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

LICENSING COMMITTEE REPORT
July 18, 2024

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Trevor Chandler, Public Member, Vice-Chairperson
Renee Barker, PharmD, Licensee Member
Jessica Crowley, PharmD, Licensee Member
Satinder Sandhu, PharmD, Licensee Member
Jason Weisz, Public Member

I. Call to Order and Establishment of Quorum

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

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

III. Approval of the April 10, 2024 Licensing Committee Meeting Minutes

Attachment 1 includes the draft minutes from the April 10, 2024 meeting.

IV. Discussion and Consideration of Proposed Amendment to Business and Professions Code Section 4038 Related to the Definition of Pharmacy Technician Trainee

Relevant Law
Business and Professions Code (BPC) section 4038 establishes the definition of a "pharmacy technician trainee" as a person enrolled in a pharmacy technician training program operated by a California public postsecondary education institution or by a private postsecondary vocational institution as specified.

BPC section 4115.5 establishes the requirements and conditions pursuant to which a pharmacy technician trainee may be placed in a pharmacy to complete an externship for the purpose of obtaining practical training.

Background
As part of its ongoing review and evaluation of the pharmacy technician licensing program, during the April 2024 Licensing Committee meeting, members received presentations from various program providers describing the requirements for their respective certification or accreditation programs that provide a pathway to licensure for individuals seeking licensure as a pharmacy technician.

As part of those discussions, members discussed the current definition of "pharmacy technician trainee" and questioned whether the Board should consider clarifying whether pharmacy-based technician training programs should allow participants (who are currently not "pharmacy technician trainees" as defined in BPC section 4038) to obtain practical experience in the same or similar manner as specified in BPC section 4115.5. Members noted that by expanding the definition, more programs may be able to train their students in a pharmacy as a pharmacy technician trainee as the current limitation in the definition would be removed.

Members noted that expanding the definition to include pharmacy-based pharmacy technician training programs could increase learning, increase training options, and reduce barriers to entry.

For Committee Consideration and Discussion
During the meeting, members will have the opportunity to consider draft statutory language to expand the definition of "pharmacy technician trainee" to include individuals participating in other types of pharmacy technician training programs, including employer-based training programs.

Attachment 2 includes a copy of the draft language.

V. Discussion and Consideration of Survey Results Received Related to Pharmacist to Pharmacy Technician Ratio

Relevant Law
Paragraph (1) of subdivision (g) of BPC section 4115 provides that a pharmacy with only one pharmacist shall have no more than one pharmacy technician performing the tasks specified in subdivision (a) of BPC section 4115.[1] This paragraph further provides that the ratio of pharmacy technicians

[1] Subdivision (a) of BPC section 4115 states: "A pharmacy technician may perform packaging, manipulative, repetitive, or other nondiscretionary tasks only while assisting, and while under the direct supervision and control of, a pharmacist. The pharmacist shall be responsible for the duties performed under their supervision by a technician."

performing the tasks specified in subdivision (a) to any additional pharmacist shall not exceed 2:1, except that this ratio shall not apply to personnel performing clerical functions pursuant to BPC sections 4116 or 4117, nor shall this ratio apply for the following:

1. An inpatient of a licensed health facility.
2. A patient of a licensed home health agency.
3. An inmate of a correctional facility of the Department of Corrections and Rehabilitation.
4. A person receiving treatment in a facility operated by the State Department of State Hospitals, the State Department of Developmental Services, or the Department of Veterans Affairs.

Paragraph (2) of subdivision (g) of BPC section 4115 provides authority for the Board to adopt regulations establishing the ratio of pharmacy technicians performing the tasks specified in subdivision (a) to pharmacists applicable to the filling of prescriptions of an inpatient of a licensed health facility and for a patient of a licensed home health agency.

California Code of Regulations, title 16, section 1793.7(f) specifies that for the preparation of a prescription for an inpatient of a licensed health facility and for a patient of a licensed home health agency, the ratio shall not be less than one pharmacist on duty for a total of two pharmacy technicians on duty.

Background

Over the years there have been several legislative attempts to change the ratio requirements. Further, the Board has received numerous requests from the public to schedule a discussion on the current ratio requirements. (**Note**: As was mentioned during the April 2024 Licensing Committee meeting, legislation (Senate Bill 1365, Glazer, 2024) was introduced that would have changed the ratio in California. The Board established an oppose position on this measure, which was held in Senate Appropriations Committee.)

During the Committee's October 2023 meeting, members and stakeholders considered a number of policy questions related to the current ratio and potential opportunities for change. After consideration, the Committee indicated its desire to develop a survey for pharmacists soliciting feedback on the issue of ratios.

During the January 2024 Committee meeting, members reviewed and approved a draft survey to solicit feedback from pharmacists on the topic. The survey was released on March 6, 2024 and ended March 25, 2024.

During the April 2024 Committee meeting, members were provided with a brief presentation on the survey results prepared by experts within the DCA Office of Professional Examination Services (OPES). As part of the presentation, members were advised that over 4,517 responses were analyzed. Survey respondent demographic information was provided. Further analysis of responses was provided for specific pharmacy settings (institutional and noninstitutional) where pharmacists were asked to respond to questions related to their belief about the current pharmacist to pharmacy technician ratio. This data was further broken down to include respondents that indicated they were in a management or administrative position for their employer.

Institutional Setting

1. The majority of respondents working in a management or administrative position indicated they do not believe the current ratio of 1:2 is appropriate (58.5%)

   Further, such respondents indicated that the appropriate ratio for an institutional setting was as follows:
   - 1:3 Ratio (41.5%)
   - PIC Determination (29.6%)
   - 1:4 Ratio (14.7%)
   - 1:2 Ratio (8.5%)
   - Other (5.7%)
2. The majority of respondents designated as a PIC indicated they do not believe the current ratio of 1:1 is appropriate (82.6%)

   Further, such respondents indicated that the appropriate ratio for an institutional setting was as follows:
   - 1:3 Ratio (40.5%)
   - PIC Determination (29.0%)
   - 1:4 Ratio (13.3%)
   - 1:2 Ratio (11.7%)
   - Other (5.6%)

Noninstitutional Setting

1. The majority of respondents working in a management or administrative position indicated they do not believe the current ratio of 1:1 is appropriate (83.7%)

   Further, such respondents indicated that the appropriate ratio for a noninstitutional setting was as follows:
   - 1:2 Ratio (38.3%)
   - 1:3 Ratio (27.3%)
   - PIC Determination (22.2%)
   - 1:4 Ratio (8.8%)

- Other (3.5%)

2. The majority of respondents designated as a PIC indicated they do not believe the current ratio of 1:1 is appropriate (82.6%)

   Further, such respondents indicated that the appropriate ratio for a noninstitutional setting was as follows:
   - 1:2 Ratio (41.8%)
   - 1:3 Ratio (26.1%)
   - PIC Determination (20.1%)
   - 1:4 Ratio (9.2%)
   - Other (2.8%)

Following discussion, members requested that additional data be provided describing the data for respondents that indicated they are not in a management or administrative position. Following the discussion, staff worked with OPES to prepare the analysis requested.

For Committee Consideration and Discussion
During the meeting, members will review the results of the survey and determine what, if any, additional action should be taken. The Board has previously noted that the issue is appropriate for inclusion in the Board's upcoming sunset review.

Attachment 3 includes a summary of the survey results previously provided to the Committee.

VI. Discussion and Consideration of Proposal to Establish Reinstatement of a Retired Pharmacist License

Relevant Law
BPC section 4200.5 establishes the provisions for a retired pharmacist license. As provided in this section, the holder of a retired license may restore their license through reapplication for a pharmacist license, including passing the examinations that are required for initial licensure with the Board.

Background
As part of the November 1-2, 2023 Board meeting, members received public comment requesting that the Board consider development of a process to allow for a step-down pharmacist licensure category. Public comment suggested that the Board consider a model used in Nevada. Following the request, the matter was referred to the Licensing Committee for consideration.

During the April 2024 Licensing Committee meeting, members reviewed relevant Nevada laws that provide for a fee waiver for any person who has been registered as a pharmacist in Nevada for at least 50 years. (NAC 639.220.)

Staff notes that while Nevada law establishes provisions for an inactive pharmacist license (NAC 639.218), similar to the inactive licensure provisions in California, Nevada law requirements for reactivation are more robust. Specifically, NAC 639.219 requires that if a pharmacist whose certificate of registration has been placed on inactive status wishes to resume the practice of pharmacy in Nevada, the pharmacist must submit evidence either (1) that they hold an active certificate, license, or registration to practice pharmacy in another state, or (2) that they have both (i) completed 30 units of CE within the 2 years immediately preceding the date on which the application for return to active status is filed **AND** (ii) passed a written continuing education examination on law provided by the Nevada Board of Pharmacy.

Following discussion, members requested that staff further review the issue and bring forward a statutory proposal to establish a step-down approach for pharmacists seeking to retire their license.

For Committee Consideration and Discussion
During the meeting, members will have the opportunity to discuss a statutory proposal to amend BPC section 4200.5 to establish parameters for a retired pharmacist to restore their license under specified conditions.

Attachment 4 includes a copy of the statutory proposal.

VII. Discussion and Consideration of Compounding by Pharmacy Technicians Outside of Pharmacies

Relevant Law
BPC section 4038 defines "pharmacy technician" as an individual who assists a pharmacist **in a pharmacy** in the performance of their pharmacy related duties, as specified in BPC section 4115.

Federal Food, Drug and Cosmetic Act Section 503A generally establishes the conditions under which a drug product may be compounded. The section provides in part that the compounding must be done in compliance with the United States Pharmacopoeia (USP) chapter on pharmacy compounding.

USP General Chapter <797> *Pharmaceutical Compounding – Sterile Preparations* describes the minimum requirements that apply to all persons who prepare compounded sterile preparations (CSPs) and all places where

CSPs are prepared for human and animal patients. This includes pharmacists and technicians in all places including, but not limited to, medical and surgical patient treatment sites, infusion facilities, pharmacies, and physicians' and veterinarian practice sites.[2]

Background

As the Enforcement and Compounding Committee previously discussed before referral of this topic to the Licensing Committee, it is not uncommon for a pharmacy technician to be hired by a prescriber to perform compounding activities. Staff notes that in some instances it appears pharmacy technicians are specifically recruited to perform compounding in a physician's office, unlicensed infusion center, oncology clinic, IV hydration clinic, etc. Although the Board does not generally license these locations, inspector staff have inspected such practices and noted significant deviation from USP <797> requirements where pharmacy technicians are compounding, creating the potential for patient harm.

When a pharmacy technician compounds in a pharmacy, such activity can only be performed while assisting, and while under the direct supervision and control of, a pharmacist. (See BPC sections 4038(a) and 4115(a).) Similar oversight generally does not appear to exist outside of Board-licensed facilities, however.

During its prior discussion, members considered several policy questions related to this issue.

1. Should the Board seek explicit authority to inspect locations where pharmacy technicians are performing compounding activities outside of licensed pharmacies? (Note: BPC Section 4008 may already provide the Board such authority; however, it may be beneficial to have more explicit authority.)
2. Should the Board develop educational materials to provide to other health care professional boards and associations reminding such entities of the Board's inspection authority?
3. Generally, the Board does not inspect facilities where compounding occurs outside of a Board-licensed facility unless requested or referred to the Board for such action by another entity, *e.g.*, the FDA, FBI, DEA, etc. Does the Committee wish to provide direction to staff to proactively perform some inspections of such facilities to learn more about compounding practices?

[2] See <797> FAQs, #4, available at https://go.usp.org/USP_GC_797_FAQs

4. Does the Committee believe it is appropriate to allow for a pharmacy technician to compound under the direct supervision and control of a pharmacist when **outside** of a licensed pharmacy?
5. Should the Board consider establishing a requirement for offices, clinics, etc. that are compounding but not currently licensed by the Board to provide notification to the Board that Board licensees are compounding at their location or alternatively require Board licensees to notify the Board if they are compounding outside of a Board-licensed facility?
6. Should the Board develop educational materials reminding pharmacy technicians of the requirements of USP <797> and federal law related to compounding of drug preparations?

During the discussion, members noted the need to increase educational awareness of the Board's authority to conduct inspections of locations where compounding occurs, including non-licensed areas. Members expressed concern about the compounding environment in some of these non-licensed locations including locations where pharmacy technicians are compounding preparations. Members noted the importance for patient safety of ensuring the compounding environment is compliant with applicable USP standards and that many people don't realize that compounding is a high-risk activity.

Members highlighted the Board's role to safeguard the health and safety of the public and that the Board should proactively go out and inspect such locations consistent with the Board's authority. There appeared to be consensus among members that more oversight of such locations appears appropriate to ensure compliance with USP standards.

Members discussed the current challenge of providing regulatory oversight of pharmacy technicians compounding outside of a pharmacy and outside of the direct supervision and control of a pharmacist and considered if a notification requirement would be appropriate, including potentially through a web-based portal to facilitate the notification.

<u>For Committee Consideration and Discussion</u>
During the meeting, members will have the opportunity to consider a draft statutory proposal that would, as proposed, facilitate two changes consistent with the Committee's discussion:

1. Establish authority for a pharmacy technician to compound outside of a licensed pharmacy under the direct supervision and control of a pharmacist.
2. Establish a requirement to notify the Board where such compounding activities occur.

Attachment 5 includes a copy of the statutory proposal to amend BPC section 4115.

VIII. Presentations on Central Fill Pharmacy Models in Use in California

Relevant Law

California Code of Regulations, title 16, section 1707.4 generally provides authority for a pharmacy licensed by the Board to process a request for refill of a prescription received by a pharmacy within California under specified conditions including:

1. The pharmacy that is to refill the prescription either has a contract with the pharmacy which received the prescription or has the same owner as the originating pharmacy.
2. The prescription container meets labeling requirements and clearly shows the name and address of the pharmacy refilling the prescription and/or the name and address of the pharmacy which receives the refilled prescription for dispensing to the patient.
3. The patient is provided with written information that describes which pharmacy to contact if the patient has any questions about the prescription or medication.
4. Both pharmacies maintain complete and accurate records of the refill, as specified.
5. Both pharmacies shall each be responsible for ensuring the order has been properly filled.
6. The originating pharmacy is responsible for compliance with the requirements set forth in California Code of Regulations, title 16, sections 1707.1 (duty to maintain medication profiles), 1707.2 (duty to consult), and 1707.3 (duty to review drug therapy and patient medication record prior to delivery).

Background

As part of the October 2023 Committee meeting, members considered the Board's current regulations and several policy questions. Members received significant public comment during the meeting.

Following discussion, it was determined that changes to the Board's regulations are necessary to provide clarity on the Board's regulation of central fill pharmacies.

During the January 2024 meeting, members considered proposed amendments to 16 CCR section 1707.4. At the time of the discussion, members did not take action on the proposed language; however, the Committee requested presentations on central fill models used within California and nationally.

More recently, during the April 2024 meeting, members received presentations by Walgreens and Albertsons on their respective central fill operations. Following the presentations and discussion, members noted that the presentations were helpful, but expressed the need to understand more about the current use of central fill pharmacies in California.

For Committee Consideration and Discussion
During the meeting, members will receive a presentation from Supervising Inspector Dang on central fill models in use in California.

Attachment 6 includes the presentation slides.

IX. Discussion and Consideration of Proposed Amendment to California Code of Regulations, Title 16, Section 1707.4 Related to Central Fill Pharmacies

For Committee Consideration and Discussion
Following the presentation, members will have the opportunity to again discuss the proposed amendments to 16 CCR section 1707.4 and provide direction to staff on the next steps. Staff note that minor changes have been made to the language addressing the issue of product verification found in (a)(5).

Following discussion, should the Committee determine proposed changes to the Board's regulations previously identified are appropriate, the following motion could be used to recommend action to the Board.

> **Possible Motion**: Recommend initiation of a rulemaking to amend California Code of Regulations, title 16, section 1707.4 [insert either "as proposed to be amended" or "consistent with the Committee's discussion"]. Authorize the executive officer to further refine the language consistent with the Committee's discussion and to make any nonsubstantive changes prior to presenting the proposed rulemaking to the Board.

Attachment 7 includes the draft regulation language.

X. Discussion and Consideration of Licensure and Other Requirements for Nonresident Pharmacies

Relevant Law
BPC section 4112 provides that 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. The section also establishes the licensure requirements for such a pharmacy. As part of these requirements, a nonresident pharmacy shall not permit a pharmacist whose license has been revoked by the Board to provide any pharmacy-related service to a person residing in California.

BPC section 4120 also establishes some licensure requirements for nonresident pharmacies.

Background

During the October 2023 Committee meeting, members initiated discussion on requirements for mail order pharmacies and noted that generally, all pharmacies are regulated under the same legal requirements. Although the Board does have some regulations that may establish a unique requirement for a specified type of license (*e.g.*, central fill requirements discussed under the prior agenda item, or laws related to chain community pharmacies), generally all pharmacies must comply with the same laws. While this approach may allow for simplicity, it can also create some confusion. Further, a broad approach can at times lead to patient safety concerns.

As part of the Committee's initial consideration, discussion focused on mail order pharmacies. Members discussed the need for inspection authority for nonresident pharmacies and also voiced concerns about temperature control issues that may need to be addressed in the nonresident mail order pharmacy context.

Following discussion, members determined that the focus of the discussion should change to nonresident pharmacies more generally and that the issue may be appropriate for inclusion in the Board's upcoming sunset report.

During the April 2024 meeting, members considered a number of policy questions.

1. The Committee has previously indicated that inspections should be performed at nonresident pharmacies. Does the Committee wish to establish a minimum frequency for conducting such inspections, *e.g.*, every four years?
   Committee Discussion: Members spoke in support of inspections of nonresident pharmacy facilities, but did not reach consensus on the frequency of such inspections.

2. Board staff has recently learned that some states are allowing pharmacists licensed in Canada to secure licensure and/or work in their respective

state without taking the NAPLEX and/or law examination. Such individuals could then provide pharmacy-related services to California patients.

a. Does the Committee have concerns with this practice?
   Committee Discussion: Some members expressed concerns with this while other requested additional information on Canadian licensing standards.
b. Does the Committee wish to prohibit such practice like the approach taken for pharmacist licenses revoked in California?
c. Does the Committee wish to require all pharmacists providing services into California to be licensed in California?
   Committee Discussion: Members considered these two questions together and discussed the potential for chain link reciprocity and the need to break that link. Members noted that additional discussion was necessary.

As a reminder, separate from this discussion, the Board has previously voted to pursue a statutory change to require the pharmacist-in-charge of a nonresident pharmacy to be licensed in California. It is anticipated that this statutory proposal will be raised as part of the Board's sunset report.

For Committee Consideration and Discussion
During the meeting, members will have the opportunity to discuss if additional statutory changes regarding nonresident pharmacies may be appropriate to reduce potential harm to California consumers. As proposed, the draft language would update the requirements as follows:

1. Update requirements for pharmacists working in a nonresident pharmacy that are not licensed in California as a pharmacist.
2. Would establish provisions for mandatory inspections of nonresident pharmacies.

Should the Committee agree with the proposed language, the following motion could be used to recommend that the Board sponsor legislation to update the requirements established in BPC section 4112.

Possible Motion: Recommend the Board pursue a statutory change to update the requirements for nonresident pharmacies consistent with the language [insert either "as proposed to be amended" or "consistent with the Committee's discussion"].

Attachment 8 includes a copy of the proposed statutory language to amend BPC section 4112.

XI. Discussion and Consideration of Proposed Amendments to Pharmacy Law to Transition to a More Robust Standard of Care Model for Some Pharmacist-Provided Patient Care Services

Relevant Law

Former BPC section 4301.3 required the Board to discuss whether moving to a standard of care enforcement model would be feasible and appropriate for the regulation of pharmacy, and to make recommendations to the Legislature about the outcome of its discussions through a report submitted to the Legislature on or before July 1, 2023.

BPC sections 4052 – 4052.10 generally establish the scope of practice for pharmacists.

BPC section 4301, subdivisions (v) and (w) establish as unprofessional conduct, actions or conduct that would subvert the efforts of a pharmacist or pharmacist-in-charge, to comply with laws and regulations, or exercise professional judgment, including creating or allowing conditions that may interfere with a pharmacist's ability to practice with competency and safety or creating or allowing an environment that may jeopardize patient care.

BPC section 4306.5 establishes as unprofessional conduct acts or omissions that involve, in whole or in part, the inappropriate exercise of a pharmacist's education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the Board. The section further establishes as unprofessional conduct failure of a pharmacist to exercise or implement their best professional judgment or corresponding responsibility with regard to the dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices, or with regard to the provision of services. Also, the section provides that the failure to consult appropriate patient, prescription, or other records pertaining to the performance of any pharmacy function is unprofessional conduct, as is the failure to maintain and retain appropriate patient-specific information pertaining to the performance of any pharmacy function.

Background

Consistent with the legislative mandate of former BPC section 4301.3, the Board established an ad hoc committee to evaluate the issue and submitted its report as required. The Board's final recommendations included that the hybrid enforcement model used by the Board remains appropriate for the practice of pharmacy for consumer protection. The Board also noted that,

based on the information received and considered, California patients would benefit from pharmacists gaining additional independent authority to provide patient care services, not limited to the traditional dispensing tasks performed at licensed facilities, consistent with their respective education, training, and experience.

The Board further recommended revisions to certain provisions detailing a pharmacist's authorized scope of practice for specified clinical patient care services and transition to a standard of care model for provisions of specified patient care services where sufficient safeguards are in place to ensure pharmacists retain autonomy to utilize professional judgment in making patient care decisions. The Board concluded that under those conditions, transitioning to greater use of a standard of care model in the provision of specified patient care services could benefit patients by providing expanded and timely access to patient care from suitably educated, trained, and experienced health care providers.

More recently, during the April 2024 meeting, members considered draft statutory language. Provided below are highlights of the proposed changes and the relevant sections of law.

BPC section 4052: Consolidates various provisions of Pharmacy Law into this section and simplifies the language. Further, would make the following changes:

1. Would expand provisions for pharmacists to perform CLIA waived tests, beyond those currently allowed in BPC section 4052.4.
2. Would allow a pharmacist to perform a therapeutic interchange under specified conditions.
3. Would establish authority for pharmacists to furnish FDA approved or authorized medication that is preventative or does not require a diagnosis under specified conditions.
4. Would expand upon pharmacists' current authority to administer biologics and would allow a pharmacist to furnish an FDA approved or authorized noncontrolled medication for the treatment of minor, non-chronic health conditions or for which a CLIA waived test provides diagnosis and the treatment is limited in duration.
5. Would expand current authority for pharmacists to complete missing information on a noncontrolled medication if there is evidence to support the change.
6. Would expand authority for pharmacists to substitute medications that are generally considered interchangeable (*i.e.*, if insurance will only cover one medication but an interchangeable medication was prescribed).

7. Would allow for medication therapy management and adjust treatments to manage chronic conditions diagnosed by a prescriber to optimize drug therapy (*i.e.*, adjusting medication dosing in response to laboratory results such as for warfarin, or medication to better control diabetes).

As part of its prior discussion, members noted that the issue should be included as part of the Board's sunset report and highlighted that the language does not remove specific authorities for pharmacists that currently exist, but rather, expands the language and removes some of the prescriptive authorities that currently exist. Members noted that the transition to the standard of care as proposed provided for more patient-focused care with individual pharmacists making the decision how to care for a patient. Members generally agreed that pharmacists need more flexibility to take care of patients with some concern noted that pharmacists in some environments may not have sufficient autonomy to use their professional judgment or access to necessary medical information to make appropriate patient care decisions.

Members of the public spoke generally in support of the proposal and also noted the need to make conforming changes in other areas of California law, including provisions in the Health and Safety Code.

Related to this topic, staff are seeking information on California's DxF Data Sharing Agreement, which is the first-ever, required statewide data sharing agreement in California.

For Committee Consideration and Discussion
In preparation for the Board's upcoming sunset report, and to ensure sufficient time to finalize proposed statutory changes, during the meeting, members will resume consideration a legislative proposal to implement the recommendations from the Board's legislative report. The updated proposal includes language to address some of the concerns raised by members including liability issues and access to patient medical records.

Attachment 9 includes a copy of the updated draft statutory proposal that is being provided to assist with the Committee's discussion.

XII. Discussion and Consideration of Senate Bill 523 (Leyva, Chapter 630, Statutes of 2022) Related to Contraception Access, Including Possible Amendment to Business and Professions Code Section 4052.3

Background
Senate Bill 523 (Leyva, Chapter 630, Statutes of 2022) made various changes to expand coverage of contraceptives by a health care service plan contract or

health insurance policy as specified in the measure. As part of the changes, effective January 1, 2024, a health care service plan or health insurer is required to provide point-of-sale coverage for over-the-counter FDA-approved contraceptive drugs, devices, and products at in-network pharmacies without cost sharing or medical management restrictions.

While OTC hormonal contraception is available to patients, implementation of health care service plan coverage is stymied because of requirements related to reimbursement, most notably, insurers generally require a prescription to reimburse for medications, even those determined by the FDA to be OTC. To remedy this issue, a change to BPC section 4052.3 is necessary to allow pharmacists to prescribe OTC hormonal contraception. Further, clarification to existing law may be appropriate to explicitly state that current provisions related to pharmacist-furnished hormonal contraception are only applicable to prescription-only products.

For Committee Consideration and Discussion
During the meeting, members will have the opportunity to consider draft statutory language that could provide pharmacists with the authority to prescribe OTC hormonal contraception.

Attachment 10 includes a copy of the proposed amendments.

XIII. Discussion and Consideration of Committee's Strategic Objectives

Background
The Board's Strategic Plan 2022-2026 includes nine strategic objectives to guide the work of the Licensing Committee.

For Committee Consideration and Discussion
During the meeting, members will have the opportunity to review the strategic objectives and actions taken related to the objectives. It may be appropriate for the Committee to confirm if the strategic objectives remain appropriate. It may also be appropriate for the Committee to determine if there is a priority for the remaining objectives and additional actions it wishes to take related to objectives.

1.1 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.

July 2022 Status: The Board sponsored legislation to make permanent provisions for remote work for pharmacists currently being performed via a broad waiver. The legislation was controversial and did not move forward.

July 2023 Status: Board sponsors AB 1557 (Flora) provisions to make permanent authority for pharmacists to perform medication chart order review from outside of the licensed premises as specified.
July 2024 Status: Board considered proposed changes to allow for a pharmacy technician to compound outside of a licensed pharmacy under the direct supervision and control of a pharmacist. Board considers a Standard of Care proposal to allow for a pharmacist to perform additional functions outside of a licensed pharmacy.

1.2 Consider and pursue necessary changes in the law regarding various pharmacy practice settings to ensure variances in the practice are appropriate.

July 2023 Status: Board implements provisions related to the use of mobile units as an extension of a pharmacy under specified conditions. The Board supports Assembly Bill 663 (Haney) related to expansion of the use of mobile units.
July 2024 Status: Board evaluates the requirements for nonresident pharmacies and central fill pharmacies and considers proposed amendments to pharmacy law and regulations related to both business models.

1.3 Explore, and pursue changes in law as appropriate, for the authorized duties of a pharmacy technician and potential expansion based on other jurisdictions to expand authorized duties. (Complete)

July 2022 Status: The Committee convened listening sessions and released surveys soliciting feedback from licensees on potential changes to pharmacy technician authorities. The Committee continues its evaluation of the results of the information received.
July 2023 Status: The Board sponsors Assembly Bill 1286 (Haney), a comprehensive patient safety measure. Among the changes, the Board proposes changes to expand authorized duties a pharmacy technician may perform to assist a pharmacist.
July 2024 Status: Governor signs AB 1286 (Haney, Chapter 470, Statutes of 2023), which expands the authorized functions of a pharmacy technician.

1.4 Determine if application requires for a pharmacist-in-charge (PIC) are appropriate to ensure sufficient knowledge, skills, and abilities for individuals seeking to serve as a PIC.

July 2022 Status: October 2021, Board approved development of regulations to establish minimum requirements for pharmacists seeking to serve as a PIC. Further, development of a training program is underway.
July 2024 Status: The approved regulations were Noticed for 45-day public comment in November 2023 and 15-day public comment in April 2024. Public comments received during the 15-day public comment

period are pending review by the Board at the July 2024 Board meeting.

1.5 Engage with the California Division of Occupational Safety and Health (Cal/OSHA) on pharmacy working conditions to ensure sufficient resources and appropriate conditions exists to facilitate safe patient care.

July 2022 Status: The Medication Error Reduction and Workforce Committee continues its assessment of working conditions and medication errors.

1.6 Consider results, and change laws as appropriate, regarding the Office of Professional Examination Services audit of the California Multi-State Jurisprudence Pharmacy Examination and pharmacy law requirements to ensure exams are relevant. (Completed)

July 2022 Status: January 2022, Board received results of audit conducted by OPES, which concludes that OPES does not recommend use of the MPJE as it would be inconsistent with Business and Professions Code section 139.

Results of the audit performed by OPES were released.

1.7 Decrease licensing processing times to improve customer service and support applicants and licensees.

July 2022 Status: July 1, 2022, Board secures authority to hire two additional staff to assist with the processing of site applications.

July 2023 Status: Application processing for several license types have improved with the completion of onboarding of staff. Further, staff schedule meetings with applicants seeking site licenses to discuss outstanding items. Notification is sent confirming receipt of applications and notification when licenses are issued.

July 2024 Status: Application processing times or individual license types is within 30-day performance measure. Implementation of Temporary Military Applications is developed and automated for online submission and processing.

1.8 Streamline the licensing process to improve efficiency and staff performance.

July 2023 Status: Business modernization steps completed including completion of business process mapping and could be mapping.

July 2024 Status: Business process and requirements activities concluded. New Project Request considered by DCA governance to allow for next steps in the Business Modernization process.

1.9 Migrate the entire licensing process online to promote timeliness, reduce staff workload, and provide better customer service.

July 2022 Status: Business Process Mapping for cashiering and licensing related functions completed.

July 2023 Status: All business process mapping and could be mapping completed.

July 2024 Status: Business process and requirements activities completed. New Project Request considered by DCA governance to allow for next steps in the Business Modernization process.

XIV. Discussion and Consideration of Licensing Statistics

Licensing statistics for FY 2023/24 (July 1, 2023 – May 31, 2024) are provided in **Attachment 11**.

During the first eleven months of FY 2023/24, the Board has received 12,080 initial applications, including:

- 1,156 intern pharmacists
- 2,940 pharmacist exam applications 1,617 new, 1,322 retake)
- 143 advanced practice pharmacists
- 4,594 pharmacy technicians
- 362 community pharmacy license applications (17 chain, 345 nonchain)
- 65 sterile compounding pharmacy license applications 48 LSC, 16 NSC, 1 SCP)
- 126 nonresident pharmacy license applications
- 10 hospital pharmacy license applications

During the first eleven months of FY 2023/24, the Board has received 6 request for temporary individual applications (Military Spouses/Partners), including:

- 6 temporary pharmacy technicians

During the first eleven months of FY 2023/24, the Board has received 498 requests for temporary site license applications, including:

- 264 community pharmacy license applications
- 45 sterile compounding pharmacy license applications
- 90 nonresident pharmacy license applications
- 19 hospital pharmacy license applications

During the first eleven months of FY 2023/24, the Board has issued 8,365 individual licenses, including:

- 1,157 intern pharmacists
- 1,542 pharmacists
- 119 advanced practice pharmacists
- 5,302 pharmacy technicians

During the first eleven months of FY 2023/24, the Board has issued 4 temporary individual applications (Military Spouses/Partners), including:

- 4 temporary pharmacy technicians

During the first eleven months of FY 2023/24, the Board has issued 651 site licenses without temporary license requests, including:

- 290 automated drug delivery systems 287 AUD, 3 APD)
- 78 community pharmacies
- 1 hospital pharmacy

During the first eleven months of FY 2023/24, the Board has issued 375 temporary site licenses, including:

- 231 community pharmacies
- 15 hospital pharmacies

Site Application Type	Application Processing Times as of 4/1/2024	Application Processing Times as of 7/5/2024	Deficiency Mail Processing Times as of 4/1/2024	Deficiency Mail Processing Times as of 7/5/2024
Pharmacy	48	68	161	102
Nonresident Pharmacy	60	105	278	134
Sterile Compounding	28	Current	70	45
Nonresident Sterile Compounding	51	Current	80	21
Outsourcing	28	21	39	57
Nonresident Outsourcing	7	14	50	57
Hospital Satellite Compounding Pharmacy	Current	15	Current	32
Hospital	11	Current	Current	Current
Clinic	80	23	138	57
Wholesaler	14	16	157	35
Nonresident Wholesaler	25	16	125	32
Third-Party Logistics Provider	14	11	Current	21
Nonresident Third-Party Logistics Provider	10	18	64	35
Automated Drug Delivery System	28	15	Current	Current
Automated Patient Dispensing System	Current	Current	Current Combined with ADD	Current Combined with ADD
Emergency Medical Services Automated Drug Delivery System	Current	Current	Current Combined with ADD	Current Combined with ADD

Individual Application Type	Application Processing Times as of 4/1/2024	Application Processing Times as of 7/5/2024	Deficiency Mail Processing Times as of 4/1/2024	Deficiency Mail Processing Times as of 7/5/2024
Exam Pharmacist	5	Current	7	4
Pharmacist Initial Licensure	Current	Current	Current	Current
Advanced Practice Pharmacist	10	11	4	10
Intern Pharmacist	11	Current	7	Current
Pharmacy Technician	6	25	8	4
Designated Representative	10	11	15	4
Designated Represenatives-3PL	7	Current	Combined with Designated Representative	Combined with Designated Representative
Designated Representatives-Reverse Distributor	Current	Current	Combined with Designated Representative	Combined with Designated Representative
Designated Paramedic	14	Current	Combined with Designated Representative	Combined with Designated Representative

XV. Future Committee Meeting Dates

October 17, 2024

XVI. Adjournment

Attachment 1

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

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

Date: April 10, 2024

Location: OBSERVATION AND PUBLIC COMMENT IN PERSON:
California State Board of Pharmacy
2720 Gateway Oaks Drive,
First Floor Hearing Room
Sacramento, CA 95833

California State Board of Pharmacy staff members were present at the observation and public comment location.

PUBLIC PARTICIPATION AND COMMENT FROM A REMOTE LOCATION: WebEx

Board Members Present:
Seung Oh, PharmD, Licensee Member, Chairperson
Trevor Chandler, Public Member, Vice Chairperson
Renee Barker, PharmD, Licensee Member
Jessi Crowley, PharmD, Licensee Member
Jason Weisz, Public Member

Staff Present:
Anne Sodergren, Executive Officer
Julie Ansel, Assistant Executive Officer
Corinne Gartner, DCA Counsel
Jennifer Robbins, DCA Counsel
Debbie Damoth, Executive Specialist Manager
Sara Jurrens, Public Information Officer

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

Chairperson Oh called the meeting to order at approximately 9:07 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. The following members were present via WebEx: Trevor Chandler, Public Member; Renee Barker, Licensee Member; Jessi Crowley, Licensee Member; Jason Weisz, Public Member; and Seung Oh, Licensee Member. A quorum was established.

Dr. Oh reminded Committee members to remain visible with cameras on throughout the open session of the meeting. Dr. Oh advised if members needed to temporarily turn off their camera due to challenges with internet connectivity, they must announce the reason for their nonappearance when the camera was turned off.

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.

No public comment was made in Sacramento.

Public comment was received via WebEx.

A specialty pharmacist thanked the Board for their continued efforts to find an author to sponsor proposed amendments to the remote processing statute.

A representative of CSHP requested that the Office of Administrative Law (OAL) comments for the ADDS self-assessment regulations on the Legislation and Regulation Committee meeting agenda for 4/11/24 be made public for transparency.

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

III. Approval of the January 22, 2024 Licensing Committee Meeting Minutes

The draft minutes of the January 22, 2024 Licensing Committee meeting were presented for review and approval.

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

Motion: Accept the January 22, 2024 Licensing Committee meeting minutes as presented in the meeting materials.

M/S: Chandler/Crowley

Members of the public were provided the opportunity to comment in Sacramento and via WebEx; however, no comments were made.

Support: 5 Oppose: 0 Abstain: 0 Not Present: 0

Board Member	Vote
Barker	Support
Chandler	Support
Crowley	Support
Oh	Support
Weisz	Support

IV. Presentation Regarding Pharmacy Technician Certification Programs

Chairperson Oh recalled from the January 2024 meeting, the Committee discussed pharmacy technician training programs, including employer-based training programs. The Committee noted at that time what appeared to be great variability in the quality of employer-based programs and suggested perhaps the need for greater oversight of such training programs. The Committee also discussed work being performed by the Department of Consumer Affairs (DCA) Office of Professional Examination Services (OPES), which was performing an occupational analysis for the Board for the pharmacy technician licensure program. Dr. Oh noted the analysis may help inform the Committee in its assessment of training program requirements moving forward.

Dr. Oh added during prior Committee discussions, members suggested it would be helpful to learn more about pharmacy technician programs and accreditation requirements. To that end, Dr. Oh introduced representatives from the Pharmacy Technician Certification Board (PTCB) and National Healthcareers Association (NHA) to provide presentations about their respective pharmacy technician certification programs. Dr. Oh reminded members that certification from either of these organizations was a pathway to licensure as a pharmacy technician in California.

Dr. Oh welcomed PTCB Chief Professional Officer Liza Chapman, PharmD, and PTCB Chief Assessment and Credentialing Officer Levi Boren, PhD.

Dr. Chapman provided a PTCB overview including its mission and vision, and an update on PTCB as of December 31, 2023.

Dr. Boren reviewed the CPhT program content outline, information on the CPhT program job analysis, and CPhT eligibility pathways. Dr. Boren then discussed education and training program recognition for the CPhT program, noting there are 167 PTCB-recognized education/training programs in California as well as online programs available to pharmacy technicians in California. Dr. Boren added approximately 21 programs are ASHP-accredited but noted that program recognition was not the same as accreditation. Next, Dr. Boren discussed the types of programs that could be recognized as a CPhT program (*e.g.*, certificate and degree programs; College of Pharmacy associated programs; employer training; high school programs; and military training programs). Finally, Dr. Boren reviewed California PTCE pass rates for 2021-2023, noting that they were comparable to the national averages for those years.

Dr. Chapman then reviewed the value of PTCB certification, the various credentials available for PTCB-certified pharmacy technicians, and the requirements to earn the CPhT-Adv credential.

Dr. Oh thanked Dr. Chapman and Dr. Boren. Members were provided the opportunity to comment.

Member Chandler asked how the compounding certification has changed as the compounding industry has changed. Dr. Boren advised that changes have been made in accordance with USP changes, and noted that PTCB is constantly assessing and updating the program.

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

Members of the public participating via WebEx were provided the opportunity to comment.

A pharmacist asked about the cost of PTCB certification.

Dr. Chapman provided that the cost of the exam is $129 with a fee of $55 due every two years to maintain the certification. The assessment-based certificate programs cost $89 per exam. The cost for the CSPT exam is $149 with a $50 application fee. Dr. Boren acknowledged awareness of the costs for pharmacy technicians and noted the cost for the PTCE has been the same for 15 years.

Dr. Oh thanked Dr. Chapman and Dr. Boren for their presentation and time.

Dr. Oh next welcomed Jessica Langley, Executive Director of Education and Advocacy for the NHA.

Ms. Langley provided an overview of the Ascend Learning mission and brands, noting that NHA is part of Ascend Learning. Ms. Langley also discussed the background, vision, and mission of NHA.

Ms. Langley next discussed the ExCPT, including pharmacy technician industry research as well as examination statistics and evaluation. Ms. Langley reviewed the test plan and preparation resources as well as updates with the new examination effective in 2025. Ms. Langley noted the current ExCPT exam price was $125 with new prices effective July 1, 2024. Ms. Langley provided updates on resources available, recertification processes, and learning resources.

Dr. Oh thanked Ms. Langley for her presentation. Members were provided the opportunity comment.

Member Chandler asked about the lower passing rates for pharmacy technicians. Ms. Langley provided it could be related to variety of things including a need for a newer exam to align with industry standards, evaluating domain areas, and working with clients.

Member Chandler also asked about the increase of customers from 2022 to 2023. Ms. Langley noted that could be evidence of a couple items such as an increased push for certifications, and/or increased number of states requiring certification as a licensure requirement.

Members of the public participating from Sacramento and via WebEx were provided the opportunity to comment; however, no comments were made.

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

V. Presentation by the American Society of Health System Pharmacists Regarding Technician Training Program Accreditation

Chairperson Oh referenced meeting materials detailing several relevant sections of pharmacy law including California Code of Regulations (CCR), title 16, section 1793.6, which specifies that a pharmacy technician training program approved by the Board for purposes of licensure as a pharmacy technician includes a training program that is accredited by the American Society of Health-Systems Pharmacists (ASHP). Dr. Oh recalled during the January 2024 Committee meeting, members indicated that a presentation on the pharmacy technician accreditation program would be helpful.

Dr. Oh welcomed to the meeting Lisa Lifshin, Senior Director of Pharmacy Technician Accreditation and Residency Services with the ASHP Office of Accreditation Services, to provide a presentation on the ASHP accreditation program for pharmacy technician training programs.

Ms. Lifshin first provided background on the ASHP/ACPE collaboration to create the Pharmacy Technician Accreditation Commission (PTAC) as well as the process used to update requirements. Ms. Lifshin then reviewed guidance documents and the model curriculum.

Ms. Lifshin advised the application fee for a site was $775 with a fee of $3,100 to start the program. Ms. Lifshin noted there were two levels of programs including entry and advanced programs and reviewed the curriculum length for both types of programs. Finally, Ms. Lifshin provided an overview of the standards used.

Dr. Oh thanked Ms. Lifshin for her presentation. Members were provided the opportunity comment.

Member Chandler asked to what extent the employers cover the cost. Ms. Lifshin clarified that the accreditation is for the program and not the individual.

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

Members of the public participating via WebEx were provided the opportunity to comment.

A pharmacist commented that creating and maintaining an accredited program is a significant cost for the industry.

A representative of CVS Health commented there were five states that currently, or will soon, require ASHP accredited training for pharmacy technicians: South Dakota, Virginia, Louisiana, Illinois, and Utah. Louisiana has proposed a change that would remove the ASHP accreditation requirement as it was seen as a barrier to entry that has caused a tech shortage. Similarly, Utah has received requests to remove the accreditation requirement before it is implemented in 2025.

A representative of Walgreens commented that Walgreens has an ASHP accredited training program, encourages certification for all pharmacy technicians, and pays for the exam, training time, and recertification fees for their employees. The representative commented Walgreens sees a benefit in certification.

The chief executive officer of the PTCB commented that PTCB has a lot of data indicating employers will train pharmacy technicians in-house to lower the cost and barriers to entry. He continued with PTCB certification best success is seen when pharmacy technicians are trained on the job, which keeps costs for the pharmacy technician down.

Before moving on to the next agenda item, President Oh asked members whether a pharmacy-based technician training program should allow participants who are currently not a "pharmacy technician trainee" as defined by Business and Professions Code (BPC) section 4038 to obtain practical experience similar to BPC section 4115.5. Dr. Oh noted this would require expansion of the statutory definition of "pharmacy technician trainee" but might allow more opportunity for pharmacy technician training programs and wanted to see if members were agreeable.

Member Chandler confirmed he would be in favor of expanding options rather than narrowing. Dr. Oh confirmed that was the intent.

Member Crowley requested clarification on the intention on the expansion of the definition. Dr. Oh explained employer-based training programs aren't currently allowed to use pharmacy technician trainees to do the

duties of a pharmacy technician. By expanding the definition, more programs will be able to train in a pharmacy as a pharmacy technician trainee. Ms. Sodergren clarified that the current statute states that to be considered a "pharmacy technician trainee" the person must be enrolled in a pharmacy technician training program operated by a California public postsecondary education institution or by a private postsecondary vocational institution approved by the Bureau for Private Postsecondary and Vocational Education. Employer-based training programs or other training programs are not allowed by law to train a pharmacy technician trainee in a pharmacy to gain experience. By expanding the definition of "pharmacy technician trainee," it will increase the number of people who will be able to be trained with hands on learning as a pharmacy technician trainee.

Member Barker commented in support of expanding the definition to include pharmacy-based pharmacy technician training programs for increasing learning, increasing options, and reducing barriers to entry.

The Committee took a break from 10:49 a.m. to 11:05 a.m. Roll call was taken. The following members were present via WebEx: Trevor Chandler, Public Member; Renee Barker, Licensee Member; Jessi Crowley, Licensee Member; Jason Weisz, Public Member; and Seung Oh, Licensee Member. A quorum was established.

VI. Discussion and Consideration of Survey Results Received Related to Pharmacist to Pharmacy Technician Ratio

Chairperson Oh recalled his intention to focus Committee discussion on strategic objective 1.3 related to the exploration and pursuit of changes in law as appropriate for the authorized duties of a pharmacy technician. Dr. Oh noted an important first step in this evaluation included this Committee convening listening sessions and soliciting feedback from licensees regarding potential changes. The results of these efforts were incorporated in Assembly Bill 1286 which became effective on January 1, 2024.

Dr. Oh reminded members that during the October 2023 meeting, the Committee initiated a review of the Board's ratio requirement. The meeting materials detailed the current law related to ratios and noted members routinely receive public comment indicating that California has one of the most restrictive ratios. Dr. Oh reminded members a review of various state ratios does not necessarily provide an apples-to-apples

comparison, as jurisdictions have varying approaches on provisions for services within a pharmacy, including where some jurisdictions require all pharmacy personnel to be licensed as a pharmacy technician if performing even basic functions such as data entry - which is not the case in California. Dr. Oh highlighted this to remind members that when comments are received, context matters. Dr. Oh noted the meeting materials highlight a few approaches taken by various states.

Dr. Oh recalled during the January 2024 Committee meeting, members reviewed and approved a draft survey to solicit feedback from pharmacists on this topic. The survey was released March 6, 2024, and ended March 25, 2024. During the survey period over 5,100 responses were received. Dr. Oh noted the Board was fortunate to have an extremely engaged licensee population and thanked everyone who participated in the survey.

Dr. Oh thanked Board staff and experts within the DCA Office of Professional Examination Services for working to develop, deploy, and evaluate the survey results. Dr. Oh added included in the meeting materials were the presentation slides with the survey results. Dr. Oh then introduced Ms. Sodergren to provide a summary of the survey results.

Ms. Sodergren provided an overview of the survey population, noting over 5,100 survey responses were received with 4,517 survey responses analyzed as approximately 634 responses could not be used (*e.g.*, not licensed in California, not practicing in California, and incomplete survey responses). Survey questions included asking if the respondent was a pharmacist-in-charge (PIC); currently supervises pharmacy technicians or other personnel in the pharmacy; and uses pharmacy technicians in the pharmacy. Other questions asked about types of worksites utilizing pharmacy technicians; types of clinical services provided at the worksite; whether technology was used in the dispensing process; whether the worksite has pharmacists working overlapping hours; and what the average prescription volume is at the worksite.

Ms. Sodergren continued reviewing responses to questions asking if the current pharmacist to pharmacy technician ratio in noninstitutional settings (currently 1:1) and institutional settings (currently 1:2) was appropriate. For both settings, the majority of respondents thought a 1:2 ratio was appropriate. Over half of the respondents believed they could provide more comprehensive patient care if the number of pharmacy technicians

a pharmacist can supervise increased. When broken down by worksite, over half community chain and nonchain pharmacists believed they could provide more comprehensive patient care if the number of pharmacy technicians a pharmacist can supervise increased, whereas less than half of inpatient hospital pharmacists believed they could provide more comprehensive patient care if the number of pharmacy technicians a pharmacist can supervise increased. In addition, over half of the respondents thought there should be specific determination by the PIC for increasing pharmacist to pharmacy technician ratios and that the pharmacist should be able to refuse to supervise additional pharmacy technicians. Ms. Sodergren continued reviewing survey questions from respondents self-identifying as working in a managerial or administrative position as well as PIC capacity for their employers.

Dr. Oh commented that he found some of the results very interesting, including the responses specifically from pharmacists that identified as either in management positions or serving as the PIC. Dr. Oh also highlighted that as referenced in the meeting materials, there is pending legislation that, if enacted, would change the pharmacist to pharmacy technician ratio to 1:6. Dr. Oh added that this measure was agendized for discussion as part of the April 11, 2024 Legislation and Regulation Committee meeting, and that he wanted to ensure the Licensing Committee's discussion today focused on the survey results. He also noted that the information reviewed by Ms. Sodergren represented summary information, and that if there were additional data points that members thought would be helpful to the Committee, he encouraged members to note those in their comments.

Members were provided the opportunity to comment.

Dr. Crowley commented that she would be interested in data from pharmacists who are not in a management position and what they would want the ratio to be, noting that this would give a different perspective. Dr. Crowley also expressed concern about the issue of liability associated with supervising additional technicians, noting that she wasn't sure pharmacists know that the pharmacy technician isn't held accountable under the law. Dr. Crowley stressed the need to keep the liability issue in the discussion.

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

Members of the public participating via WebEx were provided the opportunity to comment.

A representative for the CPhA commented the survey results seem consistent with feedback CPhA has seen from its members on this issue. The representative agreed with Dr. Crowley that it might be good to know the results from nonmanagement and pharmacists who are not serving as the PIC. The representative also asked if the subgroup analysis for management in institutional and noninstitutional could be broken by worksite.

A representative from CCPC spoke in agreement and support that the 1:1 ratio in a noninstitutional setting was not appropriate. CCPC agreed modifying the ratio to 1:2 or 1:3 would make a significant difference in day-to-day pharmacy operations. The representative commented that data across the country shows that an increase in the ratio would not jeopardize patient care. The representative further noted that a change in the ratio wouldn't have to be a mandate but could be an authorization for pharmacists to supervise additional pharmacy technicians as needed.

A pharmacist commented SB 1365 (Glazer) would allow for an increase in the ratio of pharmacy technicians to pharmacist as 1:6 similar to the ratio in Montana but the definition of pharmacy technician in Montana includes anyone working in a pharmacy including cashiers and clerk typist. The pharmacist commented the Board's survey results and recommendations of the Board would be meaningful to Senator Glazer's office with the possibility to amend the current bill.

A representative of UFCW commented in support of Dr. Crowley's request for further breakdown of the data to hear from nonmanagement pharmacists. The representative noted there was no cap around ancillary staff in the pharmacy and wondered if pharmacists would want a cap for ancillary staff. The representative thought it would be helpful to know what other protections pharmacists and pharmacy staff might want if there was an increase in the ratio (*e.g.*, liability, *etc.*) as well as including the perspective of pharmacy technicians about increasing the ratios.

A pharmacist commented the type of liability (*e.g.*, administrative, civil, *etc.*) needs to be clarified when discussing liability. The pharmacist provided a personal account of the establishment of pharmacy technician duties.

Members were provided the opportunity to comment after having received public comment.

Member Weisz noted that it seemed like the ratio was too low but he would also like to get feedback from pharmacists who were not in management.

Member Chandler thought there was a lot of middle ground, and room for consensus, between the current ratio and the 1:6 ratio proposed in SB 1365.

Chairperson Oh commented that the Committee will continue the discussion at future meetings, with additional data points, and added that this issue will likely be wrapped into the Board's upcoming sunset review.

VII. Discussion and Consideration of Implementation of Senate Bill 339 (Wiener, Chapter 1, Statutes of 2024) Related to HIV Preexposure Prophylaxis (PrEP) and Postexposure prophylaxis (PEP), including Draft Emergency Regulations

Chairperson Oh noted that the meeting materials included background information and relevant law on this agenda item. Dr. Oh advised in response to recently enacted legislation, the Board must pursue emergency regulations to implement the expanded provisions for pharmacist-furnished HIV preexposure prophylaxis. Dr. Oh noted that with recent passage of Assembly Bill 317 related to reimbursement, he was hopeful that some of the barriers to implementation that have previously been identified, including for pharmacist-furnished care such as PrEP and PEP, have been addressed to allow access for patients with commercial health plans.

Dr. Oh thanked the Office of AIDS and the California Department of Health Care Services, pharmacist-experts that have provided input as well as the Medical Board Director Varghese and Medical Board President Dr. Hawkins for their consultation and review of the proposed emergency and permanent regulations. Dr. Oh added that the language included in attachment 4 in the meeting materials incorporated the feedback from many individuals, and that he was informed that the Medical Board had no concerns or edits to the language. Dr. Oh also advised that since emergency regulations were not something the Board generally pursues,

DCA regulation counsel Jennifer Robbins was available to assist the Committee with questions.

Finally, Dr. Oh reminded members and the public to be mindful that pharmacists are routinely providing healthcare in a very prescriptive manner because of specificity provided in the law. Dr. Oh believed as healthcare professionals it was appropriate to start empowering pharmacists to rely on their professional judgement when providing patient care and cautioned members to not be overly prescriptive on the proposed regulation language. Dr. Oh appreciated the proposed draft changes and believed they were appropriate without being overly prescriptive.

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

Motion: As an emergency exists by law, recommend initiation of an emergency rulemaking to amend California Code of Regulations, Title 16, section 1747 as proposed and a regular rulemaking to make the regulation amendments permanent. Authorize the executive officer to further refine the language consistent with the committee's discussion and to make any nonsubstantive changes prior to presenting the proposed emergency and regular rulemakings to the Board.

DEPARTMENT OF CONSUMER AFFAIRS
TITLE 16. PHARMACY

PROPOSED EMERGENCY REGULATORY LANGUAGE
HIV Preexposure Prophylaxis

Legend:	Added text is indicated with an underline. Deleted text is indicated by ~~strikeout~~.

Amend section 1747 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1747. Independent HIV Preexposure and Postexposure Prophylaxis Furnishing.

(a) Prior to independently initiating and furnishing HIV preexposure and/or postexposure prophylaxis to a patient

pursuant to Business and Professions Code sections 4052.02 and 4052.03, a pharmacist shall successfully complete a training program approved by the board, provided by a provider accredited by an approved accreditation agency, or as part of an equivalent curriculum-based training program completed from a recognized school of pharmacy. The training program shall satisfy the following criteria:
(1) Each training program shall be specific to the use of HIV preexposure and postexposure prophylaxis, and include at least 1.5 hours of instruction covering, at a minimum, the following areas:
(A) HIV preexposure and postexposure prophylaxis pharmacology.
(B) Requirements for independently initiating and furnishing HIV preexposure and postexposure prophylaxis contained in Business and Professions Code sections 4052.02 and 4052.03.
(C) Patient counseling information and appropriate counseling techniques, including at least, counseling on sexually transmitted diseases and sexual health.
(D) Patient referral resources and supplemental resources for pharmacists.
(E) Financial assistance programs for preexposure and postexposure prophylaxis, including the Office of AIDS' PrEP Assistance Program (PrEP-AP).
(F) Clinical eligibility recommendations provided in the federal Centers for Disease Control and Prevention (CDC) guidelines defined in Business and Professions Code sections 4052.02(c) and 4052.03(c).
(2) The training program shall require the passing of an assessment based on the criteria of (a)(1) with a score of 70% or higher to receive documentation of successful completion of the training program.
(b) A pharmacist who independently initiates or furnishes HIV preexposure and/or postexposure prophylaxis pursuant to Business and Professions Code sections 4052.02 and 4052.03 shall maintain documentation of their successful completion of the training program for a period of four (4) years. Training obtained as part of an equivalent curriculum-based training program, as identified in (a), can be documented by written certification from the registrar or training director of the educational institution or program from which the licensee

graduated stating that the training is included within the institution's curriculum required for graduation at the time the pharmacist graduated, or within the coursework that was completed by the pharmacist. Documentation of training maintained pursuant to this subdivision must be made available upon request of the board.
(c) For the purposes of this section, documentation of preexposure prophylaxis furnished and services provided shall be maintained in patient records, in the record system maintained by the pharmacy, for a minimum of three years from the date when the preexposure prophylaxis was furnished. Such records shall be made available upon request of the Board, consistent with the provisions of Business and Professions Code sections 4081 and 4105.

NOTE: Authority cited: Sections 4005, 4052.02 and 4052.03, Business and Professions Code. Reference cited: Sections 4052, 4052.02, ~~and~~ 4052.03, 4081 and 4105, Business and Professions Code; and Section 120972, Health and Safety Code.

M/S: Chandler/Barker

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

Members of the public were provided the opportunity to comment via WebEx.

A pharmacist commented in support of the effort, and of the urgency of the legislation and proceedings. The commenter noted subsection (c) indicates that the records of the treatment of these patients could be maintained for a minimum of three years, and expressed his view that this isn't long enough based on the fact that they are health care treatment records.

Members were provided the opportunity comment after having heard public comment.

Dr. Crowley agreed with the commenter that the retention period should be longer. Dr. Crowley also asked if the language as drafted went beyond the intention of SB 339 (Weiner, Chapter 1, Statutes of 2024). Ms. Sodergren

noted, and Counsel Robbins agreed, that the regulatory language being proposed does not go beyond the statute.

Dr. Oh noted he was in support of expanding the retention period but cautioned that the Board should take a more holistic approach to this issue.

Member Weisz spoke in support of the motion and agreed with taking a holistic approach to retention requirements rather than piece by piece. Dr. Oh and Dr. Crowley agreed. Dr. Crowley requested reviewing it at the Board meeting and asked Board staff to compare record retention for similar boards and bureaus within the Department of Consumer Affairs (DCA).

Member Barker agreed as more latitude is given to the pharmacists and treatments involving patient care, the larger discussion of records retention should be discussed and compared to similar regulatory bodies.

Dr. Oh indicated the Board would need to address record retention as a holistic idea for the sunset report.

Counsel Robbins added in existing CCR section 1707.1 (a)(2) the general records retention requirement is for at least one year.

Support: 5 Oppose: 0 Abstain: 0 Not Present: 0

Board Member	Vote
Barker	Support
Chandler	Support
Crowley	Support
Oh	Support
Weisz	Support

VIII. Discussion and Consideration of Possible Amendment to California Code of Regulations, Title 16, Section 1713, Related to the Use of Automated Drug Delivery Systems

Chairperson Oh refenced meeting materials detailing the relevant laws related to this agenda item and noted BPC section 4427.6 provides specific requirements for the use of automated patient dispensing systems (APDS) and specifically, subdivision (f) provides that all prescribed drugs

and devices dispensed to a patient from an APDS shall be accompanied by a consultation conducted by a pharmacist licensed by the Board via a telecommunications link that has two-way audio and video. This requirement became effective in 2019 as part of SB1447 (Hernandez, Chapter 666, Statutes of 2018). Dr. Oh added CCR, title 16, section 1713, specifically subdivision (d), provides authority for a pharmacy to use an APDS to deliver medications to a patient under specified conditions. One such condition is that an immediate consultation with a pharmacist be provided upon the request of the patient either in-person or via telephone. Dr. Oh noted section 1713 was amended in 2019, to make some conforming changes based on the provisions of Senate Bill 1447; however, the proposed changes to the regulation text at that time did not differentiate the technology requirements consistent with the statutory requirements. The lack of differentiation has led to some confusion among stakeholders about when two-way audio and video is required, consistent with BPC section 4427.6 and the regulation. To provide clarity to the regulated public, it was recommended that the Board amend section 1713(d) to be more specific to licensees and consolidate both technology requirements in a single location to allow for ease of use and ensure a common understanding of the two legal requirements.

Dr. Oh appreciated the recommendation offered by staff and agreed with the proposed changes included in attachment 5 of the meeting materials. Members were provided the opportunity to comment.

Members agreed the language being proposed was awkward. Ms. Sodergren suggested, "A patient shall receive consultation by a pharmacist from an APDS for the first time the prescribed drug is dispensed as specified in BPC section 4427.6 (a), via a telecommunications link that has two-way audio and video. Further, the pharmacy is able to provide an immediate consultation with the pharmacist either in person or via telephone upon the request of the patient." Members agreed the language provided by Ms. Sodergren was clear. Counsel Robbins cautioned on reiterating statute in the regulation as OAL views this as unnecessary duplication of a statute, and noted that the language was drafted as proposed to address that concern. Dr. Oh understood the concern but believed the language proposed by Ms. Sodergren at the meeting would be clearer for the regulated public.

Motion: Recommend initiation of a rulemaking to amend California Code of Regulations, Title 16, section 1713 consistent with the

committee's discussion. Authorize the executive officer to further refine the language consistent with the committee's discussion and to make any nonsubstantive changes prior to presenting the proposed rulemaking to the Board.

DEPARTMENT OF CONSUMER AFFAIRS
TITLE 16. PHARMACY

PROPOSED REGULATORY LANGUAGE
Automated Patient Dispensing Systems Consultation

Legend:	Added text is indicated with an underline. Deleted text is indicated by ~~strikeout~~.

Amend section 1713 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1713. Receipt and Delivery of Prescriptions and Prescription Medications Must be To or From Licensed Pharmacy.

(a) Except as otherwise provided in this Division, no licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.
(b) A licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services. In addition, the Board may, in its sole discretion, waive application of subdivision (a) for good cause shown.
(c) A patient or the patient's agent may deposit a prescription in a secure container that is at the same address as the licensed pharmacy premises. The pharmacy shall be responsible for the security and confidentiality of the prescriptions deposited in the container.
(d) A pharmacy may use an automated patient dispensing system (APDS) to deliver prescription medications to patients provided:
(1) A pharmacist has determined that each patient using the APDS meets inclusion criteria for use of the APDS established by the pharmacy prior to delivery of prescription medication to that patient.

(2) The APDS has a means to identify each patient and only release that patient's prescription medications to the patient or patient's agent.
(3) A patient shall receive consultation by a pharmacist from an APDS for the first time the prescribed drug is dispensed as specified in Business and Professions Code section 4427.6 (a), via a telecommunications link that has two-way audio and video. Further, ~~The~~ the pharmacy is able to provide~~s~~ an immediate consultation with a pharmacist, either in-person or via telephone, upon the request of a patient.
(4) Any incident involving the APDS where a complaint, delivery error, or omission has occurred shall be reviewed as part of the pharmacy's quality assurance program mandated by Business and Professions Code section 4125.
(e) Any pharmacy making use of an APDS shall maintain, and on an annual basis review, written policies and procedures providing for:
(1) Maintaining the security of the APDS and the dangerous drugs within the APDS.
(2) Determining and applying inclusion criteria regarding which medications are appropriate for placement in the APDS and for which patients, including when consultation is needed.
(3) Ensuring that patients are aware that consultation with a pharmacist is available for any prescription medication, including for those delivered via the APDS.
(4) Describing the assignment of responsibilities to, and training of, pharmacy personnel regarding the maintenance and filing procedures for the APDS.
(5) Orienting participating patients on use of the APDS, notifying patients when expected prescription medications are not available in the APDS, and ensuring that patient use of the APDS does not interfere with delivery of prescription medications.
(6) Ensuring the delivery of medications to patients in the event the APDS is disabled or malfunctions.
(f) Written policies and procedures shall be maintained at least three years beyond the last use of an APDS.

Credits

NOTE: Authority cited: Sections 4005, 4075 and 4114, Business and Professions Code. Reference: Sections 4005, 4017.3, 4052, 4116, 4117, 4427, 4427.1, 4427.2, 4427.3, 4427.4, 4427.5, 4427.6, 4427.7 and 4427.8, Business and Professions Code.

M/S: Crowley/Barker

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

Members of the public were provided the opportunity to comment via WebEx.

A pharmacist commented in agreement with the newly proposed language.

Support: 5 Oppose: 0 Abstain: 0 Not Present: 0

Board Member	Vote
Barker	Support
Chandler	Support
Crowley	Support
Oh	Support
Weisz	Support

IX. Discussion and Consideration of Proposal to Establish Authority to Waive the Renewal Fee Requirement for Pharmacists Licensed Over 50 Years

Chairperson Oh recalled that following a request from the public, the Board referred this item to the Committee for consideration. Dr. Oh noted that background information on this agenda item was included in the meeting materials, and added that public comment received suggested that the Board consider development of a step-down licensure process for pharmacists getting ready to retire. It was suggested through public comment that the Board consider the approach used by Nevada. Dr. Oh referenced the meeting materials indicating a pharmacist that has been registered with Nevada for at least 50 years is not required to pay renewal fees after that time.

Dr. Oh added that based on the number of pharmacists that have currently been licensed for over 50 years in California, such a change could result in a loss of annual revenue to the Board of about $250,000. Dr. Oh believed the loss of revenue would not have too significant a negative impact to the Board's fund. Dr. Oh noted if the Committee believed such a change was appropriate, he could work with staff before the July 2024 meeting to develop statutory language. Dr. Oh noted this issue may be appropriate to include in the Board's sunset report.

Members were provided the opportunity to comment.

Member Chandler commented in support in concept but was concerned about loss of revenue. Dr. Oh spoke in alignment with Mr. Chandler.

Member Weisz asked if other approaches were reviewed to achieve similar results. Dr. Oh indicated other avenues were researched but this seemed to be most feasible. Ms. Sodergren noted the distinction between retired and reactivated licenses status. When a pharmacist retires a license, they no longer pay any fees and to restore a license, they must meet all requirements of law at reapplication. When a pharmacist puts a license on inactive status, the pharmacist still pays the fee but does not need to earn continuing education and to reactivate the license, continuing education must be completed. In Nevada, after placing a license on inactive status, the pharmacist must provide proof of having completed continuing education and pass an examination on law provided by the Nevada Board of Pharmacy.

Members discussed reducing the fees for pharmacists who have been licensed for 50 years to allow for pharmacists to maintain license at a lower cost. Members also discussed not adding barriers to reentry in the case of an emergency. Some members were concerned with the fiscal impact to the Board.

Dr. Oh indicated there would be further discussion at the next meeting.

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

Members of the public were provided the opportunity to comment via WebEx.

The Committee received comments from pharmacists and a pharmacy owner who spoke in support of having a reduced or eliminated fee for pharmacists licensed over 50 years or more.

Members were provided the opportunity to comment after having received public comment; however, no comments were made.

The Committee took a lunch break from 12:26 pm to 1:15 pm. Roll call was taken. The following members were present via WebEx: Trevor Chandler, Public

Member; Renee Barker, Licensee Member; Jessi Crowley, Licensee Member; Jason Weisz, Public Member; and Seung Oh, Licensee Member. A quorum was established.

X. Discussion and Consideration of Compounding by Pharmacy Technicians Outside of Pharmacies

Chairperson Oh advised the Enforcement and Compounding Committee referred the discussion of compounding by pharmacy technicians outside of pharmacies to the Licensing Committee. Dr. Oh recalled during previous meetings, the Committee has discussed the requirements for licensure for a pharmacy technician. By definition, pharmacy technicians work in a pharmacy under the direct supervision and control of a pharmacist.

Dr. Oh referenced meeting materials highlighting USP General Chapter 797 describing the minimum requirements that apply to all persons who prepare compounded sterile preparations and all places where sterile preparations are compounded. This includes pharmacists and pharmacy technicians compounding in all places including those areas outside of a pharmacy. Dr. Oh also noted federal law, section 503A of the Food Drug and Cosmetic Act, makes clear that authority to compound a drug preparation is in part predicated on compliance with USP compounding chapters. To assist in its assessment of this issue, the Committee discussed policy questions which may be appropriate to address in the Board's sunset report.

Policy Question #1 - Should the Board seek more explicit authority to inspect locations where pharmacy technicians are performing compounding activities outside of licensed pharmacies? (Note: BPC section 4008 may already provide the Board such authority; however, it may be beneficial to have more explicit authority.)

Dr. Oh appreciated the note included in the meeting materials referencing BPC section 4008, which appears to already provide such authority to the Board. Dr. Oh thought maybe additional educational awareness of the Board's existing authority may be needed. Dr. Oh also noted that there may need to be some improvements on enforcement possibilities for non-licensed areas as currently there was limited actions the Board could take. Dr. Oh would like to improve BPC section 4008 to improve enforcement ability (*e.g.*, add cease and desist, citation and fines, *etc.*) for non-licensed areas.

Members were provided the opportunity to comment.

Mr. Chandler asked for clarification about the problem that needed to be solved. Dr. Oh explained that the Board has become aware of instances where pharmacy technicians are practicing compounding in a non-licensed facility (*e.g.*, IV hydration clinics, doctor's offices, unlicensed infusion centers, *etc.*), with reports that standards are significantly less than what would be required in a pharmacy. Board Supervising Inspector Christine Acosta, who was present via WebEx, clarified that this was a potential patient safety issue because a pharmacy technician can only compound when working in a pharmacy under the supervision of a pharmacist who is responsible for the actions of the pharmacy technician. Ms. Sodergren added that USP 797 was clear on who needs to comply with the compounding standards and this includes pharmacy technicians. Ms. Sodergren noted the Board has found compounding outside of a pharmacy in a less than standard environment. Ms. Sodergren underscored the issue was how can the Board more effectively regulate tin this environment to ensure consumer protection.

Mr. Chandler asked if the compounding was being done with substances not within the Board's jurisdiction. Ms. Sodergren noted that licensees operate in variety of manners and locations, adding that pharmacy technicians were sometimes sought out to compound in some of these locations outside of a pharmacy. Ms. Sodergren added that unlike in pharmacies, at these locations there is no direct supervision and control over the individuals who are also not following USP compounding standards. Ms. Sodergren concluded the Board did not have jurisdiction over the non-licensed site, but the Board has jurisdiction over the Board-licensed individuals.

Dr. Crowley hoped that the Board was able to inspect facilities that were doing compounding regardless of whether they were licensed with the Board. Dr. Crowley asked how the Board knew that pharmacy technicians were being hired for compounding in facilities not licensed by the Board. Dr. Acosta provided the pharmacy technicians are referred to or self-identify as a pharmacy technician.

Dr. Barker added with compounding the environment and how the environment was maintained was of significant importance and she

supported bolstering the Board's existing authority to enable the Board to inspect these locations.

Policy Question #2 – Should the Board develop educational materials to provide to other health care professional Boards and associations reminding such entities of the Board's inspection authority?

Dr. Oh believed this would be appropriate. Dr. Oh recommended referring to the Communication and Public Education Committee to develop a brochure similar to the Board's inspection brochure that inspectors would be able to provide at the time of inspection.

Members were provided the opportunity to comment.

Dr. Crowley agreed educational materials should be developed. Dr. Barker thought educational materials should consist of letting entities know the Board can inspect a location if there was compounding being done at the location, and general information about what was required for compounding. Dr. Oh noted that many people don't realize that compounding is a high risk activity and that there is a potential for patient harm.

Policy Question #3 – Generally, the Board does not inspect facilities where compounding occurs outside of a Board-licensed facility unless requested or referred to the Board for such action by another entity, (e.g., the FDA, FBI, DEA, etc.). Does the Committee wish to provide direction to staff to proactively perform some inspections of such facilities to learn more about compounding practices?

Dr. Oh expressed his strong belief that it would be great to perform inspections to gain a better understanding of compliance of Board licensees with state and federal law and compounding standards, but stated he was also concerned with the increased workload this would create for Board staff.

Mr. Chandler asked if there was a way to work with referring partners, as a way to avoid the need for a statutory fix. Ms. Sodergren noted that other agencies may not have the subject matter expertise in compounding that the Board has, and as a result they look to the Board to provide guidance.

Dr. Crowley inquired about a collaborative effort at the state level with other boards and bureaus. Mr. Chandler indicated it may be more appropriate to receive statutory clarification from the legislature. Dr. Oh believed statutory authority already exists in BPC section 4008. Board Counsel Gartner clarified existing statutory authority in BPC section 4008 (a) where it states that the Board does have inspection authority to inspect during business hours any place where drugs or devices are compounded, prepared, furnished, dispensed, or stored.

Mr. Weisz added in the Board's role to safeguard the health and safety of the public, the Board should proactively go out and investigate within the Board's ability, capacity, and legal authority as well as educate the public of the Board's authority.

Dr. Crowley agreed there needed to be more oversight and wanted to understand what would happen if the Board went into a facility not licensed by the Board, found compounding below USP standards, and what the Board's next steps would need to be (*e.g.*, refer to federal agency, *etc.*).

Policy Question #4 - Does the Committee believe it is appropriate to allow for a pharmacy technician to compound under the direct supervision and control of a pharmacist when outside of a licensed pharmacy?

Dr. Oh thought a way to approach this would be, if the compounding was being done outside of a licensed pharmacy, there should be a pharmacist overseeing the compounding.

Dr. Crowley agreed and from her understanding of the definition of a pharmacy technician, a pharmacy technician should not be compounding if a pharmacist was not there, nor should a tech be compounding outside of a pharmacy. Dr. Crowley added pharmacy technicians may not know they can't be compounding outside of a pharmacy, which underscored the importance of the educational component.

Dr. Barker noted there were so many concerns regarding compounding (*e.g.*, practices, environment, risk, *etc.*) and added that while she understood requiring a pharmacist she also thought the compounding area should be licensed.

Policy Question # 5 - Should the Board consider establishing a requirement for offices, clinics, etc. that are compounding but not currently licensed by the Board to provide notification to the Board that Board licensees are compounding at their location, or alternatively require Board licensees to notify the Board if they are compounding outside of a Board licensed facility?

Dr. Oh was in support of a minimum notification requirement and believed it should be established as a requirement for Board-licensees to notify the Board, as opposed to placing the requirement on the facility itself.

Dr. Crowley thought notification to the Board could be overwhelming to Board staff but the Board did need a baseline to know where to start.

Dr. Barker noted there may be a need to establish a requirement for offices/clinics to complete a self-assessment or attestation to create understanding of what is required.

Mr. Chandler agreed that it was prudent as a baseline to have pharmacy technicians alert the Board when they are performing compounding outside of a licensed facility, but was interested in hearing about staff capacity to absorb this additional notice.

Ms. Sodergren noted the Board could partner with DCA to establish an easy web-based portal and manage notification through an IT solution for minimal staff involvement for that portion. Ms. Sodergren added this would allow the Board to understand the frequency of the practice, and the Board could also do random inspections. The data from the inspections could be used by the Board to help form the Board's policy.

Policy Question #6 - Should the Board develop educational materials reminding pharmacy technicians of the requirements of USP 797 and federal law related to the compounding of drug preparations?

Dr. Oh thought this was appropriate to help educate pharmacy technicians. Dr. Barker also spoke in support of this concept.

Dr. Oh summarized where the Committee had consensus was to provide educational materials for technicians and educational materials for licensees by the Communication and Public Education Committee.

Dr. Oh noted there was not clear consensus to increase inspections of these facilities. If agreeable, the Committee could discuss further at the next Committee meeting, including discussion of what actions and proposals could be included in the sunset report to better protect California consumers who are receiving high risk medication or products from non-licensed facilities.

Mr. Chandler was interested in seeing if there was consensus at the Board level in having pharmacy technicians report to the Board when they are compounding outside of a non-licensed facility.

Dr. Crowley thought this was an urgent issue to address as soon as possible. Dr. Crowley agreed with a notification requirement but wasn't clear on whether facilities or licensees should be asked to provide the notice. The members continued to discuss the notification issue, with no clear consensus reached.

Dr. Oh asked if the Committee would be agreeable to inspecting some facilities in preparation for the sunset report as a way of gathering information to help inform the Board's next steps. Dr. Barker and Mr. Weisz both expressed support for this.

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

Members of the public participating via WebEx were provided the opportunity to comment.

A pharmacist commented that in addition to medical spas and hydration clinics, there are oncology infusion centers where pharmacy technicians are compounding for cancer patients. The pharmacist expressed concern about compounding occurring in this setting and suggested that rather than looking at pharmacy technicians, the Board should focus its attention on the businesses/facilities that are engaging in this high risk practice.

A pharmacist who worked in a licensed sterile compounding pharmacy for cancer treatment was happy to see this as an agenda item. The pharmacist noted this was also an issue with cancer care facilities that only hire pharmacy technicians which is a safety concern and undermines the

pharmacists. The commenter agreed with the previous commenter that these facilities are exploiting a loophole in the law.

A member of the public agreed with the previous commenters and noted that there is confusion in the provider community about whether these locations need and/or can obtain a license from the Board. The commenter thought more education and clarity was needed in this area and agreed that the Board should focus more on the facilities as opposed to the personnel.

A representative of CSHP applauded the Board for the direction it was taking on this issue. The representative didn't want to discourage use of pharmacy technicians in these practice settings, though. The representative thought a pharmacy technician with some training was better than an unlicensed medical assistant with no training, and warned of actions, such as mandated self-reporting, that might discouraged pharmacy technicians from performing these functions.

A pharmacist commented the Board was headed in the right direction. The pharmacist provided a personal account of federal and state laws and compounding terminology.

XI. Presentations on Central Fill Pharmacy Models

Chairperson Oh recalled in January 2024, the Committee began discussions about central fill pharmacies and requested receiving presentations from representatives of companies that currently use a central fill model. Dr. Oh advised the Committee would hear from representatives of Albertsons and Walgreens.

First, Dr. Oh introduced and welcomed Rob Geddes, PharmD, Director, Pharmacy Legislative and Regulatory Affairs with Albertsons.

Dr. Geddes reviewed the components of central fill and the flow of the prescription from the dispensing pharmacy to the central fill pharmacy and back to the dispensing pharmacy. Dr. Geddes advised central fill pharmacies are highly automated environments.

Members were provided the opportunity to comment.

Dr. Crowley asked if Albertsons used central fill in California. Dr. Geddes advised a small number of Albertsons stores in California currently use central fill as a service.

Mr. Chandler asked if Albertsons had studied medication errors through central fill versus non-central fill. Dr. Geddes advised that Albertsons conducts multiple safety checks and has stringent SOPs that function to reduce errors. Dr. Geddes provided examples of safety checks used by pharmacy personnel in a central fill pharmacy. Dr. Geddes advised after six months of operation, there had not been an incident identified where the wrong medication was given to the patient. Dr. Geddes noted Albertsons believed the safety checks and balances built into the processes and systems were very safe and well designed.

Dr. Barker asked how Albertsons determines when a store needs central fill support. Dr. Geddes provided that they use an algorithm that helps determine this based on volume and proximity. Dr. Geddes provided they use the wholesaler to get medications back to the pharmacy and noted that central fill is available to help a store if there is a staffing crisis. Dr. Barker also asked if the prescription was checked by the dispensing pharmacist when the prescription arrives from central fill. Dr. Geddes provided there wasn't a required check by the dispensing pharmacist as both the central fill and receiving pharmacy were licensed by the Board and it was viewed as a corresponding responsibility issue. Dr. Barker asked if the dispensing pharmacist wanted to check the prescription if they were able to. Dr. Geddes provided pharmacists could check the prescriptions but this wasn't required.

Mr. Weisz asked how many prescriptions an average Albertsons fills in a day. Dr. Geddes provided the central fill pharmacy can fill 20,000 prescriptions in an 8-hour shift so that a day consisting of three 8-hour shifts would be 60,000 prescriptions at full capacity. Dr. Geddes noted an average pharmacy fills about 1,000-1,200 prescriptions a week. For a pharmacy using central fill support, approximately 30 percent of the prescriptions are filled by central fill support noting some types of prescriptions such as the maintenance chronic medications that filled by the central fill support. Dr. Geddes advised locations of central fill pharmacies are selected based on wholesaler proximity and maximum number of pharmacies that it could potentially service and encouraged the Board to reconsider and steer away from central fill pharmacies being required to be in California and service only California. Dr. Geddes noted

a central fill for California may be best located in Nevada to best serve California pharmacies.

Mr. Weisz asked if there was any difference between how the central fill model and the direct to consumer model (*i.e.*, mail order) functioned. Dr. Geddes advised Albertsons did not utilize a direct to consumer model, noting there were differences (*e.g.*, label requirements, counseling, *etc.*) but the technology leveraged was similar.

Dr. Crowley asked how the volume in California locations compared to other states. Dr. Geddes provided the California locations do not have as high of a volume as some stores across the country fill up to 4,000 prescriptions a week.

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

Members of the public via WebEx were provided an opportunity to comment.

A representative of CCPC commented on the next agenda item, indicating that CCPC has concerns about the proposed regulatory language.

Dr. Oh next introduced and welcomed Lorri Walmsley, RPh, Director of Pharmacy Affairs with Walgreens.

Ms. Walmsley began her presentation by observing that central fulfillment enables the future of pharmacy. Walgreens currently has 11 central fill pharmacies servicing 32 states. Ms. Walmsley reviewed an infographic explaining the journey for centrally filled prescriptions, and provided samples of prescription record keeping for automation central fill and manual central fill.

Members were provided the opportunity to comment.

Dr. Crowley asked how many Walgreens pharmacies receive central fill service in California. Ms. Walmsley advised that currently there were no Walgreens pharmacies in California that are serviced by central fill. Ms. Walmsley added terms of service for central fill pharmacies were based on

wholesale distribution schedules to minimize carbon footprint and ensure centrally-filled prescriptions arrived with the other medications.

Dr. Crowley also asked if Walgreens had a similar method as Albertsons of determining what pharmacies use central fill and how the volume of prescriptions filled in California compares to the country. Ms. Walmsley provided the goal was to service all of their pharmacies regardless of volume.

Members of the public in Sacramento and via WebEx were provided an opportunity to comment; however, no comments were made.

Dr. Oh thanked Dr. Geddes and Ms. Walmsley for their presentations, noting that he believed it was helpful to inform the Committee about this pharmacy model and will be useful as the Committee continues its assessment of the Board's current central fill regulation.

Dr. Oh surveyed the Committee to see if they received enough information to make decisions for the next agenda item. Members agreed the two presentations were excellent but they wanted to hear from additional companies about their central fill practices including those that were located in California. The Committee agreed to skip agenda item XII until additional information could be obtained for the Committee's review.

The Committee took a break from 3:22 p.m. to 3:45 p.m. Roll call was taken. The following members were present via WebEx: Trevor Chandler, Public Member; Jessi Crowley, Licensee Member; Jason Weisz, Public Member; and Seung Oh, Licensee Member. A quorum was established.

XII. Discussion and Consideration of Proposed Amendment to California Code of Regulations, Title 16, Section 1707.4 Related to Central Fill Pharmacies

This agenda item was not discussed and was postponed to another meeting date.

XIII. Discussion and Consideration of Licensure and Other Requirements for Nonresident Pharmacies

Chairperson Oh expressed concern about the Board's inability to regulate nonresident pharmacies, including mail order pharmacies. Dr. Oh further explained nonresident pharmacies can create unique challenges for

patients, and recalled investigations that resulted in discipline stemming from these challenges that were placing patients at risk. Dr. Ph continued by noting that over the last two years, the Board has referred 11 nonresident pharmacies to the Office of the Attorney General for formal discipline and issued 39 citations. In addition, the Board took disciplinary action on 12 nonresident pharmacies. The underlying violations varied in egregiousness and included extremely serious causes of action including clearly excessive furnishing of controlled substances. Dr. Oh reminded members that there was no current requirement for pharmacists working in these nonresident pharmacies who are providing services to California patients to be licensed in California, and that the Board has previously voted and would be pursuing a statutory change to require the PIC of a nonresident pharmacy to be licensed in California.

Dr. Oh also expressed concern about the actions undertaken by some states to eliminate law and jurisprudence examinations as well as recent actions by Michigan and North Dakota that allow pharmacists licensed in Canada to reciprocate licensure without taking the North American Pharmacist Licensure Examination (NAPLEX).

Policy Question #1
The Committee has previously indicated that inspections should be performed at nonresident pharmacies. Does the Committee wish to establish a minimum frequency for conducting such inspections?

Dr. Oh stated that he believed inspections every four years might be an appropriate frequency and suggested that the Board tie the requirement to the renewal of the license. Dr. Oh noted based on July 2023 statistics, the Board renewed 499 nonresident pharmacy licenses in fiscal year 2022/23. Assuming that number remains constant, the Board would conduct about 125 inspections of nonresident pharmacies annually. Dr. Oh added that he believed a statutory change would be necessary to implement the provisions.

Members were provided the opportunity to comment.

Dr. Crowley thought that inspections every four years might not be frequent enough. She acknowledged the time and the expense to the Board but thought it was necessary and would recommend more frequent inspections.

Mr. Chandler asked what was a common time frame and cost for inspections. Dr. Oh advised the Board inspects pharmacies in California every four years. Ms. Sodergren added based on what the Committee and Board determined, staff would probably recommend pursuing a statutory proposal that would allow the Board to recover the inspection costs similar to the nonresident sterile compounding pharmacy inspections.

Mr. Weisz asked what the precedent was for the Board staff to go out of state for inspections. Ms. Sodergren explained now the Board inspects nonresident sterile compounding pharmacies. Mr. Weisz thought this would be a great expansion for the Board and indicated he was in support of conducting inspections every four years.

Member Barker returned to the meeting at 3:54 p.m.

Policy Question #2
Board staff has recently learned that some states are allowing pharmacists licensed in Canada to secure licensure and/or work in their respective state without taking the NAPLEX and/or law examination. Such individuals could then provide pharmacy-related services to California patients.
a. Does the Committee have concerns with this practice?

Dr. Oh reiterated North Dakota and Michigan recently took action to recognize pharmacists for licensure by reciprocity under specified conditions. Dr. Oh understood in Michigan an applicant for licensure as a pharmacist in Michigan who has passed the Pharmacy Examining Board of Canada Pharmacists Qualifying Examination, completed an educational program accredited by the Canadian Council for Accreditation of Pharmacy Programs, and who has a minimum of 1,600 hours of pharmacy practice either through an approved internship or practice as a pharmacist, would meet requirements for licensure in Michigan. Dr. Oh noted there were 11 nonresident pharmacies located in Michigan and licensed in as a nonresident pharmacy in California. In the 11 nonresident pharmacies, the pharmacist providing services into California has not demonstrated minimum competency on an examination that meets the requirements of BPC section 139.

Members were provided opportunity to comment.

Mr. Chandler asked what the federal role (*i.e.*, FDA) was on licensure. Dr. Oh and Ms. Sodergren provided licensure was at the state level. Members also inquired about licensure requirements for Canadian pharmacists, but the information was not available but could be researched if the Committee desired.

b. Does the Committee wish to prohibit such practice like the approach taken for pharmacist licenses revoked in California?
c. Does the Committee wish to require all pharmacists providing services into California to be licensed in California?

Dr. Oh noted the Board already has a requirement for nonresident pharmacies to ensure that a pharmacist whose license has been revoked in California is prohibited from providing pharmacy services to California patients. Dr. Oh posed the question if the Board should require pharmacists working for nonresident pharmacists to be licensed in California. Dr. Oh thought that might be too far but there may be a prohibition for pharmacists in certain circumstances from being able to practice and verify medications to California patients. The alternative would be to allow pharmacists licensed in Canada to practice in California.

Member were provided the opportunity to comment.

Mr. Chandler understood the issue of reciprocity and agreed there should be a failsafe.

Dr. Oh thought this could be explored further and have some next steps in subsequent meetings. Dr. Oh reminded members that the PIC licensure requirements were already supported by the Board by seeking statutory change through the sunset process.

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

Members of the public via WebEx were provided the opportunity to comment.

A pharmacist representative of Kaiser Permanente encouraged the Board to see what other jurisdictions were doing about inspecting nonresident pharmacies (*e.g.*, submit inspection report from another state or third-party, *etc.*).

A pharmacist commented about where the NAPLEX was accepted and commented in support of the Board inspecting nonresident pharmacies. The commenter was concerned about a license being required by a pharmacist in another state who was only providing clinical services as it would severely limit the options for California residents to get care.

A representative of Walgreens agreed with the comments from the Kaiser Permanente representative as well as recommended focusing inspections on pharmacies with disciplinary action. The representative voiced concern about all pharmacists providing services into California being required to be licensed in California as a pharmacist, noting that this would limit current services being provided to California residents without a patient safety benefit.

A representative of CCPC commented on concern for requiring California licensure for out of state pharmacists. The representative suggested exploring licensure compacts or reciprocity through the sunset report process.

A representative of CVS Health noted that licensure statistics provided at the NABP District Meeting indicated that pharmacy school enrollment and NAPLEX passage rates are both dropping. The representative said the Federal Trade Commission (FTC) was asking states to look at different ways to increase license portability, so the discussion about requiring all nonresident pharmacists to be licensed in California bucks that trend.

Members were provided the opportunity to comment after having heard public comment.

Dr. Crowley noted that she was not comfortable with the suggestion of accepting other states' inspection reports and recommended aiming to have in-person inspections for nonresident pharmacies.

XIV Discussion and Consideration of Proposed Amendments to Pharmacy Law to Transition to a More Robust Standard of Care Model for Some Pharmacist-Provided Patient Care Services

Chairperson Oh referenced relevant laws and regulations that generally detailed the scope of practice for pharmacists. Dr. Oh reminded members that as required by the Board's last sunset review, the Board was required

to evaluate if moving to a standard of care enforcement model was feasible and appropriate for the regulation of pharmacy. Through an ad hoc committee, the Board took a deep dive into the issue and ultimately concluded that the Board's current hybrid approach to the regulation of the practice of pharmacy was appropriate. At that time the Board also noted that based on information received, California patients would benefit from pharmacists gaining additional authority to provide some patient care services consistent with their respective education, training, and experience; however, any such change would require legislation.

Dr. Oh noted that today the Committee had the opportunity to begin discussion of potential statutory language that could facilitate such a transition. Dr. Oh added draft statutory language was prepared to assist the Committee as a place to start the discussion. Dr. Oh believed the basic tenets of the proposal were appropriate. Dr. Oh provided a summary of the proposal:

1. Would expand provisions for pharmacists to perform CLIA waived tests, beyond those currently allowed in BPC section 4052.4.
2. Would allow a pharmacist to perform a therapeutic interchange under specified conditions.
3. Would establish authority for pharmacists to furnish FDA approved or authorized medication that is preventative or does not require a diagnosis under specified conditions.
4. Would expand upon pharmacists' current authority to administer biologics and would allow a pharmacist to furnish an FDA approved or authorized noncontrolled medication for the treatment of minor, nonchronic health conditions or for which a CLIA waived test provides diagnosis and the treatment is limited in duration.
5. Would expand current authority for pharmacists to complete missing information on a noncontrolled medication if there is evidence to support the change.
6. Would expand authority for pharmacists to substitute medications that are generally considered interchangeable (*i.e.*, if insurance will only cover one medication but an interchangeable medication was prescribed.)
7. Would allow for medication therapy management and adjust treatments to manage chronic conditions diagnosed by a prescriber to optimize drug therapy (*i.e.*, adjusting medication dosing in response to laboratory results such as for warfarin, or medication to better control diabetes.)

Dr. Oh acknowledge that for some this proposal may seem too expansive and to others it may not go far enough, but expressed that he believed it provided a good starting place for the discussion.

Members were provided the opportunity to comment but wanted to hear public comment first.

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

Members of the public via WebEx were provided an opportunity to comment.

A pharmacist representative of Kaiser Permanente appreciated that the draft statutory language clarifies that prescriptions issued by a pharmacist pursuant to a collaborative practice agreement pursuant to BPC section 4052(a)(13) are valid prescriptions. The representative encouraged the Committee to recognize that some tasks in the proposed language could also be done pursuant to a collaborative practice agreement and he would want to preserve the ability to do the task under a collaborative practice agreement as well as in the proposed statutory language.

A representative of CPhA thanked the Board for the proposed language, noting its comprehensive nature. CPhA supports the Board in the current approach.

Another representative of CPhA agreed with the prior commenter. The representative spoke in support of the Board's approach, noting that it will release the profession to be able to function in a way with better patient outcomes, and that this would help with the affordability with health care as well as increase equity and access.

A pharmacist agreed with the previous commenters and recommended that the Board also clean up the Health and Safety Code provisions that cross-reference BPC sections that are being amended by this proposal. The commenter stated that the Board should also reconsider whether pharmacists can prescribe for off-label uses.

Members were provided the opportunity to comment having heard public comment.

Mr. Weisz asked about next steps. Dr. Oh explained that no formal action was needed at this time; rather, he is just looking for consensus and any formal action would be taken by the Board as part of the sunset report process in December 2024.

Mr. Chandler recommended making sure the public knows the Board wasn't removing access to these items but expanding pharmacists'; ability to provide certain services, thus making access easier. Dr. Oh agreed.

Dr. Crowley expressed concerns that the language was too expansive. Specifically, under Section 5 regarding "upon patient consent," Dr. Crowley was concerned about not reaching out to the doctor before changing medications as there was information not available in a retail pharmacy (*e.g.*, laboratory results, *etc*.). In addition, under Section 10, Dr. Crowley believed there was too much room for interpretation as well as the definition of "preventative" and that there should be limitations. Dr. Crowley also had a question in Section 16 under question 2 and asked how it differs from what was currently allowed and if it was intended to address emergency use authorization (EUA).

Dr. Oh noted the practice of pharmacy historically had been prescriptive and putting it into the standard of care pharmacy model, there would need to be the understanding that not every practice will be cited by statute or regulation but determined by the practitioner of what is right. Dr. Oh noted this was an opportunity to increase efficiency and provided an example of how this could improve patient care.

Ms. Sodergren believed the language regarding immunizations was consistent with the intent of the prior legislation to cover the COVID vaccines.

Dr. Crowley understood the intention and agreed there was a need for more flexibility, but expressed concern that some pharmacists weren't autonomous enough to actually utilize this model in practice because of employer-imposed policies and procedures.

XV. Discussion and Consideration of Licensing Statistics

Chairperson Oh referenced meeting materials including a summary of the licensing statistics for the first eight months of the fiscal year. Dr. Oh noted the processing times for individual licenses, which as of April 1, 2024, was at

or below 15 days for both initial applications and to process deficiency items. He noted that unfortunately there are some site application processing times well beyond the Board's 30-day processing times. He believed this was in part because of the loss of staff including a manager. Dr. Oh noted the Committee will continue to monitor the progress made by staff.

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

Members of the public were provided the opportunity to comment in Sacramento or via WebEx; however, no comments were made.

XVI. Future Committee Meeting Dates

Chairperson Oh advised the next Licensing Committee meeting was currently scheduled for July 18, 2024.

XVII. Adjournment

The meeting adjourned at 4:47 p.m.

Attachment 2

Proposed Amendments Related to Pharmacy Technician Trainees

Business and Professions Code Section 4038 is amended as follows:
4038.
(a) "Pharmacy technician" means an individual who assists a pharmacist in a pharmacy in the performance of his or her pharmacy related duties, as specified in Section 4115.

(b) A "pharmacy technician trainee" is a person who is enrolled in a pharmacy technician training program ~~operated by a California public postsecondary education institution or by a private postsecondary vocational institution approved by the Bureau for Private Postsecondary and Vocational Education~~.

Business and Professions Code Section 4115.5 is amended as follows:
4115.5.
(a) Notwithstanding any other law, a pharmacy technician trainee may be placed in a pharmacy to complete an externship for the purpose of obtaining practical training required to become licensed as a pharmacy technician.

(b) (1) A pharmacy technician trainee participating in an externship as described in subdivision (a) may perform the duties described in subdivision (a) of Section 4115 only under the direct supervision and control of a pharmacist.

(2) A pharmacist supervising a pharmacy technician trainee participating in an externship as described in subdivision (a) shall be directly responsible for the conduct of the trainee.

(3) A pharmacist supervising a pharmacy technician trainee participating in an externship as described in subdivision (a) shall verify any prescription prepared by the trainee under supervision of the pharmacist by initialing the prescription label before the medication is disbursed to a patient or by engaging in other verification procedures that are specifically approved by board regulations.

(4) A pharmacist may only supervise one pharmacy technician trainee at any given time.

(5) A pharmacist supervising a pharmacy technician trainee participating in an externship as described in subdivision (a) shall certify attendance for the pharmacy technician trainee and certify that the pharmacy technician trainee has met the educational objectives established <u>by the training program</u> ~~by a California public postsecondary education institution or the private postsecondary vocational institution in which the trainee is enrolled, as established by the institution~~.

(c) (1) Except as described in paragraph (2), an externship in which a pharmacy technician trainee is participating as described in subdivision (a) shall be for a period of no fewer than 120 hours and no more than 140 hours.

(2) When an externship in which a pharmacy technician trainee is participating as described in subdivision (a) involves rotation between a community and hospital

pharmacy for the purpose of training the student in distinct practice settings, the externship may be for a period of up to 340 hours.

(d) An externship in which a pharmacy technician trainee may participate as described in subdivision (a) shall be for a period of no more than six consecutive months in a community pharmacy and for a total of no more than 12 months if the externship involves rotation between a community and hospital pharmacy. The externship shall be completed while the trainee is enrolled in ~~a course of instruction at the institution~~the training program.

(e) A pharmacy technician trainee participating in an externship as described in subdivision (a) shall wear identification that indicates the pharmacy technician trainee's status as a trainee.

Attachment 3

Tech Ratio Survey Data

CA Board of Pharmacy

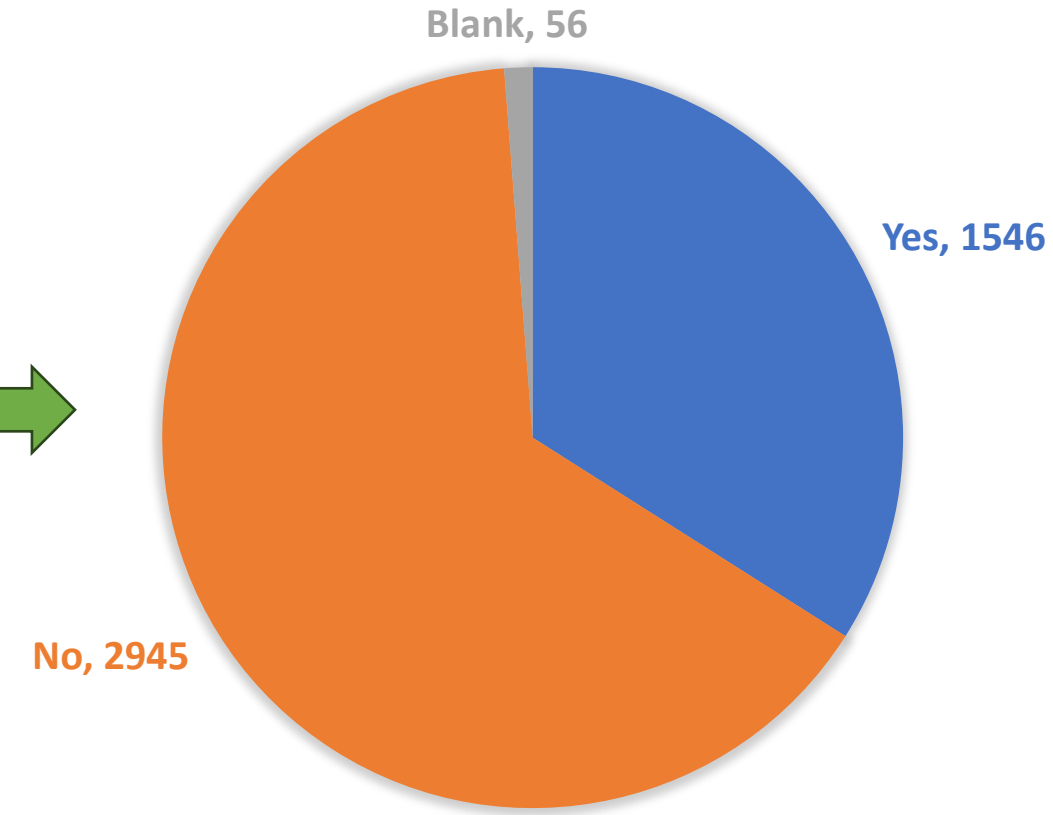
Survey Population

- 5151 total survey respondents (before removing the following);
  - 201 not licensed in CA
  - Another 384 not actively practicing in CA
  - Another 49 indicated they are licensed in CA but did not respond to any other question

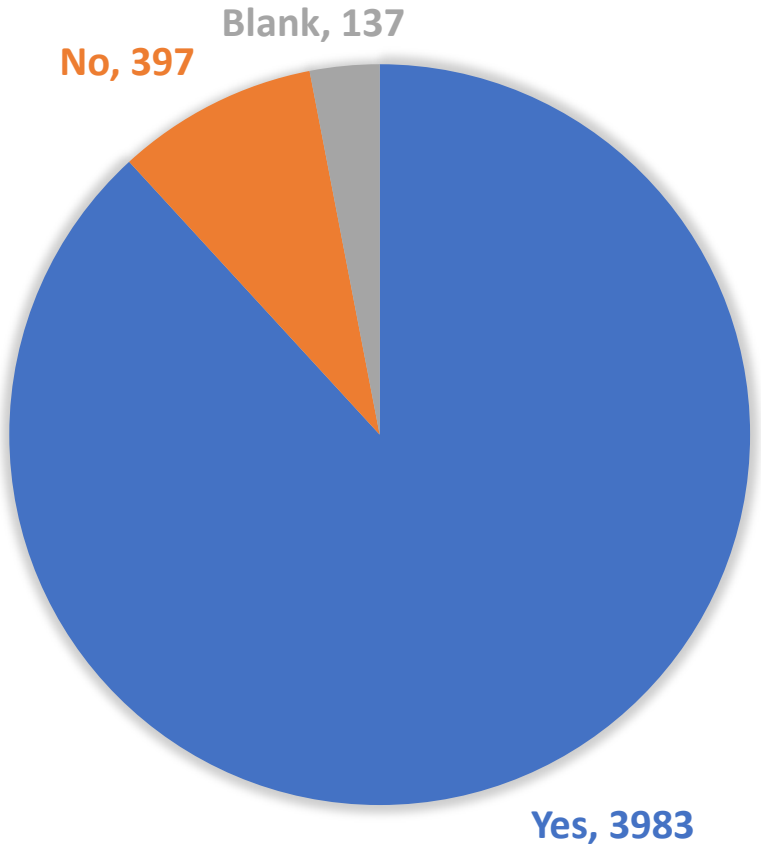
- 4517 responses analyzed

Are you a PIC?

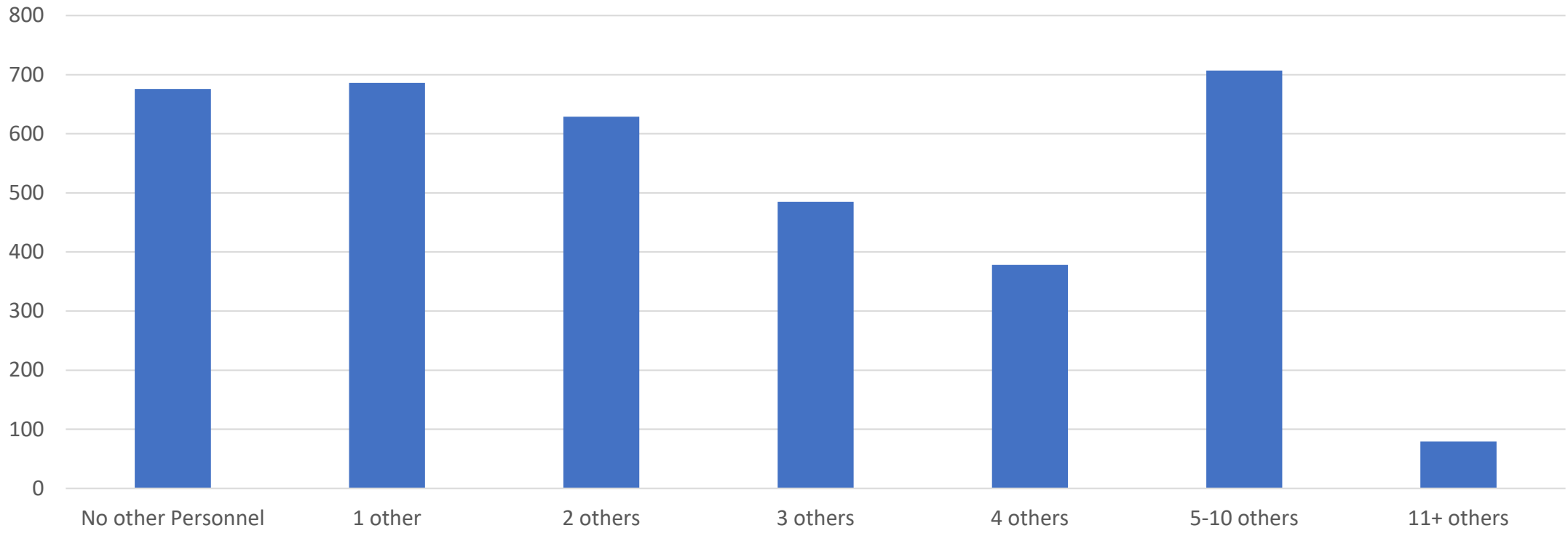
4517 Respondents



Do you currently supervise a pharmacy technician?

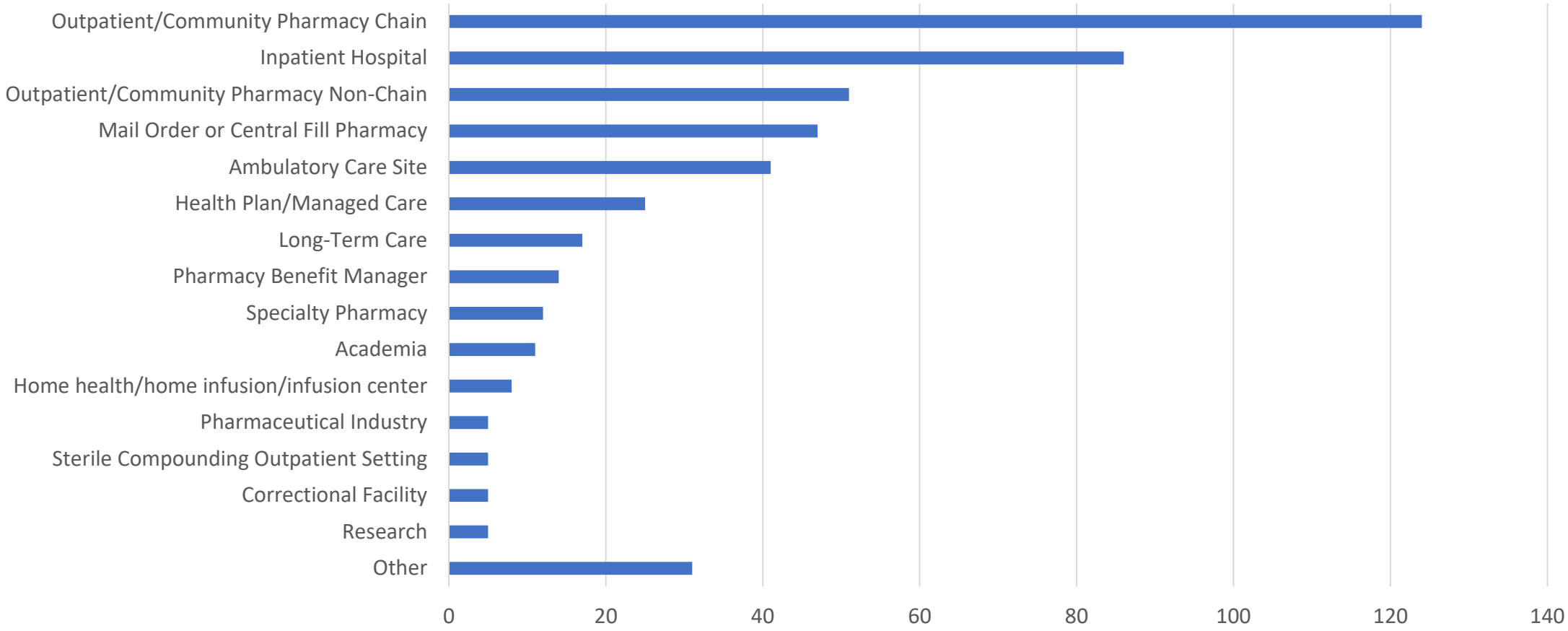


Of those who supervise a pharmacy technician, how many other personnel do you supervise?



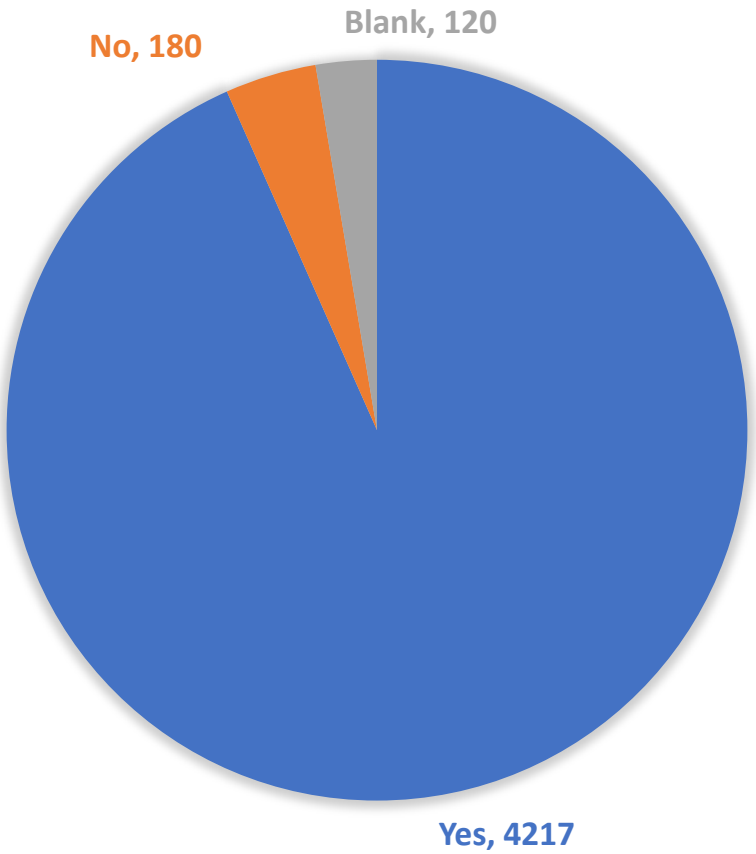
*29 did not respond

Work setting for those respondents who do not supervise a pharmacy technician

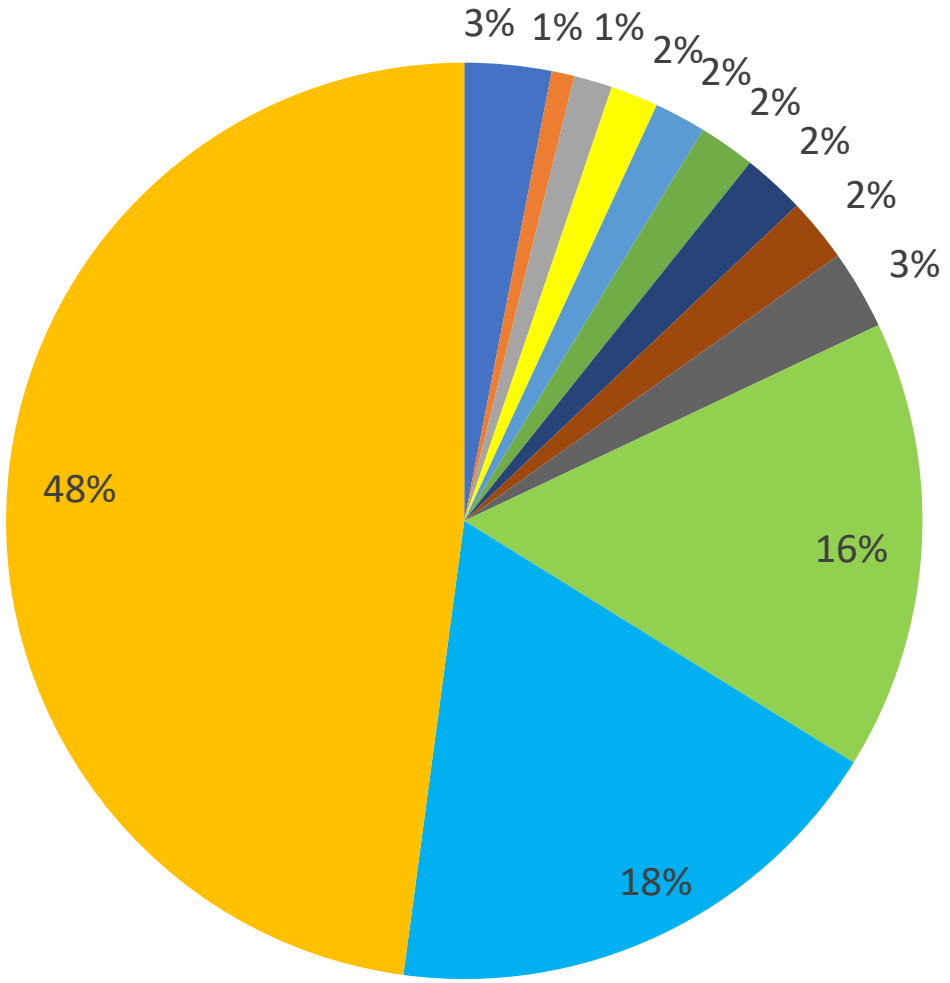


*47 did not respond

Does your worksite utilize pharmacy technicians?

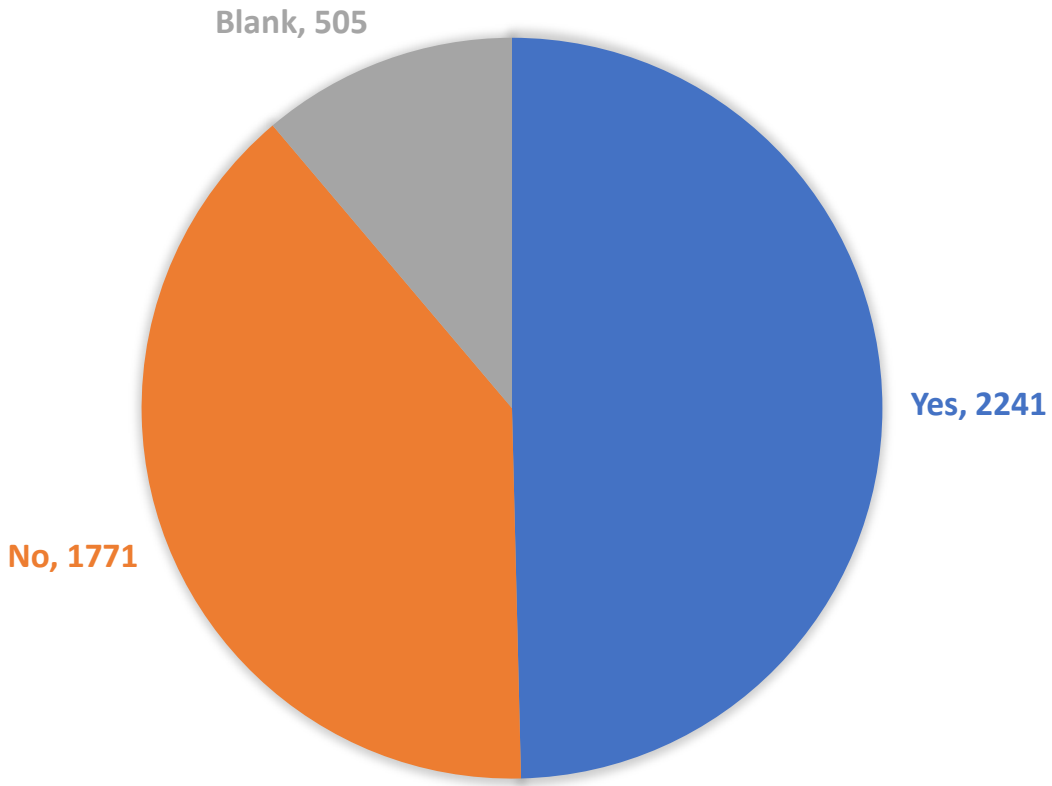


Type of worksites utilizing pharmacy technicians

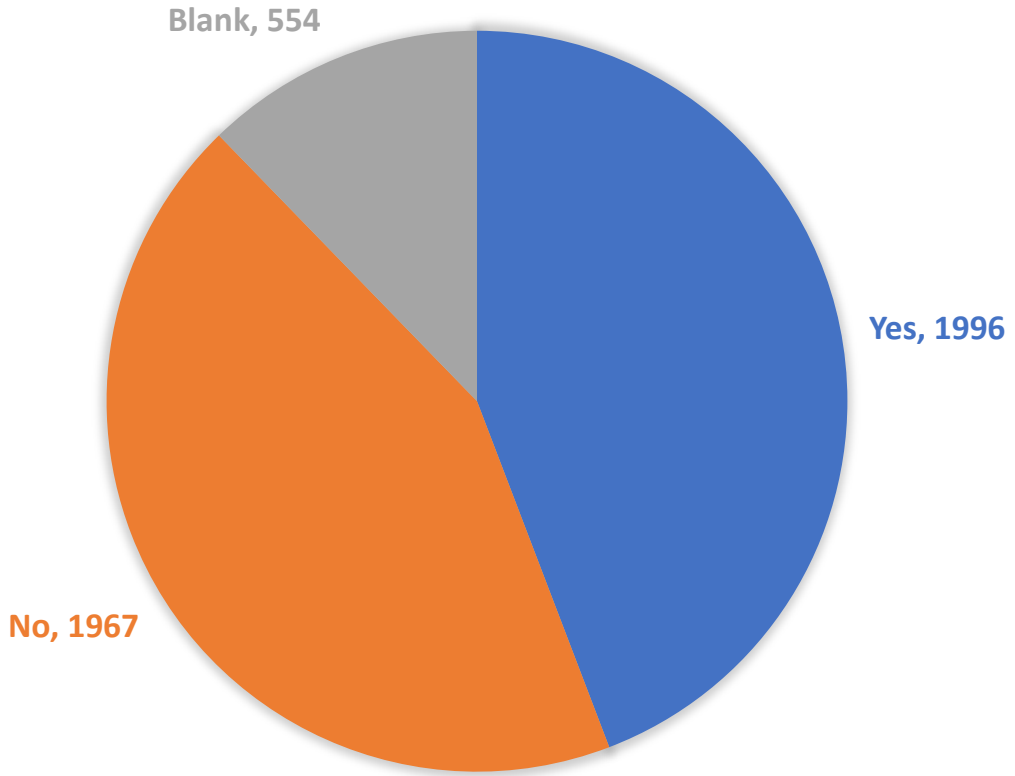


- Other (Incl. Pharmaceutical, Academia, Research, Benefit Manager)
- Correctional Facility
- Health Plan/Managed Care
- Sterile Compounding Outpatient Setting
- Home health/home infusion/infusion center
- Ambulatory Care Site
- Mail Order or Central Fill Pharmacy
- Specialty Pharmacy
- Long-Term Care
- Inpatient Hospital
- Outpatient/Community Pharmacy Non-Chain
- Outpatient/Community Pharmacy Chain

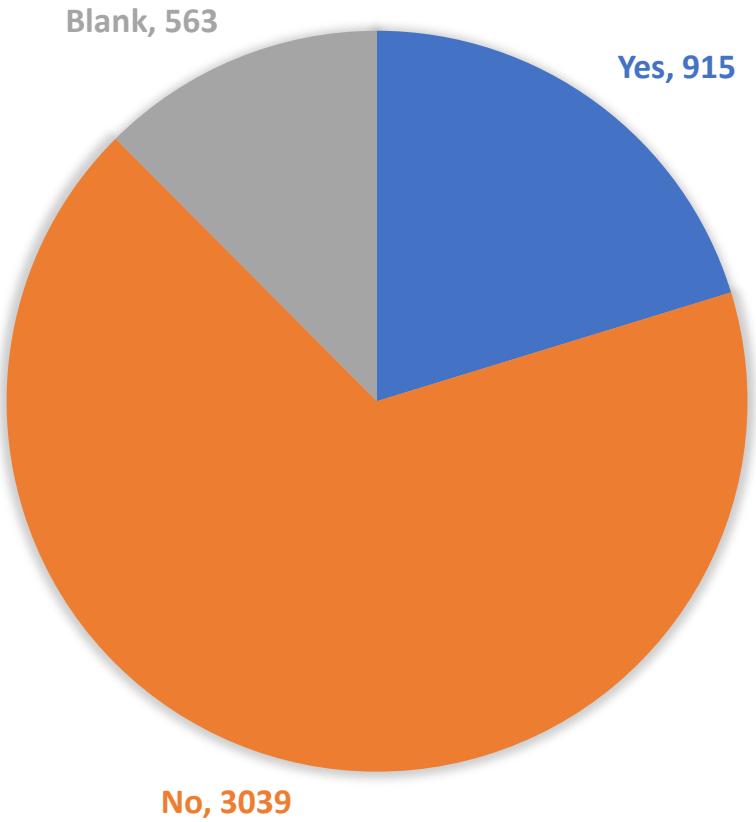
Does your pharmacy also provide immunizations and other clinical services during a typical day at your primary worksite?



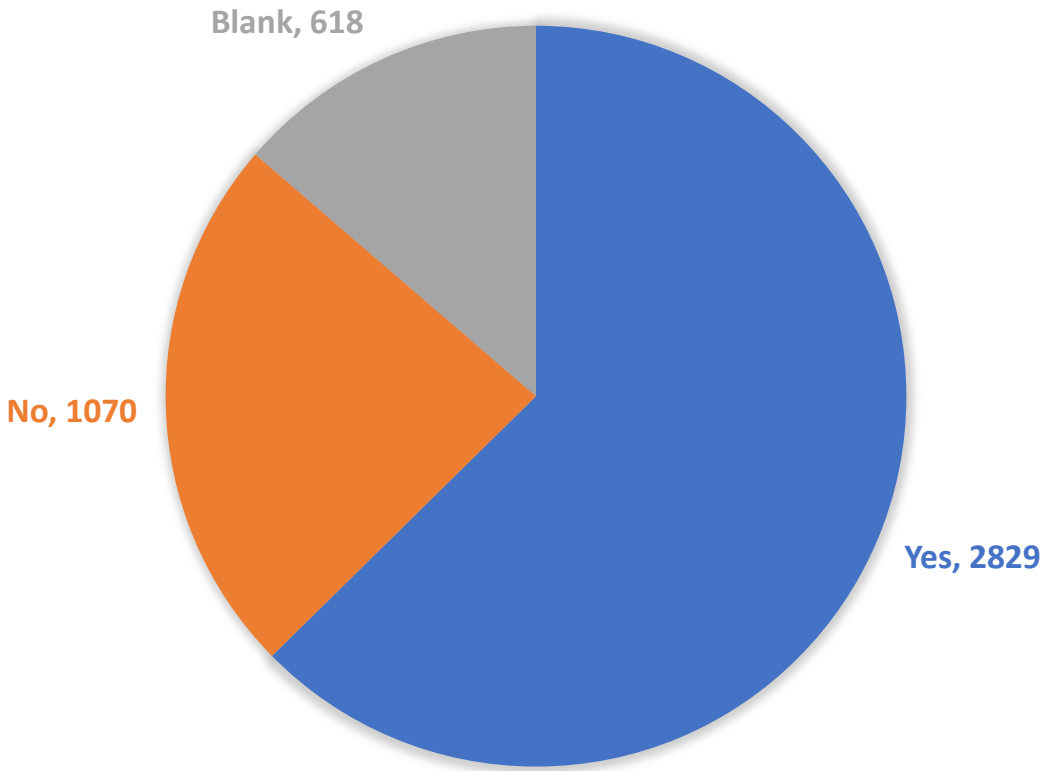
Does your worksite use any technology as part of the dispensing process?



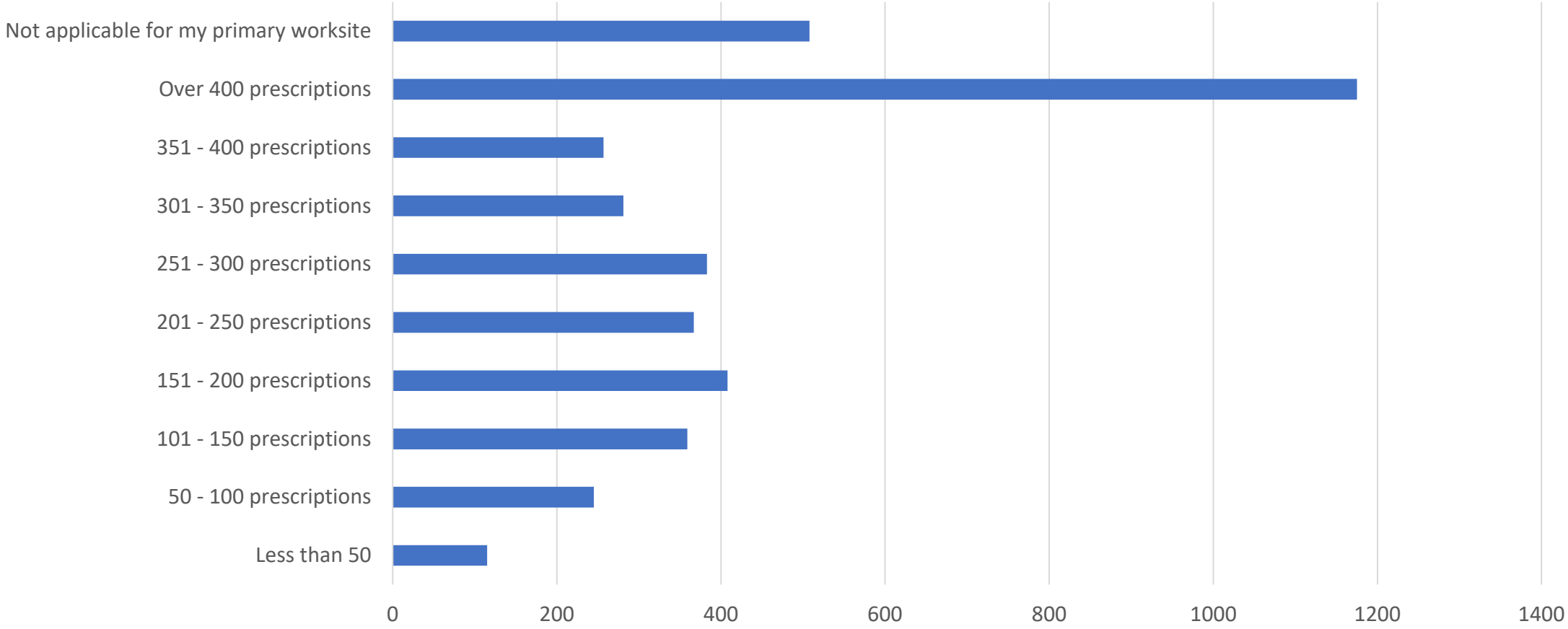
Is your worksite a closed-door pharmacy?



Does your worksite have pharmacists working overlapping hours?

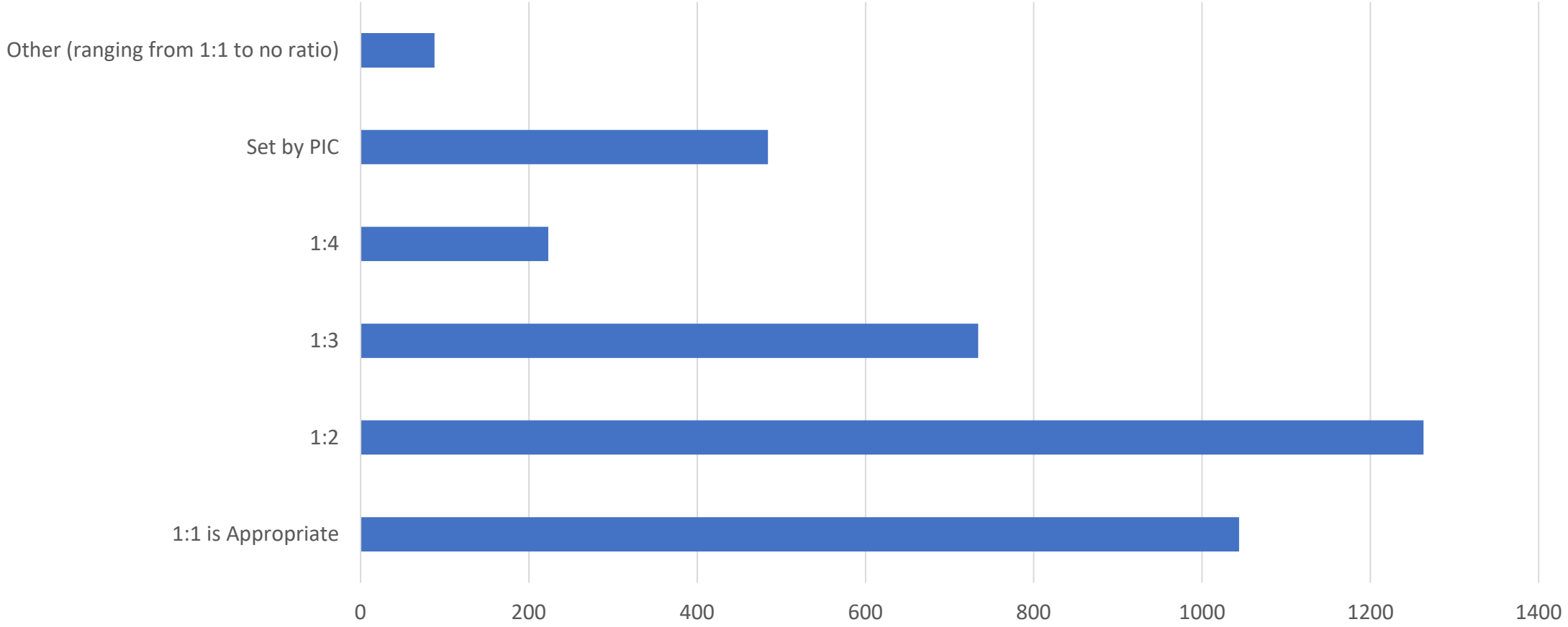


What is the average prescription volume during a typical day at your primary worksite?



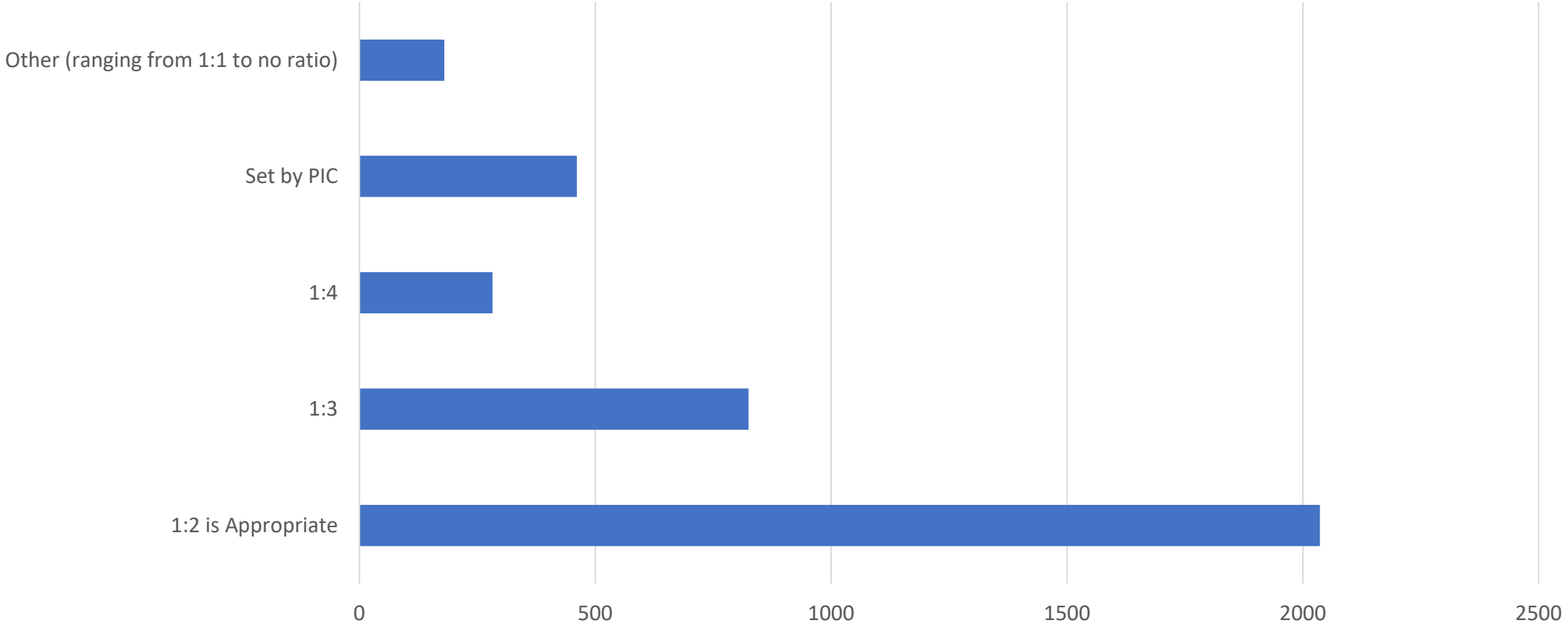
*419 did not respond

Do you believe the current pharmacist to pharmacy technician ratio in a **non-institutional** setting (currently 1:1) is appropriate?



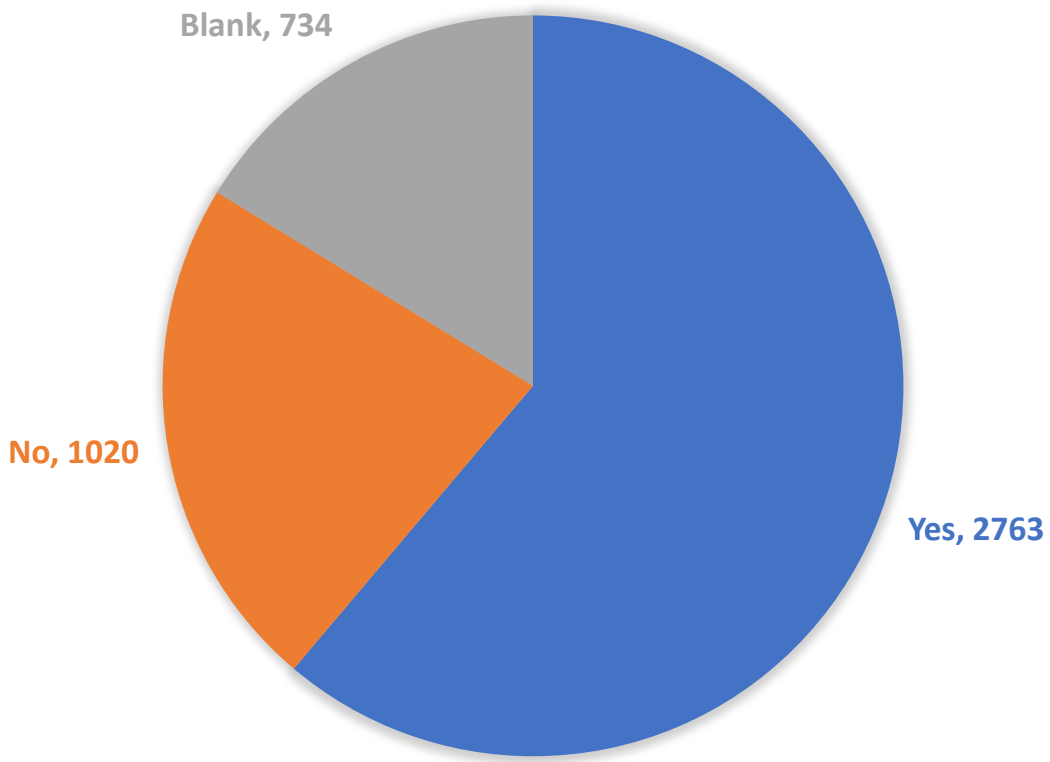
*681 did not respond

Do you believe the current pharmacist to pharmacy technician ratio in a **institutional setting** (currently 1:2) is appropriate?



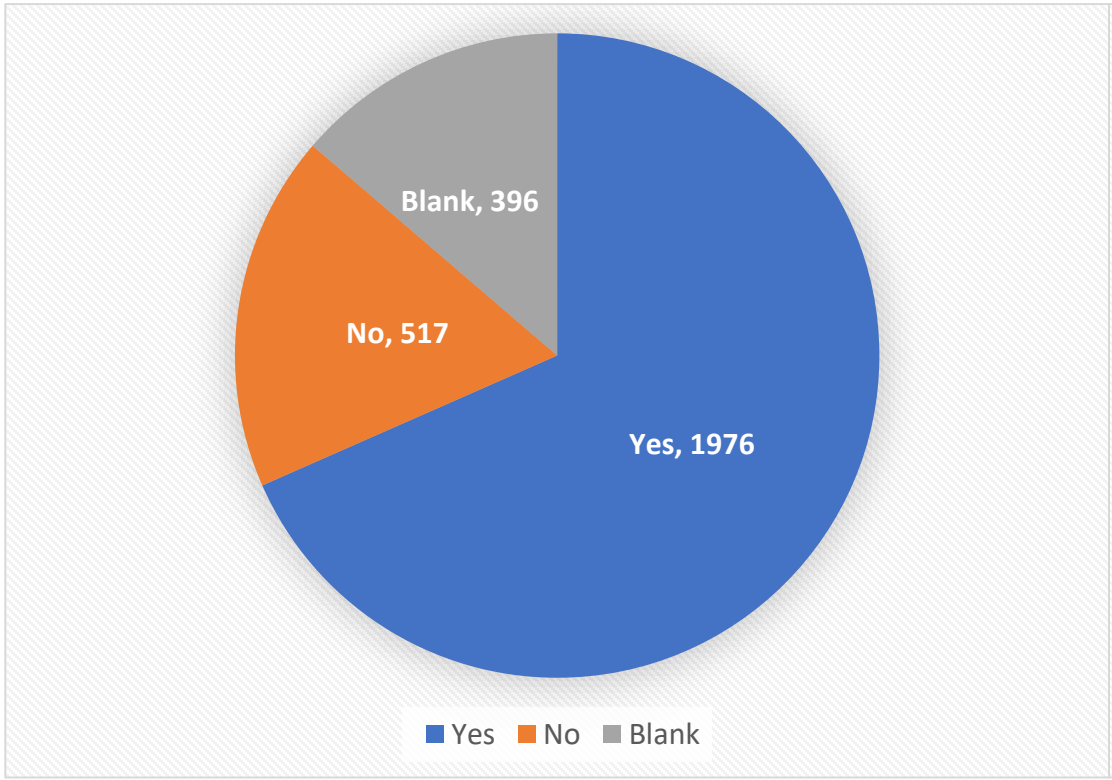
*733 did not respond

In your setting, do you believe you could provide more comprehensive patient care if the number of pharmacy technicians a pharmacist can supervise is increased?

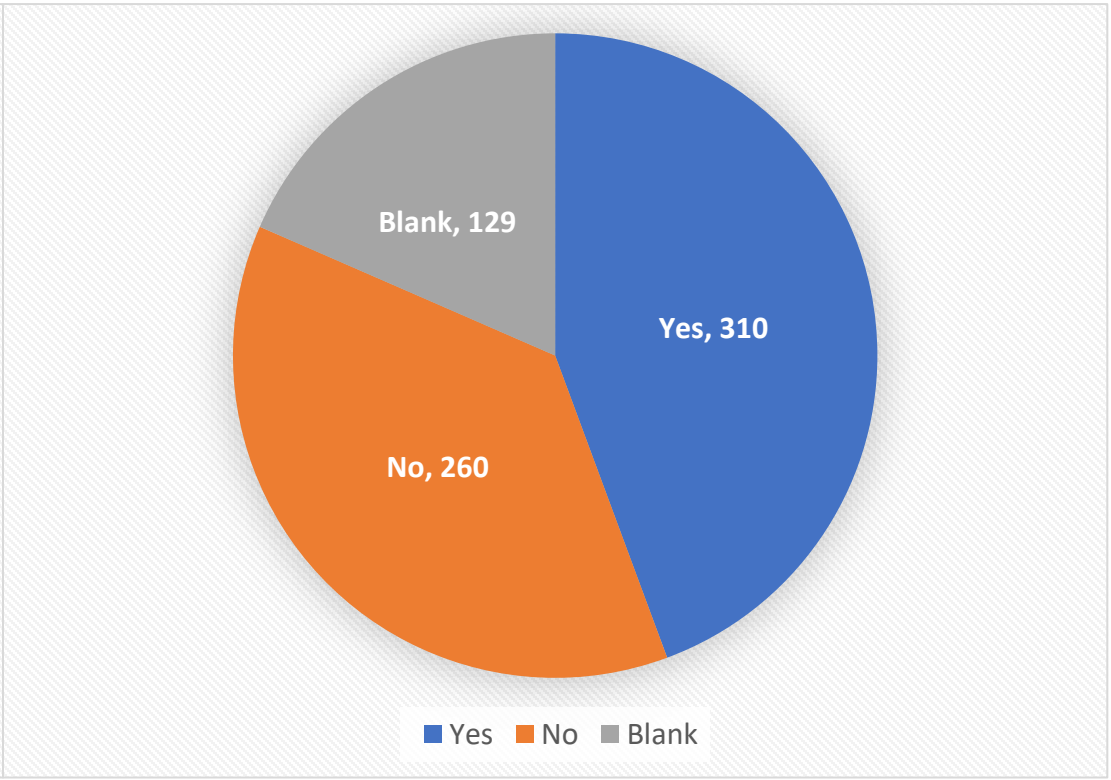


Responses by Worksite*

Community Chain and Non-Chain

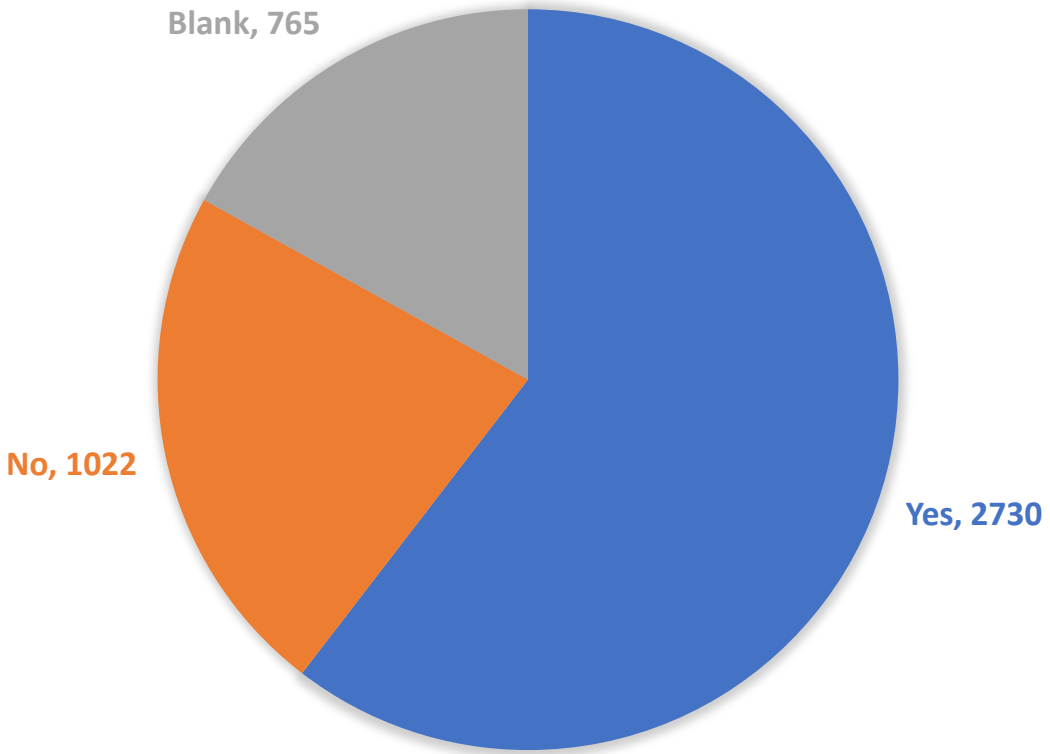


Inpatient Hospital

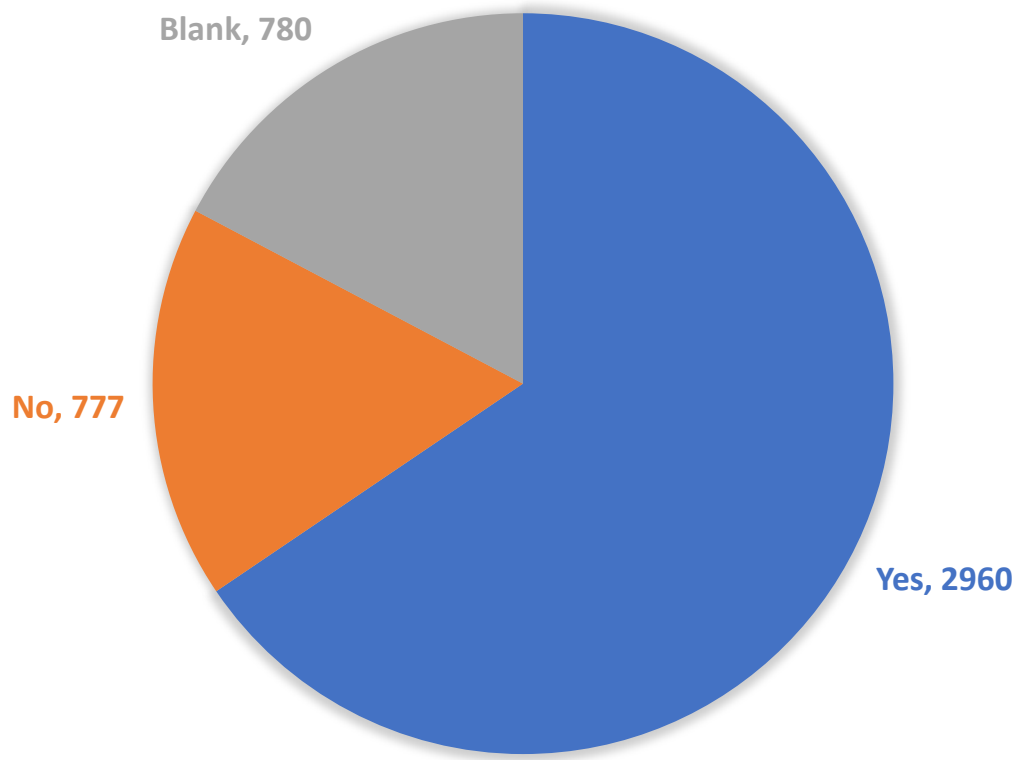


***This data accounts for 3,988 of the total 4517 respondents (88%)**

If the Board increased the number of pharmacy technicians a pharmacist could supervise, do you believe the PIC should be required to make a specific determination for the ratio to be used at their worksite?



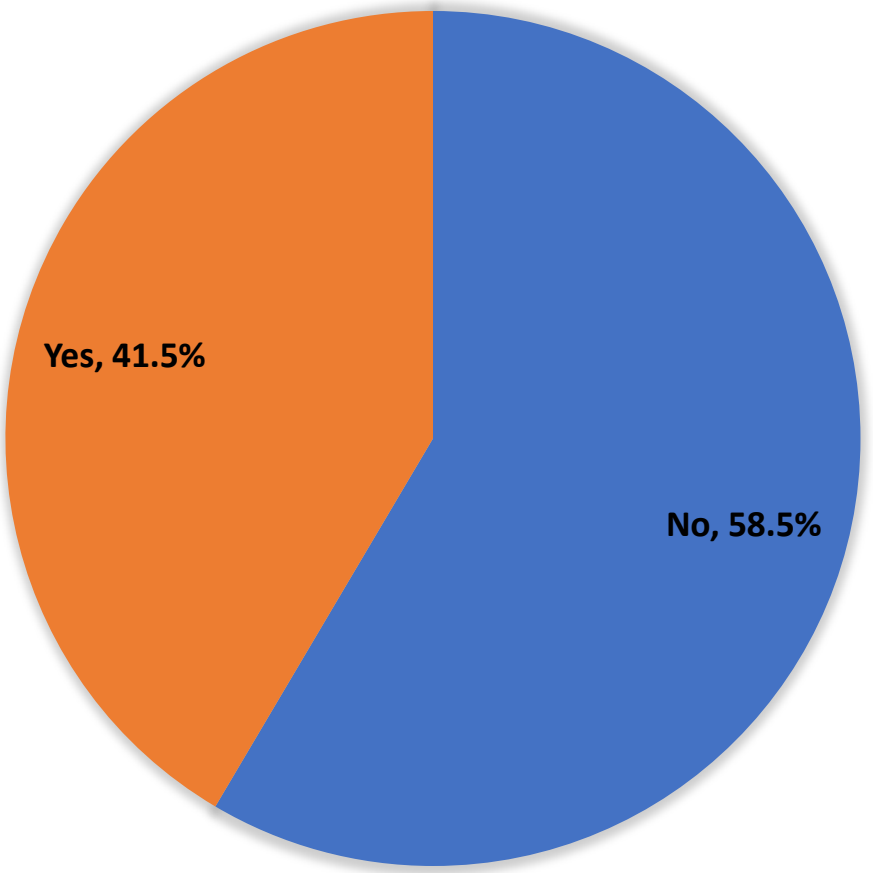
If there is an increase in the number of pharmacy technicians that can be supervised by a pharmacist, do you believe the pharmacist should have the authority to refuse to supervise the additional pharmacy technicians?



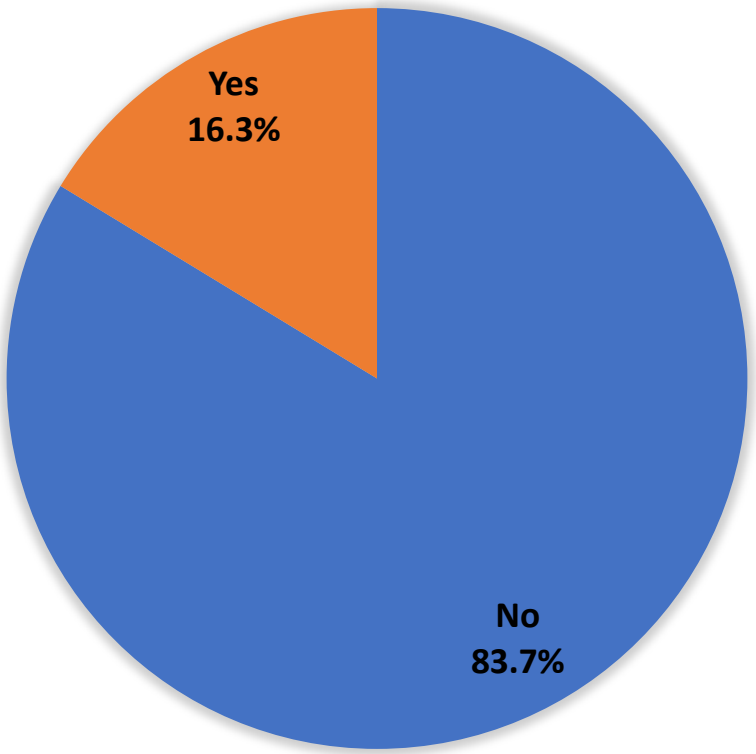
Are you in a management or administrative position for your employer (yes n=997)

and

Do you believe the current pharmacist to pharmacy technician ratio in the institutional setting (currently 1:2) is appropriate?



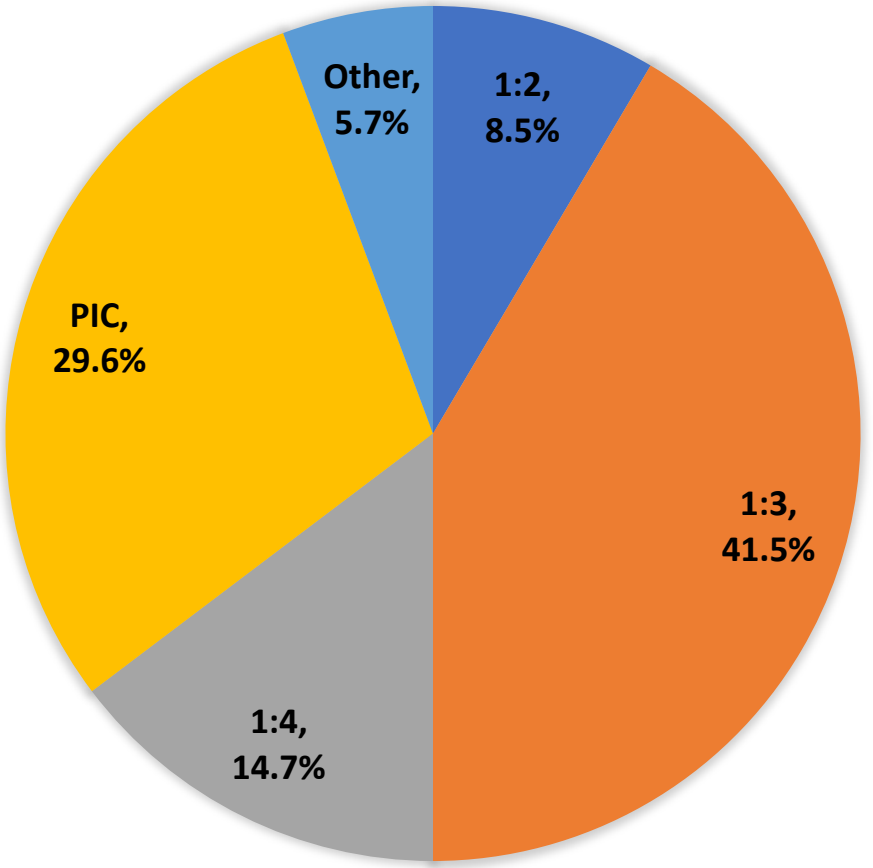
Are you in a management or administrative position for your employer (yes n=1,001)
and
Do you believe the current pharmacist to pharmacy technician ratio in the non-institutional setting (currently 1:1) is appropriate?



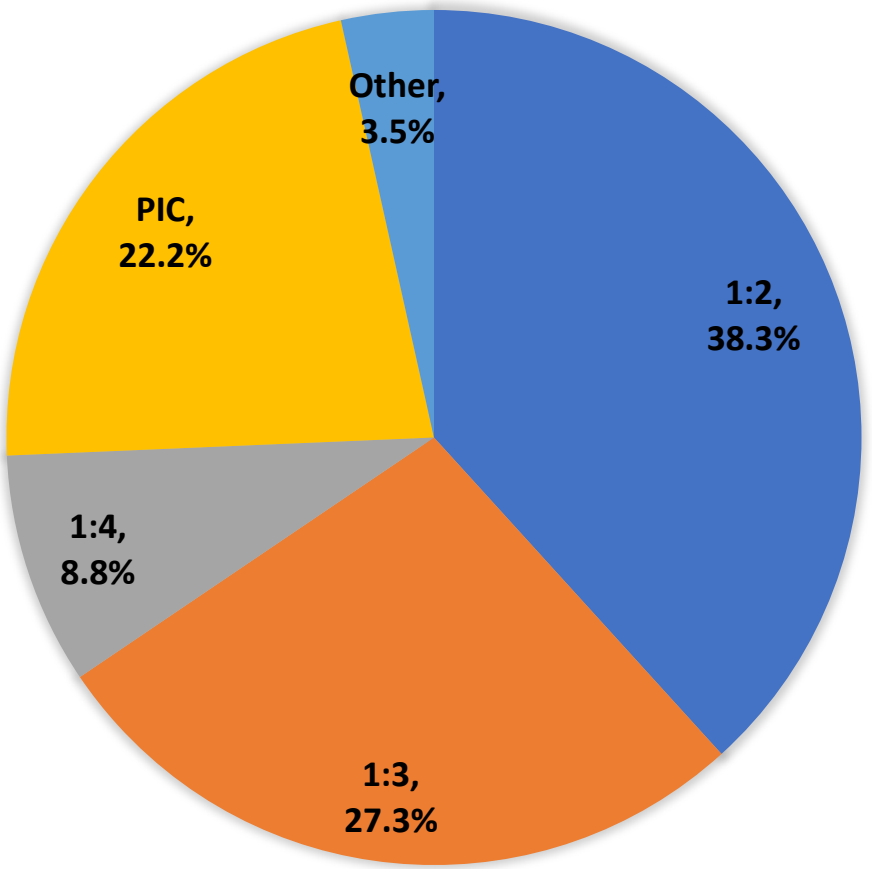
Are you in a management or administrative position for your employer (yes n=648)

and

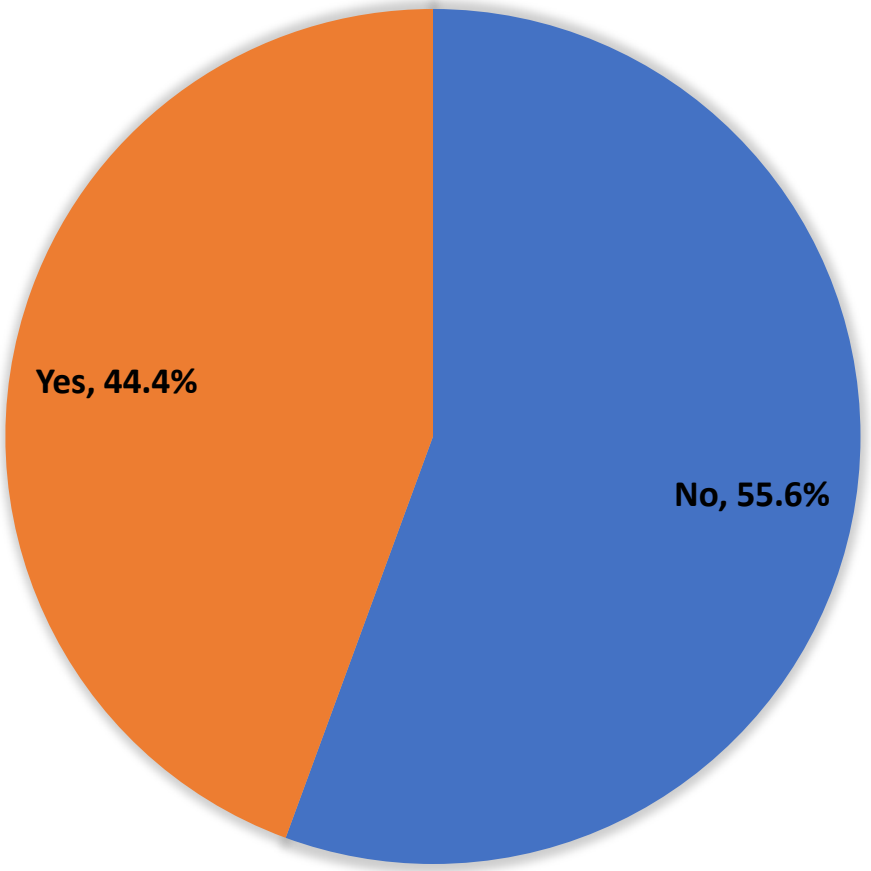
What is the appropriate ratio in an institutional setting. (Must have said 1:2 is not appropriate)



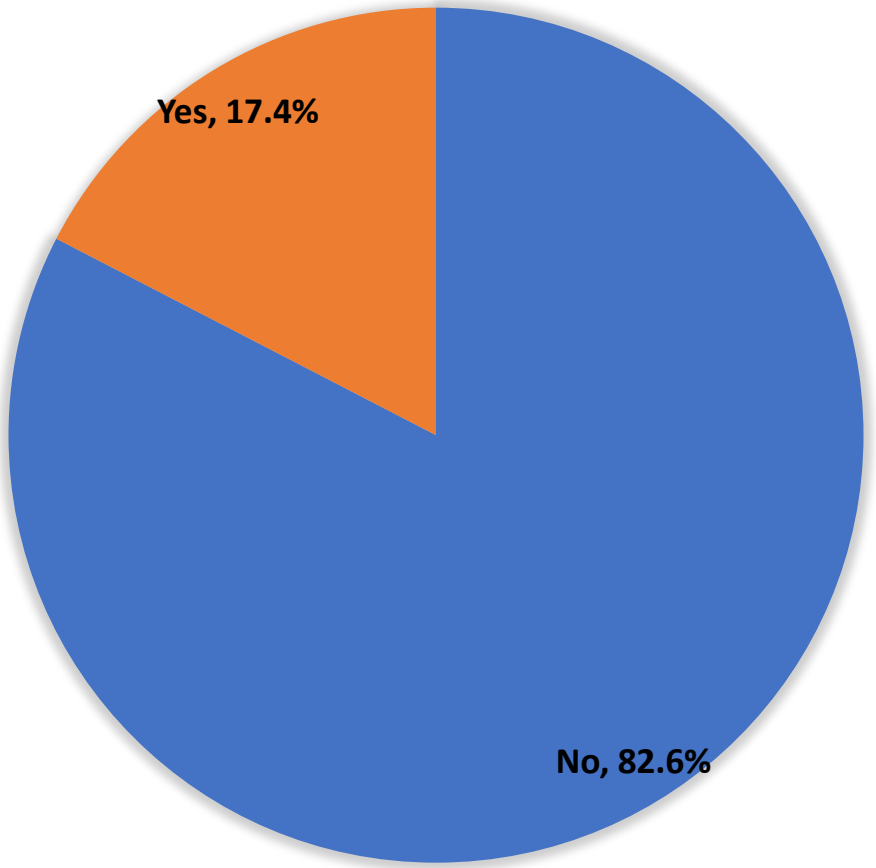
Are you in a management or administrative position for your employer (yes n=866)
and
What is the appropriate ratio in an non-institutional setting.
(Must have said 1:1 is not appropriate)



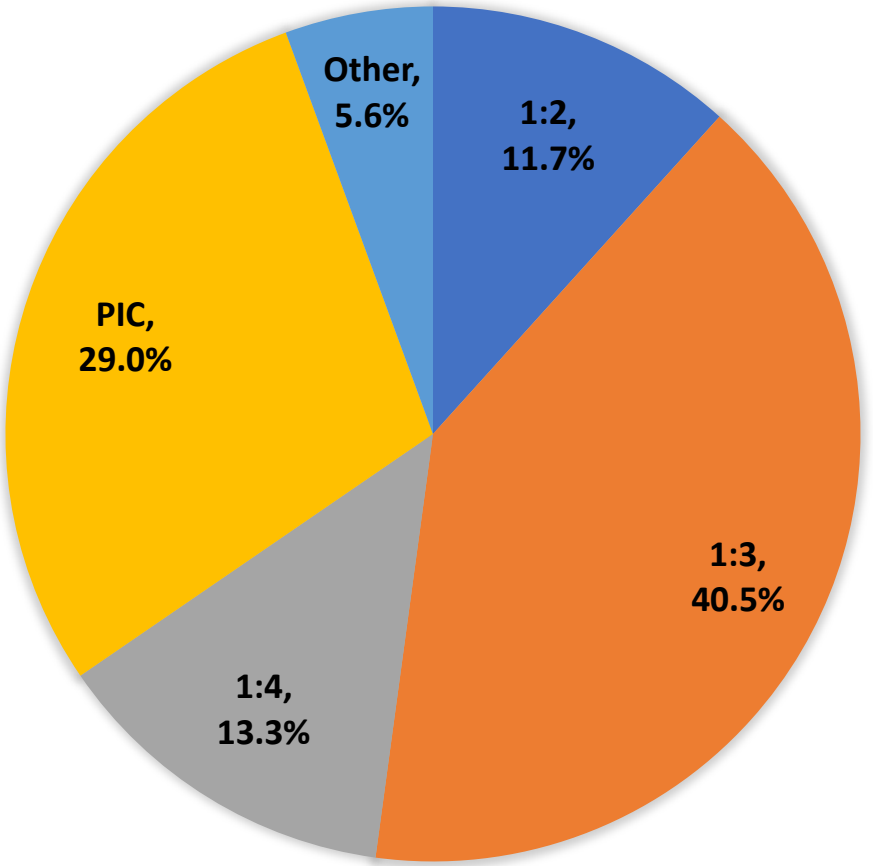
Are you the designated PIC at your primary worksite?
(yes n=1,393)
and
Do you believe the current pharmacist to pharmacy technician ratio in the institutional setting (currently 1:2) is appropriate



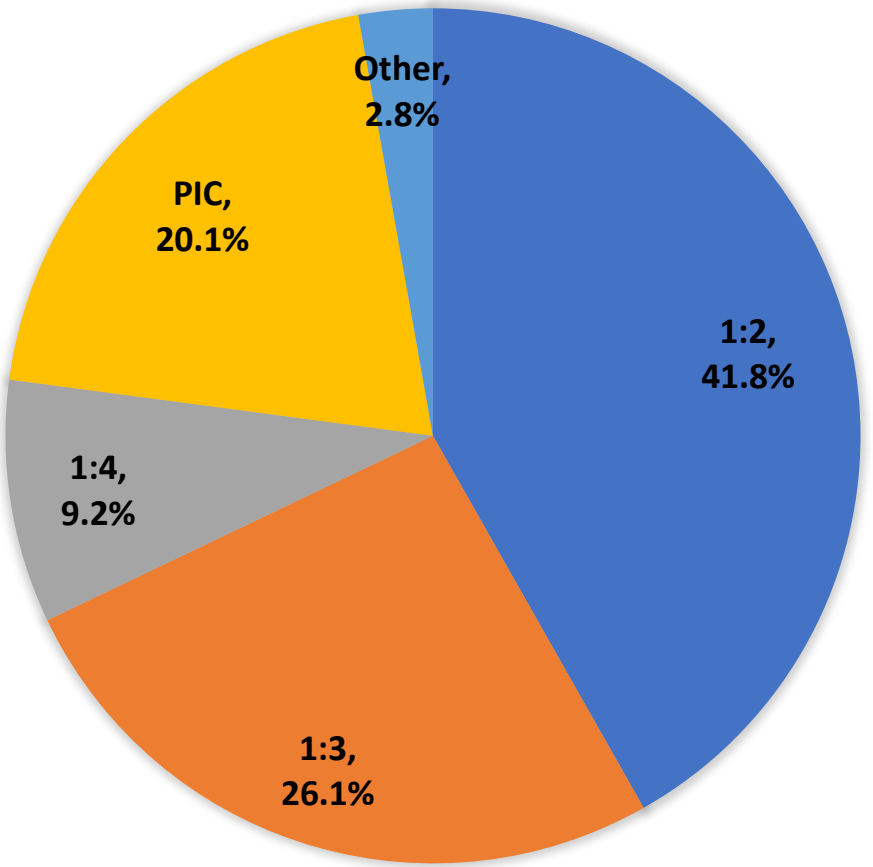
Are you the designated PIC at your primary worksite?
(yes n=1,403)
and
Do you believe the current pharmacist to pharmacy technician ratio in a non-institutional setting (currently 1:1) is appropriate?



Are you the designated PIC at your primary worksite? (yes n=880) and What is the appropriate ratio in an institutional setting. (must have said 1:2 is not appropriate)



Are you the designated PIC at your primary worksite? (yes n=1,200) and What is the appropriate ratio in an non-institutional setting. (must have said 1:1 is not appropriate)



Attachment 4

Proposed Amendments Related to Retired Pharmacist License

Business and Professions Code Section 4200.5 is amended as follows:
4200.5.

(a) The board shall issue, upon application and payment of the fee established by Section 4400, a retired license to a pharmacist who has been licensed by the board. The board shall not issue a retired license to a pharmacist whose license has been revoked.

(b) The holder of a retired license issued pursuant to this section shall not engage in any activity for which an active pharmacist's license is required. A pharmacist holding a retired license shall be permitted to use the titles "retired pharmacist" or "pharmacist, retired."

(c) The holder of a retired license shall not be required to renew that license.

(d) The holder of a retired license may request to restore their pharmacist license to active status within three years of issuance of the retired license. Such a request must be accompanied by the renewal fee established by Section 4400(e) and demonstration that, within the two years preceding the request for restoration, the pharmacist has successfully completed continuing education consistent with the requirements set forth in Section 4231(b).

(e) If more than three years have elapsed since the issuance of the retired license, ~~I~~in order for the holder of a retired license issued pursuant to this section to restore their ~~his or her~~ license to active status, they~~he or she~~ shall be required to reapply for licensure as a pharmacist as consistent with the provisions of 4200. ~~pass the examination that is required for initial licensure with the board.~~

Attachment 5

ARTICLE 7. Pharmacies [4110 - 4126.10]
(Article 7 added by Stats. 1996, Ch. 890, Sec. 3.)

4115.
(a) A pharmacy technician may perform packaging, manipulative, repetitive, or other nondiscretionary tasks only while assisting, and while under the direct supervision and control of, a pharmacist. The pharmacist shall be responsible for the duties performed under their supervision by a technician.

(b) (1) In addition to the tasks specified in subdivision (a) a pharmacy technician may, under the direct supervision and control of a pharmacist, prepare and administer influenza and COVID-19 vaccines via injection or intranasally, prepare and administer epinephrine, perform specimen collection for tests that are classified as waived under CLIA, receive prescription transfers, and accept clarification on prescriptions under the following conditions:

(A) The pharmacy has scheduled another pharmacy technician to assist the pharmacist by performing the tasks provided in subdivision (a).

(B) The pharmacy technician is certified pursuant to paragraph (4) of subdivision (a) of Section 4202 and maintains that certification.

(C) The pharmacy technician has successfully completed at least six hours of practical training approved by the Accreditation Council for Pharmacy Education and includes hands-on injection technique, the recognition and treatment of emergency reactions to vaccines, and an assessment of the pharmacy technician's injection technique.

(D) The pharmacy technician is certified in basic life support.

(2) "CLIA" means the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a; Public Law 100-578).

(c) This section does not authorize the performance of any tasks specified in subdivisions (a) and (b) by a pharmacy technician without a pharmacist on duty.

(d) This section does not authorize a pharmacy technician to perform any act requiring the exercise of professional judgment by a pharmacist.

(e) The board shall adopt regulations to specify tasks pursuant to subdivision (a) that a pharmacy technician may perform under the supervision of a pharmacist. Any pharmacy that employs a pharmacy technician shall do so in conformity with the regulations adopted by the board.

(f) A person shall not act as a pharmacy technician without first being licensed by the board as a pharmacy technician.

(g) (1) A pharmacy with only one pharmacist shall have no more than one pharmacy technician performing the tasks specified in subdivision (a). A pharmacy with only one pharmacist shall have no more than one pharmacy technician performing the tasks

specified in subdivision (b). If a pharmacy technician is performing the tasks specified in subdivision (b), a second pharmacy technician shall be assisting a pharmacist with performing tasks specified in subdivision (a). The ratio of pharmacy technicians performing the tasks specified in subdivision (a) to any additional pharmacist shall not exceed 2:1, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117. This ratio is applicable to all practice settings, except for an inpatient of a licensed health facility, a patient of a licensed home health agency, as specified in paragraph (2), an inmate of a correctional facility of the Department of Corrections and Rehabilitation, and for a person receiving treatment in a facility operated by the State Department of State Hospitals, the State Department of Developmental Services, or the Department of Veterans Affairs.

(2) The board may adopt regulations establishing the ratio of pharmacy technicians performing the tasks specified in subdivision (a) to pharmacists applicable to the filling of prescriptions of an inpatient of a licensed health facility and for a patient of a licensed home health agency. Any ratio established by the board pursuant to this subdivision shall allow, at a minimum, at least one pharmacy technician for a single pharmacist in a pharmacy and two pharmacy technicians for each additional pharmacist, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117.

(3) A pharmacist scheduled to supervise a second pharmacy technician may refuse to supervise a second pharmacy technician if the pharmacist determines, in the exercise of their professional judgment, that permitting the second pharmacy technician to be on duty would interfere with the effective performance of the pharmacist's responsibilities under this chapter. A pharmacist assigned to supervise a second pharmacy technician shall notify the pharmacist-in-charge in writing of their determination, specifying the circumstances of concern with respect to the pharmacy or the pharmacy technician that have led to the determination, within a reasonable period, but not to exceed 24 hours, after the posting of the relevant schedule. An entity employing a pharmacist shall not discharge, discipline, or otherwise discriminate against any pharmacist in the terms and conditions of employment for exercising or attempting to exercise in good faith the right established pursuant to this paragraph.

(h) Notwithstanding subdivisions (a) to (c), inclusive, the board shall by regulation establish conditions to permit the temporary absence of a pharmacist for breaks and lunch periods pursuant to Section 512 of the Labor Code and the orders of the Industrial Welfare Commission without closing the pharmacy. During these temporary absences, a pharmacy technician may, at the discretion of the pharmacist, remain in the pharmacy but may only perform nondiscretionary tasks. The pharmacist shall be responsible for a pharmacy technician and shall review any task performed by a pharmacy technician during the pharmacist's temporary absence. This subdivision shall not be construed to authorize a pharmacist to supervise pharmacy technicians in greater ratios than those described in subdivision (g).

(i) The pharmacist on duty shall be directly responsible for the conduct of a pharmacy technician supervised by that pharmacist.

(j) In a health care facility licensed under subdivision (a) of Section 1250 of the Health and Safety Code, a pharmacy technician's duties may include any of the following:

(1) Packaging emergency supplies for use in the health care facility and the hospital's emergency medical system or as authorized under Section 4119.

(2) Sealing emergency containers for use in the health care facility.

(3) Performing monthly checks of the drug supplies stored throughout the health care facility. Irregularities shall be reported within 24 hours to the pharmacist-in-charge and the director or chief executive officer of the health care facility in accordance with the health care facility's policies and procedures.

(k) Notwithstanding the definition of a pharmacy technician in 4038(a), a pharmacy technician may, outside of a licensed pharmacy, perform compounding activities only under the direct supervision and control of a pharmacist. The board shall be notified in writing by the supervising pharmacist of the location where such compounding activities occur.

Attachment 6

CENTRAL FILL PHARMACIES

JULY 2024

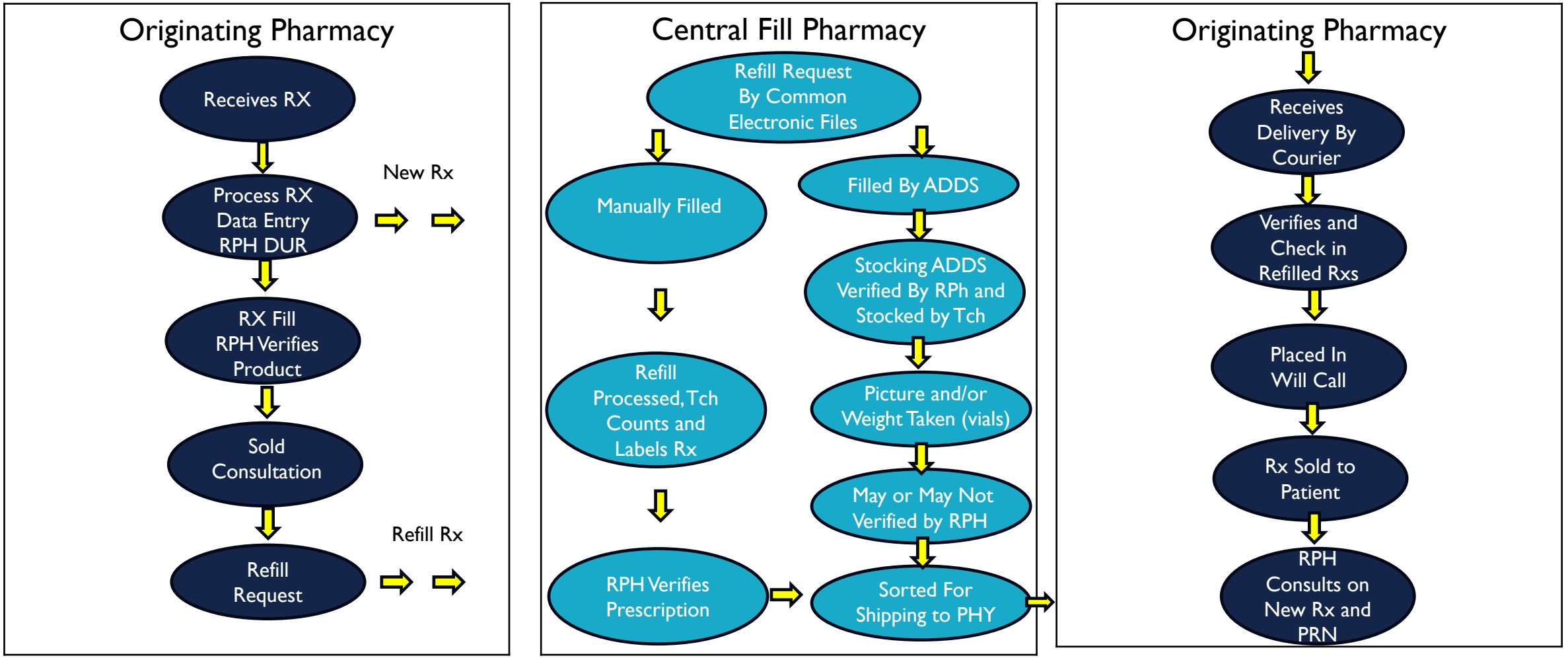
CALIFORNIA STATE BOARD OF PHARMACY

CURRENT PHARMACY LAW

CCR 1707.4 – Procedures for Refill Pharmacies

- (a) Pharmacy licensed by the board may process a request for refill of a prescription received by a pharmacy within this state
  - (1) The pharmacy that is to refill the prescription either has a contract with the pharmacy which received the prescription or has the same owner as the other pharmacy
  - (2) The prescription container
    - is clearly labeled with all information required by BPC 4076.
    - Clearly shows the name and address of the pharmacy filling the prescription and/or the name and address of the pharmacy which receives the refilled prescription for dispensing to the patient
  - (3) The patient is provided with written information, either on the prescription label or with the prescription container, that describes which pharmacy to contact if the patient has any questions about the prescription or medication.
  - (4) Both pharmacies maintain complete and accurate records of the refill.
    - Name of the pharmacist who refilled the prescription.
    - Name of the pharmacy refilling the prescription.
    - The name of the pharmacy that received the refill request.
  - (5) The pharmacy which refills the prescription and the pharmacy to which the refilled prescription is provided for dispensing to the patient shall each be responsible for ensuring the order has been properly filled.
  - (6) The originating pharmacy is responsible for the compliance with the requirements set forth in CCR 1707.1, 1707.2 and 1707.3.
- (b) Nothing in this section shall be construed as barring a pharmacy from also filling new prescriptions presented by a patient or a patient's agent or transmitted to it by a prescriber.

General Overview



CENTRAL FILL PHARMACIES INSPECTED

Central Fill Pharmacies in California
2 – Northern California
1 – Central California
3 - Southern California

Type of Central Fill Pharmacy
3 – Serviced Community Pharmacies
1 – Serviced Correctional Facility Pharmacies
2 - Serviced Long Term Care Pharmacies

GENERAL INFORMATION

	Community Pharmacy	Specialty & Correctional Facility Pharmacy	LTC Pharmacy
LOCATION OF ORIGINATING PHARMACY (IN STATE, OUT OF STATE)	• CA and Licensed in Other States	• CA only	• CA and Other State
AVERAGED # OF PRESCRIPTIONS DISPENSED	• 10,000 – 13,000 Rxs/Day	• Rxs/Day • 7000 Rx/Week or 1000 Rx/Day	• Services prescriptions for 60 - 300 facilities. 1400 – 3000 Rxs/Day
# OF DAYS IN OPERATION	• 6 – 7 days/week	• 5 – 6 days/week	• 24 hours / 7 days
TYPE OF FILL (NEW, REFILL)	• New, Refills	• New, Refills	• Refills for cycles

STAFFING

	Community Pharmacy	Specialty & Correctional Facility Pharmacy	LTC Pharmacy
# OF PHARMACISTS (AVERAGE OR DURING INSPECTION)	• 5-10 RPH/Day	• 5 – 10 RPH/Day	• 5 - 6 During Inspection
# OF PHARMACY TECHNICIANS (AVERAGE OR DURING INSPECTION)	• 8 - 20 TCH/Day	• 11 – 21 TCH/Day	• 8 - 9 During Inspection

FULFILLMENT PROCESS

	Community Pharmacy	Specialty & Correctional Facility Pharmacy	LTC Pharmacy
TYPE OF PACKAGING / CONTAINER USED	• Vials	• Vials and original manufacture container • Bubble Cards / Strip Packs	• Bubble Cards, Strip Packs
HOW INVENTORY IS ACQUIRED	• Drug Wholesaler	• Wholesalers and Pharmacies • FDA Repackager	• Wholesalers and Repackager
TYPE OF MEDICATIONS DISPENSED	• Noncontrolled substance tablets and capsules; inhalers, creams, ointments, birth control. No specialty and pet only drugs.	• Slow moving expensive drugs • Noncontrolled substance tablets and capsules.	• Noncontrolled substances; controlled substances; ointments, creams, birth control; no specialty drugs.
ARE CONTROLLED SUBSTANCES DISPENSED	• No	• No	• Yes
ARE REFRIGERATED DRUGS DISPENSED	• Depended on the pharmacy	• No	• Yes

TYPE OF DISPENSING PROCESSES USED IN CENTRAL FILL PHARMACIES

TYPE OF ADDS:	DESCRIPTION:	EXAMPLES:
Manual Dispensing	Counts tablets only	Kirby Lester
ADDS Cabinet Style	Automated dispensing built as a cabinet housing canisters of drugs. Counts and Labels Prescription Container	Yuyama ScriptPro Parata
ADDS Modular Style	Automated dispensing with use of robotic arm to fill vials and bubble cards	IA Smart (Vials OnDemand Omnicell TCGRx (bubble cards)

FULLFILLMENT PROCESS (CONTINUE)

	Community Pharmacy	Specialty & Correctional Facility Pharmacy	LTC Pharmacy
METHOD(S) OF DISPENSING (ADDS, MANUAL)	• ADDS, Manual	• ADDS, Manual • ADDS for bubble card and Strip Pack (unit dose packaging, non-patient specific)	• ADDS, Manual
TYPE OF TECHNOLOGY USED	• Parata Uber, Parata Express, Kalish, Arxium, Kirby Lester for manual fill	• Parata Max 2; Kirby Lester for manual • Bubble Cards from FDA repackager electronically selected and labeled. Hopper manually restocked and barcode scanned for location. Non-patient strip packs are manually selected and provided to pharmacies.	• TCRx multi-dose packager, Auto Label Verify (ALV), OnDemand Express II, Parata
MAINTENANCE OF ADDS	• Chutes are cleaned monthly and between canister fills; canisters cleaning varies depending on amount of dust build up.	• Weekly maintenance cleaning • Minimal maintenance due to drugs already prepackaged	• Monthly and when replenished and as needed due to powder build up
TRACKING MECHANISM	• Puck with RFID computer chip • Barcode scanning of vial	• Barcode	• Barcode

FULLFILLMENT PROCESS (CONTINUE)

	Community Pharmacy	Specialty & Correctional Facility Pharmacy	LTC Pharmacy
RESTOCKING PROCESS: PHARMACIST INVOLVEMENT	• Yes, Pharmacist verify manufacturer bottles prior to restocking canister	• Yes, Pharmacist verifies prior to restocking the ADDS. • Yes, pharmacist will verify bubble card received from FDA repackager, but not before restocking into the hopper.	• Pharmacist verify manufacture bottle prior to tch restocking the On Demand Express TCGRx Omnicell.
RESTOCKING PROCESS: PHARMACY TECHNICIAN INVOLVEMENT	• Yes, selects and scans barcodes on drug product containers and restocks the canister after pharmacist verification.	• Yes, tch scans and replenish canisters • Yes, will scan repackager barcode prior to restocking into the hopper.	• Tech scans and replenish canisters
RESTOCKING PROCESS: LABELING OF CANISTERS	• Label with drug name and RFID chip.	• Label with drug name and barcode. • Bubble cards – NA	• Canister labeled with drug name and barcode.

FULLFILLMENT PROCESS (CONTINUE)

	Community Pharmacy	Specialty &Correctional Facility Pharmacy	LTC Pharmacy
PRESCRIPTION LABEL: WHICH PHARMACY'S INFORMATION IS PRINTED	• Both, originating and Central Fill Pharmacy info • Originating pharmacy info only	• Originating pharmacy • Both, Central Fill Pharmacy and FDA Repackager information.	• Central Fill Pharmacy info
PICTURES TAKEN (LABEL, CONTENTS)	• Yes, picture of drug in vial and compares to a library of pictures of drugs.	• No	• No
WEIGHT TAKEN (DRUG, CONTAINER, PAPERWORK, MAILER, ETC)	• Yes, weighed at the end; includes total weight of vial + drug and compared to expected weight	• No	• No
PHARMACIST PERFORMS FINAL CHECK	• Yes, after pictures and weight is taken.	• Yes • Final verification only when bubble card is rejected if misfilled or unable to read prescription label.	• All cards prior to rx labeling are 100% verified. When rx label is placed on bubble card only 2% verified; All unit of use drug products 100% verified.
WHICH PHARMACIST IS LISTED AS DISPENSING THE PRESCRIPTION	• Pharmacist performing final product verification reviewing pictures to actual drug dispensed.	• Pharmacist doing the physical verification • The pharmacist scheduled as the dispensing pharmacist for the day.	• Pharmacists assigned to the reviewing station who reviews the 2% is responsible for all cards; Manual fills are physically verified by pharmacist.

PACKAGING AND SHIPPING

	Community Pharmacy	Specialty & Correctional Facility Pharmacy	LTC Pharmacy
SORTING METHOD	• Manually, Rx vial and paperwork goes into a plastic bag that is barcoded, scanned and placed in a tote for the originating pharmacy.	• Scan barcode then placed in bins by originating pharmacy. • Barcode on label is read electronically and directed to the tote of the originating pharmacy.	• Tch scans barcode to determine which tote to place bubble care.
TYPE OF CONTAINER / PACKAGING USED FOR TRANSPORTATION	• In totes for each originating pharmacy.	• Mailer bags • Sealed totes	• Canvas security bags • Totes
TYPE OF COURIER USED TO DELIVER TO ORIGINATING PHARMACY	• Wholesaler is contracted to pick up and deliver to each originating pharmacy.	• Mailed USPS to Originating Pharmacy • Contracted wholesaler drivers.	• Direct facility accounts: Central Fill Pharmacy drivers deliver directly to each facility. Facility accounts for other originating pharmacies: Central Fill Pharmacy drivers delivers to the Originating pharmacy. Originating pharmacy drivers delivers to facilities.
TRACKING METHOD FOR DELIVERY	• Barcode scanned	• Barcode scanned	• Barcode scanned

RECEIVING AT ORIGINATING PHARMACY

	Community Pharmacy	Specialty & Correctional Facility Pharmacy	LTC Pharmacy
METHOD OF CHECKING PRESCRIPTIONS DELIVERED	• Originating pharmacy scans barcodes on each bag to confirm delivery.	• Pharmacy scans as received and placed in will call area. • Drivers compare manifest from central fill pharmacy, then pharmacists counts # of totes received to # of totes shipped; Originating pharmacy will scan each bubble card.	• Direct facility accounts: Driver receives delivery and facility signs for delivery. • Facility accounts for other originating pharmacy: Driver receives delivery from central fill pharmacy, delivers to originating pharmacy then scans as received. Barcode is scanned at the originating pharmacy and at each facility.

HANDLING OF MEDICATION ERRORS

	Community Pharmacy	Specialty & Correctional Facility Pharmacy	LTC Pharmacy
TYPE OF MED ERRORS	• Wrong quantity; Wrong drug, Shipping Errors	• Mailing issues sending to wrong originating pharmacy • None	• Wrong quantity in bubbles and broken tablets.
HOW IS THE CENTRAL FILL PHARMACY NOTIFIED OF A MED ERROR?	• Originating pharmacy, patient or call center contacts the central fill pharmacy.	• From Originating pharmacy.	• From Originating pharmacy or Facility notifies Central Fill Pharmacy
WHO IS RESPONSIBLE FOR CORRECTING THE MED ERROR?	• Originating pharmacy.	• Originating pharmacy; if central fill related originating pharmacy will notify central fill pharmacy. • Originating pharmacy.	• Originating Pharmacy
WHO IS RESPONSIBLE FOR DOCUMENTING THE MED ERROR REPORT?	• Originating pharmacy initiates the QA report; both PICs work to investigate.	• Central Fill Pharmacy PIC,	• PIC at Central Fill Pharmacy
WHO IS RESPONSIBLE FOR REPORTING AN ADDS MED ERROR TO THE BOP?	• PIC submits QA report to Pharmacy's Compliance Team who will review and submit to the Board. Unlicensed ADDS reports annually.	• PIC at Central Fill if central fill pharmacy related. Education provided to submit annually with renewal	• PIC at Central Fill Pharmacy. Education provided to submit annually for unlicensed ADDS

THANK YOU

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Attachment 7

DEPARTMENT OF CONSUMER AFFAIRS
Title 16. Board of Pharmacy

PROPOSED REGULATORY LANGUAGE
Central Fill Pharmacies

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

Amend Section 1707.4 to Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1707.4. Procedures for ~~Refill~~ Central Fill Pharmacies.

(a) A central fill pharmacy located in California and licensed by the B~~b~~oard may process a request for ~~refill of a~~ prescription medication received by ~~a~~ another pharmacy within this state, provided:
(1) The pharmacy that is to ~~re~~fill the ~~prescription~~ medication either has a contract with the pharmacy which received the prescription or has the same owner as the other pharmacy.
(2) The prescription container:
(A) is clearly labeled with all information required by S~~s~~ections 4076 and 4076.5 of the Business and Professions Code; and
(B) as applicable, clearly shows the name and address of the pharmacy ~~re~~filling the ~~prescription~~ medication ~~and/~~or the name and address of the pharmacy which receives the ~~refilled prescription~~ medication to dispense to the patient. Nothing in this subsection should be interpreted as preventing inclusion of the name and address of both pharmacies.
(3) The patient is provided with written information indicating that the prescription may be filled at a central fill pharmacy, and written information, either on the prescription label or with the prescription container, that describes which pharmacy to contact if the patient has any questions about the prescription or medication.
(4) Both pharmacies maintain complete and accurate records ~~of the refill~~, including:
(A) the name of the pharmacist who ~~re~~filled the prescription;
(B) the name of the pharmacy ~~re~~filling the prescription; and
(C) the name of the pharmacy that received the prescription ~~refill request~~.
(5) The pharmacy which ~~re~~fills the prescription and the pharmacy to which the ~~refilled~~ prescription is provided for dispensing to the patient shall each be responsible for ensuring the order has been properly filled. Pharmacists working at the originating pharmacy ~~must~~ may perform final product verification prior to

dispensing, ~~which may~~ includ~~ing throughe~~ review of photographs of the final product in lieu of physical visual verification. A pharmacist shall not be required to perform final product verification where product verification by a pharmacist is performed at the time of stocking the automated dispensing device, if the dispensing device is not further accessed by pharmacy personnel.

(6) The originating pharmacy is responsible for compliance with the requirements set forth in ~~S~~sections 1707.1, 1707.2, and 1707.3 of the California Code of Regulations.

~~(b) Nothing in this section shall be construed as barring a pharmacy from also filling new prescriptions presented by a patient or a patient's agent or transmitted to it by a prescriber.~~

(b) For purposes of this section, a central fill pharmacy is defined as a California-licensed pharmacy that, pursuant to a contract or on behalf of a pharmacy under common ownership, prepares and packages prescriptions for another pharmacy to dispense to the patient.

Credits

NOTE: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4063, 4076, 4076.5, 4081, and 4333, Business and Professions Code.

Attachment 8

Proposal to Amend BPC 4112 As Follows:

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) 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, 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 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 <u>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 California patients under any of the following conditions</u>:

(<u>1</u>) <u>The pharmacist's</u> ~~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~~.

(2) The pharmacist is not licensed in California and has not successfully passed the North American Pharmacist Licensure Examination or the Multi-state Jurisprudence Examination.

(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) A nonresident pharmacy licensed pursuant to this section shall be subject to inspection by the board as a condition of renewal once every four years, unless the board determines more frequent inspections are necessary. In addition to paying the fees established in Section 4400, the nonresident pharmacy shall deposit, when notified by the board, a reasonable amount, as determined by the board, necessary to cover the board's estimated costs of performing the inspection. If the required deposit is not received or if the actual costs of the inspection exceed the amount deposited, the board shall issue an invoice for the remaining amount and shall not take action on the renewal application until the full amount has been paid to the board. If the amount deposited exceeds the amount of actual and necessary costs incurred, the board shall remit the difference to the applicant.

(l) Nothing in this section shall be construed to authorize the dispensing of contact lenses by nonresident pharmacists except as provided by Section 4124.

Attachment 9

Proposal to Amend Business and Professions Code Section 4052.

(a) Notwithstanding any other law, a pharmacist may do all of the following:

(1) Furnish a reasonable quantity of compounded drug product to a prescriber for office use by the prescriber.

(2) Transmit a valid prescription to another pharmacist.

(3) Administer drugs and biological products that have been ordered by a prescriber.

(4) ~~Perform procedures or functions in a licensed health care facility as authorized by Section 4052.1~~. Initiate and perform routine patient assessment procedures including skin puncture and clinical laboratory tests that are classified as waived pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (42 (U.S.C. Sec. 263a) and the regulations adopted thereunder by the federal Health Care Financing Administration as authorized by section 12 06.5 or section 12 06. 6. A pharmacist exercising these authorities must do so in collaboration with a patient's primary care provider or diagnosing prescriber, if applicable.

~~(5) Perform procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, as authorized by Section 4052.2.~~ Upon patient consent, perform therapeutic interchanges unless the prescriber has indicated "Do not substitute" "Do not alter" or similar words. Such interchanges include use of biosimilars, different dosage forms, drugs within the same drug classification, and generic substitutions intended to optimize patient care.

(6) Perform procedures or functions as authorized by Section 4052.6.

(7) Manufacture, measure, fit to the patient, or sell and repair dangerous devices, or furnish instructions to the patient or the patient's representative concerning the use of those devices.

(8) ~~Provide consultation, training, and education to patients about drug therapy, disease management, and disease prevention~~. Prescribe over-the-counter medications if requested.

(9) Provide professional information, including clinical or pharmacological information, advice, or consultation to patients and ~~other~~ health care professionals, and participate in multidisciplinary review of patient progress, including appropriate access to medical records.

(10) Furnish an FDA approved or authorized medications that is preventative or does not require a diagnosis. The pharmacist shall notify the patient's primary care provider of any drugs or devices furnished to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by that primary care provider. If the patient does not have a primary care

provider, the pharmacist shall provide the patient with a written record of the drugs or devices furnished and advise the patient to consult a physician of the patient's choice. This section shall not allow a pharmacist to furnish a medication for off-label use.

(11) Furnish an FDA approved or authorized noncontrolled medication for the treatment of conditions that

(a) are minor, non-chronic health conditions

(b) or for which a CLIA waived test provides diagnosis and the treatment is limited in duration.

The pharmacist shall notify the patient's primary care provider of any drugs or devices furnished to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by that primary care provider. If the patient does not have a primary care provider, the pharmacist shall provide the patient with a written record of the drugs or devices furnished and advise the patient to consult a primary care provider. This section shall not allow a pharmacist to furnish a medication for off-label use.

(12) Order and interpret drug therapy related tests. ~~tests for the purpose, monitoring and managing the efficacy and toxicity of drug therapies.~~ A pharmacist who orders and interprets tests pursuant to this paragraph shall ensure that the ordering of those tests is done in coordination with the patient's primary care provider or diagnosing prescriber, as appropriate, including promptly transmitting written notification to the patient's diagnosing prescriber or entering the appropriate information in a patient record system shared with the prescriber, when available and as permitted by that prescriber.

(13) Initiate, adjust, or discontinue drug therapy for a patient under any of the following:

(A) A collaborative practice agreement with any health care provider with prescriptive authority. The collaborative practice agreement may be between a single or multiple pharmacists and a single or multiple health care providers with prescriptive authority.

(B) Pursuant to an order or authorization made by the patient's prescriber and in accordance with the policies, procedures, or protocols of the entity providing health care services unless a patient's treating prescriber otherwise prohibits such action.

(14) Provide medication used to treat substance use disorder~~-assisted treatment pursuant to a state protocol,~~ to the extent authorized by federal law.

(15) Complete missing information on a prescription for a noncontrolled medication if there is evidence to support the change.

(16) Initiate and administer any FDA approved or authorized immunization for persons three years of age and older.

(17) Adjust prescription treatment drug regime consistent with medication therapy management reviews for chronic conditions. A pharmacist exercising these authorities must do so in collaboration with a patient's primary care provider or diagnosing prescriber, if applicable.

(b) A pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy pursuant to this section shall personally register with the federal Drug Enforcement Administration.

(c) This section does not affect the applicable requirements of law relating to either of the following:

(1) Maintaining the confidentiality of medical records.

(2) The licensing of a health care facility.

(d) Nothing in this section shall be construed as establishing an obligation on a pharmacist to perform or provide a service or function authorized by subdivision (a) where the pharmacist has made a professional determination that (1) they lack sufficient education, training, or expertise, or access to sufficient patient medical information, to perform such service or function properly or safely; or (2) performing or providing such service or function would place a patient at risk.

Amend BPC 4050 as follows:

(a) In recognition of and consistent with the decisions of the appellate courts of this state, the Legislature hereby declares the practice of pharmacy to be a profession.

(b) ~~Pharmacy~~ Pharmacist practice is a dynamic, patient-oriented health service that applies a scientific body of knowledge to improve and promote patient health by means of patient-care activities to optimize appropriate drug use, drug-related therapy, disease management and prevention, and communication for clinical and consultative purposes. ~~Pharmacy~~ Pharmacist practice is continually evolving to include more sophisticated and comprehensive patient care activities.

(c) The Legislature further declares that pharmacists are health care providers who have the authority to provide health care services.

Amend BPC 4051 as follows:

(a) Except as otherwise provided in this chapter, it is unlawful for any person to manufacture, compound, furnish, sell, or dispense a dangerous drug or dangerous device, or to dispense or compound a prescription pursuant to Section 4040 of a prescriber unless he or she is a pharmacist under this chapter.

(b) Notwithstanding any other law, a pharmacist may authorize the initiation of a prescription, pursuant to Section 4052~~.1, 4052.2, 4052.3, or 4052.6,~~ and otherwise provide clinical advice, services, information, or patient consultation, as set forth in this chapter, if all of the following conditions are met:

(1) The clinical advice, services, information, or patient consultation is provided to a health care professional or to a patient or patient's agent.

(2) The pharmacist has access to prescription, patient profile, or other relevant medical information for purposes of patient and clinical consultation and advice.

(3) Access to the information described in paragraph (2) is secure from unauthorized access and use.

Amend BPC 4036 as follows:

4036. Pharmacist "Pharmacist" means a natural person to whom a license has been issued by the board, under Section 4200, except as specifically provided otherwise in this chapter. The holder of an unexpired and active pharmacist license issued by the board is entitled to practice pharmacy as defined by this chapter, within or outside of a licensed pharmacy ~~as authorized by this chapter~~.

Amend BPC 4040 as follows:
(a) "Prescription" means an oral, written, or electronic transmission order that is both of the following:

(1) Given individually for the person or persons for whom ordered that includes all of the following:

(A) The name or names and address of the patient or patients.

(B) The name and quantity of the drug or device prescribed and the directions for use.

(C) The date of issue.

(D) Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, the prescriber's license classification, and the prescriber's federal registry number, if a controlled substance is prescribed.

(E) A legible, clear notice of the condition or purpose for which the drug is being prescribed, if requested by the patient or patients.

(F) If in writing, signed by the prescriber issuing the order, or the certified nurse-midwife, nurse practitioner, physician assistant, or naturopathic doctor who issues a drug order pursuant to Section 2746.51, 2836.1, 3502.1, or 3640.5, respectively, or

the pharmacist who issues a drug order ~~pursuant to Section 4052.1, 4052.2, or 4052.6~~.

(2) Issued by a physician, dentist, optometrist, doctor of podiatric medicine, veterinarian, or naturopathic doctor pursuant to Section 3640.7 or, if a drug order is issued pursuant to Section 2746.51, 2836.1, 3502.1, or 3460.5, by a certified nurse-midwife, nurse practitioner, physician assistant, pharmacist, or naturopathic doctor licensed in this state~~, or pursuant to Section 4052.1, 4052.2, or 4052.6 by a pharmacist~~ licensed in this state.

(b) Notwithstanding subdivision (a), a written order of the prescriber for a dangerous drug, except for any Schedule II controlled substance, that contains at least the name and signature of the prescriber, the name and address of the patient in a manner consistent with paragraph (2) of subdivision (a) of Section 11164 of the Health and Safety Code, the name and quantity of the drug prescribed, directions for use, and the date of issue may be treated as a prescription by the dispensing pharmacist as long as any additional information required by subdivision (a) is readily retrievable in the pharmacy. In the event of a conflict between this subdivision and Section 11164 of the Health and Safety Code, Section 11164 of the Health and Safety Code shall prevail.

(c) "Electronic transmission prescription" includes both image and data prescriptions. "Electronic image transmission prescription" means any prescription order for which a facsimile of the order is received by a pharmacy from a licensed prescriber. "Electronic data transmission prescription" means any prescription order, other than an electronic image transmission prescription, that is electronically transmitted from a licensed prescriber to a pharmacy.

(d) The use of commonly used abbreviations shall not invalidate an otherwise valid prescription.

~~4052.01.~~

~~—~~

~~(a) Notwithstanding any other provision of law, a pharmacist may furnish naloxone hydrochloride in accordance with standardized procedures or protocols developed and approved by both the board and the Medical Board of California, in consultation with the California Society of Addiction Medicine, the California Pharmacists Association, and other appropriate entities. In developing those standardized procedures or protocols, the board and the Medical Board of California shall include the following:~~

~~(1) Procedures to ensure education of the person to whom the drug is furnished, including, but not limited to, opioid overdose prevention, recognition, and response, safe administration of naloxone hydrochloride, potential side effects or adverse events, and the imperative to seek emergency medical care for the patient.~~

~~(2) Procedures to ensure the education of the person to whom the drug is furnished regarding the availability of drug treatment programs.~~

(3) Procedures for the notification of the patient's primary care provider with patient consent of any drugs or devices furnished to the patient, or entry of appropriate information in a patient record system shared with the primary care provider, as permitted by that primary care provider, and with patient consent.

(b) A pharmacist furnishing naloxone hydrochloride pursuant to this section shall not permit the person to whom the drug is furnished to waive the consultation required by the board and the Medical Board of California.
(c) Prior to performing a procedure authorized under this section, a pharmacist shall complete a training program on the use of opioid antagonists that consists of at least one hour of approved continuing education on the use of naloxone hydrochloride.
(d) The board and the Medical Board of California are each authorized to ensure compliance with this section. Each board is specifically charged with enforcing this section with respect to its respective licensees. This section does not expand the authority of a pharmacist to prescribe any prescription medication.
(e) The board may adopt emergency regulations to establish the standardized procedures or protocols. The adoption of regulations pursuant to this subdivision shall be deemed to be an emergency and necessary for the immediate preservation of the public peace, health, safety, or general welfare. The emergency regulations authorized by this subdivision are exempt from review by the Office of Administrative Law. The emergency regulations authorized by this subdivision shall be submitted to the Office of Administrative Law for filing with the Secretary of State and shall remain in effect until the earlier of 180 days following their effective date or the effective date of regulations adopted pursuant to subdivision (a).
(Added by Stats. 2014, Ch. 326, Sec. 1. (AB 1535) Effective January 1, 2015.)

4052.02.

(a) Notwithstanding any other law, a pharmacist may initiate and furnish HIV preexposure prophylaxis in accordance with this section.
(b) For purposes of this section, "preexposure prophylaxis" means a fixed-dose combination of tenofovir disoproxil fumarate (TDF) (300 mg) with emtricitabine (FTC) (200 mg), or another drug or drug combination determined by the board to meet the same clinical eligibility recommendations provided in CDC guidelines.
(c) For purposes of this section, "CDC guidelines" means the "2017 Preexposure Prophylaxis for the Prevention of HIV Infection in the United States–2017 Update: A Clinical Practice Guideline," or any subsequent guidelines, published by the federal Centers for Disease Control and Prevention.
(d) Before furnishing preexposure prophylaxis to a patient, a pharmacist shall complete a training program approved by the board, in consultation with the Medical Board of California, on the use of preexposure prophylaxis and postexposure prophylaxis. The training shall include information about financial assistance programs for preexposure prophylaxis and postexposure prophylaxis, including the HIV prevention program described in Section 120972 of the Health and Safety Code. The board shall consult with the Medical Board of California as well as relevant stakeholders, including, but not

limited to, the Office of AIDS, within the State Department of Public Health, on training programs that are appropriate to meet the requirements of this subdivision.

(e) A pharmacist shall furnish at least a 30-day supply, and up to a 60-day supply, of preexposure prophylaxis if all of the following conditions are met:

(1) The patient is 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 or from a rapid, point-of-care fingerstick blood test approved by the federal Food and Drug Administration. If the patient does not provide evidence of a negative HIV test in accordance with this paragraph, the pharmacist shall order an HIV test. If the test results are not transmitted directly to the pharmacist, the pharmacist shall verify the test results to the pharmacist's satisfaction. If the patient tests positive for HIV infection, the pharmacist or person administering the test shall direct the patient to a primary care provider and provide a list of providers and clinics in the region.

(2) The patient does not report any signs or symptoms of acute HIV infection on a self-reported checklist of acute HIV infection signs and symptoms.

(3) The patient does not report taking any contraindicated medications.

(4) The pharmacist provides counseling to the patient on the ongoing use of preexposure prophylaxis, which may include education about side effects, safety during pregnancy and breastfeeding, adherence to recommended dosing, and the importance of timely testing and treatment, as applicable, for HIV, renal function, hepatitis B, hepatitis C, sexually transmitted diseases, and pregnancy for individuals of childbearing capacity. The pharmacist shall notify the patient that the patient must be seen by a primary care provider to receive subsequent prescriptions for preexposure prophylaxis and that a pharmacist may not furnish a 60-day supply of preexposure prophylaxis to a single patient more than once every two years.

(5) The pharmacist documents, to the extent possible, the services provided by the pharmacist in the patient's record in the record system maintained by the pharmacy. The pharmacist shall maintain records of preexposure prophylaxis furnished to each patient.

(6) The pharmacist does not furnish more than a 60-day supply of preexposure prophylaxis to a single patient more than once every two years, unless directed otherwise by a prescriber.

(7) The pharmacist notifies the patient's primary care provider that the pharmacist completed the requirements specified in this subdivision. If the patient does not have a primary care provider, or refuses consent to notify the patient's primary care provider, the pharmacist shall provide the patient a list of physicians and surgeons, clinics, or other health care service providers to contact regarding ongoing care for preexposure prophylaxis.

(f) A pharmacist initiating or furnishing preexposure prophylaxis shall not permit the person to whom the drug is furnished to waive the consultation required by the board.

(g) The board, by July 1, 2020, shall adopt emergency regulations to implement this section in accordance with CDC guidelines. The adoption of regulations pursuant to this subdivision shall be deemed to be an emergency and necessary for the immediate preservation of the public peace, health, safety, or general welfare. The board shall consult with the Medical Board of California in developing regulations pursuant to this subdivision.
(Amended by Stats. 2020, Ch. 370, Sec. 5. (SB 1371) Effective January 1, 2021.)

4052.03.

(a) Notwithstanding any other law, a pharmacist may initiate and furnish HIV postexposure prophylaxis in accordance with this section.
(b) For purposes of this section, "postexposure prophylaxis" means any of the following:
(1) Tenofovir disoproxil fumarate (TDF) (300 mg) with emtricitabine (FTC) (200 mg), taken once daily, in combination with either raltegravir (400 mg), taken twice daily, or dolutegravir (50 mg), taken once daily.

(2) Tenofovir disoproxil fumarate (TDF) (300 mg) and emtricitabine (FTC) (200 mg), taken once daily, in combination with darunavir (800 mg) and ritonavir (100 mg), taken once daily.

(3) Another drug or drug combination determined by the board to meet the same clinical eligibility recommendations provided in CDC guidelines.

(c) For purposes of this section, "CDC guidelines" means the "Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV–United States, 2016," or any subsequent guidelines, published by the federal Centers for Disease Control and Prevention.
(d) Before furnishing postexposure prophylaxis to a patient, a pharmacist shall complete a training program approved by the board, in consultation with the Medical Board of California, on the use of preexposure prophylaxis and postexposure prophylaxis. The training shall include information about financial assistance programs for preexposure prophylaxis and postexposure prophylaxis, including the HIV prevention program described in Section 120972 of the Health and Safety Code. The board shall consult with the Medical Board of California as well as relevant stakeholders, including, but not limited to, the Office of AIDS, within the State Department of Public Health, on training programs that are appropriate to meet the requirements of this subdivision.
(e) A pharmacist shall furnish a complete course of postexposure prophylaxis if all of the following conditions are met:
(1) The pharmacist screens the patient and determines the exposure occurred within the previous 72 hours and the patient otherwise meets the clinical criteria for postexposure prophylaxis consistent with CDC guidelines.

(2) The pharmacist provides HIV testing that is classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a) or determines the patient is willing to undergo HIV testing consistent with CDC guidelines. If the patient refuses to undergo HIV testing but is otherwise eligible for

postexposure prophylaxis under this section, the pharmacist may furnish postexposure prophylaxis.

(3) The pharmacist provides counseling to the patient on the use of postexposure prophylaxis consistent with CDC guidelines, which may include education about side effects, safety during pregnancy and breastfeeding, adherence to recommended dosing, and the importance of timely testing and treatment, as applicable, for HIV and sexually transmitted diseases. The pharmacist shall also inform the patient of the availability of preexposure prophylaxis for persons who are at substantial risk of acquiring HIV.

(4) The pharmacist notifies the patient's primary care provider of the postexposure prophylaxis treatment. If the patient does not have a primary care provider, or refuses consent to notify the patient's primary care provider, the pharmacist shall provide the patient a list of physicians and surgeons, clinics, or other health care service providers to contact regarding followup care for postexposure prophylaxis.

(f) A pharmacist initiating or furnishing postexposure prophylaxis shall not permit the person to whom the drug is furnished to waive the consultation required by the board.
(g) The board, by July 1, 2020, shall adopt emergency regulations to implement this section in accordance with CDC guidelines. The adoption of regulations pursuant to this subdivision shall be deemed to be an emergency and necessary for the immediate preservation of the public peace, health, safety, or general welfare. The board shall consult with the Medical Board of California in developing regulations pursuant to this subdivision.
(Added by Stats. 2019, Ch. 532, Sec. 3. (SB 159) Effective January 1, 2020.)

4052.1.

(a) Notwithstanding any other provision of law, a pharmacist may perform the following procedures or functions in a licensed health care facility in accordance with policies, procedures, or protocols developed by health professionals, including physicians, pharmacists, and registered nurses, with the concurrence of the facility administrator:
(1) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.

(2) Ordering drug therapy-related laboratory tests.

(3) Administering drugs and biologicals by injection pursuant to a prescriber's order.

(4) Initiating or adjusting the drug regimen of a patient pursuant to an order or authorization made by the patient's prescriber and in accordance with the policies, procedures, or protocols of the licensed health care facility.

(b) Prior to performing any procedure authorized by this section, a pharmacist shall have received appropriate training as prescribed in the policies and procedures of the licensed health care facility.

(Added by Stats. 2006, Ch. 777, Sec. 5. Effective January 1, 2007.)

4052.2.

(a) Notwithstanding any other law, a pharmacist may perform the following procedures or functions as part of the care provided by a health care facility, a licensed home health agency, licensed correctional clinic, a licensed clinic in which there is physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, in accordance with the policies, procedures, or protocols of that facility, home health agency, licensed correctional clinic, licensed clinic, health care service plan, or physician, and in accordance with subdivision (c):

(1) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.

(2) Ordering drug therapy-related laboratory tests.

(3) Administering drugs and biologicals by injection pursuant to a prescriber's order.

(4) Initiating or adjusting the drug regimen of a patient pursuant to a specific written order or authorization made by the individual patient's treating prescriber, and in accordance with the policies, procedures, or protocols of the health care facility, home health agency, licensed correctional clinic, licensed clinic, health care service plan, or physician. Adjusting the drug regimen does not include substituting or selecting a different drug, except as authorized by the protocol. The pharmacist shall provide written notification to the patient's treating prescriber, or enter the appropriate information in an electronic patient record system shared by the prescriber, of any drug regimen initiated pursuant to this paragraph within 24 hours.

(b) A patient's treating prescriber may prohibit, by written instruction, any adjustment or change in the patient's drug regimen by the pharmacist.

(c) The policies, procedures, or protocols referred to in this subdivision shall be developed by health care professionals, including physicians, pharmacists, and registered nurses, and shall, at a minimum, do all of the following:

(1) Require that the pharmacist function as part of a multidisciplinary group that includes physicians and direct care registered nurses. The multidisciplinary group shall determine the appropriate participation of the pharmacist and the direct care registered nurse.

(2) Require that the medical records of the patient be available to both the patient's treating prescriber and the pharmacist.

(3) Require that the procedures to be performed by the pharmacist relate to a condition for which the patient has first been seen by a physician.

(4) Except for procedures or functions provided by a health care facility, a licensed correctional clinic, as defined in Section 4187, a licensed clinic in which there is

physician oversight, or a provider who contracts with a licensed health care plan with regard to the care or services provided to the enrollees of that health care service plan, require the procedures to be performed in accordance with a written, patient-specific protocol approved by the treating or supervising physician. Any change, adjustment, or modification of an approved preexisting treatment or drug therapy shall be provided in writing to the treating or supervising physician within 24 hours.

(d) Prior to performing any procedure authorized by this section, a pharmacist shall have done either of the following:

(1) Successfully completed clinical residency training.

(2) Demonstrated clinical experience in direct patient care delivery.

(Amended by Stats. 2019, Ch. 497, Sec. 5. (AB 991) Effective January 1, 2020.)

4052.3.

(a) (1) Notwithstanding any other law, a pharmacist may furnish self-administered hormonal contraceptives in accordance with standardized procedures or protocols developed and approved by both the board and the Medical Board of California in consultation with the American Congress of Obstetricians and Gynecologists, the California Pharmacists Association, and other appropriate entities. The standardized procedure or protocol shall require that the patient use a self-screening tool that will identify patient risk factors for use of self-administered hormonal contraceptives, based on the current United States Medical Eligibility Criteria (USMEC) for Contraceptive Use developed by the federal Centers for Disease Control and Prevention, and that the pharmacist refer the patient to the patient's primary care provider or, if the patient does not have a primary care provider, to nearby clinics, upon furnishing a self-administered hormonal contraceptive pursuant to this subdivision, or if it is determined that use of a self-administered hormonal contraceptive is not recommended.

(2) The board and the Medical Board of California are both authorized to ensure compliance with this subdivision, and each board is specifically charged with the enforcement of this subdivision with respect to its respective licensees. This subdivision does not expand the authority of a pharmacist to prescribe any prescription medication.

(b) (1) Notwithstanding any other law, a pharmacist may furnish emergency contraception drug therapy in accordance with either of the following:

(A) Standardized procedures or protocols developed by the pharmacist and an authorized prescriber who is acting within his or her scope of practice.

(B) Standardized procedures or protocols developed and approved by both the board and the Medical Board of California in consultation with the American Congress of Obstetricians and Gynecologists, the California Pharmacists Association, and other appropriate entities. The board and the Medical Board of California are both authorized to ensure compliance with this clause, and each board is specifically charged with the enforcement of this provision with respect

~~to its respective licensees. This subdivision does not expand the authority of a pharmacist to prescribe any prescription medication.~~

~~(2) Prior to performing a procedure authorized under this subdivision, a pharmacist shall complete a training program on emergency contraception that consists of at least one hour of approved continuing education on emergency contraception drug therapy.~~

~~(3) A pharmacist, pharmacist's employer, or pharmacist's agent shall not directly charge a patient a separate consultation fee for emergency contraception drug therapy services initiated pursuant to this subdivision, but may charge an administrative fee not to exceed ten dollars ($10) above the retail cost of the drug. Upon an oral, telephonic, electronic, or written request from a patient or customer, a pharmacist or pharmacist's employee shall disclose the total retail price that a consumer would pay for emergency contraception drug therapy. As used in this paragraph, total retail price includes providing the consumer with specific information regarding the price of the emergency contraception drugs and the price of the administrative fee charged. This limitation is not intended to interfere with other contractually agreed-upon terms between a pharmacist, a pharmacist's employer, or a pharmacist's agent, and a health care service plan or insurer. Patients who are insured or covered and receive a pharmacy benefit that covers the cost of emergency contraception shall not be required to pay an administrative fee. These patients shall be required to pay copayments pursuant to the terms and conditions of their coverage. This paragraph shall become inoperative for dedicated emergency contraception drugs if these drugs are reclassified as over-the-counter products by the federal Food and Drug Administration.~~

~~(4) A pharmacist shall not require a patient to provide individually identifiable medical information that is not specified in Section 1707.1 of Title 16 of the California Code of Regulations before initiating emergency contraception drug therapy pursuant to this subdivision.~~

~~(c) For each emergency contraception drug therapy or self-administered hormonal contraception initiated pursuant to this section, the pharmacist shall provide the recipient of the drug with a standardized factsheet that includes, but is not limited to, the indications and contraindications for use of the drug, the appropriate method for using the drug, the need for medical followup, and other appropriate information. The board shall develop this form in consultation with the State Department of Public Health, the American Congress of Obstetricians and Gynecologists, the California Pharmacists Association, and other health care organizations. This section does not preclude the use of existing publications developed by nationally recognized medical organizations.~~
~~*(Amended by Stats. 2013, Ch. 469, Sec. 7. (SB 493) Effective January 1, 2014.)*~~

~~4052.4.~~
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~~(a) Notwithstanding Section 2038 or any other provision of law, a pharmacist may perform skin puncture in the course of performing routine patient assessment procedures or in the course of performing any procedure authorized under Section 1206.5 or 1206.6. For purposes of this section, "routine patient assessment procedures" means: (a) procedures that a patient could, with or without a prescription, perform for themselves, or (b) clinical laboratory tests that are classified as waived pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a) and the regulations adopted thereunder by the federal Health Care Financing Administration, as authorized by paragraph (11) of subdivision (a) of Section 1206.5 or Section 1206.6. A pharmacist performing these functions shall report the results obtained from a test to the patient and any physician designated by the patient. Any pharmacist who performs the service authorized by this section shall not be in violation of Section 2052.~~

~~(b) A pharmacist may perform any aspect of any FDA-approved or -authorized test that is classified as waived pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a) and the regulations adopted thereunder by the federal Health Care Financing Administration, under all of the following conditions:~~

~~(1) The test meets the criteria in subparagraph (A) or (B) and does not require the use of specimens collected by vaginal swab, venipuncture, or the collection of seminal fluid.~~

~~(A) The test is used to detect or screen for any of the following illnesses, conditions, or diseases:~~

~~(i) SARS-CoV-2 or other respiratory illness, condition or disease.~~

~~(ii) Mononucleosis.~~

~~(iii) Sexually transmitted infection.~~

~~(iv) Strep throat.~~

~~(v) Anemia.~~

~~(vi) Cardiovasular health.~~

~~(vii) Conjunctivitis.~~

~~(viii) Urinary tract infection.~~

~~(ix) Liver and kidney function or infection.~~

~~(x) Thyroid function.~~

~~(xi) Substance use disorder.~~

~~(xii) Diabetes.~~

(B) Other tests classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a) and the regulations adopted thereunder by the federal Health Care Financing Administration and approved by the board by regulation, in conjunction with the Medical Board of California and Laboratory Field Services in the State Department of Public Health.

(2) The pharmacist completes the testing in a pharmacy laboratory that is appropriately licensed in California as a laboratory pursuant to Section 1265, unless otherwise authorized in law.

(3) The pharmacist has completed necessary training as specified in the pharmacy's policies and procedures maintained pursuant to subdivision (b) of Section 4119.10, and that allows the pharmacist to demonstrate sufficient knowledge of the illness, condition, or disease being tested, as applicable.

(Amended by Stats. 2021, Ch. 604, Sec. 3. (SB 409) Effective January 1, 2022.)

4052.5.

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(a) In addition to the authority allowed under Section 4073, a pharmacist filling a prescription order for a drug product may select a different form of medication with the same active chemical ingredients of equivalent strength and duration of therapy as the prescribed drug product when the change will improve the ability of the patient to comply with the prescribed drug therapy.
(b) In no case shall a selection be made pursuant to this section if the prescriber personally indicates, either orally or in his or her own handwriting, "Do not substitute" or words of similar meaning. Nothing in this subdivision shall prohibit a prescriber from checking a box on a prescription marked "Do not substitute" if the prescriber personally initials the box or checkmark.
(c) Selection pursuant to this section is within the discretion of the pharmacist, except as provided in subdivision (b). The pharmacist who selects the drug product to be dispensed pursuant to this section shall assume the same responsibility for selecting the dispensed drug product as would be incurred in filling a prescription for a drug product using the prescribed form of medication. There shall be no liability on the prescriber for an act or omission by a pharmacist in selecting, preparing, or dispensing a drug product pursuant to this section.
(d) This section shall apply to all prescriptions, including those presented by or on behalf of persons receiving assistance from the federal government or pursuant to the California Medical Assistance Program set forth in Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code.
(e) When a substitution is made pursuant to this section, the use of the different form of medication shall be communicated to the patient, and the name of the dispensed drug product shall be indicated on the prescription label, unless the prescriber orders otherwise.

(f) This section shall not permit substitution between long-acting and short-acting forms of a medication with the same chemical ingredients or between one drug product and two or more drug products with the same chemical ingredients.
(Added by Stats. 2001, Ch. 631, Sec. 1. Effective January 1, 2002.)

4052.7.
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(a) A pharmacy may, at a patient's request, repackage a drug previously dispensed to the patient or to the patient's agent pursuant to a prescription.
(b) Any pharmacy providing repackaging services shall have in place policies and procedures for repackaging these drugs and shall label the repackaged prescription container with the following:
(1) All the information required by Section 4076.

(2) The name and address of the pharmacy repackaging the drug and the name and address of the pharmacy that initially dispensed the drug to the patient.

(c) The repackaging pharmacy and the pharmacy that initially dispensed the drug shall only be liable for its own actions in providing the drug to the patient or the patient's agent.
(Added by Stats. 2001, Ch. 728, Sec. 27. Effective January 1, 2002.)

4052.8.
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(a) In addition to the authority provided in paragraph (11) of subdivision (a) of Section 4052, a pharmacist may independently initiate and administer any vaccine that has been approved or authorized by the federal Food and Drug Administration and received a federal Advisory Committee on Immunization Practices individual vaccine recommendation published by the federal Centers for Disease Control and Prevention (CDC) for persons three years of age and older.
(b) In order to initiate and administer an immunization described in subdivision (a), a pharmacist shall do all of the following:
(1) Complete an immunization training program endorsed by the CDC or the Accreditation Council for Pharmacy Education that, at a minimum, includes hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines, and shall maintain that training.

(2) Be certified in basic life support.

(3) Comply with all state and federal recordkeeping and reporting requirements, including providing documentation to the patient's primary care provider and entering information in the appropriate immunization registry designated by the immunization branch of the State Department of Public Health.

~~(c) A pharmacist administering immunizations pursuant to this section, or paragraph (11) of subdivision (a) of Section 4052, may also initiate and administer epinephrine or diphenhydramine by injection for the treatment of a severe allergic reaction.~~
~~*(Amended by Stats. 2021, Ch. 655, Sec. 1. (AB 1064) Effective January 1, 2022.)*~~

~~4052.9.~~
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~~(a) A pharmacist may furnish nicotine replacement products approved by the federal Food and Drug Administration for use by prescription only in accordance with standardized procedures and protocols developed and approved by both the board and the Medical Board of California in consultation with other appropriate entities and provide smoking cessation services if all of the following conditions are met:~~

~~(1) The pharmacist maintains records of all prescription drugs and devices furnished for a period of at least three years for purposes of notifying other health care providers and monitoring the patient.~~

~~(2) The pharmacist notifies the patient's primary care provider of any drugs or devices furnished to the patient, or enters the appropriate information in a patient record system shared with the primary care provider, as permitted by that primary care provider. If the patient does not have a primary care provider, the pharmacist provides the patient with a written record of the drugs or devices furnished and advises the patient to consult a physician of the patient's choice.~~

~~(3) The pharmacist is certified in smoking cessation therapy by an organization recognized by the board.~~

~~(4) The pharmacist completes one hour of continuing education focused on smoking cessation therapy biennially.~~

~~(b) The board and the Medical Board of California are both authorized to ensure compliance with this section, and each board is specifically charged with the enforcement of this section with respect to their respective licensees. Nothing in this section shall be construed to expand the authority of a pharmacist to prescribe any other prescription medication.~~
~~*(Added by Stats. 2013, Ch. 469, Sec. 10. (SB 493) Effective January 1, 2014.)*~~

Amend BPC 4064 as follows:
(a) A prescription for a dangerous drug or dangerous device may be refilled without the prescriber's authorization if the prescriber is unavailable to authorize the refill and if, in the pharmacist's professional judgment, failure to refill the prescription might interrupt the patient's ongoing care and have a significant adverse effect on the patient's well-being.

(b) The pharmacist shall inform the patient that the prescription was refilled pursuant to this section.

(c) The pharmacist shall inform the prescriber within a reasonable period of time of any refills dispensed pursuant to this section.

~~(d) Prior to refilling a prescription pursuant to this section, the pharmacist shall make every reasonable effort to contact the prescriber. The pharmacist shall make an appropriate record, including the basis for proceeding under this section.~~

(e) The prescriber shall not incur any liability as the result of a refilling of a prescription pursuant to this section.

(f) Notwithstanding Section 4060 or any other law, a person may possess a dangerous drug or dangerous device furnished without prescription pursuant to this section.

~~(g) During a proclaimed state of emergency, nothing in either this section or any other provision of this chapter prohibits a pharmacist, a clinic licensed under Section 4180, or a mobile pharmacy or clinic described in subdivision (c) of Section 4062 from refilling a prescription if the prescriber is unavailable, or if after a reasonable effort has been made, the pharmacist, clinic, or mobile pharmacy is unable to contact the prescriber.~~

Amend BPC 4064.5 as follows**:**
(a) A pharmacist may dispense not more than a 90-day supply of a dangerous drug other than a controlled substance pursuant to a valid prescription that specifies an initial quantity of less than a 90-day supply followed by periodic refills of that amount if all of the following requirements are satisfied:

(1) The patient has completed an initial 30-day supply of the dangerous drug.

(2) The total quantity of dosage units dispensed does not exceed the total quantity of dosage units authorized by the prescriber on the prescription, including refills.

(3) The prescriber has not specified on the prescription that dispensing the prescription in an initial amount followed by periodic refills is medically necessary.

(4) The pharmacist is exercising his or her professional judgment.

(b) For purposes of this section, if the prescription continues the same medication as previously dispensed in a 90-day supply, the initial 30-day supply under paragraph (1) of subdivision (a) is not required.

(c) A pharmacist dispensing an increased supply of a dangerous drug pursuant to this section shall notify the prescriber of the increase in the quantity of dosage units dispensed.

~~(d) In no case shall a pharmacist dispense a greater supply of a dangerous drug pursuant to this section if the prescriber personally indicates, either orally or in his or her own handwriting, "No change to quantity," or words of similar meaning. Nothing in this subdivision shall prohibit a prescriber from checking a box on a prescription marked "No change to quantity," provided that the prescriber personally initials the box or checkmark. To indicate that an increased supply shall not be dispensed pursuant to this section for an electronic data transmission prescription as defined in subdivision (c) of Section 4040, a prescriber may indicate "No change to quantity," or words of similar meaning, in the prescription as transmitted by electronic data, or may check a box~~

~~marked on the prescription "No change to quantity." In either instance, it shall not be required that the prohibition on an increased supply be manually initialed by the prescriber.~~

(e) This section shall not apply to psychotropic medication or psychotropic drugs as described in subdivision (d) of Section 369.5 of the Welfare and Institutions Code.

(f) Except for the provisions of subdivision (d), this section does not apply to FDA-approved, self-administered hormonal contraceptives.

(1) A pharmacist shall <u>furnish</u> or dispense, at a patient's request, up to a 12-month supply of an FDA-approved, self-administered hormonal contraceptive pursuant to a valid prescription that specifies an initial quantity followed by periodic refills.

~~(2) A pharmacist furnishing an FDA-approved, self-administered hormonal contraceptive pursuant to Section 4052.3 under protocols developed by the Board of Pharmacy may furnish, at the patient's request, up to a 12-month supply at one time.~~

(3) Nothing in this subdivision shall be construed to require a pharmacist to dispense or furnish a drug if it would result in a violation of Section 733.

(g) Nothing in this section shall be construed to require a health care service plan, health insurer, workers' compensation insurance plan, pharmacy benefits manager, or any other person or entity, including, but not limited to, a state program or state employer, to provide coverage for a dangerous drug in a manner inconsistent with a beneficiary's plan benefit.

~~4073.~~

~~(a) A pharmacist filling a prescription order for a drug product prescribed by its trade or brand name may select another drug product with the same active chemical ingredients of the same strength, quantity, and dosage form, and of the same generic drug name as determined by the United States Adopted Names (USAN) and accepted by the federal Food and Drug Administration (FDA), of those drug products having the same active chemical ingredients.~~

~~(b) In no case shall a selection be made pursuant to this section if the prescriber personally indicates, either orally or in his or her own handwriting, "Do not substitute," or words of similar meaning. Nothing in this subdivision shall prohibit a prescriber from checking a box on a prescription marked "Do not substitute"; provided that the prescriber personally initials the box or checkmark. To indicate that a selection shall not be made pursuant to this section for an electronic data transmission prescription as defined in subdivision (c) of Section 4040, a prescriber may indicate "Do not substitute," or words of similar meaning, in the prescription as transmitted by electronic data, or may check a box marked on the prescription "Do not substitute." In either instance, it shall not be required that the prohibition on substitution be manually initialed by the prescriber.~~

(c) Selection pursuant to this section is within the discretion of the pharmacist, except as provided in subdivision (b). The person who selects the drug product to be dispensed pursuant to this section shall assume the same responsibility for selecting the dispensed drug product as would be incurred in filling a prescription for a drug product prescribed by generic name. There shall be no liability on the prescriber for an act or omission by a pharmacist in selecting, preparing, or dispensing a drug product pursuant to this section. In no case shall the pharmacist select a drug product pursuant to this section unless the drug product selected costs the patient less than the prescribed drug product. Cost, as used in this subdivision, is defined to include any professional fee that may be charged by the pharmacist.

(d) This section shall apply to all prescriptions, including those presented by or on behalf of persons receiving assistance from the federal government or pursuant to the California Medical Assistance Program set forth in Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code.

(e) When a substitution is made pursuant to this section, the use of the cost-saving drug product dispensed shall be communicated to the patient and the name of the dispensed drug product shall be indicated on the prescription label, except where the prescriber orders otherwise.

4073.5.

(a) A pharmacist filling a prescription order for a prescribed biological product may select an alternative biological product only if all of the following:

(1) The alternative biological product is interchangeable.

(2) The prescriber does not personally indicate "Do not substitute," or words of similar meaning, in the manner provided in subdivision (d).

(b) Within five days following the dispensing of a biological product, a dispensing pharmacist or the pharmacists' designee shall make an entry of the specific biological product provided to the patient, including the name of the biological product and the manufacturer. The communication shall be conveyed by making an entry that can be electronically accessed by the prescriber through one or more of the following electronic records systems:

(1) An interoperable electronic medical records system.

(2) An electronic prescribing technology.

(3) A pharmacy benefit management system.

(4) A pharmacy record.

(c) Entry into an electronic records system as described in subdivision (b) is presumed to provide notice to the prescriber.

(d) If the pharmacy does not have access to one or more of the entry systems in subdivision (b), the pharmacist or the pharmacist's designee shall communicate the name of the biological product dispensed to the prescriber using facsimile, telephone,

~~electronic transmission, or other prevailing means, except that communication shall not be required in this instance to the prescriber when either of the following apply:~~

~~(1) There is no interchangeable biological product approved by the federal Food and Drug Administration for the product prescribed.~~

~~(2) A refill prescription is not changed from the product dispensed on the prior filling of the prescription.~~

~~(e) In no case shall a selection be made pursuant to this section if the prescriber personally indicates, either orally or in his or her own handwriting, "Do not substitute," or words of similar meaning.~~

~~(1) This subdivision shall not prohibit a prescriber from checking a box on a prescription marked "Do not substitute," provided that the prescriber personally initials the box or checkmark.~~

~~(2) To indicate that a selection shall not be made pursuant to this section for an electronic data transmission prescription, as defined in subdivision (c) of Section 4040, a prescriber may indicate "Do not substitute," or words of similar meaning, in the prescription as transmitted by electronic data, or may check a box marked on the prescription "Do not substitute." In either instance, it shall not be required that the prohibition on substitution be manually initialed by the prescriber.~~

~~(f) Selection pursuant to this section is within the discretion of the pharmacist, except as provided in subdivision (e). A pharmacist who selects an alternative biological product to be dispensed pursuant to this section shall assume the same responsibility for substituting the biological product as would be incurred in filling a prescription for a biological product prescribed by name. There shall be no liability on the prescriber for an act or omission by a pharmacist in selecting, preparing, or dispensing a biological product pursuant to this section. In no case shall the pharmacist select a biological product that meets the requirements of subdivision (a) unless the cost to the patient of the biological product selected is the same or less than the cost of the prescribed biological product. Cost, as used in this subdivision, includes any professional fee that may be charged by the pharmacist.~~

~~(g) This section shall apply to all prescriptions, including those presented by or on behalf of persons receiving assistance from the federal government or pursuant to the Medi-Cal Act set forth in Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code.~~

~~(h) When a selection is made pursuant to this section, the substitution of a biological product shall be communicated to the patient.~~

~~(i) The board shall maintain on its public Internet Web site a link to the current list, if available, of biological products determined by the federal Food and Drug Administration to be interchangeable.~~

~~(j) For purposes of this section, the following terms shall have the following meanings:~~

~~(1) "Biological product" has the same meaning that applies to that term under Section 351 of the federal Public Health Service Act (42 U.S.C. Sec. 262(i)).~~

~~(2) "Interchangeable" means a biological product that the federal Food and Drug Administration has determined meets the standards set forth in Section 262(k)(4) of Title 42 of the United States Code, or has been deemed therapeutically equivalent by the federal Food and Drug Administration as set forth in the latest addition or supplement of the Approved Drug Products with Therapeutic Equivalence Evaluations.~~

~~(3) "Prescription," with respect to a biological product, means a prescription for a product that is subject to Section 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 353(b)).~~

~~(k) This section shall not prohibit the administration of immunizations, as permitted in Sections 4052 and 4052.8.~~

~~(l) This section shall not prohibit a disability insurer or health care service plan from requiring prior authorization or imposing other appropriate utilization controls in approving coverage for any biological product.~~

Attachment 10

Proposal to amend BPC 4052.3 as follows:

4052.3.

(a) (1) Notwithstanding any other law, a pharmacist may furnish prescription-only self-administered hormonal contraceptives in accordance with standardized procedures or protocols developed and approved by both the board and the Medical Board of California in consultation with the American Congress of Obstetricians and Gynecologists, the California Pharmacists Association, and other appropriate entities. The standardized procedure or protocol shall require that the patient use a self-screening tool that will identify patient risk factors for use of self-administered hormonal contraceptives, based on the current United States Medical Eligibility Criteria (USMEC) for Contraceptive Use developed by the federal Centers for Disease Control and Prevention, and that the pharmacist refer the patient to the patient's primary care provider or, if the patient does not have a primary care provider, to nearby clinics, upon furnishing a prescription-only self-administered hormonal contraceptive pursuant to this subdivision, or if it is determined that use of a self-administered hormonal contraceptive is not recommended.

(2) The board and the Medical Board of California are both authorized to ensure compliance with this subdivision, and each board is specifically charged with the enforcement of this subdivision with respect to its respective licensees. This subdivision does not expand the authority of a pharmacist to prescribe any prescription medication.

(b) (1) Notwithstanding any other law, a pharmacist may furnish emergency contraception drug therapy in accordance with either of the following:

(A) Standardized procedures or protocols developed by the pharmacist and an authorized prescriber who is acting within his or her scope of practice.

(B) Standardized procedures or protocols developed and approved by both the board and the Medical Board of California in consultation with the American Congress of Obstetricians and Gynecologists, the California Pharmacists Association, and other appropriate entities. The board and the Medical Board of California are both authorized to ensure compliance with this clause, and each board is specifically charged with the enforcement of this provision with respect to its respective licensees. This subdivision does not expand the authority of a pharmacist to prescribe any prescription medication.

(2) Prior to performing a procedure authorized under this subdivision, a pharmacist shall complete a training program on emergency contraception that consists of at least one hour of approved continuing education on emergency contraception drug therapy.

(3) A pharmacist, pharmacist's employer, or pharmacist's agent shall not directly charge a patient a separate consultation fee for emergency contraception drug therapy services initiated pursuant to this subdivision, but may charge an administrative fee not to exceed ten dollars ($10) above the retail cost of the drug. Upon an oral, telephonic, electronic, or written request from a patient or customer, a

pharmacist or pharmacist's employee shall disclose the total retail price that a consumer would pay for emergency contraception drug therapy. As used in this paragraph, total retail price includes providing the consumer with specific information regarding the price of the emergency contraception drugs and the price of the administrative fee charged. This limitation is not intended to interfere with other contractually agreed-upon terms between a pharmacist, a pharmacist's employer, or a pharmacist's agent, and a health care service plan or insurer. Patients who are insured or covered and receive a pharmacy benefit that covers the cost of emergency contraception shall not be required to pay an administrative fee. These patients shall be required to pay copayments pursuant to the terms and conditions of their coverage. This paragraph shall become inoperative for dedicated emergency contraception drugs if these drugs are reclassified as over-the-counter products by the federal Food and Drug Administration.

(4) A pharmacist shall not require a patient to provide individually identifiable medical information that is not specified in Section 1707.1 of Title 16 of the California Code of Regulations before initiating emergency contraception drug therapy pursuant to this subdivision.

(c) For each emergency contraception drug therapy or prescription-only self-administered hormonal contraception initiated pursuant to subdivisions (a) or (b) of this section, the pharmacist shall provide the recipient of the drug with a standardized factsheet that includes, but is not limited to, the indications and contraindications for use of the drug, the appropriate method for using the drug, the need for medical followup, and other appropriate information. The board shall develop this form in consultation with the State Department of Public Health, the American Congress of Obstetricians and Gynecologists, the California Pharmacists Association, and other health care organizations. This section does not preclude the use of existing publications developed by nationally recognized medical organizations.

(d) Notwithstanding any other law, a pharmacist may furnish FDA-approved over-the-counter contraceptives without the need to comply with the standardized procedures or protocols required by subdivision (a)(1) for prescription-only self-administered hormonal contraceptives.

Attachment 11

CALIFORNIA STATE BOARD OF PHARMACY

QUARTERLY LICENSING STATISTICS FISCAL YEAR 2023/2024

* numbers reported through 5/31/2024, updated numbers through 6/30/2024 will be provided prior to the meeting 7/18/2024

APPLICATIONS RECEIVED

Individual Applications	July - Sept	Oct-Dec	Jan-Mar	Apr-May	Total FYTD
Designated Representatives (EXC)	100	85	92	75	352
Designated Representatives Vet (EXV)	0	4	3	0	7
Designated Representatives-3PL (DRL)	33	31	44	31	139
Designated Representatives-Reverse Distributor (DRR)	1	0	3	2	6
Designated Paramedic (DPM)	0	0	1	0	1
Intern Pharmacist (INT)	858	132	80	86	1,156
Pharmacist Exam Applications	231	167	178	1,041	1,617
Pharmacist Retake Exam Applications	415	415	350	143	1,323
Pharmacist Initial License Application (RPH)	659	480	172	221	1,532
Advanced Practice Pharmacist (APH)	40	29	43	31	143
Pharmacy Technician (TCH)	1,206	1,087	1,312	989	4,594
Total	**3,543**	**2,430**	**2,278**	**2,619**	**10,870**

Temporary Individual Applications (Military Spouses/Partners)	July - Sept	Oct-Dec	Jan-Mar	Apr-May	Total FYTD
Temp-Designated Representatives-Wholesaler (TEX)	0	0	0	0	0
Temp-Designated Representatives-3PL (TDR)	0	0	0	0	0
Temp-Designated Representatives-Reverse Distributor (TRR)	0	0	0	0	0
Temp-Designated Paramedic (TDP)	0	0	0	0	0
Temp-Intern Pharmacist (TIN)	0	0	0	0	0
Temp-Pharmacist (TRP)	0	0	0	0	0
Temp-Advanced Practice Pharmacist (TAP)	0	0	0	0	0
Temp-Pharmacy Technician (TTC)	1	3	1	1	6
Total	**1**	**3**	**1**	**1**	**6**

Site Applications	July - Sept	Oct-Dec	Jan-Mar	Apr-May	Total FYTD
Automated Drug Delivery System (ADD(AUD))	72	45	79	28	224
Automated Drug Delivery System (ADD(APD))	1	0	2	1	4
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	0	0	0	0
Clinics (CLN)	32	33	35	25	125
Clinics Government Owned (CLE)	23	15	11	10	59
Drug Room (DRM)	0	0	0	0	0
Drug Room Government Owned (DRE)	0	0	0	0	0
Hospitals (HSP)	2	5	4	1	12
Hospitals Government Owned (HPE)	0	1	7	0	8
Hospital Satellite Sterile Compounding (SCP)	0	0	0	1	1
Hospital Satellite Sterile Compounding Government Owned (SCE)	0	0	0	0	0
Hypodermic Needle and Syringes (HYP)	1	1	15	3	20
Correctional Pharmacy (LCF)	0	0	0	0	0
Outsourcing Facility (OSF)	0	0	2	2	4
Outsourcing Facility Nonresident (NSF)	2	2	1	0	5
Pharmacy (PHY)	96	74	98	72	340
Pharmacy (PHY) Chain	5	5	3	4	17
Pharmacy Government Owned (PHE)	1	3	1	0	5
Remote Dispensing Pharmacy (PHR)	0	0	0	0	0
Pharmacy Nonresident (NRP)	25	36	35	30	126
Sterile Compounding (LSC)	10	8	11	9	38
Sterile Compounding Government Owned (LSE)	1	1	8	0	10
Sterile Compounding Nonresident (NSC)	2	4	6	4	16
Surplus Medication Collection Distribution Intermediary (SME)	0	0	0	0	0
Third-Party Logistics Providers (TPL)	3	3	1	3	10
Third-Party Logistics Providers Nonresident (NPL)	8	5	7	4	24
Veterinary Food-Animal Drug Retailer (VET)	0	0	0	0	0
Wholesalers (WLS)	22	13	14	9	58
Wholesalers Government Owned (WLE)	1	0	0	0	1
Wholesalers Nonresident (OSD)	26	20	25	26	97
Total	**333**	**274**	**365**	**232**	**1,204**
*Number of applications received includes the number of temporary applications received.					
Applications Received with Temporary License Requests	**July - Sept**	**Oct-Dec**	**Jan-Mar**	**Apr-May**	**Total FYTD**
Drug Room -Temp (DRM)	0	0	0	0	0
Drug Room Government Owned-Temp (DRE)	0	0	0	0	0
Hospital - Temp (HSP)	2	4	4	1	11
Hospital Government Owned - Temp (HPE)	1	1	6	0	8
Hospital Satellite Sterile Compounding - Temp (SCP)	0	0	0	1	1
Hospital Satellite Sterile Compounding Government Owned - Temp (SCE)	0	0	0	0	0
Correctional Pharmacy -Temp (LCF)	0	0	0	0	0
Outsourcing Facility - Temp (OSF)	0	0	2	0	2
Outsourcing Facility Nonresident - Temp (NSF)	0	0	1	0	1
Pharmacy - Temp (PHY)	82	51	74	55	262
Pharmacy Government Owned - Temp (PHE)	2	0	0	0	2
Remote Dispensing Pharmacy - Temp (PHR)	0	0	0	0	0
Pharmacy Nonresident - Temp (NRP)	15	23	34	18	90
Sterile Compounding - Temp (LSC)	7	6	9	4	26
Sterile Compounding Government Owned - Temp (LSE)	1	1	6	0	8
Sterile Compounding Nonresident - Temp (NSC)	1	2	5	2	10
Third-Party Logistics Providers - Temp (TPL)	1	4	0	0	5
Third-Party Logistics Providers Nonresident - Temp (NPL)	2	2	4	3	11
Veterinary Food-Animal Drug Retailer - Temp (VET)	0	0	0	0	0
Wholesaler - Temp (WLS)	8	9	4	2	23
Wholesaler Government Owned - Temp (WLE)	0	0	0	0	0
Wholesalers Nonresident - Temp (OSD)	7	7	12	12	38
Total	**129**	**110**	**161**	**98**	**498**

LICENSES ISSUED

Individual Licenses Issued	July - Sept	Oct-Dec	Jan-Mar	Apr-May	Total FYTD
Designated Representatives (EXC)	57	78	155	72	362
Designated Representatives Vet (EXV)	0	7	3	0	10
Designated Representatives-3PL (DRL)	16	43	56	21	136
Designated Representatives-Reverse Distributor (DRR)	2	1	0	3	6
Designated Paramedic (DPM)	0	0	0	1	1
Intern Pharmacist (INT)	458	503	117	79	1,157
Pharmacist (RPH)	665	465	187	225	1,542
Advanced Practice Pharmacist (APH)	19	31	32	37	119
Pharmacy Technician (TCH)	1,228	1,546	1,623	905	5,302
Total	**2,445**	**2,674**	**2,173**	**1,343**	**8,635**

Temporary Individual Licenses (Military Spouses/Partners) Issued	July - Sept	Oct-Dec	Jan-Mar	Apr-May	Total FYTD
Temp-Designated Representatives-Wholesaler (TEX)	0	0	0	0	0
Temp-Designated Representatives-3PL (TDR)	0	0	0	0	0
Temp-Designated Representatives-Reverse Distributor (TRR)	0	0	0	0	0
Temp-Designated Paramedic (TDP)	0	0	0	0	0
Temp-Intern Pharmacist (TIN)	0	0	0	0	0
Temp-Pharmacist (TRP)	0	0	0	0	0
Temp-Advanced Practice Pharmacist (TAP)	0	0	0	0	0
Temp-Pharmacy Technician (TTC)	0	1	2	1	4
Total	**0**	**1**	**2**	**1**	**4**

Site Licenses Issued	July - Sept	Oct-Dec	Jan-Mar	Apr-May	Total FYTD
Automated Drug Delivery System (ADD(AUD))	93	94	50	50	287
Automated Drug Delivery System (ADD(APD))	0	1	1	1	3
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	0	0	0	0
Clinics (CLN)	7	33	9	14	63
Clinics Government Owned (CLE)	23	15	20	6	64
Drug Room (DRM)	0	0	0	0	0
Drug Room Government Owned (DRE)	0	0	0	0	0
Hospitals (HSP)	0	0	0	1	1
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	2	0	2
Correctional Pharmacy (LCF)	0	0	0	0	0
Outsourcing Facility (OSF)	0	0	0	1	1
Outsourcing Facility Nonresident (NSF)	1	0	2	0	3
Pharmacy (PHY)	16	23	25	5	69
Pharmacy Government Owned (PHE)	3	0	2	3	8
Remote Dispensing Pharmacy (PHR)	0	1	0	0	1
Pharmacy Nonresident (NRP)	4	2	1	7	14
Sterile Compounding (LSC)	1	5	4	1	11
Sterile Compounding Government Owned (LSE)	1	0	0	1	2
Sterile Compounding Nonresident (NSC)	2	1	1	0	4
Surplus Medication Collection Distribution Intermediary (SME)	0	0	0	0	0
Third-Party Logistics Providers (TPL)	0	2	1	0	3
Third-Party Logistics Providers Nonresident (NPL)	8	4	9	1	22
Veterinary Food-Animal Drug Retailer (VET)	0	0	6	0	6
Wholesalers (WLS)	13	8	6	5	32
Wholesalers Government Owned (WLE)	0	0	1	0	1
Wholesalers Nonresident (OSD)	11	10	16	17	54
Total	**183**	**199**	**156**	**113**	**651**

Site Temporary Licenses Issued	July - Sept	Oct-Dec	Jan-Mar	Apr-May	Total FYTD
Drug Room -Temp (DRM)	0	0	0	0	0
Drug Room Government Owned -Temp (DRE)	0	0	0	0	0
Hospital - Temp (HSP)	1	2	3	1	7
Hospital Government Owned - Temp (HPE)	1	1	6	0	8
Hospital Satellite Sterile Compounding - Temp (SCP)	0	0	0	0	0
Hospital Satellite Sterile Compounding Government Owned - Temp (SCE)	0	0	0	0	0
Correctional Pharmacy - Temp (LCF)	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)	64	77	45	43	229
Pharmacy Government Owned - Temp (PHE)	2	0	0	0	2
Remote Dispensing Pharmacy - Temp (PHR)	0	0	0	0	0
Pharmacy Nonresident - Temp (NRP)	11	19	22	6	58
Sterile Compounding - Temp (LSC)	2	3	3	6	14
Sterile Compounding Government Owned - Temp (LSE)	0	1	6	0	7
Sterile Compounding Nonresident - Temp (NSC)	0	0	1	3	4
Third-Party Logistics Providers - Temp (TPL)	1	1	0	0	2
Third-Party Logistics Providers Nonresident - Temp (NPL)	3	1	1	0	5
Veterinary Food-Animal Drug Retailer - Temp (VET)	0	0	0	0	0
Wholesaler - Temp (WLS)	6	3	4	5	18
Wholesaler Government Owned - Temp (WLE)	0	0	0	0	0
Wholesalers Nonresident - Temp (OSD)	5	3	6	7	21
Total	**96**	**111**	**97**	**71**	**375**

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

Individual Applications Pending	July - Sept	Oct-Dec	Jan-Mar	Apr-May
Designated Representatives (EXC)	267	273	212	207
Designated Representatives Vet (EXV)	7	4	4	4
Designated Representatives-3PL (DRL)	118	107	95	105
Designated Representatives-Reverse Distributor (DRR)	2	1	4	2
Designated Paramedic (DPM)	0	0	1	0
Intern Pharmacist (INT)	269	102	64	72
Pharmacist (exam not eligible)	1,271	1,399	135	1,716
Pharmacist (exam eligible)	1,325	854	1,021	1,062
Advanced Practice Pharmacist (APH)	125	123	134	119
Pharmacy Technician (TCH)	2,463	2,011	1,584	1,616
Total	**5,847**	**4,874**	**3,254**	**4,903**

Temporary Individual Applications Pending (Military Spouses/Partners)	July - Sept	Oct-Dec	Jan-Mar	Apr-May
Temp-Designated Representatives-Wholesaler (TEX)	0	0	0	0
Temp-Designated Representatives-3PL (TDR)	0	0	0	0
Temp-Designated Representatives-Reverse Distributor (TRR)	0	0	0	0
Temp-Designated Paramedic (TDP)	0	0	0	0
Temp-Intern Pharmacist (TIN)	0	0	0	0
Temp-Pharmacist (TRP)	0	0	0	0
Temp-Advanced Practice Pharmacist (TAP)	0	0	0	0
Temp-Pharmacy Technician (TTC)	1	2	1	1
Total	**1**	**2**	**1**	**1**

Site Applications Pending	July - Sept	Oct-Dec	Jan-Mar	Apr-May
Automated Drug Delivery System (ADD(AUD))	159	97	59	36
Automated Drug Delivery System (ADD(APD))	46	1	2	0
Automated Drug Delivery System EMS (ADE)	0	0	0	0
Automated Patient Dispensing System 340B Clinic (ADC)	0	0	0	0
Centralized Hospital Packaging Government Owned (CHE)	1	1	1	1
Centralized Hospital Packaging (CHP)	0	0	0	0
Clinics (CLN)	172	168	192	198
Clinics Government Owned (CLE)	27	24	15	16
Drug Room (DRM)	1	1	1	1
Drug Room Government Owned (DRE)	0	0	0	0
Hospitals (HSP)	7	10	11	11
Hospitals Government Owned (HPE)	1	1	2	2
Hospital Satellite Sterile Compounding (SCP)	2	1	1	1
Hospital Satellite Sterile Compounding Government Owned (SCE)	0	0	0	1
Hypodermic Needle and Syringes (HYP)	13	14	27	29
Correctional Pharmacy (LCF)	1	1	1	1
Outsourcing Facility (OSF)	1	1	3	4
Outsourcing Facility Nonresident (NSF)	13	15	12	11
Pharmacy (PHY)	262	214	240	257
Pharmacy Government Owned (PHE)	6	10	11	12
Remote Dispensing Pharmacy (PHR)	5	4	4	4
Pharmacy Nonresident (NRP)	181	175	185	192
Sterile Compounding (LSC)	64	58	59	61
Sterile Compounding - Government Owned (LSE)	10	10	12	12
Sterile Compounding Nonresident (NSC)	16	18	20	19
Surplus Medication Collection Distribution Intermediary (SME)	0	0	0	0
Third-Party Logistics Providers (TPL)	6	6	6	9
Third-Party Logistics Providers Nonresident (NPL)	69	69	66	69
Veterinary Food-Animal Drug Retailer (VET)	0	0	0	0
Wholesalers (WLS)	70	70	75	73
Wholesalers Government Owned (WLE)	2	2	1	1
Wholesalers Nonresident (OSD)	161	167	167	166
Total	**1,296**	**1,138**	**1,173**	**1,187**

Applications Pending with Temporary Licenses Issued - Pending Full License	July - Sept	Oct-Dec	Jan-Mar	Apr-May
Drug Room -Temp (DRM)	1	0	0	0
Drug Room Government Owned-Temp (DRE)	0	0	0	0
Hospital - Temp (HSP)	4	3	5	4
Hospital Government Owned - Temp (HPE)	1	2	7	7
Hospital Satellite Sterile Compounding - Temp (SCP)	0	0	0	0
Hospital Satellite Sterile Compounding Government Owned - Temp (SCE)	0	0	0	0
Correctional Pharmacy -Temp (LCF)	0	0	0	0
Outsourcing Facility - Temp (OSF)	1	0	0	1
Outsourcing Facility Nonresident - Temp (NSF)	0	0	0	0
Pharmacy - Temp (PHY)	102	126	108	101
Pharmacy Government Owned - Temp (PHE)	2	2	1	0
Remote Dispensing Pharmacy - Temp (PHR)	0	0	0	0
Pharmacy Nonresident - Temp (NRP)	21	28	37	38
Sterile Compounding - Temp (LSC)	6	4	6	9
Sterile Compounding Government Owned - Temp (LSE)	0	1	7	7
Sterile Compounding Nonresident - Temp (NSC)	2	0	1	4
Third-Party Logistics Providers - Temp (TPL)	1	1	0	0
Third-Party Logistics Providers Nonresident - Temp (NPL)	3	3	1	0
Veterinary Food-Animal Drug Retailer - Temp (VET)	0	0	0	0
Wholesaler - Temp (WLS)	6	5	3	6
Wholesaler Government Owned - Temp (WLE)	0	0	0	0
Wholesalers Nonresident - Temp (OSD)	6	5	7	10
Total	**156**	**180**	**183**	**187**

APPLICATIONS WITHDRAWN

Individual Applications	July - Sept	Oct-Dec	Jan-Mar	Apr-May	Total FYTD
Designated Representatives (EXC)	0	0	1	6	7
Designated Representatives Vet (EXV)	0	0	0	0	0
Designated Representatives-3PL (DRL)	0	0	0	1	1
Designated Representatives-Reverse Distributor (DRR)	0	0	0	0	0
Designated Paramedic (DPM)	0	0	0	0	0
Intern Pharmacist (INT)	1	0	1	0	2
Pharmacist (exam applications)	0	0	43	169	212
Advanced Practice Pharmacist (APH)	0	0	0	9	9
Pharmacy Technician (TCH)	2	0	124	41	167
Total	**3**	**0**	**169**	**226**	**398**

Temporary Individual Applications (Military Spouses/Partners)	July - Sept	Oct-Dec	Jan-Mar	Apr-May	Total FYTD
Temp-Designated Representatives-Wholesaler (TEX)	0	0	0	0	0
Temp-Designated Representatives-3PL (TDR)	0	0	0	0	0
Temp-Designated Representatives-Reverse Distributor (TRR)	0	0	0	0	0
Temp-Designated Paramedic (TDP)	0	0	0	0	0
Temp-Intern Pharmacist (TIN)	0	0	0	0	0
Temp-Pharmacist (TRP)	0	0	0	0	0
Temp-Advanced Practice Pharmacist (TAP)	0	0	0	0	0
Temp-Pharmacy Technician (TTC)	0	0	0	0	0
Total	**0**	**0**	**0**	**0**	**0**

Site Applications	July - Sept	Oct-Dec	Jan-Mar	Apr-May	Total FYTD
Automated Drug Delivery System (ADD(AUD))	27	12	67	3	109
Automated Drug Delivery System (ADD(APD))	0	44	0	0	44
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	0	0	0	0
Clinics (CLN)	3	4	2	5	14
Clinics Government Owned (CLE)	0	2	0	2	4
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 Ownerd (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)	1	0	0	1	2
Correctional Pharmacy (LCF)	0	0	0	0	0
Outsourcing Facility (OSF)	0	0	0	0	0
Outsourcing Facility Nonresident (NSF)	0	0	2	0	2
Pharmacy (PHY)	5	22	3	4	34
Pharmacy Government Owned (PHE)	0	0	0	0	0
Remote Dispensing Pharmacy (PHR)	0	0	0	0	0
Pharmacy Nonresident (NRP)	12	21	1	4	38
Sterile Compounding (LSC)	2	6	3	0	11
Sterile Compounding - Government Owned (LSE)	2	0	0	0	2
Sterile Compounding Nonresident (NSC)	2	1	2	1	6
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)	4	0	0	0	4
Veterinary Food-Animal Drug Retailer (VET)	0	0	0	0	0
Wholesalers (WLS)	2	1	0	0	3
Wholesalers Government Owned (WLE)	0	0	0	0	0
Wholesalers Nonresident (OSD)	1	0	2	3	6
Total	**61**	**114**	**82**	**23**	**280**

APPLICATIONS DENIED

Individual Applications	July - Sept	Oct-Dec	Jan-Mar	Apr-May	Total FYTD
Designated Representatives (EXC)	1	2	1	1	5
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	1	1	0	2
Pharmacist (exam application)	0	0	2	0	2
Pharmacist (exam eligible)	0	1	1	4	6
Advanced Practice Pharmacist (APH)	0	0	0	0	0
Pharmacy Technician (TCH)	5	9	16	11	41
Total	**6**	**13**	**21**	**16**	**56**

Temporary Individual Applications (Military Spouses/Partners)	July - Sept	Oct-Dec	Jan-Mar	Apr-May	Total FYTD
Temp-Designated Representatives-Wholesaler (TEX)	0	0	0	0	0
Temp-Designated Representatives-3PL (TDR)	0	0	0	0	0
Temp-Designated Representatives-Reverse Distributor (TRR)	0	0	0	0	0
Temp-Designated Paramedic (TDP)	0	0	0	0	0
Temp-Intern Pharmacist (TIN)	0	0	0	0	0
Temp-Pharmacist (TRP)	0	0	0	0	0
Temp-Advanced Practice Pharmacist (TAP)	0	0	0	0	0
Temp-Pharmacy Technician (TTC)	0	0	0	0	0
Total	**0**	**0**	**0**	**0**	**0**

Site Applications	July - Sept	Oct-Dec	Jan-Mar	Apr-May	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)	0	0	0	0	0
Pharmacy (PHY)	1	2	0	0	3
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)	0	0	0	0	0
Sterile Compounding Government Owned (LSE)	0	0	0	0	0
Sterile Compounding Nonresident (NSC)	0	1	0	0	1
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	**1**	**3**	**0**	**0**	**4**

RESPOND TO STATUS INQUIRIES

Email Inquiries	July - Sept	Oct-Dec	Jan-Mar	Apr-May	Total FYTD
Designated Representative Received	405	424	393	347	1,569
Designated Representative Responded	115	67	276	193	651
Advanced Practice Pharmacist Received	227	189	185	296	897
Advanced Practice Pharmacist Responded	29	73	88	185	375
Pharmacist/Intern Received	2,216	1,501	1,197	856	5,770
Pharmacist/Intern Responded	2,216	1,501	1,197	856	5,770
Pharmacy Technician Received	2,721	1,851	1,524	1,028	7,124
Pharmacy Technician Responded	1,551	854	786	724	3,915
Pharmacy Received	2,297	2,073	2,832	1,989	9,191
Pharmacy Responded	1,837	1,269	2,288	1,719	7,113
Sterile Compounding/Outsourcing Received	647	720	1,019	478	2,864
Sterile Compounding/Outsourcing Responded	342	513	521	383	1,759
Wholesale/Hypodermic/3PL Received	811	468	394	754	2,427
Wholesale/Hypodermic/3PL Responded	549	592	924	712	2,777
Clinic Received	462	494	467	393	1,816
Clinic Responded	525	428	349	289	1,591
Automated Drug Delivery Systems Received	574	258	449	339	1,620
Automated Drug Delivery Systems Responded	440	174	374	178	1,166
Pharmacist-in-Charge Received	1,063	1,091	1,143	806	4,103
Pharmacist-in-Charge Responded	1,074	1,030	1,078	739	3,921
Change of Permit Received	598	577	768	365	2,308
Change of Permit Responded	502	481	669	378	2,030
Renewals Received	1,719	1,238	1,483	923	5,363
Renewals Responded	1,524	1,064	1,358	889	4,835

Telephone Calls Received	July - Sept	Oct-Dec	Jan-Mar	Apr-May	Total FYTD
Designated Representative	0	20	0	0	20
Advanced Practice Pharmacist	98	70	107	50	325
Pharmacist/Intern	1,787	742	510	633	3,672
Pharmacy	634	535	529	321	2,019
Sterile Compounding/Outsourcing	106	73	62	21	262
Wholesale/Hypodermic/3PL	112	102	80	82	376
Clinic	152	63	55	64	334
Automated Drug Delivery Systems	10	4	8	4	26
Pharmacist-in-Charge	384	164	141	120	809
Change of Permit	90	72	84	30	276
Renewals*	961	1,785	2,284	0	5,030
Reception*	21,879	18,305	22,580	0	62,764

*Q4 (Apr-MayE) the total number of phone calls for Renewals and Reception is not reported as the Department is providing data will update once received

UPDATE LICENSING RECORDS

Change of Pharmacist-in-Charge	July - Sept	Oct-Dec	Jan-Mar	Apr-May	Total FYTD
Received	476	489	464	335	1,764
Processed	502	450	533	271	1,756
Approved	444	496	544	283	1,767
Pending (Data reflects number of pending at the end of the quarter.)	295	291	182	231	231

Change of Designated Representative-in-Charge	July - Sept	Oct-Dec	Jan-Mar	Apr-May	Total FYTD
Received	36	35	50	23	144
Processed	37	22	63	22	144
Approved	29	22	62	28	141
Pending (Data reflects number of pending at the end of the quarter.)	39	51	39	34	34

Change of Responsible Manager	July - Sept	Oct-Dec	Jan-Mar	Apr-May	Total FYTD
Received	13	8	8	6	35
Processed	10	8	11	6	35
Approved	10	7	15	8	40
Pending (Data reflects number of pending at the end of the quarter.)	12	14	8	6	6

Change of Professional Director	July - Sept	Oct-Dec	Jan-Mar	Apr-May	Total FYTD
Received	9	12	24	15	60
Processed	7	7	28	15	57
Approved	12	12	31	16	71
Pending (Data reflects number of pending at the end of the quarter.)	33	31	24	22	22

Change of Permits	July - Sept	Oct-Dec	Jan-Mar	Apr-May	Total FYTD
Received	645	655	440	397	2,137
Processed	908	977	1,116	363	3,364
Approved	513	1,532	1,354	415	3,814
Pending (Data reflects number of pending at the end of the quarter.)	3,497	2,446	1,518	1,427	1,427

Discontinuance of Business	July - Sept	Oct-Dec	Jan-Mar	Apr-May	Total FYTD
Received	134	175	141	87	537
Processed	131	161	179	89	560
Approved	95	111	203	210	619
Pending (Data reflects number of pending at the end of the quarter.)	290	355	310	215	215

Intern Pharmacist Extensions	July - Sept	Oct-Dec	Jan-Mar	Apr-May	Total FYTD
Received	29	18	48	48	143
Processed	46	23	48	46	163
Completed	41	23	35	61	160
Pending (Data reflects number of pending at the end of the quarter.)	17	16	29	13	13

Requests Approved	July - Sept	Oct-Dec	Jan-Mar	Apr-May	Total FYTD
Address/Name Changes	2,990	2,326	2,479	1,661	9,456
Off-site Storage	198	14	19	36	267
Transfer of Intern Hours	10	6	12	8	36
License Verification	135	127	144	126	532

DISCONTINUED BUSINESS

discontinued by reported date of closure

Site Licenses	July - Sept	Oct-Dec	Jan-Mar	Apr-May	Total FYTD
Automated Drug Delivery System (ADD(AUD))	29	19	65	23	136
Automated Drug Delivery System (ADD(APD))	0	3	0	0	3
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	0	0	0	0
Clinics (CLN)	4	3	2	0	9
Clinics Government Owned (CLE)	4	9	7	4	24
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	1	0	0	1
Correctional Pharmacy (LCF)	1	1	0	0	2
Outsourcing Facility (OSF)	0	1	0	0	1
Outsourcing Facility Nonresident (NSF)	1	0	0	0	1
Pharmacy (PHY)	23	18	22	12	75
Pharmacy (PHY) Chain	36	74	57	43	210
Pharmacy Government Owned (PHE)	0	0	1	0	1
Remote Dispensing Pharmacy (PHR)	0	0	0	0	0
Pharmacy Nonresident (NRP)	6	10	7	2	25
Sterile Compounding (LSC)	9	11	7	4	31
Sterile Compounding Government Owned (LSE)	0	0	0	0	0
Sterile Compounding Nonresident (NSC)	1	1	0	1	3
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)	2	1	0	2	5
Veterinary Food-Animal Drug Retailer (VET)	0	0	0	0	0
Wholesalers (WLS)	6	2	2	2	12
Wholesalers Government Owned (WLE)	0	0	0	0	0
Wholesalers Nonresident (OSD)	6	8	7	4	25
Total	**128**	**162**	**177**	**97**	**564**

LICENSES RENEWED

Individual Licenses Renewed	July - Sept	Oct-Dec	Jan-Mar	Apr-May	Total FYTD
Designated Representatives (EXC)	655	576	669	376	2,276
Designated Representatives Vet (EXV)	16	5	12	10	43
Designated Representatives-3PL (DRL)	111	90	100	63	364
Designated Representatives-Reverse Distributor (DRR)	0	5	2	3	10
Designated Paramedic (DPM)	1	1	0	0	2
Pharmacist (RPH)	6,374	5,809	5,252	3,850	21,285
Advanced Practice Pharmacist (APH)	144	142	148	92	526
Pharmacy Technician (TCH)	7,883	6,858	6,136	4,232	25,109
Total	**15,184**	**13,486**	**12,319**	**8,626**	**49,615**

Site Licenses Renewed	July - Sept	Oct-Dec	Jan-Mar	Apr-May	Total FYTD
Automated Drug Delivery System (ADD(APD & AUD))	192	637	69	77	975
Automated Drug Delivery System EMS (ADE)	0	0	1	0	1
Automated Patient Dispensing System 340B Clinic (ADC)	0	1	0	0	1
Centralized Hospital Packaging Government Owned (CHE)	1	0	0	0	1
Centralized Hospital Packaging (CHP)	4	0	3	1	8
Clinics (CLN)	419	281	445	166	1,311
Clinics Government Owned (CLE)	57	798	44	9	908
Drug Room (DRM)	3	5	9	3	20
Drug Room Government Owned (DRE)	1	8	0	0	9
Hospitals (HSP)	61	160	87	61	369
Hospitals Government Owned (HPE)	43	13	3	10	69
Hospital Satellite Sterile Compounding (SCP)	2	1	0	0	3
Hospital Satellite Sterile Compounding Government Owned (SCE)	2	0	0	1	3
Hypodermic Needle and Syringes (HYP)	63	42	53	36	194
Correctional Pharmacy (LCF)	5	49	0	0	54
Outsourcing Facility (OSF)	1	1	1	0	3
Outsourcing Facility Nonresident (NSF)	2	4	5	4	15
Pharmacy (PHY)	1,153	2,065	1,238	1,178	5,634
Pharmacy Government Owned (PHE)	51	58	12	11	132
Remote Dispensing Pharmacy (PHR)	0	2	0	1	3
Pharmacy Nonresident (NRP)	125	124	160	81	490
Sterile Compounding (LSC)	143	263	130	92	628
Sterile Compounding Government Owned (LSE)	58	6	5	14	83
Sterile Compounding Nonresident (NSC)	8	14	13	10	45
Surplus Medication Collection Distribution Intermediary (SME)	1	0	0	0	1
Third-Party Logistics Providers (TPL)	13	4	10	4	31
Third-Party Logistics Providers Nonresident (NPL)	47	36	25	11	119
Veterinary Food-Animal Drug Retailer (VET)	2	3	10	2	17
Wholesalers (WLS)	125	81	102	67	375
Wholesalers Government Owned (WLE)	3	5	0	1	9
Wholesalers Nonresident (OSD)	212	158	182	112	664
Total	**2,797**	**4,819**	**2,607**	**1,952**	**12,175**

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

Individual Licenses	July - Sept	Oct-Dec	Jan-Mar	Apr-May
Designated Representatives (EXC)	2,829	2,823	2,902	2,911
Designated Representatives Vet (EXV)	55	58	61	60
Designated Representatives-3PL (DRL)	480	509	549	576
Designated Representatives-Reverse Distributor (DRR)	15	16	16	19
Designated Paramedic (DPM)	3	3	2	3
Intern Pharmacist (INT)	4,740	4,900	4,876	4,421
Pharmacist (RPH)	49,906	50,154	50,051	49,893
Advanced Practice Pharmacist (APH)	1,210	1,241	1,272	1,348
Pharmacy Technician (TCH)	65,218	65,803	66,098	65,793
Total	**124,456**	**125,507**	**125,827**	**125,024**

Temporary Individual Licenses (Military Spouses/Partners)	July - Sept	Oct-Dec	Jan-Mar	Apr-May
Temp-Designated Representatives-Wholesaler (TEX)	0	0	0	0
Temp-Designated Representatives-3PL (TDR)	0	0	0	0
Temp-Designated Representatives-Reverse Distributor (TRR)	0	0	0	0
Temp-Designated Paramedic (TDP)	0	0	0	0
Temp-Intern Pharmacist (TIN)	0	0	0	0
Temp-Pharmacist (TRP)	0	0	0	0
Temp-Advanced Practice Pharmacist (TAP)	0	0	0	0
Temp-Pharmacy Technician (TTC)	0	1	3	4
Total	**0**	**1**	**3**	**4**

Site Licenses	July - Sept	Oct-Dec	Jan-Mar	Apr-May
Automated Drug Delivery System (ADD(AUD))	1,094	1,118	1,133	1,102
Automated Drug Delivery System (ADD(APD))	20	18	16	17
Automated Drug Delivery System EMS (ADE)	1	1	1	1
Automated Patient Dispensing System 340B Clinic (ADC)	1	1	1	1
Centralized Hospital Packaging Government Owned (CHE)	2	2	2	2
Centralized Hospital Packaging (CHP)	8	8	8	8
Clinics (CLN)	1,404	1,429	1,436	1,456
Clinics Government Owned (CLE)	938	944	956	950
Drug Room (DRM)	21	21	21	21
Drug Room Government Owned (DRE)	10	10	10	10
Hospitals (HSP)	399	399	397	396
Hospitals Government Owned (HPE)	77	78	84	84
Hospital Satellite Sterile Compounding (SCP)	4	4	4	4
Hospital Satellite Sterile Compounding Government Owned (SCE)	4	4	4	5
Hypodermic Needle and Syringes (HYP)	237	231	233	233
Correctional Pharmacy (LCF)	57	56	56	55
Outsourcing Facility (OSF)	4	4	3	3
Outsourcing Facility Nonresident (NSF)	20	20	21	21
Pharmacy (PHY)	6,091	6,072	5,990	5,944
Pharmacy Government Owned (PHE)	144	144	145	147
Remote Dispensing Pharmacy (PHR)	2	3	3	3
Pharmacy Nonresident (NRP)	599	607	602	601
Sterile Compounding (LSC)	707	706	692	686
Sterile Compounding Government Owned (LSE)	103	104	109	110
Sterile Compounding Nonresident (NSC)	58	58	57	54
Surplus Medication Collection Distribution Intermediary (SME)	1	1	1	1
Third-Party Logistics Providers (TPL)	36	39	40	40
Third-Party Logistics Providers Nonresident (NPL)	140	143	153	157
Veterinary Food-Animal Drug Retailer (VET)	18	18	18	18
Wholesalers (WLS)	477	481	482	485
Wholesalers Government Owned (WLE)	10	10	11	11
Wholesalers Nonresident (OSD)	809	809	818	824
Total	**13,496**	**13,543**	**13,507**	**13,450**
Total Population of Licenses	**137,952**	**139,051**	**139,337**	**138,478**