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

Enforcement and Compounding Committee Report

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a. Discussion and Consideration of Enrolled or Recently Signed Legislation Impacting the Practice of Pharmacy

1. Assembly Bill 107 (Salas) Licensure: Veterans and Military Spouses.
   Summary: Requires the Board to issue temporary licenses to practice. As provided, the Board would be required to issue the temporary license within 30 days of receiving fingerprint background checks. Further, pharmacist applicants would be required to take and pass the CPJE prior to issuance of the temporary license.
   Implementation: Although the provisions become effective July 1, 2023, there are implementation activities that must begin in advance. Such activities include developing the appropriate attestations for each of the Board's license types, updating application and instruction forms, developing internal tracking systems, developing educational on the provisions and securing the necessary programming changes. It appears appropriate to develop regulations detailing the types of evidence needed to show compliance with the provisions (e.g., proof of marriage, domestic partnership, etc.) and well as under what circumstances the Board may request information. The Committee may wish to recommend referral of another committee to further development the scope and language for proposed regulations.

2. Assembly Bill 527 (Wood, Chapter 618, Statutes of 2021) Controlled Substances
   Summary: Exempts specified non-narcotic combination product controlled substances from the California controlled substances schedule.
   Implementation: Implementation efforts should be minimal and include education of the change.

3. Assembly Bill 1064 (Fong) Pharmacy Practice: Vaccines: Independent Initiation and Administration
   Summary: Expands authority to allow a pharmacist to independently initiate and administer any vaccine that has been approved or authorized by the FDA and received an ACIP recommendation published by the CDC for persons 3 years of age and older.
   Implementation: Implementation efforts will focus primarily on education of the change.

4. Assembly Bill 1533 (Assembly Committee on Business and Professions, Chapter 629, Statutes of 2021) Pharmacy

BPC 4001, 4003 Summary: This measure extends the operations of the Board until January 1, 2026. Further, modifies the allocation of pharmacist members to also include a pharmacy compounding specializing in human drug preparation.

Implementation: Staff recommends completion of an annual report to include the primary reporting elements of the Sunset report to be reviewed as part of the July meeting for each year. Staff notes that changes to the membership of the Board will be implemented by the administration.

BPC 4052(a)(13) Summary: Expands authority for pharmacists to initiate, adjust, or discontinue drug therapy for a patient under a collaborative practice agreement with a healthcare provider with prescriptive authority.

Implementation: Implementation efforts will focus primarily on education about the provisions, which could be extensive.

BPC 4052(a)(14) Summary: Expands authority for pharmacists to provide medication-assist treatment pursuant to a state protocol.

Implementation: Will require the Board to develop a state protocol via regulation. It may be appropriate for the Committee to determine if a recommendation should be offered to the Board regarding which committee should spearhead this effort.

BPC 4052.6 Summary: Expands that authority for an advanced practice pharmacist to initiate, adjust, or discontinue drug therapy beyond health care facilities.

Implementation: Implementation efforts will focus primarily on education about the provisions and should reiterate the provisions for coordination of care and education with the patient's diagnosing prescriber.

BPC 4110, 4126.10 Summary: Establishes the requirement for a pharmacy to report, as part of the renewal application, notification to the Board regarding compounding practices and reporting requirements for pharmacies distributing compounded human drug preparations. Note: These provisions are necessary to allow the Board to enter into the FDA MOU. The Board will also need to secure the necessary resources to meet the obligations of the MOU.

Implementation: Implementation efforts will include updating renewal forms and data systems, instructions and other educational materials.

BPC 4129 Summary: Expands authority for outsourcing facilities licensed by the Board to dispense patient-specific compounded drug preparations under specified conditions, including that the outsourcing facility comply with the same requirements of a pharmacy.

Implementation: Implementation efforts will include the development of educational materials and extensive education on the relevant provisions that outsourcers must comply with when exercising this new authority. Such education is necessary to allow for harmony with federal provisions while ensuring patients have access to pharmacist care, including drug utilization review, patient-centered labeling, patient consultation, etc.

Section 4161 Summary: Creates alternative pathways to licensure as a nonresident third-party logistics provider to allow for a pre-licensure inspection by the Board or evidence of accreditation by the NABP Drug Distributor Accreditation program.

Implementation: Implementation efforts will include updating application instructions and forms and development of forms. Further, in response to the COVID-19 pandemic, under its waiver authority, the Board granted waivers to issue temporary licenses to entities to facilitate

distribution of various items, including ventilators and vaccines. As these licenses are limited in duration, transition activities will need to be undertaken to ensure continuity of patient care effective January 1, 2022.

Section 4210 Summary: Alters the application requirements for an advanced practice pharmacy to allow for qualification under a single pathway, if the pathway requires completion of a second criterion.

Implementation: Implementation efforts will include updating application instructions and forms and the development of educational materials. Staff will also review pending applications to determine if the changes provided in the measure will impact applicant eligibility.

Section 4232.5 Summary: Requires a pharmacist with authority to prescribe a controlled substance to complete an education course on the risks of addiction to Schedule II drugs.

Implementation: Implementation efforts will include updating the Board's renewal application requirements via regulation to give notice of this requirement and how to demonstrate compliance. The Committee may wish to recommend referral of another committee to further development the scope and language for proposed regulations.

Section 4301.3 Summary: Requires the Board to convene a working group of interested stakeholders to discuss whether moving to a standard of care enforcement model would be feasible and appropriate. Also, requires the Board to make recommendations to the Legislature after these discussions.

Implementation: Education on standard of care, including how the Board currently uses such a model and assessment of further use will be required. Under the provisions of the Board's administrative procedure manual, the president has the authority to establish an ad hoc committee. Such an approach may be appropriate. Given the short duration of time to conduct this work and prepare a report, it is recommended that the efforts begin in the third quarter of the current fiscal year.

Section 4317.5 Summary: Provides the Board with authority to issue fines of up to $100,000 for repeated violations within five years by three or more community chain pharmacies operating under common ownership. Further provides the Board with authority to issue fines up to $150,000 for any violation of this chapter demonstrated to be the result of a written policy or which was expressly encouraged by the owner or manager. The measure provides an opportunity to cure a violation as long as the violation did not result in actual harm to any consumer or pose serious potential harm to the public.

Implementation: Implementation will include education about the provisions and evaluation of investigations to determine if the new authorities provided are applicable. Data on implementation will be maintained and reported back to the Committee and Board. Data collected will also be a required element of the Board's next Sunset Report.

Section 4427.65 Summary: Expands the locations where unit-dose automated drug delivery systems may be located.

Implementation: Implementation will include education on the provisions.

5. Senate Bill 306 (Pan, Chapter 486, Statutes of 2021) Sexually Transmitted Disease: Testing

Summary: This bill will allow a pharmacist to dispense a medication without an individual name if the prescriptions includes "expedited partner therapy" or EPT. Further, requires a pharmacist to provide a written notice that describes the right of an individual receiving EPT to consult with a pharmacist about the therapy and potential drug interactions.

Implementation: Implementation efforts will focus primarily on education of the change.

6. Senate Bill 310 (Rubio, Chapter 541, Statutes of 2021) Unused Medications: Cancer Medication Recycling
   Summary: Creates a cancer medication collection and distribution program under the direction of a surplus medication collection and distribution intermediary licensed by the Board. Provides allowances for patients to donate previously dispensed medications back to a participating practitioner for redistribution to other patients of the same practitioner or medical practice. Provides authority for the Board to request records to evaluate for compliance with the provisions and to prohibit a practitioner from participating under specified conditions.
   Implementation: Implementation efforts will focus primarily on education about the provisions of the measure to the public as well as extensive education of identified Board staff to ensure the appropriate development of policies and procedures, drug manufacturing requirements, etc. to ensure appropriate patient protections exist for the recycled medications. Data will be collected and reported to the Committee.

7. Senate Bill 311 (Hueso, Chapter 384, Statutes of 2021) Compassionate Access to Medical Cannabis or Ryan's Law
   Summary: Requires health care facilities to allow a terminally ill patient to use medical cannabis under specified conditions. Specifies that health care facilities permitting patient use of medicinal cannabis must comply with drug and medication requirements applicable to Schedule II, III, and IV drugs and shall be subject to enforcement actions by the California Department of Public Health.
   Implementation: Late amendments to the measure, notably HSC Section 1649.3, appear to create some conflicts within the measure itself including the requirements that medicinal cannabis comply with provisions related to Schedule II-IV medications. Such a requirement creates a number of questions about the applicability of provisions of the Board's regulations including storage, inventory control, acquisition, etc. It appears appropriate for the Committee to evaluate this issue and work to resolve the conflicts with other regulators and stakeholders. Similar issues have occurred in other states where additional concerns regarding federal laws and regulations that impact health facility licensure, accreditation and reimbursement have limited the access. In the interim, it may be appropriate for the Committee to consider if it is appropriate to provide staff with direction on the approach to education and enforcement until clarification via statute can be achieved.

8. Senate Bill 362 (Newman, Chapter 334, Statutes of 2021) Chain Community Pharmacies: Quotas
   Summary: Prohibits a community chain pharmacy from using a quota to evaluate the performance of a pharmacist or pharmacy technician.
   Implementation: Implementation efforts will include education about the provisions as well as the process a pharmacist or pharmacy technician may use to file a complaint. Educational efforts should also include information about whistleblower protections. Data on implementation will be provided to the Committee.

9. Senate Bill 409 (Caballero, Chapter 604, Statutes of 2021) Pharmacy Practice: Testing
   Summary: Expands authority for pharmacists to provide CLIA-waived tests under specified conditions.

Implementation: Implementation efforts will include education of the provisions and updates to the Board's Health Services Registry to capture these additional services for patients.

b. Discussion and Consideration of Released Revised Proposed Changes to USP Chapters 795 and 797 and the Board's Current Policy Statement

Relevant Law

Section 503A of the Food, Drug and Cosmetic Act establishes requirements for preparing human drug compounded preparations within a state-licensed pharmacy, federal facility, or by a licensed physician that is not registered with the FDA as an outsourcing facility.

BPC Section 4126.8 provides that compounding of drug preparations shall be consistent with standards established in the pharmacy compounding chapters of the current version of the United States Pharmacopeia-National Formulary (USP-NF), including relevant testing and quality assurance. Further, the Board may adopt regulations to impose additional standards.

BPC Section 4127(c) requires the Board to review any formal revision to General Chapter 797 of the USP-NF relating to the compounding of sterile preparations, no later than 90 days after the revisions become official to determine whether amendments are necessary for the regulations adopted by the Board.

BPC Section 4342 provides authority for the Board to institute any action provided by law, that in its discretion, is necessary to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength provided in the latest addition of USP or that violate any provisions of the Sherman Food, Drug, and Cosmetic Law.

California Code of Regulations Section 1708.3 – 1708.5 provides general requirements for radioactive drugs.

California Code of Regulations Section 1735 et seq. establishes requirements for the compounding of preparations. Further, California Code of Regulations Section 1751 et. seq. establishes additional requirements for the compounding of sterile preparations.

Background

In response to significant proposed changes to USP compounding chapters, the Board established an ad hoc Compounding Committee to review the proposed changes and determine what, if any, changes to the Board's regulations were necessary to ensure appropriate, safe and efficacious compounded preparations are provided to California consumers. In 2019 the Committee convened several meetings to provide education on the new proposed chapters as well as consider current regulation requirements and offer recommendations to change the current requirements. The meetings were well attended and provided an opportunity for robust discussion and development of language in response to proposed 2019 changes. Appeals were received by USP in response to the proposed Chapters which resulted in a delay in implementation. Based on USP, the Board similarly postponed additional action.

On September 1, 2021, USP released proposed updates to USP General Chapters 795 and 797. As provided in these proposed revisions, the minimum standards described apply when preparing compounded nonsterile and sterile preparations for humans and animals.

For Committee Consideration and Discussion

Given the release of the proposed revisions it appears appropriate for the Committee to determine whether it should resume education efforts and begin evaluation of the Board's regulations. It may also be appropriate to release an updated policy statement providing guidance to licensees about the Board's understanding of the current status of the provisions governing the practice of compounding.

Provided in **Attachment 1** includes high level comparison charts detailing current USP standards, USP 2019 proposed version and newly released 2021 versions of USP Chapters 795 and 797. Also, provided is a draft policy statement that could be used to provide guidance to licensees.

c. Updates on FDA Actions Related to Human Compounding

1. FDA's Final MOU on Interstate Distribution of Compounded Drug Products (For Information only)

On August 9, 2021, the FDA released a notice of extension of the period before it intends to begin enforcing the statutory five percent limit on out of state distribution of human drug products. Under the summary of the notice, the FDA is extending the period to October 27, 2022, providing states with an additional year to complete evaluation and make necessary changes to law to meet the obligations of the MOU.

2. Guidance for Industry Hospital and Health System Compounding (For Information Only)

On October 7, 2021 the FDA released a draft guidance document, Hospital and Health System Compounding Under Section 503A of the Federal Food, Drug, and Cosmetic Act Guidance for Industry. The draft guidance describes how the FDA intends to apply certain provisions of section 503A of the FD&C to human drug products that are compounded by state-licensed pharmacies for distribution within a hospital or health-system. Written comments must be submitted by December 6, 2021.

d. Review and Discussion of Enforcement Statistics

Since July 1, 2021, the board received 715 complaints and has closed 813 investigations. The board has issued 92 Letters of Admonishment, 359 Citations and referred 49 cases to the Office of the Attorney General. The board has secured 0 interim suspension orders and granted 0 Penal Code 23 suspensions. Further, the board has revoked 19 licenses, accepted the disciplinary surrender of 18 licenses, denied 1 application, and imposed other levels of discipline against 31 licensees and/or applicants.

As of October 1, 2021, the board had 974 field investigations pending. Below is a breakdown providing more detail in the various investigation process:

	July 3, 2021		October 1, 2021	
	Volume	Average Days	Volume	Average Days
Cases Under Review for Assignment	41	18	71	14
Cases Under Investigation	631	150	560	146
Investigation Pending Supervisor Review	141	40	134	40
Investigations Pending Second Level Review	30	16	42	47
Investigations Awaiting Final Closure	410	70	167	75

Attachment 2 includes the current fiscal year enforcement statistics.

e. <u>Future Committee Meeting Dates</u>

- January 18, 2022
- April 20, 2022
- July 19, 2022
- October 19, 2022

Attachment 1

Item	Current 2008	USP 2019	USP 2021
Personal Hygiene and Garbing	No specific requirements	Gloves are required for all compounding activities Other garb must be used as appropriate for the type of compounding	If gown is to be reused it must remain in the compounding area
Garb and Glove requirements	No specific requirements	A gown may be reused if not soiled and stored in the compounding area. Gloves, shoe covers, face and head covers and masks may not be reused. Non-disposal garb must be appropriately sanitized with 70% IPA.	No additional requirements
Building and facilities	Adequate space specifically designated for compounding and well organized. components, equipment and containers stored off the floor.	Compounding non-hazardous CNSPs shall not be in the same area as hazardous CNSP. Surfaces of ceilings, walls, floors, fixtures, shelving, counters and cabinets must be cleanable and kept clean. Carpet is not allowed	Designated space for nonsterile compounding Space is controlled Space is cleanable and clean Must monitor temperatures in the storage area
Cleaning and Sanitizing	No specific requirements	CVE and work surfaces outside CVE: each shift, after spills , contamination, between CNSPs Clean and sanitize the horizontal work surface of the CVE between compounding of different drugs. Equipment: Before first use and per manufacture	Work surfaces: each shift, after spills , contamination, between CNSPs Floors: daily Walls: 3 months Ceilings/storage shelving: when soiled or contamination Cleaning must always be performed prior to sanitizing. Must be documented
Equipment	Store and cleaned appropriately. Special equipment to avoid cross contamination.	Must be non-reactive. Stored to prevent contamination. Manipulation of any component must take place in the CVE CVE must be cleaned CVE must be certified annually	No additional requirements
Components	Allows the use of non-FDA components or analytical grade components. Purified water shall be used	APIs must be manufactured by an FDA-registered facility Each API must be accompanied by a valid COA	Purified water USP or better must be used in compounding.
Component Storage and evaluation	Store per manuf. Guidelines and off the floor. If no expiration date, three years from purchase.	Packages of ingredients that lack vendor expiration must not be used after 1 year from the date of receipt. Verify component prior to use.	Packages of ingredients that lack vendor expiration must not be used after 3 year from the date of receipt.
Master Formulation and Compounding records	Master Formulation and Compounding record must be reviewed by the compounder. Comply with local state BOP for records requirements	Master formulation record (MFR) for each unique formulation of a CNSP. 8 required elements for MFR Compounding record created for all CNSPs. 13 required elements for compounding record	13 required elements for MFR
BUD 795	Water containing oral formulations = 14 days Water-containing topical/dermal and mucosal liquids and semisolid = 30 days Nonaqueous formulations = 180 days	Non-preserved aqueous (Aw > 0.6) = 14 days Preserved aqueous (Aw > 0.6) = 35 days Nonaqueous dosage forms (Aw ≤ 0.6) = 90 days Solid dosage forms = 180 days	Without stability information: Aqueous (Aw > 0.6) Non-preserved = 14 days frig Aqueous (Aw > 0.6) preserved = 35 days CRT or frig Nonaqueous (Aw ≤ 0.6) oral liquid = 90 days CRT or frig Nonaqueous (Aw ≤ 0.6) other dosage forms = 180 days CRT or frig With stability information: Aqueous must have USP antimicrobial effectiveness test Must assign per USP-NF monograph Max 180 days

Adapted from: USP Open Forum on 9/8/21, https://www.usp.org/events-training/virtual-open-forum-series-proposed-revisions-to-compounding-general-chapters

Item	Current 2008	USP 2019	USP 2021
Visual observation of hand hygiene and garbing	Annually	Category 1 & 2: Every 6 months Category 3: Every 3 months for personnel who compound Category 3 CSPs	Category 1 & 2: Every 6 months Category 3: Every 3 months for personnel who compound Category 3 CSPs
Gloved fingertip and thumb sampling	Initially 3 separate times Low/Medium-Risk CSPs: Annually High-Risk CSPs: Semi-annually	Initially 3 separate times then every 6 months	Initially 3 separate times Category 1 & 2: Every 6 months Category 3: Every 3 months for personnel who compound Category 3 CSPs as part of garbing competency and aseptic competency
Media-fill testing	Low/Medium-Risk CSPs: Annually High-Risk CSPs: Semi-annually	Every 6 months	Category 1 & 2: Every 6 months Category 3: Every 3 months for personnel who compound Category 3 CSPs
Garbing Requirements	Gown Dedicated shoes or shoe covers Head and facial hair covers Face masks Sterile gloves	Gown Disposable covers for shoes Disposable covers for head and facial hair Face mask Sterile gloves If using RABS → disposable gloves inside of gauntlet gloves	Gown Disposable covers for shoes Disposable covers for head and facial hair Face mask Sterile gloves If using RABS → disposable gloves inside of gauntlet gloves Category 3: 1.Not allow any exposed skin in the buffer room. (i.e., face and neck must be covered) 2. All low-lint garb must be sterile 3. Disposable garbing items must not be reused, and laundered garb must not be reused without being laundered and resterilized with a validated cycle
Viable air sampling	Every 6 months	Initially then every 6 months	Category 1 & 2: Initially then every 6 months Category 3: Monthly
Surface sampling	Periodically	Initially then monthly	Category 1 & 2: Initially then monthly Category 3: Initially then weekly
Master Formulation Record	No specific requirements	CSPs are prepared in a batch for multiple patients or when CSPs are prepared from nonsterile ingredients	Required for: Category 1, Category 2, Category 3, and immediate-use CSPs prepared for more than one patient or CSPs prepared from nonsterile ingredient(s)
Compounding Record	No specific requirements	Every CSP prepared	Required for: Category 1, Category 2, Category 3, and immediate-use CSPs prepared for more than one patient or CSPs prepared from nonsterile ingredient(s)
Release Inspections and Testing	1) Visual Inspection: solutions 2) Sterility Testing: High-risk: ≥ 25, MDV, extended pre-sterilization time 3) Bacterial Endotoxins Testing: High-risk: ≥ 25, MDV, extended pre-sterilization time	1) Visual Inspection 2) Sterility Testing: Required for - Category 2 CSPs assigned a BUD that requires sterility 3) Bacterial Endotoxins Testing: Required for - Category 2 injectable CSPs compounded from one or more nonsterile component(s) and assigned a BUD that requires sterility testing	1) Visual Inspection: 2) Sterility Testing: Required for - Category 2 CSPs assigned a BUD that requires sterility testing, and for all Category 3 CSPs 3) Bacterial Endotoxins Testing: Required for - Category 2 injectable CSPs compounded from one or more nonsterile component(s) and assigned a BUD that requires sterility testing Category 3 injectable CSPs compounded from one or more nonsterile component(s)
BUD	Immediate use CSPS: 1 hr Low risk in SCA: 12 hrs Low risk: 48 hrs CRT, 14 days frig, 45 days frozen Medium Risk: 30 hrs CRT, 9 days frig, 45 days frozen High risk: 24 hrs CRT, 3 days frig, 45 days frozen	Immediate use CSPS: 4hrs Category 1: ≤ 12hr CRT, ≤ 24 hrs frig Category 2: Nonsterile – sterility test: 1 day CRT, 4 days frig, 45 days frozen Sterile – no sterility test: 4 days CRT, 10 days frig, 45 days frozen Nonsterile or sterile + sterility test: 30 days CRT, 45 days frig, 60 days frozen Terminally sterilized – sterility test: 14 days CRT, 28 days frig, 45 days frozen Terminally sterilized + sterility test: 45 days CRT, 60 days frig, 90 days frozen	Immediate use CSPS: 4 hrs Category 1: same Category 2: same Category 3: Aseptically processed: 60 days CRT, 90 days Frig, 120 days frozen Terminally sterilized: 90 days, CRT, 120 days Frig, 180 days frozen Max: 180 days is additional requirements are met

Adapted from: USP Open forum Event 9/15/21, https://www.usp.org/events-training/virtual-open-forum-series-proposed-revisions-to-compounding-general-chapters

Draft Policy Statement

In light of the September 1, 2021 release by USP of proposed updates to USP General Chapters <795> and <797>, the California State Board of Pharmacy (Board) wishes to update its stakeholders on the anticipated next steps the Board will be taking and also remind stakeholders about the current status of legal requirements for pharmacies compounding drug preparations. It is the Board's understanding that USP published proposed revisions to USP General Chapter <795> Pharmaceutical Compounding – Nonsterile Preparations and General Chapter <797> Pharmaceutical Compounding – Sterile Preparations for public comment. It is the Board's understanding that comments may be submitted on or before January 31, 2022. Further, USP will host virtual Compounding Open Forum Series in January 2022.

The Board understands that based on the appeals to the 2019 proposed revisions to Chapters <795> and <797>, further changes were made to these proposed chapters. Accordingly, the current Chapters <795> (last revised in 2014) and <797> (last revised in 2008) remain the official versions of USP standards. In addition, all licensees must adhere to all relevant sections of Pharmacy Law and regulations, including but not limited to the Board's current regulations – title 16, California Code of Regulations, section 1735 et. Seq (Article 4.5, Compounding); section 1751 et. Seq. (Article 7, Sterile Compounding); and section 1708.3 to section 1708.5 (related to radioactive drugs) – and Business and Professions Code section 4126.8 and other relevant state and federal provisions.

It is the Board's understanding that USP is not offering any additional changes to Chapter <800> or Chapter <825>. Because Chapter <800> and Chapter <825> are not referenced in the current versions of Chapters <795> and <797>, Chapters <800> and <825> appear informational and not compendially applicable (or a required standard under USP) until the amendments in Chapters <795> and <797> are finalized. Like USP, the Board encourages utilization of amended Chapter <800> in the interest of advancing public health before it becomes a required USP standard by USP adoption of revised Chapters <795> and <797>. States and other regulators with jurisdiction, also may incorporate USP chapters that are not compendially applicable (required USP standards) into their own statutes or regulations, or "through other steps in accordance with their own policy making processes" to apply or enforce chapters that are not yet required USP standards.

As required in Business in Professions Code section 4127(c), the Board's Enforcement and Compounding Committee intends to resume it discussion of the new proposed revised chapters. Although it is the Board's goal to seek conformity with USP where possible, consistent with the Board's consumer protection mandate and the authority granted to the Board by the Legislature in Business and Professions Code section 4126.8, it is anticipated that the Board's efforts may result in updates to its current regulations, including higher standards if deemed necessary for public protection. Information on meetings will be posted on the website and meeting materials made available in advance.

October 2021

Attachment 2

Enforcement Workload Statistics FY 2021/22

Complaint Investigations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Received	661	0	0	0	661
Closed	755	0	0	0	755
Pending	1,308	0	0	0	1,308
Average Days for Investigation	246	0	0	0	246

Cases Under Investigation (By Team)	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Quarter Ending
Compliance / Routine	484	0	0	0	484
Drug Diversion / Fraud	144	0	0	0	144
Prescription Drug Abuse	107	0	0	0	107
Compounding	38	0	0	0	38
Outsourcing	15	0	0	0	15
Probation / PRP	19	0	0	0	19
Enforcement	235	0	0	0	235
Criminal Conviction	266	0	0	0	266

Application Investigations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Received	54	0	0	0	54
Closed					
Approved	36	0	0	0	36
Denied	16	0	0	0	16
Total Closed (includes withdrawn)	***54***	***0***	***0***	***0***	***54***
Pending	74	0	0	0	74

Complaint Closure Outcomes Not Resulting in Further Action	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Insufficient Evidence	189	0	0	0	189
Non-Jurisdictional	119	0	0	0	119
No Violation	92	0	0	0	92
No Further Action	59	0	0	0	59
Other - Non-Substantiated	7	0	0	0	7
Subject Educated	20	0	0	0	20

Letter of Admonishment / Citations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
LOA Issued	92	0	0	0	92
Citations Issued	359	0	0	0	359
Proof of Abatement Requested	89	0	0	0	89
Appeals Received	27	0	0	0	27
Dismissed	5	0	0	0	5
Total Fines Collected	***$205,461***	***$0***	***$0***	***$0***	***$205,461***

Administrative Cases	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Referred to the AG's Office	44	0	0	0	44
Pleadings Filed	51	0	0	0	51
Pending					Quarter Ending
Pre-Accusation	85	0	0	0	85
Post-Accusation	153	0	0	0	153
Total Pending	**242**	**0**	**0**	**0**	**242**
Total Closed	50	0	0	0	50

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Revocation					
Pharmacist	2	0	0	0	2
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	5	0	0	0	5
Designated Representative	1	0	0	0	1
Wholesaler	0	0	0	0	0
Pharmacy	10	0	0	0	10
Sterile Compounding	1	0	0	0	1
Outsourcing	0	0	0	0	0
Total	***19***	***0***	***0***	***0***	***19***

Administrative Case Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Revocation; stayed suspension/probation					
Pharmacist	0	0	0	0	0
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	0	0	0	0	0
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	0	0	0	0	0
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	***0***	***0***	***0***	***0***	***0***

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Revocation; stayed; probation					
Pharmacist	10	0	0	0	10
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	1	0	0	0	1
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	6	0	0	0	6
Sterile Compounding	2	0	0	0	2
Outsourcing	0	0	0	0	0
Total	***19***	***0***	***0***	***0***	***19***

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Surrender / Voluntary Surrender					
Pharmacist	4	0	0	0	4
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	3	0	0	0	3
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	11	0	0	0	11
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	***18***	***0***	***0***	***0***	***18***

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Public Reproval / Reprimand					
Pharmacist	3	0	0	0	3
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	1	0	0	0	1
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	5	0	0	0	5
Sterile Compounding	1	0	0	0	1
Outsourcing	0	0	0	0	0
Total	***10***	***0***	***0***	***0***	***10***

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Licenses Granted					
Pharmacist	1	0	0	0	1
Intern Pharmacist	1	0	0	0	1
Pharmacy Technician	0	0	0	0	0
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	0	0	0	0	0
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	***2***	***0***	***0***	***0***	***2***

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Licenses Denied					
Pharmacist	0	0	0	0	0
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	1	0	0	0	1
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	0	0	0	0	0
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	***1***	***0***	***0***	***0***	***1***

Administrative Case Cost Recovery Efforts	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Cost Recovery Requested	***$348,542***	***$0***	***$0***	***$0***	***$348,542***
Cost Recovery Collected	***$262,261***	***$0***	***$0***	***$0***	***$262,261***

Immediate Public Protection Sanctions	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Interim Suspension Orders	0	0	0	0	0
Automatic Suspension Orders	1	0	0	0	1
Penal Code 23 Restrictions	0	0	0	0	0
Cease and Desist - Outsourcing	1	0	0	0	1
Cease and Desist - Unlicensed Activity	0	0	0	0	0
Cease and Desist - Sterile Compounding	0	0	0	0	0

Probation Statistics	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Quarter Ending
Licenses on Probation					
Pharmacist	223	0	0	0	223
Intern Pharmacist	3	0	0	0	3
Pharmacy Technician	29	0	0	0	29
Designated Representative	2	0	0	0	2
Wholesaler	3	0	0	0	3
Pharmacy	68	0	0	0	68
Sterile Compounding	10	0	0	0	10
Total	***338***	***0***	***0***	***0***	***338***

Probation Statistics	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Probation Office Conferences	18	0	0	0	18
Probation Site Inspections	127	0	0	0	127
Probation Terminated / Completed	30	0	0	0	30
Referred to AG for Non-Compliance	6	0	0	0	6

As of 9/30/2021

Board of Pharmacy

Citation and Fine Statistics FY 2021/22

Citation Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Pharmacist with Fine	88	0	0	0	88
Pharmacist no Fine	61	0	0	0	61
Pharmacy with Fine	74	0	0	0	74
Pharmacy no Fine	66	0	0	0	66
Pharmacist-in-Charge with Fine*	44	0	0	0	44
Pharmacist-in-Charge no Fine	70	0	0	0	70
Pharmacy Technician with Fine	20	0	0	0	20
Pharmacy Technician no Fine	0	0	0	0	0
Wholesalers	2	0	0	0	2
Designated Representative	4	0	0	0	4
Clinics	0	0	0	0	0
Drug Room	0	0	0	0	0
Exempt Hospital	2	0	0	0	2
Hospital Pharmacy	4	0	0	0	4
Miscellaneous**	36	0	0	0	36
Unlicensed Premises	2	0	0	0	2
Unlicensed Person	1	0	0	0	1

*These numbers are also represented in the RPH columns, but reflect how many RPHs were cited as PICs

**Intern Pharmacist, Licensed Correctional Facilities, Exempt Pharmacies, Non-Resident Pharmacies, and Vet Retailers

Top Ten Violations by License Type

Pharmacists	%	Pharmacies	%	Pharmacists In Charge	%
1716 - Variation from prescription	52%	1716 - Variation from prescription	50%	1716 - Variation from prescription	38%
1764/56.10 - Unauthorized disclosure of prescription and medical information	9%	1764/56.10 - Unauthorized disclosure of prescription and medical information	15%	1764/56.10 - Unauthorized disclosure of prescription and medical information	10%
1714(b) - Operational Standards and Security; pharmacy responsible for pharmacy security	6%	1714(b) - Operational Standards and Security; pharmacy responsible for pharmacy security	7%	1735.8(c) - Compounding Quality Assurance requires the pharmacy to have qualitative and quantitative reports on the integrity, potency, quality of its compounded drug products	8%
1761(a) - No pharmacist shall compound or dispense any prescription, which contains any significant error or omission…	6%	1707.3 - Duty to review drug therapy	6%	1714(b) - Operational Standards and Security; pharmacy responsible for pharmacy security	8%
1735.8(c) - Compounding Quality Assurance requires the pharmacy to have qualitative and quantitative reports on the integrity, potency, quality of its compounded drug products	6%	1714(C) - Operational Standards and Security; pharmacy, fixtures and equipment shall be maintained in a sanitary and orderly condition	4%	4081(a)/1718 - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory/Current Inventory Defined	7%
4306.5(a) - Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist	5%	1735.8(c) - Compounding Quality Assurance requires the pharmacy to have qualitative and quantitative reports on the integrity, potency, quality of its compounded drug products	4%	1715(a) - Self-assessment form of a pharmacy by the pharmacist-in-charge; shall complete a self-assessment of pharmacy compliance with federal and state pharmacy law	7%
1735.3(a)(2)(F) - Records of Compounded Drug Products- For each compounded drug preparation, the pharmacy record shall include a compounding log consisting of a single document containing the manufac	5%	1715(a) - Self-assessment form of a pharmacy by the pharmacist-in-charge; shall complete a self-assessment of pharmacy compliance with federal and state pharmacy law	3%	1761(a) - No pharmacist shall compound or dispense any prescription, which contains any significant error or omission…	5%
4081(a)/1718 - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory/Current Inventory Defined	5%	4113(d) - Every pharmacy shall notify the board in writing within 30 days of the date of a change in pharmacist-in-charge	3%	1735.3(a)(2)(F) - Records of Compounded Drug Products- For each compounded drug preparation, the pharmacy record shall include a compounding log consisting of a single document containing the manufac	5%
1707.3 - Duty to review drug therapy	5%	4081(a) - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory	3%	1714(d) - Operational Standards and Security; Pharmacist responsible for pharmacy security	5%
4301(l) - Unprofessional Conduct - Conviction of a crime substantially related to the practice of pharmacy	4%	4081(a)/1718 - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory/Current Inventory Defined	3%	1707.3 - Duty to review drug therapy	5%

California State Board of Pharmacy
SB 1441 Uniform Standards

The data includes licensees participating in the Pharmacist Recovery Program (PRP) and licensees on probation with substance use disorders.

Board of Pharmacy	July -Sep	Oct – Dec	Jan-Mar	Apr-Jun	Total 21/22
PRP Intakes					
PRP Self-Referrals					
PRP Probation Referrals					
PRP Under Investigation	1				1
PRP In Lieu Of (investigation conducted)					
Total Number of PRP Intakes	1				1
New Probationers					
Pharmacists	1				1
Intern Pharmacists					
Pharmacy Technicians	1				1
Total New Probationers	2				2
PRP Participants and Recovery Agreements					
Total PRP Participants	52				N/A
Recovery Agreements Reviewed	40				40
Probationers and Inspections					
Total Probationers	70				N/A
Inspections Completed	44				44
Referrals to Treatment					
Referrals to Treatment (PRP and Probationers)	1				1
Drug Tests					
Drug Test Ordered (PRP and Probationers)	694				694
Drug Tests Conducted (PRP and Probationers)	661				661
Relapses (Break in Sobriety)					
Relapsed (PRP and Probationers)					
Major Violation Actions					
Cease Practice/Suspension (PRP and Probationers)	1				1
Termination from PRP					
Probationers Referred for Discipline	3				3
Closure					
Successful Completion (PRP and Probationers)	3				3
Termination (Probation)					
Voluntary Surrender (Probation)	2				2
Surrender as a result of PTR (Probation)					
Closed Public Risk (PRP)					
Non-compliance (PRP and Probationers)	51				51
Other (PRP)					
Patients Harmed					
Number of Patients Harmed (PRP and Probationers)					Zero

SB 1441 Uniform Standards

The data includes licensees participating in the Pharmacist Recovery Program (PRP) and licensees on probation with substance use disorders.

Board of Pharmacy	July -Sep	Oct – Dec	Jan-Mar	Apr-Jun	Total 21/22
Drug of Choice at PRP Intake or Probation					
Pharmacists	**July-Sep**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total 20/21**
Alcohol	1				1
Ambien					
Opiates					
Hydrocodone					
Oxycodone					
Morphine					
Benzodiazepines					
Barbiturates					
Marijuana					
Heroin					
Cocaine					
Methamphetamine					
Pharmaceutical Amphetamine					
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Clonazepam					
Tramadol					
Carisprodol					
Phendimetrazine					
Promethazine w/Codeine					
Intern Pharmacists	**July-Sep**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total 20/21**
Alcohol					
Opiates					
Hydrocodone					
Oxycodone					
Benzodiazepines					
Barbiturates					
Marijuana					
Heroin					
Cocaine					
Methamphetamine					
Pharmaceutical Amphetamine					
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Clonazepam					
Tramadol					
Carisprodol					
Phendimetrazine					
Promethazine w/Codeine					
Pharmacy Technicians	**July-Sep**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total 20/21**
Alcohol	1				1
Opiates					
Hydrocodone					
Oxycodone					
Benzodiazepines					
Barbiturates					
Marijuana					
Heroin					
Cocaine					
Methamphetamine					
Pharmaceutical Amphetamine					
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Clonazepam					
Tramadol					
Carisprodol					
Phendimetrazine					
Promethazine w/Codeine					