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

Enforcement and Compounding Committee Report

Maria Serpa, Licensee Member, Chair
Albert Wong, Licensee Member, Vice Chair
Greg Lippe, Public Member
Ricardo Sanchez, Public Member
Debbie Veale, Licensee Member

a. Discussion and Consideration of Policy Statement Regarding Applicability of Board Compounding Regulations and USP Compounding Chapters While Pending Appeals Before USP

Attachment 1

Background

On September 23, 2019, USP announced a delay in the official date of the of the revised Chapters 795 and 797 and the new Chapter 825 until further notices. The delay results from appeals received on certain provisions of the respective Chapters. Subsequent to that action, as part of its November 2019 meeting, the Board voted and released a policy statement to ensure stakeholders have a clear understanding of the legal requirements for pharmacies compounding drug preparations.

On March 12, 2020, USP issued final decisions on appeals to the revisions to Chapters <795> and <797> and new Chapter <825>. Specifically, the appeals panel granted the appeals to General Chapters <795> and <797> and is remanding the Chapters to the Compounding Expert Committee with the recommendation for further engagement on the issues raised concerning the beyond-use-date provisions. The appeals panel denied the General Chapter <825> and encouraged the appellant to submit the narrower request presented at the hearing to the Chemical Medicines Monograph 4 Expert Committee as a request for revision.

For Board Consideration

In light of the appeal decisions, it appears appropriate for the Board to consider an update to its policy statement. Working with the Committee Chair, board staff is recommending updates to the policy statement to provide information to stakeholders.

Should the Board determine such an update is appropriate, the following motion could be used.

Suggested Motion: Accept the revised draft policy statement

Attachment 1 includes a copy of a recommended policy statement and the USP Appeals Panel Decisions notification.

b. Review of Enforcement Statistics

Attachment 2

Enforcement statistics are for the first three quarters of FY 2019/20 have been provided as **Attachment 2.**

Since July 1, the board received 2,002 complaints and has closed 2,068 investigations. The board has issued 253 Letters of Admonishment, 1,080 Citations and referred 171 cases to the Office of the Attorney General. The board has secured six interim suspension orders, been granted three Penal Code 23 suspensions, and issued one Cease and Desist. Further, the board has revoked 92 licenses, accepted the disciplinary surrender of 80 licenses, denied seven applications, and imposed other levels of discipline against 78 licensees and/or applicants.

As of April 10, 2020, the board has 1,566 field investigations. Below is a breakdown providing more detail in the various investigation process:

- 102 cases under review for assignment, averaging 23 days
- 893 cases under investigation, averaging 192 days
- 307 investigations under supervisor review, averaging 49 days
- 178 investigations under second level review, averaging 37 days
- 86 investigations waiting final closure (typically issuance of a citation or letter of admonishment) averaging 44 days

As part of the January Board Meeting, members expressed concern with the average time reported to supervisor review, which at the time was reported to be 107 days on average.

Other data points indicate increases in the average processing times, varying from an increase in 3 days to 21 days across the various other investigative steps. Management staff are monitoring times and evaluating potential impacts to board operations as we transition staff to a teleworking model.

Attachment 1

Draft Policy Statement

May 7, 2020

Compounding Requirements –Following USP Appeal Decisions

In light of USP's March 12, 2020, final decision on appeals of the proposed revised Chapters <795> and <797> and the new Chapter <825>, the California State Board of Pharmacy (Board) provides its stakeholders with this current status of the legal requirements for pharmacies compounding drug preparations.

As the Board reads the decisions, some of the appeals to Chapters <795> and <797> were granted, sending the chapters back to the committee for further discussion. Accordingly, the current chapters of <795> (last revised in 2014) and <797> (last revised in 2008) remain official. 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, sections 1735 et. seq (Article 4.5, Compounding), 1751 et. seq (Article 7, Sterile Compounding), and 1708.3-1708.5 (related to radioactive drugs), and Business and Professions Code section 4126.8, and other relevant sections.

Although USP has indicated that Chapter <800> is informational and not compendially applicable unless and until Chapters <795> and <797> are revised and reference Chapter <800>, the board's current regulations on compounding hazardous drug preparations remain in effect. Like USP, the board encourages utilization of Chapter <800> in the interest of advancing public health.

The Board's Compounding Committee has been reintegrated into the Board's Enforcement Committee. At this time, the Board does not intend to pursue changes to the current regulations governing compounded preparations. The board will continue to communicate with stakeholders as information becomes available. This is a link to the Appeals Panel decisions on USP Chapters <795>, <797>, and <825>:

https://www.usp.org/sites/default/files/usp/document/our-work/compounding/decisions-appeals-fs.pdf

The board reminds licensees that in response to the COVID-19 pandemic, waivers to provisions of Pharmacy Law have been granted. Information regarding the waivers is provided on the board's website.

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USP Appeals Panel issues decisions on compounding chapters

Rockville, MD, March 12, 2020 – After thoughtful deliberation and evaluation of the record and hearings from appellants on January 21 and 22, 2020, the USP Appeals Panel has completed deliberations and delivered its decisions on the second level of appeals to revised USP General Chapter <795> Pharmaceutical Compounding – Nonsterile Preparation, <797> Pharmaceutical Compounding – Sterile Preparations, and new <825> Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging.

The Appeals Panel has granted the appeals to General Chapters <795> and <797> and is remanding the chapters to the Compounding Expert Committee (CMP EC). The Appeals Panel did not determine that the chapters require revision but noted that the beyond-use date issues raised in the appeals warrant additional dialogue and consideration.

The currently official versions of <795> (last revised in 2014) and <797> (last revised in 2008) remain official as a result of the remand. Recognizing the public health impact of these standards, USP is committed to further stakeholder engagement through forums, roundtables, and other avenues to gather more input on the beyond-use date issues raised in the appeals. USP and the CMP EC are committed to moving forward in an open, transparent, and balanced manner as soon as practicable to enable the chapters to be finalized and implemented in a timely manner.

The Appeals Panel has denied the appeal to General Chapter <825> and is encouraging the appellant to submit the narrower request presented at the hearing before the Panel to the Chemical Medicines Monographs 4 Expert Committee (CHM4 EC) as a request for revision.

Due to the denial of the appeal to <825>, the CHM4 EC may reinstate the official date of this new chapter. Based on USP's Bylaws, the Expert Committee must provide at least another six-month implementation period for this Chapter. USP will announce an official date once it is determined. At this time, General Chapter <825> will be informational unless otherwise required by a regulatory body.

With the appeals decisions having been made and communicated, the Appeals Panel has concluded its service. "These complex Panel-level appeals were a first in USP's 200-year history, and we thank the Appeals Panel for their meticulous and thoughtful review of the appellants' issues and concerns," commented Jaap Venema, Ph.D., Executive Vice President & Chief Science Officer at USP. "We will continue to remain transparent and seek stakeholder input to create independent standards that help ensure the quality of medicines and patient safety."

The members of the Appeals Panel will maintain strict confidentiality in connection with their involvement in the adjudication of the appeals. Any questions about the Compounding Chapters or the USP appeals process should be directed to Healthcare Quality & Safety staff at compoundingSL@usp.org.

Download as PDF here:
https://www.usp.org/sites/default/files/usp/document/about/newsroom/usp-appeals-panel-issues-decisions-on-compounding-chapters.pdf

About USP

USP is an independent scientific organization that collaborates with the world's top experts in health and science to develop quality standards for medicines, dietary supplements, and food ingredients. Through our standards, advocacy and education, USP helps increase the availability of quality medicines, supplements and food for billions of people worldwide. For more information about USP, visit www.usp.org.

Attachment 2

Board of Pharmacy Enforcement Workload Statistics FY 2019/20

Complaint Investigations	July - Sept	Oct - Dec	Jan - March	Apr - Jun
Received	682	625	695	
Closed	663	774	631	
Pending	1,995	1,748	1,841	
Average Days for Investigation	234	265	217	

Cases Under Investigation (By Team)	July - Sept	Oct - Dec	Jan - March	Apr - Jun
Compliance / Routine	971	935	1,037	
Drug Diversion / Fraud	254	225	221	
Prescription Drug Abuse	90	76	76	
Compounding	66	71	72	
Outsourcing	13	17	28	
Probation / PRP	74	57	44	
Enforcement	263	107	98	
Criminal Conviction	264	260	265	

Application Investigations	July - Sept	Oct - Dec	Jan - March	Apr - Jun
Received	123	98	63	
Closed				
Approved	67	79	46	
Denied	14	20	7	
Total	***94***	***107***	61	
Pending	83	69	62	

Complaint Closure Outcomes Not Resulting in Further Action	July - Sept	Oct - Dec	Jan - March	Apr - Jun
Insufficient Evidence	144	144	130	
Non-Jurisdictional	74	100	105	
No Violation	88	76	86	
No Further Action	63	67	68	
Other - Non-Substantiated	13	7	6	
Subject Educated	29	32	21	

Letter of Admonishment / Citations	July - Sept	Oct - Dec	Jan - March	Apr - Jun
LOA Issued	67	124	62	
Citations Issued	245	540	295	
Proof of Abatement Requested	63	174	84	
Appeals Received	12	52	23	
Dismissed	5	4	2	
Total Fines Collected	***$152,458***	***$296,810***	***$317,833***	

Administrative Cases	July - Sept	Oct - Dec	Jan - March	Apr - Jun
Referred to the AG's Office	63	56	52	
Pleadings Filed	70	83	57	
Pending				
Pre-Accusation	158	119	112	
Post-Accusation	210	234	210	
Total	***368***	***353***	322	
Closed	101	72	82	

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun
Revocation				
Pharmacist	6	7	3	
Intern Pharmacist	0	1	1	
Pharmacy Technician	20	18	23	
Designated Representative	0	0	1	
Wholesaler	0	1	1	
Pharmacy	2	3	4	
Sterile Compounding	0	1	0	
Outsourcing	0	0	0	
Total	***28***	***31***	***33***	

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

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun
Revocation; stayed; probation				
Pharmacist	22	8	17	
Intern Pharmacist	2	2	1	
Pharmacy Technician	5	3	4	
Designated Representative	0	1	0	
Wholesaler	0	1	0	
Pharmacy	7	3	2	
Sterile Compounding	0	0	0	
Outsourcing	0	0	0	
Total	***36***	***18***	***24***	

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun
Surrender / Voluntary Surrender				
Pharmacist	7	7	5	
Intern Pharmacist	0	0	1	
Pharmacy Technician	15	6	7	
Designated Representative	1	2	1	
Wholesaler	1	0	0	
Pharmacy	9	9	8	
Sterile Compounding	0	0	1	
Outsourcing	0	0	0	
Total	***33***	***24***	***23***	

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun
Public Reproval / Reprimand				
Pharmacist	8	3	2	
Intern Pharmacist	1	0	0	
Pharmacy Technician	1	0	3	
Designated Representative	0	0	2	
Wholesaler	2	0	1	
Pharmacy	11	4	1	
Sterile Compounding	0	1	0	
Outsourcing	1	0	0	
Total	***24***	***8***	***9***	

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun
Licenses Granted				
Pharmacist	1	0	1	
Intern Pharmacist	0	1	0	
Pharmacy Technician	1	0	2	
Designated Representative	0	0	0	
Wholesaler	0	0	0	
Pharmacy	0	0	0	
Sterile Compounding	0	0	0	
Outsourcing	1	0	0	
Total	***3***	***1***	***3***	

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun
Licenses Denied				
Pharmacist	2	1	1	
Intern Pharmacist	0	0	1	
Pharmacy Technician	3	1	1	
Designated Representative	0	0	0	
Wholesaler	0	0	0	
Pharmacy	0	0	0	
Sterile Compounding	0	0	0	
Outsourcing	0	0	0	
Total	***5***	***2***	***3***	

Administrative Case Cost Recovery Efforts	July - Sept	Oct - Dec	Jan - March	Apr - Jun
Cost Recovery Requested	***$838,758***	***$402,895***	***$415,529.00***	
Cost Recovery Collected	***$274,908***	***$301,746***	***$240,231.00***	

Immediate Public Protection Sanctions	July - Sept	Oct - Dec	Jan - March	Apr - Jun
Interim Suspension Orders	3	3	0	
Automatic Suspension Orders	0	1	1	
Penal Code 23 Restrictions	0	2	1	
Cease and Desist - Unlicensed Activity	1	0	0	
Cease and Desist - Sterile Compounding	0	0	0	

Probation Statistics	July - Sept	Oct - Dec	Jan - March	Apr - Jun
Licenses on Probation				
Pharmacist	231	226	236	
Intern Pharmacist	9	11	11	
Pharmacy Technician	20	22	26	
Designated Representative	1	1	2	
Wholesaler	3	2	3	
Pharmacy	81	73	74	
Sterile Compounding	2	2	2	
Total	***347***	***337***	***354***	

Probation Statistics	July - Sept	Oct - Dec	Jan - March	Apr - Jun
Probation Office Conferences	31	31	25	
Probation Site Inspections	129	129	149	
Probation Terminated / Completed	25	25	23	
Referred to AG for Non-Compliance	2	2	2	

As of 3/31/2020

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.

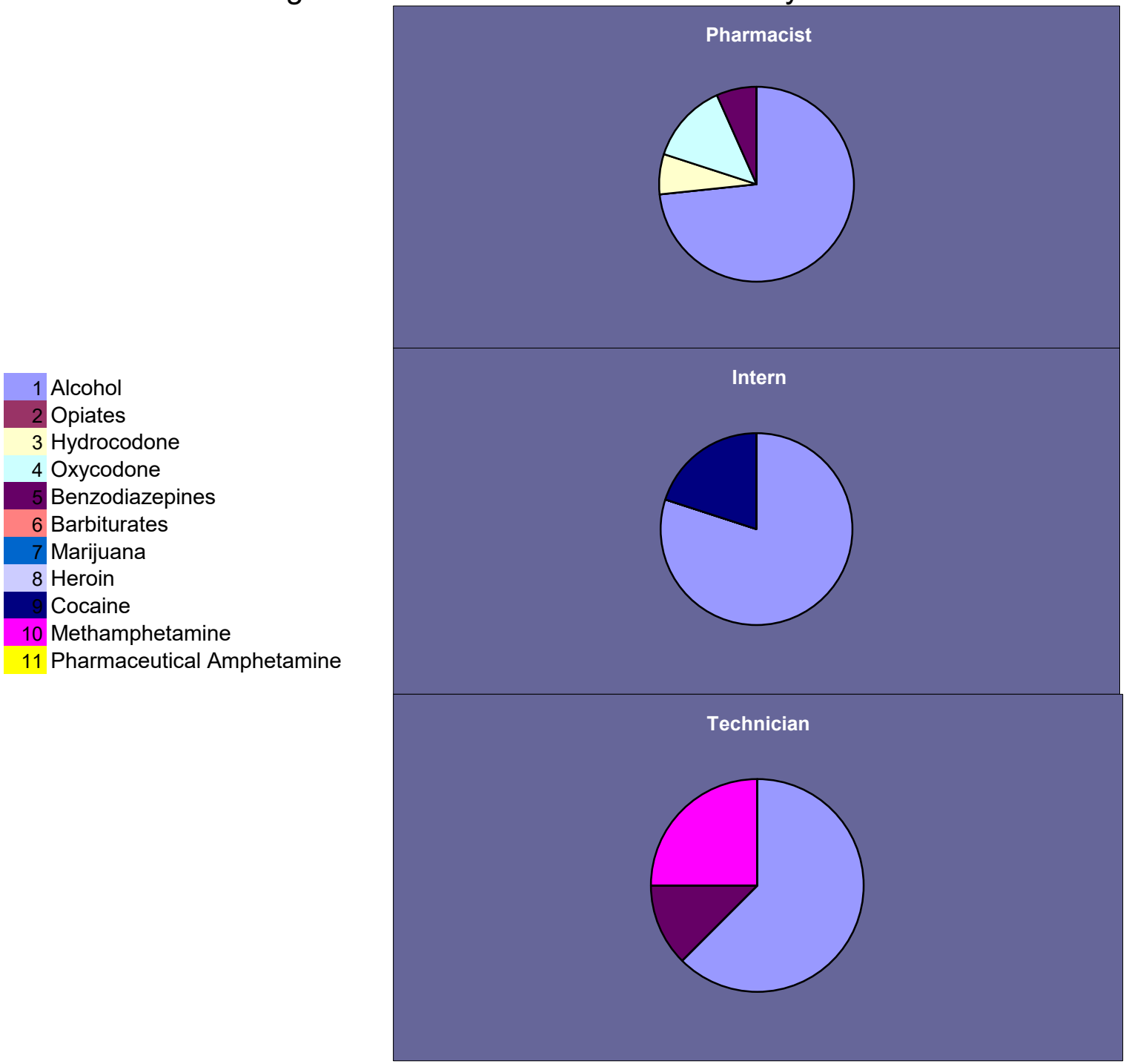
Board of Pharmacy	July -Sep	Oct – Dec	Jan-Mar	Apr-Jun	Total 19/20
PRP Intakes					
PRP Self-Referrals	1	1			2
PRP Probation Referrals	3		2		5
PRP Under Investigation	1	1	1		3
PRP In Lieu Of (investigation conducted)					
Total Number of PRP Intakes	5	2	3		10
New Probationers					
Pharmacists	3		3		6
Intern Pharmacists	1		1		2
Pharmacy Technicians	3	2	3		8
Total New Probationers	7	2	7		16
PRP Participants and Recovery Agreements					
Total PRP Participants	58	58	60		N/A
Recovery Agreements Reviewed	56	52	57		165
Probationers and Inspections					
Total Probationers	76	76	80		232
Inspections Completed (Information not available)	N/A	N/A	N/A	N/A	N/A
Referrals to Treatment					
Referrals to Treatment (PRP and Probationers)	5	4	2		11
Drug Tests					
Drug Test Ordered (PRP and Probationers)	742	726	737		2205
Drug Tests Conducted (PRP and Probationers)	716	709	732		2157
Relapses (Break in Sobriety)					
Relapsed (PRP and Probationers)	2				2
Major Violation Actions					
Cease Practice/Suspension (PRP and Probationers)	7	6	9		22
Termination from PRP	1	1			2
Probationers Referred for Discipline					
Closure					
Successful Completion (PRP and Probationers)	2	1	3		6
Termination (Probation)		2			2
Voluntary Surrender (Probation)	2	1	1		4
Surrender as a result of PTR (Probation)					
Closed Public Risk (PRP)	1	1			2
Non-compliance (PRP and Probationers)	3	5	22		30
Other (PRP)	1	2			3
Patients Harmed					
Number of Patients Harmed (PRP and Probationers)	None	None	None	None	None

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 19/20
Drug of Choice at PRP Intake or Probation					
Pharmacists	**July-Sep**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total 19/20**
Alcohol	8		3		11
Ambien					
Opiates			1		1
Hydrocodone			2		2
Oxycodone		1			1
Morphine					
Benzodiazepines					
Barbiturates					
Marijuana	1				1
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 19/20**
Alcohol	2		2		4
Opiates					
Hydrocodone					
Oxycodone					
Benzodiazepines					
Barbiturates					
Marijuana					
Heroin					
Cocaine		1			1
Methamphetamine					
Pharmaceutical Amphetamine					
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone		1			1
Clonazepam					
Tramadol		1			1
Carisprodol					
Phendimetrazine					
Promethazine w/Codeine					
Pharmacy Technicians	**July-Sep**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total 19/20**
Alcohol	3	1	1		5
Opiates					
Hydrocodone					
Oxycodone					
Benzodiazepines			1		1
Barbiturates					
Marijuana					
Heroin					
Cocaine					
Methamphetamine		1	1		2
Pharmaceutical Amphetamine					
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Clonazepam					
Tramadol					
Carisprodol					
Phendimetrazine					
Promethazine w/Codeine					

Drug Of Choice - Data entered from July 2019 to March 2020



Printed on 4/28/2020

Pharmacy Citation and Fine Statistics FY 2019/20

Citation Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun
Pharmacist with Fine	75	171	1080	n/a
Pharmacist no Fine	21	75	35	n/a
Pharmacy with Fine	24	84	41	n/a
Pharmacy no Fine	43	110	65	n/a
Pharmacist-in-Charge with Fine*	23	91	50	n/a
Pharmacist-in-Charge no Fine	35	78	38	n/a
Pharmacy Technician with Fine	47	29	24	n/a
Pharmacy Technician no Fine	2	7	4	n/a
Wholesalers	5	1	0	n/a
Designated Representative	1	0	0	n/a
Clinics	2	0	1	n/a
Drug Room	0	0	0	n/a
Exempt Hospital	0	1	1	n/a
Hospital Pharmacy	2	24	3	n/a
Miscellaneous**	22	39	14	n/a
Unlicensed Premises	0	8	1	n/a
Unlicensed Person	0	0	0	n/a

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

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

Top Ten Violations by License Type

Pharmacists	%	Pharmacies	%	Pharmacists In Charge	%
1716 - Variation from prescription	42%	1716 - Variation from prescription	51%	1716 - Variation from prescription	28%
1761(a)(b)/11153 - No pharmacist shall compound or dispense any prescription, which contains any significant error or omission…;Even after conferring with a prescriber, a pharmacist shall not compound	22%	4113(d) - Every pharmacy shall notify the board in writing within 30 days of the date of a change in pharmacist-in-charge	7%	4081(a)/1718 - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory/Current Inventory Defined	15%
1707.2(b)(1)(A) - In addition to the obligation to consult…a pharmacist shall provide oral consultation to his or her patients…whenever the prescription drug has not previously been dispensed to a patient	5%	1761(a)(b)/11153 - No pharmacist shall compound or dispense any prescription, which contains any significant error or omission…;Even after conferring with a prescriber, a pharmacist shall not compound	7%	1761(a)(b)/11153 - No pharmacist shall compound or dispense any prescription, which contains any significant error or omission…; Even after conferring with a prescriber, a pharmacist shall not compound	11%
4301(h) - Unprofessional Conduct – The administering to oneself, of any controlled substance, or the use of any dangerous drug or of alcoholic beverages to the extent or in a manner as to be dangerous	5%	1714(b) - Operational Standards and Security; pharmacy responsible for pharmacy security	5%	11165(d) - For each prescription for a Schedule II or Schedule III controlled substance, the dispensing pharmacy shall report to the Department of Justice...	8%
4301(l) - Unprofessional Conduct - Conviction of a crime substantially related to the practice of pharmacy	5%	1711(d)&(e) - Quality assurance program - each pharmacy shall use the finding of its quality assurance program to develop pharmacy systems/advance error prevention	5%	1707.2(b)(1)(A) - In addition to the obligation to consult…a pharmacist shall provide oral consultation to his or her patients…whenever the prescription drug has not previously been dispensed to a patient	8%
1711(d)&(e) - Quality assurance program - each pharmacy shall use the finding of its quality assurance program to develop pharmacy systems/advance error prevention	4%	1707.2(b)(1)(A) - In addition to the obligation to consult…a pharmacist shall provide oral consultation to his or her patients…whenever the prescription drug has not previously been dispensed to a patient	5%	11164(a) - Each prescription for a controlled substance classified in Schedule II, III, IV, or V, except as authorized by subdivision (b), shall be made on a controlled substance prescription form as	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	4%	11165(d) - For each prescription for a Schedule II or Schedule III controlled substance, the dispensing pharmacy shall report to the Department of Justice...	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	6%
11165(d) - For each prescription for a Schedule II or Schedule III controlled substance, the dispensing pharmacy shall report to the Department of Justice...	4%	1764/56.10(a) - Unauthorized disclosure of prescription and medical information	5%	1735.6(a) - Compounding Facilities and Equipment- Any pharmacy engaged in compounding shall maintain written documentation regarding the facilties and equipment necessary for safe and accurate compounding	6%
4105(a)(b)(c) - Retaining Records of Dangerous Drugs and Devices on Licensed Premises; All records... shall be retained on the licensed premises in a readily retrievable form/Removal of original documentation	3%	4081(a)/1718 - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory/Current Inventory Defined	4%	1714(b) - Operational Standards and Security; pharmacy responsible for pharmacy security	6%
1746.4(a)(b)(2) - A pharmacist initiating and/or administering vaccines pursuant to sections 4052 or 4052.8 of the Business and Professions Code shall follow the requirements specified in subdivisions	3%	1735.6(a) - Compounding Facilities and Equipment- Any pharmacy engaged in compounding shall maintain written documentation regarding the facilties and equipment necessary for safe and accurate compounding	4%	1711(d) - Quality assurance program finding shall be used to develop systems to prevent medication errors…	6%