California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

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

LICENSING COMMITTEE REPORT
April 5, 2023

Seung Oh, Licensee Member, Chairperson
Jignesh Patel, Licensee Member, Vice-Chairperson
Indira Cameron-Banks, Public Member
Travis Chandler, Public Member
Jessica Crowley, Licensee Member
Jason Weisz, Public Member

I. Call to Order and Establishment of Quorum

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

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

III. Approval of the January 24, 2023, Licensing Committee Meeting Minutes

Attachment 1 includes the draft minutes from the January 24, 2023, meeting.

IV. Discussion and Consideration of Provisions for Remote Processing

Relevant Law
BPC 4071.1, subdivision (a) permits a pharmacist (or a prescriber or prescriber's agent) to "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." This is known as "remote order entry."

Background
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 BPC 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. More recently, as part of the January 2023 Licensing Committee Meeting and February 2023 Board Meeting, members voted to sponsor legislation to address an acute need for hospitals and other licensed health care facilities to establish provisions for remote processing of medication chart orders necessary to ensure continuity of patient care for inpatients.

Agreement was not reached specific to if, and under what conditions, permanent authority for remote processing should be established for community pharmacies. Previous discussions have highlighted the complexity

of the issue and various competing interests. Ultimately, it is incumbent on the Board to determine what is in the best interest of California patients.

Comments have also been made regarding other topics regarding pharmacists' authority to perform services outside of a licensed pharmacy. The Board's strategic plan includes strategic objective 1.1 to "Evaluate, and change if appropriate, legal requirements for authorized duties that can occur outside of a pharmacy to reflect the dynamic nature of the practice of pharmacy." It is recommended that the committee continue is discussion of remote processing. It is anticipated that discussion on the strategic objective will begin in the coming year.

For Committee Consideration and Discussion

During its January 2023 Meeting, members considered a number of policy questions, but did not reach consensus on the appropriate outcome for community pharmacy provisions, which would include mail order pharmacies. The meeting minutes, included as an attachment to the meeting materials provide information on the discussion. At the request of Chairperson Oh, to assist the committee and stakeholders with continuing its evaluation of the issue, draft statutory language was developed that could serve as a starting place.

It is suggested that during the meeting, members consider the proposal including the high-level concepts developed as well as the more detailed language. In general, the provisions include the following requirements.

1. The provisions would be limited to California licensed pharmacists, performing remote processing within California, on behalf of a California licensed pharmacy.
2. The provisions would specify the remote functions authorized and would only be allowed after the PIC of the pharmacy has made a determination, in writing, that remote work is necessary to enable improved direct patient care by pharmacists working in the pharmacy. Further, the written determination would state that reliance on remote work would not be used as a means to reduce staffing levels.
3. Pharmacists performing remote processing would be required to identify the specific location and consent to inspection of the location.
4. Policies and procedures must outline the authorized functions that can be performed and establish provisions to protect confidentiality of patient information as specified. Training must be provided.

5. Any breach of confidentiality must be reported to the Board and could result in enforcement action or the issuance of a citation and fine.
6. Any other violation of the provisions may also result in administrative or disciplinary action as specified or the issuance of a citation and fine.

Attachment 2 includes a copy of the language.

V. Discussion and Consideration of Changes to the Board's Sample CPA Related to MAT to Remove Reference to Data 2000 Waiver

Background
In October 2020 the Board released a sample collaborative practice agreement (CPA) for pharmacists to provide medication-assisted treatment (MAT) to patients with opioid use disorder (OUD) in collaboration with a medical care provider.

More recently, and related to MAT, the Board approved draft a protocol that, once approved through the rulemaking process, will provide a means for pharmacists to independently furnish MAT.

For Committee Consideration and Discussion
As discussed during the January 2023 Committee Meeting, President Biden recently signed legislation to expand access to MAT. In support of this action, the DATA Waiver requirement was removed. With this action, it is appropriate to update the Board's sample CPA to remove this requirement.

Although pharmacists will have the authority to independently furnish MAT once the Board's draft regulations are approved, the CPA provides another means to expand access to MAT.

Attachment 3 includes a draft of the updated sample CPA.

VI. Discussion and Consideration of Possible Regulations to Implement Government Code Section 16.5 Related to Digital Signatures and Development of Policy State to Facilitate Implementation of Digital Signatures on Applications and Other Notices

Relevant Law
Government Code Section 16.5 generally provides the authority for a public entity to accept digital signatures under specified conditions, including that the digital signature meets specific attributes detailed in the law. This section makes clear that use or acceptance of a digital signature shall be at the

option of the parties, and nothing shall require a public entity to use or permit the use of a digital signature.

Title 2, Division 7, Chapter 10 of the California Code of Regulations generally further defines Government Code section 16.5, including two forms of acceptable technology, including "public key cryptography" and "signature dynamics."

Background
Licensees and applicants are looking for alternative means to interact with the Board. Long term solutions to automate interactions with the Board will be through the Board's Business Modernization Activities currently underway. However, there are interim steps the Board can take to ease some of the current challenges licensees and applicants experience specifically related to signature requirements.

After reviewing the requirements established in regulations, Board staff recommend use of digital signatures that meet the requirements of public key cryptography. DocuSign is one example of the public key cryptography.

For Committee Consideration and Discussion
During the meeting, members will have the opportunity to discuss the issue and determine if changes to the Board's processes are appropriate to facilitate use of digital signatures. Should members believe such a transition is appropriate, staff will work with counsel to develop draft regulation language for member consideration at a future meeting.

Further, members may wish to request that staff begin accepting digital signatures meeting public key cryptography while development of the regulations is underway.

Attachment 4 includes a possible policy statement that could be used to facilitate communication to stakeholders about the Board's transition to accepting digital signatures.

VII. Discussion and Consideration of Licensing Statistics

Licensing statistics through from July 1, 2022 – February 28, 2023, are provided in **Attachment 5**.

Since July 1, 2022, the Board has received 9,390 initial applications, including:

- 1,158 intern pharmacists

- 1,697 pharmacist exam applications (572 new, 1,125 retake)
- 118 advanced practice pharmacists
- 3,582 pharmacy technicians
- 248 community pharmacy license applications (247 PHY - 13 chain, 232 nonchain, 1 PHR)
- 44 sterile compounding pharmacy license applications (32 LSC, 11 NSC)
- 77 nonresident pharmacy license applications
- 9 hospital pharmacy license applications

Since July 1, 2022, the Board has received 308 requests for temporary site license applications, including:

- 178 community pharmacy license applications
- 18 sterile compounding pharmacy license applications
- 46 nonresident pharmacy license applications
- 7 hospital pharmacy license applications

As of February 28, 2023, the Board has issued 5,720 individual licenses, including:

- 1,196 intern pharmacists
- 1,515 pharmacists
- 112 advanced practice pharmacists
- 2,492 pharmacy technicians

As of February 28, 2023, the Board has issued 372 site licenses without temporary license requests, including:

- 152 automated drug delivery systems (148 AUD, 4 APD)
- 46 community pharmacies
- 0 hospital pharmacies

As of February 28, 2023, the Board has issued 216 temporary site licenses, including:

- 135 community pharmacies
- 4 hospital pharmacies

Processing Times

Site Application Type	Application Processing Times as of 10/10/2022	Application Processing Times as of 3/24/2023	Deficiency Mail Processing Times as of 10/10/2022	Deficiency Mail Processing Times as of 3/24/2023
Pharmacy	95	121	70	164
Nonresident Pharmacy	112	164	119	185
Sterile Compounding	191	43	192	23
Nonresident Sterile Compounding	262	14	Mail combined with Sterile	Mail combined with Sterile
Outsourcing	Current	Current	Current	Current
Nonresident Outsourcing	315	Current	180	103
Hospital Satellite Compounding Pharmacy	Current	Current	146	Current
Hospital	83	7	50	78
Clinic	48	31	Current	8
Wholesaler	87	87	47	155
Nonresident Wholesaler	91	112	Combined with Wholesaler	Combined with Wholesaler
Third-Party Logistics Provider	27	39	Combined with Wholesaler	Combined with Wholesaler
Nonresident Third-Party Logistics Provider	48	105	Combined with Wholesaler	Combined with Wholesaler
Automated Drug Delivery System	31	8	Current	Current
Automated Patient Dispensing System	Current	Current	Current	Current
Emergency Medical Services Automated Drug Delivery System	Current	Current	Current	Current

Individual Application Type	Application Processing Times as of 10/10/2022	Application Processing Times as of 3/24/2023	Deficiency Mail Processing Times as of 10/10/2022	Deficiency Mail Processing Times as of 3/24/2023
Exam Pharmacist	10	14	5	Current
Pharmacist Initial Licensure	Current	Current	n/a	Current
Advanced Practice Pharmacist	5	49	Current	39
Intern Pharmacist	6	23	3	31
Pharmacy Technician	13	81	Current	9
Designated Representative	116	129	47	79
Designated Represenatives-3PL	111	10	Combined with Designated Representative	Combined with Designated Representative
Designated Representatives-Reverse Distributor	94	23	Combined with Designated Representative	Combined with Designated Representative
Designated Paramedic	53	Current	Combined with Designated Representative	Combined with Designated Representative

VIII. Future Committee Meeting Dates

- July 19, 2023
- October 18, 2023

IX. Adjournment

Attachment 1

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California State Board of Pharmacy
Department of Consumer Affairs
DRAFT Licensing Committee Meeting Minutes

Date: January 24, 2023

Location: Pursuant to the provisions of Government Code section 11133, neither a public location nor teleconference locations are provided.

Board Members Present:
Seung Oh, Licensee Member, Chair
Trevor Chandler, Public Member
Jessi Crowley, Licensee Member
Jason Weisz, Public Member

Board Members Not Present:
Jig Patel, Licensee Member, Vice-Chairperson
India Cameron-Banks, Public Member

Staff Present:
Anne Sodergren, Executive Officer
Eileen Smiley, DCA Staff Counsel
Debbie Damoth, Executive Manager Specialist

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

Chairperson Oh called the meeting to order at approximately 9:00 a.m. As part of the opening announcements, Chairperson Oh reminded everyone that the Board is a consumer protection agency charged with administering and enforcing Pharmacy Law. Department of Consumer Affairs' staff provided instructions for participating in the meeting.

Roll call was taken. Members present: Trevor Chandler, Public Member; Jessi Crowley, Licensee Member; Jason Weisz, Public Member; and Seung Oh, Licensing Member. A quorum was established.

II. Public Comments on Items Not on the Agenda/Agenda Items for Future Meetings

Members of the public were provided the opportunity to provide comment; however, no comments were made.

III. Approval of the October 18, 2022, Licensing Committee Meeting Minutes

Members were provided the opportunity to provide comments on the draft minutes; however, no comments were provided.

Motion: Approve the October 18, 2022, Licensing Committee meeting minutes

M/S: Crowley/Weisz

Members of the public were provided the opportunity to provide public comments; however, no comments were provided.

Support: 4 Oppose: 0 Abstain: 0 Not Present: 2

Board Member	Vote
Cameron-Banks	Not present
Chandler	Support
Crowley	Support
Oh	Support
Patel	Not present
Weisz	Support

IV. Discussion and Consideration and Possible Action on 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

Chairperson Oh advised the Board previously considered and established a support position on Senate Bill 1259 which sought to amend Business and Professions Code (BPC) section 4052.01 to provide the authority for a pharmacist to furnish federal Food Drug and Administration (FDA) approved opioid antagonist in accordance with standardized procedures or protocols developed under specified conditions. The Governor signed this measure which became effective January 1, 2023.

Chairperson Oh provided the statute requires the Board of Pharmacy and the Medical Board of California must approve the regulation with consultation of the California Society of Addiction Medicine, the California Pharmacists Association, and other appropriate entities. The statute also

specified areas that must be included in the standardized procedures. Dr. Oh noted the required protocol for pharmacists was included in California Code of Regulations (CCR) section 1746.3 and established the requirements of the standardized procedures established for a pharmacist to furnish naloxone hydrochloride pursuant to BPC section 4052.01.

Chairperson Oh recalled from discussions that as products are approved by the FDA it was appropriate to evaluate the Board's current regulation to establish flexibility in the regulation for furnishing of additional opioid antagonists approved by the FDA. Dr. Oh added since the last meeting, staff developed language and secured feedback as required by the statute. Dr. Oh thanked Dr. Gasper for sharing knowledge and expertise in this area with staff to develop the proposed revisions for consideration by the Licensing Committee. Dr. Gasper was in attendance and available to answer questions.

Chairperson Oh advised as required by the statute, following drafting of the proposed language, the draft was provided to the California Society of Addiction Medicine, who was offering one comment for consideration, which was moving a portion of the language to earlier in the section. No comments or concerns were identified by the Medical Board of California. Dr. Oh referenced the summary of changes being proposed in the meeting materials. Dr. Oh provided as required by statute, this proposal change must be approved by the Medical Board as well. Assuming the Committee recommended action and that recommendation was approved by the Board during the February 2023 Board Meeting, the executive officer would present before the Medical Board as part of its February 9-10, 2023, Board Meeting to request their consideration and approval.

Members were provided the opportunity to comment.

Member Chandler appreciated the work that went into the changes to help with the opioid epidemic.

Member Crowley agreed with the language and noted it made it easier for pharmacists provide naloxone and other opioid antagonists.

Motion: 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.

16 CCR § 1746.3

§ 1746.3. Protocol for Pharmacists Furnishing Opioid Antagonists ~~Naloxone Hydrochloride~~.

A pharmacist furnishing an opioid antagonist ~~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 semi-synthetic 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 Opioid Antagonists ~~Naloxone Hydrochloride~~.

Before providing an opioid antagonist ~~naloxone hydrochloride~~, the pharmacist shall:

~~(1) Screen the potential recipient by asking the following questions:~~ Make a reasonable inquiry to determine:

~~(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.~~
(~~2~~1) Provide the recipient training in opioid overdose prevention, recognition, response, and administration of the opioid antagonist ~~antidote naloxone~~.
(~~3~~2) 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.
(~~4~~3) 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.
(~~5~~4) 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~~5) 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.

M/S: Chandler/Crowley

Members of the public were provided the opportunity to comment.

A representative from CSHP commented in support of the amendment to the regulation and spoke in support of the regulation for a drug class rather than a specific drug. The representative applauded the Board's effort.

A retired pharmacist applauded the Board for making this change in the middle of the opioid epidemic. The commenter thought naloxone was going to be made OTC and requested clarification on the impact if made OTC.

Support: 4 Oppose: 0 Abstain: 0 Not Present: 2

Board Member	Vote
Cameron-Banks	Not present
Chandler	Support
Crowley	Support
Oh	Support
Patel	Not present
Weisz	Support

V. 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

Chairperson Oh referenced meeting materials including BPC 4052(a)(14) that provides authority for pharmacists to provide medication-assisted treatment pursuant to a state protocol and advised the Committee had the opportunity to consider proposed regulations establishing such a protocol.

Chairperson Oh reviewed and summarized MAT was used to treat substance use disorders as well as to sustain recovery and prevent overdose. Dr. Oh added recently federal law was changed to expand access to MAT including removal of the x-waiver requirement. With this change in the federal law and the Board's proposed regulation, Dr. Oh believed pharmacists that choose to provide MAT would be well positioned to serve as an important access point for patients in need of MAT and referenced meeting materials that included the proposed regulation language. Dr. Oh noted from the meeting materials, experts in this field assisted staff with the development of the draft proposal and thanked Dr. Gasper, Dr. Puzantian, and Dr. Geier for sharing their expertise with staff in the development of the proposed protocol.

Members were provided the opportunity to comment.

Member Crowley commented overall the proposal was great but had questions. Dr. Crowley asked about (b) that requires a pharmacist must ensure a confidential patient care area and inquired as to what that meant (e.g., private room, off to the side, etc.) and clarification as to what the physical assessment means (e.g., diagnosis). Dr. Crowley inquired what it meant to work in collaboration with other health care providers (e.g., referrals, treatment plans, etc.).

Chairperson Oh responded to subsection (b) due to the sensitive nature of the discussion, the conversation should be private.

Dr. Gasper advised the assessment was already built into the pharmacy practice act for advanced practice pharmacists. Dr. Gasper noted the difference between diagnosis and assessment was somewhat arbitrary. Dr. Gasper continued if a patient presents with a history of substance use

disorder then any signs or symptoms can be assessed and diagnosed by a pharmacist within the scope. Dr. Crowley asked if it was open to advanced practice pharmacists only. Dr. Gasper advised it was open to all pharmacists. Dr. Crowley thought confidential area should be clarified to be a private area or closed area.

Member Chandler commented he was excited about this and believed in an all-inclusive strategy when it comes to recovery. Mr. Chandler asked if any practitioner could start MAT and wanted to understand how MAT would come about and, if not initiated by a pharmacist, how this would be started.

Dr. Gasper commented up until recent change in federal statute the only drug pharmacists weren't able to prescribe under a collaborative practice agreement (CPA) was buprenorphine for opioid use disorder. This regulation removes the requirement with CPA. The change in law was the ultimate and low barrier access to treatment. Dr. Gasper noted the collaboration at that point was up to the pharmacist to bring in additional healthcare providers. Dr. Gasper noted this allowed for decisions that needed to be made quickly to save lives can be done immediately and additional treatment requirements can be brought in over time.

Member Chandler thanked the Board for the work on this regulation to be able to act immediately.

Member Weisz questioned about Dr. Crowley's concern how privacy was maintained. Ms. Sodergren provided in general pharmacies have private and sensitive information noting the Board receives a number of complaints alleging health information was shared in a manner they believe was inconsistent with the law. Ms. Sodergren inquired if Dr. Crowley was offering a change from "confidential" to "private." Mr. Weisz didn't want to inhibit the ability for people to access MAT. Dr. Crowley agreed a private patient area made sense but was concerned that it would be launched in chain pharmacies without having the dedicated time to develop a thorough treatment plan. Dr. Crowley shared she had a brother-in-law who died of an overdose from mixing buprenorphine and alcohol that could have been prevented.

Member Chandler amended the motion to change "confidential patient area" to "private patient area" in (a)(b).

Chairperson Oh agreed with the proposed language and was excited as a pharmacist about the possibility of providing MAT services in a more autonomous manner. Dr. Oh was hopeful that as a profession many would lean into this opportunity and create a safe and convenient access point for patients.

Motion: Recommend initiation of a rulemaking to add CCR section 1746.6 as proposed on the screen changing (a)(b) from "confidential" patient area to "private" patient area. 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.

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.

M/S: Chandler/Crowley

Members of the public were provided the opporuntity to comment.

A retired pharmacist commented in support but thought changing "confidential" to "private" as "private" implies closure where "confidential" means pharmacist protects information. The pharmacist thought this would be done in other environments. The pharmacist recommended withdrawing motion as confidential was a well-known definition where private was not required. The pharmacist noted pharmacies handle sensitive topics without an enclosed area.

A representative of CSHP commented the proposed language was broad enough where other institutions develop CPAs and wanted to make sure it doesn't preclude use of the CPAs.

A pharmacist had concerns with the distinction of "private" and "confidential" as a "confidential" area was already required. The pharmacist warned there was not always the discretion of the pharmacist and corporate pressures to offer certain services. The pharmacist had concerns if the pharmacies weren't set up properly.

Chairperson Oh asked Counsel Smiley about the difference between private versus confidential. Ms. Smiley commented about federal HIPAA

laws that govern in the privacy area and explicit California constitutional right to privacy. Ms. Smiley said it was a legal determination by the Board. Ms. Smiley stated there was no legal prohibition for requiring a private area versus a confidential area.

Member Weisz wanted to ensure MAT was made available and would like to go forward with the motion as originally written. Mr. Chandler asked if this could be modified as part of the rulemaking process. Dr. Oh confirmed it was the beginning of the process. Ms. Sodergren added can flag as a policy question to the full Board requesting the Board's policy decision for "confidential" versus "private."

Support: 4 Oppose: 0 Abstain: 0 Not Present: 2

Board Member	Vote
Cameron-Banks	Not present
Chandler	Support
Crowley	Support
Oh	Support
Patel	Not present
Weisz	Support

The Committee took a break from 9:44 a.m. to 9:50 a.m. Roll call was taken. Members present: Trevor Chandler, Public Member; Jessi Crowley, Licensee Member; Jason Weisz, Public Member; and Seung Oh, Licensee Member. A quorum was established.

VI. Discussion and Consideration of Pharmacist Provided HIP Preexposure and Postexposure Prophylaxis, Including Presentations

Chairperson Oh advised meeting materials contained a number of ways in which a pharmacy can engage with a patient to provide HIV PrEP and PEP including traditional dispensing functions, collaborative practice agreements, and provisions established in Senate Bill 159. Dr. Oh recalled at the October 2022 Board Meeting, the Board received a presentation on research underway on pharmacist-furnished HIV prevention. Dr. Oh advised the results of the research were not available yet but the Board would receive a presentation on the outcome.

Chairperson Oh provided the Committee would receive presentations on pharmacist-driven models currently used to expand access to HIV PrEP

and PEP. Dr. Oh welcomed Dr. Lopez, Chairperson and Residency Program Director with Mission Wellness Pharmacy.

Dr. Lopez provided an overview of San Francisco Department of Public Health (SFDPH) Capacity Building Assistance (CBA) Program. Dr. Lopez provided a history of pharmacy HIV testing and PrEP Services with Virginia Department of Public Health (VDPH) in collaboration with a chain pharmacy in Virginia and Kelly-Ross Pharmacy "One-Step PrEP" CPA with a private physician. Washington passed a landmark decision that went into effect in 2016 that mandated payment for all providers for clinical services in Washington. Dr. Lopez shared a map of the US that had PrEP Legislation and national pharmacist PrEP and PEP authority. Dr. Lopez shared a map of all pharmacy PrEP and PEP specific bills that have passed in the country since 2019. Dr. Lopez advised California was the first in the country to allow PrEP and PEP. Five states have passed legislation to provide ongoing PrEP and PEP. Four states have mandated reimbursement at 100 percent. Some states were working out the laboratory payment but Colorado and Nevada have a mandated laboratory reimbursement. Dr. Lopez noted the CDC identifies 57 Priority Jurisdictions and reviewed priority communities.

Dr. Lopez provided the priority communities as gay and bisexual men of all races and ethnicities; Black/African Americans; Hispanic/Latinos; Persons who inject drugs (PWID); and Transgender Individuals. Dr. Lopez noted PWID account for 10 percent of new infections. By gender men account for 81 percent and women account for 19 percent. HIV incidence by race/ethnicity by race for all genders, Blacks/African Americans account for 41 percent; Hispanic/Latino account for 29 percent; White account for 25 percent; Multiracial account for 3 percent; Asian account for 2 percent; and American Indian/Alaska Native account for 1 percent. Among men, gay, bisexual, and other men who have sex with men account for 70 percent of infections.

Dr. Lopez reviewed the pharmacist PrEP collaborative practice agreement with the San Francisco Department of Public Health including published findings: Between April 2018-March 2019, 51 patients initiated on PrEP and 6 patients received PEP; 60 percent utilized navigational assistance; and 47 percent of patients identified as Hispanic/Latino and 10 percent as Black/African American. For trans individuals, Black trans women account for 62 percent; Hispanic/Latina trans women account for 35 percent; and White trans women account for 17 percent. Dr. Lopez reported the CDC

was very supportive of low barrier prep mechanisms so the patients can access PrEP.

Dr. Lopez provided a review of the PrEP visit workflow including intake, pharmacist visit, and follow up. Dr. Lopez reviewed barriers and facilitators to the Mission Wellness Program. Barriers included implementation of CPA and lack of funding infrastructure and inability to bill pharmacist-initiated services. Facilitators included CPA permits ongoing PrEP; referrals in place and collaboration for follow up; and ease of laboratory tests access supplied by DPH.

Dr. Lopez reviewed SB 159 barriers included implementation of the CPA such as physical barriers to create examination rooms and ongoing barriers include lack of funding for infrastructure as they were unable to bill for pharmacists-initiated services. Facilitators include collaborative practice agreements permit ongoing PrEP; referrals in place and collaboration for follow up; and ease of laboratory tests access supplied by DPH.

Dr. Lopez provided additional SB 159 barriers including 60-day limitation; financial – payment in California for services was limited but necessary in order to support testing, staffing and education; education for pharmacists and awareness to patients; and SB 159's intent was for pharmacists to follow best practice guidelines and guidance from the CDC but how the language structure had been a barrier and should be more flexible. An example provided was defined guidelines written every 5-6 years where the CDC publishes additional updates more often than "the Guidelines" and should include language that permits other CDC guidance documents. Another example was it utilizes prescriptive legislation: PrEP and PEP medications, tests, counseling, etc.

Dr. Lopez shared PrEP Basics document and SB 159 pamphlet developed by SFDPH for patient education.

Chairperson Oh thanked Dr. Lopez. Members were provided an opportunity to comment.

Member Chandler thanked Dr. Lopez and requested to have SFDPH resources to be added to the Board's website to help assist the education gap. Mr. Chandler inquired if reimbursement was an issue limiting the implementation of SB 159 as well as the 60-day limit. Dr. Lopez agreed the

labs were important but also the patient time with the pharmacist was needed.

Member Weisz thanked Dr. Lopez for the presentation and requested information on adherence rates. Dr. Lopez stated adherence rates weren't able to be completed due to lack of funding and COVID impacts. Dr. Lopez provided the Kelley-Ross Pharmacy reported 90 percent of the patients had number of days covered as greater than 80 proportional days covered.

Members of the public were provided the opportunity to comment.

A representative of CSHP commented the 60-day limitation was on PrEP but noted there was no limitation on PEP. The representative spoke in support of modifying the statute and indicated it would be appreciated.

Member Crowley inquired if the Committee could look to other states such as Washington to reduce barriers for PrEP and PEP medication.

Dr. Lopez provided Washington's program was specific to financial reimbursement and done at the Board of Pharmacy level. Dr. Lopez recommended reviewing Colorado and Nevada that have unlimited practice or Idaho that has added protocols. Dr. Lopez added the Dakotas allow for pharmacists to conduct CLIA-waived test and provide medication for flu/strep with a positive test. Dr. Crowley stated having this as a future agenda item would help understand how other states are operating.

Ms. Sodergren noted a crossover with Standard of Care Ad Hoc Committee and suggested researching how other jurisdictions handled barriers in reimbursement.

Member Chandler added the 10 percent from drug users need to be connected to how best to treat addiction and remove barriers. If pharmacists were not being reimbursed for the HIV prevention work and potentially treating addiction, it was a failure of the system. Mr. Chandler noted barriers must be removed.

Chairperson Oh introduced Dr. Clint Hopkins, CEO of Pucci's Pharmacy and Pucci's Long Term Care Pharmacy.

Dr. Hopkins provided a background on the Pucci's Pharmacy ownership and patients serviced for prescriptions as well as CLIA-waiver being obtained in 2019. Dr. Hopkins provided additional information about the past and present owners of Pucci's Pharmacy providing service to people living with HIV from the 1980s to 2022 as well as patients served from 2020 to 2022. Dr. Hopkins reviewed Pucci's Pharmacy's impact in providing over 27,000+ COVID and 6,268 MPOX vaccines. Dr. Hopkins added in 2022, Pucci's started providing HIV Prep and HIV Treatment injectables in the pharmacy under a CPA.

Dr. Hopkins provided SB 159 background authorizes pharmacists to initiate and furnish HIV PrEP and PEP and expands Medi-Cal schedule of benefits to include HIV PrEP and PEP as pharmacist services. Dr. Hopkins advised SB 159 prohibits plan and insurers from requiring step therapy or prior authorization to antiretroviral drugs, and prohibits plans and insurers from prohibiting, or allowing a pharmacy benefit manager to prohibit a pharmacy provider from providing HIV PrEP and PEP. Dr. Hopkins advised unfortunately plans are not doing this on their own even though it is in the law. Dr. Hopkins advised on January 12, 2023, a rejection was received for PrEP because the plan said PrEP had to be received from a mail order pharmacy. Dr. Hopkins has not heard back from the plan and intends to reach out to the Department of Managed Health Care (DMHC) as the plan was in violation of SB 159.

Dr. Hopkins reviewed SB 159 pharmacist requirements including pharmacists training for competency; HIV testing; HIV counseling; prescribing; dispensing; PrEP and PEP counseling; and notifying PCP.

Dr. Hopkins provided for SB 159 for PrEP the pharmacist must ensure the patient is HIV negative [BPC section 4052.02 (e)(1)]. The burden falls 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 antibody-only test from a rapid, point-of-care fingerstick blood test approved by the FDA." If the patient does not provide evidence of a negative HIV test…"the pharmacist shall order an HIV test." SB 159 gave the pharmacist the authority to provide, order, and perform the test but does not mandate the test shall be covered and paid.

Dr. Hopkins provided SB 159 for PEP, the pharmacist must ensure the patient is HIV negative [BPC section 4053.03 (e)(2)]. The burden was placed 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 determined the patient is willing to undergo HIV testing consistent with CDC guidelines. Dr. Hopkins advised if the patient refuses to undergo HIV testing but is otherwise eligible for postexposure prophylaxis under this section, the pharmacist may furnish postexposure prophylaxis.

Dr. Hopkins reviewed SB 159 coverage including Medicaid patients covered by Medi-Cal; uninsured patients covered by PrEP-AP noting the pharmacy must contract separately with CDPH to bill PrEP-AP; largest percentage of Californians covered by commercial plans noting there was no requirement for these plans to cover pharmacist provided HIV testing or to recognize the pharmacist as a provider for non-dispensing related services; and Sacramento County Public Health has offered to share their HIV tests but added the funding would still be lacking for pharmacist time spend providing testing, counseling, etc. Dr. Hopkins added there was lots of paperwork to be completed for their program and was not viable for most pharmacies.

Dr. Hopkins reviewed the current state at Pucci's Pharmacy as referring patients to willing providers for testing and they prescribe; LGBT Center tests and refers to healthcare provider while some patients are stigmatized by going to "LGBT" center or an "HIV/AIDS" center; Pucci's dispenses HIV PrEP, PEP, and treatment; and noted referring out often causes delay in start as many patients get infected during this window. Dr. Hopkins reported patient perception was negative of the overall health system and not viable for pharmacies who do not have a willing referral destination.

Dr. Hopkins reviewed the hope for removing barriers to care including 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; and removal of the 60-day limitation of initiating and providing PrEP once in a two-year timeframe. Dr. Hopkins pointed to the extra level that LGBT+ patients are subject to where services like naloxone and oral contraceptives are not subject. Dr. Hopkins added it was not fair and needed to be addressed.

Chairperson Oh thanked Dr. Hopkins for presenting today and sharing expertise.

Member Chandler commented he wasn't aware that a test wasn't required to start PEP. Dr. Hopkins stated it was written in SB 159 but Dr. Hopkins would want to discuss with patients that it was not in the patient's best interest to do that and it would be medically irresponsible. Mr. Chandler thanked Dr. Hopkins for discussing the stigma noting more needs to be done to remove the stigma. Mr. Chandler agreed the LGBTQ+ community shouldn't be discriminated against in getting immediate treatment for something that overwhelmingly impacts them directly in their community and it needs to be highlighted as a solution is developed.

Member Crowley inquired how long it takes for someone coming into a pharmacy to get tested, how many tests Pucci's Pharmacy does a day and what the staffing looks like to provide the services. Dr. Hopkins advised the turnaround time for most patients is 24-48 hours. Dr. Hopkins reported zero tests have been done at Pucci's Pharmacy because of the reimbursement issue. Patients were referred so the patients do not have to pay for testing. Dr. Hopkins advised there were four total pharmacists at Pucci's Pharmacy with two private clinic rooms to see patients and have private discussions with the patients. The clinic rooms were also used for strep and COVID tests as well.

Member Crowley wasn't aware of the prohibitions on insurance from restriction and was wondering how best to educate pharmacists as well as what pharmacists can do to navigate situations when they occur. Dr. Hopkins thought it was worthwhile to put together an education piece on how to handle the insurance rejection and what to do (e.g., appeal, DMHC, etc.) as well as send information out from the Board to pharmacists.

Dr. Lopez advised the CDC guidance allows for PEP to be initiated without HIV test. The recommendation was to have an HIV test but PEP does have a 72-hour limit which was important as time passes, the efficacy decreases based on the data. Dr. Lopez noted employer-based plans are allowed to require mail order and it has been a barrier where HIV positive patients lose their medicines and the insurance plan will not allow the local pharmacy to fill the medicine. The exclusion for the employer-based plans was where the denial was seen at the point of sale in Dr. Lopez's experience. Dr. Lopez stated they have done over 100,000 COVID vaccines and was able to see the impact of pharmacists because they were mandated by the federal government. Dr. Lopez noted the issue was when something was not mandated (e.g., flu vaccines were not required, etc.) and insurances deny which is discriminatory practices by the plans.

Member Weisz thanked Dr. Lopez and Dr. Hopkins. Mr. Weisz inquired if reimbursement issues were with uninsured and employer-based insurance. Dr. Hopkins advised Medi-Cal was not 100 percent but the language does require it. Dr. Hopkins didn't want to have testing for a certain group of people and not available for everyone. Mr. Weisz asked if insurance plans were reimbursing more than before SB 159 started. Dr. Hopkins advised only prescriptions are paid for and the numbers are decreasing. Dr. Lopez advised no private insurance plans are paying for PrEP and PEP for pharmacist services or laboratory services. Medi-Cal has a system in place to pay for the pharmacist visit but have been told there was not a payment process in place for pharmacist-based laboratory tests. Testing was not paid by Medi-Cal. AIDS Drug Assistance Program (ADAP) for uninsured patients will only pay the one-time incentive fee for enrollment but not for the visit nor laboratory tests. Dr. Hopkins advised the payment reimbursement does not cover the testing costs.

Members of the public were provided the opportunity to comment; however, no comments were made.

Chairperson Oh shared thoughts before moving on noting the last three agenda items all highlighted the unique access point pharmacists provide to expanded care for patients and the legislature's recognition of pharmacists as appropriate healthcare providers to engage in such expanded patient care activities. Dr. Oh believed this theme had also been identified through the Standard of Care Ad Hoc Committee. Dr. Oh believed there were actions that could be taken to remove barriers to care, but believed actions must also be taken by others, including payors to fully actualize this expanded access to care. Dr. Oh asked staff to work with the Office of AIDS to expand education on funding sources available for pharmacists if any. Dr. Oh believed it was appropriate to also convene a dedicated meeting to discuss the challenges experienced with reimbursements and suggested that such a meeting be convened after the results of the research were available which should be coming in the next few months.

Chairperson Oh thanked Dr. Lopez and Dr. Hopkins for their participation.

The Committee took a break from 11:01 a.m. to 11:10 a.m. Roll call was taken. Members present: Trevor Chandler, Public Member; Jessi Crowley, Licensee

Member; Jason Weisz, Public Member; and Seung Oh, Licensee Member. A quorum was established.

VII. 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

Chairperson Oh recalled at the October 2022 meeting, the Committee initiated review of the Board's requirements for discontinuance of business (DOB) referring to relevant provisions of pharmacy law noted in the meeting materials. Dr. Oh noted the Board's current DOB process requires notification to the Board. As highlighted in the meeting materials, the current provisions in the law do not establish conditions for continuity of patient care which was very problematic and appears contrary to the Board's mandate.

Chairperson Oh recalled during the last meeting, the Committee discussed general areas of complaints received related to this issue including scenarios where a pharmacy has closed, and a patient cannot receive a refill because they are unable to contact the pharmacy to request a prescription transfer or where a pharmacy has closed and transferred patient prescription refills to another pharmacy not of the patient's choosing.

Chairperson Oh reported the Committee also considered a number of policy questions which were detailed in the meeting materials. After consideration of the issue and policy questions, the Committee determined changes to current regulation requirements were appropriate and requested staff develop proposed language for our consideration.

Chairperson Oh noted the meeting materials summarize the proposed changes and included the proposed language. Dr. Oh added there were additional policy questions that were necessary to further refine the language.

1. The time frame within which the notice must be provided to impacted patients.

   Member Crowley originally proposed 30 days but having gone through acquisition when a neighboring pharmacy closed. Dr.

Crowley stated they were given less than a week notice of the closing neighboring pharmacy and noted many didn't know about the acquisition 30 days after with the largest barriers being patients who have prescriptions for controlled substances. Dr. Crowley thought 30 days' notice would be a bare minimum but that 60-day notice was more reasonable.

Chairperson Oh supported 30 days based on previous public comment.

2. The parameters defining the patients that must receive the notice (i.e., patients that received a prescription filled within the last 365 days).

   Chairperson Oh stated the disciplinary language was 30 or 60 days but thought it should be minimum 90 days because many patients receive 90-day prescriptions.

   Member Crowley thought prescriptions could be picked up within a year. Dr. Oh stated it was reasonable.

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?

   Chairperson Oh stated pharmacies were required to have the patient's physical address on record but was not always the case for email addresses.

   Member Chandler's thought using the mailing address seemed most logical.

   Motion: Recommend initiation of a rulemaking to amend CCR section 1708.2 as proposed with (a)(1) being 30 days 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.

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 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, 4113,

4332 and 4333, Business and Professions Code; and Section 11205, Health and Safety Code.

M/S: Crowley/Chandler

Members of the public were provided the opportunity to comment.

A pharmacist asked for allowance to use email or text.

A retired pharmacists inquired if the Board of Pharmacy would provide direction to consumer when the Board of Pharmacy receives the notice from the pharmacy. If not, the pharmacist said the time frame should be longer than 90 days.

Support: 4 Oppose: 0 Abstain: 0 Not Present: 2

Board Member	Vote
Cameron-Banks	Not present
Chandler	Support
Crowley	Support
Oh	Support
Patel	Not present
Weisz	Support

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

Chairperson Oh referenced meeting materials including the definition of a "pharmacist-in-charge" (PIC) as a pharmacist proposed by a pharmacy and approved by the Board as the supervisor or manager responsible for ensuring the pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy. Dr. Oh noted as required by law every pharmacy must designate a PIC who was responsible for the pharmacy's compliance with state and federal laws. California law requires that any pharmacy located outside this state that provides services into California shall be considered a nonresident pharmacy. The section requires licensure as a nonresident pharmacy. There were no current requirements for pharmacists working in these pharmacies to be licensed in California even when providing care to California patients. Further, there was no requirement for the PIC of the

nonresident pharmacy to be licensed in California. Rather, California law currently established a prohibition for a pharmacist to provide services to California patients if the pharmacist's license was revoked in California.

Chairperson Oh recalled during prior meetings, the Committee reviewed the model rules provided by the National Association of Board of Pharmacy provided for Boards to consider as part of its regulation of the practice of pharmacy. The model rules required a pharmacist to be licensed in the state in which it is providing services to patients. Dr. Oh advised the Committee also reviewed the range of requirements other states require for licensure of staff working out of state but providing care to their residents.

Chairperson Oh advised meeting materials included a few examples of actions taken against nonresident pharmacies. Dr. Oh reported at prior meetings, the Committee spoke in general in support of establishing a requirement for a California licensed pharmacist to be the PIC of a nonresident pharmacy while also identifying some potential challenges. Dr. Oh advised staff developed proposed statutory language for consideration included in the meeting materials.

Chairperson Oh reported working with staff in the development of this language and believed it struck a balance moving the Board towards a model of regulation of such entities that improves patient care in California.

Member Crowley requested clarification for (d) that the pharmacist needs to be physically working in the nonresident pharmacy and not virtual/remote working as the PIC. Counsel Smiley indicated this could be subject to interpretation or could be clarified with regulations. Ms. Smiley read it as employed and working at the nonresident pharmacy noting if they had corporate headquarters a California pharmacist working in the headquarters could technically qualify under the section. Dr. Crowley was concerned with that interpretation and thought the PIC should be in the pharmacy. Dr. Oh would be supportive of leaving it as it is but start the process. Ms. Smiley also wanted to check on (d) as she read the language was saying as a prerequisite to registering with the Board, they have to identify a California license pharmacist and need to confirm that that the language required maintaining the California license. Ms. Sodergren referenced (c).

Motion: 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.

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.

M/S: Chandler/Crowley

Members of the public were provided the opportunity to comment.

A representative from CRA/NACDS commented concerns requiring nonresident PICs and would have negative impact to patient access. The representative thought there were other avenues such as registration.

A representative from CVS Heath commented based on the cost of multi-state licensure, the representative referenced a 2018 FTC policy perspective addressing occupational license portability and cited states that have licensing compacts. CVS Health requested the Committee not approve the draft language and contact FTC and NABP.

A retired pharmacist requested consideration to CVS Health's comment as the request requires more than one person provided if the pharmacist is sick, another pharmacist is required. The retired pharmacist commented licensure and registration were the same under California law.

A representative from Walgreens agreed with CVS Health's comment and noted this would impact mail order pharmacies and specialty pharmacies. The representative commented it could reduce patient access to Californians and recommended other options.

A pharmacist commented in support of full licensure and added it was important that a pharmacist-in-charge needs to be aware of California laws. The pharmacist noted it was possible as the pharmacist was licensed in 17 states.

Support: 3 Oppose: 0 Abstain: 1 Not Present: 2

Board Member	Vote
Cameron-Banks	Not present
Chandler	Support
Crowley	Support
Oh	Support
Patel	Not present
Weisz	Abstain

IX. 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

Chairperson Oh Members referenced meeting materials that included relevant law and background on the issue. Dr. Oh recalled the issue was referred to develop regulations following a discussion by the Enforcement and Compounding Committee about implementation related activities surrounding Assembly Bill 2194.

Chairperson Oh advised draft regulation language was included in the meeting materials to establish the continuing education requirements for cultural competency as required by the legislation. Dr. Oh highlighted the provisions related to pharmacists also included consolidation of various CE requirements for pharmacists that were currently included in various provisions of statute and regulation. Dr. Oh advised the proposed language established new regulations defining the continuing education requirements for pharmacy technicians that mirror the process used for pharmacist renewal.

Members were provided the opportunity to comment.

Member Crowley appreciated consolidating the continuing education regulations. Dr. Crowley added the cultural competency continuing education needed to include LGBTQ+ and intersectionality. Ms. Sodergren stated it was reviewed by DCA Regulation Legal and could have it reviewed again prior to Board meeting.

Motion: 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.

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, 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 demonstrating compliance with the provisions of this section.

(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 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.

M/S: Crowley/Weisz

Members of the public were provided the opportunity to comment.

A pharmacist commented leaving the cultural competency as broad was better as both LGBTQ+ and racial competency were both needed.

Support: 4 Oppose: 0 Abstain: 0 Not Present: 2

Board Member	Vote
Cameron-Banks	Not present
Chandler	Support
Crowley	Support
Oh	Support
Patel	Not present
Weisz	Support

X. Discussion and Consideration of Business and Professions Code section 4111

Chairperson Oh recalled at the July 2022 meeting considered the issue of ownership prohibitions specifically related to prescriber ownership including a prohibition by a person who shares a community or other financial interest with the prescriber. Dr. Oh noted at that time, the Committee considered proposed language that could be used to create flexibility for such ownership while maintaining the legislative intent of the prohibition. Dr. Oh referenced meeting materials provided significant background on the issue and highlighted at the time of discussion in response to public comment, the Committee determined that additional consideration of other forms of ownership prohibitions should be considered related to pharmacist ownership. Dr. Oh noted the draft language provided could be used to expand provisions to allow a pharmacist that is authorized to issue a drug order under specified conditions to also own a pharmacy.

Members were provided an opportunity to comment; however, comments were not made.

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

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 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</u>

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.

M/S: Crowley/Chandler

Members of the public were provided the opportunity to comment; however, no comments were made.

Support: 3 Oppose: 0 Abstain: 1 Not Present: 2

Board Member	Vote
Cameron-Banks	Not present
Chandler	Support
Crowley	Support
Oh	Support
Patel	Not present
Weisz	Abstain

The Committee took a lunch break from 11:53 a.m. to 12:45 p.m. Roll call was taken. Members present included Trevor Chandler, Public Member; Jessi Crowley, Licensee Member; and Seung Oh, Licensee Member. A quorum **was not** established. Chairperson Oh provided the Committee would continue with the discussion but would not be able to provide a recommendation to the Board at the Board Meeting without quorum. Counsel Smiley clarified without the quorum, the Committee could not make a recommendation which meant at the Board Meeting, a motion, first and second will be needed if the Board decided to take action.

XI. Discussion and Consideration of Provisions for Remote Processing

Chairperson Oh advised the Committee would be discussing the Board's legal requirements for remote processing. Dr. Oh noted to facilitate physical distancing early in the COVID-19 pandemic, the Board approved a waiver to extend the provisions for remote processing based on the Board's authority in BPC section 4062 and was limited in duration. Dr. Oh added because of the length of the public health emergency, Dr. Oh believed there may be some licensees that have become accustomed to working under the remote waiver. Dr. Oh advised last year, the Board voted to pursue legislation; however, the measure was controversial and as such failed to move early in the year due to significant opposition from all stakeholders coupled with a lack of support and engagement for the measure.

Chairperson Oh advised with the remote processing waiver set to expire, the Board was asked to again consider if changes to the Board's law were appropriate. Dr. Oh referenced meeting materials containing the relevant section of the law that established authority for remote processing. Dr. Oh provided through the years it appeared that some may have overstated the provisions and flexibilities provided in California law. Dr. Oh continued the approval and release of the waiver then appeared to cause a stir among some that may have implemented practices that exceed what the law provides in California. Dr. Oh advised this would not be a point of discussion.

Chairperson Oh provided under the conditions of the waiver, the Board expanded authority for pharmacist to receive, interpret, evaluate, clarify, and approve mediation orders and prescriptions, including such orders for controlled medications. The waiver allowed for 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 medications for administration. Dr. Oh advised the waiver did not permit dispensing of a drug or final product verification by remote processing. Dr. Oh added although the waiver had been in place for a significant period of time, it was limited in duration and unless legislation was passed, at the end of the waiver, provisions of the law will return to those currently included in BPC 4071.1.

Chairperson Oh asked Counsel Smiley to remind members about the general structure of pharmacy law and practice and how it is related to this issue.

Counsel Smiley advised the Board's interpretation was not new. Ms. Smiley continued the structure of pharmacy law and certain definitions generally tie the traditional pharmacy (e.g., storing, preparing, dispensing) that is narrowed to the location of a pharmacy that is identified in a license issued by the Board. Ms. Smiley noted a lot of commenters have tried to state that the definition of a pharmacist that says they are entitled to practice pharmacy as defined by this chapter within or outside of a licensed pharmacy but they leave out the last part of the sentence which means as authorized by this chapter which was an important limit. Ms. Smiley noted there were different provisions in BPC section 4052 that allowed the practice of pharmacy in other locations (e.g., hospitals) other

parts of pharmacy law that allow it but added BPC section 4071.1 was the only authority in pharmacy law governing the prescription dispensing and storage process. Ms. Smiley noted if the Board wanted to expand BPC 4071.1 to include some or all of the activities that were authorized by the Board's emergency waiver, the statute would need to be changed. Ms. Smiley added there was no statutory authority for pharmacist interns or pharmacy technicians to do anything outside of a pharmacy. Pharmacists' ability to be able to input, interpret and the dispensing process for a prescription was currently narrowed to the location of the pharmacy identified in the license issued by the Board.

Ms. Smiley recommended the Committee and commenters concentrate their efforts and comments on evaluating based on three years of working with the expanded provision of remote services allowable under the Board's remote processing waiver. Ms. Smiley added the Committee and commenters should focus on where the permanent law should be and concentrate on explaining why such changes are necessary as well as appropriate including how they can be done safely with due consideration and concern to the security of the prescription, ordering, and dispensing process and patients' rights under federal law, state law and the California Constitution to the right to privacy for the treatment and access to Californians' medical and financial information. Ms. Smiley reminded participants that the Q&A format was not intended for commenters to pose questions to the Committee about what the commenters may or may not do with specific remote processing that may have been done in excess of current California law. Ms. Smiley recommended participants concentrate on where they believe the law should be now.

Ms. Smiley inquired if the Members had any questions. The Members did not have any questions.

Chairperson Oh thanked Ms. Smiley for the quick summary and overview. Dr. Oh began discussion of the policy questions outlined in the meeting materials. Dr. Oh noted it was essential that when questions were considered, the Committee must be mindful of the possible unintended consequences of decisions. Dr. Oh provided as an example, the Board has been working diligently to reinforce the vital role a PIC must play in ensuring operational compliance with the requirements of pharmacy law. Dr. Oh reminded the Committee must ensure decisions made do not undermine the Board's efforts in that area. Dr. Oh believed it was

important to remember that regrettably remote access to computer records was a primary way billing fraud was conducted with the activities occurring outside of the oversight of the PIC. Dr. Oh noted the Committee should not be taking any actions that will usurp the authority of the PIC.

Chairperson Oh noted the Committee must be mindful that pharmacists working in community pharmacies provide a unique and important access point for healthcare services for many Californians. Dr. Oh added it was important that the Committee's actions do not diminish the ability for patients to access this care in this setting. Dr. Oh suggested that the Committee also consider if there was a need to predicate any legislation moving forward on the benefit to patients and provisions to ensure pharmacists in community pharmacies are made available to provide these patient care services where remote processing was described in the current waiver, or as determined appropriate would be allowed.

Members were provided the opportunity to make any global statements; however, no comments were made.

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?**

   Chairperson Oh believed there was an opportunity to expand the current authority under BPC section 4071.1; however, warned moving cautiously. Dr. Oh believed the need for the permanent authority resides more acutely with inpatients where regulators such as CMS require that nonemergency orders be reviewed by a pharmacist prior to administration. Dr. Oh noted as not all hospitals have a pharmacist onsite (e.g., critical access hospitals) access by services of an offsite pharmacist to meet these requirements were necessary to ensure continuity of patient care and to ensure compliance with regulatory requirements. Dr. Oh suspected this dynamic was mostly in acute rural areas.

   Members were provided the opportunity to comment.

Member Crowley thought the demand wasn't the same as at the beginning of the pandemic and during vaccine distributions. Dr. Crowley thought there was an obvious understaffing issue as being discussed with the Medication Error Reduction and Workforce Committee.

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?**

   Chairperson Oh was familiar with a few enforcement matters where portions of the dispensing process were being conducted in unlicensed locations by unlicensed personnel. Based on the public comments received recently at meetings and the written comments received in advance of the meeting, Dr. Oh believed stakeholders were interested in permanently expanding some provisions for remote processing.

   Members were provided the opportunity to comment.

   Member Crowley experienced prior to the pandemic using remote ordering. Dr. Crowley understood the prescription entry was putting information into system but not order/prescription verification and it allowed lower volume pharmacies to help higher volume pharmacies.

   Chairperson Oh requested clarification that remote processing was at an unlicensed site. Ms. Sodergren advised that was one of the policy questions before the Committee. Ms. Sodergren noted a pharmacist helping another pharmacist was a different model than contemplated under the waiver which was allowing at an unlicensed location. Ms. Sodergren noted the Committee could discuss with stakeholders what was appropriate and develop a proposal based on the discussions.

   Member Chandler commented there were opportunities in the crises to learn from and move forward. Based on the different versions of remote processing, the Board can rethink this but would have to protect the consumer including privacy. Mr. Chandler had concerns if protected information was viewed at an unsecure network at home or at a public place versus at a licensed facility. Mr. Chandler was intrigued of smaller

pharmacies being able to assist larger pharmacies. By having it on premise, it makes it easier to follow breaks, etc.

Member Crowley shared privacy and record keeping concerns in unlicensed sites. Dr. Crowley agreed with Mr. Chandler's concern about adherence to labor law (e.g., rest breaks, lunch breaks, etc.). Dr. Crowley expressed a concern about future remote pharmacists not being overworked.

3. **Have operations under the Waiver revealed benefits to expanded remote processing authority that are worth carrying forward into a post-pandemic regulatory environment?**

   Chairperson Oh believed at least some provisions of the waiver were vital for inpatients to ensure patient care including authorizing the release of medication for administration. Dr. Oh believed if the Committee could not reach consensus on anything else, the Committee must ensure inpatients receive the medication they need.

   Chairperson Oh believed some of the comments received appear to indicate that there may be benefits to pharmacists who appear to have gained a better work life balance through provisions of remote work. Dr. Oh also believed for other pharmacists, remote work makes the job more difficult. Dr. Oh recalled a recent disciplinary matter involving several pharmacies under common ownership that bifurcated out the dispensing process which resulted in medication errors and a failure to exercise corresponding responsibility. Dr. Oh added the enforcement case highlighted some challenges with remote processing provisions.

   Member Crowley added benefits included potential to alleviate workload in community pharmacy setting; increases accessibility for people to work; profession more accessible; ability to verify without distraction; and reduce COVID transmission.

   3.a. 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?

3.b. 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?

Chairperson Oh believed benefits existed.

Member Crowley noted concern for remote verification for controlled substances and corresponding responsibility. Dr. Crowley recommended limiting to noncontrolled substances. Dr. Oh agreed.

Member Chandler added the core goal of the Board is consumer protection. Mr. Chandler added in disciplinary issues for premises that are able to be corrected and addressed at an in-person pharmacy and wondered in looking at these potential avenues what might not be caught or missed by moving them off-site. Mr. Chandler noted these were desirable for work-life balance and needed to figure out the most effective way to create that work-life balance for people with disabilities who want to be a part of the profession but needed to be done in a way that ensures accountability, protection against bad actors, and consumer protection.

Member Crowley believed that a dispensing pharmacist should make decision on how and when a controlled substance was dispensed. Dr. Crowley questioned who was liable when a DUR or ADR was missed (e.g., PIC from the dispensing pharmacy, remote processing pharmacist).

3.c. 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.

Chairperson Oh recommended tabling this issue for another time.

3.d. Are there other functions that pharmacists or other pharmacy staff should be allowed to perform remotely or from a non-pharmacy location?

Chairperson Oh believed starting with non-controlled substances noting there needed to be something beyond technology. Dr. Oh believed there were many opportunities with consultation and ability to help teams in the pharmacies

Member Crowley noted remote positions could be used for insurance prior authorization, MTM, etc. Dr. Crowley acknowledged that the security of the internet and the computers used need to be addressed.

3.e. 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?

Ms. Sodergren advised many took advantage of the waiver. When the wavier expired, the Board received a lot of requests to extend the waiver. Ms. Sodergren advised the Board had the opportunity to investigate inappropriate use that went beyond the provisions of the waiver (e.g., allowing non-pharmacy personnel to use the waiver).

Chairperson Oh asked when public comment was opened if stakeholders could share their thoughts about perceived benefits and risks of remote processing and the technology solutions that best facilitate remote processing.

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?**

Chairperson Oh believed it should be limited to pharmacists at this point and would be cautious of expanding it at this time.

Member Crowley agreed.

Members of the public were provided the opportunity to comment.

Board Member Jha commented as a meeting participant in support of some sort of remote processing. Mr. Jha noted the pandemic showed remote work can be valuable when people are sick or in isolation after being sick. Mr. Jha stated the number of people who can do certain tasks (e.g., TPN, IV, etc.) aren't widely available and it helps the pharmacy expand or maintain services. Mr. Jha noted it allows operation when adequate staffing was not available by pharmacists. Mr. Jha supported keeping some sort of remote processing available for pharmacists.

A retail specialty pharmacist in the Los Angeles area who worked remotely for two years commented about being good for medical issues and being able to work while family had COVID or was isolated because of COVID. The pharmacist noted the there was a VPN, computers were locked, and monitored including all calls being recorded.

A pharmacist working as a health outcome clinical and data review pharmacist for a chain pharmacy focusing on medication adherence and education. The pharmacist had health and mobility issues that allowed her to stay employed in the profession. Benefits included helping health care shortage, access to patient care, essential during pandemic, riots, natural disasters, etc. The pharmacist said working from home allows her to be more accurate, work faster and was better for patient safety. The waiver should be renewed until a permanent solution can be identified.

A representative of CSHP thanked the acknowledging for the application for acute care hospitals was vastly different and the requirement for the view of medication orders before administration in the critical care access hospital that can't afford to have a pharmacist on site 24/7. Having the remote processing was critical for the continued existence for the hospital. The representative cautioned not to be overbroad on the outpatient side so as to exclude existing call centers.

A pharmacist commented using remote access for after hours emergency for hospice patients so that the robots can prepare the medication, the pharmacist can pick up the medication and deliver the medication to the patients as well as keeping the pharmacist safe during the middle of the night. The other area of concern was limiting data entry at a licensed site (e.g., vaccine pop-up, skilled nursing facility, etc.). The pharmacist added technological advances allow remote verification can be seen by the pharmacist as the pills are going into the bottle and viewing the bottle. Systems allow for every step of the process to be viewed. The pharmacist added if this was not allowed people would be removed from the workforce noting the health plans and PBMs have people working from home.

A Kaiser pharmacist in an inpatient setting commented once the medication order is reviewed by the pharmacist, the medication is instantaneously available out of the automated dispensing machine. Advantages included preventing COVID transmission, smaller hospitals the pharmacist can review remotely 24-hours which allows for faster patient care, and specialist pharmacists can review remotely to ensure patient safety. All remote work was done through VPN. Controlled substances for hospital patients were different because the patients need their medication immediately not including discharge medications.

A CVS specialty pharmacist commented being trained and able to perform all duties remotely without any issues. The pharmacist explained the security at CVS included double password system. Benefits included work from home after recovering from illness/surgery, less distraction, help with traffic, lower chronic depression/illness, less unemployment, and money savings.

A CVS specialty front end specialist explained work area at home with two large screens, hard wired with desktop, space, electronics, and secure network. In retail pharmacy, there are HIPPA issues due to proximity and noise. Benefits include family proximity for emergencies, maintaining employment and reduction in pollution.

A PIC at community pharmacist and worked also as MTM pharmacist at home commented proceed with caution about practice settings and moving forward.

A CVS specialty front end specialist who also worked in an inpatient setting commented when worked at home they were better prepared and energy as well as better job performance. The pharmacist stated the Board's mission was able to be maintained while working from home as well as reduction in medication errors, improved attendance, and improved COVID transmission control. If required to work at CVS call center in Redlands, the pharmacist said there would not be enough desk to fit everyone (30 desks short), sharing cubicles would be unhygienic, shared airspace, noise pollution, potential HIPAA violation, and decline for patient care if unable to continue remote work. Maintaining the remote work would promote employee safety and maximize patient care.

A pharmacist representative from CVS Health commented 25 states have permanent allowances for pharmacy technicians to work remotely while nearly all states allow pharmacists to work remotely. The pharmacist said it was an industry standard. Benefits to remote work increases public safety by being relatively free of distraction resulting increase of public safety and impossible to divert controlled substances. The pharmacist said the DEA allows for remote work involving controlled substances and many other states as well. The pharmacist didn't agree with language of the current waiver or interpretation of BPC section 4071. The pharmacist stated CVS Health recommends the Board declare that the definition of pharmacy allows for the practice of pharmacy both within and without a pharmacy without the need for additional regulation. If the Board decided a statutory regulation was required, CVS Health suggested striking the phrase "as authorized by this chapter" as read by DCA Counsel within the definition of pharmacist only and the Board concentrate their efforts by allowing technicians and unlicensed personnel to work remotely.

A pharmacist representative of Cedar Sinai Health System requested the Board consider the positive impact for acute care hospital inpatient setting which was different from retail setting. Remote process was found to be a safe and effective way to provide pharmacy services in

a hospital setting and enhance patient care. It was also a critical strategy for hospitals to provide care during times of high patient census. It allowed remote patient monitoring to help reduce readmission. Controlled substances shouldn't be excluded since medications are needed for inpatients who are under the care and supervision of the providers. Health systems used diversion prevention safety and privacy strategies in place to monitor remote processing. Cedars Sinai Health System appreciated consideration for making remote processing permanent after the waiver expires.

A front-end pharmacist in a specialty pharmacy setting switched from PIC in retail and took the position because remote work was available. The pharmacist said it enabled the pharmacist to expand their scope of practice. The pharmacist worked in a separate area with a secure network taking orders electronically. The pharmacist was able to take breaks and lunches. It also increased patient access.

A representative from UFCW WSC spoke in strong opposition to allow remote processing from an unlicensed facility. The representative shared similar concerns to Committee Members. DCA acted rapidly in extraordinary time of the pandemic. Concerns centered around HIPAA violations, laptop usage, and security of sensitive patient information.

A pharmacist commented in support of extending the waiver, using technology advances and meeting industry standard of profession. This would also help non-English speaking patients.

A representative of CRA/NACDS spoke in support of action beyond access of the waiver and the need for permanent remote processing past waiver. The commenter stated most states allow remote pharmacists and half allow remote pharmacy technician work. Benefits included less distractions and less errors noting safeguards in place to safeguard patient privacy. The representative spoke in support of the Board taking the necessary steps to ensure all types of remote work can continue for all pharmacy settings including community pharmacies. Additional benefits included reduced medication errors, inability for people working remotely to divert drugs, ability to perform prescription verification and assist with medication adherence remotely as well as

the pharmacists in the stores working to better care for the patients in the stores. Pharmacy technicians should also be included.

A retired pharmacist agreed with many comments and noted there was a concern about privacy but added it has been done for the past 30 years. Pharmacies, pharmacists, and all licensed professionals including pharmacy technicians fall under a legal and ethical obligation to protect the privacy of patients and the confidentiality of communications. They are considered covered entities under HIPAA. Medication errors have been reduced with remote processing. The commenter cautioned on placing too many restrictions.

A pharmacist for 20 years commented on the need to protect patient information which can be done through technology (e.g., computer, hard wired internet, etc.). Benefits included helping reduce COVID transmission, helping those with disabilities, working at home allows ability to discuss patient counseling openly and increased work/life balance.

A home infusion specialty pharmacist commented no paper is used when working at home as everything was through e-fax and electronic prescription. The pharmacist noted there were clinical and production teams and the workflow was the same with no distinction for working in the office or at home. Security was of the most importance using crypted devices, MFA and bio-VPN.

The Committee took a break from 10:30 a.m. to 10:40 a.m. Roll call was taken. Members present included Trevor Chandler, Public Member; Jessi Crowley, Licensee Member; and Seung Oh, Licensee Member. A quorum was not established.

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?**

   Chairperson Oh believed that the PIC must have the authority to determine if remote processing will be allowed and well as what

functions and under what conditions such remote process may occur within the confines of the law.

Members were provided the opportunity to comment.

Member Crowley agreed as the PIC is responsible and should have autonomy to decide. Dr. Crowley inquired if under the waiver the PIC was being held liable. Ms. Sodergren added she would have to review the investigations.

6. **Can a subsequent pharmacist-in-charge make a contrary determination/declaration?**

   Chairperson Oh understood this could be a challenging dynamic for other pharmacists employed at the pharmacy. Dr. Oh believed the decision making must reside with the PIC, even if they change, about the allowable provisions and use of remote processing for the pharmacy. Dr. Oh wanted to make sure however, that he didn't intend for the PIC to require a pharmacist to perform remote processing, rather was speaking to if remote processing should be allowed and under what conditions.

   Members were provided the opportunity to comment; however, no comments were made.

7. **Should pharmacy staff members be required to consent to performing remote functions?**

   Chairperson Oh believed pharmacists should be required to consent to performing remote functions unless the requirement was clearly detailed in a job duty statement.

   Members were provided the opportunity to comment.

   Member Chandler commented it would require safety, privacy, HIPPA, etc. Mr. Chandler stated it would be just a consent to perform but agreement to all of the requirements needed to do the job.

8. **Should remote order entry and remote processing functions be authorized only for California-licensed pharmacists 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?

Chairperson Oh believed provisions should be limited to California licensed pharmacists, working in California for a California licensed pharmacy.

Members were provided the opportunity to comment.

Member Crowley agreed with Dr. Oh.

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?**

   Chairperson Oh strongly believed the remote provisions must be limited to California only.

   Members were provided the opportunity to comment; however, no comments were made.

   Members of the public were provided the opportunity to comment.

   A retired pharmacist commented when CMS required all hospital orders must be reviewed by pharmacist except for emergency as The Joint Commission did as well and it was a labor issue. The commenter noted there were licensed pharmacists in California working remotely for hospitals outside of California. The commenter requested knowing why Chairperson Oh and Member Crowley were only comfortable with a licensed California pharmacist in a California licensed pharmacy.

   A representative from CSHP commented the pharmacist shouldn't have to be located in California.

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?**

    Chairperson Oh stated this was tough and thought there should be a balance.

    Members were provided the opportunity to comment.

    Member Crowley commented it was a complicated issue that varied from setting to setting. Dr. Crowley noted there would be a big difference for someone working at home strictly verifying electronic with no paper protected health information (PHI) versus a pharmacy that does have PHI which Dr. Crowley was hesitant to allow outside of a brick-and-mortar licensed facility.

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?**

    Chairperson Oh believed the Board should have authority to inspect when employees were working and that would have to be a compromise the employees were willing to make. Dr. Oh noted the systems were so complex that once they are set up, there was opportunity for bad players to circumvent rules and regulations as well as inspecting authorities. Dr. Oh suggested a registration requirement of some type with the understanding that it would be complicated.

    Members were provided the opportunity to comment.

    Member Crowley thought it could be challenging to manage.

    Member Chandler commented in support of finding out what Board Inspectors thought of this option in terms of risk factors.

    Ms. Sodergren said her team has started discussions on how this could be implemented and addressed existing vulnerabilities in what currently

exists and wanted to ensure additional vulnerabilities are being created. Ms. Sodergren didn't envision routine inspections but inspections as a result of a complaint or investigation.

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?**

    Chairperson Oh thought this was another challenging question and biometrics would have to be associated with the individual doing the work. Pharmacy records must include an audit trail of all individuals that access the record and perform functions. The records must be maintained and available to the Board. Dr. Oh also believed the PIC should have some responsibility to review the records to confirm that only licensed and authorized individuals were gaining access to records and performing authorized functions.

    Members were provided the opportunity to comment.

    Member Crowley thought work should be only electronic so as not to have a loss of PHI. The pharmacy should have a list to show what prescriptions were processed remotely for that day so the PIC was aware of everything that was happening.

13. **Again, should the law specify that any remote site must be located in California?**

    Chairperson Oh believed the remote site must be located in California. Dr. Oh was uncomfortable with it being done by anyone or anywhere.

    Members were provided the opportunity to comment; however, no comments were made.

14. **Should there be any limit on the number of pharmacies for which any pharmacist, 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?

Chairperson Oh didn't think the Board should set arbitrary numbers or requirement to go into the pharmacy.

Members were provided the opportunity to comment.

Member Crowley didn't want to see limits.

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?**

Chairperson Oh believed the decision should reside with the PIC as the PIC will be determining under what conditions remote processing will be allowed.

Members were provided the opportunity to comment; however, no comments were made.

Members of the public were provided the opportunity to comment.

A pharmacist commented who lived in northern California but works in southern California that the laws were the same. The pharmacist requested to consider impact that some may lose their jobs.

A retired pharmacist agreed there shouldn't be arbitrary distance set with technology that works well and was important for rural areas or throughout the state. The Board should allow during operating hours for someone at the pharmacy to be available to discuss the prescription with the patient.

The Committee heard a comment to take into consideration pollution and money being earned in an area to be spent in the area.

A pharmacist commented that an arbitrary distance shouldn't be mandated as the pharmacist worked with patients on the east coast and had a good connection with the patients. The pharmacist noted specialty pharmacy requires a lot of training and should work from home be discontinued after the waiver, it would have a huge detriment on the specialty patient populations. The pharmacist estimated taking six months to one year to get pharmacists trained after removing the work from home element.

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 in-pharmacy?**

    Chairperson Oh stated where remote processing would be used, there must be an audit trail of all individuals involved in the dispensing process and accessing records both from remote locations as well as from within the pharmacy. Dr. Oh believed it would have to be with a biometric requirement that couldn't be altered to identify the individual doing the work.

    Members were provided the opportunity to comment; however, no comments were made

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

    Chairperson Oh commented the HIPAA Security Rules may be sufficient to cover ePHI created and transmitted and believed there was an associated risk. Dr. Oh believed staff could consult with experts to confirm that HIPAA Security Rules would be sufficient.

    Members were provided the opportunity to comment.

Member Chandler agreed with exceeding best practices.

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?**

    Chairperson Oh stated the Board must have access to the records in their entirety to evaluate for compliance with the provisions that would be included in any legislative change. Dr. Oh believed the Board could rely on its current authority in both BPC sections 4081 and 4105 to secure access. Dr. Oh asked staff to check with the Attorney General's Office that the Board would not require additional records authority. Ms. Sodergren would check with the Attorney General's Office to make sure it was covered under BPC 4081 and 4105 as well as ensure there were no holes in the laws.

    Members were provided the opportunity to comment; however, no comments were made.

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?**

    Chairperson Oh believed the answer was yes and since the risk is being taken they should be held liable for what happens. Dr. Oh believed the PIC should be aware of what was happening. The PIC, pharmacist and company would have to be responsible.

    Members were provided the opportunity to comment.

    Member Crowley agreed provided the PIC had the ability to approve and be part of the decision to do remote work. Dr. Crowley was hesitant to put the liability on the PIC if the PIC wasn't part of the decision.

Member Chandler agreed and believed there may need to be mutual responsibility. If the PIC didn't have the authority, that would be an issue. Mr. Chandler believed some level of accountability was required 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?

Chairperson Oh believed the pharmacy should be required at a minimum to notify the Board of the locations of remote processing including any changes.

Members were provided the opportunity to comment.

Member Chandler believed the mutual accountability with the PIC and pharmacy license was needed.

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?

Chairperson Oh noted the scenarios described in this question was one of the primary causes for Dr. Oh's hesitation with expanding remote processing in the outpatient setting. Dr. Oh added the Board has seen too many enforcement cases that involve the activity described in the question. Dr. Oh added if the Board does ultimately determine that expanding provisions for remote processing was appropriate, Dr. Oh requested the Executive Officer work with investigator staff to identify conditions to safeguard against these illegal activities. Dr. Oh noted the requiring registration of each location where remote processing occurs, leaving the decision making to the PIC, and requiring the PIC to audit records may be part of the solution, but was not sure if that was sufficient.

Members were provided the opportunity to comment; however, no comments were made.

Members of the public were provided the opportunity to comment; however, no comments were made.

Chairperson Oh thanked participants for the discussion. Dr. Oh suggested given there appeared to be some consensus around expanding provisions for remote processing that staff work with counsel to develop some language for consideration at the next meeting. Staff will use the feedback provided to develop the language.

Members were provided the opportunity to comment.

Member Crowley stated significant concerns with final verification of products done remotely without the tactile examination of the pills. Dr. Crowley noted there was the potential for assisting community pharmacy staffing but was concerned that staffing in the brick and mortar were reduced even further.

Member Chandler added California needs to be accessible and on the cutting edge without diminishing the consumer protection. Mr. Chandler had overall concerns with data privacy and stigma. If the pharmacies were willing to tie the license to the actions of the pharmacy that would help alleviate a significant number of concerns. Mr. Chandler appreciated the significant feedback by stakeholders.

Chairperson Oh thanked all stakeholders for participation.

XII. Future Committee Meeting Dates

Chairperson Oh advised the next Licensing Committee Meetings were scheduled for April 5, 2023; July 19, 2023; and October 18, 2023. Dr. Oh thanked participants for their time and participation.

XIII. Adjournment

The meeting adjourned at 3:32 p.m.

Attachment 2

Draft Statutory Proposal: Community Pharmacy Remote Processing

(a) A pharmacist licensed in California, employed by and acting on behalf of a pharmacy licensed in California may, from any location outside of the licensed pharmacy and within California, perform certain remote functions, only where:

(1) The remote functions performed are limited to: order entry and other data entry; prospective drug utilization review; interpretation of clinical data; insurance processing; therapeutic intervention; provision of drug information; authorizing medication release for administration; or other pharmacist clinical services authorized in this chapter.

(2) The pharmacist-in-charge for the pharmacy has made and signed, under penalty of perjury, a written determination that (a) remote work by pharmacists is necessary to enable provision of improved direct patient care by pharmacists working in the pharmacy, and (b) reliance on remote work by pharmacists will not be used as a means to, or lead to, reduced staffing levels in the pharmacy, and on those grounds the pharmacist-in-charge authorizes remote functions, and the pharmacy has provided that writing to the board. The board may request a renewal of this writing on an annual basis or more frequently where circumstances warrant. The pharmacy shall also keep and maintain a copy consistent with the provisions of sections 4081 and 4105.

(3) Each pharmacist who will be performing remote functions has signed, under penalty of perjury, a written consent form designating the location from which that pharmacist will perform remote functions, certifying that the location is secure, acknowledging that the board may inspect that location, and consenting to such inspection. Each signed consent shall be provided to the board. The pharmacy shall also keep and maintain a copy of each signed consent consistent with the provisions of sections 4081 and 4105.

(4) The pharmacy, under the supervision of the pharmacist-in-charge, has developed and implemented policies and procedures that outline the authorized functions to be performed and describe methods for protecting the confidentiality and integrity of patient information. The policies and procedures shall expressly prohibit the removal of written, printed, or electronic pharmacy records from the pharmacy in hardcopy or on an electronic storage device, and the printing and storage of protected health information on a device that is outside of the licensed pharmacy. The policies and procedures shall be made available to the board upon request.

(5) The pharmacy, under the supervision of the pharmacist-in-charge, has ensured that each pharmacist designated to perform remote functions is trained on the scope and limitations of such services, and on the pharmacy's policies and procedures.

(b) Each pharmacy authorizing pharmacists to perform remote functions shall ensure:

(1) That all such pharmacists have secure electronic access to the pharmacy's patient information and to other electronic systems accessible by onsite pharmacists during business hours. A pharmacy's system shall always use biometrics or similar technology to ensure the identity of any pharmacist working remotely. Pharmacists working remotely cannot use portable electronic devices or laptop computers to perform such functions.

(2) That each record created, viewed, modified, or deleted by a pharmacist working remotely complies with all recordkeeping requirements for pharmacies established in this chapter, including capturing the positive identification of the pharmacist involved in the remote review and verification of a medication order or prescription. A pharmacy shall continue to maintain records of all medication orders and prescriptions orders in the pharmacy's information system. Such records shall be reviewed by the pharmacist-in-charge to confirm compliance. All records shall be maintained in an auditable form detailing each access to a record, whether onsite or remote. All records shall be kept in accordance with section 4081 and be readily retrievable as required in section 4105.

(c) Any pharmacy, pharmacist-in-charge, or pharmacist that discovers any violation or possible violation of the federal Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191) or the Confidentiality of Medical Information Act (Civ. Code, § 56 et seq.), shall, within 30 days of such discovery, report the incident to the board. In addition to any other enforcement action that may be taken by the board, a violation of this sort may result in the issuance of a citation pursuant to the citation and fine authority of the board, with a fine not to exceed $[fine amount] per occurrence.

(d) Nothing in this subdivision shall authorize a pharmacist to dispense a drug or perform final product verification via remote connection or without being present.

(e) Notwithstanding any other provision of law, a violation of this section may subject the person or entity that has committed the violation to either a fine of up to ten thousand dollars ($10,000) for the first occurrent pursuant to a citation issued by the board or a civil penalty of ten thousand dollars ($10,000) for the first occurrence. A second violation of this section may subject the person or entity that has committee the violation to either a fine of up to fifty thousand dollars ($50,000) or a civil penalty of fifty thousand dollars ($50,000) for the second occurrence. Any subsequent violation of this section may subject the person or entity that has committee the violation to either a fine of up to two hundred fifty thousand dollars ($250,000) or a civil penalty of two hundred fifty thousand dollars ($250,000) for all subsequent occurrences.

Attachment 3

SAMPLE

Collaborative Practice Agreement:

Pharmacist Protocol for Management of Opioid Use Disorders

I. Authority: California Business and Professions Code §§ 4050-4052.2.

II. Purpose: To formally identify the function that the undersigned pharmacist(s) may perform in providing drug therapy management to patients with opioid use disorder (OUD) in collaboration with the undersigned provider(s) consistent with the policies, procedures, and protocols of the undersigned [provider or prescriber].

III. Referral criteria
   a. Patients with a known or suspected opioid use disorder are referred by a provider, patient care team member, or
   b. By patient self-referral.

IV. Pharmacist may perform the following authorized functions in accordance with this protocol and the standards of care for the treatment of opioid use disorder:
   a. Assessment of opioid use disorder including physical and laboratory examination for signs and symptoms of opioid use and opioid use disorder sequalae.
   b. Medication Management
      i. Initiate, modify, discontinue, and administer medications for the treatment of opioid withdrawal symptoms including but not limited to alpha-2 agonists, antiemetics, antihistamines, anticonvulsants,

antidiarrheal agents, analgesics, and sedative-hypnotics.

ii. Initiate, modify, discontinue, and administer formulations of buprenorphine indicated for OUD in collaboration with a DATA 2000 waivered prescriber.

iii. Initiate, modify, discontinue, and administer naltrexone for opioid use disorder.

iv. Initiate, modify, discontinue, and administer naloxone for overdose prevention.

v. Initiate, modify, discontinue, and administer medications for the treatment of opioid induced side effects.

c. Develop a treatment plan for opioid use disorder including referral to medical services, case management, psychosocial services, substance use counseling, and residential treatment as indicated.

i. For patients who self-refer to the pharmacist for treatment, the pharmacist will have direct communication with the collaborating physician to review the treatment plan by a method and frequency determined by the collaborating physician.

V. Documentation

a. The pharmacist's assessment, clinical findings, and plan of care will be documented in a health record mutually accessible by the referring provider, collaborating physician, and/or primary care provider. If a mutually accessible health record is not available documentation will be shared via facsimile or other secured communication platform.

VI. References

a. Substance Abuse and Mental Health Services Administration. Medications for Opioid Use Disorder. Treatment Improvement Protocol (TIP) Series 63. HHS Publication No. (SMA) 18-5063EXSUMM. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2018.

VII. Signatures

Physician	License #	Date
Sign		

Pharmacist	License #	Date
Sign		

This collaborative practice agreement remains in effect unless withdrawn by either party.

Attachment 4

Draft Policy Statement – Digital Signatures

The Board is aware of some licensees' and applicants' desire to submit documents with digital signatures. Government Code Section 16.5 establishes authority for government agencies to accept digital signatures that meet specified conditions. "If a public entity elects to use a digital signature, that digital signature shall have the same force and effect as the use of a manual signature if and only if it embodies all of the following attributes:"

(1) It is unique to the person using it.
(2) It is capable of verification.
(3) It is under the sole control of the person using it.
(4) It is linked to data in such a manner that if the data is changed, the digital signature is invalidated,
(5) It conforms to regulations adopted by the Secretary of State.

The Secretary of State has established regulations specifying acceptable technologies for acceptance of digital signatures and designates Public Key Cryptography as an acceptable technology. (Cal. Code Regs., tit.2 § 22003.)

While the Board has not established any formal rules requiring the use of digital signatures, it understands that stakeholders are interested in using digital signatures. The Board will not require any applicant or licensee to provide information using a digital signature in lieu of a wet signature; however, in the interest of meeting stakeholder requests, the Board will accept documents that are digitally signed using technology known as Public Key Cryptography consistent with the regulations established by the Secretary of State in Section 22003 as cited above.

Attachment 5

CALIFORNIA STATE BOARD OF PHARMACY
QUARTERLY LICENSING STATISTICS FISCAL YEAR 2021/2022

***Jan-Mar is reporting through 2/28/2023 full Quarter totals will be provided at Board Meeting**

APPLICATIONS RECEIVED

Individual Applications	July - Sept	Oct-Dec	*Jan-Mar	Apr-Jun	Total FYTD
Designated Representatives (EXC)	100	98	78	0	276
Designated Representatives Vet (EXV)	0	3	0	0	3
Designated Representatives-3PL (DRL)	34	17	31	0	82
Designated Representatives-Reverse Distributor (DRR)	33	0	0	0	33
Designated Paramedic (DPM)	1	0	0	0	1
Intern Pharmacist (INT)	985	99	74	0	1,158
Pharmacist Exam Applications	296	152	124	0	572
Pharmacist Retake Exam Applications	476	441	208	0	1,125
Pharmacist Initial License Application (RPH)	716	657	129	0	1,502
Advanced Practice Pharmacist (APH)	53	42	23	0	118
Pharmacy Technician (TCH)	1,405	1,272	905	0	3,582
Total	**4,099**	**2,781**	**1,572**	**0**	**8,452**

Site Applications	July - Sept	Oct-Dec	*Jan-Mar	Apr-Jun	Total FYTD
Automated Drug Delivery System (ADD(AUD))	80	56	17	0	153
Automated Drug Delivery System (ADD(APD))	2	0	1	0	3
Automated Drug Delivery System EMS (ADE)	0	0	0	0	0
Automated Patient Dispensing System 340B Clinic (ADC)	0	1	0	0	1
Centralized Hospital Packaging Government Owned (CHE)	0	0	0	0	0
Centralized Hospital Packaging (CHP)	0	0	0	0	0
Clinics (CLN)	168	17	16	0	201
Clinics Government Owned (CLE)	12	12	10	0	34
Drug Room (DRM)	0	0	0	0	0
Drug Room Government Owned (DRE)	0	0	0	0	0
Hospitals (HSP)	4	1	4	0	9
Hospitals Government Owned (HPE)	0	0	0	0	0
Hospital Satellite Sterile Compounding (SCP)	0	1	0	0	1
Hospital Satellite Sterile Compounding Government Owned (SCE)	0	0	0	0	0
Hypodermic Needle and Syringes (HYP)	0	2	3	0	5
Correctional Pharmacy (LCF)	1	0	0	0	1
Outsourcing Facility (OSF)	0	0	1	0	1
Outsourcing Facility Nonresident (NSF)	4	1	0	0	5
Pharmacy (PHY)	80	83	69	0	232
Pharmacy (PHY) Chain	9	3	1	0	13
Pharmacy Government Owned (PHE)	0	2	0	0	2
Remote Dispensing Pharmacy (PHR)	1	0	0	0	1
Pharmacy Nonresident (NRP)	25	24	28	0	77
Sterile Compounding (LSC)	11	9	10	0	30
Sterile Compounding Government Owned (LSE)	0	0	2	0	2
Sterile Compounding Nonresident (NSC)	5	4	2	0	11
Surplus Medication Collection Distribution Intermediary (SME)	0	0	0	0	0
Third-Party Logistics Providers (TPL)	1	1	2	0	4
Third-Party Logistics Providers Nonresident (NPL)	12	12	8	0	32
Veterinary Food-Animal Drug Retailer (VET)	2	0	0	0	2
Wholesalers (WLS)	18	6	14	0	38
Wholesalers Government Owned (WLE)	0	0	0	0	0
Wholesalers Nonresident (OSD)	27	38	15	0	80
Total	**462**	**273**	**203**	**0**	**938**

*Number of applications received includes the number of temporary applications received.

Applications Received with Temporary License Requests	July - Sept	Oct-Dec	*Jan-Mar	Apr-Jun	Total FYTD
Drug Room -Temp (DRM)	0	0	0	0	0
Hospitals - Temp (HSP)	3	2	2	0	7
Hospital Satellite Sterile Compounding - Temp (SCP)	0	0	0	0	0
Outsourcing Facility - Temp (OSF)	0	0	1	0	1
Outsourcing Facility Nonresident - Temp (NSF)	1	0	0	0	1
Pharmacy - Temp (PHY)	65	63	50	0	178
Remote Dispensing Pharmacy - Temp (PHR)	0	0	0	0	0
Pharmacy Nonresident - Temp (NRP)	16	17	13	0	46
Sterile Compounding - Temp (LSC)	6	5	1	0	12
Sterile Compounding Nonresident - Temp (NSC)	4	1	1	0	6
Third-Party Logistics Providers - Temp (TPL)	1	2	1	0	4
Third-Party Logistics Providers Nonresident - Temp (NPL)	4	3	1	0	8
Veterinary Food-Animal Drug Retailer - Temp (VET)	2	0	0	0	2
Wholesalers - Temp (WLS)	7	3	4	0	14
Wholesalers Nonresident - Temp (OSD)	15	18	6	0	39
Total	**124**	**114**	**80**	**0**	**318**

LICENSES ISSUED

Individual Licenses	July - Sept	Oct-Dec	*Jan-Mar	Apr-Jun	Total FYTD
Designated Representatives (EXC)	82	141	77	0	300
Designated Representatives Vet (EXV)	0	0	1	0	1
Designated Representatives-3PL (DRL)	32	44	21	0	97
Designated Representatives-Reverse Distributor (DRR)	3	2	1	0	6
Designated Paramedic (DPM)	0	1	0	0	1
Intern Pharmacist (INT)	970	158	68	0	1,196
Pharmacist (RPH)	735	658	122	0	1,515
Advanced Practice Pharmacist (APH)	46	60	6	0	112
Pharmacy Technician (TCH)	1,211	834	447	0	2,492
Total	**3,079**	**1,898**	**743**	**0**	**5,720**

Site Licenses	July - Sept	Oct-Dec	*Jan-Mar	Apr-Jun	Total FYTD
Automated Drug Delivery System (ADD(AUD))	35	50	63	0	148
Automated Drug Delivery System (ADD(APD))	2	0	1	0	3
Automated Drug Delivery System EMS (ADE)	0	0	0	0	0
Automated Patient Dispensing System 340B Clinic (ADC)	0	0	1	0	1
Centralized Hospital Packaging Government Owned (CHE)	0	0	0	0	0
Centralized Hospital Packaging (CHP)	0	0	0	0	0
Clinics (CLN)	14	9	158	0	181
Clinics Government Owned (CLE)	14	14	4	0	32
Drug Room (DRM)	0	0	0	0	0
Drug Room Government Owned (DRE)	0	0	0	0	0
Hospitals (HSP)	0	0	0	0	0
Hospitals Government Owned (HPE)	0	0	0	0	0
Hospital Satellite Sterile Compounding (SCP)	0	0	0	0	0
Hospital Satellite Sterile Compounding Government Owned (SCE)	2	0	0	0	2
Hypodermic Needle and Syringes (HYP)	2	0	0	0	2
Correctional Pharmacy (LCF)	0	0	0	0	0
Outsourcing Facility (OSF)	0	0	0	0	0
Outsourcing Facility Nonresident (NSF)	1	0	0	0	1
Pharmacy (PHY)	14	14	15	0	43
Pharmacy Government Owned (PHE)	2	1	0	0	3
Remote Dispensing Pharmacy (PHR)	0	0	0	0	1
Pharmacy Nonresident (NRP)	10	7	8	0	25
Sterile Compounding (LSC)	6	4	3	0	13
Sterile Compounding Government Owned (LSE)	1	1	0	0	2
Sterile Compounding Nonresident (NSC)	1	0	1	0	2
Surplus Medication Collection Distribution Intermediary (SME)	0	0	0	0	0
Third-Party Logistics Providers (TPL)	1	1	1	0	3
Third-Party Logistics Providers Nonresident (NPL)	0	8	3	0	11
Veterinary Food-Animal Drug Retailer (VET)	0	0	0	0	0
Wholesalers (WLS)	5	1	4	0	10
Wholesalers Government Owned (WLE)	0	0	0	0	0
Wholesalers Nonresident (OSD)	19	14	5	0	38
Total	**129**	**124**	**267**	**0**	**521**

Site Temporary Licenses	July - Sept	Oct-Dec	*Jan-Mar	Apr-Jun	Total FYTD
Drug Room -Temp (DRM)	0	0	0	0	0
Hospitals - Temp (HSP)	3	0	1	0	4
Hospital Satellite Sterile Compounding - Temp (SCP)	0	0	0	0	0
Outsourcing Facility - Temp (OSF)	0	0	0	0	0
Outsourcing Facility Nonresident - Temp (NSF)	0	0	0	0	0
Pharmacy - Temp (PHY)	55	47	33	0	135
Remote Dispensing Pharmacy - Temp (PHR)	0	0	0	0	0
Pharmacy Nonresident - Temp (NRP)	16	11	4	0	31
Sterile Compounding - Temp (LSC)	10	4	3	0	17
Sterile Compounding Nonresident - Temp (NSC)	0	1	0	0	1
Third-Party Logistics Providers - Temp (TPL)	0	1	0	0	1
Third-Party Logistics Providers Nonresident - Temp (NPL)	0	5	1	0	6
Veterinary Food-Animal Drug Retailer - Temp (VET)	0	0	0	0	0
Wholesalers - Temp (WLS)	1	4	1	0	6
Wholesalers Nonresident - Temp (OSD)	6	7	2	0	15
Total	**91**	**80**	**45**	**0**	**216**

PENDING APPLICATIONS (Data reflects number of pending applications at the end of the quarter)

Individual Applications	July - Sept	Oct-Dec	*Jan-Mar	Apr-Jun
Designated Representatives (EXC)	316	273	171	0
Designated Representatives Vet (EXV)	8	11	7	0
Designated Representatives-3PL (DRL)	101	73	76	0
Designated Representatives-Reverse Distributor (DRR)	4	1	0	0
Designated Paramedic (DPM)	1	0	0	0
Intern Pharmacist (INT)	182	82	61	0
Pharmacist (exam not eligible)	1,403	1,276	1,203	0
Pharmacist (exam eligible)	1,557	894	902	0
Advanced Practice Pharmacist (APH)	102	84	101	0
Pharmacy Technician (TCH)	1,103	1,414	1,812	0
Total	**4,777**	**4,108**	**4,333**	**0**

Site Applications	July - Sept	Oct-Dec	*Jan-Mar	Apr-Jun
Automated Drug Delivery System (ADD(AUD))	168	171	125	0
Automated Drug Delivery System (ADD(APD))	45	45	45	0
Automated Drug Delivery System EMS (ADE)	0	0	0	0
Automated Patient Dispensing System 340B Clinic (ADC)	0	1	0	0
Centralized Hospital Packaging Government Owned (CHE)	1	1	1	0
Centralized Hospital Packaging (CHP)	2	1	1	0
Clinics (CLN)	263	264	120	0
Clinics Government Owned (CLE)	24	8	14	0
Drug Room (DRM)	2	2	2	0
Drug Room Government Owned (DRE)	0	0	0	0
Hospitals (HSP)	7	8	10	0
Hospitals Government Owned (HPE)	1	1	1	0
Hospital Satellite Sterile Compounding (SCP)	1	2	2	0
Hospital Satellite Sterile Compounding Government Owned (SCE)	0	0	0	0
Hypodermic Needle and Syringes (HYP)	12	15	18	0
Correctional Pharmacy (LCF)	0	0	0	0
Outsourcing Facility (OSF)	0	0	1	0
Outsourcing Facility Nonresident (NSF)	9	9	9	0
Pharmacy (PHY)	196	215	224	0
Pharmacy Government Owned (PHE)	7	8	8	0
Remote Dispensing Pharmacy (PHR)	5	5	5	0
Pharmacy Nonresident (NRP)	176	169	184	0
Sterile Compounding (LSC)	59	56	59	0
Sterile Compounding - Government Owned (LSE)	9	9	11	0
Sterile Compounding Nonresident (NSC)	23	19	19	0
Surplus Medication Collection Distribution Intermediary (SME)	0	0	0	0
Third-Party Logistics Providers (TPL)	4	3	4	0
Third-Party Logistics Providers Nonresident (NPL)	68	63	66	0
Veterinary Food-Animal Drug Retailer (VET)	2	2	2	0
Wholesalers (WLS)	58	59	68	0
Wholesalers Government Owned (WLE)	1	1	1	0
Wholesalers Nonresident (OSD)	122	137	145	0
Total	**1,097**	**1,103**	**1,020**	**0**

Applications Pending with Temporary Licenses Issued - Pending Full License	July - Sept	Oct-Dec	*Jan-Mar	Apr-Jun
Drug Room -Temp (DRM)	1	0	0	0
Hospitals - Temp (HSP)	4	2	1	0
Hospital Satellite Sterile Compounding - Temp (SCP)	0	0	0	0
Outsourcing Facility - Temp (OSF)	0	0	0	0
Outsourcing Facility Nonresident - Temp (NSF)	0	0	0	0
Pharmacy - Temp (PHY)	108	97	89	0
Remote Dispensing Pharmacy - Temp (PHR)	0	0	0	0
Pharmacy Nonresident - Temp (NRP)	41	19	15	0
Sterile Compounding - Temp (LSC)	13	12	4	0
Sterile Compounding Nonresident - Temp (NSC)	1	1	1	0
Third-Party Logistics Providers - Temp (TPL)	0	0	0	0
Third-Party Logistics Providers Nonresident - Temp (NPL)	1	3	2	0
Veterinary Food-Animal Drug Retailer - Temp (VET)	0	0	0	0
Wholesalers - Temp (WLS)	1	4	2	0
Wholesalers Nonresident - Temp (OSD)	7	5	5	0
Total	**177**	**143**	**119**	**0**

APPLICATIONS WITHDRAWN

Individual Applications	July - Sept	Oct-Dec	*Jan-Mar	Apr-Jun	Total FYTD
Designated Representatives (EXC)	0	1	105	0	106
Designated Representatives Vet (EXV)	0	0	3	0	3
Designated Representatives-3PL (DRL)	0	2	6	0	8
Designated Representatives-Reverse Distributor (DRR)	0	1	0	0	1
Designated Paramedic (DPM)	0	0	0	0	0
Intern Pharmacist (INT)	0	35	23	0	58
Pharmacist (exam applications)	2	239	16	0	257
Advanced Practice Pharmacist (APH)	0	0	0	0	0
Pharmacy Technician (TCH)	17	89	0	0	106
Total	**19**	**367**	**153**	**0**	**539**

Site Applications	July - Sept	Oct-Dec	*Jan-Mar	Apr-Jun	Total FYTD
Automated Drug Delivery System (ADD(AUD))	2	3	0	0	5
Automated Drug Delivery System (ADD(APD))	0	0	0	0	0
Automated Drug Delivery System EMS (ADE)	0	0	0	0	0
Automated Patient Dispensing System 340B Clinic (ADC)	0	0	0	0	0
Centralized Hospital Packaging Government Owned (CHE)	0	0	0	0	0
Centralized Hospital Packaging (CHP)	0	1	0	0	1
Clinics (CLN)	3	8	2	0	13
Clinics Government Owned (CLE)	0	14	0	0	14
Drug Room (DRM)	0	0	0	0	0
Drug Room Government Owned (DRE)	0	0	0	0	0
Hospitals (HSP)	1	0	1	0	2
Hospitals Government Ownerd (HPE)	0	0	0	0	0
Hospital Satellite Sterile Compounding (SCP)	0	0	0	0	0
Hospital Satellite Sterile Compounding Government Owned (SCE)	0	0	0	0	0
Hypodermic Needle and Syringes (HYP)	0	0	0	0	0
Correctional Pharmacy (LCF)	0	0	0	0	0
Outsourcing Facility (OSF)	0	0	0	0	0
Outsourcing Facility Nonresident (NSF)	1	1	0	0	2
Pharmacy (PHY)	5	5	8	0	18
Pharmacy Government Owned (PHE)	0	0	0	0	0
Remote Dispensing Pharmacy (PHR)	0	0	0	0	0
Pharmacy Nonresident (NRP)	0	9	0	0	9
Sterile Compounding (LSC)	2	3	2	0	7
Sterile Compounding - Government Owned (LSE)	1	0	0	0	1
Sterile Compounding Nonresident (NSC)	2	5	1	0	8
Surplus Medication Collection Distribution Intermediary (SME)	0	0	0	0	0
Third-Party Logistics Providers (TPL)	1	0	0	0	1
Third-Party Logistics Providers Nonresident (NPL)	1	4	1	0	6
Veterinary Food-Animal Drug Retailer (VET)	0	0	0	0	0
Wholesalers (WLS)	1	1	0	0	2
Wholesalers Government Owned (WLE)	0	0	0	0	0
Wholesalers Nonresident (OSD)	0	4	0	0	4
Total	**18**	**55**	**15**	**0**	**88**

APPLICATIONS DENIED

Individual Applications	July - Sept	Oct-Dec	*Jan-Mar	Apr-Jun	Total FYTD
Designated Representatives (EXC)	1	1	0	0	2
Designated Representatives Vet (EXV)	0	0	0	0	0
Designated Representatives-3PL (DRL)	0	0	0	0	0
Designated Representatives-Reverse Distributor (DRR)	0	0	0	0	0
Designated Paramedic (DPM)	0	0	0	0	0
Intern Pharmacist (INT)	0	0	2	0	2
Pharmacist (exam application)	3	2	2	0	7
Pharmacist (exam eligible)	0	0	0	0	0
Advanced Practice Pharmacist (APH)	0	0	0	0	0
Pharmacy Technician (TCH)	8	10	8	0	26
Total	**12**	**13**	**12**	**0**	**37**

Site Applications	July - Sept	Oct-Dec	*Jan-Mar	Apr-Jun	Total FYTD
Centralized Hospital Packaging Government Owned (CHE)	0	0	0	0	0
Centralized Hospital Packaging (CHP)	0	0	0	0	0
Clinics (CLN)	0	0	0	0	0
Clinics Government Owned (CLE)	0	0	0	0	0
Drug Room (DRM)	0	0	0	0	0
Drug Room Government Owned (DRE)	0	0	0	0	0
Hospitals (HSP)	0	0	0	0	0
Hospitals Government Owned (HPE)	0	0	0	0	0
Hospital Satellite Sterile Compounding (SCP)	0	0	0	0	0
Hospital Satellite Sterile Compounding Government Owned (SCE)	0	0	0	0	0
Hypodermic Needle and Syringes (HYP)	0	0	0	0	0
Correctional Pharmacy (LCF)	0	0	0	0	0
Outsourcing Facility (OSF)	0	0	0	0	0
Outsourcing Facility Nonresident (NSF)	2	0	0	0	2
Pharmacy (PHY)	3	3	4	0	10
Pharmacy Government Owned (PHE)	0	0	0	0	0
Remote Dispensing Pharmacy (PHR)	0	0	0	0	0
Pharmacy Nonresident (NRP)	0	0	0	0	0
Sterile Compounding (LSC)	1	0	0	0	1
Sterile Compounding Government Owned (LSE)	0	0	0	0	0
Sterile Compounding Nonresident (NSC)	2	0	0	0	2
Surplus Medication Collection Distribution Intermediary (SME)	0	0	0	0	0
Third-Party Logistics Providers (TPL)	0	0	0	0	0
Third-Party Logistics Providers Nonresident (NPL)	0	0	0	0	0
Veterinary Food-Animal Drug Retailer (VET)	0	0	0	0	0
Wholesalers (WLS)	0	0	0	0	0
Wholesalers Government Owned (WLE)	0	0	0	0	0
Wholesalers Nonresident (OSD)	0	0	0	0	0
Total	**8**	**3**	**4**	**0**	**15**

RESPOND TO STATUS INQUIRIES

Email Inquiries	July - Sept	Oct-Dec	*Jan-Mar	Apr-Jun	Total FYTD
Designated Representative Received	444	475	306	0	1,225
Designated Representative Responded	139	230	276	0	645
Advanced Practice Pharmacist Received	179	147	76	0	402
Advanced Practice Pharmacist Responded	99	150	39	0	288
Pharmacist/Intern Received	2,244	1,808	827	0	4,879
Pharmacist/Intern Responded	405	1,631	827	0	2,863
Pharmacy Technician Received	1,293	1,154	1,536	0	3,983
Pharmacy Technician Responded	1,498	1,111	332	0	2,941
Pharmacy Received	2,151	1,990	1,325	0	5,466
Pharmacy Responded	1,900	1,724	931	0	4,555
Sterile Compounding/Outsourcing Received	1,116	607	496	0	2,219
Sterile Compounding/Outsourcing Responded	1,015	510	365	0	1,890
Wholesale/Hypodermic/3PL Received	731	652	562	0	1,945
Wholesale/Hypodermic/3PL Responded	479	388	301	0	1,168
Clinic Received	287	279	173	0	739
Clinic Responded	265	240	123	0	628
Automated Drug Delivery Systems Received	96	56	47	0	199
Automated Drug Delivery Systems Responded	96	56	47	0	199
Pharmacist-in-Charge Received	1,096	1,320	767	0	3,183
Pharmacist-in-Charge Responded	1,006	1,261	692	0	2,959
Change of Permit Received	537	440	388	0	1,365
Change of Permit Responded	272	268	186	0	726
Renewals Received	2,080	1,965	1,412	0	5,457
Renewals Responded	1,821	1,683	1,214	0	4,718

Telephone Calls Received	July - Sept	Oct-Dec	*Jan-Mar	Apr-Jun	Total FYTD
Designated Representative	0	0	0	0	0
Advanced Practice Pharmacist	179	147	84	0	410
Pharmacist/Intern	865	1,653	806	0	3,324
Pharmacy	275	452	529	0	1,256
Sterile Compounding/Outsourcing	81	80	58	0	219
Wholesale/Hypodermic/3PL	97	0	4	0	101
Clinic	5	4	57	0	66
Automated Drug Delivery Systems	13	14	2	0	29
Pharmacist-in-Charge	116	134	101	0	351
Change of Permit	72	57	26	0	155
Renewals	1,255	1,079	1,136	0	3,470
Reception	18,430	15,224	12,985	0	46,639

UPDATE LICENSING RECORDS

Change of Pharmacist-in-Charge	July - Sept	Oct-Dec	*Jan-Mar	Apr-Jun	Total FYTD
Received	616	590	370	0	1,576
Processed	627	642	270	0	1,539
Approved	659	575	301	0	1,535
Pending (Data reflects number of pending at the end of the quarter.)	295	305	374	0	n/a
Change of Designated Representative-in-Charge	**July - Sept**	**Oct-Dec**	***Jan-Mar**	**Apr-Jun**	**Total FYTD**
Received	48	41	21	0	110
Processed	46	46	21	0	113
Approved	66	59	20	0	145
Pending (Data reflects number of pending at the end of the quarter.)	61	42	43	0	n/a
Change of Responsible Manager	**July - Sept**	**Oct-Dec**	***Jan-Mar**	**Apr-Jun**	**Total FYTD**
Received	9	10	5	0	24
Processed	8	10	3	0	20
Approved	7	8	5	0	20
Pending (Data reflects number of pending at the end of the quarter.)	11	13	13	0	n/a
Change of Professional Director	**July - Sept**	**Oct-Dec**	***Jan-Mar**	**Apr-Jun**	**Total FYTD**
Received	44	35	9	0	88
Processed	31	31	12	0	74
Approved	52	55	13	0	120
Pending (Data reflects number of pending at the end of the quarter.)	70	45	41	0	n/a
Change of Permits	**July - Sept**	**Oct-Dec**	***Jan-Mar**	**Apr-Jun**	**Total FYTD**
Received	673	461	248	0	1,382
Processed	307	196	183	0	686
Approved	254	191	193	0	638
Pending (Data reflects number of pending at the end of the quarter.)	3,139	3,424	3,455	0	n/a
Discontinuance of Business	**July - Sept**	**Oct-Dec**	***Jan-Mar**	**Apr-Jun**	**Total FYTD**
Received	187	100	66	0	353
Processed	84	155	103	0	342
Approved	76	142	174	0	392
Pending (Data reflects number of pending at the end of the quarter.)	432	379	0	0	n/a
Intern Pharmacist Extensions	**July - Sept**	**Oct-Dec**	***Jan-Mar**	**Apr-Jun**	**Total FYTD**
Received	51	23	16	0	90
Processed	48	29	12	0	89
Completed	46	44	11	0	101
Pending (Data reflects number of pending at the end of the quarter.)	31	10	16	0	n/a
Requests Approved	**July - Sept**	**Oct-Dec**	***Jan-Mar**	**Apr-Jun**	**Total FYTD**
Address/Name Changes	3,192	2,381	1,719	0	7,292
Off-site Storage	24	24	18	0	66
Transfer of Intern Hours	9	14	3	0	26
License Verification	127	115	69	0	311

DISCONTINUED OF BUSINESS

discontinued by date of closure

Site Licenses	July - Sept	Oct-Dec	*Jan-Mar	Apr-Jun	Total FYTD
Automated Drug Delivery System (ADD(AUD))	12	0	0	0	12
Automated Drug Delivery System (ADD(APD))	0	0	0	0	0
Automated Drug Delivery System EMS (ADE)	0	0	0	0	0
Automated Patient Dispensing System 340B Clinic (ADC)	0	0	0	0	0
Centralized Hospital Packaging Government Owned (CHE)	0	0	0	0	0
Centralized Hospital Packaging (CHP)	1	0	0	0	1
Clinics (CLN)	3	15	1	0	19
Clinics Government Owned (CLE)	6	13	2	0	21
Drug Room (DRM)	0	0	0	0	0
Drug Room Government Owned (DRE)	0	0	0	0	0
Hospitals (HSP)	0	0	1	0	1
Hospitals Government Owned (HPE)	0	0	1	0	1
Hospital Satellite Sterile Compounding (SCP)	0	0	0	0	0
Hospital Satellite Sterile Compounding Government Owned (SCE)	0	0	0	0	0
Hypodermic Needle and Syringes (HYP)	0	0	0	0	0
Correctional Pharmacy (LCF)	0	2	0	0	2
Outsourcing Facility (OSF)	0	0	0	0	0
Outsourcing Facility Nonresident (NSF)	0	0	0	0	0
Pharmacy (PHY)	34	27	21	0	82
Pharmacy (PHY) Chain	97	11	15	0	123
Pharmacy Government Owned (PHE)	0	0	0	0	0
Remote Dispensing Pharmacy (PHR)	0	0	0	0	0
Pharmacy Nonresident (NRP)	6	4	3	0	13
Sterile Compounding (LSC)	19	8	2	0	29
Sterile Compounding Government Owned (LSE)	0	1	2	0	3
Sterile Compounding Nonresident (NSC)	2	0	0	0	2
Surplus Medication Collection Distribution Intermediary (SME)	0	0	0	0	0
Third-Party Logistics Providers (TPL)	0	0	0	0	0
Third-Party Logistics Providers Nonresident (NPL)	1	1	2	0	4
Veterinary Food-Animal Drug Retailer (VET)	0	0	0	0	0
Wholesalers (WLS)	4	3	2	0	9
Wholesalers Government Owned (WLE)	0	0	0	0	0
Wholesalers Nonresident (OSD)	4	4	5	0	13
Total	**177**	**89**	**57**	**0**	**323**

LICENSES RENEWED

Individual Licenses Renewed	July - Sept	Oct-Dec	*Jan-Mar	Apr-Jun	Total FYTD
Designated Representatives (EXC)	524	544	441	0	1,509
Designated Representatives Vet (EXV)	13	7	5	0	25
Designated Representatives-3PL (DRL)	75	70	70	0	215
Designated Representatives-Reverse Distributor (DRR)	1	2	0	0	3
Designated Paramedic (DPM)	0	0	0	0	0
Pharmacist (RPH)	5,838	5,073	3,552	0	14,463
Advanced Practice Pharmacist (APH)	144	124	86	0	354
Pharmacy Technician (TCH)	7,517	7,166	4,588	0	19,271
Total	**14,112**	**12,986**	**8,742**	**0**	**35,840**

Site Licenses Renewed	July - Sept	Oct-Dec	*Jan-Mar	Apr-Jun	Total FYTD
Automated Drug Delivery System (ADD)	80	669	26	0	775
Automated Drug Delivery System EMS (ADE)	0	0	1	0	1
Automated Patient Dispensing System 340B Clinic (ADC)	0	0	0	0	0
Centralized Hospital Packaging Government Owned (CHE)	0	0	0	0	0
Centralized Hospital Packaging (CHP)	3	1	3	0	7
Clinics (CLN)	396	239	186	0	821
Clinics Government Owned (CLE)	34	795	13	0	842
Drug Room (DRM)	2	3	6	0	11
Drug Room Government Owned (DRE)	2	7	0	0	9
Hospitals (HSP)	57	156	57	0	270
Hospitals Government Owned (HPE)	38	21	2	0	61
Hospital Satellite Sterile Compounding (SCP)	2	1	0	0	3
Hospital Satellite Sterile Compounding Government Owned (SCE)	1	0	0	0	1
Hypodermic Needle and Syringes (HYP)	46	68	21	0	135
Correctional Pharmacy (LCF)	3	53	0	0	56
Outsourcing Facility (OSF)	1	2	0	0	3
Outsourcing Facility Nonresident (NSF)	3	4	4	0	11
Pharmacy (PHY)	687	2,512	526	0	3,725
Pharmacy Government Owned (PHE)	52	55	8	0	115
Remote Dispensing Pharmacy (PHR)	0	2	0	0	2
Pharmacy Nonresident (NRP)	87	136	107	0	330
Sterile Compounding (LSC)	132	275	96	0	503
Sterile Compounding Government Owned (LSE)	58	4	5	0	67
Sterile Compounding Nonresident (NSC)	10	13	2	0	25
Surplus Medication Collection Distribution Intermediary (SME)	0	0	0	0	0
Third-Party Logistics Providers (TPL)	11	2	4	0	17
Third-Party Logistics Providers Nonresident (NPL)	35	24	19	0	78
Veterinary Food-Animal Drug Retailer (VET)	4	2	2	0	8
Wholesalers (WLS)	110	82	72	0	264
Wholesalers Government Owned (WLE)	4	6	0	0	10
Wholesalers Nonresident (OSD)	182	142	106	0	430
Total	**2,040**	**5,274**	**1,266**	**0**	**8,580**

CURRENT LICENSES - Data reflects number of licenses at the end of the quarter.

Individual Licenses	July - Sept	Oct-Dec	*Jan-Mar	Apr-Jun
Designated Representatives (EXC)	2,814	2,860	2,935	0
Designated Representatives Vet (EXV)	54	52	52	0
Designated Representatives-3PL (DRL)	419	446	466	0
Designated Representatives-Reverse Distributor (DRR)	10	12	13	0
Designated Paramedic (DPM)	3	4	4	0
Intern Pharmacist (INT)	5,788	5,438	5,392	0
Pharmacist (RPH)	49,458	49,791	49,871	0
Advanced Practice Pharmacist (APH)	1,084	1,143	1,149	0
Pharmacy Technician (TCH)	68,129	66,915	67,356	0
Total	**127,759**	**126,661**	**127,238**	**0**

Site Licenses	July - Sept	Oct-Dec	*Jan-Mar	Apr-Jun
Automated Drug Delivery System (ADD(AUD))	1,035	1,008	1,041	0
Automated Drug Delivery System (ADD(APD))	58	58	59	0
Automated Drug Delivery System EMS (ADE)	1	1	1	0
Automated Patient Dispensing System 340B Clinic (ADC)	0	0	1	0
Centralized Hospital Packaging Government Owned (CHE)	2	2	2	0
Centralized Hospital Packaging (CHP)	9	9	9	0
Clinics (CLN)	1,253	1,259	1,413	0
Clinics Government Owned (CLE)	928	930	922	0
Drug Room (DRM)	20	20	20	0
Drug Room Government Owned (DRE)	10	10	10	0
Hospitals (HSP)	394	394	395	0
Hospitals Government Owned (HPE)	78	77	77	0
Hospital Satellite Sterile Compounding (SCP)	4	4	4	0
Hospital Satellite Sterile Compounding Government Owned (SCE)	4	4	4	0
Hypodermic Needle and Syringes (HYP)	237	237	237	0
Correctional Pharmacy (LCF)	59	58	57	0
Outsourcing Facility (OSF)	4	4	4	0
Outsourcing Facility Nonresident (NSF)	20	20	20	0
Pharmacy (PHY)	6,243	6,163	6,143	0
Pharmacy Government Owned (PHE)	139	139	139	0
Remote Dispensing Pharmacy (PHR)	2	2	2	0
Pharmacy Nonresident (NRP)	588	588	592	0
Sterile Compounding (LSC)	729	724	719	0
Sterile Compounding Government Owned (LSE)	104	105	103	0
Sterile Compounding Nonresident (NSC)	55	54	55	0
Surplus Medication Collection Distribution Intermediary (SME)	1	1	1	0
Third-Party Logistics Providers (TPL)	40	42	41	0
Third-Party Logistics Providers Nonresident (NPL)	122	134	137	0
Veterinary Food-Animal Drug Retailer (VET)	21	21	21	0
Wholesalers (WLS)	545	541	536	0
Wholesalers Government Owned (WLE)	13	13	13	0
Wholesalers Nonresident (OSD)	785	799	801	0
Total	**12,468**	**12,413**	**12,538**	**0**
Total Population of Licenses	**140,227**	**139,074**	**139,776**	**0**