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

LEGISLATION AND REGULATION COMMITTEE
MEETING MINUTES

DATE:	January 18, 2022
LOCATION:	Teleconference Public Committee Meeting Note: Pursuant to the provisions of Government Code section 11133, neither a public location nor teleconference locations are provided.
COMMITTEE MEMBERS PRESENT:	Seung Oh, Licensee Member Chair Maria Serpa, Licensee Member Vice Chair Lavanza Butler, Licensee Member Jose De La Paz, Public Member Shirley Kim, Public Member Nicole Thibeau, Licensee Member
STAFF MEMBERS PRESENT:	Anne Sodergren, Executive Officer Eileen Smiley, DCA Staff Counsel Lori Martinez, Senior Admin and Policy Manager

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

Chairperson Seung Oh called the meeting to order at 2:30 p.m. Chairperson Oh reminded all present that the Board is a consumer protection agency charged with administering and enforcing Pharmacy Law.

The meeting moderator provided instructions on how to participate during the meeting, including the process to provide public comment.

Chairperson Oh took roll call. Members present included: Maria Serpa, Lavanza Butler, Jose De La Paz, Shirley Kim, Nicole Thibeau and Seung Oh. A quorum was established.

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

Members of the public were provided the opportunity to provide comments for items not on the agenda; however, none were provided.

III. Approval of July 15, 2021, Legislation and Regulation Committee Meeting Minutes

Members were advised that the July 15, 2021, was cancelled.

IV. Discussion and Consideration of Draft Frequently Asked Questions Related to Senate Bill 212 (Chapter 1004, Statutes of 2018) Solid Waste: Pharmaceutical and Sharp Waste Stewardship

Chairperson Oh referenced meeting materials which provided background information including some of the relevant provisions of law. As noted, under provisions of the bill, covered entities, are required to report specified information to the Board, including a list and description of drugs or sharps that are considered covered or not covered.

Chairperson Oh reminded members the Board has undertaken implementation of the stewardship law with Cal Recycle, staff have identified several common questions related to the Board's purview for the stewardship programs. To assist covered entities and others with an understanding of the requirements, frequently asked questions (FAQs) have been developed. The FAQs have been reviewed by staff at the California Department of Public Health and Cal Recycle. Dr. Oh noted he hoped members had an opportunity to review the draft FAQs. Dr. Oh inquired if members had any questions or comments.

Member Serpa suggested that an opening paragraph or a link to the underlying legislation that explain the program be added. Staff will work with counsel to develop an introductory paragraph and link to the program.

Motion: Recommend approval of the FAQs with the inclusion of an opening paragraph and link.

Draft – Frequently Asked Questions: Pharmaceutical and Sharps Waste Stewardship Programs

1. How does a covered entity submit a list of products?
   You can email the list of covered and non-covered products to BOPStewardship@dca.ca.gov. The Board provides a template (add the link) to facilitate the submission and its review. Pursuant to Public Resources Code section 42031(a)(1), a covered entity must submit both a list of covered products, and a "a list and description of any drugs or sharps that are not covered products" to the Board. A covered entity is responsible for the accuracy and completeness of the list.
   Reference: PRC 42031(a)(1)

2. How often shall a covered entity submit the list of products?
   Public Resources Code section 42031(a)(2) specifies that a covered entity or a stewardship organization on behalf of a group of covered entities shall submit an updated list with highlighted changes to the Board on or before January 15 of each year or upon request.
   Reference: PRC 42031(a)(2)

3. Are auto-injectors and pre-filled syringes "covered products"?
   Yes. Pursuant to Public Resource Code (PRC) section 42030 (g), "covered product" means a covered drug or home-generated sharps waste.
   Reference: PRC 42030(g);

4. Are intramuscular injection needles used by ultimate users at home "covered products"?
   Yes. Intramuscular injection needles, such as the ones for testosterone injection, are used to penetrate skin for the delivery of medication. They are "home-generated sharps waste" pursuant to Health & Safety Code Section 117671, and thus "covered products" pursuant to Public Resource Code section 42030 (g).
   Reference: PRC 42030(g); HSC 117671

5. Can an ultimate user bring sharps waste to a pharmacy or deposit sharps waste into a drug take-back kiosk?

   Pursuant to CCR 1776.1(e), medical sharps and needles shall not be deposited into a drug take-back kiosk. Under BPC 4146, a pharmacy is permitted but not required to accept sharps containers. Please check https://www.calrecycle.ca.gov/epr/pharmasharps/sharps/ for more information about sharps waste stewardship.
   Reference: CCR 1776.1(e); BPC 4146

6. Some drugs are only being used in clinical settings. Are they "covered drugs"?

   Pursuant to Public Resource Code section 42030(e)(1), a "covered drug" means a drug sold, offered for sale, or dispensed in or into the State of California. Additionally, Business and Professions Code section 4024 defines "dispense" and BPC 4016 defines "administer". Based on the relevant sections of the law, a drug that is SOLELY administered in clinical settings within the definition of BPC section 4016, and not offered, sold or dispensed to a patient in California, would not be considered a "covered drug". The Board prefers that potential covered entities submit to the Board a statement why its drugs should not be considered "covered drugs" based on any such statutory interpretation. The potential covered entity is responsible for the truthfulness of such statement.
   Reference: PRC 42030(e)(1); BPC 4016, 4024

7. Are APIs (Active Pharmaceutical Ingredients) "covered drugs"?
   APIs are not finished drugs, thus not "covered drugs" pursuant to Public Resource Code section 42030(e).
   Reference: PRC 42030(e)

8. How do I know if I am a "covered entity"?
   Please refer to Public Resource Code section 42030(f) for the definition of "covered entity". Please contact CalRecycle at pharmasharpsenforcement@calrecycle.ca.gov for interpretive questions regarding a "covered entity".
   Reference: PRC 42030(f)

9. Where can I find the list of "covered products" and "covered entities"?
   Pursuant to California Public Resource Code 42035(a)(1), on or before June 30, 2022, CalRecycle will post on its Internet Web site (https://www.calrecycle.ca.gov/epr/pharmasharps) a list of stewardship organizations, including entities with an approved stewardship plan, and covered entities, authorized collection sites, retail pharmacies, and retail pharmacy chains provided in the stewardship plans that are in compliance with this chapter. The law does not require posting of a list of "covered products".
   Reference: PRC 42035(a)(1)

10. Where can I find information regarding stewardship organizations and stewardship plans?
    You can find information about potential stewardship organizations at https://www.calrecycle.ca.gov/epr/pharmasharps/coveredentities
    You can find information about Pharmaceutical Stewardship Plans at https://www.calrecycle.ca.gov/epr/pharmasharps/pharma/plan, and Home-Generated Sharps Waste Plans at https://www.calrecycle.ca.gov/epr/pharmasharps/sharps/plan.

11. What are the responsibilities of a wholesaler in compliance with SB212?
    A wholesaler may be considered a "covered entity" per the tiered definition under Public Resource Code 42030(f). Wholesalers should coordinate with appropriate entities in their supply chains to determine how statutory and regulatory requirements will be met.
    In addition, a wholesaler has the reporting responsibility pursuant to Public Resource Code 42035(c). A wholesaler shall determine if covered products are in compliance with the law, by verifying that the covered entities providing the covered products are in compliance with the law and shall notify CalRecycle if it determines that the covered entity is not listed on CalRecycle's Internet Web site.
    Reference: PRC 42030(f), Reference: PRC 42035(c)

12. How can a pharmacy participate in a stewardship plan for pharmaceutical or home-generated sharps waste?

    A pharmacy can contact approved stewardship plan operators for participating in the program. Please check https://www.calrecycle.ca.gov/epr/pharmasharps/coveredentities/for approved stewardship plans and their contact information.

13. Are compounded medications "covered drugs"?
    Compounded medications are exempted from section 505 of the Federal Food, Drug and Cosmetics Act (21 U. S.C. 355). Therefore, compounded medications are not "covered drugs" under the stewardship program.
    Reference: PRC 42030(e)(1)

14. Can a covered entity include non-covered drugs to the covered drug list?
    The intent of the SB212 is to ensure the safe disposal of pharmaceutical and home-generated sharps wastes. In the spirit of the law, the Board does not view it as a violation of

law if a covered entity voluntarily elects non-covered drugs to be covered under a stewardship plan.

15. Where can I get more information if needed?
    You can find more information at CalRecycle's web site: https://www.calrecycle.ca.gov/epr/pharmasharps. Questions regarding "covered drugs" or "covered products" should be directed to bopstewardship@dca.ca.gov. Questions regarding "covered entity" and other provision of SB212 should be directed to pharmasharpsenforcement@calrecycle.ca.gov

16. How do I know if an over-the-counter drug is a "covered drug"?
    Public Resource Code 42030(e)(1)(B) states a drug marketed under an over-the-counter drug monograph is a "covered drug". Pursuant to Public Resource Code 42030(e)(1)(A), non-prescription drugs (over-the-counter drugs) marketed under NDA or ANDA pursuant to Section 505 of the Federal Food, Drug and Cosmetic Act or Section 351 of the Federal Public Health Service Act are also "covered drugs". There are some exclusions pursuant to Public Resource Code 42030(e)(2)(C). Please note whether a product is a cosmetic or/and a drug under the law is determined by a product's intended use. Different laws and regulations apply to each type of product. The Board recommends potential covered entities examine their over-the-counter drugs for their intended uses and contact appropriate agents, including potentially a lawyer, for guidance of whether their particular product is a covered drug.
    Reference: PRC 42030(e)(1)(A); 42030(e)(1)(B); 42030(e)(2)(C); FDA Is It a Cosmetic, or a Drug, or Both?

Rev 1/11/2022

M/S: Serpa/Butler

Members of the public were provided with an opportunity to provide comment.

The committee received public comment requesting clarification if a 3PL is considered a covered entity.

The committee heard public comment in support of including opening information and suggested that definitions are necessary.

Counsel advised members that the Board's FAQs are limited to those items within its purview.

Support: 6 Oppose: 0 Abstain: 0 Not Present: 0

Committee Member	Vote
Butler	Support
De La Paz	Support
Kim	Support
Oh	Support
Serpa	Support
Thibeau	Support

V. Discussion and Consideration of California Code of Regulations Sections 1717 and 1717.4 Related to Electronic Prescriptions Including Possible Changes

Chairperson Oh advised members the next item for discussion was possible changes to sections 1717 and 1717.4 related to electronic prescriptions. He recalled effective January 1, 2022, most prescriptions are required to be e-prescribed and the provisions are detailed in Business and Professions Code (BPC) section 688 which became effective January 1, 2022.

Chairperson Oh noted as referenced in the meeting materials, to remove conflicts between the statute and regulations, amendments to the regulation were necessary. He added as the language was undergoing legal review at the time the meeting materials were released, he asked counsel if there were any comments on the draft language under consideration. Counsel Smiley indicated comments were included in the meeting materials.

Members were provided the opportunity to provide comment. Dr. Oh expressed concern of unintended consequences by changing "may" to "shall" by requiring pharmacists to do something they aren't able to do. After a discussion, members agreed "shall" is accepted as it is only discussing what is permitted under federal law.

Motion: Recommend initiation of a rulemaking to amend CCR sections 1717 and 1717.4 based on the policy discussions. Authorize the chair and executive officer to further refine the language consistent with the policy discussions as may be required by control agencies (DCA or Agency). Additionally, authorize the executive officer to make any non-substantive changes prior to initiation of the rulemaking. Further, if no adverse comments are received during the 45-day comment period and no hearing is requested, authorize the executive officer to

take all steps necessary to complete the rulemaking and adopt the proposed regulation at sections 1717 and 1717.4 as noticed for public comment.

Title 16. Board of Pharmacy
Proposed Text

Proposed changes to current regulation text are indicated with ~~single strikethrough~~ for deletions and single underline for additions.

Amend Section 1717 of Article 2 of Division 17 of Title 16 of the California Code of Regulations to read:

§ 1717. Pharmacy Practice.

a) No medication shall be dispensed on prescription except in a new container which conforms with standards established in the official compendia.
Notwithstanding the above, a pharmacist may dispense and refill a prescription for non-liquid oral products in a clean multiple-drug patient medication package (patient med pak), provided:
(1) a patient med pak is reused only for the same patient;
(2) no more than a one-month supply is dispensed at one time; and
(3) each patient med pak bears an auxiliary label which reads, “store in a cool, dry place.”
(b) In addition to the requirements of Business and Professions Code section 4040, the following information shall be maintained for each prescription on file and shall be readily retrievable:
(1) The date dispensed, and the name or initials of the dispensing pharmacist. All prescriptions filled or refilled by an intern pharmacist must also be initialed by the supervising pharmacist before they are dispensed.
(2) The brand name of the drug or device; or if a generic drug or device is dispensed, the distributor's name which appears on the commercial package label; and
(3) If a prescription for a drug or device is refilled, a record of each refill, quantity dispensed, if different, and the initials or name of the dispensing pharmacist.
(4) A new prescription must be created if there is a change in the drug, strength, prescriber or directions for use, unless a complete record of all such changes is otherwise maintained.
(c) Promptly upon receipt of an orally transmitted prescription, the pharmacist shall reduce it to writing, and initial it, and identify it as an orally transmitted prescription. If the prescription is then dispensed by another pharmacist, the dispensing pharmacist shall also initial the prescription to identify him or herself. All orally transmitted prescriptions shall be received and transcribed by a pharmacist prior to compounding, filling, dispensing, or furnishing. Chart

orders as defined in section 4019 of the Business and Professions Code are not subject to the provisions of this subsection.
(d) A pharmacist may furnish a drug or device pursuant to a written or oral order from a prescriber licensed in a State other than California in accordance with Business and Professions Code section 4005.
(e) A pharmacist ~~may~~ shall transfer a prescription for Schedule III, IV or V controlled substances to another pharmacy for refill purposes in accordance with Title 21, Code of Federal Regulations, section 1306.25.
Prescriptions for other dangerous drugs which are not controlled substances ~~may~~ shall also be transferred by direct communication between pharmacists or by the receiving pharmacist's access to prescriptions or electronic files that have been created or verified by a pharmacist at the transferring pharmacy. The receiving pharmacist shall create a written prescription; identifying it as a transferred prescription; and record the date of transfer and the original prescription number. When a prescription transfer is accomplished via direct access by the receiving pharmacist, the receiving pharmacist shall notify the transferring pharmacy of the transfer. A pharmacist at the transferring pharmacy shall then assure that there is a record of the prescription as having been transferred, and the date of transfer. Each pharmacy shall maintain inventory accountability and pharmacist accountability and dispense in accordance with the provisions of section 1716 of this Division. Information maintained by each pharmacy shall at least include:
(1) Identification of pharmacist(s) transferring information;
(2) Name and identification code or address of the pharmacy from which the prescription was received or to which the prescription was transferred, as appropriate;
(3) Original date and last dispensing date;
(4) Number of refills and date originally authorized;
(5) Number of refills remaining but not dispensed;
(6) Number of refills transferred.
(f) The pharmacy must have written procedures that identify each individual pharmacist responsible for the filling of a prescription and a corresponding entry of information into an automated data processing system, or a manual record system, and the pharmacist shall create in his/her handwriting or through hand-initializing a record of such filling, not later than the beginning of the pharmacy's next operating day. Such record shall be maintained for at least three years.

Note: Authority cited: Sections 4005, 4075 and 4114, Business and Professions Code. Reference: Sections 688, 4005, 4019, 4027, 4050, 4051, 4052, 4075, 4114, 4116, 4117 and 4342, Business and Professions Code.

Amend Section 1717.4 of Article 2 of Division 17 of Title 16 of the California Code of Regulations to read:

§ 1717.4. Electronic Transmission of Prescriptions

(a) Except as otherwise ~~prohibited~~ allowed by law, prescriptions ~~may~~ shall be transmitted by electronic means from the prescriber to the pharmacy.
(b) An electronically transmitted prescription which meets the requirements of this regulation shall be deemed to be a prescription within the meaning of Business and Professions Code section 4040.
(c) An electronically transmitted prescription order shall include the name and address of the prescriber, a telephone number for oral confirmation, date of transmission and the identity of the recipient, as well as any other information required by federal or state law or regulations. The prescriber's address, license classification and federal registry number may be omitted if they are on file and readily retrievable in the receiving pharmacy.
(d) An “interim storage device” means as electronic file into which a prescription is entered for later retrieval by an authorized individual. Any interim storage device shall, in addition to the above information, record and maintain the date of entry and/or receipt of the prescription order, date of transmission from the interim storage device and identity of the recipient of such transmission. The interim storage device shall be maintained so as to ensure against unauthorized access and use of prescription information, including dispensing information.
(e) A pharmacy receiving an electronic image transmission prescription shall either receive the prescription in hard copy form or have the capacity to retrieve a hard copy facsimile of the prescription from the pharmacy's computer memory. Any hard copy of a prescription shall be maintained on paper of permanent quality.
(f) An electronically transmitted prescription shall be transmitted only to the pharmacy of the patient's choice. This requirement shall not apply to orders for medications to be administered in an acute care hospital.
(g) Electronic equipment for transmitting prescriptions (or electronic transmittal technology) shall not be supplied or used so as to violate or circumvent Business and Professions Code section 4000 et seq., Health and Safety Code section 11150 et seq., or any regulations of the board.
(h) Any person who transmits, maintains or receives any prescription or prescription refill, orally, in writing or electronically, shall ensure the security, integrity, authenticity, and confidentiality of the prescription and any information contained therein.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 688, 4019, 4040, 4071, 4072 and 4075, Business and Professions Code; and Section 11150, et seq., Health and Safety Code.

M/S: Serpa/Kim

Members of the public were provided with an opportunity to provide public comment.

Members heard public comment stating that the proposed change is fine and provided comments about the prior agenda item.

The Committee heard comment that encouraged the committee to vote down the motion, evaluate the information and consider unintended consequences, and stated that the regulation was premature.

Ms. Sodergren commented staff will follow the direction of the committee and recommended looking at the language a little more globally. She continued if the Board makes it "shall" for controlled substances the Board needs to ensure the retention of the permissive value of the current language.

After consideration of public comment, the motion was rescinded. The committee directed the executive officer to work with the chairperson to monitor BPC 688 implementation and bring forward a solution.

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

Chairperson Oh referenced the meeting materials regarding four measures reviewed. He noted staff reached out to the respective authors' offices to request status updates.

Chairperson Oh reported Assembly Bill 458 would create the Affordable Prescription Drug Importation Program. He noted that the Board did not take a position last year and the author's office has indicated that they have not decided to move the bill at this time. Dr. Oh indicated he didn't believe any action was required at the time.

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

Chairperson Oh noted Assembly Bill 646 would require professional licensing boards under the Department of Consumer Affairs that post information on their internet website about a revoked license due to a criminal conviction to update or remove information about the revoked license should the Board receive an expungement order related to the condition.

Dr. Oh reported the Board did not establish a position on this measure and he didn't believe any action on this measure was required.

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

Chairperson Oh reported Assembly Bill 1328 would amend several provisions of law to expand authority for pharmacists to provide CLIA-waived tests with some exceptions. The exceptions include CLIA-waived tests that are used for surgery, diagnosis or treatment of heart failure, female fertility or ovulation prediction. The measure generally also includes requirements for notification to primary care providers or other specified physician for any abnormal test results. Dr. Oh reported the Board has a support position on the measure. Staff was advised by the author's office that a decision on the measure will be made later this year. Dr. Oh added he did not believe any action is necessary.

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

Chairperson Oh reported the Board established an Oppose Unless Amended position on Senate Bill 731 because it would impede the Board's authority to consider relevant arrest and conviction information prior to making a licensing decision. As noted in the meeting materials, as a consumer protection agency, the Board must have full information to evaluate an individual's background prior to making a licensing decision. The author's office indicated that they intend to move the bill this year. Dr. Oh stated he recommended the committee maintain the same position.

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

Chairperson Oh noted the remaining items were for information only. As detailed in the meeting materials and associated attachments, the Board has several regulations in various stages of promulgation.

Chairperson Oh noted for Agenda Items VII – IX, the Board currently had four regulations undergoing final review by the Office of Administrative Law, one regulation undergoing pre-notice review and one regulation with staff to prepare the necessary rulemaking documents required to initiate the formal process.

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

VII. Board Adopted Regulations Under Final Review by the Office of the Administrative Law

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

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

X. Future Committee Meeting Dates

The Committee was reminded that future Committee meeting dates were April 26, 2022, and July 18, 2022.

XI. Adjournment

Chairperson Oh adjourned the meeting at 3:14 p.m.