california **pharmacists** association

April 21, 2021

Maria Serpa, PharmD
Chair, Enforcement and Compounding Committee
Board of Pharmacy
2720 Gateway Oaks Blvd, Ste. 100
Sacramento, CA 95833

Dear Chair Serpa,

The California Pharmacists Association (CPhA) appreciates the committee's continued willingness to address the compounding of components such as methylcobalamin as well as the opportunity to comment on the topic.

As previously stated, CPhA agrees with the FDA's interpretation of "an applicable USP or NF monograph" to mean a drug monograph, not a dietary supplement monograph as it relates to the conditions under which a 503A compounding pharmacy may compound using bulk drug substances. While there may not be a specific USP drug monograph for methylcobalamin, this is only one of the options that the Food, Drug and Cosmetic Act sets forth for the ability to compound from bulk substance. The applicable option that 503A compounding pharmacies use to compound methylcobalmin is the fact that it "*If such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, appears on a list developed by the Secretary through regulations issued by the Secretary under subsection (c) of section 503A* (Category 1 list)." Further, the other two requirements for bulk substances to be compounded are that it must "*be accompanied by a valid certificate of analysis and must have been manufactured by an establishment registered with FDA under section 510 of the FD&C Act*." Methylcobalamin meets all of these requirements set forth by the FDA for FDA-registered facilities that contain valid COAs for the substance.

At the January 20 Committee meeting, the Committee introduced the FDA's Guidance for Industry on Insanitary Conditions at Compounding Pharmacies. In reviewing the Guidance, CPhA would like to make it clear that we do not support the compounding of any product in any pharmacy where conditions are insanitary or don't follow United State Pharmacopeia (USP) standards. However, in our opinion, the Committee's interpretation of the guidance of the compounding of methylcobalamin shift that ability to compound methylcobalamin exclusively to 503B outsourcing facilities simply because they follow Current Good Manufacturing Process (cGMP) standards and not USP standards.

At the January 20 meeting, the committee referenced an FDA 483 report on a pharmacy using 'non-pharmaceutical grade' Methylcobalamin in the same conversation regarding "insanitary conditions" and having the Board "consistently point patients to potential sources to obtain such products [Methylcobalamin]" which indicate 503B facilities. CPHA does have concerns about this approach. . First, the single cited 483 observation letter (as opposed to a 483 warning letter) redacts nearly all information of the facility, noting only that the facility is a "producer of sterile and non-sterile drugs," and that the facility used "non-pharmaceutical grade" Methylcobalamin. Interestingly, the information that follows the "non-pharmaceutical grade" observation is also redacted. This raises a number of questions, including "Was this a 503A compounding pharmacy or a 503B Outsourcing Facility?" "If it was a 503A compounding pharmacy, was it located in California?" "Did the FDA caution the facility

against the use of this "non-pharmaceutical grade" Methylcobalamin?" "Did the Methylcobalamin meet all of the other requirements (valid COA and obtained from an FDA-registered facility)?"

Secondly, by combining the discussion on Insanitary Conditions with the 483 observation letter, the Board seems to be directly (or indirectly through the FDA) implying that the use of "non-pharmaceutical grade" Methylcobalamin is unsafe for patients. The guidance on Insanitary Conditions lists specifically that one of the observations noted was:

Using active ingredients, inactive ingredients, or processing aides, that have or may have higher levels of impurities compared to compendial or pharmaceutical grade equivalents (e.g., ingredients with potentially harmful impurities, ingredients labeled with "not for pharmaceutical use" or an equivalent statement)

During the January 20 meeting, Board staff indicated concerns of potential impurities from the "non-pharmaceutical grade" Methylcobalamin that may exist, such as lead, arsenic and other heavy metal poisons. If the Board is concerned about these impurities and whether they exist, there are facilities that test for these impurities that compounding pharmacists can use. During public testimony, the Board heard from many patients, pharmacists, and physicians who are prescribed or are prescribing Methylcobalamin and have actually tested for impurities. They stated that the results showed impurities either below the recommended level or not present at all. A potential solution could be to require compounding pharmacists to test for these toxins prior to dispensing to a patient and follow the same procedures relating to recalls that pharmacies are now required to do. This would not only satisfy the concerns over safety, but also keep the needed access avenues for patients.

CPhA understands and appreciates the Board's desire to educate pharmacies about this issue, as well as exercise enforcement discretion. Unfortunately, there is a lack of clarity, as well as uncertainty, around what exactly the pharmacy is being educated. For example, there is no definition of "pharmaceutical grade" at the state or federal level. Yet, pharmacies are being educated by Board staff that they can only use "pharmaceutical grade" products for compounding. Pharmacies are also being educated by Board staff that if they are using "non-pharmaceutical grade" Methylcobalamin for compounding, they are violating Health and Safety Code 111250 relating to 'adulterated drugs or devices' because, by definition, "non-pharmaceutical grade" Methylcobalamin is automatically considered 'dietary grade' which is considered adulterated and therefore not allowed.

CPhA believes that providing a definition of "pharmaceutical grade" would alleviate almost all of the concerns by pharmacies about whether they are complying with the law.

Lastly, the meeting materials reference the FDA's Adverse Events Reporting System (AERS) as something that the Committee requested information. A search of adverse events on Methylcobalamin by year resulted in 41 self-reported cases in 2020, 31 cases in 2019 and 21 cases in 2018. CPhA would ask the Board to consider these numbers in relation to the hundreds of thousands of prescriptions of Methylcobalamin in the same time period. Additionally, the FDA's disclaimer on their website reads (in part):

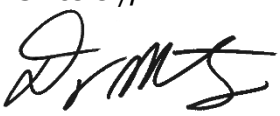
- "*Submission of a safety report does not consitute an admission that medical personnel, user facility, importer, distributor, manufacturer, or product caused or contributed to the event. Although these reports are a valuable source of information, this surveillance system has limitations, including the potential submission of incomplete, inaccurate, untimely, or unverified*

information. In addition, the incidence or prevalence of an event cannot be determined from this reporting system alone due to potential under-reporting of events and lack of information about frequency of use."

CPhA appreciates the opportunity to continue this very important, complex, and necessary conversation with the Board. We share the same goal, and that is patient access and safety. CPhA believes that a couple of answers to questions mentioned in this letter, as well as an additional testing requirement of methylcobalamin, could very well put this issue to rest for all parties involved and continue to provide access to this important and necessary medication for specialized patient populations.

Should you have any questions about these comments, please feel free to contact me at (916) 779-4519 or at dmartinez@cpha.com. Thank you for your consideration.

Sincerely,



Danny Martinez
Director, Regulatory Affairs & Policy Development
California Pharmacists Association.

Attachment 3

CALIFORNIA STATE BOARD OF PHARMACY

IMPORTATION OF PRESCRIPTION DRUGS – FINAL RULE

General Provisions

Section 804 Importation Program Sponsors (SIP)

SIP PROPOSAL

Eligible Drugs: eligible drugs are those that could be sold legally on either the Canadian market or American market with appropriate labeling.

Foreign Seller: Licensed as wholesaler by health Canada and Registered with the FDA as a Foreign Seller

Importer: Wholesaler or Pharmacy licensed in the US

Supply Chain: Limited to three entities

FDA AUTHORIZATION

- Pre-Import Request
- Entry of a Shipment

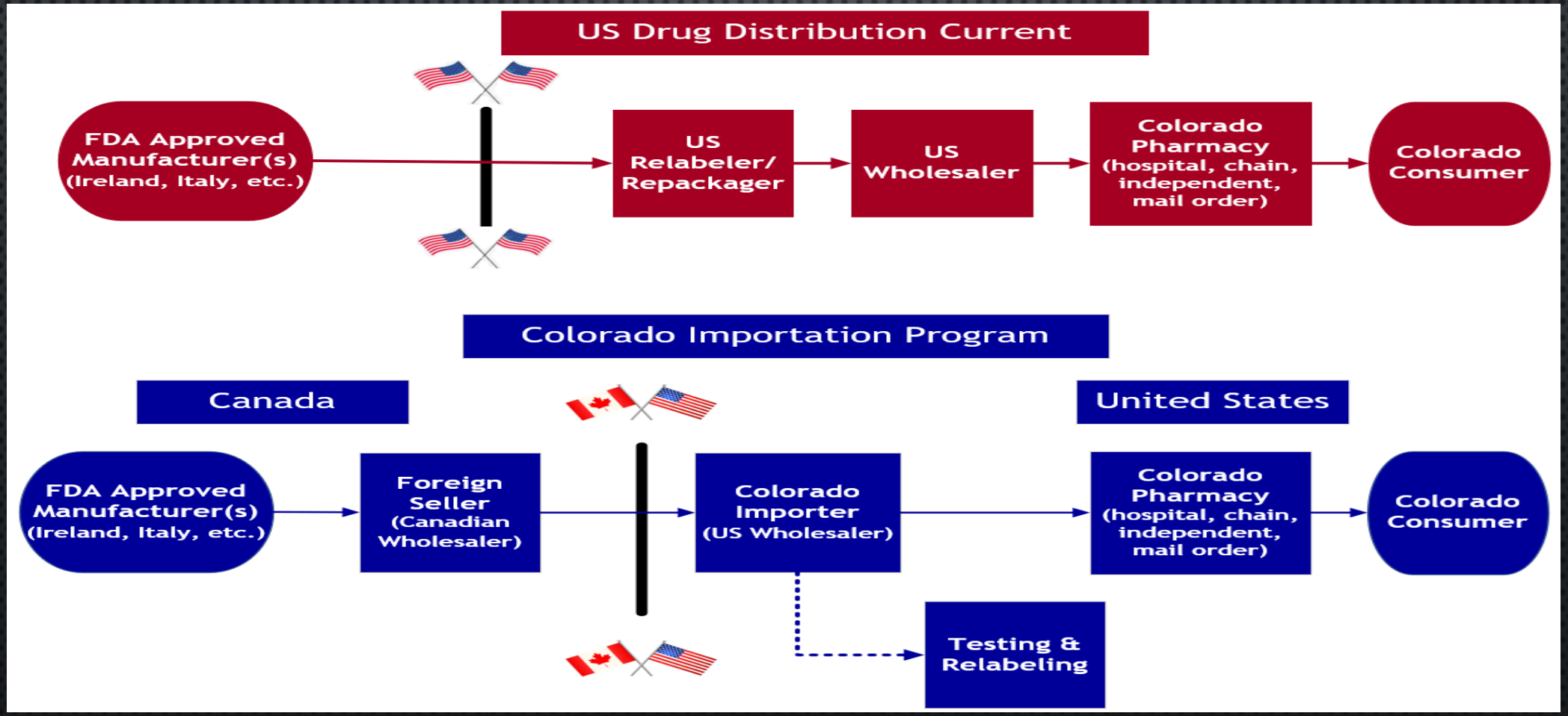
TESTING OF ELIGIBLE PRODUCTS

MANUFACTURER OR IMPORTER RESPONSIBILITY

Other SIP requirements

- SIP's cost savings
- Adverse events, Field alerts
- Recall Requirements

COLORADO'S PROGRAM



Attachment 4

BPC Section 312.2

California State
Board of Pharmacy

April 22, 2021

Overview

- Background
- Data Collection Process
- All Agencies
- Board of Pharmacy

Background

- 2015: SB 467 is Passed
- 2016: BPC 312.2 Becomes Effective
- 1/1/2018: First Annual Report Published

  (data from Fiscal Year 2016-17)
- 1/1/2021: Fourth Annual Report Published

  (data from Fiscal Year 2019-20)

  1. 36 Agencies
  2. Licensing
  3. Health Quality Enforcement

How Data was Collected

- ProLaw is our Case Management System
- Approximately 200 ProLaw Users – HQE / Licensing
- Each Case Opened and Tracked in ProLaw
  - All Users Enter Data
  - Paralegals Audit and Validate Data

General Statistics – All Agencies
(Licensing and HQE Combined)

	FY 18-19	FY 19-20	Change
• Accusations	52%	52%	No Change
• Referrals	3,964	3,530	11% decrease
• Rejected	3%	5%	2% increase
• Further Inv	5%	7%	2% increase
• Adjudicated	3,929	3,377	14% decrease

BPC 312.2, subdivisions (a)(1) and (a)(2)

Accusation Matters Referred to the AG
Matters Rejected

	FY 2018-19	FY 2019-20
Accusations Referred to Attorney General	346	372 (8% increase)
Matters Rejected	8	9 (13% increase)

BPC 312.2, subdivisions (a)(3) and (a)(4)

Further Investigation Requested
Further Investigation Received

	FY 2018-19	FY 2019-20
Further Investigation Requested	13	24 (85% increase)
Further Investigation Received	11	18 (64% increase)

BPC 312.2, subdivision (a)(5)
Accusations Filed

	FY 2018-19	FY 2019-20
Accusations Filed	273	237 (13% decrease)

BPC 312.2, subdivisions (a)(6)and (a)(7)

Accusations Withdrawn
Accusation Matters Adjudicated

	FY 2018-19	FY 2019-20
Accusations Withdrawn	7	1 (86% decrease)
Accusation Matters Adjudicated	335	289 (14% decrease)

Average Days
BPC 312.2, subdivisions (b)(1) and (b)(2)
Accusation Received to Accusation Filed
Accusation Filed After Further Investigation

	FY 2018-19	FY 2019-20
Accusation Received to Accusation Filed	222 days (267)	214 days (221) 4% decrease
Accusation Filed After Further Investigation	385 days (21)	490 days (14) 27% increase

Average Days
BPC 312.2, subdivisions (b)(3) and (b)(4)
Accusation Filed to Settlement
Accusation Filed to Default

	FY 2018-19	FY 2019-20
Accusation Filed to Settlement	290 days (169)	368 days (173) 27% increase
Accusation Filed to Default	118 days (101)	117 days (80) 1% decrease

Average Days
BPC 312.2, subdivisions (b)(5) and (b)(6)
Accusation Filed to Hearing Requested
Hearing Date Received to Hearing Commenced

	FY 2018-19	FY 2019-20
Accusation Filed to Hearing Requested	149 days (66)	154 days (60) 3% increase
Hearing Date Received to Hearing Commenced	167 days (42)	146 days (21) 13% decrease
Total	316 days	300 days 5% decrease

Conclusions

- What can be Measured can be Improved
- CPEI Goal of 18 Months is Challenging
- Agencies Vary
- Speed versus Due Process

California State Board of Pharmacy

The Board of Pharmacy regulated 139,473 licensees in Fiscal Year 2018–19, with 28 license types. The board receives consumer complaints and routinely inspects pharmacies for compliance. Most complaints received by the board are investigated by the board's own inspectors, who are licensed pharmacists themselves. There were multiple respondents in about 41 percent of the board's accusation cases prosecuted by the Office of the Attorney General in Fiscal Year 2019–20. There is no statute of limitations within which to file accusations for this agency.

The tables below show data for Fiscal Year 2019–20.

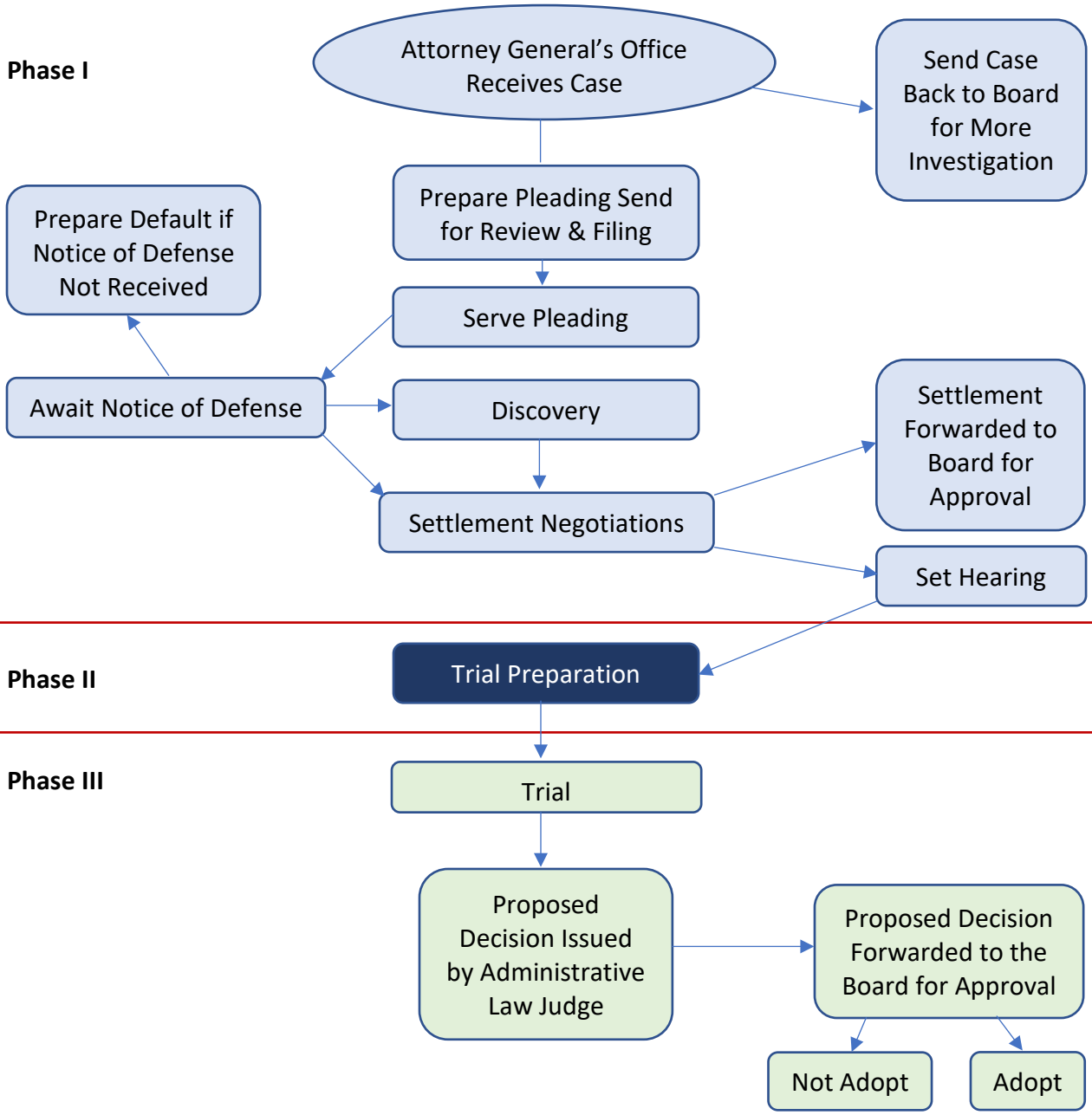
Table 1 – Business and Professions Code Section 312.2, Subdivision (a)	
Number of –	Count
(1) accusation matters referred to the Attorney General.	372
(2) accusation matters rejected for filing by the Attorney General.	9
(3) accusation matters for which further investigation was requested by the Attorney General.	24
(4) accusation matters for which further investigation was received by the Attorney General.	18
(5) accusations filed.	237
(6) accusations withdrawn.	1
(7) accusation matters adjudicated by the Attorney General.	289

Table 2 is based on the adjudicated accusation matters reported under Business and Professions Code section 312.2, subdivision (a)(7) in Table 1.

Table 2 – Business and Professions Code Section 312.2, Subdivision (b)				
Average number of days for adjudicated accusation matters –	Mean	Median	SD	Count
(1) from receipt of referral by the Attorney General to when an accusation is filed.	214	138	224	221
(2) to prepare an accusation for a case that is rereferred to the Attorney General after further investigation is received.	490	386	346	14
(3) from the filing of an accusation to when a stipulated settlement is sent to the agency.	368	277	329	173
(4) from the filing of an accusation to when a default decision is sent to the agency.	117	61	135	80
(5) from the filing of an accusation to the Attorney General requesting a hearing date.	154	106	136	60
(6) from the Attorney General's receipt of a hearing date to the commencement of a hearing.	146	124	152	21

Attachment 5

GENERAL CASE PROCESS



Attachment 6

Enforcement Workload Statistics FY 2020/21

Complaint Investigations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Received	592	481	528	0	1,601
Closed	561	627	659	0	1,847
Pending	1,649	1,776	1,642	0	1,642
Average Days for Investigation	227	257	223	0	223

Cases Under Investigation (By Team)	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Quarter Ending
Compliance / Routine	820	661	524	0	524
Drug Diversion / Fraud	175	160	141	0	141
Prescription Drug Abuse	62	68	74	0	74
Compounding	67	75	64	0	64
Outsourcing	24	20	5	0	5
Probation / PRP	28	24	9	0	9
Enforcement	187	469	532	0	532
Criminal Conviction	286	299	294	0	294

Application Investigations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Received	51	64	62	0	177
Closed					
Approved	47	49	46	0	142
Denied	8	9	10	0	27
Total Closed (includes withdrawn)	***74***	***69***	***58***	***0***	201
Pending	89	85	89	0	89

Complaint Closure Outcomes Not Resulting in Further Action	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Insufficient Evidence	124	168	177	0	469
Non-Jurisdictional	69	85	95	0	249
No Violation	70	44	88	0	202
No Further Action	47	47	48	0	142
Other - Non-Substantiated	6	7	10	0	23
Subject Educated	34	13	10	0	57

Letter of Admonishment / Citations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
LOA Issued	48	72	66	0	186
Citations Issued	226	262	248	0	736
Proof of Abatement Requested	53	64	88	0	205
Appeals Received	17	31	22	0	70
Dismissed	0	6	10	0	16
Total Fines Collected	***$204,815***	***$207,140***	***$199,225***	***$0***	***$611,180***

Administrative Cases	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Referred to the AG's Office	48	36	49	0	133
Pleadings Filed	56	42	45	0	143
Pending					Quarter Ending
Pre-Accusation	117	105	108	0	108
Post-Accusation	205	180	153	0	153
Total Pending	**322**	**285**	**261**	**0**	**261**
Total Closed	50	71	80	0	201

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Revocation					
Pharmacist	1	2	5	0	8
Intern Pharmacist	0	1	0	0	1
Pharmacy Technician	9	15	16	0	40
Designated Representative	0	1	0	0	1
Wholesaler	0	0	0	0	0
Clinic	0	0	0	0	0
Pharmacy	1	3	1	0	5
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	***11***	***22***	***22***	***0***	***55***

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	1	0	1
Pharmacy Technician	0	0	0	0	0
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Clinic	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***	***1***	***0***	***1***

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Revocation; stayed; probation					
Pharmacist	12	13	20	0	45
Intern Pharmacist	1	0	1	0	2
Pharmacy Technician	5	4	2	0	11
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Clinic	0	0	0	0	0
Pharmacy	4	0	7	0	11
Sterile Compounding	0	0	2	0	2
Outsourcing	0	0	0	0	0
Total	***22***	***17***	***32***	***0***	***71***

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Surrender / Voluntary Surrender					
Pharmacist	10	2	5	0	17
Intern Pharmacist	0	1	0	0	1
Pharmacy Technician	2	3	7	0	12
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Clinic	0	0	0	0	0
Pharmacy	13	9	7	0	29
Sterile Compounding	0	0	1	0	1
Outsourcing	0	0	2	0	2
Total	***25***	***15***	***22***	***0***	***62***

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Public Reproval / Reprimand					
Pharmacist	5	8	12	0	25
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	0	1	2	0	3
Designated Representative	1	0	0	0	1
Wholesaler	1	0	0	0	1
Clinic	0	0	1	0	1
Pharmacy	1	12	15	0	28
Sterile Compounding	0	0	2	0	2
Outsourcing	2	0	0	0	2
Total	***10***	***21***	***32***	***0***	***63***

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Licenses Granted					
Pharmacist	0	2	0	0	2
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	0	1	1	0	2
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Clinic	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***	***3***	***1***	***0***	***4***

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Licenses Denied					
Pharmacist	0	1	0	0	1
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	1	0	2	0	3
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Clinic	0	0	0	0	0
Pharmacy	0	1	0	0	1
Sterile Compounding	0	0	0	0	0
Outsourcing	0	1	0	0	1
Total	***1***	***3***	***2***	***0***	***6***

Administrative Case Cost Recovery Efforts	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Cost Recovery Requested	***$448,360***	***$439,165***	***$676,662***	***$0***	***$1,564,187***
Cost Recovery Collected	***$380,388***	***$405,001***	***$364,386***	***$0***	***$1,149,775***

Immediate Public Protection Sanctions	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Interim Suspension Orders	5	5	1	0	11
Automatic Suspension Orders	0	0	0	0	0
Penal Code 23 Restrictions	0	1	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	236	239	236	0	236
Intern Pharmacist	13	9	7	0	7
Pharmacy Technician	29	30	31	0	31
Designated Representative	2	2	2	0	2
Wholesaler	3	3	3	0	3
Pharmacy	73	70	70	0	70
Sterile Compounding	2	2	3	0	3
Total	***358***	***355***	***352***	***0***	***352***

Probation Statistics	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Probation Office Conferences	2	25	32	0	59
Probation Site Inspections	121	139	55	0	315
Probation Terminated / Completed	7	29	26	0	62
Referred to AG for Non-Compliance	0	2	1	0	3

As of 3/31/2021

Board of Pharmacy

Citation and Fine Statistics FY20/21

Citation Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	***Total***
Pharmacist with Fine	60	66	66	0	192
Pharmacist no Fine	38	77	43	0	158
Pharmacy with Fine	42	54	41	0	137
Pharmacy no Fine	47	65	59	0	171
Pharmacist-in-Charge with Fine*	29	35	25	0	89
Pharmacist-in-Charge no Fine	31	62	44	0	137
Pharmacy Technician with Fine	17	14	16	0	47
Pharmacy Technician no Fine	1	1	0	0	2
Wholesalers	3	1	0	0	4
Designated Representative	2	0	0	0	2
Clinics	0	0	0	0	0
Drug Room	0	0	0	0	0
Exempt Hospital	0	0	1	0	1
Hospital Pharmacy	6	2	1	0	9
Miscellaneous**	12	14	15	0	41
Unlicensed Premises	1	7	5	0	13
Unlicensed Person	0	0	0	0	0
Total Issued	289	398	316	0	1003

*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	56%	1716 - Variation from prescription	57%	1716 - Variation from prescription	41%
1764/56.10(a) - Unauthorized disclosure of prescription and medical information	9%	1764/56.10(a) - Unauthorized disclosure of prescription and medical information	10%	1764/56.10(a) - Unauthorized disclosure of prescription and medical information	13%
1761(a) - No pharmacist shall compound or dispense any prescription, which contains any significant error or omission…	9%	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...	9%
1707.3 - Duty to review drug therapy	7%	1707.3 - Duty to review drug therapy	5%	1714(b) - Operational Standards and Security; pharmacy responsible for pharmacy security	9%
1711(d) - Quality assurance program finding shall be used to develop systems to prevent medication errors…	6%	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	6%
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	3%	1711(d) - Quality assurance program finding shall be used to develop systems to prevent medication errors…	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	6%
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	3%	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	4%	1711(d) - Quality assurance program finding shall be used to develop systems to prevent medication errors…	6%
1761(a)(b)/11164(a)/11152 - No pharmacist shall compound or dispense any prescription, which contains any significant error or omission…/Each prescription for a controlled substance classified in Sche	2%	4081(a)/1718 - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory/Current Inventory Defined	3%	1735.2(d)(3) - Compounding commericially available products	4%
1761 - Erroneous or uncertain prescriptions	2%	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	2%	1714(d)/4113(c) - Operational Standards and Security; Pharmacist responsible for pharmacy security/Pharmacist in Charge shall be responsible for compliance with all state and federal laws pertaining to the practice of pharmacy	4%
1735.2(d)(3) - Compounding commericially available products	2%	4169(a)(4) - Purchase, trade, sell, or transfer dangerous drugs or dangerous devices after or beyond use date on the label	2%	4301 - Unprofessional Conduct	4%

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.

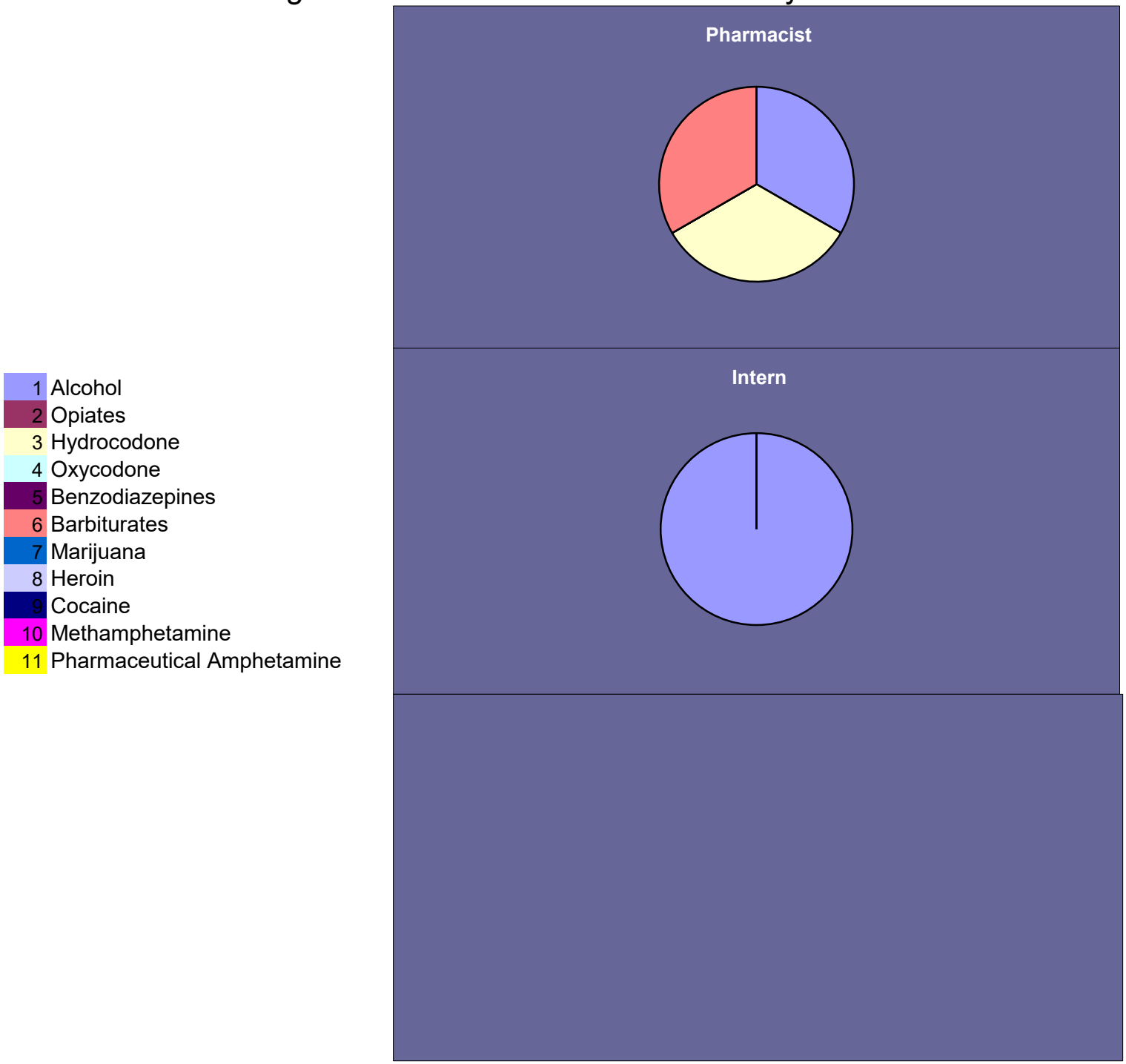
Board of Pharmacy	July Sep	Oct – Dec	Jan-Mar	Apr Jun	Total 20/21
PRP Intakes					
PRP Self-Referrals					
PRP Probation Referrals	2		2		4
PRP Under Investigation		1	1		2
PRP In Lieu Of (investigation conducted)			1		1
Total Number of PRP Intakes					
New Probationers					
Pharmacists	3		3		6
Intern Pharmacists	1		2		3
Pharmacy Technicians	2	3	1		6
Total New Probationers	6	3	6		15
PRP Participants and Recovery Agreements					
Total PRP Participants	58	55	56		N/A
Recovery Agreements Reviewed	56	53	48		157
Probationers and Inspections					
Total Probationers	80	76	75		N/A
Inspections Completed	53	62	58		173
Referrals to Treatment					
Referrals to Treatment (PRP and Probationers)			1		1
Drug Tests					
Drug Test Ordered (PRP and Probationers)	744	761	699		2204
Drug Tests Conducted (PRP and Probationers)	721	694	683		2098
Relapses (Break in Sobriety)					
Relapsed (PRP and Probationers)	1	2	1		4
Major Violation Actions					
Cease Practice/Suspension (PRP and Probationers)	3	7	10		20
Termination from PRP	1	1			2
Probationers Referred for Discipline			1		1
Closure					
Successful Completion (PRP and Probationers)	1	5	5		11
Termination (Probation)			1		1
Voluntary Surrender (Probation)	4		2		6
Surrender as a result of PTR (Probation)					
Closed Public Risk (PRP)		1			1
Non-compliance (PRP and Probationers)	23	14	14		51
Other (PRP)	2	1	1		4
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 20/21
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	1				1
Hydrocodone					
Oxycodone					
Morphine	1				1
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	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					
Pharmacy Technicians	**July-Sep**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total 20/21**
Alcohol	2	2	1		5
Opiates					
Hydrocodone					
Oxycodone					
Benzodiazepines					
Barbiturates					
Marijuana					
Heroin					
Cocaine					
Methamphetamine		1			1
Pharmaceutical Amphetamine					
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Clonazepam					
Tramadol					
Carisprodol					
Phendimetrazine					
Promethazine w/Codeine					

Drug Of Choice - Data entered from July 2020 to March 2021



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