PrEP medications to facilitate medication access.

Under SB159, a pharmacist may furnish a 30-60 day supply of PrEP if all of the following requirements are met:

- Patient is HIV negative, documented within prior 7 days.
 - Test can be Ab only or Ag/Ab or FDA approved rapid finger stick blood Point of Care test. If test result is not provided by the patient, pharmacist should order HIV test.
- Patient does not have signs/symptoms of acute HIV on a self-reported checklist.
 - Symptoms of acute HIV include: flu-like symptoms such as fever, fatigue, myalgias, pharyngitis, cervical adenopathy, night sweats, diarrhea, and rash.
- Patient does not report taking any contraindicated medications.
- Pharmacist provides counseling to patient regarding ongoing use of PrEP, which may include:
 - Counseling on side effects and adherence
 - Safety during pregnancy and breastfeeding Importance of timely testing and treatment
 Notify patient they must be seen by a PCP for ongoing
 - for HIV, renal function, hepatitis B, hepatitis C, STIs, and pregnancy
- prescription and that a pharmacist can only furnish a 60-day supply of PrEP once every 2 years
- Services provided must be documented in the patient record in the pharmacy.
- Pharmacist should not furnish more than a 60-day supply once every 2 years to a patient.*
- Pharmacist should notify patient's PCP, unless the patient does not have one or refuses consent. The pharmacist should then provide a list of physicians and clinics for PrEP.
- The patient cannot waive the consultation.

*Unless otherwise directed by a prescriber or under collaborative practice agreement.

Pharmacist can furnish a full 30-day course of PEP if all of the following requirements are met:

- 1 Pharmacist determines the HIV exposure occurred within the past 72 hours and the patient meets clinical eligibility for PEP consistent with CDC guidelines.
- Pharmacist provides HIV testing that is classified as CLIA waived or determines patient is willing to undergo HIV testing consistent with CDC guidelines.
 - If patient refuses to undergo testing but is otherwise eligible for PEP, pharmacist can still provide PEP.
- Pharmacist provides counseling to patient on the use of PEP consistent with CDC guidelines, which may include:
 - · Side effects, safety during pregnancy and breastfeeding, adherence, and importance of timely testing and treatment, as applicable for HIV, renal function, hepatitis B, hepatitis C, STIs, pregnancy
 - Inform the patient on the availability of PrEP for persons who have ongoing risk of HIV acquisition.
- Pharmacist should notify patient's PCP, unless the patient does not have one or refuses consent. The pharmacist should then provide a list of physicians and clinics for PEP.
- The patient cannot waive the consultation.

Checklist for implementing SB159

- · Complete 90-minute Continuing Education requirement.
- Become familiar with CDC PrEP and PEP Guidelines.
- Consider HIV testing options for PrEP and PEP patients in the pharmacy.
- · Compile referral lists for lab-based testing, ongoing PrEP providers, substance use services, and social support.

HIV testing in the pharmacy setting

- · CDC recommends laboratory 4th generation Ag/Ab test or rapid, point-of-care fingerstick blood test.
- Rapid HIV tests can be conducted in a pharmacy that obtains a CLIA waiver certificate. allowing patients to access same-day PrEP starts.
- Trained staff members may perform CLIA-waivered point-of-care testing. Consider utilizing a phlebotomist under collaborative practice or referring patients to a nearby laboratory.

Where can pharmacists complete PrEP and PEP training for SB159?

- California State Board of Pharmacy: www.bit.ly/CApharm PrEP
- California Society of Health System Pharmacists: www.bit.ly/cshp_training
- California Pharmacists Association: www.bit.ly/cpha_course

How can pharmacists connect patients to long term PrEP care?

- · Partner with local Community Based Organizations that provide navigation services to long term PrEP care.
- Compile a referral list of local PrEP care providers and other social support services.
- PrEP provider locator can be found at www.preplocator.org.





5/2022

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Questions



Implementing SB159

Clint Hopkins, PharmD, RPh, APh

Pucci's Pharmacy - Background

- Opened in 1930
- Previous owner began servicing PLWHIV in the 1980s
 - 2020 268 patients for HIV treatment, PrEP, & PEP
 - 2021 282 patients
 - 2022 303 patients
- Patients served for Rxs
 - 2020 5787
 - 2021 10541
 - 2022 11738
- 2019 CLIA waiver obtained
 - Flu & Strep testing
 - COVID testing started in Oct 2020
 - HIV and HCV testing soon!

Pucci's Pharmacy - Background

- January 2021 One of the first non-chain pharmacy sites in California to vaccinate against COVID in collaboration with Public Health to provide mobile vaccinations
- 27,000+ COVID vaccines administered to date
- July 2022 Contacted by Sacramento County Public Health to assist with MPOX vaccines
- 6,268 MPOX vaccines administered to date
- 2022 Providing Apretude (HIV PrEP) and Cabenuva (HIV Treatment) injectables

SB 159 - Background

- Authorizes pharmacist to initiate and furnish HIV PrEP and HIV PEP
- Expands Medi-Cal schedule of benefits to include HIV PrEP and PEP as pharmacist services
- Prohibits plans and insurers from requiring step therapy or prior authorization to antiretroviral drugs
- Prohibits plans and insurers from prohibiting, or allowing a pharmacy benefit manager to prohibit, a pharmacy provider from providing HIV PrEP and PEP

SB 159 – Pharmacist Requirements

- Pharmacists must complete training for competency
- HIV Testing
- HIV Counseling
- Prescribing
- Dispensing
- PrEP/PEP Counseling
- Notify PCP

SB 159 for PrEP

- For PrEP, ensure patient is HIV negative 4052.02 (e) (1)
- Burden on the patient to prove they are "HIV negative, as documented by a negative HIV test result obtained within the previous seven days from an HIV antigen/antibody test or antibodyonly test from a rapid, point-of-care fingerstick blood test approved by the FDA"
- If patient does not provide evidence of a negative HIV test... "the pharmacist shall order an HIV test".

SB159 for PEP

- For PEP, ensure patient is HIV negative [4053.03 (e) (2)]
- Burden on the pharmacist to provide HIV testing that is classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a) or determines the patient is willing to undergo HIV testing consistent with CDC guidelines.
- If the patient refuses to undergo HIV testing but is otherwise eligible for postexposure prophylaxis under this section, the pharmacist may furnish postexposure prophylaxis.

SB159 Coverage

- Medicaid patients covered by Medi-Cal
- Uninsured patients covered by PrEP-AP
 - Pharmacy must contract separately with CDPH to bill PrEP-AP
- Largest percentage of Californians are covered by commercial plans
 - No requirement for these plans to cover pharmacist provided HIV testing OR to recognize pharmacist as a provider for non-dispensing related services
- Sac County Public Health has offered to share their HIV tests
 - Still would lack funding for pharmacist time spent providing test, counseling, etc.
 - Lots of paperwork to be completed for their program
 - Not viable for most pharmacies

Current State

- Referring patients to willing providers for testing & they prescribe
- LGBT Center tests and refers to telehealth provider
 - Some patients are stigmatized by going to "LGBT" center or an "HIV/AIDS" center
- Pucci's dispenses HIV PrEP, PEP, and treatment
- Referring out often causes delay in start
 - Patient may get infected during this window
 - Patient perception is negative of the overall health system
 - Not viable for pharmacies who don't have a willing referral destination

Remove Barriers to Care

- Pharmacists to provide testing upon request
- Mandate that pharmacies are to be reimbursed by all health plans for HIV testing and all related professional services
- Remove the 60-day limitation of initiating and providing PrEP once in a two-year timeframe

Attachment 4

16 CCR § 1708.2

Proposal to Amend § 1708.2. Discontinuance of Business as follows:

- (a) Any permit holder shall contact the board prior to transferring or selling any dangerous drugs, devices or hypodermics inventory as a result of termination of business or bankruptcy proceedings (collectively referred to as a "closure") and shall follow official instructions given by the board applicable to the transaction. (b) In addition to the requirements in (a), a pharmacy that shall cease operations due to a closure shall complete the following:
 - (1) Provide written notice to its patients that have received a prescription within the last year, at least 30 days in advance of the closure. At a minimum this notice shall include:
 - (A) the name of the patient and/or legal representative of the patient, if known,
 - (B) the name and physical address of the pharmacy closure,
 - (C) the name of pharmacy where patient records will be transferred or maintained, and
 - (D) information on how to request a prescription transfer prior to closure of the pharmacy.
 - (2) Reverse all prescriptions for which reimbursement was sought that are not picked up by patients,
 - (3) Provide the board with a copy of the notice specified in subsection (b)(1),
- (4) The pharmacist-in-charge shall certify compliance with the requirements in this section. In the event the pharmacist-in-charge is no longer available, the owner must certify the compliance along with a pharmacist retained to perform these functions.

NOTE: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4080, 4081, <u>4113</u>, 4332 and 4333, Business and Professions Code; and Section 11205, Health and Safety Code.

Attachment 5

ARTICLE 7. Pharmacies [4110 - 4126.10]

(Article 7 added by Stats. 1996, Ch. 890, Sec. 3.)

4112.

- (a) Any pharmacy located outside this state that ships, mails, or delivers, in any manner, controlled substances, dangerous drugs, or dangerous devices into this state shall be considered a nonresident pharmacy.
- (b) A person may not act as a nonresident pharmacy unless he or she has obtained a license from the board. The board may register a nonresident pharmacy that is organized as a limited liability company in the state in which it is licensed.
- (c) A nonresident pharmacy shall disclose to the board the location, names, and titles of (1) its agent for service of process in this state, (2) all principal corporate officers, if any, (3) all general partners, if any, and (4) the name of a California licensed pharmacist designated as the pharmacist-in-charge, and (5) all pharmacists who are dispensing controlled substances, dangerous drugs, or dangerous devices to residents of this state. A report containing this information shall be made on an annual basis and within 30 days after any change of office, corporate officer, partner, pharmacist-in-charge, or pharmacist.
- (d) All nonresident pharmacies shall comply with all lawful directions and requests for information from the regulatory or licensing agency of the state in which it is licensed as well as with all requests for information made by the board pursuant to this section. The nonresident pharmacy shall maintain, at all times, a valid unexpired license, permit, or registration to conduct the pharmacy in compliance with the laws of the state in which it is a resident. As a prerequisite to registering with the board, the nonresident pharmacy shall identify a California licensed pharmacist employed and working at the nonresident pharmacy to be proposed to serve as the pharmacist-in-charge, and shall submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which it is located.
- (e) All nonresident pharmacies shall maintain records of controlled substances, dangerous drugs, or dangerous devices dispensed to patients in this state so that the records are readily retrievable from the records of other drugs dispensed.
- (f) Any pharmacy subject to this section shall, during its regular hours of operation, but not less than six days per week, and for a minimum of 40 hours per week, provide a toll-free telephone service to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. This toll-free telephone number shall be

disclosed on a label affixed to each container of drugs dispensed to patients in this state.

- (g) A nonresident pharmacy shall not permit a pharmacist whose license has been revoked by the board to manufacture, compound, furnish, sell, dispense, or initiate the prescription of a dangerous drug or dangerous device, or to provide any pharmacy-related service, to a person residing in California.
- (h) The board shall adopt regulations that apply the same requirements or standards for oral consultation to a nonresident pharmacy that operates pursuant to this section and ships, mails, or delivers any controlled substances, dangerous drugs, or dangerous devices to residents of this state, as are applied to an in-state pharmacy that operates pursuant to Section 4037 when the pharmacy ships, mails, or delivers any controlled substances, dangerous drugs, or dangerous devices to residents of this state. The board shall not adopt any regulations that require face-to-face consultation for a prescription that is shipped, mailed, or delivered to the patient. The regulations adopted pursuant to this subdivision shall not result in any unnecessary delay in patients receiving their medication.
- (i) The registration fee shall be the fee specified in subdivision (a) of Section 4400.
- (j) The registration requirements of this section shall apply only to a nonresident pharmacy that ships, mails, or delivers controlled substances, dangerous drugs, and dangerous devices into this state pursuant to a prescription.
- (k) Nothing in this section shall be construed to authorize the dispensing of contact lenses by nonresident pharmacists except as provided by Section 4124.
- (m) Effective date July 1, 2024.

Attachment 6

Proposal to Amend § 1732.5. Renewal Requirements for Pharmacists.

- (a) Except as provided in Section 4234 of the Business and Professions Code and Section 1732.6 of this Division, each applicant for renewal of a pharmacist license shall submit proof satisfactory to the board, that the applicant has completed 30 hours of continuing education (CE) in the prior 24 months.

 (b) At least two (2) of the thirty (30) hours required for pharmacist license renewal ("required CE hours") shall be completed by participation in a Board provided CE course in Law and Ethics. Further, beginning January 1, 2024, at least one (1) hour of the required CE hours shall be completed by participation in a cultural competency course from an accreditation agency approved by the board pursuant to Section 1732.05, covering the specified content areas as required by Section 4231 of the Business and Professions Code. Pharmacists renewing their licenses which expire on or after July 1, 2019, shall be subject to the requirements of this subdivision.
- (c) Pharmacists providing specified patient-care services must complete continuing education as specified below.
- (1) At least one (1) hour of approved CE specific to smoking cessation therapy, as required by Section 4052.9 of the Business and Professions Code, if applicable.
- (2) At least two (2) hours of approved CE specific to travel medicine, as required by Section 1746.5, if applicable.
- (3) At least one (1) hour of approved CE specific to emergency contraception drug therapy as required by Business and Professions section 4052.3, if applicable.
- (4) At least one (1) hour of approved CE specific to vaccinations as required by Section 1746.4, if applicable.
- (d) For a pharmacist who prescribes a Schedule II controlled substance (as defined in Health and Safety Code section 11055), at least one (1) hour of the required CE hours shall be completed by participation in a Board approved CE course once every four (4) years on the risks of additional associated with the use of Schedule II drugs, as required by Section 4232.5 of the Business and Professions Code.
- (e) All pharmacists shall retain their certificates of completion for four (4) years following completion of a continuing education course <u>demonstrating</u> <u>compliance with the provisions of this section</u>.
- (e) "Board approved CE course" shall mean coursework from a provider meeting the requirements of Section 1732.1.

NOTE: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4052.3, 4052.8, 4052.9, 4231 and 4232, and 4232.5, Business and Professions Code.

Proposal to Add § 1732.8. Renewal Requirements for Pharmacy Technicians

- (a) Beginning January 1, 2024, as a condition of renewal, a pharmacy technician licensee shall submit proof satisfactory to the board that the applicant has completed at least one (1) hour of continuing education in a cultural competency course covering the specified content areas from an accreditation agency approved by the board pursuant to Section 1732.05 during the two years preceding the application for renewal, as required by Section 4202 of the Business and Professions Code. All pharmacy technicians shall retain their certificate of completion for four (4) years from the date of completion of the cultural competency course demonstrating compliance with the provisions of this section.
- (b) If an applicant for renewal of a pharmacy technician license submits the renewal application and payment of the renewal fee but does not submit proof satisfactory to the board that the licensee has completed the cultural competency course as required, the board shall not renew the license and shall issue the applicant an inactive pharmacy technician license.
- (c) If, as part of an investigation or audit conducted by the board, a pharmacy technician fails to provide documentation substantiating the completion of continuing education as required in subdivision (a), the board shall cancel the active pharmacy technician license and issue an inactive pharmacy technician license in its place. A licensee with an inactive pharmacy technician license issued pursuant to this section may obtain an active pharmacy technician license by submitting renewal fees due and submitting proof to the board that the pharmacy technician has completed the required continuing education.

NOTE: Authority cited: Section 462 and 4005, Business and Professions Code. Reference: Sections 462 and 4202, Business and Professions Code.

Attachment 7

Possible amendment to BPC Section 4111

- (a) Except as otherwise provided in subdivision (b), (d), or (e), the board shall not issue or renew a license to conduct a pharmacy to any of the following:
 - (1) A person or persons authorized to prescribe or write a prescription, as specified in Section 4040, in the State of California.
 - (2) A person or persons with whom a person or persons specified in paragraph (1) shares a community or other financial interest in the permit sought <u>unless</u> both the person or persons specified in paragraph (1) and the person seeking a license to conduct pharmacy provide statements disavowing any community or financial interest on behalf of the person or persons specified in paragraph (1) and transmute any such community property under the Family Law Codes of the State of California into the separate property of the person seeking a license to conduct pharmacy. In addition, the pharmacy seeking a license with an owner specified in paragraph (1) if such license is granted, shall be prohibited from filling any prescriptions, emergency or otherwise issued or prescribed by the person or persons specified in paragraph (1) or another prescriber at the same place of business as the person specified in paragraph (1) if the prescriber owns a greater than 10% interest in the practice issuing the prescription.
 - (3) Any corporation that is controlled by, or in which 10 percent or more of the stock is owned by a person or persons prohibited from pharmacy ownership by paragraph (1) or (2).
- (b) Subdivision (a) shall not preclude the issuance of a permit for an inpatient hospital pharmacy to the owner of the hospital in which it is located.
- (c) The board may require any information the board deems is reasonably necessary for the enforcement of this section.
- (d) Subdivision (a) shall not preclude the issuance of a new or renewal license for a pharmacy to be owned or owned and operated by a person licensed on or before August 1, 1981, under the Knox-Keene Health Care Service Plan Act of 1975 (Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code) and qualified on or before August 1, 1981, under subsection (d) of Section 1310 of Title XIII of the federal Public Health Service Act, as amended, whose ownership includes persons defined pursuant to paragraphs (1) and (2) of subdivision (a).
- (e) Subdivision (a) shall not preclude the issuance of a new or renewal license for a pharmacy to be owned or owned and operated by a pharmacist authorized to issue a drug order pursuant to Section 4052.1, 4052.2, or 4052.6 under the following conditions:
 - 1. The pharmacist issuing the drug order offers to provide a prescription to the patient that the patient may elect to have filled by a pharmacy of the patient's choice unless prohibited by the collaborative practice agreement.
 - 2. The pharmacist issuing the drug order must provide a full patient consultation prior to issuing the drug order.

Attachment 8

Proposal To Amend Business and Professions Code Section 4071.1.

- (a) A prescriber, a prescriber's authorized agent, or a pharmacist may electronically enter a prescription or an order, as defined in Section 4019, into a pharmacy's or hospital's computer from any location outside of the pharmacy or hospital with the permission of the pharmacy or hospital. For purposes of this section, a "prescriber's authorized agent" is a person licensed or registered under Division 2 (commencing with Section 500). This subdivision shall not apply to prescriptions for controlled substances classified in Schedule II, III, IV, or V, except as permitted pursuant to Section 11164.5 of the Health and Safety Code.
- (b) Nothing in this section shall reduce the existing authority of other hospital personnel to enter medication orders or prescription orders into a hospital's computer.
- (c) No dangerous drug or dangerous device shall be dispensed pursuant to a prescription that has been electronically entered into a pharmacy's computer without the prior approval of a pharmacist.
- (d) A pharmacist located and licensed in California may on behalf of a health care facility licensed pursuant to health and safety code 1250 verify medication chart orders for appropriateness prior to administration consistent with federal requirements as established in the health care facilities policies and procedures. The health care facility shall maintain a record of any pharmacist performing these remote functions. Such records shall meet the same requirements established in sections 4081 and 4105.

Damoth, Debbie@DCA

From: Steve <skphung@yahoo.com>
Sent: Thursday, January 19, 2023 4:17 PM

To: Sodergren, Anne@DCA
Subject: Remote processing

WARNING: This message was sent from outside the CA Gov network. Do not open attachments unless you know the sender: skphung@yahoo.com

To whom it may concern, I am a licensed and registered pharmacist in California who have worked for a major retail chain since graduating in 2003. I am writing you because I am concerned that new laws are being written that may affect the legality of remote verification. As a retail pharmacist I can attest that remote verification plays a crucial role in reducing the workload, reducing errors and increasing my time to better serve my patients. Getting rid of remote verification would do great harm to a pharmacy that is already over worked and under staffed.

Thank you , Steve phung

Sent from my iPhone

Damoth, Debbie@DCA

From: Christine Jacobs <christinejacobs@att.net>
Sent: Thursday, January 19, 2023 3:41 PM

To: Sodergren, Anne@DCA

Subject: Remote Processing Waiver Exception

WARNING: This message was sent from outside the CA Gov network. Do not open attachments unless you know the sender: christinejacobs@att.net

Hello, my name is Christine Jacobs and I am a Work At Home pharmacist with Walgreens pharmacy. I appreciate you taking the time out to read my quick note.

I would just like to quickly voice my request to have the Board of Pharmacy consider continuing to allow pharmacists to work remotely.

I believe remote pharmacy practice greatly impacts the quality of work that a pharmacist can deliver when interruptions are minimized. I also believe it allows the pharmacist in the store to provide quality service and patient care when the burden of certain tasks are removed.

Also, speaking as a person with health conditions that could worsen with the day to day activities of normal duties, remote pharmacy has allowed me to continue to work full-time in the same capacity as any other work at home pharmacist. It also allows for a wonderful work life balance.

Thank you so much for taking time to read my concerns.

Sincerely, Christine Jacobs RPh 50886

Sent from my iPhone

Damoth, Debbie@DCA

From: Julia D. <jdong81@yahoo.com>
Sent: Thursday, January 19, 2023 3:22 PM

To: Sodergren, Anne@DCA

Subject: Pharmacy working remotely waiver

WARNING: This message was sent from outside the CA Gov network. Do not open attachments unless you know the sender: jdong81@yahoo.com

Dear Dr. Oh @ CA Pharmacy Board,

Hi DR. Oh, this is Dr. Julia Dong, a fellow California pharmacist. As a retail pharmacist of 17 years, working remotely the last 4 years, I have impacted many patients health and life. But I have never had more impact on patient care than I did the last 4 years working remotely.

When I was still a retail pharmacist, I first had the experience of working at a store that was equipped with Pilot around 2015, that means a remote pharmacist helps the store to verify prescription for certain busy hours of the day. As the only pharmacist working at the time, it was such a huge help. Instead of hopping between verifying prescription on the computer, to the filling station, and to the consultation window, I had more time to focus on patient care. I was able to spend a longer time on patient consultation, to step away in the next room to giving immunization, and answering doctor phone calls on a timely manner. Because some pharmacist working remotely was helping me verifying prescription, I was able to do more pharmacist jobs, shorten patient wait time on the phone and in waiting line.

As much as I enjoyed working in a retail setting, I transferred to work remotely 4 years ago for a personal reason. My son at the time was only 3 years old and has seizure. I had received numerous calls from his preschool whenever he had a seizure episode, but I couldn't do anything because I was working nearly 1 hour away from home. I was a good pharmacist loyal to my job and patients, but I failed my duty as a mom. So I decided to work remotely to be closer to my son's preschool and be able to help whenever he has active seizure.

But after I transferred to working remotely, I realized not only I am able to help my family, I am also impacting more families out there, nationwide. Instead of verifying prescription for only 1 store, I am able to verify prescription for many states, many stores in the US. Especially during Covid time, while many stores had to shut down due to rioting, or covid outbreak, we were able to to provide nonstop patient care and saving so many more lives. Just to give u an example, my best friend is the pharmacist manager working next to LAX. During covid time, her store had to give up to 200 covid shots per day on top of other daily immunization, and she never had extra staffing help. On many days, she didn't even have full staff, because her techs/pharmacists were out with covid, She called me and said she can't thank us enough for verifying her prescriptions. Even though covid is no longer a big concern now, but our care and help should not stop. Just because Covid is no longer a pandemic, that does not mean remote

pharmacist jobs are no longer important. We are still cutting patient wait times in the window and drive through, doctors no longer have to wait on hold for 20-30 min because the pharmacist is too busy, and patient consultation does not need to be cut short because the pharmacist has to go back to her computer to verify hundreds of prescriptions.

As a pharmacist of 17 years, who cares about my patients and every patient out there, I plea the board to please allow us to work from home. Your decision will not only impact my personal life, my career, and many other pharmacist' lives and patients lives out there. Please think about every single patient we have served and helped working remotely, and every struggling retail pharmacist we helped and their patients. Let us keep working remotely and doing our pharmacist job.

Sincerely,

Julia Dong California RPH
 From:
 Mullen, Sharon

 To:
 Sodergren, Anne@DCA

 Cc:
 Mullen, Sharon

 Subject:
 remote processing

Date: Thursday, January 19, 2023 3:49:56 PM

WARNING: This message was sent from outside the CA Gov network. Do not open attachments unless you know the sender: sharon.mullen@walgreens.com

Dear Ms Sodergren,

I was dismayed to learn that the current law for remote processing of prescriptions is under scrutiny and may not be legal in its current form. It seems that it would of been the responsibility of the BOP to take correct action and rectify the law and pass the proper legislation. It would place many pharmacists on unemployment.

I have been licensed in California since 1994, I worked 24 years in retail and after suffering a heart condition from the work stress , I was able to work as a remote processor for Optum as a temp for 5 months then I secured a job with Walgreens as a remote processor in 2017. It took me 9 months to secure a job in this oversaturated market . I love my remote job and I was willing to take a large pay decrease to be able to alleviate much stress . The retail setting has become more stressful in the past years with pharmacists having to wear many more hats. Covid has increased the amount of vaccinations and tests which all require time that is never available. The job of a pharmacist is considered one of the most stressful professions , we used to be second to air traffic controllers . All my former colleagues that still work retail and hospital have stress related health conditions. All are under 40 years old. The profession has gotten worse not better.

As a remote pharmacist, I am able to verify 4 times the amount of prescriptions that I did in a retail setting. I am more accurate and efficient and my employer has found having remote workers more profitable. We are able to take on much of the workload of the pharmacist working in busy stores so that they can properly answer patient questions and administer vaccines. Walgreens has also been instrumental during times of disaster to divert prescriptions from stores that are closed for hurricanes or floods and the remote processors are able to take on the heavy lifting and get those patients their meds via central fill locations. We remote pharmacists are integral to disaster assistance. Also rural areas also benefit from this practice and also urban areas heavily affected by stores leaving certain neighborhoods. We offer an alternative for those people that need there meds who might not have mail order options of insurance.

Certainly there is something that can be done on your end to be able to continue this growing practice. Many other states have approved this practice. Thank you for your time and consideration. Sharon Mullen (47082)

From: Chia-Hui Wen

To: Sodergren, Anne@DCA
Subject: Remote Processing

Date: Thursday, January 19, 2023 4:57:10 PM

WARNING: This message was sent from outside the CA Gov network. Do not open attachments unless you know the sender: chiahuiwen1@gmail.com

To whom it may concern,

My name is Chia-Hui Wen, a Work at home pharmacist with Walgreens. I've lived in California my whole life and worked in California as a pharmacist my entire career. I love being a pharmacist!

I've worked at very high volume retail stores for most of my career. When prescriptions were remotely verified, I was able to provide better care to our patients by giving better consultations, providing vaccinations in a safe and timely manner, answering phone calls, and serving drive through patients. When the opportunity to work from home came about 7 years ago, I jumped at the opportunity. I wanted to help my peers by reducing workload. I could now focus exclusively on prescription processing so pharmacists in the front line can do better and feel better doing their work. They are overworked and errors may occur. Working remotely, I have far less distractions and ultimately less errors. Remote processing simply should NOT stop. Please re-evaluate the decision to end remote processing. This would negatively impact our community of pharmacists and our profession.

CA Board of Pharmacy licensed me as a pharmacist 20 years ago to work as a pharmacist and that's what I'd like to continue to do.

Thank you for your time,

Chia-Hui Wen PharmD

From: <u>Tiffany Wong</u>

To: Sodergren, Anne@DCA

Subject: Remote Processing (Committee Meeting)

Date: Thursday, January 19, 2023 6:09:40 PM

WARNING: This message was sent from outside the CA Gov network. Do not open attachments unless you know the sender: tiffanywong821@gmail.com

To the Board's Executive Officer and Licensing Committee Chairperson, Dr. Seung Oh, as well as all other Board and Committee members,

My name is Tiffany Wong, and I've been a practicing pharmacist since graduating from University of the Pacific in 2012. This committee meeting and its decision is near and dear to my heart as I'm currently employed as a remote processing pharmacist and my job will be directly impacted.

Following graduation from pharmacy school, I was employed as a pharmacist in the retail setting. To say it was an adjustment would be putting it lightly. The handling of work demands, patients' demands on me, and societal pressure not to make mistakes really put a lot of stress on me as a person, during and after work hours. Working in retail has taught me the importance of multitasking, but also that it means my focus is actually split and I may not be as careful in checking my work. Between my technicians, patients (in person and on the phone), managers all clamoring for my time and attention, I felt like I hardly had time to verify prescriptions.

Some time during my 6 years in retail pharmacy, my store was equipped with remote processing, meaning a large part of my prescription verification duty would be completed remotely by colleagues. It changed the whole flow of my day at work. Suddenly I had time to focus on my patients -- giving in depth consultations, immunizations, calling doctors' offices to clarify prescriptions. It enabled me to devote more of my work time helping my patients the way they needed to be helped, by listening to them and providing necessary hands-on services for them instead of just staring at the computer screen. Remote processing positively enhanced the way I practiced retail pharmacy.

Eventually I made my way to the remote processing side of my company, and this also had an enormous impact on my life. I had cut my daily commute of 2 hours to zero, allowing me to sleep more and create a better work life balance. With my new free time, I was able to recharge in my off hours and work more efficiently during my work hours. All of a sudden I was energized and even more focused while remote processing. Without phones ringing off the hook and coworkers asking for help, I could verify prescriptions in silence and decrease the chance of making a costly mistake. I feel that as a remote processing pharmacist, I greatly contribute to the success of my colleagues in the retail setting, and in turn, serve our patients in an effective and efficient way. I wholeheartedly believe that my job is vital and aligns with the Board's purpose in protecting the heath, safety, and welfare of the people of California without compromising integrity and honesty.

I am hopeful that the Board will understand the importance of the role of a remote processing pharmacist in the California healthcare system.

Thank you for your time and consideration,

Tiffany Wong

Tiffany Wong, PharmD tiffanywong821@gmail.com 626-641-8840

From: Christina Song
To: Sodergren, Anne@DCA
Subject: Remote processing

Date: Thursday, January 19, 2023 6:33:25 PM

WARNING: This message was sent from outside the CA Gov network. Do not open attachments unless you know the sender: cjsong@gmail.com

Dear Board Members,

My name is Christina and I have been a retail pharmacist for 19 years. The last 6 years I have been verifying prescriptions remotely for Walgreens. As a trained professional who used to work the front line at the store, the remote pharmacists are fundamental to providing excellent customer care in the pharmacy. We allow the retail pharmacist to spend more time with the patients, caring for their needs, and reducing errors and stress.

As a mother of twin boys, working remotely allows me to have a better work life balance. I am able to see my children more often, reduce my stress and anxiety levels, and increase my mental health.

I ask you to please reconsider and continue to allow pharmacists to verify prescriptions remotely, as we have been doing for the last decade. We are trying to work towards a more patient centered health industry and this will allow us to continue to do so.

Thank you very much for your time, Christina Song From: <u>Vazquez, Vanessa</u>
To: <u>Sodergren, Anne@DCA</u>
Subject: Remote processing

Date: Thursday, January 19, 2023 6:50:06 PM

WARNING: This message was sent from outside the CA Gov network. Do not open attachments unless you know the sender: vanessa.munoz@walgreens.com

Hello Dr. Seung Oh,

My name is Vanessa Vazquez and I am a Group Supervisor here at Walgreens. I oversee a group of California Pharmacists who process prescriptions remotely. I would like to respectfully ask that CA Pharmacists be allowed to continue working from home. They have always expressed how much they love working from home because it allows them to have a better work-life balance. They're able to do a great job providing care to the residents of California and be literally as close as possible to home, which allows them to also provide better care to their immediate families. If remote processing was no longer allowed in CA, I would lose half of my team, and my job as their leader would have to be re-evaluated. The board's decision would not only negatively impact remotely-working CA Pharmacists, but everyone including myself that works to support those Pharmacists.

Thank you for your time,

Vanessa Vazquez Group Supervisor

Walgreen Co. | 8337 Southpark Cir, Orlando, FL 32819

Telephone 407 541 4943

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From: Cabezuela, Elizabeth
To: Sodergren, Anne@DCA
Subject: Remote processing

Date: Thursday, January 19, 2023 6:52:26 PM

WARNING: This message was sent from outside the CA Gov network. Do not open attachments unless you know the sender: elizabeth.cabezuela@walgreens.com

For the Executive Officer and Licensing Committee Chairperson

Dear Dr. Seung Oh,

My name is Elizabeth Cabezuela, and I'm a California Registered Pharmacist and a remote processor for Walgreens. I have been a pharmacist for over 15 years and love every minute of it.

I started my career as a community pharmacist: verifying and dispensing medications, counseling patients, and administering vaccines. For nine years, I helped every patient as much as possible with the time and resources I was given. However, it was a stressful time in my life. Between fulfilling constant customer service needs and decreased technician hours, I was overwhelmed. When I found a job listing for a remote processor for Walgreens, I jumped and fought for it! What an excellent opportunity to work in an environment that can help many more patients!

Walgreens strives for patient safety. Patients should know their medications are in excellent care with pharmacists whose priority is safety and accuracy. My position as a remote processor is so essential. I am verifying prescriptions and reviewing patient profiles without constant distractions. I do not have ringing phones, other people around, or any other tasks-- I am focused on getting my work done safely, correctly, and promptly. Patients may not see or talk to pharmacists like me, but that's okay. I know they'll go home with the proper medication.

Pharmacists are already inundated with prescriptions, doctor and patient calls, requests, and more.

We give them time to work on other tasks, while we focus on the details of prescriptions. Ultimately making our patients satisfied and well cared for.

Personally, my job has given me the perfect work-life balance. I'm a mother of 3 childrenages 7 to 13. I spend the mornings prepping for school and the evenings with homework and bedtime. Once they are in school, I am just a few steps away from my office. I don't waste time commuting, allowing me to spend more time with my family.

I ask the California Board of Pharmacy to continue to allow Remote Processing. We are dedicated pharmacists who want to continue assisting our colleagues and patients.

Thank you for your time.

Sincerely,

Elizabeth Cabezuela

California Registered Pharmacist

License number: RPH 60027

cellphone: 858-603-2291

Pharmacist, Centralized Services

From: Stark, Aaron

To: Sodergren, Anne@DCA
Subject: Remote processing

Date: Thursday, January 19, 2023 6:54:44 PM

WARNING: This message was sent from outside the CA Gov network. Do not open attachments unless you know the sender: aaron.stark@walgreens.com

Hello,

My name is Aaron Stark, I am a CA licensed RPh currently working in a remote processing position. I have been licensed since 1996. I managed a 24 hour pharmacy in the Bay Area from 1996-2004, was a district supervisor in the central valley from 2004-2007, and managed another 24 hour pharmacy from 2007-2016. I have been in my current position from 2016 to present. My wife is also an RPh currently working in a Walgreens store. I am writing today to address the current issue facing the board with regard to remote processing. My primary concern is for patient safety, with a secondary concern of increasing the misery index for both patients and pharmacists in a climate that is already pretty miserable. Working remotely allows pharmacists to process a large volume of rx's in a controlled, distraction free environment, which is far better for patient safety than in a busy pharmacy with multiple points of constant distraction. Putting the hundreds of thousands of rx's that are currently remotely processed back into the pharmacy would cause chaos and greatly increase the chance of making errors. It would also mean less access to quality care for patients because pharmacists would be far more tied up trying to manage this workload at a time when the workload is already overwhelming.

On a personal note, this job absolutely saved my career as a pharmacist. After 20 years I was ready to move on to other interests, having seen what the working conditions had become and the negative trajectory they were on. I am now content with spending the rest of my career as a pharmacist as a result of working in a remote setting position.

Thank you very much for your consideration.

Respectfully, Aaron Stark, RPh
 From:
 Hanaa Basalious

 To:
 Sodergren, Anne@DCA

 Subject:
 Remotely Pharmacist work

Date: Thursday, January 19, 2023 8:28:34 PM

WARNING: This message was sent from outside the CA Gov network. Do not open attachments unless you know the sender: hanaamm@yahoo.com

Hi Dr. Seung Oh,

My name is Hanaa Basalious and I am a licensed Pharmacist in the state of CA. My present job is as a Walgreens Health Outcomes Pharmacist working from home in CA. I started this job 3 years ago and I appreciate doing what I can to offer patients the best healthcare possible. I am given the chance to do personalized care and medication therapy management that most patients need.

I was working as a retail pharmacist for more that 10 years, and during this period my passion and concern was how to find the opportunity to spend more time with my patients to give them the required information to adhere to their medicine and avoid the probability of not taking the medications for any reason. This includes taking the medications the right way and preventing any drug-drug interaction or misunderstanding of doctor's instructions. I provide them with health recommendations to avoid any complication of their health issues that may lead to hospitalization which is the most valid concern for health insurance institutes in the USA. As a pharmacist working in the community pharmacy I wasn't able to give the patient the amount of time or level of care I can now because of my dedicated role in patient outcomes.

Just yesterday, I was speaking with a patient about his health condition and how to get his blood sugar level and blood pressure under control to avoid various complications. He was so appreciative of the call and he told me that even the doctor had no time to inform him about these things. The patient continued to tell me that he has a cousin who had serious health issues that led to amputation because nobody informed him about how to avoid complications. The patient told me that he felt valued being treated as a human being, and not a case and he is very thankful that somebody cares for his health.

Thank you for giving me the opportunity to explain how important it is to the patient to keep this service for the sake of the health benefits for the community.

Best Regards, Hanaa Basalious Licensed CA Pharmacist
 From:
 Noreen Olmsted

 To:
 Sodergren, Anne@DCA

 Subject:
 Remote Processing

Date: Friday, January 20, 2023 7:02:19 AM

WARNING: This message was sent from outside the CA Gov network. Do not open attachments unless you know the sender: noreenie1@mac.com

Dear Dr. Seung Oh,

I am a retail pharmacist that has worked remote processing since 2018. It has come to my attention that the BOP is discussing if this will continue to be allowed. I believe it should be.

Remote Processing allows for a better and safer experience in the stores for both pharmacists and patients. By having a pharmacist remotely take care of some tasks, the pharmacist in the store can focus on patient facing tasks. This would include the final verification of the medication, but also having time for consultation and immunization. The in store pharmacist would also have more time for corresponding with prescribers to benefit patients. Pharmacy is incredibly stressful and having some of these tasks done remotely benefits every body.

Remote processing also allows another avenue of work. It provide a less physically strenuous environment. It also provides a better work life balance for those that need it.

Pharmacists of different types have been working remote for many years I truly believe it benefits all, the pharmacists, the patients, and the profession.

Thank you for your time

Noreen Olmsted PharmD

From: Delia Monsalud

To: Sodergren, Anne@DCA

Subject: Remote processing

Date: Friday, January 20, 2023 8:18:11 AM

WARNING: This message was sent from outside the CA Gov network. Do not open attachments unless you know the sender: delia.monsalud@gmail.com

Hello,

My name is Delia Monsalud. I am a work at home pharmacist with Walgreens. I have been a registered pharmacist since 2009 and I've been in the work at home position since 2015.

I have always been grateful for this position as it allowed me to practice pharmacy safely and balance my work with my family life. This position allows me to care for my patients with less disruptions and greater ability to focus on making sure I verify the correct medications as well as on communicating with the store pharmacists about patient concerns.

When I verify prescriptions remotely I'm helping out a pharmacist in the store who might be counseling or administering an immunization. While I'm verifying prescriptions, the pharmacist does not need to worry about the work load that's piling up.

I also worked in a retail pharmacy and I can say there were many times when I would have needed someone to help out verify so I could be more present for my patients, not hurrying through consultations or feel overwhelmed by the work adding up while giving immunizations or answering calls.

The work at home program is helping our in store colleagues provide better face to face care, while I can work with minimal interruptions to ensure patient safety.

On a personal level this position also allows me more flexibility at home in my personal life.

I've been grateful to be able to practice pharmacy in this way.

I respectfully ask the committee to consider my experience when evaluating the changes it intends to make to our ability to practice pharmacy in a work from home environment.

Sincerely Delia Monsalud, PharmD, Rph

Sent from my iPhone



January 20, 2023

The Honorable Seung Oh, President California State Board of Pharmacy 2720 Gateway Oaks Drive, Suite 100 Sacramento, CA 95833

Re: Board of Pharmacy Licensing Committee Discussion & Consideration of Provisions for Remote Processing

Dear President Oh,

On behalf of the California Retailers Association (CRA), I write to express our support for the practice of remote processing and to urge the Board of Pharmacy to work on a solution to ensure that pharmacy personnel can continue to work remotely to perform specified functions.

Many of CRA's pharmacy members currently utilize remote processing and have incorporated this practice into their business operations both before and during the COVID-19 pandemic. Pharmacy team members have been able to perform a variety of tasks outside of the pharmacy, including data entry. The ability for pharmacy team members to perform these duties at home has created significant, immeasurable benefits for the pharmacy workforce, which ultimately has led to better access for patients.

Ensuring that remote processing can continue is particularly timely in light of the Board's recent discussions and actions related to pharmacy working conditions and medication errors. Remote processing allows many pharmacists and pharmacy technicians to work from home, which has helped to improve work-life balance and prevent burnout. In addition, non-clinical tasks can be performed outside the pharmacy, freeing up more time inside the pharmacy to focus on direct patient care and preventing errors by reducing distractions.

If remote processing is prohibited, many pharmacy employees will either be forced to work at the pharmacy or potentially lose their jobs. Given the current lack of available workforce and the pressures the entire healthcare sector is facing, we respectfully request that the board take steps to ensure that remote processing can continue indefinitely for all pharmacy sectors, for all types of pharmacy personnel at their homes or other locations outside the pharmacy. Doing so will allow the benefits of remote processing for both pharmacy employees and patients to continue, including workforce flexibility, reduced diversion since that cannot happen remotely, and prevention of medication and other errors.

The California Retailers Association is the only statewide trade association representing all segments of the retail industry including general merchandise, department stores, mass merchandisers, online marketplaces, convenience stores, supermarkets and grocery stores, chain drug, and specialty retail such as auto, vision, jewelry, hardware, and home stores. Our members include national chains as well as independent retailers from across California. California retail is the state's largest industry, operating in

over 505,000 retail stores which accounts for over 25 percent of California's jobs with a combined \$542 billion on the state's GDP.

Please do not hesitate to contact Lindsay Gullahorn or Jennifer Snyder with Capitol Advocacy at lgullahorn@capitoladvocacy.com or jsnyder@capitoladvocacy.com if you have any questions.

Sincerely,

Rachel Michelin President & CEO

California Retailers Association

cc: Anne Sodergren, Executive Officer, Board of Pharmacy

From: Reyen, Quang
To: Sodergren, Anne@DCA

Subject: January 24, 2023 Meeting Re: Remote Processing Waiver

Date: Friday, January 20, 2023 12:13:33 PM

WARNING: This message was sent from outside the CA Gov network. Do not open attachments unless you know the sender: quang.reyen@walgreens.com

Dr. Seoung Oh,

Please take a moment to consider other components of the "Remote Processing Waiver" beyond the traditional role of data entry, data review, and clinical review.

I am a Health Outcomes Pharmacist working remotely from home. I spend more than ninety percent of my daily time reaching out to and speaking with patients in order to improve medication adherence and optimize therapy. Sometimes the conversations may be a quick five-minute check-in or a forty-five-minute medication review depending on the patient's needs. I have had the pleasure of providing this beneficial service well before the Covid-19 pandemic and the initiation of the remote processing waiver. I gladly report that many patients are positively surprised that this service is available to them and are extremely happy that a pharmacist personally checked-in on them. Due to the strain of our health care system at all levels, what my colleagues and I perform daily provides patients access to quality health care.

Two main stakeholders are the patient and the pharmacist. Without remote pharmacy services, patients will have limited access to quality health care. Rarely will you find a patient who can say that they were able to speak to a healthcare professional uninterrupted for forty-five minutes without making an appointment. Patients who experienced this service appreciate the pharmacist's compassion concerning their health. The role as a pharmacist evolved significantly over the last few decades by adapting to changes in our healthcare system. My daily interaction with patients remotely is a natural extension of that. Providing drug information services and performing therapeutic interventions at a personal level is one aspect of pharmacy services striving to improve patient health outcomes.

Please consider changes that will allow pharmacists like me to continue providing quality health care services to patients. Thank you for your attention.

Sincerely,

Dr. Quang Reyen, RPH

Ngoc Lien T. Nguyen 12521 Sundance Ave San Diego, CA 92129 January 19, 2023

California State Board of Pharmacy

Licensing Committee

Re: Letter of Support for Remote Processing

Dear Licensing Committee Chair,

My name is Ngoc Lien T. Nguyen, a Health Outcome Pharmacist at Walgreens Pharmacy. I am writing this letter to support remote processing. As a health outcome pharmacist, I work remotely to contact patients at risk of being non-adherent on their medications and work with them to identify any barriers that may be present to prevent them from taking those medications. I help them overcome those barriers through either counseling or by using various programs that Walgreens offers such as Save-A-Trip Refills and 90-day supply fills. I'm accountable of making sure that patients are being adherent on their medications to lower the risk of disease progression and further complications. Some patients live in rural areas, and they appreciate the calls to review their medications at the comfort of their home. The remote processing waiver has allowed me to help more patients with any issues they may have.

I believe the remote allowance is vital to my job. I have practiced pharmacy every day in a non-traditional setting before COVID-19. My workplace has trainings and policies to protect confidential patient information. There is also a team to review the calls to make sure we display the courtesy to patients and protect their information. In addition, working remotely has allowed me to have a work-life balance to be able to take care of my mother who is terminally ill.

I urge you to please reconsider your interpretation of remote processing, not allowing this will greatly impact my pharmacy practice for patient care, especially for the patients who have limited access to healthcare, and my work-life balance. I would like to thank you for giving me the opportunity to explain my situation.

Sincerely,

Ngoc Lien T. Nguyen, Pharm.D.

Ngoc Nguyen

From: Patel, Nima

To: Sodergren, Anne@DCA
Cc: nimapatel25@gmail.com
Subject: Remote order processing

Date: Friday, January 20, 2023 9:20:56 AM

WARNING: This message was sent from outside the CA Gov network. Do not open attachments unless you know the sender: nima.patel@walgreens.com

Dear Board of Pharmacy,

Hello. My name is Nima Patel. I am a registered pharmacist in the state of California. With over 25 years of experience, primarily in a retail setting, I have come to realize that pharmacies need help to ensure accurate prescriptions for the safety of their patients. I have had retail experience in many pharmacies, and the one thing that they all have in common is that the pharmacist is spread thin and overworked. By remote verification, we are able to reduce the stress of the retail pharmacist and ensure safety for our patients.

Since August of 2015, Walgreens has given me the opportunity to work from home. This has been very beneficial since I am able to practice pharmacy as well as balance home life. By working at home, I am able to limit the distractions and concentrate on the patient's prescription for accuracy and allow the retail pharmacist to spend more time on consultations. With the proper guardrails in place on the software systems and access points used remotely, there should not be any security concerns. Please allow us to Work at Home.

Thank you Nima Patel Rph#49648 From: Jerry Monsalud

To: Sodergren, Anne@DCA

Subject: Remote processing

Date: Friday, January 20, 2023 3:36:02 PM

WARNING: This message was sent from outside the CA Gov network. Do not open attachments unless you know the sender: jmonsalud@gmail.com

Hello,

My name is Jerry Monsalud. I have been a registered pharmacist since 2009. I have worked in the retail pharmacy field all my career. Since remote processing became available at Walgreens, my workload became more manageable. I can focus on face to face consultations and spend time with immunizations, answer calls or help out customers with finding on over the counter product. I don't have to worry about falling behind and not having prescriptions ready for our customers. I can trust the process because I know my work at home colleagues are able to focus and concentrate on accuracy and safety for our customers.

I would like to add my voice in support of continuing the remote processing program.

Sincerely

Jerry Monsalud, PharmD, Rph

From: <u>Duyen Pham</u>

To: Sodergren, Anne@DCA
Subject: Remote Processing

Date: Friday, January 20, 2023 5:36:42 PM

WARNING: This message was sent from outside the CA Gov network. Do not open attachments unless you know the sender: dtpharmd515@gmail.com

To whom it may concern:

Hello. My name is DP and I am a work at home pharmacist in California for Walgreens Pharmacy. I am writing today to share my thoughts and concern to the committee's consideration to no longer allow pharmacists to work remotely effective May 2023.

I have been blessed and fortunate enough to work both on the retail side of pharmacy as a staff and pharmacy manager for 12 years at extremely high volume 24 hour stores and remote processing side of pharmacy for 7 years and I can wholeheartedly say that taking away remote processing will have a huge negative impact on the ultimate goal of what we set out to do as a pharmacy and pharmacist; to provide the utmost quality care to the people of our community in an orderly and safe manner. Remote processing plays a crucial role in allowing pharmacists at the retail stores the additional time needed to provide quality care to patients. It frees them up to enable them to provide meaningful consultations about new to therapy medications or general questions about OTC meds. It allows them time to administer vaccinations to patients without having to worry about rushing back to verify a prescription for patients physically waiting in the pharmacy for their own medications (because we are supporting them remotely). It gives them time to call doctors to verify prescription orders and call patients to ask them about their new medications. I am able to share all the reasons above because my 24 hour pharmacy store was supported by remote processing when I was working in retail and managing it so I can attest that it truly does help to assist us in all the examples I stated above. The support that our remote processing team provides overall enhances and promotes a smoother and more efficient work flow at the retail stores and therefore reduces chaos, potential errors, mental, emotional and physical stress. It also helps to increase productivity, safety and quality care.

More importantly and personally, this remote processing role has provided me what many who work in healthcare are striving and hoping to have and that is a balanced and flexible work life and family life. Remote processing has helped me tremendously in decreasing my stress levels while still allowing me to work as a team with my retail colleagues to provide care to our patients. This has resulted in a healthier me mentally and physically and it has given me a more flexible and balanced life for myself and the people that matters the most to me in life and that is my family. For that I'm truly grateful.

Thank you for your time and I hope you will truly consider NOT taking away this remote processing from California and revising it to be allowed indefinitely. Have a great day.

Warmest Regards, DP (CA Work at Home Pharmacist)

Sent from my iPhone

From: <u>Julie W</u>

To: Sodergren, Anne@DCA
Subject: Remote processing BPC

Date: Friday, January 20, 2023 4:21:56 PM

WARNING: This message was sent from outside the CA Gov network. Do not open attachments unless you know the sender: juliezhou31@gmail.com

To Dr. Seung Oh,

My name is Julie Wan and I am emailing my testimony regarding upcoming board hearing for remote processing license.

I've been in the practice for the past 15 years and the last five years working from home has been life changing to say the least. From a pharmacist point of view, what we do as centralized pharmacists is crucial to the success of delivering quality care in this fast changing world that we all live in. We allow in-store pharmacists to spend quality time with their patients instead of worrying about the never ending Que that they must clear or the phone calls that just never stops. We give them the freedom to do what they do best, which is to connect with the community and help those who are in need. I think to take away this tremendously important help from their daily workload is a disservice to the community. From a personal point of view, I could not be where I am today with my family and career if I had not been given the opportunity to work with Walgreens WFH team. This has allowed me to continue my career path without having to sacrifice time with my family. I was able to maximize my time for work due to my lack of commute and witness more milestones of my children and family. I truly believe we all thrive to find that near perfect work life balance and I have found that here with Walgreens. Please reconsider your decision to end this remote processing license. Thank you for your time.

Sincerely,

Julie Wan, RPH

--

Julie Yin Wan

From: Sharon Mullen

To: Sodergren, Anne@DCA remote processing waivers

Date: Friday, January 20, 2023 1:34:20 PM

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To whom it may concern,

I am a remote pharmacist in the state of California. I have worked for Walgreens and Optum as a remote processor . I am not understanding why the BOP might cancel this practice. Remote pharmacists reduce the stress of store pharmacists , We take the heavy load of trying to focus and verify a prescription for accuracy off the shoulders of the store and are able to accomplish this in a quiet setting. We are more accurate and much , much faster . The BOP is supposed to govern to help public safety, instead pharmacist in the last ten years have had more and more to do with more and more regulations and no time to do all this . Your first priority is safety. Remote pharmacy is a solution, the first solution that I can remember in decades. The store pharmacists are bogged down with VAERS reports, misfill reports , audits , CURES reports , Vaccines and Covid tests . All of this prevents accuracy, patience and the opportunity of face to face with patients. Try calling a retail pharmacy and see how long you are on hold before you get a real person.

Even though the State of Emergency for Covid ends February 2023, The Gates Foundations has had another tabletop exercise predicting another pandemic in 2025 called S.E.E.R.S.. (severe epidemic enterovirus respiratory syndrome) It is expected to start in South America and have a mortality of over 70%. There is also worries of Marburg. We have also had devastating fires, floods and earthquakes and riots. The remote pharmacist can help redirect the flow of prescriptions that are e-prescribed and type and verify at another location, then the Rxs can be remotely filled. Walgreens have been recognized for their efforts to help disaster areas from hurricanes floods and rioted areas. Most of the effected are the poorer neighborhoods. How is this equity, if you don't allow remote pharmacists. Many of these patients do not have insurance to be able to have a mailorder prescription. How is the BOP helping if pharmacies are pulling out of crime ridden areas? The nation is moving forward with innovations and tele-medicine, why is California going backward? California's Covid response was mismanaged and now you will be removing a tool in the toolbox to help during Climate disasters, riots, and future pandemics. The infrastructure is already in place and working and it can not be instantly restablished in minutes, but in minutes Walgreens was able to help Hurricane victims in Florida, floods in Tennessee and Texas

The security of patient information I feel is secure with remote processing, the software does not allow us to randomly look at a patient file. We take an oath in the State of California and all our keystrokes are monitored . The Social Media giants in California have far more access to a person's private info and they work remotely. Please reconsider extending the waivers or changing the rules or law to make

remote processing permanent.

Thank you for your consideration, a future unemployed remote pharmacist

From: <u>Le, Maihieu</u>

To: Sodergren, Anne@DCA
Cc: maihieu@gmail.com
Subject: remote processing

Date: Friday, January 20, 2023 1:31:26 PM

WARNING: This message was sent from outside the CA Gov network. Do not open attachments unless you know the sender: maihieu.le@walgreens.com

To Dr Seung Oh,

My name is Mai Le and I have been practicing pharmacy at the retail level for 18 years, with the last 8 years being a work-at-home pharmacist doing remote prescription verification. I am aware of many others like me, not only at the retail practice but the hospital and PBM side alike, who have been remote processing a lot longer than I have. That being said, I am confused by the sudden reevaluation or reinterpretation of a law that would no longer allow pharmacists to provide patient care this way.

Before centralization and remote processing, as a retail pharmacist you were the sole person to run the pharmacy and ensure the patients were taken care. This could make your job and day very stressful and difficult to balance if you wanted to provide top notch care but also ensure no one waited too long, because no one else but me, the pharmacist, could verify prescriptions, administer the vaccinations, provide the consultations, take in new prescriptions, or answer patient medicine questions.

In my final weeks at the store before transitioning remotely, I witnessed something amazing. My soon-to-be colleagues who were already verifying remotely, were verifying prescriptions for my pharmacy intermittently throughout the day . That meant I could have peace of mind walking away from my computer verification workstation to focus on the other important tasks of the day mentioned previously, really building those relationships with my patients.

So when I started working from home to verify prescriptions remotely, I knew what an important and essential role I played in the care of my patients. Even if I was practicing "behind the scenes" to provide the support for my colleagues at the store level, I was contributing to patient safety and care. I could now focus solely on verifying prescriptions without the constant distractions of phone calls, people talking, and the need to multitask while verifying. And by working from home, I was able to finally have a more favorable work life balance. I never stopped practicing pharmacy, I just did it from home, processing remotely.

I urge you to please reevaluate your consideration. By re-interpreting the same law that's been in effect for ages to now so that I can no longer work from home, will have not only a personal and professional cost, but will also be disruptive to the care of our patients who see pharmacists as their first-line care.

Thank you so much, Mai Le From: Ng, Teresa

To: Sodergren, Anne@DCA

Subject: Upcoming Board Meeting regarding Remote Processing

Date: Friday, January 20, 2023 9:30:23 AM

Attachments: image003.png

WARNING: This message was sent from outside the CA Gov network. Do not open attachments unless you know the sender: prvs=377b111ff=teresa.ng@optioncare.com

Dear CA BOP, Dr Oh, or whom it may concern,

I would like to write in to request that the Board approves the current "Remote Processing Waiver" and make it permanent.

The reason for this is that since the pandemic, our organization has implemented a hybrid/remote working process our pharmacy staff, and we were allowed to WFH majority of the time, and this has been a great help not only to minimize Covid exposure as it was initially intended, but also a great improvement in Pharmacists' Quality of life, and work-health balance.

For my type of pharmacist work, I feel that the exact same work can still be done accurately, safely and effectively from home, and I saved a lot of time on my commute in LA traffic, and needless to say, the money saved on gas and helping the environment.

I believe as long as we have the right rules/ regulations, and all our advancement in technology, remote processing can be a success and will continue to move the entire pharmacy industry into the 21st century.

Please kindly consider making remote processing permanent. Thank you.

Teresa Ng, Pharm.D.

Clinical Pharmacist
Crescent Healthcare, an Option Care owned company
Los Angeles Specialty Center of Excellence
Toll free Number 877-872-4844 Ext 2841 OR Direct Dial Number 562-347-2841
Toll free Fax 866-872-4844
teresa.ng@optioncare.com

11980 Telegraph Rd, Suite 102 Santa Fe Springs, CA 90670



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From: roya r

To: Sodergren, Anne@DCA

Subject: Remote Processing Waiver Continuation

Date: Friday, January 20, 2023 10:30:07 AM

WARNING: This message was sent from outside the CA Gov network. Do not open attachments unless you know the sender: royarmerf@gmail.com

Dear Dr. Seung Oh,

My name is Roya Merfeld and I have been practicing as a full-time remote Health Outcome Clinical and prn Data Review Pharmacist for a major chain pharmacy for about 4 years. The remote processing waiver has been beneficial for both patients and myself. With the lack of distractions provided by remote work I can have longer one on ones with patients and verify prescriptions more accurately.

I am able to focus on patient education, medication consults, identify duplication of therapy, barriers in care, and gaps in therapy. Staff pharmacists cannot afford to provide the same level of care with their focus on dispensing, immunizations, and point of sales activities. Patients proclaim they have never had such in depth consultation and time given to them with any health care professional and really appreciate the service provided.

This remote position has benefited myself because of my on-going health challenges affecting my joints, mobility and ability to drive. Eliminating my ability to work remotely would severely limit my ability to contribute to my community and would force me further onto disability with no viable career alternatives.

Patient privacy and security is also a priority at my home office in California, with a closed door and windows, no access to printers, and company-provided equipment that views patient information over an encrypted connection without any data stored locally.

In light of the shortage of healthcare professionals, I feel that patients will suffer if the waiver is not renewed. I implore the board to renew this waiver and continue the efforts to permanently allow remote pharmacy practice. I really appreciate your time and help. Many thanks.

Sincerely,

Roya Merfeld Pharm. D From: <u>Vu, Katherine</u>

To: Sodergren, Anne@DCA
Subject: Remote Order Processing

Date: Friday, January 20, 2023 3:22:38 PM

WARNING: This message was sent from outside the CA Gov network. Do not open attachments unless you know the sender: katherine.vu@walgreens.com

Dear Dr. Seung Oh and to whom it may concern,

My name is Katherine, and I have been a pharmacist since 2018. During this time, my goal has always been to improve patient care and health outcomes. As a result, I have taken on a workfrom-home position that has allowed me to put patients and patient care at the forefront. In this role, I am able to speak to patients about their medications in an environment free from the usual distractions of a bustling pharmacy. Multiple patients that I have spoken to have extended their appreciation that a pharmacist outside of the store has been able to reach out to them and speak to them in detail about their medications, since the store pharmacists are so busy! Although I agree that the "work-from-home" space is relatively new and may require further regulations, I am optimistic that the Board will continue to strive towards the goals laid out in the California Board of Pharmacy Strategic Plan 2022-2026, specifically goals 3.2, 3.4, and 3.5. No matter where we are, "remote order entry" should continue in order to increase access and improve health outcomes for the public.

Thank you for your time.

Katherine V., Pharm.D. Pharmacist, Centralized Services Site Operations

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Sodergren, Anne@DCA

Sent:	
To:	
Subject:	

WARNING: This message was sent from outside the CA Gov network. Do not open attachments unless you know the sender: rphmichael65@gmail.com

Hello all,

My name is Michael and I have been a remote pharmacist with Walgreens for three years. During this time, I have provided patient consultations, medication management, and completed refill requests/immunization recommendations/answered pending questions. I am able to spend one on one time with our patients from a HIPAA secure location free of distractions such as phones ringing and needing to manage multiple waiting patients. Patients are comfortable at home with their medicines in front of them as we provide a holistic review. I am able to practice pharmacy to the fullest while also reducing the workload for our increasingly busy retail locations. The ability to work remote increases access to pharmacy services for patients in a timelier manner.

Telemedicine utilizing doctors, nurses, and pharmacists have been proven successful in expanding access to healthcare across many states. I believe it is time for the California Board of Pharmacy and California Pharmacists to participate in the next advance of healthcare.

Thank you for your time, Michael

Sodergren, Anne@DCA

Sent:	
To:	
Subject:	

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Dear Ms. Sodergren,

My name is Cecile Taylor. I am a retail pharmacist at a community chain pharmacy. We are often short handed these days and have extra duties as pharmacists to immunize and assist with covid testing, in addition to our usual verification duties. We often rely on remote verification to help with our workload. Sometimes, I would go do 3 or 4 immunizations and return to 20 or more prescriptions to verify. As the day does by, we would fall further and further behind. When remote verification is available, we can deliver prescriptions in a timely manner to our patients. It also frees us to handle issues that require special attention. Please know that remote processing and verification is a necessity and not just a luxury.

Thank you for your time,

Cecile

Sodergren, Anne@DCA

Sent: To: Subject:

WARNING: This message was sent from outside the CA Gov network. Do not open attachments unless you know the sender: thaoqd@gmail.com

Hello Dr. Seung Oh,

My name is Thao Do. I am a registered and licensed pharmacist in the state of California. I'm writing and reaching out to you with concerns regarding an agenda item, remote processing, that will be discussed at the January 24th Virtual Licensing Committee meeting. I started my career in pharmacy in 2006 and have spent the past 7 years working as a pharmacist, remotely processing and reviewing prescriptions to ensure prescriptions are entered correctly and appropriately in accordance with all applicable state and federal laws and regulations.

I believe the Board of Pharmacy, its members and pharmacists all over California have maintained that one of the key focuses of our profession is the safety and welfare of the patients we serve in our communities across the state. I can testify to the fact that patient safety is my and my colleagues' focus in our work...what's safer and beneficial to the patients than licensed and experienced (all my colleagues have years if not decades of working experience in the pharmacy retail stores as well as other pharmacy and healthcare settings) pharmacists dedicated solely to the processes of data and clinical reviews of prescriptions. Our work makes sure prescriptions are not only interpreted correctly and appropriately prescribed, but all drug interactions as well as other related issues are reviewed and resolved without distractions and interruptions.

I fully believe our work and support has been greatly beneficial to our pharmacist colleagues at the stores and our patients. Our support has enabled our pharmacist colleagues to be more accessible to patients for not only their prescriptions and healthcare related concerns, but our pharmacists at the store can further focus on delivering health services such as vaccinations, nicotine replacement therapy, naloxone, self-administered hormonal contraception, HIV PrEP and PEP services. Therefore, I do not believe a disruption or discontinuation of remote processing or of our work would be to the best interest of the patients. Thank you for your time.

Sincerely, Thao Do, PharmD, Rph