



To: Board Members

Subject: Executive Officer’s Report

a. Biannual Report of the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE) and the North American Pharmacist Licensure Examination (NAPLEX)

Attachment 1

Examination scores for the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE) and North American Pharmacist Licensure Examination (NAPLEX) are released twice a year, generally in spring and fall.

The CPJE statistical report for April 2017 through September 2017 reflects that the overall pass rate for the CPJE is 78.8 percent. The pass rate for graduates from the California schools of pharmacy is 91.0 percent. The overall pass rate for the NAPLEX is 93.3 percent. A copy of the Semi-Annual CPJE Statistical Report is provided in **Attachment 1**.

CPJE: Overall Pass Rates		
	Frequency	Percent
Fail	332	21.2
Pass	1231	78.8
Total	1563	100.00

NAPLEX: Overall Pass Rates		
	Frequency	Percent
Fail	99	6.7
Pass	1380	93.3
Total	1479	100.0

5 Year Comparison of CPJE and NAPLEX Pass Rates (Percentage)				
	CPJE		NAPLEX	
	Fail	Pass	Fail	Pass
Oct. 2012 – Sept. 2013	22.1	77.9	4.6	95.4
Oct. 2013 – Sept. 2014	19.5	80.5	4.2	98.5
Oct. 2014 – Sept. 2015	20.1	79.9	4.3	95.7
Oct. 2015 – Sept. 2016	31.4	68.6	9.4	90.6
Oct. 2016 – Sept. 2017	29.7	70.3	8.8	91.2

b. Response to FDA’s Guidance for Industry Titled “Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy”

At the July Board Meeting, the board directed that a letter be sent in response the FDA’s new policy to delay for one year implementation of the product identifier requirements to

implement the track and trace requirements for medications (from November 27, 2017 until November 17, 2018). The letter is being reviewed by Board President Gutierrez.

c. Update on the Executive Officer's Engagement at the Federal Level

Since the July Board Meeting, the executive officer has represented the board at the following meetings with national scope:

- *FDA 50-State Meeting on Compounding:* This was a two-day meeting in Washington DC where the FDA brought in the states to discuss compounding and outsourcing issues. I was asked to speak on how California regulates sterile compounding pharmacies and outsourcing facilities. I highlighted the fact that outsourcing facilities are not regulated as pharmacies by CA, how we deal with compounding for future furnishing and other related topics, and the EO's ability to issue cease and desist orders. I also met with the FDA staff that are implementing FDA's track and trace requirements.
- *National Association of Boards of Pharmacy Interactive Forum for Executive Officers:* This was a two-day meeting in Chicago to discuss national issues affecting pharmacy boards. I spoke as part of a panel on regulatory oversight following the North Carolina/FTC decision.
- *National Association of Boards of Pharmacy .Pharmacy ("dot pharmacy") Executive Committee Meeting:* I serve as the regulatory board representative on this committee, which exists to establish use of a verified top-level domain to identify legitimate web sites for purchasing drugs from the 97 percent that are not legitimate. This was the only in-person meeting of this committee during the year.
- *Department of Public Health/CDC Meeting on Opioids:* CDPH Director Karen Smith invited me to attend this day long meeting in Sacramento with three CDC staff to discuss California's approach and activities to address the opioid epidemic. It included grants provided by the CDC to CDPH for naloxone distribution principally to northern CA counties.
- *American Society of Pharmacy Law:* Immediately before the board meeting I will attend this meeting, which addresses emerging pharmacy law issues.

d. Update on Opioid Training Provided to the Board's Inspectors and Other Healing Arts Investigators

In mid-October, board inspectors attended a two-day training session in Sacramento. Part of this training included a session on appropriate opioid prescribing presented by Scott Fishman, MD, a published pain management physician from UC Davis. Investigators from other Department of Consumer Affairs healing arts boards were invited, and a number of these investigators attended. Dr. Fishman provided an overview of the philosophy of pain management over the last decade and the philosophy today about prescribing these medications, including prescribing guidelines from the California Medical Board and the CDC.

e. Update on the Joint DEA and Board of Pharmacy Training Events

The board continues to offer its popular six-hour CE programs on prescription drug abuse. During these six-hour seminars, the following topics are discussed: common drugs of abuse, corresponding responsibility, preventing pharmacy thefts, drug take back programs, preparing for a board or DEA inspection and compliance with the Combat Methamphetamine Act. Additionally, pharmacists who are interested may stay for an additional hour to gain the certification necessary to provide naloxone.

There have been three of these events since the July Board Meeting:

Date	Location	Attendance: 6 Hour Program	Attendance: Naloxone Training
8/26/17	Northstate University School of Pharmacy	160	125
10/21/17	KGI School of Pharmacy	128	116

The evening of November 7, 2017, the board will be offering a three-hour presentation in conjunction with a two-day prescription drug abuse conference being convened by the California Opioid Policy Summit that includes several sponsors, including the DEA and the Department of Public Health. As of October 30, 2017, 230 individuals have registered for the board’s program.

Board staff will be hosting seven-hour event in San Francisco at UCSF on January 27, 2018. Details are being finalized as this packet is being prepared, and an alert will be released announcing the training after the board meeting.

The assessments of participants attending these programs have been very positive.

f. Federal Re-evaluation of the Distribution of Controlled Substances

In recent weeks, there have been a number of announcements involving the regulation of controlled of controlled substances over the last years.

From the New York Times:

On October 16, 2017, President Trump directed the Department of Health and Human Services to declare the [opioid crisis](#) a public health emergency, an action to address a rapidly escalating epidemic of drug use. However, he did not declare “a national emergency” on opioids, which would have prompted the rapid allocation of federal funding to address the issue.

Among the President’s statements:

“No part of our society — not young or old, rich or poor, urban or rural — has been spared this plague of drug addiction and this horrible, horrible situation that’s taken place with opioids”

“This epidemic is a national health emergency.”

According to media reports, the result of this declaration is that this will allow for some grant money to combat opioid abuse, permit the hiring of specialists to tackle the crisis, and expand the use of telemedicine services to treat people in rural areas where doctors are in short supply. Additional federal plans linked to the announcement include a policy to develop nonaddictive painkillers and efforts to stop shipments of fentanyl. However, the declaration does not link substantial increases in federal funding that some had hoped for, nor seek out government pressure to make naloxone available at lower prices.

Meanwhile, some in Congress are reconsidering repeal of a 2016 law that made it substantially more difficult for the DEA to issue what amounts to suspension orders to drug wholesalers when excessive/suspicious opioid sales to pharmacies are detected. The issues involving enactment of this law were highlighted in a recent Washington Post series and 60 Minutes segment that were based on the report of former head of DEA’s Office of Diversion Control Joe Rannazzisi.

The new law limited the ability of the DEA to issue suspension orders to freeze drug shipments where the agency determined the shipments posed an imminent danger. Instead the standard was converted to “a substantial likelihood of an immediate threat,” a much higher standard. The debate over the law and enactment occurred during a time when deaths due to opioid overdoses were escalating.

The Washington Post article may be found using the following link:

https://www.washingtonpost.com/graphics/2017/investigations/dea-drug-industry-congress/?utm_term=.d8ac603c2b6c

g. Board’s Response to the State of Emergency Declared by Governor Brown Due to Multiple Wildfires

Attachment 2

In early October, California was burning from a number of wildfires scattered throughout the state. Thousands of people were relocated to emergency shelters, in some cases in the middle of the night.

As the Governor issued state of emergency declarations, the board issued two subscriber alerts (October 9 and 16) to remind pharmacies and pharmacists how they could assist patients who

sought emergency supplies of medications they could no longer access. A copy of the subscriber alert is provided as **Attachment 2**.

The board also issued three temporary licenses to pharmacies that were affected by the fires. The board was not advised of any destroyed pharmacies.

h. Personnel Update

Recent Hires/Transfers/Promotions

- Taydene Dalrymple was promoted to a SSM I over the Complaint Unit.
- Debi Mitchell was promoted to a SSM II over the Licensing and Administration.
- MaryJo Tobola was hired as the SSM II over the Enforcement, Complaint, and Criminal Conviction units.
- Sheri Ross-Hustana joined the board as an Inspector on SI Hunt's Compliance team.
- Louisa Tsoi joined the board as an Inspector on the Prescription Drug Abuse team.
- Lyle Matthews joined the board as an Inspector on the Compliance team.
- Sidney Truong joined the board as an Inspector on the Outsourcing team.
- Kevin Dong joined the board as an Inspector on the Compounding team.

Departures

- Veronica Wogec, SSM II, left the board in July.
- Trish Rodriguez, SSM II, left the board in September.

Recruitments Underway

- One SSM I for Licensing.
- One AGPA for Enforcement.
- One AGPA for Sterile Compounding in Licensing.
- One AGPA for the Prescription Drug Abuse Prevention Team in the Complaint Unit.
- One Office Technician in Enforcement.

Attachment 1

California State Board of Pharmacy CPJE Statistics April 2017 – September 2017

The charts below display data for all candidates who took the CPJE examination between April 2017 – September 2017, inclusive.

The board also displays NAPLEX scores associated with any candidate who took the CPJE during this six-month period and was reported to the board, regardless of when the NAPLEX may have been taken (it could have occurred outside the six-month reporting period noted above). Typically, the board reports CPJE performance data at six-month intervals.

Overall Pass Rates

CPJE

	Frequency	Percent
F	332	21.2
P	1231	78.8
Total	1563	100.0

NAPLEX

	Frequency	Percent
F	99	6.7
P	1380	93.3
Total	1479	100.0

Location of School

		CPJE		
		F	P	Total
California	Count	69	701	770
	%	9.0%	91.0%	100.0%
Other US	Count	232	482	714
	%	32.5%	67.5%	100.0%
Foreign	Count	30	47	77
	%	39.0%	61.0%	100.0%
Unclassified	Count	1	1	2
	%	50.0%	50.0%	100.0%
Total	Count	332	1231	1563
	%	21.2%	78.8%	100.0%

Location of School (continued)

		NAPLEX		
		F	P	Total
California	Count	42	699	741
	%	5.7%	94.3%	100.0%
Other US	Count	42	618	660
	%	6.4%	93.6%	100.0%
Foreign	Count	15	61	76
	%	19.7%	80.3%	100.0%
Unclassified	Count	0	2	2
	%	0.0%	100.0%	100.0%
Total	Count	99	1380	1479
	%	6.7%	93.3%	100.0%

Gender

		CPJE		
		F	P	Total
F	Count	189	807	996
	%	19.0%	81.0%	100.0%
M	Count	143	424	567
	%	25.2%	74.8%	100.0%
Total	Count	332	1231	1563
	%	21.2%	78.8%	100.0%

		NAPLEX		
		F	P	Total
F	Count	54	894	948
	%	5.7%	94.3%	100.0%
M	Count	45	486	531
	%	8.5%	91.5%	100.0%
Total	Count	99	1380	1479
	%	6.7%	93.3%	100.0%

California Schools CPJE

		CJPE P/F		
		F	P	Total
UCSF	Count	6	24	30
	%	20.0%	80.0%	100.0%
UOP	Count	16	166	182
	%	8.8%	91.2%	100.0%
USC	Count	6	141	147
	%	4.1%	95.9%	100.0%
Western	Count	6	105	111
	%	5.4%	94.6%	100.0%
Loma Linda	Count	5	59	64
	%	7.8%	92.2%	100.0%
UCSD	Count	3	31	34
	%	8.8%	91.2%	100.0%
Touro U	Count	8	69	77
	%	10.4%	89.6%	100.0%
Cal Northstate	Count	17	79	96
	%	17.7%	82.3%	100.0%
Total	Count	67	674	741
	%	9.0%	91.0%	100.0%

California Schools NAPLEX

		NAPLEX P/F		
		F	P	Total
UCSF	Count	1	29	30
	%	3.3%	96.7%	100.0%
UOP	Count	9	173	182
	%	4.9%	95.1%	100.0%
USC	Count	4	143	147
	%	2.7%	97.3%	100.0%
Western	Count	9	102	111
	%	8.1%	91.9%	100.0%
Loma Linda	Count	5	59	64
	%	7.8%	92.2%	100.0%
UCSD	Count	0	34	34
	%	0.0%	100.0%	100.0%
Touro U	Count	2	75	77
	%	2.6%	97.4%	100.0%
Cal Northstate	Count	12	84	96
	%	12.5%	87.5%	100.0%
Total	Count	42	699	741
	%	5.7%	94.3%	100.0%

US Schools of Pharmacy CPJE

		CJPE		
		F	P	Total
school graduated from	Auburn	1	0	1
	Samford	0	1	1
	U of AZ	2	9	11
	UCSF	6	24	30
	U of Pacific	16	173	189
	USC	6	145	151
	U of CO	8	20	28
	U of Conn	0	2	2
	Howard DC	1	1	2
	FL A&M	2	1	3
	U of FL	3	5	8
	Mercer	2	3	5
	U of GA	1	1	2
	Idaho SU	2	0	2
	U of IL Chi	5	7	12
	Butler U	0	2	2
	Purdue	5	6	11
	Drake	2	5	7
	U of IA	1	4	5
	U of KS	6	4	10
	U of KY	0	1	1
	NE LA U	1	1	2
	Xavier	1	2	3
	U of MD	7	10	17
	MA Col Pharm	10	15	25
	NE-MA	3	7	10
	Ferris	1	1	2
	U of MI	1	6	7
	Wayne SU	0	1	1
	U of MN	2	4	6
U of MS	1	0	1	
St. Louis Col of PH	1	11	12	
UMKC	2	2	4	
U of MT	3	2	5	

Creighton	1	15	16
U of NE	2	1	3
Rutgers	0	6	6
U of NM	1	2	3
Western	6	112	118
Midwestern U Chicago	7	25	32
A&M Schwartz	1	3	4
St. Johns	3	0	3
SUNY-Buff	4	3	7
Union U	3	4	7
UNC	1	2	3
OH Nrthrn U	1	1	2
OH State U	2	5	7
U of Cinn	0	1	1
U of Toledo	2	3	5
U of OK	2	5	7
OR State U	1	5	6
Duquesne	3	1	4
Phl C of Pharm	3	5	8
Temple	2	3	5
U of Pitt	1	5	6
U of RI	0	2	2
SD SU	1	0	1
U of TN	1	0	1
TX SO U	0	1	1
U of Hous	0	4	4
U of TX	0	2	2
U of UT	1	5	6
Med C of VA	2	2	4
U of WA	2	5	7
WA State U	4	2	6
WV U	1	1	2
U of WI-Mad	0	1	1
U of WY	1	0	1
Campbell U	0	3	3
Nova Southeastern	0	5	5
Wilkes University	0	1	1
Texas Tech	1	3	4

Bernard J Dunn	3	4	7
Midwestern AZ	10	27	37
Nevada College of Pharm	11	42	53
Loma Linda U	5	61	66
UCSD	3	32	35
MA School of Pharm - Worcester	9	25	34
Palm Beach Atlantic University	1	0	1
Lake Erie Col	4	8	12
Touro U	9	71	80
U of Charleston	2	2	4
South U School of Pharm	0	2	2
Hampton U (VA)	1	0	1
Pac U of Or	4	10	14
Wingate U	2	0	2
U of Incarnate Word	1	2	3
Sullivan U	2	3	5
Cal Northstate	18	83	101
Unclassified	1	1	2
Other/FG	30	47	77
U of HI - Hilo	5	23	28
NE Ohio Universities	0	1	1
Texas A&M	3	1	4
Thomas Jefferson U	3	7	10
Belmont U	0	1	1
Harding U	0	1	1
Husson U	2	0	2
Appalachian College of Pharm	0	2	2
Chicago St U	3	10	13
U of New England	6	4	10
Regis University	1	7	8
Notre Dame of MD	0	5	5
Union U	1	0	1
St. John Fisher	6	4	10

Concordia U Coll Pharm	1	0	1
U of Saint Joseph	2	6	8
Roosevelt U	0	1	1
Presbyterian	1	1	2
D'Youville	2	0	2
Touro New York	7	10	17
South College	2	1	3
Manchester U	2	4	6
SIUE	1	0	1
Fairleigh Dickinson	1	1	2
Cedarville U	2	0	2
U of the Sciences	2	1	3
UNTX Col Pharm	1	0	1
Total	332	1231	1563

Foreign Country CPJE

		CPJE		
		F	P	Total
country	Armenia	1	0	1
	Brazil	0	1	1
	Canada	0	3	3
	Denmark	0	1	1
	Egypt	7	18	25
	Eritrea	1	0	1
	France	1	0	1
	United Kingdom	0	1	1
	India	2	3	5
	Iraq	1	3	4
	Iran	1	1	2
	Italy	0	1	1
	Jordan	0	4	4
	S. Korea	0	1	1
	Lebanon	2	1	3
	Nigeria/New Guinea	3	1	4
	Philippines	5	5	10
	Pakistan	3	1	4
	Poland	0	1	1
	Russia	1	0	1
	Syria	2	1	3
	USA	301	1183	1484
	Venezuela	1	1	2
Total		332	1231	1563

Attachment 2

Damoth, Debbie@DCA

From: General Board of Pharmacy Subscriber List <PHARM-GENERAL@DCALISTS.CA.GOV> on behalf of Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Monday, October 09, 2017 1:19 PM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Subject: State of Emergency in Napa, Sonoma, and Yuba Counties Due to the Effects of Multiple Fires

Under a state of emergency declared by Gov. Edmund G. Brown on Monday due to multiple fires in Napa, Sonoma and Yuba Counties (<https://www.gov.ca.gov/home.php>), the California State Board of Pharmacy reminds pharmacists and pharmacies about pharmacy law provisions that can be of assistance in caring for patients displaced by the emergency relocations.

Requirements for furnishing prescription drugs, providing emergency refills without prescriber authorization and operating a mobile pharmacy in a declared emergency area are provided below and are specified in California Business and Professions Code sections 4062 and 4064.

For additional information, contact the California State Board of Pharmacy at (916) 574-7900.

[4062](#). Furnishing Dangerous Drugs during Emergency; Mobile Pharmacy

- (a) Notwithstanding Section 4059 or any other provision of law, a pharmacist may, in good faith, furnish a dangerous drug or dangerous device in reasonable quantities without a prescription during a federal, state, or local emergency, to further the health and safety of the public. A record containing the date, name, and address of the person to whom the drug or device is furnished, and the name, strength, and quantity of the drug or device furnished shall be maintained. The pharmacist shall communicate this information to the patient's attending physician as soon as possible. Notwithstanding Section 4060 or any other provision of law, a person may possess a dangerous drug or dangerous device furnished without prescription pursuant to this section.
- (b) During a declared federal, state, or local emergency, the board may waive application of any provisions of this chapter or the regulations adopted pursuant to it if, in the board's opinion, the waiver will aid in the protection of public health or the provision of patient care.
- (c) During a declared federal, state, or local emergency, the board shall allow for the employment of a mobile pharmacy in impacted areas in order to ensure the continuity of patient care, if all of the following conditions are met:
- (1) The mobile pharmacy shares common ownership with at least one currently licensed pharmacy in good standing.
 - (2) The mobile pharmacy retains records of dispensing, as required by subdivision (a).
 - (3) A licensed pharmacist is on the premises and the mobile pharmacy is under the control and management of a pharmacist while the drugs are being dispensed.
 - (4) Reasonable security measures are taken to safeguard the drug supply maintained in the mobile pharmacy.
 - (5) The mobile pharmacy is located within the declared emergency area or affected areas.
 - (6) The mobile pharmacy ceases the provision of services within 48 hours following the termination of the declared emergency.
- (Amended by Stats. 2009, Ch. 308, Sec. 48. Effective January 1, 2010.)

Section 4064. Emergency Refill of Prescription without Prescriber Authorization

- (a) A prescription for a dangerous drug or dangerous device may be refilled without the prescriber's authorization if the prescriber is unavailable to authorize the refill and if, in the pharmacist's professional judgment, failure to refill the prescription might interrupt the patient's ongoing care and have a significant adverse effect on the patient's well-being.
- (b) The pharmacist shall inform the patient that the prescription was refilled pursuant to this section.
- (c) The pharmacist shall inform the prescriber within a reasonable period of time of any refills dispensed pursuant to this

section.

(d) Prior to refilling a prescription pursuant to this section, the pharmacist shall make every reasonable effort to contact the prescriber. The pharmacist shall make an appropriate record, including the basis for proceeding under this section.

(e) The prescriber shall not incur any liability as the result of a refilling of a prescription pursuant to this section.

(f) Notwithstanding Section 4060 or any other law, a person may possess a dangerous drug or dangerous device furnished without prescription pursuant to this section.

(Amended by Stats. 1997, Ch. 549, Sec. 44. Effective January 1, 1998.)

For more information on the Board of Pharmacy, go to <http://www.pharmacy.ca.gov/>.

The CA State Board of Pharmacy protects and promotes the health and safety of California consumers by pursuing the highest quality of pharmacist care and the appropriate use of pharmaceuticals through education, communication, licensing, legislation, regulation and enforcement.

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