California State Board of Pharmacy
2720 Gateway Oaks Drive, Ste 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

To: Board Members

Subject: Agenda Item III. Discussion and Consideration of Joint Sunset Review Oversight Identified Issues, Background, and Recommendations Regarding the California State Board of Pharmacy

Background

As discussed during the November 19, 2020, Board Meeting, members were advised that, President Lippe and Executive Officer Sodergren testified on behalf of the Board during the Sunset oversight hearing held on November 18, 2020. As part of the oversight hearing, a Background Paper on the Board was released, summarizing information about the Board, and identifying current sunset review issues for the Board's response. The Board is required to respond to the current issues identified within 30 days of the oversight hearing.

For Discussion and Consideration

During the meeting members will have the opportunity to review the draft Board responses to the issues identified. For ease of the reader, Board staff incorporated draft recommended responses within the Current Sunset Review Issues portion of the Background Paper. The draft Board responses do not restate previously provided information. Rather, it provides a response to the specific current questions raised in the Background Paper.

Following is a copy of the draft responses. Members will note that several statutory proposals are referenced throughout the draft responses. With the exception of the outsourcing proposal, all such proposals were previously approved by the Board.

Upon approval by the Board, staff will finalize the report making necessary edits, formatting changes, etc., in advance of submission to the oversight committees.

For reference, the Board's Sunset Oversight Review Report 2019 and Volume 2 are posted on the Board's website. Further the Board's Sunset Oversight Review Supplemental Report 2020 and Volume 2 are also posted on the Board's website. The Background Paper for the California State Board of Pharmacy is posted on the website of the oversight committees.

CURRENT SUNSET REVIEW ISSUES FOR THE CALIFORNIA STATE BOARD OF PHARMACY

ADMINISTRATIVE ISSUES

ISSUE #1: ***Board Composition. Does the current membership on the Board appropriately balance professional expertise and public objectivity?***

Background: Statute prescribes the composition of the Board, which includes both licensed pharmacists (professional members) and individuals who are not licensees (public members). Statute provides for a total of thirteen board members. When all appointments to the Board have been made, there are a total of seven professional members and six public members, resulting in a slight majority of members as active licenseholders. In 2015, the United States Supreme Court ruled in *North Carolina State Board of Dental Examiners v. Federal Trade Commission* that when a state regulatory board features a majority share of active market participants, any allegedly anticompetitive decision-making may not be subject to *Parker* antitrust litigation immunity unless there is "active state supervision" to ensure that all delegated authority is being executed in the interest of the public and not the private commercial interests of the members.

To date, there has been no meaningful litigation against public bodies established under California law, and it is likely that the Board receives more than enough active state supervision to qualify for immunity. The Board is considered only semi-autonomous, with much of its rulemaking and disciplinary activity subject to involvement by multiple other governmental entities. Its current Executive Officer is not a licensee; however, there is no statutory prohibition against the appointment of a future Executive Officer who is also a market participant. Finally, the Department of Consumer Affairs has also worked to ensure that members are adequately trained in certain procedures to ensure an adequate record of deliberation for purposes of defense against any potential allegations of antitrust.

Notwithstanding the legal sensitivities accompanying boards with majority professional memberships, the disproportionality for the Board is arguably minor, with an advantage of only one additional member who is a licensee. Considering the numerous benefits of having professional perspectives in deliberations by the Board regarding the practice of pharmacy, this technical imbalance is unlikely to be in need of any further statutory change. However, the Board should remain mindful whenever it engages in formal decision-making that may appear to serve the economic interests of licensee populations represented on the Board.

Staff Recommendation: ***The Board should describe what efforts it has taken to ensure its decision-making is subject to state supervision so as to safeguard its members from antitrust allegations.***

Draft Board Response: The Board is a quasi-autonomous agency, under the umbrella of the Department of Consumer Affairs. While the Board has the authority to take some actions independently, such as decisions on administrative matters, policy making activities are not effectuated without significant oversight and evaluation by either the legislature and administration, in the case of statutory changes, or review and approval by various control agencies, as is the case with the promulgation of regulations. Statutory changes are less

susceptible to antitrust challenges because the Legislature in passing statutes will balance competing interests during the process. The Board is committed to its consumer protection mandate and focuses its policy making rulemaking on efforts to improve protections for Californians and ensures that the record reflects its primary goal. Also, the Board only adopts regulations after public comment during open meetings. It is very common for stakeholders to provide comments during public meetings, submit comments as part of the rulemaking process, and through the legislative process, to advocate for changes that may be contrary to the Board's consumer protection mandate.

ISSUE #2: *Board Member Expertise. Does existing law requiring the appointment of pharmacists representing specific practice settings provide sufficient expert perspectives on matters coming before the Board?*

Background: In addition to requiring both professional and public members, there is further specificity regarding who serves on the Board. Statute requires at least five of pharmacist appointees be actively engaged in the practice of pharmacy. The Board must also include "at least one pharmacist representative from each of the following practice settings: an acute care hospital, an independent community pharmacy, a chain community pharmacy, and a long-term health care or skilled nursing facility."

Notwithstanding these requirements, there are a number of perspectives that are currently not required to be reflect on the Board. One such category of professional expertise is in the area of pharmacy compounding. This area of practice has recently drawn national attention for both its importance and complexity, and the Board recently put forth a number of regulations regarding pharmacy compounding. While the Board does feature some expertise in this area there has not been a compounding pharmacist specifically represented on the Board. Amending law to require at least one of the professional members to be a compounding pharmacist may provide new meaningful expertise in Board decision-making.

Another identifiable lack of representation on the Board is the absence of a pharmacy technician member. In addition to overseeing the licensure of pharmacists, the Board is also responsible for regulating pharmacy technicians. However, the professional membership of the Board currently only includes pharmacists. Other healing arts boards are often allotted one appointment for associated licensed auxiliaries and allied professionals; it may be worthy of consideration that a technician be added to the current Board to ensure that it is conscious of distinct issues impacting that occupation.

Staff Recommendation: ***The Board should discuss whether it believes amending the Pharmacy Law to require the presence of additional professional perspectives on the Board would assist it in carrying out its public protection mission.***

Draft Board Response: Pharmacy Law establishes the provisions for representation on the Board. The Board's mandate clearly states that whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount. With consumer protection at the core of its decision making, the Board recognizes that it is not uncommon for competing interest to be present in its decision-making; however, in its decision

making the Board remains focused on its commitment to public protection as its highest priority. Policy making activities of the Board are conducted in public meetings, with stakeholders being provided the opportunity to provide comments to the Board. It is very common for differing perspectives to be shared during the public meetings. Further, the Board seeks information from experts as appropriate. Recent examples include collaboration with experts in Opioid Use Disorder who offered recommendations for the Board's consideration in its policy recommendations related to Medication Assisted Treatment and collaboration with experts in HIV pre-exposure and postexposure prophylaxis when developing its regulations in the area.

Regarding compounding specifically, Pharmacy Law provides that compounding of drug preparations shall be consistent with the standards established in the pharmacy compounding chapters of the current version of the United States Pharmacopeia-National Formulary and regulations adopted by the Board. More specifically, USP develops and publishes standards for drug substances, drug products, excipients, and dietary supplements in the USP-NF. These standards are recognized in the Federal Food, Drug and Cosmetic (FD&C) Act. USP-NF standards play a role in the determination of whether a drug is adulterated and misbranded under the FD&C but USP as an organization has no role in the enforcement of the provisions, which is the responsibility of the FDA and other government authorities in the US, including the Board. Specific to compounded preparations, USP provides both general chapters and monographs for compounded preparations. These standards are developed by the USP Compounding Expert Committee to help ensure the quality of compounded medicines.

As part of its decision making, the Board relies on the work of this group of experts as the foundation for its regulation and decision making related to compounding. Earlier this year, in response to appeals on proposed revisions to Compounding Chapters <795>, <797>, and <825>, the Board suspended its efforts to update compounding regulations.

With that understanding, the Board does not believe additional professional perspectives are necessary.

ISSUE #3: ***Board Vacancies. What solutions might be considered to address the substantial member vacancy rates that have persisted on the Board?***

Background: In recent years, the Board has experienced challenges in achieving a quorum at meetings, with an average of three vacancies existing on the Board. These vacancies have participated in large part due to difficulty recruiting qualified appointees to serve on the Board. The time commitment involved has been identified as a large driver of this problem, with the Board currently holding as many as eight meetings in a year in addition to its committee meetings. Particularly for professional members, this means time away from paid practice and can present a substantial hardship.

One potential solution to these recruitment issues is increasing the availability of teleconferencing when possible to allow Board members to participate remotely. The Board already holds some meetings via teleconference, and the format has been adopted by other boards. Increasing its use could potentially increase the range of available applicants. Further, current requirements that the

full Board review all disciplinary matters should be evaluated for whether it is a necessary burden on member time.

Staff Recommendation: ***The Board should discuss what steps it has taken to incentivize board member participation and whether it believes teleconferencing or other solutions could help address the current vacancy rate.***

Draft Board Response: Under the provisions of law, members are entitled to $100/day per diem and reimbursement for travel-related expenses although per diem payments are not permitted for public members if they are receiving pay from another State position. The Board establishes its meeting calendar typically six months to a year in advance; however, as urgent issues arise, changes to the calendar or additional meetings are at times necessary. The Board has used teleconference meetings on occasion but notes that teleconference requirements under the Open Meetings Act generally requires that all locations from which members are participating must also provide opportunity for public participation. The intent is to ensure ready public access and participation in meetings, but can sometimes present challenges, particularly if a member wants to attend a meeting from a work location.

The Board's transition to videoconferencing of meetings under the provisions established in Governor Gavin Newsom's Executive Order N-29-20, that does not require that each meeting location be available to the public, has provided the Board with an alternative meeting platform that provides a safe and efficient means to conduct meetings. The Board continues to receive significant participation from stakeholders at these meetings and believes providing permanent authority to convene meetings in such a manner without requiring public access at each teleconference site will provide Board members and stakeholders flexibility for participation that could also result in significant cost savings to the Board and time savings for Board members. Such flexibility may be most important to members trying to balance attendance at Board meetings with their professional practices.

ISSUE #4: ***Executive Officer Eligibility. Should statute be revised to ensure future Executive Officers remain sufficiently independent in their service to the Board?***

Background: The Pharmacy Law currently states that the Executive Officer "may or may not be a member of the board as the board may determine." No Executive Officer has concurrently served as a board member in recent history, and such practice is either discouraged or prohibited for similar boards because of the potential for conflicts of interest and the diminishment of independence between Board staff and the voting members. It may be practicable for Pharmacy Law to be amended to strike reference to board members serving as Executive Officer.

Additionally, there is currently nothing in the Pharmacy Law prohibiting the Executive Officer from being a licensee of the Board. While the governing statutes for most boards are silent on this issue, it may be argued that in cases where executive board staff are also licensed by the Board, there is less active state supervision over the profession and administrative functions are carried out with less objectivity. While the current Executive Officer is not a licensee, codifying a prohibition against that hypothetical may ensure the Board engages in prudent recruitment activities in the future.

Staff Recommendation: ***The Board should inform the committees of whether it believes the qualifications for its Executive Officer should be revised to specify that they be neither a member of the board or a licensee, as is currently already the case.***

Draft Board Response: The Government Code provides a distinct separation of powers between the Executive Officer and Board Members, most notably with the Executive Officer charged with serving as a complainant in administrative matters while the Board serves as the final decision maker in such matters. The Board notes that the separation of roles could become blurred if the Executive Officer was simultaneously serving as a Board member. Further, being mindful of the basic tenets of the North Carolina Decision, and in recognition of the unique authorities vested in the Executive Officer, including the issuance of cease and desist orders, it could potentially create liability to the Board should the Executive Officer also be a licensee or a Board member. The Board is cognizant of these issues and believes that it is appropriate to modify pharmacy law to prohibit a Board member from also being appointed as the Executive Officer. The Board appropriately exercises its decision-making in the appointment of the Executive Officer and believes it must otherwise retain flexibility to select the most qualified candidate for such a position.

ISSUE #5: *Board Attorney. Does the Board have sufficient legal counsel?*

Background: Business and Professions Code § 4008 expressly provides the Board with the authority to employ legal counsel. However, the Board does not currently have its own dedicated attorney. Legal representation in disciplinary prosecution is provided by the Attorney General's Licensing Section, and the Department of Consumer Affairs offers counsel as part of the centralized services it provides to boards, as needed to assist with rulemaking, address legal issues that arise, and support compliance with open meeting laws.

Dedicated board counsel is, however, considered to provide substantial value when questions of law occur regularly enough to warrant the presence of attorney who specializes in a board's practice act, and may help improve the Board's rulemaking timelines. It is under this line of thinking that the Legislature has authorized the Board to appoint its own lawyer, and any reasons for that position remaining unfilled should be discussed before the committees.

Further, the Attorney General's Office has recently transferred both deputy attorneys general who previously advised the Board. Particularly as the Attorney General's billing rate has increased substantially, these may each be factors in costlier and lengthier enforcement activities by the Board.

Staff Recommendation: ***The Board should provide insight into how the Pharmacy Law may be amended to assist it in hiring its own dedicated counsel, and should speak to whether it believes it is currently receiving adequate expert advice from the Office of the Attorney General.***

Draft Board Response: The Board supported the provisions to allow for the hiring of its own dedicated counsel and continues to support such provisions. The Board believes it is appropriate given the complexity of the state and federal law the Board is charged with regulating. The Medical Board of California currently employs independent counsel while also using DCA counsel.

Such an approach allows for subject matter expertise in the practice act and continuity in representation while also leveraging the knowledge within the DCA's legal office for cross-cutting legal issues, e.g., compliance with Open Meetings Act requirements, Public Records Act, Information Practices Act, rulemaking process, etc. The Board supports this model and would welcome the opportunity to collaborate with the legislature and administration on this issue. The Board appreciates the representation provided by the OAG.

FISCAL ISSUES

ISSUE #6: *Attorney General Billing Rate. Will the abrupt increase in the Attorney General's client billing rate for hours spent representing the Board in disciplinary matters result in cost pressures for the Board's special fund?*

Background: In July of 2019, the California Department of Justice announced that it was utilizing language included in the Governor's Budget authorizing it to increase the amount it billed to client agencies for legal services. The change was substantial: the attorney rate increased by nearly 30% from $170 to $220, the paralegal rate increased over 70% from $120 to $205, and the analyst rate increased 97% from $99 to $195. While justification was provided for why an adjustment to the rates was needed, the rate hike occurred almost immediately and without any meaningful notice to any client agencies.

For special funded entities such as the Board, unexpected cost pressures can be devastating. The Board has indicated that it estimates added costs of $1.3 million annually solely as a result of the Attorney General's rate increase. As the Board recently secured a fee increase prior to rate increase, the committees should be informed of whether the Attorney General's Office or the Administration has informed the Board of any efforts to provide assistance with ensuring that the Board is able to maintain a healthy fund condition going forward.

Staff Recommendation: ***The Board should discuss with the committees the impact of the Attorney General's rate increase and whether any action is needed by the Administration or the Legislature to safeguard the health of its special fund.***

Draft Board Response: Like other programs within the DCA, it relies heavily on the services of the Office of the Attorney General (OAG) for representation in a variety of matters and appreciates its representation. The Board does not anticipate the need to increase fees as a result of OAG billing rate increase but will be closely monitoring its fund. The Board also looks forward to working with the OAG to identify opportunities to achieve savings where possible.

LICENSING ISSUES

ISSUE #7: *Advanced Pharmacy Technicians. Should the Board be authorized to grant licenses for pharmacy technicians qualified to engage in advanced practice?*

Background: Over the last several years, the Board has voted to support the development of a

legislative proposal to create a new mid-level practitioner in pharmacy settings. This proposed advanced pharmacy technician would be authorized to carry out certain duties that pose a low risk of harm but may currently only be performed by pharmacists, allowing a pharmacist to spend more time engaged in patient care.

While the Board has formally pursued legislation to establish a new license category for advanced pharmacy technicians and enable these mid-level practitioners to serve in pharmacies, no legislative attempt has been successful to date. There are doubtlessly many issues to be resolved regarding what qualifications an advanced pharmacy technician would have to possess and what duties they would be allowed to perform. Nevertheless, the topic may still be worthy of discussion, and the committees should be made aware of any renewed efforts underway to implement the proposal.

Staff Recommendation: ***The Board should provide the committees with an overview of whether and why the advanced pharmacy technician license type should be established, and what steps may be taken to begin constructive dialogue with stakeholders on the issue.***

Draft Board Response: Pharmacists are highly accessible, well educated, health care professionals. As California expands provisions for pharmacist-provided patient care services, workload challenges and the need for additional assistance must be considered. The Board and its Licensing Committee held a series of public meetings to develop a mid-level practitioner licensing program intended to provide meaningful assistance to pharmacists. In developing its proposal, the Board's focus has been centered on consumer protection; however, competing interests have been expressed by various stakeholders representing different constituencies. While finalizing the proposal earlier in 2020, stakeholders requested opportunity for further discussion. Regrettably, the Board's subsequent discussion on the development of the proposal was postponed in response to the COVID-19 pandemic. The Board intends to resume its public discussion in 2021.

ISSUE #8: *Fair Chance Licensing Act. What is the status of the Board's implementation of Assembly Bill 2138 (Chiu/Low) and are any statutory changes needed to enable the Board to better carry out the intent of the Act?*

Background: In 2018, Assembly Bill 2138 (Chiu/Low, Chapter 995, Statutes of 2018) was signed into law, making substantial reforms to the license application process for individuals with criminal records. Under AB 2138, an application may only be denied on the basis of prior misconduct if the applicant was formally convicted of a substantially related crime or was subject to formal discipline by a licensing board. Further, prior conviction and discipline histories are ineligible for disqualification of applications after seven years, with the exception of serious and registerable felonies, as well as financial crimes for certain boards. Among other provisions, the bill additionally requires each board to report data on license denials, publish its criteria on determining if a prior offense is substantially related to licensure, and provide denied applicants with information about how to appeal the decision and how to request a copy of their conviction history. These provisions were scheduled to go into effect on July 1, 2020.

Because AB 2138 significantly modifies current practice for boards in their review of applications for licensure, it was presumed that its implementation would require changes to current regulations

for every board impacted by the bill. Recently, the Board was in the process of finalizing its regulations to revise its denial criteria to incorporate the changes from the bill. It is also likely that the Board has identified changes to the law that it believes may be advisable to better enable it to protect consumers from license applicants who pose a substantial risk to the public.

Staff Recommendation: ***The Board should provide an update in regards to its implementation of the Fair Chance Licensing Act, as well as relay any recommendations it has for statutory changes.***

Draft Board Response: As part of its May 2019 Board Meeting, the Board voted to approve draft regulations necessary to facilitate implementation of the provisions of the Fair Chance Licensing Act. The regulation package is currently undergoing review by the Office of the Administrative Law.

Further, in addition to development of the regulations, the Board identified consumer protection concerns with the loss of some of its discretion in considering arrest or conviction background information when making a licensing decision. The Board is offering recommendations that will restore some discretion particularly with respect to practitioners with access to controlled substances to harmonize with federal requirements and in other areas that the Board believes present risks that need to be addressed either due to the type of product the licensee is involved with, or the access to sensitive patient medical information that Board licensees have.

Specifically, the Board supports provisions that will allow the Board to consider the following acts:

1. An act that would be grounds for denial of a federal registration to distribute controlled substances.
2. An act involving fraud in violation of state or federal laws related to healthcare, e.g. Medi-Cal or Medicare billing fraud, etc.
3. Conviction of a crime involving identity theft.
4. Conviction of a crime involving the sale of counterfeit products.

A copy of the proposed statutory change is provided as Attachment A.

ISSUE #9: ***Third-Party Logistics Providers. Should the Board be authorized to conduct inspections of third-party logistics providers that are not fully licensed in their resident states to allow for operation within California?***

Background: Federal law enacted in 2013 prohibits states from regulating third-party logistics providers, or 3PLs, as wholesalers. Because 3PLs are considered vital members of the supply chain that store, select, and ship prescription drugs, the Board pursued legislation in 2014 to establish licensure of 3PLs as a separate category of licensee. While other states have taken similar action in their jurisdictions, some states continue to regulate 3PLs as wholesalers. As a result, these entities are prohibited from doing business in California, because they are not appropriately licensed in their home state and therefore cannot be licensed in California.

To remedy the problem, the Board proposes to seek statutory authority to change the licensing

requirements for such 3PLs. The business would be inspected before licensure, similar to the process used for initial licensure of nonresident sterile compounding pharmacies. If the inspection confirms the business is in compliance with state and federal law, licensure as a 3PL in the home state will not be required. The board does not believe that an annual inspection would be required. Instead, inspection could be limited to every four years or until such time as the resident state makes the necessary changes to its law.

Staff Recommendation: ***The Board should further explain its proposal for modifying the licensure process of 3PLs that are not properly licensed in their home states, and provide the committees with any suggested language.***

Draft Board Response: As discussed in the Board's Sunset Report, federal law prohibits the regulation of third-party logistics providers as wholesalers. Although California and some other states developed separate regulation for such entities, not all states have taken similar action. This has created a barrier to licensure. This challenge became more pronounced during the COVID-19 pandemic, as contracts were secured between the federal government and entities located in states without separate third-party logistics provider regulation. In such cases, through delegated authority, waivers were granted on a limited basis to allow for the issuance of a temporary license to allow for the lawful distribution of products such as PPE and ventilators into California. This is a temporary solution. Long-term the Board believes a more permanent solution is appropriate.

To strike a balance with the federal requirements, the Board recommends a statutory change that will provide the Board with the authority to inspect a non-resident third-party logistics provider for compliance with federal and state requirements or allow the Board to accept accreditation from the NABP Drug Distributor Accreditation Program, in lieu of home state licensure.

A copy of the proposed statutory change is in Attachment B.

ISSUE #10: ***Advanced Practice Pharmacists. Would modifications to the minimum qualifications for licensure for Advanced Practice Pharmacists, or expansion of the practice settings in which Advanced Practice Pharmacists may work, enable these specialized licensees to further enhance access to care?***

Background: In 2013, Senate Bill 493 (Hernandez, Chapter 469, Statutes of 2013) was signed into law, creating a new license type under the Board known as the Advanced Practice Pharmacist. This new class of highly educated and trained health care professionals is intended to further the role of pharmacists in providing direct patient care, and advanced practice pharmacists are authorized to perform additional procedures that are often unavailable in low-access parts of the state. To implement the bill, the Board adopted regulations setting training and certification requirements for advanced practice pharmacists, who are authorized to perform specific care functions for patients.

To date, fewer individuals have successfully applied to become advanced practice pharmacists than anticipated, and this may be due to unnecessarily complicated or onerous qualifications and

overly limited independence in practice. The Board has proposed language that would recast the requirements for licensure as an advanced practice pharmacist license so that completion of one requirement is subsumed within completion of another requirement. Further, the Board recommends that it be acceptable if certification is earned as part of the requirements for completion of a residency or completion of 1,500 hours of collaborative practice experience or a residency is completed that included the 1,500 hours of collaborative practice experience. The Board's recommendations would potentially expand both what an advanced practice pharmacist is authorized to do, as well as the number of settings in which they are allowed to do it.

Staff Recommendation: ***The Board provide an overview of its proposal and how it believes changes to law would increase the number of advanced practice pharmacists in the state.***

Draft Board Response: As part of its post implementation review of the Advanced Practice Pharmacist (APH) licensure program, the Board assessed the requirements for licensure and identified a potential barrier to licensure. Specifically, under the current provisions of Business and Professions Code Section, 4210, an individual seeking licensure as an advanced practice pharmacist must hold an active license to practice pharmacy and satisfy two of the following criteria:

1. Earned certification in a relevant area of practice.
2. Completion of a post-graduate residency.
3. Clinical experience for at least one year under a collaborative practice agreement or protocol.

When assessing application information, the Board has identified several instances when a pharmacist seeking licensure as an APH is using completion of a single criterion (e.g., completion of a residency program) that included as a condition of completion of the program, a second criterion (e.g., completion of a certification program). Under current law that is considered prohibited "double-dipping". To remedy this situation, under current law, an applicant may seek to meet another criterion, such as completion of the collaborative practice experience. After consideration of the issue, and the underlying policy goal of the original legislation, the Board believes modification to BPC 4210 (a)(2) is appropriate to clarify that if, as a condition of completion of one of the required criterion another is satisfied, that double dipping will not apply and an applicant will be deemed to satisfy both criteria.

In addition to licensure criteria, the Board also evaluated the authorized duties of an APH and noted the opportunity for expanded access to APH-provided care in settings beyond those currently authorized. Such an expansion is a natural progression of the APH authority and would facilitate expansion of the use of the collaborative practice model between the patient's diagnosing prescriber or primary care provider as part of health care teams while balancing communication between the prescriber and APH as already established in BPC 4052.6.

A copy of the proposed statutory changes is included in Attachment C.

EDUCATION AND EXAMINATION ISSUES

ISSUE #11: ***California Pharmacy Jurisprudence Examination. Is action necessary to address the recent transgressions involving the administration of the California Pharmacy Jurisprudence Exam?***

Background: The Board is responsible for administering the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE) to assess an applicant's minimum competency to safely practice pharmacy. The CPJE tests for application of the law as well as the practice standards that are unique to California and are not covered by the national examination. The Board states that in July of 2019, it received credible information about possible subversion of the CPJE. In September of 2019, the Board received further information about more pervasive acts of subversion, indicating the validity and reliability of the CPJE was compromised.

In response, the Board launched an investigation and found significant public exposure of CPJE questions that thereby invalidated the exam as a reliable measure of applicants' knowledge, skills and ability to safely practice as pharmacists. Therefore, in October 2019, the Board invalidated the current CPJE and established a plan to enable those applicants to retake the examination at no additional cost in November of 2019. In addition, the Board identified additional dates for December of 2019 for all eligible CPJE candidates to resume taking the exam.

While the discovery of the cheating scandal no doubt justified swift action by the Board to protect the integrity of the profession, the cancelation of exam results for those applicants who did not commit any breach had a predictably serious impact. Stories have been told of rescinded job offers, unrecouped travel expenses, and other significant hardships. In response, some have questioned whether the Board should be required to accept the Multistate Pharmacy Jurisprudence Exam (MPJE), a national alternative to the CPJE that includes board-approved questions for each state in which it is administered. Most states already accept the MPJE, and its adoption in California has been offered as a substantive step to address the unfortunate events surrounding the CPJE over the past year. However, it is worth noting that the MPJE was itself the subject of suspected subversion in 2007, and changing to a different examination would not necessarily prevent future pharmacy students from seeking to subvert any licensing examinations.

Staff Recommendation: ***The Board should provide insight into whether it believes adoption of the MPJE is feasible, or whether it believes any other action is advisable in response to recent incidents.***

Draft Board Response: As a consumer protection agency, it is essential that the Board assess candidates for minimum competency prior to issuing a pharmacist license to practice in California. Although the investigation into the subversion of the CPJE is ongoing, the Board has implemented safeguards to prevent future occurrences. Although regrettable, it is important to note that examination subversion is not unique to the CPJE and can and has arisen with other examinations. The Board does not believe that the recent subversion of the CPJE should result in a transition to the MPJE exam, an exam that was similarly compromised in 2007. However, as part of its ongoing program evaluation, and consistent with the provisions of BPC Section 139, it is appropriate for the Board to evaluate the pharmacist licensure examination and determine what, if any, action is appropriate. As a precursor to this evaluation, the Board entered into a contract with the DCA Office of Professions Examination Services to conduct an independent assessment of the pharmacist licensure examination. The Board looks forward to the results of the assessment to determine if changes are appropriate to the pharmacist licensure examination used to assess for

minimum competence prior to issuance of a pharmacist license.

It is important to note that examination compromise is not limited to the CPJE or to professional licensing examinations in general. Research indicates that academic dishonesty occurs in educational programs, including academic institutions for health care professionals. The International Center for Academic Integrity published a snapshot of overall trends over a 12-year period where 18% of graduate students and 39% of undergraduate students admit to cheating on tests, and a total of 43% and 68% respectively admitted to written to test cheatings.

In July 2020, the Board received a presentation on published research, Examining Student's Attitudes toward Academic Dishonesty in California Schools of Pharmacy. Although the findings of this research are not unique, the results indicated that about 66% of student-respondents stated that they had heard of or witnessed cheating in pharmacy school, about 45% admitted to being tempted to cheat in certain classes, and about 78% indicated that they would cheat if it meant passing a class. Further, the research study indicated that only about 18% of student-respondents agreed that cheating in pharmacy school would negatively affect their judgment as pharmacists in the future.

Studies have shown that students who commit dishonest acts in the education setting may also commit dishonest acts as students in the clinical setting and as professions in their practice settings. As competition increases for enrollment, internships, scholarships and ultimately jobs, pressure to perform at higher levels increases among students and academic programs. The role of colleges and universities is to prepare students to practice across an entire profession. The role of regulatory boards is to assess students for entry to practice safely, focusing on critical competencies.

The Board will continue its review of the underlying causes of the examination subversion and looks forward to working with the legislature, administration, and academic institutions to define academic dishonesty, consider development of reporting mechanisms for academic dishonesty, and look at best practices to address the issue.

ISSUE #12: *Continuing Education for Opioids. Should pharmacists who prescribe Schedule II drugs pursuant to a collaborative practice agreement complete continuing education on the risks associated with opioid use?*

Background: In October 2017, the White House declared the opioid crisis a public health emergency, formally recognizing what had long been understood to be a growing epidemic responsible for devastation in communities across the country. According to the Centers for Disease Control and Prevention, as many as 50,000 Americans died of an opioid overdose in 2016, representing a 28 percent increase over the previous year. Additionally, the number of Americans who died of an overdose of fentanyl and other opioids more than doubled during that time with nearly 20,000 deaths. These death rates compare to, and potentially exceed, those at the height of the AIDS epidemic.

Partly in response to the opioid crisis, some boards that regulate health professionals authorized to prescribe serious painkillers now require continuing education courses in the risks associated with the use of Schedule II drugs. Currently, pharmacists can prescribe Schedule II drugs under limited circumstances pursuant to a Collaborative Practice Agreement. The Board has suggested that those pharmacists who prescribe Schedule II opioids be required to complete similar continuing education (CE) related to the hazards of opioid use.

Staff Recommendation: ***The Board should discuss the advantages of requiring pharmacists who prescribe opioids through collaborative practice agreements to take CE on the associated risks.***

Draft Board Response: As the role of pharmacists change, and some, acting under a collaborative practice agreement, prescribe schedule II medications, the Board discussed existing continuing education requirements for prescribers licensed by other healing arts boards that include education specifically regarding pain medications and/or schedule II medications. The Board determined that a similar requirement would be appropriate for pharmacists prescribing such medications. Such a proactive requirement would ensure the prescribing pharmacist remains current on this topic, which is especially critical given the ongoing opioid epidemic. Further, the proposal establishes parity with other prescribers.

The Board notes that it continues to investigate matters involving pharmacists' failure to exercise corresponding responsibility.

The Board recommends the addition of to Business and Professions Code section 4052.11, to provide that a pharmacist who, under a collaborative practice agreement, is prescribing or furnishing a Schedule II controlled substance, shall complete a course covering the risks of addiction associated with of use of Schedule II drugs.

A copy of the proposed statutory change is included in Attachment D.

ENFORCEMENT ISSUES

ISSUE #13: ***Pharmacies Operating Under Common Ownership. Should the Board be better empowered to take enforcement action against the owners and operators of pharmacies under common ownership and control for system-wide violations of law?***

Background: The Pharmacy Law holds each pharmacy and its pharmacist-in-charge responsible for operations at the individual site, even if that pharmacy is part of a larger chain. However, in many cases, administrative or disciplinary action at an individual store may be the result of policies set at a corporate level. Currently, the Board's remediation and sanctions against an individual pharmacy is arguably unfair and inadequate to address a system wide issue across a large multi-store chain.

As an example of how it has sought to address this issue, the Board points to how in response to a large number of store violations regarding patient consultations several years ago, the Board worked with local district attorneys to secure large penalties against certain pharmacy chains. However, this coordination is not always possible. In addition, the Board states that violations regarding patient consultations continue, despite citations issued by the Board and fines assessed

by district attorneys.

Because the Board is limited to citing each pharmacy individually, making it difficult to address in an effective manner, violations resulting from corporate policy. In some settlements involving individual stores, the Board has stipulated that the ownership as a whole must address the issue; in such cases, however, the corporate owner must agree. This approach leaves unresolved the underlying challenge of regulating numerous entities under common ownership.

The Board has stated that it believes it may be appropriate to put into law some threshold evidence of a system-wide pharmacy failure that would allow additional enforcement tools to be used. Another possible solution suggested by the Board is to create a master license for pharmacies under common ownership and control; this would allow the Board to address system-wide issues with the owners and operators directly, rather than at the store level.

There have long been accusations of major chain-store pharmacies engaging in misconduct (for example, pushing pharmacists to meet certain output metrics for pharmacy sales that may supersede their professional judgement), but violations are technically only attributable to individual sites. The Board has asked whether there should be some additional ability for the Board to take action against entire chains for systemic violations of the law.

Staff Recommendation: ***The Board should further discuss its proposals for providing more meaningful repercussions for pharmacies under common ownership and control to ensure that the Pharmacy Law is followed in all settings.***

Draft Board Response: The Board has previously discussed challenges with obtaining compliance with Pharmacy Law provisions where the same violations occur at several pharmacies under common control. When such a pattern occurs, it is difficult for the Board to secure the necessary system-wide change. Although the contributing factors may be many, the fundamental core issue appears to be corporate policies that impede either directly or inadvertently pharmacy operations and the professional judgement of staff pharmacists, and result in violations of Pharmacy Law. The Board does not believe that its current options to either issue a citation with a maximum fine of $5,000 or placing a specific pharmacy on probation has resulted in the necessary changes in corporate practice to facilitate improved patient care.

One possible solution would be to increase the fine authority for common violations identified within pharmacies under common control. As an example, if the Board substantiated similar violations of three or more pharmacies under common control, such a threshold could be used to establish a pattern of a corporate practice and under such circumstances, the Board's citation and fine authority could be increased. Alternatively, the Board could secure authority to issue a fine to the corporate owner when such a threshold is reached at various locations under common ownership.

The Board looks forward to working with the legislature and administration on this issue.

ISSUE #14: ***Alternative Dispute Resolution. Would enabling the Board to participate in alternate disciplinary processes for licensees whose misconduct is likely to result in a citation and fine provide for speedier disciplinary cases and prove more cost efficient for Board staff?***

Background: An appeals process exists for licensees who are being subjected a citation and fine through a request for an informal office conference. As previously discussed, this office conference allows the licensee the opportunity to present additional or mitigating information to the Board's executive officer or designee and a supervising inspector. Stakeholders within the profession have suggested that a similar opportunity to meet informally with Board staff should be available when a licensee is being subjected to disciplinary action. Currently, the Board has no authority to settle a case prior to the filing of an action by the Attorney General. Allowing licensees to meet with Board staff and pursue a mutually agreeable outcome would likely alleviate case resolution timelines and provide cost savings to the Board.

Staff Recommendation: ***The Board should inform the committees of whether it believes some form of pre-accusation alternative dispute resolution would be of benefit and provide any suggested language that it believes would achieve this goal.***

Draft Board Response: The Board continues to consider development of a proposal that could facilitate a pre-pleading resolution that could speed up resolution of administrative cases and reduce costs while ensuring appropriate disposition of the matter. As the policy discussion is ongoing, the Board does not have language to provide at this time.

ISSUE #15: ***Standard of Care Model for Pharmacy Practice. Should the Board begin moving toward more of a standard of care model for its disciplinary actions against licensees?***

Background: A number of healing arts licensing boards are granted a substantial amount of flexibility in investigations when determining whether a licensee should be subject to discipline. Rather than enforcing strict adherence to codified practice requirements, boards may instead focus on the question of whether a licensee followed the "standard of care" and acted reasonably under the circumstances as a trained professional. It has been argued that a similar model should be enacted for the Board in regards to its actions against its licensees. The Board does currently employ 56 licensed pharmacists who assist with investigations as professional experts; therefore, it is arguable that something resembling the standard of care is already applied when the Board is determining whether an investigation should result in an action for discipline.

Staff Recommendation: ***The Board should discuss whether it believes a standard of care model would be appropriate and what steps it might take over the next few years to move toward that model.***

Draft Board Response: Pharmacy Law at the federal and state level is very prescriptive in some areas, such as handling and dispensing controlled substances, while, general in others, relying on a pharmacist to apply professional judgement. In all instances, a pharmacist's standard of care will always encompass compliance with federal and state law.

In areas that require a pharmacist to apply professional judgement, the Board regulates to a more generic standard of care. For example, under the provisions of Health and Safety Code section 11153, a pharmacist is required to exercise corresponding responsibility in making an independent determination that a prescription was written for a legitimate medical purpose prior to dispensing

a controlled substance. In this instance the law does not establish the specific steps a pharmacist must take. The Board provides education about the standard of care and designated a case as precedential to assist pharmacists in understanding their obligations. In other instances, law establishes the general provisions of a requirement, but includes requirements for a pharmacist to also exercise professional judgement. Such an example can be found in Title 16, California Code of Regulations section 1707.2, which establishes the minimum requirement for patient consultation, but also establishes a requirement for a pharmacist to exercise professional judgement and provide information as appropriate. When evaluating for compliance with this section, the Board uses a hybrid of assessment, first determining if consultation was provided, and secondarily, if the consultation was appropriate.

With the expansion of authority for pharmacists to provide additional patient care services, California has taken a conservative approach in implementing such expanded authorities, many times requiring the Board to implement regulations to specify the manner in which such authority can be performed. As an example, under Pharmacy Law, a pharmacist may furnish self-administered hormonal contraceptives; however, such furnishing must be done in accordance with standardized procedures or protocols developed by the Board and Medical Board, in consultation with the American Congress of Obstetrician and Gynecologists, the California Pharmacists Association, and other appropriate entities. Such an approach is contrary to a pure standard of care model. As pharmacy education evolves and encompasses more patient-care instruction, specific requirements on how to carry out patient care may no longer be necessary. However, the Board has not previously considered this policy issue and would require time to more thoroughly review the issue and understand the potential impacts and as such is not in a position to offer a recommendation at this time.

Should the legislature determine that such consideration is appropriate, the Board would respectfully suggest it would be appropriate to first ensure stakeholder agreement that further transition to such a model is appropriate.

PRACTICE ISSUES

ISSUE #16: *Independent Contractors. Does the new test for determining employment status, as prescribed in the court decision* Dynamex Operations West Inc. v. Superior Court, *have any unresolved implications for licensees working in the pharmacy profession as independent contractors?*

Background: In the spring of 2018, the California Supreme Court issued a decision in *Dynamex Operations West, Inc. v. Superior Court* (4 Cal.5th 903) that significantly confounded prior assumptions about whether a worker is legally an employee or an independent contractor. In a case involving the classification of delivery drivers, the California Supreme Court adopted a new test for determining if a worker is an independent contractor, which is comprised of three necessary elements:

A. That the worker is free from the control and direction of the hirer in connection with the performance of the work, both under the contract for the performance of such work and in

fact;

B. That the worker performs work that is outside the usual course of the hiring entity's business; and
C. That the worker is customarily engaged in an independently established trade, occupation, or business of the same nature as the work performed for the hiring entity.

Commonly referred to as the "ABC test," the implications of the *Dynamex* decision are potentially wide- reaching into numerous fields and industries utilizing workers previously believed to be independent contractors. Occupations regulated by entities under the Department of Consumer Affairs have been no exception to this unresolved question of which workers should now be afforded employee status under the law. In the wake of *Dynamex*, the new ABC test must be applied and interpreted for licensed professionals and those they work with to determine the rights and obligations of employees.

In 2019, the enactment of Assembly Bill 5 (Gonzalez, Chapter 296, Statutes of 2019) effectively codified the *Dynamex* decision's ABC test while providing for clarifications and carve-outs for certain professions. Specifically, physicians and surgeons, dentists, podiatrists, psychologists, and veterinarians were among those professions that were allowed to continue operating under the previous framework for independent contractors. However, pharmacists were not included in the bill, and some have suggested that they should be afforded an exemption to prevent unnecessary disruption to the pharmacy profession.

Staff Recommendation: ***The Board should inform the committees of any discussions it has had about the* Dynamex *decision and AB 5, and whether there is potential to impact the current landscape of the pharmacy profession unless an exemption is enacted.***

Draft Board Response: The Board has not discussed the matter, nor has the Board received any requests from stakeholders to hold such a discussion. The Board is aware that some pharmacists act as consultants for skilled nursing facilities and hospitals and such individuals may be impacted by the provisions. The Board notes that earlier this year Senate Bill 966 (Nielsen) was introduced and would have expanded the above-described exemptions to also include individuals who are licensed pharmacists.

ISSUE #17: *Medication Errors. Are there opportunities for statutory revision that would potentially reduce the frequency of medication errors resulting in patient harm?*

Background: The Board has listed medication error as the number one violation resulting in a citation in nearly every year within the last review cycle. According to the *Journal of the American Medical Association*, 46 percent of adults cannot understand the information listed on their prescription drug labels. Furthermore, the Institute of Medicine of the National Academies indicates that medication errors are among the most common medical errors, harming at least 1.5 million people annually.

The California Patient Medication Safety Act directed the Board promulgate regulations to require a "standardized, patient-centered, prescription drug label on all prescription medicine dispensed to patients in California." The resulting language specifies that drug container label information must be clustered into one area of the label comprising at least 50 percent of the label, and that each

item must be printed in at least a 12-point sans serif typeface. The regulations provide template language and recommend formatting to provide added emphasis.

Following the implementation of the patient-centered prescription label requirements, the Board also promulgated a regulation to amend its *Notice to Consumers* poster, which has also been printed in six additional languages, and which is available upon request from BOP or available for download from the Board's website. The Board also developed a "Point to Your Language" poster, which is required to be posted in pharmacies at or adjacent to the pharmacy counter so that consumers can point to a language to receive interpreter services; the text is printed in twelve languages.

Despite these efforts, patient advocates, particularly for those within the senior citizen community, continue to advocate for statutory changes that would reduce medication errors. This has included requiring all prescription containers to indicate the purpose of a medication unless requested otherwise by the patient, as well as efforts to increase enforcement of patient consultation requirements. As these proposals continue to be debated, the Board should play an active role in making any recommendations it believes would improve patient safety.

Staff Recommendation: ***The Board should provide the committees with any recommendations it may have regarding how medication errors could be reduced with help of statutory changes.***

Draft Board Response: According to the Agency for Healthcare Research and Quality (Agency) there are approximately 67,000 retail/community pharmacies dispensing 4.4 billion prescriptions each year. The Agency notes that community pharmacies are chaotic environments where most community pharmacists struggle to manage day-to-day activities of taking care of their patients and filling prescriptions. Despite pharmacists' best efforts, evidence suggests that medication errors occur at a rate of 1.7%–22%. Medication errors can range in severity and at times result in patient death.

Challenges identified as being faced by pharmacists include limited access to patients' medical records, limited ability to control the rate of work, and third-party payment issues.

The media has reported on the issue resulting from interviews with pharmacists describing understaffed and chaotic workplaces where pharmacists are reporting it has become difficult to perform their jobs safely, putting the public at risk of medication errors. Pharmacists have noted that they struggle to fill prescriptions, give flu-shots, tend the drive-through, answer phones, etc. while at the same time working to meet performance metrics.

The Board believes that there are several contributing factors to medication errors and no single solution will solve the issue. Although studies at the national level provide some indication of what may be occurring in California, because there is no mandatory reporting requirement for medication errors, the Board does not have transparency into the full scope of the issue. The Board notes that under the provisions of existing law, a Quality Assurance review is required whenever a medication error occurs. Regrettably when conducting investigations, the Board sometimes identifies that such a review was not performed, the review was completed but does not appear to be meaningful, or the record no longer exists because of the current records retention requirement.

As a condition of licensure, every general acute care hospital and other specified entities are required to adopt a formal plan to eliminate or substantially reduce medication-related errors. As part of this plan, the entity is required to rely on expert scientific advice and data that has been shown effective in eliminating or substantially reducing medication-related errors. Under the provisions of the law the California Department of Public Health is required to either approve the plan or return it to the facility with comments or suggestions for improvement. Although the Board is unclear whether this model is scalable to the community pharmacy setting, developing some proactive requirements for reducing medication errors appears to also be appropriate for consideration.

The issue of medication errors must be addressed to improve patient health. The issue warrants study in California, where conditions within a pharmacy may be different than on a national level. Further, consideration should be given to determine if the Board or some other entity should receive reports of medication errors to gain a better understanding of the scope of the issue and report on the findings. It appears appropriate to conduct a survey on working conditions to ascertain if conditions in California may be a contributing factor.

ISSUE #18: ***Patient-Specific Outsourcing. Under what conditions should a licensed outsourcing facility be allowed to fill patient-specific prescriptions?***

Background: Since June of 2017, the Board has issued licenses to outsourcing facilities concurrently with applicable licensure by the federal Food and Drug Administration. Outsourcing facilities are authorized to compound sterile and nonsterile products in compliance with regulations issued by the Board and are subject to inspection wherever they are located, with inspections occurring prior to license issuance or renewal for facilities doing business within or into California. The Board has issued 31 outsourcings licenses and performed 77 inspections since implementing the program.

While outsourcing facilities receive significant oversight and have proven successful at providing compounding services, statute currently prohibits a licensed outsourcing facility from filling individual prescriptions for individual patients. It is worth considering whether easing or eliminating this prohibition may result in greater access to pharmacy services. If such a change were to be made, licensed outsourcing facilities providing patient-specific care should be provided the same obligations and corresponding responsibilities as traditional pharmacists, and the Board should ensure any additional safeguards are incorporated.

Staff Recommendation: ***The Board should discuss whether it believes allowing licensed outsourcing facilities to fill patient-specific prescriptions would be of potential value and suggest any language it believes would be necessary to successfully achieve this purpose.***

Draft Board Response: Following enactments of the Drug Supply Chain Security Act (DSCSA), the provisions of which included, established outsourcing facilities, the Board developed its regulation of such entities. Under federal and state law, licensed outsourcing facilities may compound drug preparations under current good manufacturing practices (CGMP) under specified conditions.

Federal Law allows for such compounding pursuant to a patient specific prescription; however, California law does not currently allow for such activity.

Having regulated and evaluated outsourcing facilities for several years, the Board believes, given the significant safeguards and patient protections required by compliance with CGMPs, it is appropriate to remove the prohibition from outsourcing facilities providing patient specific medications, under specified conditions. Specifically, an outsourcing facility dispensing patient specific compounded preparations must be required to comply with all dispensing provisions of a pharmacy, including clinical services, patient consultation, drug therapy review, etc.

A copy of the proposed statutory change is included in Attachment E.

ISSUE #19: ***Collaborative Practice Agreements. Could statute be updated to expand the capacity of pharmacists to engage in expanded services pursuant to collaborative practice agreements?***

Background: Current law authorizes pharmacists to enter into collaborative practice agreements with physicians to provide additional care to patients. These agreements are believed to take advantage of a pharmacist's knowledge, skills, and abilities as a means to reduce demands on health professionals and improve patient care. Existing law allows for pharmacists to engage in limited activities pursuant to a collaborative practice agreement.

Opportunities may exist to expand the use of the conditions under which pharmacists could operate under a collaborative practice agreement, as well as the conditions under which an advanced practice pharmacist could perform authorized duties. The Board has made some recommendations for ways in which statute could be updated to allow for these expansions. These recommendations should be considered in the balance of ensuring patients receive quality care while also increasing access to that care wherever possible.

Staff Recommendation: ***The Board should provide its recommendations for expanding the authority of pharmacists to engage in activities pursuant to a collaborative practice agreement.***

Draft Board Response: Pharmacists are highly educated drug therapy experts with a well-established history of performing safely under collaborative practice agreements. The Board believes that current limitations on the use of collaborative practice agreements may be impeding innovative team-based care approaches. The Board supports a proposal that would expand the authority for a pharmacist to initiate, adjust, or discontinue drug therapy for patients if a pharmacist is performing the functions under a collaborative practice agreement.

A copy of proposed statutory language is provided in Attachment F.

ISSUE #20: ***Medication-Assisted Treatments. Should pharmacists be further authorized to directly dispense non-opioid medication assisted treatments (MAT) to increase access to care for patients with substance abuse disorders?***

Background: Statute allows for pharmacists to furnish certain medications directly to a patient, including self-administered hormonal contraceptives, nicotine replacement products, and preexposure and postexposure prophylaxis. It has been suggested that similar authority be established for pharmacists to directly furnish non-opioid MAT to patients pursuant to a statewide protocol. MAT is the use of medications, in combination with counseling and behavioral therapies, to treat substance use disorders. MAT has proven successful in helping addicted patients enter recovery and are commonly used for the treatment of addiction to opioids. While some forms of MAT, such as buprenorphine, are themselves a type of opioid, other forms of MAT do not contain opioids. It may be appropriate to allow pharmacists to furnish these medications directly to patients as a way to help address the sustained opioid crisis.

Staff Recommendation: ***The Board should discuss any recommendations it has for authorizing pharmacists to directly furnish non-opioid MAT to patients.***

Draft Board Response: As California and the rest of the nation continue to grapple with the opioid epidemic, the Board consulted with experts in Opioid Use Disorders, to identify actions the Board could take to strengthen access to Medication Assisted Treatment. One such solution identified was expanding the authority for pharmacists to provide non-opioid MAT, naltrexone. Naltrexone does not have the same regulatory restrictions as other MAT treatments.

The Board notes that other states have developed varying authorities for pharmacist to engage in MAT services, including a statewide protocol to allow for the pharmacists to provide non-opioid MAT. The Board supports such an approach.

A copy of proposed statutory language is provided in Attachment G.

ISSUE #21: *Pharmaceutical Compounding. Should the Board engage in greater collaboration with the Veterinary Medical Board of California in its promulgation of any compounding requirements intended to apply to licensed veterinarians?*

Background: The Board's regulation of prescribing, dispensing, and administering medication extends to the practice of veterinary medicine, where licensees of the Veterinary Medical Board (VMB) are required to comply with the Board's regulations when working with prescription drugs. In the context of veterinary pharmaceuticals, both regulatory boards are expected to interact and coordinate when resolving cross-cutting issues that impact both professions. For example, SB 1193 (Hill, Chapter 484, Statutes of 2016) provided authority for veterinarians and registered veterinary technicians to perform limited drug compounding. In promulgating regulations to implement this mandate, the VMB worked with the Board to determine appropriate parameters for veterinary in-office compounding.

However, the VMB has expressed concerns over the Board's recently proposed regulation that would authorize a pharmacy to only compound a compounded sterile preparation (CSP) after the pharmacy has received a valid patient specific prescription document or prepare and provide a limited quantity of CSPs to a veterinarian based on a contract between the pharmacy and veterinarian for office use administration only. The VMB is concerned that this proposal does not take into account how veterinary clinics and hospitals operate, and would severely limit a veterinarian's ability to provide medication and treat animal patients in a timely manner.

The VMB and the Board are undergoing Sunset Review concurrently. The committees believe that this is a timely opportunity to address how both boards can improve long-term communication and coordination regarding regulatory proposals that impact both professions.

Staff Recommendation: ***The Board should provide its perspective on any recent issues involving veterinary compounding and the promulgation of its regulations and speak to whether there are any opportunities for greater communication and collaboration between the two boards.***

Draft Board Response: Federal and state law establish the requirements for the compounding of drug preparations. The United States Pharmacopeia USP develops and publishes standards for drug substances, drug products, excipients, and dietary supplements in the United States Pharmacopeia–National Formulary (USP–NF). These standards have been recognized in the Federal Food, Drug and Cosmetic (FD&C) Act since it was first enacted in 1938. Consistent with the provisions of federal law, and the USP compounding Chapters developed by experts, the Board believes compounding should be performed either consistent with current good manufacturing practices (cGMPs) or USP standards.

As a public agency, the Board is subject to provisions of both the Open Meetings Act, and specific to this topic, the Administrative Procedures Act governing the process for rulemaking. In 2019, in response to proposed changes to various USP Compounding Chapters, the Board undertook a review of the USP proposed changes along with its current compounding regulations, to determine if changes would be necessary to the Board's compounding regulations. This was conducted through a series of public meetings. During this process, Board staff notified staff of the Veterinary Medical Board (VMB) of the Board's efforts and suggested a meeting. During this meeting, Board staff discussed some of the current challenges and enforcement related issues identified by Board staff and its intention to address some of these issues through regulation process. During this meeting, no solutions were identified.

Subsequent to this informal meeting, in September 2019, draft regulation language was developed and discussed during a public meeting as part of the board's ongoing efforts to assess its compounding regulations. During this meeting, representatives of the VMB provided public comment to the Board's Compounding Committee expressing concern with the draft language. At that time, the Committee encouraged participation by the VMB and requested that suggested language be submitted for the Board's consideration.

Subsequent to that meeting, later in September 2019, the USP released an announcement indicating that, in light of appeals received in response to the proposed compounding chapters, and consistent with the bylaws of USP, USP would delay the official dates of the revised chapters.

It is the Board's understanding that as part of the VMB's October 2019 Board meeting, the VMB discussed the Board's proposed draft language. As indicated in the Veterinary Medical Board's materials, it acknowledged the issue, the proposed USP Compounding Chapters, and the Board's efforts to strike a balance.

In response to the decision by the USP to delay its proposed revised chapters, during its November

5-6, 2019 Board meeting, the Board approved a policy statement advising stakeholder of its intention to similarly delay action regulation changes currently under consideration, pending further action by USP.

> In light of the USP's September 23, 2019 announcement regarding the appeals and resulting postponement of the official dates of the revised USP Chapters 795 and 797 and the new USP Chapter 825, the California State Board of Pharmacy (board) wishes to ensure that stakeholders have a clear understanding of the legal requirements pharmacies must comply with to compound drug preparations.
>
> At minimum, all pharmacies must adhere to all relevant sections of Pharmacy Law and regulation, including but not limited to the board's current regulations California Code of Regulations, title 16, sections 1735 et.seq, 1751 et.seq, and 1708.3-1708.5. Further, effective January 1, 2020, all pharmacies must adhere to current USP Chapters relating to compounding, including Chapters 795 and 797.
>
> The board notes that while USP has indicated that Chapter 800 is informational while it reviews the appeals of related compounding chapters, the board's current regulations on compounding hazardous drug preparations remain in effect. Like USP, the board encourages utilization of 800 in the interest of advancing public health. Waivers previously granted to allow for physical construction or alteration to a facility pursuant to California Code of Regulations 1735.6 will not be extended and sunset on December 1, 2019.
>
> Prior to September 23, 2019, the board voted to initiate a rulemaking process to effectuate proposed changes to regulations for pharmaceutical compounding of nonsterile preparations. At this time, the board will delay initiation of the formal rulemaking process until additional information is available from the USP.
>
> Although the board's compounding committee had completed its review of proposed regulations for pharmaceutical compounding of sterile preparations, the board will delay proceeding with any regulation changes until additional information is available from the USP.
>
> The board encourages its licensees to continue efforts to transition to proposed USP requirements that ensure the safety and efficacy of compounded drug preparations and patient safety. The board will continue to communicate with stakeholders as information becomes available.

Subsequent to approval of this policy statement, in November 2019, board staff advised VMB staff of the Board's action and again reiterated the Board's interest in receiving suggested language from the VMB to address the concerns of both regulatory agencies. As indicated in this communication the Board indicated its desire to provide a mechanism that complies with USP standards while continuing to allow veterinary patients access to safe medication.

DCA Director Kimberly Kirchmeyer also convened a meeting between staff of the two boards.

During the meeting, clarification was provided on the requirements of state and federal law regarding compounding, USP requirements, and the Board's compounding regulations.

Board staff continue to share information related to veterinary compounding with staff of the VMB, and the respective agencies provide referrals for investigations. Further, Board staff have offered training on Pharmacy Law as it relates to veterinary compounding. When the Board resumes its discussion on compounding regulations it looks forward to considering suggested language from the VMB.

ISSUE #22: ***Automated Drug Delivery Systems. Should statute be revised to allow the placement of Automated Drug Delivery Systems (ADDS) in additional locations?***

Background: An ADDS is a mechanical system controlled remotely by a pharmacist that performs operations or activities relative to the storage, dispensing, or distribution of prepackaged dangerous drugs or devices. A specific type of ADDS is an Automated Unit Dose System (AUDS), used for storage and retrieval of unit doses of drugs for administration to patients by health practitioners. The law requires that there be specific written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenances of the quality, potency and purity of drugs located at the clinic. Use of an ADDS is authorized only in specific locations, including certain types of clinics serving low- income Californians and fire departments under certain conditions.

The Board recommends amending existing statutes to expand authority for pharmacies to license and operate AUDS in additional settings to provide medication management services. Such entities would include jails, correctional treatment centers, hospice facilities, psychiatric health facilities, and other locations.

Staff Recommendation: ***The Board should discuss its recommendations regarding the expansion of ADDS placements with the committees and share language for any proposals it may have.***

Draft Board Response: As part of its post implementation review of several measures related to the use of Automated Drug Delivery Systems, the Board identified locations where use of such a system would be appropriate given the many of the safeguards inherent in such systems. After review and discussion with stakeholders, the Board believes that a pharmacy should be provided authority to operate an ADDS in other health and care facilities where pharmacy services are provided. Examples of such locations include the following:

1. Mental Health Rehabilitation Center (MHRC). An MHRC is a residential facility that is licensed by the State Department of Health Care Services.
2. Psychiatric Health Facility (PHF). A PHF is considered a health facility as defined in Health and Safety Code section 1250 that provides 24-hour inpatient care for people with mental health disorders or other persons as specified.
3. Jails. Many county jails currently obtain drugs from either a county hospital system or a pharmacy contracted with the jail.
4. Juvenile Hall Clinic. Such a clinic is part of a county's juvenile hall detention center under a

probation department.

5. Correctional Treatment Center (CTC). A CTC is a health facility operated by the Department of Corrections and Rehabilitation, Division of Juvenile Facilities, or a county, city or other law enforcement agency that provides inpatient health care services.
6. Hospice Facility. Such facilities are health facilities are licensed by the Department of Public Health.

A copy of the proposed statutory provisions is provided in Attachment H.

IMPLEMENTATION ISSUES

ISSUE #23: ***Unused Cancer Medication Transfers. Should statute authorizing county-level voluntary drug repository and distribution programs be updated to enable the donation of unused cancer medications?***

Background: In 2005, the Legislature passed Senate Bill 798 (Simitian, Chapter 444, Statutes of 2005) authorizing county-level voluntary drug repository and distribution programs for the purpose of distributing surplus medications to persons in need of financial assistance to ensure access to necessary pharmaceutical therapies.

Under these programs, hospitals and other health facilities, as well as drug manufacturers and wholesalers, may donate unused medications to a pharmacy owned by or in contract with a county. These pharmacies may then dispense medications to indigent patients at no cost. Currently, at least three counties have implemented such a program, including the counties of San Francisco, Santa Clara, and San Mateo. As of April 2018, Santa Clara's Better Health Pharmacy has distributed more than 31,000 free prescriptions from 180 donors around California, at an estimated cost to residents of over than $2,000,000. The program has been amended several times to allow for more donor entities and create a new category of licensure for purposes of medication transfers.

Currently, most cancer medications are not eligible for donation through any existing voluntary drug repository and distribution program. Some patient advocates believe that this excludes numerous low- income cancer patients who are unable to afford their medications and who would benefit from a secondhand medication donation program. This specific issue joins numerous other medications that may benefit from increased recycling authority.

Staff Recommendation: ***The Board should discuss whether there are any statutory changes it believes would potentially expand county-level voluntary drug repository and distribution programs to include the transfer unused cancer medications.***

Draft Board Response: The Board is not aware of any statutory prohibition that precludes a county-level voluntary drug repository and distribution program from including the transfer of unused cancer medications. It is the Board's understanding that one program allows for the redistribution of oral anticancer medications and other medications used to treat cancer as part of its formulary.

COVID-19 PANDEMIC ISSUES

ISSUE #23: ***Temporary Licensure. Should the Board's authority to grant temporary licenses in the event of a declared emergency be strengthened or expanded?***

Background: Since the onset of the COVID-19 pandemic, state health experts have continued to highlight the ongoing need to bolster the California's capacity to respond to a surge in patient needs across the state's health care system. On March 30, 2020, Governor Newsom announced his an initiative to "expand California's health care workforce and recruit health care professionals to address the COVID-19 surge" and signed Executive Order N-39-20. This executive order established the waiver request process under the Department of Consumer Affairs and included other provisions authorizing the waiver of licensing, certification, and credentialing requirements for health care providers.

Additionally, existing law authorizes the Director of the Emergency Medical Services Authority (EMSA) to exempt from state licensure any health care practitioner who possesses a license in another state or territory and seeks to provide care within California during a state of emergency. Under this process, pharmacists who are licensed outside of California may provide service within the state with the approval of the EMSA Director for as long as the COVID-19 declaration remains in place. The Board has worked with EMSA to direct potential candidates for this temporary waiver to that process.

The Board has also worked to provide temporary approval to pharmacies that have been established to address identified surge areas. The Pharmacy Law provides that the Board "may, at its discretion, issue a temporary permit upon the conditions and for any periods of time as the board determines to be in the public interest." While this statute is not related to the sections of the Pharmacy Law specifically related to declared states of emergency, the Board has utilized it to allow for temporary pharmacies intended to improve access to care in response to COVID-19. To date, the Board has issued 16 temporary licenses.

However, the temporary license process for pharmacy and wholesaler permits is limited. The Pharmacy Law only allows these permits to be issued for a maximum of 180 days, whereas other license waivers may be extended for the duration of the emergency. The provisions; however, do not apply to all facility licenses, such as community clinics. The Board may believe its authority to issue temporary licenses should be extended to all facility license types.

Staff Recommendation: ***The Board should make recommendations for statutory changes to expand its authority to grant temporary licensure to pharmacies and other facilities during an emergency.***

Draft Board Response: In response to the COVID-19 pandemic, the Board has relied upon the temporary license provisions to secure licensure of alternative case sites and other entities that are necessary to aid in patient care and distribution of necessary products. These provisions have allowed the Board to act quickly; however, using the provisions for something other than what it is intended for, has created some challenges. As the Board evaluates disaster preparedness through the lens of a pandemic (as opposed to a local or short-term disaster) the Board believes new authority to issue temporary licenses is appropriate. The Board welcomes the opportunity to work with the legislature and the administration on this issue.

ISSUE #24: ***Licensee Outreach. Does current law sufficiently ensure that the Board's licensees have access to important information during a state of emergency?***

Background: As the state works to address the COVID-19 crisis, there have been numerous changes in state law and shifts in priorities articulated by health officials. During this type of health emergency, it is vital that health professionals like pharmacists have immediate access to up-to-date information.
Under existing law, the Board is not authorized to require its licensees to provide an e-mail address as part of an application for initial licensure or license renewal. However, the Board has stated that it believes "electronic communication is the fastest way to disseminate important information on policy, regulatory, enforcement and consumer matters to patients, licensees and stakeholders. This has been especially true during the pandemic." Currently, the Board communicates with its licensees using a "subscriber alert system," a system that licensees are required to enroll in within 60 days of receiving or renewing a license. Licensees also must update their email addresses with the board within 30 days of any change of email address.

Professional associations representing individuals licensed by the Board have expressed interest in obtaining authority to expand outreach efforts to pharmacists and other licensees during states of emergency via electronic communication. Current law does not include e-mail addresses among the categories of licensee contact information that can be requested by members of the public. One organization has requested that licensee e-mail addresses be made available to bona fide professional associations for purposes of contacting licensees with important information. While this proposal may implicate considerations of licensee privacy and discussions around the appropriate use of e-mail addresses collected by the Board, it could meaningfully result in greater access to time-sensitive information regarding the practice of pharmacy during states of emergency such as the COVID-19 pandemic.

Staff Recommendation: ***The Board should discuss its current authority to collect licensee e-mail addresses and whether it believes statute should be modified to expand access to information among its licensees.***

Draft Board Response: It is important to note that the Board has no requirement to collect licensee email addresses. However, Board licensees are required to sign up for and enroll in the Board's listserve, a system used by the Board to disseminate information. The Board would strongly oppose any requirement for the Board to be required to produce email addresses to any entity.

California has a long history of supporting privacy protections. To that end, the Public Records Act defines what information must be released upon request. During recent policy discussion by the Board regarding email addresses, the Board expressed concerns with the potential disclosure of email addresses. The Board believes that a licensee should have the same expectation of protection of personal information such as an email address as other members of the public. That is, a licensee should get to independently decide to whom they provide an email address. The Board believes a mandate to require the Board to provide or otherwise make available email addresses of licensees is an end run around privacy law.

Should the legislature disagree with the Board's position on this issue, the Board respectfully requests that any such statutory proposal be pursued in a measure separate from the Board's Sunset measure.

TECHNICAL CLEANUP

ISSUE #25: ***Technical Cleanup. Is there a need for technical cleanup?***

Background: As the pharmacy profession continues to evolve and new laws are enacted, many provisions of the Business and Professions Code relating to pharmacy become outmoded or superfluous. The Board should recommend cleanup amendments for statute.

Staff Recommendation: The Board should work with the committees to enact any technical changes to the Business and Professions Code needed to add clarity and remove unnecessary language.

Draft Board Response: The Board appreciates the committees' interest in recommendations to enact technical changes to Pharmacy Law.

A copy of some recommended statutory changes is provided in Attachment I.

CONTINUED REGULATION OF THE PHARMACY PROFESSION BY THE CALIFORNIA STATE BOARD OF PHARMACY

ISSUE #26: ***Continued Regulation. Should the licensing of pharmacy professionals be continued and be regulated by the California State Board of Pharmacy?***

Background: In consideration of the Board's critical public protection mission in its regulation of the pharmacy profession in California, it is likely that the committees will ultimately determine that the Board's repeal date should be extended for an additional term.

Staff Recommendation: ***The Board's current regulation of the pharmacy profession should be continued, to be reviewed again on a future date to be determined.***

Draft Board Response: The Board agrees with the staff recommendation.

ATTACHMENT A

Proposal to Amend BPC Section 480 as follows:

(a) Notwithstanding any other provision of this code, a board may deny a license regulated by this code on the grounds that the applicant has been convicted of a crime or has been subject to formal discipline only if either of the following conditions are met:

(1) The applicant has been convicted of a crime within the preceding seven years from the date of application that is substantially related to the qualifications, functions, or duties of the business or profession for which the application is made, regardless of whether the applicant was incarcerated for that crime, or the applicant has been convicted of a crime that is substantially related to the qualifications, functions, or duties of the business or profession for which the application is made and for which the applicant is presently incarcerated or for which the applicant was released from incarceration within the preceding seven years from the date of application. However, the preceding seven-year limitation shall not apply in either of the following situations:

(A) The applicant was convicted of a serious felony, as defined in Section 1192.7 of the Penal Code or a crime for which registration is required pursuant to paragraph (2) or (3) of subdivision (d) of Section 290 of the Penal Code.

(B) The applicant was convicted of a financial crime currently classified as a felony that is directly and adversely related to the fiduciary qualifications, functions, or duties of the business or profession for which the application is made, pursuant to regulations adopted by the board, and for which the applicant is seeking licensure under any of the following:

(i) Chapter 1 (commencing with Section 5000) of Division 3.

(ii) Chapter 6 (commencing with Section 6500) of Division 3.

(iii) Chapter 9 (commencing with Section 7000) of Division 3.

(iv) Chapter 11.3 (commencing with Section 7512) of Division 3.

(v) Licensure as a funeral director or cemetery manager under Chapter 12 (commencing with Section 7600) of Division 3.

(vi) Division 4 (commencing with Section 10000).

(vii) Chapter 9 (commencing with Section 4000) of Division 2.

(C) The applicant seeks licensure under the provisions of Chapter 9 (commencing with Section 4000) of Division 2 and has done any of the following:

(i) Performed an act that would be grounds for denial of a federal registration to distribute controlled substances.

(ii) Performed an act involving fraud in violation of state or federal laws related to healthcare.

(iii) Been convicted of a crime involving identity theft.

(iv) Been convicted of a crime involving the sale of counterfeit products.

(2) The applicant has been subjected to formal discipline by a licensing board in or outside California within the preceding seven years from the date of application based on professional misconduct that would have been cause for discipline before the board for which the present application is made and that is substantially related to the qualifications, functions, or duties of the business or profession for which the present application is made. However, prior disciplinary action by a licensing board within the preceding seven years shall not be the basis for denial of a license if the basis for that disciplinary action was a conviction that has been dismissed pursuant to Section 1203.4, 1203.4a, 1203.41, or 1203.42 of the Penal Code or a comparable dismissal or expungement.

(b) Notwithstanding any other provision of this code, a person shall not be denied a license on the basis that he or she has been convicted of a crime, or on the basis of acts underlying a conviction for a crime, if he or she has obtained a certificate of rehabilitation under Chapter 3.5 (commencing with Section 4852.01) of Title 6 of Part 3 of the Penal Code, has been granted clemency or a pardon by a state or federal executive, or has made a showing of rehabilitation pursuant to Section 482.

(c) Notwithstanding any other provision of this code, a person shall not be denied a license on the basis of any conviction, or on the basis of the acts underlying the conviction, that has been dismissed pursuant to Section 1203.4, 1203.4a, 1203.41, or 1203.42 of the Penal Code, or a comparable dismissal or expungement. An applicant who has a conviction that has been dismissed pursuant to Section 1203.4, 1203.4a, 1203.41, or 1203.42 of the Penal Code shall provide proof of the dismissal if it is not reflected on the report furnished by the Department of Justice.

(d) Notwithstanding any other provision of this code, a board shall not deny a license on the basis of an arrest that resulted in a disposition other than a conviction, including an arrest that resulted in an infraction, citation, or a juvenile adjudication.

(e) A board may deny a license regulated by this code on the ground that the applicant knowingly made a false statement of fact that is required to be revealed in the application for the license. A board shall not deny a license based solely on an applicant's failure to disclose a fact that would not have been cause for denial of the license had it been disclosed.

(f) A board shall follow the following procedures in requesting or acting on an applicant's criminal history information:

(1) A board issuing a license pursuant to Chapter 3 (commencing with Section 5500), Chapter 3.5 (commencing with Section 5615), Chapter 10 (commencing with Section 7301), Chapter 20 (commencing with Section 9800), or Chapter 20.3 (commencing with Section 9880), of Division 3, or Chapter 3 (commencing with Section 19000) or Chapter 3.1 (commencing with Section 19225) of Division 8 may require applicants for licensure under those chapters to disclose criminal conviction history on an application for licensure.

(2) Except as provided in paragraph (1), a board shall not require an applicant for licensure to disclose any information or documentation regarding the applicant's criminal history. However, a board may request mitigating information from an applicant regarding the

applicant's criminal history for purposes of determining substantial relation or demonstrating evidence of rehabilitation, provided that the applicant is informed that disclosure is voluntary and that the applicant's decision not to disclose any information shall not be a factor in a board's decision to grant or deny an application for licensure.

(3) If a board decides to deny an application for licensure based solely or in part on the applicant's conviction history, the board shall notify the applicant in writing of all of the following:

(A) The denial or disqualification of licensure.

(B) Any existing procedure the board has for the applicant to challenge the decision or to request reconsideration.

(C) That the applicant has the right to appeal the board's decision.

(D) The processes for the applicant to request a copy of his or her complete conviction history and question the accuracy or completeness of the record pursuant to Sections 11122 to 11127 of the Penal Code.

(g) (1) For a minimum of three years, each board under this code shall retain application forms and other documents submitted by an applicant, any notice provided to an applicant, all other communications received from and provided to an applicant, and criminal history reports of an applicant.

(2) Each board under this code shall retain the number of applications received for each license and the number of applications requiring inquiries regarding criminal history. In addition, each licensing authority shall retain all of the following information:

(A) The number of applicants with a criminal record who received notice of denial or disqualification of licensure.

(B) The number of applicants with a criminal record who provided evidence of mitigation or rehabilitation.

(C) The number of applicants with a criminal record who appealed any denial or disqualification of licensure.

(D) The final disposition and demographic information, consisting of voluntarily provided information on race or gender, of any applicant described in subparagraph (A), (B), or (C).

(3) (A) Each board under this code shall annually make available to the public through the board's Internet Web site and through a report submitted to the appropriate policy committees of the Legislature deidentified information collected pursuant to this subdivision. Each board shall ensure confidentiality of the individual applicants.

(B) A report pursuant to subparagraph (A) shall be submitted in compliance with Section 9795 of the Government Code.

(h) "Conviction" as used in this section shall have the same meaning as defined in Section 7.5.

(i) This section does not in any way modify or otherwise affect the existing authority of the following entities in regard to licensure:

(1) The State Athletic Commission.

(2) The Bureau for Private Postsecondary Education.

(3) The California Horse Racing Board.

(j) This section shall become operative on July 1, 2020.

(Repealed and added by Stats. 2018, Ch. 995, Sec. 4. (AB 2138) Effective January 1, 2019. Section operative July 1, 2020, by its own provisions.)

ATTACHMENT B

Proposal to Amend BPC Section 4161 as follows:

(a) A person located outside this state that (1) ships, sells, mails, warehouses, distributes, or delivers dangerous drugs or dangerous devices into this state or (2) sells, brokers, warehouses, or distributes dangerous drugs or devices within this state shall be considered a nonresident wholesaler or a nonresident third-party logistics provider.

(b) A nonresident wholesaler or nonresident third-party logistics provider shall be licensed by the board prior to shipping, selling, mailing, warehousing, distributing, or delivering dangerous drugs or dangerous devices to a site located in this state or selling, brokering, warehousing, or distributing dangerous drugs or devices within this state.

(c) (1) A separate license shall be required for each place of business owned or operated by a nonresident wholesaler or nonresident third-party logistics provider from or through which dangerous drugs or dangerous devices are shipped, sold, mailed, warehoused, distributed, or delivered to a site located in this state or sold, brokered, warehoused, or distributed within this state. Each place of business may only be issued a single license by the board, except as provided in paragraph (2). A license shall be renewed annually and shall not be transferable.

(2) A nonresident wholesaler and a nonresident third-party logistics provider under common ownership may be licensed at the same place of business provided that all of the following requirements are satisfied:

(A) The wholesaler and the third-party logistics provider each separately maintain the records required under Section 4081.

(B) Dangerous drugs and dangerous devices owned by the wholesaler are not commingled with the dangerous drugs and dangerous devices handled by the third-party logistics provider.

(C) Any individual acting as a designated representative for the wholesaler is not concurrently acting as a designated representative-3PL on behalf of the third-party logistics provider. Nothing in this subparagraph shall be construed to prohibit an individual from concurrently holding a license to act as a designated representative and to act as a designated representative-3PL.

(D) The wholesaler has its own designated representative-in-charge responsible for the operations of the wholesaler and the third-party logistics provider has its own responsible manager responsible for the operations of the third-party logistics provider. The same individual shall not concurrently serve as the responsible manager and the designated representative-in-charge for a wholesaler and a third-party logistics provider licensed at the same place of business.

(E) The third-party logistics provider does not handle the prescription drugs or prescription devices owned by a prescriber.

(F) The third-party logistics provider is not a reverse third-party logistics provider.

(G) The wholesaler is not acting as a reverse distributor.

(d) The following information shall be reported, in writing, to the board at the time of initial application for licensure by a nonresident wholesaler or a nonresident third-party logistics provider, on renewal of a nonresident wholesaler or nonresident third-party logistics provider license, or within 30 days of a change in that information:

(1) Its agent for service of process in this state.

(2) Its principal corporate officers, as specified by the board, if any.

(3) Its general partners, as specified by the board, if any.

(4) Its owners if the applicant is not a corporation or partnership.

(e) A report containing the information in subdivision (d) shall be made within 30 days of any change of ownership, office, corporate officer, or partner.

(f) A nonresident wholesaler or nonresident third-party logistics provider shall comply with all 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.

(g) A nonresident wholesaler or nonresident third-party logistics provider shall maintain records of dangerous drugs and dangerous devices sold, traded, transferred, warehoused, or distributed to persons in this state or within this state, so that the records are in a readily retrievable form.

(h) A nonresident wholesaler or nonresident third-party logistics provider shall at all times maintain a valid, unexpired license, permit, or registration to conduct the business of the wholesaler or nonresident third-party logistics provider in compliance with the laws of the state in which it is a resident. An application for a nonresident wholesaler or nonresident third-party logistics provider license in this state shall include a license verification from the licensing authority in the applicant's state of residence. <u>The board may waive the home state licensure requirement for a nonresident third-party logistics provider if the location is inspected by the board and found in compliance with this article and any regulations adopted by the board or the applicant provides evidence of its accreditation by the National Association of Boards of Pharmacy Drug Distributor Accreditation Program. The nonresident third-party logistics provider shall reimburse the board for all actual and necessary costs incurred by the board in conducting an inspection of the location, pursuant to subdivision (v) of Section 4400.</u>

(i) (1) The board shall not issue or renew a nonresident wholesaler license until the nonresident wholesaler identifies a designated representative-in-charge and notifies the board in writing of the identity and license number of the designated representative-in-charge.

(2) The board shall not issue or renew a nonresident third-party logistics provider license until the nonresident third-party logistics provider identifies a responsible manager and notifies the board in writing of the identity and license number of the designated representative-3PL who will be the responsible manager.

(j) The designated representative-in-charge shall be responsible for the compliance of the nonresident wholesaler with state and federal laws governing wholesalers. The responsible manager shall be responsible for the compliance of the nonresident third-party logistics provider's place of business with state and federal laws governing third-party logistics providers. A nonresident wholesaler or nonresident third-party logistics provider shall identify and notify the board of a new designated representative-in-charge or responsible manager within 30 days of the date that the prior designated representative-in-charge or responsible manager ceases to be the designated representative-in-charge or responsible manager.

(k) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. A temporary license fee shall be five hundred fifty dollars ($550) or another amount established by the board not to exceed the annual fee for renewal of a license to compound sterile drug products. When needed to protect public safety, a temporary license may be issued for a period not to exceed 180 days, subject to terms and conditions that the board deems necessary. If the board determines that a temporary license was issued by mistake or denies the application for a permanent license, the temporary license shall terminate upon either personal service of the notice of termination upon the licenseholder or service by certified mail, return receipt requested, at the licenseholder's address of record with the board, whichever occurs first. Neither for purposes of retaining a temporary license, nor for purposes of any disciplinary or license denial proceeding before the board, shall the temporary licenseholder be deemed to have a vested property right or interest in the license.

(l) The registration fee shall be the fee specified in subdivision (f) of Section 4400.

ATTACHMENT C

Proposal to Amend BPC Section 4210 as follows:

(a) A person who seeks recognition as an advanced practice pharmacist shall meet all of the following requirements:

(1) Hold an active license to practice pharmacy issued pursuant to this chapter that is in good standing.

(2)(A) Satisfy any two of the following criteria:

(~~A~~i) Earn certification in a relevant area of practice, including, but not limited to, ambulatory care, critical care, geriatric pharmacy, nuclear pharmacy, nutrition support pharmacy, oncology pharmacy, pediatric pharmacy, pharmacotherapy, or psychiatric pharmacy, from an organization recognized by the Accreditation Council for Pharmacy Education or another entity recognized by the board.

(~~B~~ii) Complete a postgraduate residency through an accredited postgraduate institution where at least 50 percent of the experience includes the provision of direct patient care services with interdisciplinary teams.

(~~C~~iii) Have provided clinical services to patients for at least one year under a collaborative practice agreement or protocol with a physician, advanced practice pharmacist, pharmacist practicing collaborative drug therapy management, or health system.

(B) For purposes of this subsection, if, as a condition of completion of one of the required criteria fulfillment of a second criteria is also required such completion shall be deemed to satisfy the requirements of this subsection.

(3) File an application with the board for recognition as an advanced practice pharmacist.

(4) Pay the applicable fee to the board.

(b) An advanced practice pharmacist recognition issued pursuant to this section shall be valid for two years, coterminous with the certificate holder's license to practice pharmacy.

(c) The board shall adopt regulations establishing the means of documenting completion of the requirements in this section.

(d) The board shall, by regulation, set the fee for the issuance and renewal of advanced practice pharmacist recognition at the reasonable cost of regulating advanced practice pharmacists pursuant to this chapter. The fee shall not exceed three hundred dollars ($300).

Proposal to Amend BPC Section 4052.6 as follows:

(a) A pharmacist recognized by the board as an advanced practice pharmacist may do all of the following:
(1) Perform patient assessments.
(2) Order and interpret drug therapy-related tests.
(3) Refer patients to other health care providers.
(4) Participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers.
(5) Initiate, adjust, or discontinue drug therapy ~~in the manner specified in paragraph (4) of subdivision (a) of Section 4052.2.~~
(b) A pharmacist who adjusts or discontinues drug therapy shall promptly transmit written notification to the patient's diagnosing prescriber or enter the appropriate information in a patient record system shared with the prescriber, as permitted by that prescriber. A pharmacist who initiates drug therapy shall promptly transmit written notification to, or enter the appropriate information into, a patient record system shared with the patient's primary care provider or diagnosing provider, as permitted by that provider.
(c) This section shall not interfere with a physician's order to dispense a prescription drug as written, or other order of similar meaning.
(d) Prior to initiating or adjusting a controlled substance therapy pursuant to this section, a pharmacist shall personally register with the federal Drug Enforcement Administration.
(e) A pharmacist who orders and interprets tests pursuant to paragraph (2) of subdivision (a) 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.

ATTACHMENT D

Proposal to add BPC Section 4052.11 as follows:

Effective [six months of the effective date of the legislation] a pharmacist who, pursuant to any authority of this article, prescribes a Schedule II controlled substance, shall have completed an education course on the risks of addiction associated with the use of Schedule II drugs. A pharmacist who has completed such a course within the last four years shall be deemed to have satisfied this requirement.

ATTACHMENT E

Proposal to Amend BPC Section 4129 as follows:

(a) A facility ~~licensed~~ registered as an outsourcing facility with the federal Food and Drug Administration (FDA) shall be concurrently licensed with the board as an outsourcing facility if it compounds 172 sterile medication or nonsterile medication for non-patient specific distribution within or into California.
(b) A facility premises licensed with the board as a sterile compounding pharmacy shall not be concurrently licensed with the board as an outsourcing facility at the same location.
(c) The board may adopt regulations in accordance with the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code) to establish policies, guidelines, and procedures to implement this article.
(d) The board shall review any formal requirements or guidance documents developed by the FDA regarding outsourcing facilities within 90 days after their release in order to determine whether revisions are necessary for any regulations promulgated by the board.
(e) An outsourcing facility licensed by the board dispensing patient-specific compounded preparations pursuant to a prescription for an individual patient, shall not be required to be licensed as a pharmacy, but shall otherwise comply with the same requirements of a pharmacy.

ATTACHMENT F

Proposal to Amend BPC Section 4052 as follows:

(a) Notwithstanding any other law, a pharmacist may:
(1) Furnish a reasonable quantity of compounded drug product to a prescriber for office use by the prescriber…
(13) Initiate, adjust, or discontinue drug therapy for a patient under 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.

ATTACHMENT G

Proposal to Amend BPC Section 4052 as follows:

Furnishing to Prescriber; Permitted Procedures by Pharmacist
(a) Notwithstanding any other law, a pharmacist may:
(1) Furnish a reasonable quantity of compounded drug product to a prescriber for office use by the prescriber…

(14) Provide non-opioid medication-assisted treatment pursuant to a state protocol.

ATTACHMENT H

Proposal to Amend BPC Section 4427.3 as follows:

(a) An ADDS shall be placed and operated inside an enclosed building, with a premises address, at a location approved by the board.
(b) An ADDS shall be placed and operated in one of the following locations:
(1) Adjacent to the secured pharmacy area of the pharmacy holding the ADDS license.
(2) A health facility licensed pursuant to Section 1250 of the Health and Safety Code that complies with Section 1261.6 of the Health and Safety Code.
(3) A clinic licensed pursuant to Section 1204 or 1204.1 of the Health and Safety Code, or Section 4180 or 4190 of this code.
(4) A correctional clinic licensed pursuant to Section 4187.1.
(5) If the ADDS is an APDS, in a location as provided in Section 4427.6.
(6) If the ADDS is an AUDS, in a location as provided in Section 4427.65(a).
(c) Prior to installation, the pharmacy holding the ADDS license and the location where the ADDS is placed pursuant to subdivision (b) shall jointly develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the ADDS, as well as quality, potency, and purity of the drugs and devices. These policies…

Proposal to Add Section 4427.65 to read as follows:
(a) In addition to the locations authorized in Section 4427.3, an AUDS may also be located and operated in any of the following locations:
(1) Facility licensed by this state with the statutory authority to provide pharmaceutical services.
(2) Jail, youth detention facility, or other correctional facility where drugs are administered within the facility under the authority of the medical director.
(b) The pharmacy operating the AUDS shall develop and implement, and review annually, written policies and procedures pertaining to the device.
(c) The pharmacy shall operate the AUDS in compliance with the following requirements:
(1) Transaction information shall be made readily available in a written format for review and inspection by individuals authorized by law. These records shall be maintained in the facility for a minimum of three years.
(2) Individualized and specific access to automated drug delivery systems shall be limited to facility and contract personnel authorized by law to administer drugs.
(3) (A) The facility and the pharmacy shall develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of stored drugs. Policies and procedures shall define access to the automated drug delivery system and limits to access to equipment and drugs.

(B) All policies and procedures shall be maintained at the pharmacy operating the automated drug delivery system and the location where the automated drug delivery system is being used.

(4) When used as an emergency pharmaceutical supplies container, drugs removed from the automated drug delivery system shall be limited to the following:

(A) A new drug order given by a prescriber for a patient of the facility for administration prior to the next scheduled delivery from the pharmacy, or 72 hours, whichever is less. The drugs shall be retrieved only upon authorization by a pharmacist and after the pharmacist has reviewed the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions.

(B) Drugs that a prescriber has ordered for a patient on an as-needed basis, if the utilization and retrieval of those drugs are subject to ongoing review by a pharmacist.

(C) Drugs designed by the patient care policy committee or pharmaceutical service committee of the facility as emergency drugs or acute onset drugs. These drugs may be retrieved from an automated drug delivery system pursuant to the order of a prescriber for emergency or immediate administration to a patient of the facility. Within 48 hours after retrieval under this paragraph, the case shall be reviewed by a pharmacist.

(5) When used to provide pharmacy services pursuant to Section 4017.3 of, and Article 25 (commencing with Section 4427) of Chapter 9 of Division 2 of, the Business and Professions Code, the automated drug delivery system shall be subject to all of the following requirements:

(A) Drugs removed from the automated drug delivery system for administration to a patient shall be in properly labeled units of administration containers or packages.

(B) A pharmacist shall review and approve all orders prior to a drug being removed from the automated drug delivery system for administration to a patient. The pharmacist shall review the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions.

(C) The pharmacy providing services to the facility pursuant to Article 25 (commencing with Section 4427) of Chapter 9 of Division 2 of the Business and Professions Code shall control access to the drugs stored in the automated drug delivery system.

(D) Access to the automated drug delivery system shall be controlled and tracked using an identification or password system or biosensor.

(E) The automated drug delivery system shall make a complete and accurate record of all transactions that will include all users accessing the system and all drugs added to, or removed from, the system.

(F) After the pharmacist reviews the prescriber's order, access by licensed personnel to the automated drug delivery system shall be limited only to drugs ordered by the prescriber and reviewed by the pharmacist and that are specific to the patient. When the prescriber's order requires a dosage variation of the same drug, licensed personnel shall have access to the drug ordered for that scheduled time of administration.

(G) Systems that allow licensed personnel to have access to multiple drugs and are not patient specific in their design, shall be allowed under this subdivision if those systems have electronic and mechanical safeguards in place to ensure that the drugs delivered to the patient are specific to that patient.

(6) The stocking of an automated drug delivery system shall be performed by a pharmacist. If the automated drug delivery system utilizes removable pockets, cards, drawers, similar technology, or unit of use or single dose containers as defined by the United States Pharmacopoeia, the stocking system may be done outside of the facility and be delivered to the facility if all of the following conditions are met:

(A) The task of placing drugs into the removable pockets, cards, drawers, or unit of use or single dose containers is performed by a pharmacist, or by an intern pharmacist or a pharmacy technician working under the direct supervision of a pharmacist.

(B) The removable pockets, cards, drawers, or unit of use or single dose containers are transported between the pharmacy and the facility in a secure tamper-evident container.

(C) The facility, in conjunction with the pharmacy, has developed policies and procedures to ensure that the removable pockets, cards, drawers, or unit of use or single dose containers are properly placed into the automated drug delivery system.

(7) Review of the drugs contained within, and the operation and maintenance of, the automated drug delivery system shall be done in accordance with law and shall be the responsibility of the pharmacy. The review shall be conducted on a monthly basis by a pharmacist and shall include a physical inspection of the drugs in the automated drug delivery system, an inspection of the automated drug delivery system machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system.

ATTACHMENT I

Amend BPC sections 4127.3, 4129.4, and 4316 Relating to the Cease and Desist Appeal Hearing

Proposal to amend BPC section 4127.3. as follows:
(a) Whenever the board has a reasonable belief, based on information obtained during an inspection or investigation by the board, that a pharmacy compounding sterile drug products poses an immediate threat to the public health or safety, the executive officer of the board may issue an order to the pharmacy to immediately cease and desist from compounding sterile drug products. The cease and desist order shall remain in effect for no more than 30 days or the date of a hearing seeking an interim suspension order, whichever is earlier.
(b) Whenever the board issues a cease and desist order pursuant to subdivision (a), the board shall immediately issue the owner a notice setting forth the acts or omissions with which the owner is charged, specifying the pertinent code section or sections.
(c)The order shall provide that the owner, within 15 days of receipt of the notice, may request a hearing before the president of the board to contest the cease and desist order. Consideration of the owner's contest of the cease and desist order shall comply with the requirements of Section 11425.10 of the Government Code. The hearing shall be held no later than five business days from the date the request of the owner is received by the board. The president shall render a written decision within five business days of the hearing. In the absence of the president of the board, the vice president of the board may conduct the hearing permitted by this subdivision. Review of the decision of the president of the board may be sought by the owner or person in possession or control of the pharmacy pursuant to Section 1094.5 of the Code of Civil Procedure.
(d) Failure to comply with a cease and desist order issued pursuant to this section shall be unprofessional conduct.

Proposal to amend BPC section 4129.4 as follows:
(a)Whenever the board has a reasonable belief, based on information obtained during an inspection or investigation by the board, that an outsourcing facility compounding sterile drug products or nonsterile drug products poses an immediate threat to the public health or safety, the executive officer of the board may issue an order to the outsourcing facility to immediately cease and desist compounding sterile drug products or nonsterile drug products. The cease and desist order shall remain in effect for no more than 30 days or the date of a hearing seeking an interim suspension order, whichever is earlier.
(b)Whenever the board issues a cease and desist order pursuant to subdivision (a), the board shall immediately issue a notice to the owner setting forth the acts or omissions with which the owner is charged, specifying the pertinent code section or sections and any regulations.
(c)The cease and desist order shall state that the owner, within 15 days of receipt of the notice, may request a hearing before the president of the board to contest the cease and desist order. Consideration of the owner's contest of the cease and desist order shall comply with the requirements of Section 11425.10 of the Government Code. The hearing shall be held no later than five business days after the date the request of the owner is received by

the board. The president shall render a written decision within five business days after the hearing. In the absence of the president of the board, the vice president of the board may conduct the hearing permitted by this subdivision. Review of the decision may be sought by the owner or person in possession or control of the outsourcing facility pursuant to Section 1094.5 of the Code of Civil Procedure.
(d)Failure to comply with a cease and desist order issued pursuant to this section shall be unprofessional conduct.

Proposal to amend BPC section 4316 as follows:
(a)The board, through its executive officer, is authorized to issue a cease and desist order for operating any facility under this chapter that requires licensure without obtaining that licensure.
(b)Whenever the board issues a cease and desist order pursuant to subdivision (a), the board shall immediately issue the facility a notice setting forth the acts or omissions with which it is charged, specifying the pertinent code section or sections and any regulations.
(c)The order shall provide that the facility, within 15 days of receipt of the notice, may request a hearing before the president of the board to contest the cease and desist order. Consideration of the facility's contest of the cease and desist order shall comply with the requirements of Section 11425.10 of the Government Code. The hearing shall be held no later than five business days from the date the request of the owner is received by the board. The president shall render a written decision within five business days of the hearing. In the absence of the president of the board, the vice president of the board may conduct the hearing permitted by this subdivision. Review of the decision of the president of the board may be sought by the owner or person in possession or control of the facility pursuant to Section 1094.5 of the Code of Civil Procedure.

Amend BPC section 4343 to Expand the Prohibition Against Non Pharmacies Using any Words for Licensed Pharmacy

Proposal to amend BPC section 4343 as follows:
No building shall have upon it or displayed within it or affixed to or used in connection with it a sign bearing the word or words "Pharmacist," "Pharmacy," "Apothecary," "Drugstore," "Druggist," "Drugs," "Medicine," "Medicine Store," "Drug Sundries," "Remedies," or any word or words of similar or like import; or the characteristic symbols of pharmacy; or the characteristic prescription sign (Rx) or similar design, unless there is upon or within the building a pharmacy holding a license issued by the board pursuant to Section 4110. Further, no website shall have within it or used in connection with it a sign bearing the words "Pharmacist," "Pharmacy," "Apothecary," "Drugstore," "Druggist," "Drugs," "Medicine," "Medicine Store," "Drug Sundries," "Remedies," or any word or words of similar or like import; or the characteristic symbols of pharmacy; or the characteristic prescription sign (Rx) or similar design, unless the website is under the control of a pharmacy holding a license issued by the board pursuant to Section 4110.

Amend BPC section 4400 and add BPC section 4127.5 to Assess a Fee for an Inspection Resulting from the Remodel of a Sterile Compounding Pharmacy.

Proposal to Amend Business and Professions Code section 4400 as follows:

The amount of fees and penalties prescribed by this chapter, except as otherwise provided, is that fixed by the board according to the following schedule:

(a) The fee for a nongovernmental pharmacy license shall be five hundred twenty dollars ($520) and may be increased to five hundred seventy dollars ($570). The fee for the issuance of a temporary nongovernmental pharmacy permit shall be two hundred fifty dollars ($250) and may be increased to three hundred twenty-five dollars ($325).

…

(u) The fee for issuance of a nongovernmental sterile compounding pharmacy license or a hospital satellite compounding pharmacy shall be one thousand six hundred forty-five dollars ($1,645) and may be increased to two thousand three hundred five dollars ($2,305). The fee for a temporary license shall be five hundred fifty dollars ($550) and may be increased to seven hundred fifteen dollars ($715). The annual renewal fee of the license shall be one thousand three hundred twenty-five dollars ($1,325) and may be increased to one thousand eight hundred fifty-five dollars ($1,855). <u>The fee for the inspection of a remodeled facility shall be $780 dollars.</u>

(v) The fee for the issuance of a nonresident sterile compounding pharmacy license shall be two thousand three hundred eighty dollars ($2,380) and may be increased to three thousand three hundred thirty-five dollars ($3,335). The annual renewal of the license shall be two thousand two hundred seventy dollars ($2,270) and may be increased to three thousand one hundred eighty dollars ($3,180). In addition to paying that application fee, the nonresident sterile compounding pharmacy shall deposit, when submitting the application, a reasonable amount, as determined by the board, necessary to cover the board's estimated cost of performing the inspection required by Section 4127.2. If the required deposit is not submitted with the application, the application shall be deemed to be incomplete. If the actual cost of the inspection exceeds the amount deposited, the board shall provide to the applicant a written invoice for the remaining amount and shall not take action on the 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. <u>The fee for inspection of a remodeled facility shall be $780 dollars. In addition to paying the remodel inspection fee, the nonresident sterile compounding pharmacy shall deposit, when requested by the board following receipt of a remodel notification, a reasonable amount, as determined by the board, necessary to cover the board's estimated cost of performing the inspection required by Section 4127.5. If the required deposit is not submitted, the remodel notification will be deemed to be incomplete. If the actual cost of the inspection exceeds the amount deposited, the board</u>

shall provide to the applicant a written invoice for the remaining amount. Any remaining outstanding balance will be added to renewal costs.

…

Proposal to Add Business and Professions Code section 4127.5

A pharmacy licensed pursuant to 4127.1 or 4127.2 must notify the board of its intentions to remodel a facility within 30 days of initiation of the remodel. As part of the notification the licensee must provide the anticipated date of completion and the provisions for patient care during the remodel. For any remodel that results in recertification of an ISO classified area under USP 797 the board must perform an inspection to confirm compliance with this article and regulations approved by the board prior to resumption of sterile compounding within the facility. When possible, the board will conduct the inspection within the preceding 90 days of renewal of the license. In such instances a remodel inspection fee shall not be required.

Amend BPC section 4312 to Expand the Provisions for Cancellation of a Facility License

Proposal to amend BPC Section 4312 as follows:

(a) The board may cancel ~~the license of~~ a ~~wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, or outsourcing~~ license of a facility which is licensed by the board if the licensed premises remain closed, as defined in subdivision (e), other than by order of the board. For good cause shown, the board may cancel a license after a shorter period of closure. To cancel a license pursuant to this subdivision, the board shall make a diligent, good faith effort to give notice by personal service on the licensee. If a written objection is not received within 10 days after personal service is made or a diligent, good faith effort to give notice by personal service on the licensee has failed, the board may cancel the license without the necessity of a hearing. If the licensee files a written objection, the board shall file an accusation based on the licensee remaining closed. Proceedings shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code, and the board shall have all the powers granted in that chapter.

(b) If ~~the~~ a facility license issued by the board ~~of a wholesaler, third party logistics provider, pharmacy, veterinary food animal drug retailer, or outsourcing facility~~ is canceled pursuant to subdivision (a) or revoked pursuant to Article 19 (commencing with Section 4300), or a ~~wholesaler, third party logistics provider, pharmacy, veterinary food animal drug retailer, or outsourcing~~ facility notifies the board of its intent to remain closed or to discontinue business, the licensee shall, within 10 days thereafter, arrange for the transfer of all dangerous drugs and controlled substances or dangerous devices to another licensee authorized to possess the dangerous drugs and controlled substances or dangerous devices. The licensee transferring the dangerous drugs and controlled

substances or dangerous devices shall immediately confirm in writing to the board that the transfer has taken place.

(c) If a ~~wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, or outsourcing~~ licensed facility fails to comply with subdivision (b), the board may seek and obtain an order from the superior court in the county in which the ~~wholesaler, third party logistics provider, pharmacy, veterinary food animal drug retailer, or outsourcing~~ facility licensed by the board is located, authorizing the board to enter the ~~wholesaler, third party logistics provider, pharmacy, veterinary food animal drug retailer, or outsourcing~~ licensed facility and inventory and store, transfer, sell, or arrange for the sale of, all dangerous drugs and controlled substances and dangerous devices found in the ~~wholesaler, third party logistics provider, pharmacy, veterinary food animal drug retailer, or outsourcing~~ licensed facility.

(d) If the board sells or arranges for the sale of any dangerous drugs, controlled substances, or dangerous devices pursuant to subdivision (c), the board may retain from the proceeds of the sale an amount equal to the cost to the board of obtaining and enforcing an order issued pursuant to subdivision (c), including the cost of disposing of the dangerous drugs, controlled substances, or dangerous devices. The remaining proceeds, if any, shall be returned to the licensee from whose premises the dangerous drugs or controlled substances or dangerous devices were removed.

(1) The licensee shall be notified of his or her right to the remaining proceeds by personal service or by certified mail, postage prepaid.

(2) If a statute or regulation requires the licensee to file with the board his or her address, and any change of address, the notice required by this subdivision may be sent by certified mail, postage prepaid, to the latest address on file with the board and service of notice in this manner shall be deemed completed on the 10th day after the mailing.

(3) If the licensee is notified as provided in this subdivision, and the licensee fails to contact the board for the remaining proceeds within 30 calendar days after personal service has been made or service by certified mail, postage prepaid, is deemed completed, the remaining proceeds shall be deposited by the board into the Pharmacy Board Contingent Fund. These deposits shall be deemed to have been received pursuant to Chapter 7 (commencing with Section 1500) of Title 10 of Part 3 of the Code of Civil Procedure and shall be subject to claim or other disposition as provided in that chapter.

(e) For the purposes of this section, "closed" means not engaged in the ordinary activity for which a license has been issued for at least one day each calendar week during any 120 day period.

(f) Nothing in this section shall be construed as requiring a pharmacy to be open seven days a week.

Amended BPC section 4314 to Clarify that a Citation is not Considered Disciplinary Action

Proposal to amend BPC section 4314 as follows:

(a)The board may issue citations containing fines and orders of abatement for any violation of Section 733, for any violation of this chapter or regulations adopted pursuant to this chapter, or for any violation of Division 116 (commencing with Section 150200) of the Health and Safety Code, in accordance with Sections 125.9, 148, and 4005 and the regulations adopted pursuant to those sections.
(b)Where appropriate, a citation issued by the board, as specified in this section, may subject the person or entity to whom the citation is issued to an administrative fine.
(c)Notwithstanding any other provision of law, where appropriate, a citation issued by the board may contain an order of abatement. The order of abatement shall fix a reasonable time for abatement of the violation. It may also require the person or entity to whom the citation is issued to demonstrate how future compliance with the Pharmacy Law, and the regulations adopted pursuant thereto, will be accomplished. A demonstration may include, but is not limited to, submission of a corrective action plan, and requiring completion of up to six hours of continuing education courses in the subject matter specified in the order of abatement. Any continuing education courses required by the order of abatement shall be in addition to those required for license renewal.
(d)Nothing in this section shall in any way limit the board from issuing a citation, fine, and order of abatement pursuant to Section 4067 or Section 56.36 of the Civil Code, and the regulations adopted pursuant to those sections.
(e) The issuance of a citation pursuant to subdivision (b) of section BPC 4314 shall not be construed as a disciplinary action or discipline for purposes of licensure or the reporting of discipline for licensure.

Proposed Amendments to the following Business and Professions Code Sections 4022.5, 4022.7, 4053, 4053.1 and 4053.2.

Proposal to Amend BPC Section 4022.5 as follows:

(a) "Designated representative" means an individual to whom a license has been granted pursuant to Section 4053. A pharmacist fulfilling the duties of Section 4053 shall not be required to obtain a license as a designated representative.
(b) "Designated representative-in-charge" means a designated representative, ~~or~~ a designated representative-reverse distributor, or a pharmacist licensed in the home state proposed by a wholesaler or veterinary food-animal drug retailer and approved by the board as the supervisor or manager responsible for ensuring the wholesaler's or veterinary food-animal drug retailer's compliance with all state and federal laws and regulations pertaining to practice in the applicable license category.

Proposal to Amend BPC Section 4022.7 as follows:

(a) "Designated representative-3PL" means an individual to whom a license has been granted pursuant to Section 4053.1. A pharmacist fulfilling the duties of Section 4053.1 shall not be required to obtain a license as a designated representative-3PL.

(b) "Responsible manager" means a designated representative-3PL or a pharmacist licensed in the home state selected by a third-party logistics provider and approved by the board as responsible for ensuring compliance of the licensed place of business with state and federal laws with respect to dangerous drugs and dangerous devices received by, stored in, or shipped from the licensed place of business of the third-party logistics provider.

Proposal to Amend BPC Section 4053 as follows:

(a) Notwithstanding Section 4051, the board may issue a license as a designated representative to provide sufficient and qualified supervision in a wholesaler or veterinary food-animal drug retailer. The designated representative shall protect the public health and safety in the handling, storage, and shipment of dangerous drugs and dangerous devices in the wholesaler or veterinary food-animal drug retailer.
(b) An individual who is at least 18 years of age may apply for a designated representative license. In order to obtain and maintain that license, the individual shall meet all of the following requirements:
(1) He or she shall be a high school graduate, ~~or~~ possess a general education development certificate equivalent, or have earned a degree from an accredited post-secondary institution.
(2) He or she shall have a minimum of one year of paid work experience in a licensed pharmacy, or with a drug wholesaler, drug distributor, or drug manufacturer, in the past three years, related to the distribution or dispensing of dangerous drugs or dangerous devices or meet all of the prerequisites to take the examination required for licensure as a pharmacist by the board.
(3) He or she shall complete a training program approved by the board that, at a minimum, addresses each of the following subjects:
(A) Knowledge and understanding of California law and federal law relating to the distribution of dangerous drugs and dangerous devices.
(B) Knowledge and understanding of California law and federal law relating to the distribution of controlled substances.
(C) Knowledge and understanding of quality control systems.
(D) Knowledge and understanding of the United States Pharmacopoeia standards relating to the safe storage and handling of drugs.
(E) Knowledge and understanding of prescription terminology, abbreviations, dosages, and format.
(4) The board may, by regulation, require training programs to include additional material.
(5) The board may not issue a license as a designated representative until the applicant provides proof of completion of the required training to the board.
(c) The veterinary food-animal drug retailer or wholesaler shall not operate without a pharmacist or a designated representative on its premises.

(d) Only a pharmacist or a designated representative shall prepare and affix the label to veterinary food-animal drugs.
(e) Section 4051 shall not apply to any laboratory licensed under Section 351 of Title III of the Public Health Service Act (Public Law 78-410).

Proposal to Amend BPC Section 4053.1 as follows:

(a) Notwithstanding Section 4051, the board may issue a license to a qualified individual as a designated representative-3PL to provide sufficient and qualified supervision of a third-party logistics provider's place of business. The designated representative-3PL shall protect the public health and safety in the handling, storage, warehousing, distribution, and shipment of dangerous drugs and dangerous devices in the third-party logistics provider's place of business.
(b) An individual who is at least 18 years of age may apply for a designated representative-3PL license. In order to obtain and maintain that license, the individual shall meet all of the following requirements:
(1) He or she shall be a high school graduate, ~~or~~ possess a general education development certificate equivalent, or have earned a degree from an accredited post-secondary institution.
(2) He or she shall meet one of the following requirements:
(A) Have a minimum of one year of paid work experience in the past three years with a third-party logistics provider.
(B) Have a minimum of one year of paid work experience in the past three years in a licensed pharmacy, or with a drug wholesaler, drug distributor, or drug manufacturer, performing duties related to the distribution or dispensing of dangerous drugs or dangerous devices.
(C) Meet all of the prerequisites to take the examination required for licensure as a pharmacist by the board.
(3) (A) He or she shall complete a training program approved by the board that, at a minimum, addresses each of the following subjects:
(i) Knowledge and understanding of California law and federal law relating to the distribution of dangerous drugs and dangerous devices.
(ii) Knowledge and understanding of California law and federal law relating to the distribution of controlled substances.
(iii) Knowledge and understanding of quality control systems.
(iv) Knowledge and understanding of the United States Pharmacopoeia or federal Food and Drug Administration standards relating to the safe storage, handling, and transport of dangerous drugs and dangerous devices.
(B) The board may, by regulation, require the training program required under this paragraph to include additional material.
(C) The board shall not issue a license as a designated representative-3PL until the applicant provides proof of completion of the training required by this paragraph to the board.

(c) A third-party logistics provider shall not operate without a pharmacist or ~~at least one~~ designated representative-3PL present at each of its licensed places of business as required under Section 4160.

Proposal to Amend BPC Section 4053.2 as follows:

(a)Notwithstanding Sections 4051 and 4053, the board may issue a designated representative-reverse distributor license to a qualified individual who shall provide sufficient and qualified supervision over a licensed wholesaler that only acts as a reverse distributor. The designated representative-reverse distributor shall protect the public health and safety in the handling, storage, warehousing, and destruction of outdated or nonsaleable dangerous drugs and dangerous devices.
(b)An individual who is at least 18 years of age may apply for a designated representative-reverse distributor license. In order to obtain and maintain that license, the individual shall meet all of the following requirements:
(1) He or she shall be a high school graduate, ~~or~~ possess a general education development certificate equivalent, or have earned a degree from an accredited post-secondary institution.
(2) He or she shall meet one of the following requirements:
(A)Have a minimum of one year of paid work experience in the past three years with a licensed wholesaler, third-party logistics provider, or pharmacy performing duties related to the distribution, dispensing, or destruction of dangerous drugs or dangerous devices.
(B) Have a minimum of one year of paid work experience in the destruction of outdated or nonsaleable dangerous drugs or dangerous devices pharmaceutical waste.
(C) Meet all of the prerequisites to take the examination required for licensure as a pharmacist by the board.
(3)(A) He or she shall complete a training program approved by the board that, at a minimum, addresses each of the following subjects:
(i)Knowledge and understanding of California law and federal law relating to the distribution of dangerous drugs and dangerous devices.
(ii)Knowledge and understanding of California law and federal law relating to the distribution of controlled substances.
(iii)Knowledge and understanding of California law and federal law relating to the removal and destruction of dangerous drugs, dangerous devices, and pharmaceutical waste.
(iv)Knowledge and understanding of the United States Pharmacopoeia or federal Food and Drug Administration standards relating to the safe storage, handling, and transport of dangerous drugs and dangerous devices.
(B)The board may, by regulation, require the training program required under this paragraph to include additional material.

(C)The board shall not issue a license as a designated representative-reverse distributor until the applicant provides proof of completion of the training required by this paragraph to the board.
(c)A reverse distributor shall not operate without a pharmacist, ~~at least one~~ designated representative, or designated representative-reverse distributor present at each of its licensed places of business as required under Section 4160.

Amend BPC sections 4119.11 and 4427.7 Relating to Self-Assessment Form Requirements

Proposal to Amend BPC Section 4427.7 as follows:

(a)A pharmacy holding an ADDS license shall complete a ~~an annual~~ self-assessment, performed pursuant to Section 1715 of Title 16 of the California Code of Regulations, evaluating the pharmacy's compliance with pharmacy law relating to the use of the ADDS. All information regarding operation, maintenance, compliance, error, omissions, or complaints pertaining to the ADDS shall be included in the self-assessment.
(b)The pharmacy shall comply with all recordkeeping and quality assurance requirements established in pharmacy law and regulation, and shall maintain those records within the licensed pharmacy holding the ADDS license and separate from other pharmacy records.

Proposal to Amend BPC Section 4119.11 as follows:

(a)A pharmacy located in the state may provide pharmacy services to the patients of a "covered entity," as defined in Section 256b of Title 42 of the United States Code, through the use of an automated patient dispensing system located on the premises of the covered entity or on the premises of medical professional practices under contract to provide medical services to covered entity patients, which need not be the same location as the pharmacy, if all of the following conditions are met:
(1)The pharmacy obtains a license from the board to operate the automated patient dispensing system at the covered entity or affiliated site. As part of the application, the pharmacy shall provide the address at which the automated patient dispensing system shall be placed and identify the covered entity. A separate license shall be required for each location and shall be renewed annually concurrent with the pharmacy license. The application and renewal fee shall be three hundred dollars ($300) and may be increased to five hundred dollars ($500). The board is authorized to lower the renewal fee to not less than two hundred dollars ($200) if a lower fee level will provide sufficient resources to support the regulatory activities.
(2)The pharmacy providing the pharmacy services to the patients of the covered entity, including, unless otherwise prohibited by any other law, patients enrolled in the Medi-Cal program, shall be under contract with that covered entity as described in Section 4126 to provide those pharmacy services through the use of the automated patient dispensing system.
(3)Drugs stored in an automated patient dispensing system shall be part of the inventory of the pharmacy providing pharmacy services to the patients of the covered entity and drugs

dispensed from the automated patient dispensing system shall be considered to have been dispensed by that pharmacy.
(4)The pharmacy shall maintain records of the acquisition and disposition of dangerous drugs stored in the automated patient dispensing system separate from other pharmacy records.
(5)The pharmacy shall be solely responsible for the security, operation, and maintenance of the automated patient dispensing system.
(6)The pharmacy shall provide training regarding the operation and use of the automated patient dispensing system to both pharmacy and covered entity personnel using the system.
(7)The operation of the automated patient dispensing system shall be under the supervision of a licensed pharmacist acting on behalf of the pharmacy providing services to the patients of the covered entity. The pharmacist need not be physically present at the site of the automated patient dispensing system and may supervise the system electronically.
(8)Notwithstanding Section 4107, the board may issue a license for the operation of an automated patient dispensing system at an address for which it has issued another site license.
(9)The board, within 30 days after receipt of an application for an automated patient dispensing system license, shall conduct a prelicensure inspection at the proposed location of the automated patient dispensing system. Relocation of the automated patient dispensing system shall require a new application for licensure. Replacement of an automated patient dispensing system shall require notice to the board within 30 days.
(10)The automated patient dispensing system license shall be canceled by operation of law if the underlying pharmacy license is not current, valid, and active. Upon reissuance or reinstatement of the underlying pharmacy license, a new application for an automated patient dispensing system license may be submitted to the board.
(11)A pharmacy that holds an automated patient dispensing system license shall advise the board in writing within 30 days if use of the automated patient dispensing system is discontinued.
(b)For purposes of this section, the following definitions shall apply:
(1)An "automated drug delivery system" (ADDS) means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of drugs. An ADDS shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability.
(2)An "automated patient dispensing system" (APDS) is an ADDS for storage and dispensing of prescribed drugs directly to patients pursuant to prior authorization by a pharmacist.
(3)An "automated unit dose system" (AUDS) is an ADDS for storage and retrieval of unit doses of drugs for administration to patients by persons authorized to perform these functions.
(c)(1) An automated patient dispensing system shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability.
(2)Transaction information shall be made readily available in a downloadable format for review and inspection by individuals authorized by law. These records shall be maintained by the pharmacy for a minimum of three years.

(d) Drugs from the automated patient dispensing system may be dispensed directly to the patient if all of the following requirements are met:
(1)The pharmacy shall develop, implement, and annually review written policies and procedures with respect to all of the following:
(A)Maintaining the security of the automated patient dispensing system and the dangerous drugs and devices within that automated patient dispensing system.
(B)Determining and applying inclusion criteria regarding which drugs and devices are appropriate for placement in the automated patient dispensing system and for which patients.
(C)Ensuring that patients are aware that consultation with a pharmacist is available for any prescription medication, including those delivered via the automated patient dispensing system.
(D) Describing assignment of responsibilities to, and training of, pharmacy personnel, and other personnel using the automated patient dispensing system at the location where the automated patient dispensing system is placed, regarding maintenance and filing procedures for the automated patient dispensing system.
(E)Orienting participating patients on the use of the automated patient dispensing system, notifying patients when expected prescription medications are not available in the automated patient dispensing system, and ensuring that patient use of the automated patient dispensing system does not interfere with delivery of drugs and devices.
(F)Ensuring delivery of drugs and devices to patients expecting to receive them from the automated patient dispensing system in the event the automated patient dispensing system is disabled or malfunctions.
(2) The automated patient dispensing system shall only be used for patients who have signed a written consent demonstrating their informed consent to receive prescribed drugs and devices from an automated patient dispensing system and whose use of the automated patient dispensing system meet the criteria pursuant to paragraph (1).
(3) The automated patient dispensing system shall have a means to identify each patient and only release the identified patient's drugs and devices to the patient or the patient's agent.
(4)A pharmacist shall perform all clinical services conducted as part of the dispensing process, including, but not limited to, drug utilization review and consultation.
(5) Drugs shall be dispensed from the automated patient dispensing system only upon authorization from a pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions.
(6) All prescribed drugs and devices dispensed from the automated patient dispensing system for the first time 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.
(7) The automated patient dispensing system shall include a notice, prominently posted on the automated patient dispensing system, that provides the name, address, and telephone number of the pharmacy that holds the automated patient dispensing system license for that automated patient dispensing system.
(8)The labels on all drugs dispensed by the automated patient dispensing system shall comply with Section 4076 of this code and with Section 1707.5 of Title 16 of the California Code of Regulations.

(9) Any complaint, error, or omission involving the automated patient dispensing system shall be reviewed as part of the pharmacy's quality assurance program pursuant to Section 4125.
(10) The board shall not issue a pharmacy more than 15 licenses for automated patient dispensing system units under this section. Consistent with Section 4001.1, the board may adopt regulations to reduce the number of automated patient dispensing system licenses that may be issued to a pharmacy.
(11) The pharmacy holding the license for the automated patient dispensing system shall maintain the policies and procedures developed pursuant to paragraph (1) for three years after the last date of use of that automated patient dispensing system.
(e)Access to the automated patient dispensing system shall be controlled and tracked using an identification or password system or biosensor. A system that is accessed via a password system shall include a camera that records a picture of the individual accessing the machine. Picture records shall be maintained for a minimum of 180 days.
(f)The automated patient dispensing system shall make a complete and accurate record of all transactions that will include all users accessing the system and all drugs added to, or removed from, the system.
(g)The stocking of an automated patient dispensing system shall be performed by a pharmacist. If the automated patient dispensing system utilizes removable pockets, cards, drawers, similar technology, or unit of use or single dose containers as defined by the United States Pharmacopeia, the stocking system may be done outside of the facility and be delivered to the facility if all of the following conditions are met:
(1) The task of placing drugs into the removable pockets, cards, drawers, similar technology, or unit of use or single dose containers is performed by a pharmacist, or by an intern pharmacist or a pharmacy technician working under the direct supervision of a pharmacist.
(2) The removable pockets, cards, drawers, similar technology, or unit of use or single dose containers are transported between the pharmacy and the facility in a secure tamper-evident container.
(3) The pharmacy, in conjunction with the covered entity, has developed policies and procedures to ensure that the removable pockets, cards, drawers, similar technology, or unit of use or single dose containers are properly placed into the automated patient dispensing system.
(h)Review of the drugs contained within, and the operation and maintenance of, the automated patient dispensing system shall be done in accordance with law and shall be the responsibility of the pharmacy. The review shall be conducted on a monthly basis by a pharmacist and shall include a physical inspection of the drugs in the automated patient dispensing system, an inspection of the automated patient dispensing system machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system.
(i) A pharmacy holding an automated patient dispensing system license shall complete <u>a</u> ~~an annual~~ self-assessment, performed pursuant to Section 1715 of Title 16 of the California Code of Regulations, evaluating the pharmacy's compliance with pharmacy law relating to the use of the automated patient dispensing system. All information regarding operation, maintenance, compliance, error, omissions, or complaints pertaining to the automated patient dispensing system shall be included in the self-assessment.

(j) The pharmacy shall comply with all recordkeeping and quality assurance requirements pursuant to this chapter, and shall maintain those records within the pharmacy holding the automated patient dispensing system license and separately from other pharmacy records. (Added by Stats. 2018, Ch. 647, Sec. 1. (AB 2037) Effective September 21, 2018.)