To: Board Members

Subject: Agenda Item X. Executive Officer's Report

a. Update on Substance Abuse Prevention Billboard

Attachment 1

Background

At its February 2018 meeting, the board approved a design chosen by the Communication and Public Education Committee for a billboard to raise awareness about drug abuse prevention. Board Member Ryan Brooks' firm, Outfront Media, has agreed to donate five billboards for the project – two in Northern California, one in Central California, and two in Southern California.

A copy of the billboard is provided in **Attachment 1**.

Also at the February meeting, the committee reported that staff is revamping the drug abuse prevention page on the website. The new page will have a fresh look and contain updated resources for drug abuse information and treatment. Eventually, the billboard image will be displayed on the website as a link to the new drug abuse prevention page.

Update

Board staff and Outfront Media are working to finalize a no-cost contract for the project. Staff is working with DCA's Business Services Office (BSO), which is responsible for preparing and processing all contracts for the board, to finalize the contract.

In the meantime, staff has updated the drug abuse information on the board's website. The new webpage is cleaner and visually more interesting, with logos identifying organizations and resources. It also includes an embedded video of the board's public service announcement about prescription drug abuse.

b. Update on the Substance Abuse Coordination Committee Meeting Held 6/27/18

Attachment 2

Background

SB 1441 (Ridley-Thomas, Chapter 548, Statutes of 2008) created the Substance Abuse Coordination Committee under the Department of Consumer Affairs. The committee was tasked with creating a set of uniform standards to be used by the healing arts boards to deal with substance-abusing licensees in the health care professions.

The Uniform Standards, released in 2011, cover a wide range of issues related to substance abuse rehabilitation, including clinical diagnostic evaluation, testing frequency, standard of

treatment, consequences for violations and more.

SB 796 (Hill, 2017, Chapter 600) requires the Department of Consumer Affairs to reconvene the Substance Abuse Coordination Committee (SACC) to specifically review the existing criteria for Uniform Standard #4 related to drug testing. The committee must determine whether the existing criteria for Uniform Standard #4 should be updated and report to the Legislature by January 1, 2019.

The committee is composed of the executive officers of the Department of Consumer Affairs' healing arts boards and a designee of the State Department of Health Care Services, and it is chaired by the Director of Consumer Affairs. The director may invite individuals or stakeholders who have expertise in the area of substance abuse to advise the committee.

Update

The second meeting of the Substance Abuse Coordination Committee was held on June 27, 2018. During this meeting, the committee held discussions about the various modes to test for abstinence and ensure adherence to treatment requirements, including when a participant has a need to leave the state (e.g., to settle an estate outside the USA). Frequency of testing especially for the first year of program participation where the testing frequency is 52 to 104 times a year was also discussed. There will likely be at least one additional meeting of the SACC to focus on testing frequencies for program participants.

A copy of the meeting agenda is provided in **Attachment 2**.

c. Report on the Certification of the CURES System by the CA Department of Justice and Resulting Changes

Attachment 3

Background

The California Department of Justice certified the CURES 2.0 system on April 2, 2018. This also means that on October 2, 2018, prescribers will be required, with some exceptions, to check CURES before prescribing Schedule II, III or IV drugs to a patient for the first time (pursuant to provisions enacted in 2016 (Lara, Chapter 708)), and at least every four months thereafter if therapy with the controlled substances is ongoing. These provisions can be found in Health and Safety Code section 11165.4.

The board released a subscriber alert on 5/16/18 to inform pharmacists about the requirements for prescribers to check CURES before prescribing these medications. A copy of the subscriber alert is provided in **Attachment 3.**

Update

The Department of Justice released the following CURES data for January through May 2018.

CURES Registrants: January May 2018			
Pharmacists	41,884		
Total Number of Individuals Registered	183,048		
Percentage of Pharmacists Registrants	22.9%		

Patient Activity Reports Generated: January May 2018				
By Pharmacists	3,480,376			
Total Number of Reports Generated	6,067,400			
Percentage Reports Generated by Pharmacists	57.4%			

Number of Times CURES Accessed: January May 2018		
Accessed by Pharmacists	1,457,410	
Total Times Accessed by Anyone	2,480,641	
Percentage of Time Pharmacists Accessed CURES	58.8%	

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Prescriptions Entered Into CURES: January May 2018						
	January	February	March	April	May	Total
Schedule II	1,726,990	1,480,870	1,588,066	1,533,991	1,667,542	7,998,459
Schedule III	310,252	264,141	288,155	282,299	305,624	1,450,471
Schedule IV	1,761,696	1,506,128	1,649,786	1,591,822	1,682,599	8,192,031
Schedule V	72,753	50,045	49,681	39,282	39,454	251,215
Total	3,871,691	3,301,184	3,575,688	3,447,394	3,695,219	17,892,176

d. Update on the Board's 2018 Pharmacy Law Continuing Education Webinar

Background

A recent change in continuing education requirements mandates that effective July 1, 2019, at least two of the 30 units required for CA pharmacist license renewal be obtained by participation in a board-provided continuing education course. The specific requirement is provided below:

§1732.5 Renewal Requirements for Pharmacists

- (a) Except as provided in Section 4234 of the Business and Professions Code and Section 1732.6 of this Division, each applicant for renewal of a pharmacist license shall submit proof satisfactory to the board, that the applicant has completed 30 hours of continuing education in the prior 24 months.
- (b) At least two (2) of the thirty (30) hours required for pharmacist license renewal shall be completed by participation in a Board provided CE course in Law and Ethics. Pharmacists renewing their licenses which expire on or after July 1, 2019, shall be subject to the requirements of this subdivision.
- (c) All pharmacists shall retain their certificates of completion for four (4) years following completion of a continuing education course

Update

Board staff has developed a program that covers 2018 new pharmacy laws. Board staff worked with DCA's SOLID Training and Development Unit to create a free video webinar that integrates a live presentation on pharmacy law by the executive officer, with quiz questions intended to monitor participation and learning objectives. Upon completion pharmacists will be awarded one hour of CE toward the fulfillment of the requirement in 1732.5(b) and will have the ability to print a certificate of completion for their records. The webinar will be available on the board's website in early August.

<u>Additional Ways to Fulfill the CE Requirement:</u>

Board staff will begin developing another webinar focusing on pharmacy ethics to fulfill a part the second hour of CE required by 1732.5(b). Additionally, once the 2018 legislative year is over, staff will develop a 2019 pharmacy law component to this series.

The Communication and Public Education Committee at its next meeting will discuss a means to award one hour of CE for reading the board's newsletter, *The Script*.

The board has also agreed to allow licensees to use two of the six hours awarded for attendance at the Prescription Drug Abuse Presentations as fulfillment of the CE requirement for a renewal period.

e. Update on the Board's Naloxone Certification Webinar

Attachment 4

Background

At the February 2018 Board Meeting, the board approved a recommendation by the Communication and Public Education Committee to create a webinar course for pharmacists to furnish naloxone, which reverses opioid overdose. The webinar would provide one hour of CE credit to satisfy the training requirement for furnishing naloxone under the board's protocol in CCR section 1746.3. The board also approved materials for the webinar created by Dr. Talia Puzantian of Keck Graduate School of Pharmacy and Dr. James Gasper of California Department of Health Care Services.

Update

Staff has been working with DCA's SOLID Training and Development Unit to create the free webinar that will be available on the board's website. SOLID is preparing the webinar PowerPoint for ADA compliance. Staff is developing a script for voice-over that will accompany the webinar. Pharmacists who view the full webinar will be able to print out a certificate of completion.

Because of SOLID's workflow – including development of a law and ethics webinar for the board – the naloxone webinar is expected to be completed in late summer.

A copy of the naloxone webinar materials is in **Attachment 4**.

f. Staff Development and Training Update

To ensure ongoing knowledge and competency in compounding, all board inspectors are completing another three-day in-person training through Clinical IQ. In order to take this training, inspectors are required complete a 40-hour webinar training program. To ensure better and more consistent inspections in California, the board offered pharmacy consultants in the Department of Public Health the opportunity to join in the training sessions with the board's inspectors.

In the future board members will be given an opportunity to take the 40-hour compounding webinar training.

To foster a more collegial work environment as the board continues to grow, in recent months board staff has attended team building sessions led by trainers in DCA's SOLID Office.

g. Update on the Relocation of the Board's Office

For the past year board staff has been working with DCA and the Department of General Services to locate new office space that can accommodate the board's significant growth.

Recently, the board signed a lease for new office space located at 2720 Gateway Oaks Drive Suite, approximately three miles from our current location. The tentative start date of the lease is February 1, 2019; however, that date could be impacted by construction timelines, necessary approvals, etc.

h. Update on the July Issue of *The Script*

The second newsletter of 2018 will be published in mid-July. The cover story explores potential health risks to consumers who shop for prescription drugs on the internet, and how pharmacists can educate their patients about buying medications online. This article has been shared with other healing arts boards in DCA. Other newsletter articles report

on ways to help reduce medication errors, new board regulations related to disciplinary guidelines and beyond use dates for compounded drug medications, and tips for wholesalers on how to prepare for inspections and how to report suspicious orders of controlled substances.

Information on the Department of Health Care Services Grant for Drug Take Back Programs

The executive officer is working with the California Department of Health Care Services on a possible grant to provide reimbursement for drug take back services. This project is in the early development phases and more information will be provided at the board meeting or as it becomes available.

j. Report on the 2018 USP Workshop on Safe Compounding

In May, the executive officer was invited to attend a USP workshop to address compounding issues entitled: Inaugural USP Workshop on Evolution and Advances in Compounding. Ms. Herold provided a presentation "Advancing Quality Compounding, the State Perspective." In the presentation, Ms. Herold described the board's requirements, inspections conducted, and the learning experiences of moving to implement portions of USP 800 and its huge impact on pharmacy building standards.

k. Report on the National Association of Boards of Pharmacy Development of Recommended Parameters Regarding Suspicious Order Notification from Wholesalers

In mid-May, the executive officer was invited to work with the National Association of Boards of Pharmacy on the development of parameters to trigger suspicious order notifications by wholesalers to state boards of pharmacy involving irregular sales of controlled substances by wholesalers to pharmacies. In 2017, California and other states enacted provisions to require wholesalers to add to federal notification requirements a provision for state reporting when wholesalers receive suspicious orders from pharmacies. However, what constitutes "suspicious" is not clearly defined. The definition of suspicious orders currently include, but are not limited to, orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

I. Changes to the California Department of Corrections' Drug Distribution Model

Enacted as part of the trailer bills to the state's 2018/19 budget is a bill that altered the manner in which the state's prisons handle and provide prescription medication to inmates. The general plan is to use a clinic-based model with ADDS machines to provide medication to the state's prison population one dose at a time. This is expected to result in an increase hundreds of licenses and registrations.

m. Report of Multi-Year Comparisons of Licensing and Enforcement Statistics

Attachment 5

Enforcement Statistics

Attachment 5 contains a three-year comparison of data for the board's enforcement operations. A review of the three-year comparison reveals the board completed about 229 more investigation in FY 2017/18 versus FY 2015/16, about an 8 percent increase, and the overall total of investigations pending decreased by 16 percent.

During this same time period, the number of citations issued increased about 10 percent and the number of proof of abatements requested doubled. Staff anticipate additional growth in abatements as the board continues its focus on education as an appropriate resolution to some violations.

Over the three-year period there has been a 15 percent decrease in the number of cases referred to the Attorney General's Office, with overall pending matters at the AG's Office also decreasing by 24 percent. The overall number of licenses revoked shows a 22 percent decrease over the reporting period along with a 29 percent decrease in the number of penalties that include a suspension as part of the disciplinary order. The overall number of licenses placed on probation (including orders with or without a suspension) indicates a 19 percent increase, the number of surrenders accepted by the board increased by 10 percent, and the number of public reprovals ordered increased by 55 percent.

Pharmacy technicians continue to represent the greatest number of licenses revoked by the board, while pharmacists represent the greatest number of licensees placed on probation or subject to public reproval.

Licensing Statistics

In fiscal year 2017/2018, the board received 16,459 applications for licensure, issued 11,067 new licenses and renewed 64,644 licenses. In addition, licensing staff processed 15,264 change notices, responded to 34,858 email inquiries and answered 7,784 phone calls. The board's overall licensing population at the end of the fiscal year was 139,640.

The three-year comparison of the board's licensing programs shows that the number of applications received and licenses renewed has remained relatively flat overall. The board's overall licensing population has grown about 1 percent. There has been a notable 17 percent increase in the number of pharmacist exam applications received and a 63 percent increase in the number of pharmacy applications received. The most significant decrease in volume was a 13 percent decrease in pharmacy technician applications.

During this time frame the board has added six new licensing programs including

- Advanced practice pharmacist
- Designated paramedic
- Designated representative-reverse distributor

- Emergency medical services automated drug delivery system
- Hospital satellite sterile compounding
- Outsourcing facilities (resident and nonresident)

As is apparent from the above list, there has also been significant growth in program complexity. These six programs are in various stages of implementation and in some cases, fully implemented. For example, the advance practice pharmacist licensure category has 334 licensees.

n. Update on Status of Board Sponsored Legislation Related to Fees for Government Owned Facilities

In 2017 as part of the enactment of SB 443 (Hernandez, Chapter 547), a discussion occurred with the Department of Finance about why the board exempts government facilities from having to pay licensure fees. In subsequent discussion with the board, the board opted to end this subsidy in the future. This year, Senator Hill has agreed to add provisions to SB 1480. The amendments will be made when the Legislature returns from its summer recess in August. The change will result in an approximate annual increase of \$400,000 to the board's budget.

Report on the FDA Approval of Seizure Medication Containing Cannabidiol and the Implementation of AB 710 (Wood)

Attachment 6

Epidiolex was approved by the FDA on June 25, 2018. A copy of the FDA's statement is provided in **Attachment 6**.

The Drug Enforcement Administration (DEA) now has 90 days to schedule the medication. The product will also need to be rescheduled under the state's controlled substance act in those states that control marijuana and its compounds in Schedule I.

In California, Governor Brown signed AB 710 on July 9 which addresses this drug. A copy of AB 710 is provided in **Attachment 6**.

Below is a description of AB 710 from the Legislative Counsel's Digest:

Existing law, the California Uniform Controlled Substances Act, classifies controlled substances into 5 designated schedules, with the most restrictive limitations generally placed on controlled substances classified in Schedule I, and the least restrictive limitations generally placed on controlled substances classified in Schedule V. Existing law designates cannabis in Schedule I. Cannabidiol is a compound contained in cannabis.

Existing law restricts the prescription, furnishing, possession, sale, and use of

controlled substances, including cannabis and synthetic cannabinoid compounds, and makes a violation of those laws a crime, except as specified.

This bill, if one of specified changes in federal law regarding the controlled substance cannabidiol occurs, would deem a physician, pharmacist, or other authorized healing arts licensee who prescribes, furnishes, or dispenses a product composed of cannabidiol, in accordance with federal law, to be in compliance with state law governing those acts. The bill would also provide that upon the effective date of one of those changes in federal law regarding cannabidiol, the prescription, furnishing, dispensing, transfer, transportation, possession, or use of that product in accordance with federal law is for a legitimate medical purpose and is authorized pursuant to state law.

Existing law, the Medicinal and Adult-Use Cannabis Regulation and Safety Act, regulates the cultivation, processing, and sale of medicinal and adult-use cannabis within the state.

This bill would expressly exclude from regulation under that act, any medicinal product composed of cannabidiol approved by the federal Food and Drug Administration and either placed on a schedule of the federal Controlled Substances Act other than Schedule I, or exempted from one or more provisions of that act.

This bill would declare that it is to take effect immediately as an urgency statute.

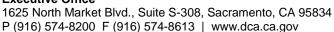
Attachment 1



Attachment 2



Executive Office





NOTICE OF PUBLIC MEETING AND AGENDA PUBLIC SUBSTANCE ABUSE COORDINATION COMMITTEE MEETING

WEDNESDAY, JUNE 27, 2018

Date:	Wednesday, June 27 at 10:00AM
Location:	1747 North Market Blvd., 1 st Floor Hearing Room
Location.	Sacramento, CA 95834

AGENDA

- I. Call to Order, Establishment of Quorum
- II. Public Comment on Items Not on the Agenda

 Note: The committee may not discuss or take action on any matter raised during this public comment section that is not included on this agenda, except to decide whether to place the matter on the agenda of a future meeting.
- III. Approval of the April 23 Substance Abuse Coordination Committee meeting minutes
- IV. Overview of Contracted Diversion and Traditional Probationary Processes
- V. Overview of Uniform Standard #4 Key Components
- VI. Update on Data Collection for Uniform Standard #4 and Uniform Standard #16
- VII. Discussion and Panel Discussion of Drug Testing Methodologies and Technological Advancements by Current DCA Laboratory Testing and Sample Collection Vendors

- VIII. Discussion and Consideration of Possible Changes to Uniform Standard #4
- IX. Next Steps and Future Meetings
- X. Adjournment

<u>NOTICE</u>: The meeting is accessible to the physically disabled. A person who needs a disability-related accommodation or modification in order to participate in the meeting may make a request by contacting Patrick Le at (916) 574-8200, emailing a written request to <u>Patrick.Le@DCA.ca.gov</u> or mailing a written request to that person at the Department of Consumer Affairs, at 1625 North Market Blvd., Suite S-308, Sacramento, CA 95834. Providing your request at least five (5) business days before the meeting will help ensure availability of the requested accommodation.

Attachment 3

DOJ Certifies CURES for Statewide Use;

Mandatory Use by Prescribers Begins Oct. 2, 2018

On April 2, 2018, the California Department of Justice (DOJ) certified that CURES is ready for statewide use. Pursuant to <u>Health and Safety Code section 11165.4(e)</u>, beginning Oct. 2, 2018, certain health care practitioners must consult CURES before prescribing a Schedule II, III or IV controlled substance

- for the first time, and
- at least every four months thereafter, if the controlled substance remains part of the patient's treatment plan.

The requirement applies to health care practitioners who are authorized to prescribe, order, administer of furnish controlled substances, including:

- Dentists
- Physicians
- Naturopathic doctors
- Optometrists
- Osteopathic doctors
- Physician assistants
- Podiatrists
- Registered certified nurse midwives (furnishing)
- Registered nurse practitioners (furnishing)

The mandatory CURES review requirement **does not apply to pharmacists** (or veterinarians). Nevertheless, pharmacists already are heavily using the database to prevent the diversion and abuse of controlled substances. As of March 31, 2018, pharmacists make up 24 percent of all health care providers registered to use CURES. In addition, pharmacists ran 57 percent of all patient activity reports that were reviewed in CURES in March 2018.

The Medical Board of California has established a webpage with information for prescribers, including exemptions to consulting CURES.

The Board of Pharmacy provides resources and links to websites related to CURES for licensees at www.pharmacy.ca.gov/licensees/cures. The DOJ provides information about CURES registration, user guides and frequently asked questions found at www.oag.ca.gov/cures.

For questions about CURES or training requests, contact the CURES at CURES@doj.ca.gov or (916) 210-3187.

Attachment 4

Opioid Safety: Focus on Furnishing Naloxone

A GUIDE FOR CALIFORNIA COMMUNITY PHARMACISTS

Talia Puzantian, PharmD, BCPP Associate Professor Keck Graduate Institute School of Pharmacy James J. Gasper, PharmD, BCPP Psychiatric and Substance Use Disorder Pharmacist Pharmacy Benefits Division, California Department of Health Care Services

Program Support

This program was developed in collaboration with the San Francisco Department of Public Health and funded by the California Department of Public Health, supported by Grant Number 6NU17 CE002747 from the Centers for Disease Control and Prevention







Disclosures

None

Objectives

By the end of this session, you should be able to:

- 1. Describe the scope of the opioid overdose epidemic.
- 2. Explain the requirements of the Protocol for Pharmacists Furnishing Naloxone in California.
- 3. Identify and screen patients at risk of opioid overdose.
- 4. List the steps which must be taken to furnish and bill for naloxone.
- 5. Explain the mechanism of action, formulations, dosing, efficacy and safety of naloxone.
- 6. Describe how to provide education and training to patients and caregivers in opioid overdose prevention, recognition, response and naloxone administration.



What We'll Be Covering

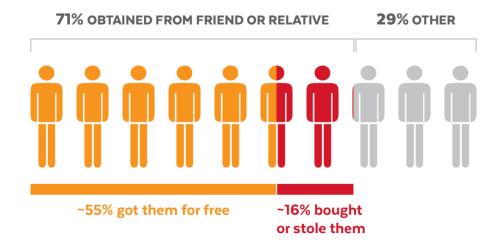
- » The scope of the opioid problem
- » The community pharmacist's role in opioid safety
- » Treating opioid use disorder
- » Providing access to naloxone
 - » Why should I furnish naloxone?
 - » Who should have naloxone?
 - » How do I furnish naloxone?

Epidemiologic Trends in Opioid Use and Overdose

- »Since 1999, sales of prescription opioids in the U.S. have quadrupled.¹
- »In 2014, 10.3 million persons reported using prescription opioids non-medically.²

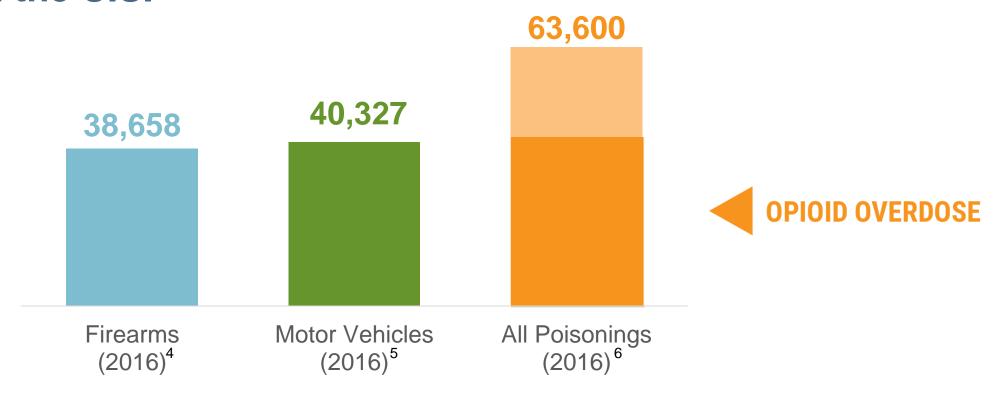


»>70% of people who abuse prescription opioids get them from a friend or relative.³



Drug Overdose Deaths

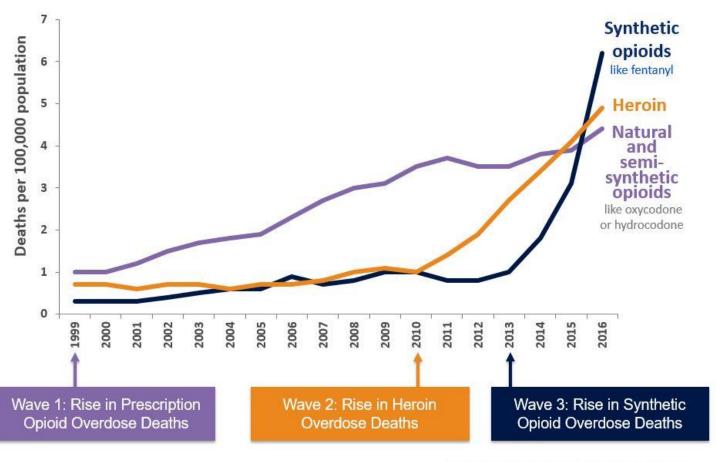
» Drug overdose is the leading cause of injury-related death in the U.S.



Opioid Overdose Deaths

» Drug overdose death rates, including those involving prescription opioids and heroin, continue to increase in the U.S.⁷



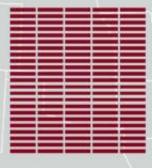


Opioid Overdose Deaths⁸

NATIONWIDE IMPACT

2 MILLION

Americans misused or were dependent on prescription opioid medications in 2014.



In 2016, an average of 115 people a day — some 42,000 Americans — overdosed on opioids and died.

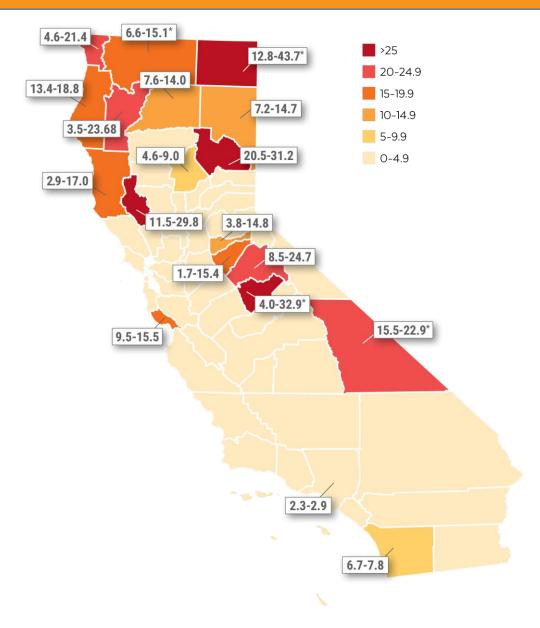


As many as 1 in 4 people who take prescription opioids long-term for pain (not related to cancer) struggles with addiction. Every day, more than 1,000 people are treated in emergency rooms across the nation for incorrectly using prescription opioids.

SOURCES: Centers for Disease Control and Prevention, American Society of Addiction Medicine

Opioid Overdose Deaths in California

Age-adjusted rate per 100,000 residents by county, 2012-2016.9



^{*}The following counties had zero deaths in noted years. Inyo: 2012, 2014, 2015. Mariposa: 2016. Modoc: 2015, 2016. Plumas: 2016. Siskiyou: 2013.

Community Pharmacist's Role in Opioid Safety



Pharmacists are uniquely poised to engage in efforts to reduce opioid misuse and opioid-related overdose

- » Preventing new cases of opioid addiction
- » Providing education about and referral to treatment for those already addicted
- » Helping reduce opioid overdose deaths by expanding pharmacy-based naloxone distribution

Ensure Appropriate Use of Opioids

- » Be well-versed in pain management
 - » CDC Guideline for Prescribing Opioids for Chronic Pain
- » Limit access to opioids for illegitimate use
 - » Look for red flags of misuse or diversion
 - » Use CURES
- » Provide opportunities for drug destruction and take-back
- » Become aware of treatment resources in your community
 - » Refer patients with opioid use disorder to medication-assisted treatment (MAT)



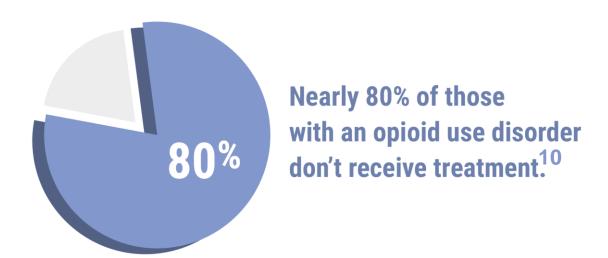




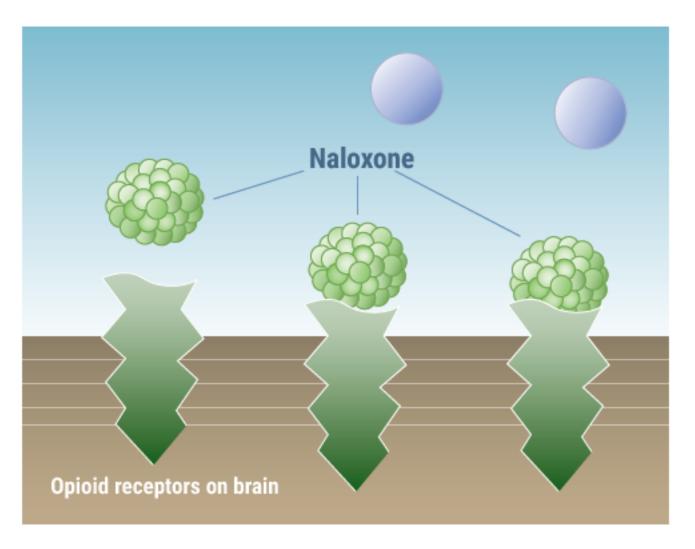


Medication-Assisted Treatment (MAT)

- » MAT for opioid use disorder increases recovery rates, decreases overdose deaths, decreases criminal activity, and lowers risk of infections such as HIV and hepatitis
 - » Buprenorphine and buprenorphine/naloxone
 - » Methadone
 - » Extended release naltrexone



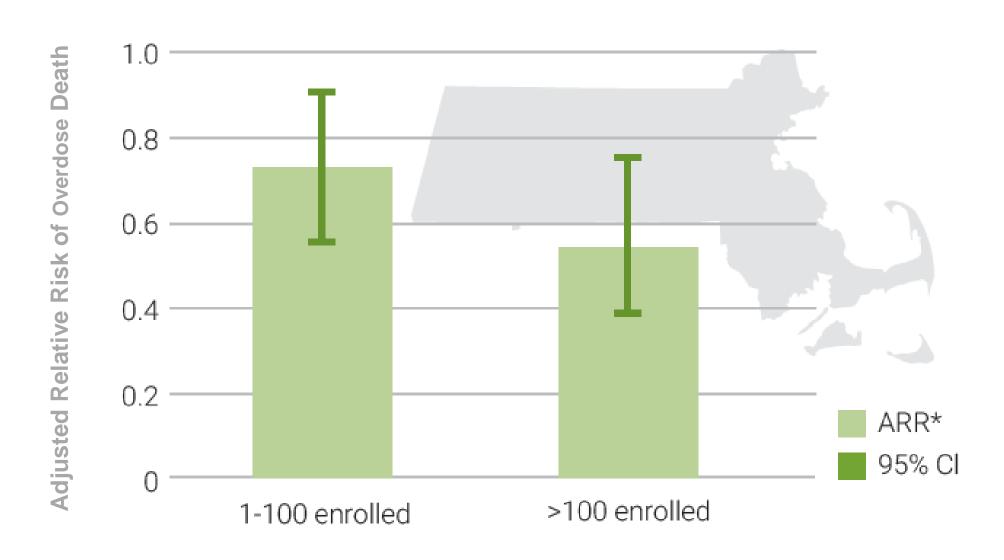
Naloxone



- Highly specific, high-affinity opioid antagonist used to reverse the effects of opioids
- Lasts 30-90 minutes
- Can be administered by laypeople
- Virtually no side effects or effects in the absence of opioids

Naloxone is not a controlled substance

Providing Naloxone to Laypeople is Effective¹¹

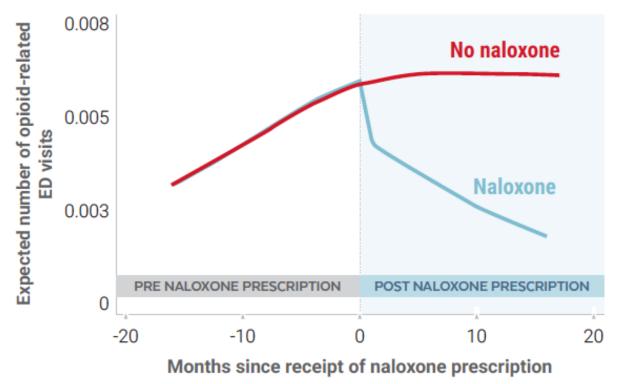


What About Non-injecting Opioid Users?¹²

- » More likely to use alone
- Less clearly defined community
- » Harder to target and educate

NALOXONE MAY REDUCE OPIOID RELATED ADVERSE EVENTS¹⁹

OPIOID RELATED EMERGENCY DEPARTMENT VISITS BY RECIPIENT OF NALOXONE PRESCRIPTION AMONG PRIMARY CARE PATIENTS ON OPIOID THERAPY FOR CHRONIC PAIN*



Prescribing naloxone to 29 patients averted 1 opioid-related emergency department visit in the following year.

^{*}In a population with a rate of opioid-related emergency department visits of 7/1000 person years.

Does Naloxone Encourage Greater Misuse of Opioids?¹³

Reactions to and Perceptions of Naloxone Prescription (N = 60)	No. (%)
Opioid-related behavior modification since receiving naloxone	
Positive	22 (37)
Neutral	38 (63)
Negative	0 (0)
Type of positive behavior modification (n = 8)	
Improved dosing	7 (88)
Improved timing	7 (88)
Improved knowledge around opioids and overdose	5 (63)
Decrease in polysubstance use	1 (12)
Decrease in using alone	1 (12)
Would want naloxone prescription in the future (n = 59)	
Yes	56 (95)
No	1 (2)
Do not know	2 (3)

Who Should Have Naloxone?



- » Patients at highest risk of overdose include
 - » Prior overdose

 - » Substance use disorder
 - » Concurrent benzodiazepine use
 - » Recent period of opioid abstinence
 - » Chronic medical illnesses that impact lung, liver, kidney functions
- » Patients, family members, friends requesting naloxone

Develop a Plan

Pharmacist fills prescription for opioid



Checks for naloxone in past year

Attaches
educational
brochure to each
opioid Rx

Asks if patient is interested in naloxone

Automatically furnishes if none in past year

Patient may request naloxone after review of brochure

If yes, furnishes and educates

How to Talk About Naloxone to Patients

» Avoid terms like "overdose"

- » Negative connotation
- » Patients equate it with heroin, addiction and illicit use
- » Prescription opioid users may not relate to it

» Instead, normalize it

"These medicines can be very strong and it's easy to have a bad reaction to them. So, I give all patients taking opioids this antidote in case that happens."



How to Talk About Naloxone to Patients

"Opioids can sometimes slow or even stop your breathing."

"Naloxone is the antidote to opioids—
it can be used if there is a bad reaction
where you can't be woken up."

"Naloxone is for opioid medication like an epinephrine pen is for someone with an allergy."

"Naloxone is important to have in the home in case someone is accidentally exposed to opioid painkillers."

Logistics: California State Board of Pharmacy Protocol for Furnishing Naloxone

- » Must meet training requirement (this program meets it)
- » Screen recipient of naloxone
 - » If patient uses or has history of using opioids
 - » If any known hypersensitivity to naloxone (unusual)
 - » Screening questions available in various languages (see Board website) http://www.pharmacy.ca.gov/licensees/naloxone_info.shtml
- » Provide education to person receiving naloxone (next slide)
- » Notify primary care provider if consent given by patient
- » Maintain records for at least three years
 - » As a prescription in pharmacy database, with pharmacist as prescriber on record
 - » If furnished to third party (family, friend), patient on record is the third party recipient

Furnishing Naloxone: Providing Education

Must provide education on the following (see slides that follow for details on each):

- » Overdose prevention, recognition, and response
- » Safe administration of naloxone (dosing, effectiveness, storage conditions, shelf-life)
- » Potential side effects
- » Importance of seeking emergency medical care
- » Availability of drug treatment programs
- » Educational <u>counseling may not be waived</u> by the person receiving naloxone

Educating Patients: Overdose Prevention

- » Only take medicine prescribed to you
- » Don't take more than prescribed; call doctor if pain not controlled
- » Don't mix with alcohol or sleeping pills
- » Don't use alone
- » Don't use opioids from an unknown source
- » Abstinence lowers tolerance; take less if restarting
- » Store in a secure place
- » Dispose of unused medications
- » Teach family and friends how to respond to an overdose and how to use naloxone
- » If you are having difficulty taking opioids safely, I can refer you to help









Educating Patients: Overdose Recognition

- »Slow or shallow breathing
- » Gasping for air while sleeping
- » Pale, clammy or bluish skin or fingernails
- » Slowed heartbeat
- » Low blood pressure
- » Won't wake up or respond (rub knuckles on sternum)

Educating Patients: Overdose Response

» Call 911

- » Quick response improves survival
- » Say "Someone is unresponsive and not breathing."
- » Give clear address and location

» Administer naloxone

- » Per instructions in patient education guides provided with products or view Prescribe to Prevent videos
- » Assess response, give repeat dose if no or minimal response in 2-3 minutes

Educating Patients: Overdose Response

» Follow 911 dispatcher instructions

- » Clear airway, give rescue breaths if not breathing and/or chest compressions
- » With victim laying flat on back, place one hand on chin, tilt head back, pinch nose closed, make seal over mouth, and breathe 1 breath every 5 seconds; chest should rise, not stomach
- » Stay until help arrives naloxone effects last 30-90 minutes
 - » Patient can go back into overdose
 - » Follow-up medical care after naloxone administration is important

Opioid safety and how to use naloxone



- Patient guide developed by SFDPH
- Available on Prescribe to Prevent website

In case of overdose:

1 Check reponsiveness

Look for any of the following:

- No reponse even if you shake them or say their name
- · Breathing slows or stops
- · Lips and fingernails turn blue or gray
- · Skin gets pale or clammy
- 2 Call 911 and give naloxone
 If no reaction in 3 minutes,
 give second naloxone dose
- 3 Do rescue breathing and/or chest compressions Follow 911 dispatcher instructions
 - >> STAY WITH PERSON
 UNTIL HELP ARRIVES.

How to give naloxone:

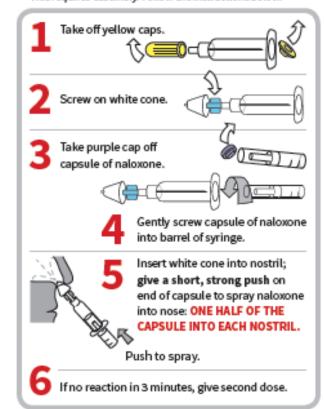
There are 4 common naloxone products. Follow the instructions for the type you have.

Nasal spray



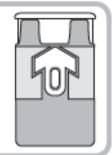
Nasal spray with assembly

This requires assembly. Follow the instructions below.



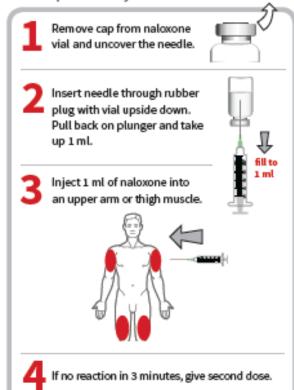
Auto-injector

The naloxone auto-injector needs no assembly and can be injected into the outer thigh, even through dothing. It contains a speaker that provides step-by-step instructions.



Injectable naloxone

This requires assembly. Follow the instructions below.





PRESCRIBERS PHARMACISTS

PATIENT EDUCATION

Videos for Download

RESEARCH & LEGAL ADVOCACY FAQ

CONTACT US

Materials

Videos

PRIMARY, CHRONIC PAIN AND PALLIATIVE CARE SET

Medical providers may have the opportunity to maximize patient quality of life those same medicines have contributed to the fact that drug overdose has over

Online Training

s, yet be the

ABOUT US

#1 cause of injury death in the United States. Providers can consider taking the stance of "risky medicines", instead of "risky patients" and engage in proactive dialogue with patients to minimize poisoning, over sedation, and overdose risk with patients who need opioid medications to improve function. Discussing an emergency overdose/poisoning/oversedation plan and naloxone prescribing is an essential component of that dialogue. We

provide some sample documents that may facilitate the process. Those desiring in-depth technical assistance can contact us for rates and availability at PrescribeToPrevent@gmail.com.

OVERDOSE RISK AND PATIENT HISTORY

- · Review medications
- Take a substance use history
- Check the prescription monitoring program
- · Take an overdose history Ask your patient whether they have:

PAGES IN THIS SECTION:

ENDORSEMENT

Primary, Chronic Pain and Palliative Care Settings

Emergency Medicine

Substance Use Disorder Treatment

CONTINUING EDUCATION UNITS

Prescribe to Prevent's CEU California Society of Addiction Medicine

Naloxone Formulations: Nasal Spray

Naloxone Nasal Spray

- » Naloxone 4 mg/0.1ml two pack
 - » NDC 69547-0353-02
- » Dispense #1 (two pack)
- »SIG: Use PRN for suspected opioid overdose. Spray into one nostril upon signs of opioid overdose. Repeat into other nostril after 2-3 minutes if no or minimal response. Call 911.



Naloxone Formulations: Auto-Injector

Evzio Auto-Injector

- » Naloxone 2 mg/0.4ml two pack
 - » NDC 60842-0051-01
- » Dispense #1 (two pack plus trainer)
- » SIG: Use PRN for suspected opioid overdose. Inject IM into outer thigh, depress and hold for 5 seconds, as directed by voice-prompt system upon signs of opioid overdose. Repeat with second device in 2-3 minutes if no or minimal response. Call 911.
- » Note: Evzio 0.4 mg auto-injector no longer manufactured



Naloxone Formulations: Injectable

Injectable – assembly required

- » Naloxone 0.4mg/ml 1ml single dose vial
 - » NDC# 00409-1215-01; 67457-0292-02; 00641-6132-25
- » Dispense #2
- » SIG: Use PRN for suspected opioid overdose. Inject 1ml IM in shoulder or thigh upon signs of opioid overdose. Repeat after 2-3 minutes if no or minimal respon
- » 3ml syringe with 25g 1" needle
- » Dispense #2
- » SIG: Use as directed for naloxone administration

Product Selection: Which to Furnish

» Convenience

» Nasal spray and auto-injector are easiest to use

» Cost

» Injectable single dose vials are lowest cost

Product Selection: Which NOT to Furnish

- » Buprenorphine/naloxone tablets or film
 - » Not appropriate for overdose reversal
 - » Naloxone is only added to buprenorphine as an abuse deterrent
- » Naloxone Carpuject Luer Lock Glass Syringe (no needle)
 - » NDC# 00409-1782-69
 - » Requires Carpuject Injector, difficult to assemble, not appropriate for lay administration
- » Min-I-Jet Fixed Needle Syringe
 - » NDC# 76329-1469-01
 - » Unable to affix nasal atomizer with fixed needle

DO NOT FURNISH THESE FOR TAKE-HOME REVERSAL OF AN OPIOID OVERDOSE!

Storage and Side Effects

- »Inform patients to alert others about naloxone, how to use it and where it's kept as it's not generally self-administered
- »Store at room temperature
- »Shelf life is 12-24 months

» Side effects:

- » Risk for withdrawal
- » Anxiety
- » Sweating
- » Nausea, vomiting
- » Shaking



Billing Issues

- » Naloxone furnished by pharmacists is covered by Medi-Cal
 - » Naloxone is a "carve out" medication; must be submitted directly to Fee For Service Medi-Cal, not the managed care Medi-Cal plan

National Plan & Provider Enumeration System

- » Also covered by many other third party payers when furnished by pharmacists
- » Prices for cash payment vary widely by formulation
- » Obtain a National Provider Identifier (NPI)
 - » This allows you to be prescriber on record
 - » nppes.cms.hhs.gov
- » Pharmacists who prescribe/furnish medications DO NOT need to be ORP (ordering, referring, or prescribing) providers with Medi-Cal for naloxone or other medications authorized under SB 493 to be covered
- » Third party prescribing must be billed under and dispensed to the person requesting it at the pharmacy

Billing Issues

» Pharmacist furnished naloxone <u>is billable</u> to Medi-Cal, Medicare Part D, and private insurances

» No separate prescription is needed to bill third party payers for naloxone

Any Legal Risk?



» California Civil Code §1714.22

- » Allows third party naloxone prescribing
- » Protects health care providers acting with reasonable care from civil and criminal liability when providing naloxone
- » Protects anyone administering naloxone (Good Samaritan)

» California Civil Code §11376.5

» Protects lay people from arrest for use or possession of small amounts of drugs when seeking medical assistance for a suspected drug overdose

And lastly...



- » Pharmacists continue to be among the most trusted professionals
- » Pharmacists are knowledgeable
- » Pharmacists are accessible
- » Pharmacists must become part of the solution for the opioid epidemic

NALOXONE SAVES LIVES...FURNISH IT!

Additional Resources

- » Prescribe to Prevent http://prescribetoprevent.org/
- » California State Board of Pharmacy http://www.pharmacy.ca.gov/licensees/naloxone_info.shtml
- » Centers for Disease Control and Prevention (CDC) https://www.cdc.gov/
- »Substance Abuse and Mental Health Services Administration (SAMHSA) https://www.samhsa.gov/
- » College of Psychiatric and Neurologic Pharmacists (CPNP) https://cpnp.org/guideline/naloxone

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- 1. Which of the following is the leading cause of injury-related death?
 - a) Motor vehicle accidents
 - b) Firearms
 - c) Drug overdoses
 - d) Natural disasters



- 2. How does naloxone work to reverse the effects of opioid overdose?
 - a) It increases the metabolism of opioids.
 - b) It antagonizes opioid receptors.
 - c) It is an opioid reuptake inhibitor.
 - d) It is a partial agonist at opioid receptors.



- 3. Which patients are at highest risk for opioid overdose?
 - a) Patients who also take benzodiazepines
 - b) Patients with substance use disorders
 - c) Patients with a recent period of opioid abstinence
 - d) Patients with a prior overdose
 - e) All of the above



- 4. When a California pharmacist is furnishing naloxone, the patient may not waive educational counseling.
 - a) True
 - b) False

5. When a California pharmacist is furnishing naloxone, the prescription CAN be billed to Medi-Cal and third party payers.

- a) True
- b) False



NALOXONE SAVES LIVES... FURNISH IT!

Attachment 5

Fiscal Year Comparison	Fiscal Year 15/16	Fiscal Year 16/17	Fiscal Year 17/18	% Change FY 15/16 to FY 17/18	Trend Lines
plaint Investigations					
Received	3,109	2,893	2,774	-11%	
Closed	2,898	3,116	3,127	8%	
Pending	2,345	2,241	1,968	-16%	
Compliance/Routine	1,079	879	781	-28%	
Drug Diversion/Fraud	429	413	330	-23%	_
Rx Abuse	124	153	69	-44%	
Compounding	105		100	-5%	
Outsourcing	N/A	80	39	N/A	
Probation/PRP	83		63	-24%	
Mediation/Enforcement	199		333	67%	
Criminal Conviction	326		256	-21%	$\overline{}$
Ciminal Conviction	320	311	230	-2170	
Received	547	507	532	-3%	
Closed	Т	T			
Approved	364		357	-2%	
Denied	89	74	79	-11%	
Total	609	532	540	-11%	
Pending	109	98	97	-11%	
LOA Issued	233	423	422	81%	
Citations Issued	1,970		2,168		
Proof Of Abatement Requested	20		30	50%	
Appeals Received	200		139	-31%	
Dismissed	30		46	53%	
Total Fines Collected	2,096,977		2,396,828	14%	
Referred to the AG's Office	413	351	350	-15%	
Pleadings Filed	342	271	307	-10%	
Pending					
Pre Accusation	258	241	207	-20%	
Post Accusation	279	214	257	-8%	
Total	602	468	458	-24%	
Closed					
Pharmacist	18	16	18	0%	
Intern Pharmacist	3	2	2	-33%	
Pharmacy Technician	112	109	79	-29%	
Designated Representative	2		0	-100%	
Wholesaler	0	1	2	N/A	
Sterile Compounding	0	1	1	N/A	
Pharmacy	6	11	8	33%	
Total	141	142	110	-22%	
Pharmacist	10		7	-30%	
Intern Pharmacist	0		0	0%	
Pharmacy Technician	1	5	0	-100%	
Designated Representative	0		0	0%	
Wholesaler	0		0	0%	
Sterile Compounding	0	0	0	0%	
Pharmacy	3	1	3	0%	
Total	14	20	10	-29%	

Fiscal Year Comparison	Fiscal Year 15/16	Fiscal Year 16/17	Fiscal Year 17/18	% Change FY 15/16 to FY 17/18	Trend Lines
Pharmacist	43	52	56	30%	
	43			100%	
Intern Pharmacist	10	13	2		
Pharmacy Technician	18		8	-56% 50%	
Designated Representative Wholesaler	2	0	3	200%	
Sterile Compounding	1	0	3	200%	
·	20				
Pharmacy Total	86	93	34 109	70% 27%	
Total	80] 33	109	27/0	
Pharmacist	19	30	20	5%	
Intern Pharmacist	1	4	0	-100%	
Pharmacy Technician	28	·	23	-18%	
Designated Representative	1	0	2	100%	
Wholesaler	1	0	1	0%	
Sterile Compounding	1	1	7	600%	
Pharmacy	19		24	26%	
Total	70	97	77	10%	
Trocar	70			10/0	
Pharmacist	6	27	12	100%	
Intern Pharmacist	0		0	0%	
Pharmacy Technician	2	3	5	150%	
Designated Representative	0	1	2	N/A	
Wholesaler	3	1	1	-67%	
Sterile Compounding	2	2	1	-50%	
Pharmacy	7	10	10	43%	
Total	20	44	31	55%	
1.000				22,0	
Pharmacist	5	4	2	-60%	
Intern Pharmacist	0		6	N/A	
Pharmacy Technician	21	6	8	-62%	
Designated Representative	0	1	0	0%	
Wholesaler	1	0	0	-100%	
Sterile Compounding	2	0	0	-100%	
Pharmacy	2	0	0	-100%	
Total	31	13	16	-48%	
,	•				
Pharmacist	0	0	0	0%	
Intern Pharmacist	1	0	0	-100%	
Pharmacy Technician	21	12	7	-67%	
Designated Representative	0	0	1	N/A	
Wholesaler	0	0	0	0%	
Sterile Compounding	0	0	2	N/A	
Pharmacy	0	0	0	0%	
Total	22	12	10	-55%	
Cost Recovery Requested	1,407,769		1,659,726		
Cost Recovery Collected	1,204,300			-38%	
Interim Suspension Order	11	2	7	-36%	
Automatice Suspensions	2	1	6	200%	
Penal Code 23 Restrictions	26	9	8	-69%	
Cease and Desist - Unlicensed	N/A	N/A	1	N/A	
Cease and Desist - Sterile Compounding	1		2	100%	

Board of Pharmacy Enforcement Statistics

Fiscal Year Comparison	Fiscal Year 15/16	Fiscal Year 16/17	Fiscal Year 17/18	% Change FY 15/16 to FY 17/18	Trend Lines
Licenses on Probation					
Pharmacist	165	190	220	33%	
Intern Pharmacist	3	4	8	167%	
Pharmacy Technician	38	36	29	-24%	
Designated Representative	1	0	2	100%	
Wholesaler	3	62	77	2467%	
Sterile Compounding	11	12	15	36%	
Pharmacy	49	62	77	57%	
Total	270	366	428	59%	
Probation Office Conferences	120	105	112	-7%	
Probation Site Inspections **	447	586	532	19%	
Successful Completion	20	33	33	65%	
Referred to AG for non-compliance	9	8	8	-11%	

				% CHANGE FY 15/16 to	
FISCAL YEAR COMPARISON	FY 15/16	FY 16/17	FY 17/18	FY 17/18	TREND LINES
<u>APPLICATIONS</u>					
A. Received					
Designated Representatives (EXC)	503	488	t	-11%	
Designated Representatives Vet (EXV)	199	10	2 82	-71%	
Designated Representatives-3PL (DRL) Designated Paramedic (DPM)	n/a	75 n/a	02	-59% n/a	
Designated Representatives-Reverse Distributor (DRR)	n/a	n/a	0	n/a	
Intern Pharmacist (INT)	2361	2462	2395	1%	
Pharmacist (exam applications)	3028	3332	3543	17%	
Pharmacist (initial licensing applications)	1959	1865	2019	3%	
Advanced Practice Pharmacist (APH)	n/a	256	258	n/a	
Pharmacy Technician (TCH)	6257	6262	5420	-13%	
Centralized Hospital Packaging (CHP)	1	0	· · · · · · · · · · · · · · · · · · ·	200%	
Clinics (CLN)	119	82	93	-22%	
Clinics Exempt (CLE)	21	33		-48% 100%	
Drug Room (DRM) Drug Room -Temp	3	1	0	-100% -100%	
Drug Room Exempt (DRE)	0	0	1	-100 / ₈ n/a	
Emergency Medical Services Automated Drug Delivery System	n/a	n/a	0	n/a	
Hospitals (HSP)	28	17	22	-21%	
Hospitals - Temp	12	14	16	33%	
Hospitals Exempt (HPE)	3	1	3	0%	
Hospital Satellite Sterile Compounding (SCP)	n/a	n/a	3	n/a	
Hospital Satellite Sterile Compounding - Temp	n/a	n/a	0	n/a	
Hospital Satellite Sterile Compounding Exempt (SCE)	n/a	n/a	0	n/a	
Hypodermic Needle and Syringes (HYP)	14	20	20	43%	
Hypodermic Needle and Syringes Exempt (HYE)	0	0	0	0%	
Correctional Pharmacy (LCF)	2	4	3	50%	
Outsourcing Facility (OSF)	n/a	7	1	n/a	
Outsourcing Facility - Temp	n/a	0	0	n/a	
Outsourcing Facility Nonresident (NSF) Outsourcing Facility Nonresident - Temp	n/a n/a	33	9	n/a n/a	
Pharmacy (PHY)	754	1139	1232	63%	
Pharmacy - Temp	419	834	178	-58%	
Pharmacy Exempt (PHE)	9	4	6	-33%	
Remote Dispensing Pharmacy (PHR)	n/a	n/a	0	n/a	
Pharmacy Nonresident (NRP)	171	124	136	-20%	
Pharmacy Nonresident Temp	35	32	55	57%	
Sterile Compounding (LSC)	89	73	105	18%	
Sterile Compounding - Temp	38	31	37	-3%	
Sterile Compounding Exempt (LSE)	7	1	5	-29%	
Sterile Compounding Nonresident (NSC)	37	23	18	-51%	
Sterile Compounding Nonresident Temp	9	5	11	22%	
Surplus Medication Collection Distribution Intermediary (SME)	1	0	0	-100%	
Third-Party Logistics Providers (TPL)	14	2	4	-71%	
Third-Party Logistics Providers - Temp Third-Party Logistics Providers Nonresident (NPL)	52	3 17	19	n/a -63%	
Third-Party Logistics Providers Norresident Temp	1	3	7	600%	
Veterinary Food-Animal Drug Retailer (VET)	6	1	0	-100%	
Veterinary Food-Animal Drug Retailer - Temp	5	0	0	-100%	
Wholesalers (WLS)	97	71	83	-14%	
Wholesalers - Temp	12	16	35	192%	
Wholesalers Exempt (WLE)	0	1	2	n/a	
Wholesalers Nonresident (OSD)	122	133	133	9%	
Wholesalers Nonresident - Temp	28	27	36		
Total	16424	17504	16459	0%	

				% CHANGE FY 15/16 to	
APPLICATIONS (continued)	FY 15/16	FY 16/17	FY 17/18	FY 17/18	TREND LINES
B. Issued					
Designated Representatives (EXC)	422	380	387	-8%	
Designated Representatives (EXV)	3	11	2	-33%	
Designated Representatives-3PL (DRL)	187	79	64	-66%	
Designated Paramedic (DPM)	n/a	n/a	0	n/a	
Designated Representatives-Reverse Distributor (DRR)	n/a	n/a	0	n/a	
Intern Pharmacist (INT)	2116	2224	2210	4%	
Pharmacist (RPH)	1978	1828	2065	4%	
Advanced Practice Pharmacist (APH)	n/a	130	204	n/a	
Pharmacy Technician (TCH)	5851	5993	5282	-10%	
Centralized Hospital Packaging (CHP)	3	2	3	0%	
Clinics (CLN)	96	121	49	-49%	
Clinics Exempt (CLE)	14	28	10	-29%	
Drug Room (DRM)	2	1	0	-100%	
Drug Room -Temp	2	2	0	-100%	
Drug Room Exempt (DRE)	0	0	0	0%	
Emergency Medical Services Automated Drug Delivery System	n/a	n/a	0	n/a	
Hospitals (HSP)	10	11	3	-70%	
Hospitals - Temp	10	14	11	10%	
Hospitals Exempt (HPE)	4	2	3	-25%	
Hospital Satellite Sterile Compounding (SCP)	n/a	n/a	0	n/a	
Hospital Satellite Sterile Compounding - Temp	n/a	n/a	0	n/a	
Hospital Satellite Sterile Compounding Exempt (SCE)	n/a	n/a	0	n/a	
Hypodermic Needle and Syringes (HYP)	14	15	6	-57%	
Hypodermic Needle and Syringes Exempt (HYE)	0	0	0	0%	
Correctional Pharmacy (LCF)	2	4	1	-50%	
Outsourcing Facility (OSF)	n/a	0	2	n/a	
Outsourcing Facility - Temp	n/a	0	0	n/a	
Outsourcing Facility Nonresident (NSF)	n/a	2	15	n/a	
Outsourcing Facility Nonresident - Temp	n/a	0	2	n/a	
Pharmacy (PHY)	671	333	243	-64%	
Pharmacy - Temp	57 7	194	135	137% -43%	
Pharmacy Exempt (PHE) Remote Dispensing Pharmacy (PHR)	n/a	n/a	0		
Pharmacy Nonresident (NRP)	113	92	68	n/a -40%	
Pharmacy Nonresident Temp	22	28	43	95%	
Sterile Compounding (LSC)	46	40	33	-28%	
Sterile Compounding - Temp	16	31	35	119%	
Sterile Compounding Exempt (LSE)	7	3	7	0%	
Sterile Compounding Nonresident (NSC)	16	15	6	-63%	
Sterile Compounding Nonresident Temp	7	7	4	-43%	
Surplus Medication Collection Distribution Intermediary (SME)	. 1	0	0	-100%	
Third-Party Logistics Providers (TPL)	15	6	1	-93%	
Third-Party Logistics Providers - Temp	1	1	1	0%	
Third-Party Logistics Providers Nonresident (NPL)	58	6	4	-93%	
Third-Party Logistics Providers Nonresident Temp	0	0	6	n/a	
Veterinary Food-Animal Drug Retailer (VET)	5	1	1	-80%	
Veterinary Food-Animal Drug Retailer - Temp	0	0	0	0%	
Wholesalers (WLS)	64	63	53	-17%	
Wholesalers - Temp	0	5	20	n/a	
Wholesalers Exempt (WLE)	0	1	1	n/a	
Wholesalers Nonresident (OSD)	88	95	59	-33%	
Wholesalers Nonresident - Temp	3	9	24	700%	
Total	11911	11784	11067	-7%	

### CPLICATIONS (continued) FY 15/16 FY 15/16 FY 15/17 FY 17/18 FY 15/16 TRE	END LINES
Designated Representatives (EXC)	
Designated Representatives (EXC)	
Designated Representatives Vet (EXV)	
Designated Paramedic (DPM)	
Designated Representatives-Reverse Distributor (DRR)	
Intern Pharmacist (INT)	
Pharmacist (exam applications) 1326 1553 1272 -4%	
Pharmacist (eligible)	
Advanced Practice Pharmacist (APH) n/a 121 174 n/a 1530 1641 1176 -23% 1530 1641 1176 -23% 1530 1641 1176 -23% 1761 1176 -23% 1761 1176 -23% 1761 1176 -23% 1761 1176 -23% 1761 1176 -23% 1761 1176 -23% 1761 1176 -23% 1761 1176 -23% 1761 1176 -23% 1761 1176 -23% 1761 1176 -23% 1761 11	
Pharmacy Technician (TCH) 1530 1641 1176 -23%	
Centralized Hospital Packaging (CHP) 9 5 2 -78% Clinics (CLN) 95 39 80 -16% Clinics Exempt (CLE) 16 10 11 -31% Drug Room (DRM) 3 0 0 -100% Drug Room Exempt (DRE) 0 0 1 n/a Emergency Medical Services Automated Drug Delivery System n/a n/a 0 n/a Hospitals (HSP) 19 4 8 -58% Hospitals Exempt (HPE) 1 1 0 -100% Hospital Satellite Sterile Compounding (SCP) n/a n/a 3 n/a Hospital Satellite Sterile Compounding Exempt (SCE) n/a n/a 0 n/a Hypodermic Needle and Syringes (HYP) 10 9 24 140% Hypodermic Needle and Syringes Exempt (HYE) 0 0 0 0 Correctional Pharmacy (LCF) 1 1 1 0 Outsourcing Facility (OSF) n/a 6 3 n/a Outsourcing Facility Nonresident (NSF) n/a 28 15 n/a	
Clinics (CLN)	
Clinics (CLN)	
Clinics Exempt (CLE)	
Drug Room (DRM) 3 0 0 -100% Drug Room Exempt (DRE) 0 0 1 n/a Emergency Medical Services Automated Drug Delivery System n/a n/a 0 n/a Hospitals (HSP) 19 4 8 -58% Hospitals Exempt (HPE) 1 1 0 -100% Hospital Satellite Sterile Compounding (SCP) n/a n/a 3 n/a n/a Hospital Satellite Sterile Compounding Exempt (SCE) n/a n/a 0 n/a n/a 0 n/a 1 1 0 n/a 1 1 0 0 0 n/a 1 0	
Drug Room Exempt (DRE) Emergency Medical Services Automated Drug Delivery System Hospitals (HSP) Hospitals Exempt (HPE) Hospital Satellite Sterile Compounding (SCP) Hospital Satellite Sterile Compounding Exempt (SCE) Hypodermic Needle and Syringes (HYP) Hypodermic Needle and Syringes Exempt (HYE) Correctional Pharmacy (LCF) Outsourcing Facility (OSF) Outsourcing Facility Nonresident (NSF)	
Emergency Medical Services Automated Drug Delivery System Hospitals (HSP) Hospitals Exempt (HPE) Hospital Satellite Sterile Compounding (SCP) Hospital Satellite Sterile Compounding Exempt (SCE) Hypodermic Needle and Syringes (HYP) Hypodermic Needle and Syringes Exempt (HYE) Correctional Pharmacy (LCF) Outsourcing Facility (OSF) Outsourcing Facility Nonresident (NSF)	
Hospitals (HSP) Hospitals Exempt (HPE) Hospital Satellite Sterile Compounding (SCP) Hospital Satellite Sterile Compounding Exempt (SCE) Hypodermic Needle and Syringes (HYP) Hypodermic Needle and Syringes Exempt (HYE) Correctional Pharmacy (LCF) Outsourcing Facility (OSF) Outsourcing Facility Nonresident (NSF)	
Hospitals Exempt (HPE) Hospital Satellite Sterile Compounding (SCP) Hospital Satellite Sterile Compounding Exempt (SCE) Hypodermic Needle and Syringes (HYP) Hypodermic Needle and Syringes Exempt (HYE) Correctional Pharmacy (LCF) Outsourcing Facility (OSF) Outsourcing Facility Nonresident (NSF) 1 1 0 -100% n/a 3 n/a 0 n/a 0 n/a 0 n/a 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	
Hospital Satellite Sterile Compounding Exempt (SCE) Hypodermic Needle and Syringes (HYP) Hypodermic Needle and Syringes Exempt (HYE) Correctional Pharmacy (LCF) Outsourcing Facility (OSF) Outsourcing Facility Nonresident (NSF) n/a n/a n/a 0 n/a 0 n/a 0 0 0 0 0 0 0 0 0 0 0 0 0	
Hypodermic Needle and Syringes (HYP) 10 9 24 140%	
Hypodermic Needle and Syringes Exempt (HYE) 0 0 0 0% — Correctional Pharmacy (LCF) 1 1 1 1 0% — Outsourcing Facility (OSF) n/a 6 3 n/a — Outsourcing Facility Nonresident (NSF) n/a 28 15 n/a	
Correctional Pharmacy (LCF) 1 1 1 0% Outsourcing Facility (OSF) n/a 6 3 n/a Outsourcing Facility Nonresident (NSF) n/a 28 15 n/a	_/
Outsourcing Facility (OSF) Outsourcing Facility Nonresident (NSF) n/a 6 3 n/a 7 n/a 28 15 n/a	
Outsourcing Facility Nonresident (NSF) n/a 28 15 n/a	
Pharmacy (PHY) 165 133 693 320%	
Pharmacy Exempt (PHE) 5 1 3 -40%	
Remote Dispensing Pharmacy (PHR) n/a n/a 0 n/a	
Pharmacy Nonresident (NRP) 121 100 91 -25%	
Sterile Compounding (LSC) 44 34 69 57% —	
Sterile Compounding Exempt (LSE) 6 5 7 17%	
Sterile Compounding Nonresident (NSC) 36 18 22 -39%	
Surplus Medication Collection Distribution Intermediary (SME) 0 0 0 0%	
Third-Party Logistics Providers (TPL) 10 8 9 -10%	
Third-Party Logistics Providers Nonresident (NPL) 46 43 49 7% 40 40 40 40 40 40 40 40 40 40 40 40 40	$\overline{}$
Veterinary Food-Animal Drug Retailer 2 1 0 -100% Whatesplace (WLS)	
Wholesalers (WLS) 72 38 43 -40% Wholesalers Fyomet (WLS) 0 4 -9	
Wholesalers Exempt (WLE) 0 0 1 n/a Wholesalers Nonresident (OSD) 117 81 120 3%	
Wholesalers Nonresident (OSD) 117 81 120 3% Total 6097 6565 7024 15%	
The number of temporary applications pending is reflected in the number reported for the primary license type.	

APPLICATIONS (continued)	FY 15/16	FY 16/17	FY 17/18	% CHANGE FY 15/16 to FY 17/18	TREND LINES
D. Withdrawn					
Designated Representatives (EXC)	51	41	19	-63%	
Designated Representatives Vet (EXV)	3	1	0	-100%	
Designated Representatives-3PL (DRL)	7	13	4	-43%	
Designated Paramedic (DPM)	n/a	n/a	0	n/a	
Designated Representatives-Reverse Distributor (DRR)	n/a	n/a	0	n/a	
Intern Pharmacist (INT)	1	40	5	400%	
Pharmacist (Exam)*	3	6	764	25367%	
Advanced Practice Pharmacist (APH)	n/a	0	1	n/a	
Pharmacy Technician (TCH)	286	82	540	89%	
* FY 17/18 There were 764 Pharmacist (exam) applications withdra	awn as a result o	of redirection of	of staff to ident	tify abandoned ap	plications
Centralized Hospital Packaging (CHP)	2	3	3	50%	
Clinics (CLN)	6	11	2	-67%	
Clinics Exempt (CLE)	0	6	4	n/a	
Drug Room (DRM)	0	2	0	0%	
Drug Room Exempt (DRE)	0	0	0	0%	
Emergency Medical Services Automated Drug Delivery System	n/a	n/a	0	n/a	
Hospitals (HSP)	5	6	2	-60%	
Hospitals Exempt (HPE)	1	0	0	-100%	
Hospital Satellite Sterile Compounding (SCP)	n/a	n/a	0	n/a	
Hospital Satellite Sterile Compounding Exempt (SCE)	n/a	n/a	0	n/a	
Hypodermic Needle and Syringes (HYP)	8	7	1	-88%	
Hypodermic Needle and Syringes Exempt (HYE)	0	0	0	0%	
Correctional Pharmacy (LCF)	0	0	2	n/a	
Outsourcing Facility (OSF)	n/a	0	0	n/a	
Outsourcing Facility Nonresident (NSF)	n/a	0	2	n/a	
Pharmacy (PHY) **	38	620	45	18%	
Pharmacy Exempt (PHE)	0	2	0	0%	
Remote Dispensing Pharmacy (PHR)	n/a	n/a	0	n/a	
Pharmacy Nonresident (NRP)	128	21	29	-77%	
Sterile Compounding (LSC)	17	4	1	-94%	
Sterile Compounding Exempt (LSE)	1	0	2	100%	
Sterile Compounding Nonresident (NSC)	13	17	4	-69%	
Surplus Medication Collection Distribution Intermediary (SME)	0	0	0	0%	
Third-Party Logistics Providers (TPL)	1	3	1	0%	
Third-Party Logistics Providers Nonresident (NPL)	5	8	2	-60%	
Veterinary Food-Animal Drug Retailer (VET)	0	1	0	0%	
Wholesalers (WLS)	8	25	7	-13%	
Wholesalers Exempt (WLE)	0	0	0	0%	
Wholesalers Nonresident (OSD)	15	58	10	-33%	
Total	599	977	1450	142%	

The number of temporary applications withdrawn is reflected in the number reported for the primary license type.

^{**} FY 16/17 There were 577 pharmacy applications withdrawn as a result of cancellation of large corporate change of ownership.

				% CHANGE FY 15/16 to	
APPLICATIONS (continued)	FY 15/16	FY 16/17	FY 17/18	FY 17/18	TREND LINES
E. Denied					
Designated Representatives (EXC)	1	0	1	0%	
Designated Representatives Vet (EXV)	0	0	0	0%	
Designated Representatives-3PL (DRL)	0	0	0	0%	
Designated Paramedic (DPM)	n/a	n/a	0	n/a	
Designated Representatives-Reverse Distributor (DRR)	n/a	n/a	0	n/a	
Intern Pharmacist (INT)	4	5	5	25%	
Pharmacist (exam applications)	10	5	8	-20%	
Pharmacist (eligible)	1	0	0	-100%	
Advanced Practice Pharmacist (APH)	n/a	0	0	n/a	
Pharmacy Technician (TCH)	62	46	37	-40%	
Centralized Hospital Packaging (CHP)	0	0	0	0%	
Clinics (CLN)	0	0	0	0%	
Clinics Exempt (CLE)	0	0	0	0%	
Drug Room (DRM)	0	0	0	0%	
Drug Room Exempt (DRE)	0	0	0	0%	
Emergency Medical Services Automated Drug Delivery System	n/a	n/a	0	n/a	
Hospitals (HSP)	0	0	0	0%	
Hospitals Exempt (HPE)	0	0	0	0%	
Hospital Satellite Sterile Compounding (SCP)	n/a	n/a	0	n/a	
Hospital Satellite Sterile Compounding Exempt (SCE)	n/a	n/a	0	n/a	
Hypodermic Needle and Syringes (HYP)	0	0	0	0%	
Hypodermic Needle and Syringes Exempt (HYE)	0	0	0	0%	
Correctional Pharmacy (LCF)	0	0	0	0%	
Outsourcing Facility (OSF)	n/a	1	2	n/a	
Outsourcing Facility Nonresident (NSF)	n/a	0	4	n/a	
Pharmacy (PHY)	17	13	14	-18%	
Pharmacy Exempt (PHE)	0	0	0	0%	
Remote Dispensing Pharmacy (PHR)	n/a	n/a	0	n/a	
Pharmacy Nonresident (NRP)	0		4	100%	
Sterile Compounding (LSC) Sterile Compounding Exempt (LSE)	0	0	0	n/a 0%	
Sterile Compounding Nonresident (NSC)	2	2	0	-100%	
Surplus Medication Collection Distribution Intermediary (SME)	0	0	0	0%	
Third-Party Logistics Providers (TPL)	0	0	0	0%	
Third-Party Logistics Providers Nonresident (NPL)	0	0	0	0%	
Veterinary Food-Animal Drug Retailer (VET)	0	0	0	0%	
Wholesalers (WLS)	0	1	1	n/a	
Wholesalers Exempt (WLE)	0	0	0	0%	
Wholesalers Nonresident (OSD)	0	0	0	0%	
Total	99	77	77	-22%	
The number of temporary applications denied is reflected in the number	r reported for t	the primary lice	ense type.		

				% CHANGE FY 15/16 to	
RESPOND TO STATUS REQUESTS	FY 15/16	FY 16/17	FY 17/18	FY 17/18	TREND LINES
A Empil Inquision					
A. Email Inquiries	n/a	n/a	1134	n/a	
Designated Represenative Received Designated Represenative Responded	n/a	n/a	447	n/a	
Pharmacist/Intern/Advanced Practice Pharmacist Received	4856	6906	8775	81%	
Pharmacist/Intern/Advanced Practice Pharmacist Responded	4636 n/a	5625	6452		
Pharmacy Technician Received	1943	5315	4914	153%	
Pharmacy Technician Responded	n/a	4451	4914	n/a	
Pharmacy Received	4631	6922	6365	37%	
Pharmacy Responded	n/a	6865	6183		
Sterile Compounding/Outsourcing/CHP Received	n/a	4353	4614	n/a	
Sterile Compounding/Outsourcing/CHP Responded	n/a	4299	4075	n/a	
Wholesale/Clinic/Hypodermic/3PL Received	4293	4669	4071	-5%	
Wholesale/Clinic/Hypodermic/3PL Responded	n/a	4832	3447		
Change of PIC/DRIC/RMG and DOB Received	1438	1616	1681	17%	
Change of PIC/DRIC/RMG and DOB Responded	n/a	1111	1311	n/a	
Change of Permit Received	3747	5029	5559	48%	
Change of Permit Responded	n/a	3815	4515	n/a	
Renewals Received	1990	4349	5389	171%	
Renewals Responded	n/a	3347	4412	n/a	
	.40	33.1.			
B. Telephone Calls Received					
Designated Represenative	n/a	n/a	27	n/a	
Pharmacist/Intern/Advanced Practice Pharmacist	n/a	1038	425	n/a	
Pharmacy	1600	1106	907	-43%	
Sterile Compounding/Outsourcing/CHP	n/a	582	411	n/a	
Wholesale/Clinic/Hypodermic/3PL	1511	939	570	-62%	
Change of PIC/DRIC/RMG and DOB	1035	722	655	-37%	
Change of Permit	1035	696	787	-24%	
Renewals	7678	7460	7784	1%	
*** The board did not collected the data separately for the items identified a	as "n/a" during F	Y 15/16 and FY	16/17.		

				% CHANGE FY 15/16 to	
UPDATE LICENSING RECORDS	FY 15/16	FY 16/17	FY 17/18	FY 17/18	TREND LINES
A. Change of Pharmacist-in-Charge					
Received	2391	2290	2193	-8%	
Processed	2428	2321	2001	-18%	
Approved	2515	2315	2037	-19%	
Pending	303	286	452	49%	
B. Change of Designated Representative-in-Charge					
Received	173	155	120	-31%	
Processed	181	157	114	-37%	
Approved	209	149	101	-52%	
Pending	23	30	48	109%	
			•		
C. Change of Responsible Manager Received	ما	40	24	44000/	
Processed	2	18 20	24 18	1100% 1700%	
Approved	3	13	16	433%	
Pending	2	6	12	500%	
				00070	
D. Change of Permit			ı		
Received	1870	1845	1736	-7%	
Processed	2079	1789	1720	-17%	
Approved	1717	1842	1618	-6%	
Pending	849	910	930	10%	
E. Automated Drug Delivery Systems					
Received	n/a	641	240	n/a	
Processed	n/a	1	844	n/a	
Approved	n/a	0	807	n/a	
Pending	n/a	640	37	n/a	
F. Clinic Co-Location					
Received	n/a	n/a	1	n/a	
Processed	n/a	n/a	0	n/a	
Approved	n/a	n/a	0	n/a	
Pending	n/a	n/a	1	n/a	
G. Discontinuance of Business	40.5	400	400		
Received	432	402	409	-5%	
Processed	423 439	394 387	357 327	-16% -26%	
Approved Pending	102	120	199	95%	
1 chains	102	120	199	95 /0	
H. Requests Processed	•				
Address/Name Changes	11992	11558	11411	-5%	
Off-site Storage	163	214	170	4%	
Transfer of Intern Hours	59	60	74	25%	
License Verification	2019	1733	2234	11%	

				% CHANGE	
Licenses Renewed	FY 15/16	FY 16/17	FY 17/18	FY 15/16 to FY 17/18	TREND LINES
Licenses Renewed	F1 13/10	F1 10/17	F1 17/10	1111110	TREND LINES
Designated Representatives (EXC)	2502	2477	2476	-1%	
Designated Representatives Vet (EXV)	66	60	58	-12%	
Designated Representatives-3PL (DRL)	53	181	202	281%	
Designated Paramedic (DPM)	n/a	n/a	0	n/a	
Designated Representatives-Reverse Distributor (DRR)	n/a	n/a	0	n/a	
Pharmacist (RPH)	20400	20029	20663	1%	
Advanced Practice Pharmacist (APH)	n/a	20029	91	n/a	
Pharmacy Technician (TCH)	30914	30666	30151	-2%	
Friamiacy recillician (TOH)	30914	30000	30131	-2 /0	
Centralized Hospital Packaging (CHP)	0	6	9	n/a	
Clinics (CLN)	975	992	1035	6%	
Clinics Exempt (CLE)	212	217	233	10%	
Drug Room (DRM)	19	21	24	26%	
Drug Room Exempt (DRE)	12	11	10	-17%	
Emergency Medical Services Automated Drug Delivery System	n/a	n/a	0	n/a	
Hospitals (HSP)	388	376	390	1%	
Hospitals Exempt (HPE)	81	85	108	33%	
Hospital Satellite Sterile Compounding (SCP)	n/a	n/a	0	n/a	
Hospital Satellite Sterile Compounding Exempt (SCE)	n/a	n/a	0	n/a	
Hypodermic Needle and Syringes (HYP)	259	260	216	-17%	
Hypodermic Needle and Syringes Exempt (HYE)	0	0	0	0%	
Correctional Pharmacy (LCF)	53	55	60	13%	
Outsourcing Facility (OSF)	n/a	0	0	n/a	
Outsourcing Facility Nonresident (NSF)	n/a	0	3	n/a	
Pharmacy (PHY)	6227	6153	6242	0%	
Pharmacy Exempt (PHE)	123	124	140	14%	
Remote Dispensing Pharmacy (PHR)	n/a	n/a	0	n/a	
Pharmacy Nonresident (NRP)	391	425	449	15%	
Sterile Compounding (LSC)	761	724	709	-7%	
Sterile Compounding Exempt (LSE)	115	116	143	24%	
Sterile Compounding Nonresident (NSC)	76	76	70	-8%	
Surplus Medication Collection Distribution Intermediary (SME)	0	1	1	n/a	
Third-Party Logistics Providers (TPL)	1	17	19	1800%	
Third-Party Logistics Providers Nonresident (NPL)	12	59	52	333%	
Veterinary Food-Animal Drug Retailer (VET)	24	17	18	-25%	
Wholesalers (WLS)	455	434	456	0%	
Wholesalers Exempt (WLE)	9	13	15	67%	
Wholesalers Nonresident (OSD)	601	608	601	0%	
Total	64729	64206	64644	0%	
	5 20	3 .230	3.3.1	370	

License Population	FY 15/16	FY 16/17	FY 17/18	% CHANGE FY 15/16 to FY 17/18	TREND LINES
<u>Elicense Population</u>	1113/10	1 1 10/17	1111/10		TREND LINES
Designated Representatives (EXC)	3055	2983	3004	-2%	
Designated Representatives Vet (EXV)	64	72	69	8%	
Designated Representatives-3PL (DRL)	198	275	286	44%	
Designated Paramedic (DPM)	n/a	n/a	0	n/a	
Designated Representatives-Reverse Distributor (DRR)	n/a	n/a	0	n/a	
Intern Pharmacist (INT)	6364	6900	6800	7%	
Pharmacist (RPH)	43818	44904	45988	5%	
Advanced Practice Pharmacist (APH)	n/a	104	334	n/a	
Pharmacy Technician (TCH)	73289	72452	71360	-3%	
Centralized Hospital Packaging (CHP)	8	8	10	25%	
Clinics (CLN)	1073	1098	1109	3%	
Clinics Exempt (CLE)	235	240	242	3%	
Drug Room (DRM)	23	23	23	0%	
Drug Room Exempt (DRE)	13	11	9	-31%	
Emergency Medical Services Automated Drug Delivery System	n/a	n/a	0	n/a	
Hospitals (HSP)	395	396	383	-3%	
Hospitals Exempt (HPE)	87	84	85	-2%	
Hospital Satellite Sterile Compounding (SCP)	n/a	n/a	0	n/a	
Hospital Satellite Sterile Compounding Exempt (SCE)	n/a	n/a	0	n/a	
Hypodermic Needle and Syringes (HYP)	285	294	293	3%	
Hypodermic Needle and Syringes Exempt (HYE)	0	0	0	0%	
Correctional Pharmacy (LCF)	55	59	58	5%	
Outsourcing Facility (OSF)	n/a	0	2	n/a	
Outsourcing Facility Nonresident (NSF)	n/a	2	18	n/a	
Pharmacy (PHY)	6440	6459	6520	1%	
Pharmacy Exempt (PHE)	126	124	126	0%	
Remote Dispensing Pharmacy (PHR)	n/a	n/a	0	n/a	
Pharmacy Nonresident (NRP)	509	530	554	9%	
Sterile Compounding (LSC)	796	766	756	-5%	
Sterile Compounding Exempt (LSE)	121	116	119	-2%	
Sterile Compounding Nonresident (NSC)	92	90	77	-16%	
Surplus Medication Collection Distribution Intermediary (SME)	0	1	1	n/a	
Third-Party Logistics Providers (TPL)	16	23	23	44%	
Third-Party Logistics Providers Nonresident (NPL)	60	65	65	8%	
Veterinary Food-Animal Drug Retailer (VET)	23	23	20	-13%	
Wholesalers (WLS)	556	534	540	-3%	
Wholesalers Exempt (WLE)	16	17	16	0%	
Wholesalers Nonresident (OSD)	726	740	750	3%	
Total	138443	139391	139640	1%	

APPLICATIONS Received 45 37 Designated Representatives (EXC) 53 449 Designated Representatives Vet (EXV) Designated Representatives-3PL (DRL) 623 346 51 97 2395 239 405 50 119 94 149 152 Intern Pharmacist (INT) 203 168 168 189 134 102 163 132 191 392 1162 539 3543 *Pharmacist (exam applications) 202 710 328 190 137 108 Pharmacist (initial licensing applications) 68 31 44 93 19 89 2019 Advanced Practice Pharmacist (APH) 33 12 22 18 13 21 20 23 32 23 21 20 258 433 5420 368 513 418 384 391 459 387 497 518 484 568 Pharmacy Technician (TCH) * total includes retake exam applications Centralized Hospital Packaging (CHP) Clinics (CLN) Clinics Exempt (CLE) Drug Room (DRM) Drug Room -Temp Drug Room Exempt (DRE) N/A N/A N/A N/A N/A N/A Emergency Medical Services Automated Drug Delivery System Hospitals (HSP) Hospitals - Temp Hospitals Exempt (HPE) N/A Hospital Satellite Sterile Compounding (SCP) N/A Hospital Satellite Sterile Compounding - Temp N/A Hospital Satellite Sterile Compounding Exempt (SCE) Hypodermic Needle and Syringes (HYP) Hypodermic Needle and Syringes Exempt (HYE) Correctional Pharmacy (LCF) Outsourcing Facility (OSF) Outsourcing Facility - Temp Outsourcing Facility Nonresident (NSF) Outsourcing Facility Nonresident - Temp 831 1232 Pharmacy (PHY) 30 178 29 Pharmacy - Temp Pharmacy Exempt (PHE) 136 Pharmacy Nonresident (NRP) Pharmacy Nonresident Temp 105 Sterile Compounding (LSC) Sterile Compounding - Temp Sterile Compounding Exempt (LSE) Sterile Compounding Nonresident (NSC) Sterile Compounding Nonresident Temp Surplus Medication Collection Distribution Intermediary (SME) Third-Party Logistics Providers (TPL) Third-Party Logistics Providers - Temp Third-Party Logistics Providers Nonresident (NPL) Third-Party Logistics Providers Nonresident Temp Veterinary Food-Animal Drug Retailer (VET) Veterinary Food-Animal Drug Retailer - Temp Wholesalers (WLS) Wholesalers - Temp Wholesalers Exempt (WLE) Wholesalers Nonresident (OSD) 133 Wholesalers Nonresident - Temp 1475 1064 1700 1948 987 770 1023 851 1063 1242 2866 1470 16459 Total

PLICATIONS (continued)													
Issued	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Designated Representatives (EXC)	26	18	39	19	29	61	34	28	25	41	36	31	387
Designated Representatives Vet (EXV)	0	0	2	0	0	0	0	0	0	0	0	0	2
Designated Representatives-3PL (DRL)	3	1	2	3	10	13	0	16	9	4	1	2	64
Intern Pharmacist (INT)	238	232	631	358	124	107	61	91	84	49	89	146	2210
Pharmacist (initial licensing applications)	109	228	691	311	103	145	89	76	41	84	18	170	2065
Advanced Practice Pharmacist (APH)	5	23	17	15	9	13	36	23	8	15	30	10	204
Pharmacy Technician (TCH)	616	609	397	474	287	359	374	459	389	447	478	393	5282
			·										
Centralized Hospital Packaging (CHP)	0	1	0	2	0	0	0	0	0	0	0	0	3
Clinics (CLN)	2	6	3	10	0	7	9	3	4	1	3	1	49
Clinics Exempt (CLE)	2	1	0	0	1	2	3	0	0	1	0	0	10
Drug Room (DRM)	0	0	0	0	0	0	0	0	0	0	0	0	0
Drug Room-Temp	0	0	0	0	0	0	0	0	0	0	0	0	0
Drug Room Exempt (DRE)	0	0	0	0	0	0	0	0	0	0	0	0	0
Emergency Medical Services Automated Drug Delivery System	N/A	N/A	N/A	N/A	N/A	N/A	0	0	0	0	0	0	0
Hospitals (HSP)	0	1	0	1	0	0	1	0	0	0	0	0	3
Hospitals - Temp	0	0	0	0	0	0	0	2	5	4	0	0	11
Hospitals Exempt (HPE)	0	2	0	0	0	0	0	0	0	0	0	1	3
Hospital Satellite Sterile Compounding (SCP)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	0	0	0
Hospital Satellite Sterile Compounding - Temp	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	0	0	0
Hospital Satellite Sterile Compounding Exempt (SCE)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	0	0	0
Hypodermic Needle and Syringes (HYP)	2	0	1	1	0	0	0	0	0	1	1	0	6
Hypodermic Needle and Syringes Exempt (HYE)	0	0	0	0	0	0	0	0	0	0	0	0	0
Correctional Pharmacy (LCF)	0	0	0	0	0	0	0	0	0	0	1	0	1
Outsourcing Facility (OSF)	0	1	0	1	0	0	0	0	0	0	0	0	2
Outsourcing Facility - Temp	0	0	0	0	0	0	0	0	0	0	0	0	0
Outsourcing Facility Nonresident (NSF)	1	0	3	0	1	3	0	1	3	1	1	1	15
Outsourcing Facility Nonresident - Temp	0	0	0	0	0	1	0	1	0	0	0	0	2
Pharmacy (PHY)	16	16	20	10	35	16	43	24	15	26	12	10	243
Pharmacy - Temp	16	10	10	5	4	28	8	11	10	11	9	13	135
Pharmacy Exempt (PHE)	0	0	0	1	0	0	1	1	0	1	0	0	4
Pharmacy Nonresident (NRP)	6	4	5	2	7	11	12	0	6	11	3	1	68
Pharmacy Nonresident Temp	2	2	1	1	2	12	8	3	5	2	4	1	43
Sterile Compounding (LSC)	1	3	2	0	0	9	3	2	4	3	2	4	33
Sterile Compounding - Temp	1	0	4	0	0	10	0	4	9	7	0	0	35
Sterile Compounding Exempt (LSE)	0	2	0	0	0	2	0	1	0	0	2	0	7
Sterile Compounding Nonresident (NSC)	2	1	0	0	0	3	0	0	0	0	0	0	6
Sterile Compounding Nonresident Temp	0	0	0	0	0	1	1	0	1	0	0	1	4
Surplus Medication Collection Distribution Intermediary (SME)	0	0	0	0	0	0	0	0	0	0	0	0	0
Third-Party Logistics Providers (TPL)	0	0	0	0	0	0	0	0	0	0	1	0	1
Third-Party Logistics Providers-Temp	0	0	0	0	0	1	0	0	0	0	0	0	1
Third-Party Logistics Providers Nonresident (NPL)	1	0	1	0	0	0	0	0	0	1	1	0	4
Third-Party Logistics Providers Nonresident Temp	0	0	0	0	1	0	3	1	1	0	0	0	6
Veterinary Food-Animal Drug Retailer (VET)	0	0	0	0	0	0	0	0	0	0	0	1	1
Veterinary Food-Animal Drug Retailer - Temp	0	0	0	0	0	0	0	0	0	0	0	0	0
Wholesalers (WLS)	5	4	5	2	4	1	8	5	5	6	4	4	53
Wholesalers - Temp	0	1	0	0	1	1	2	1	4	2	4	4	20
Wholesalers Exempt (WLE)	0	0	0	0	0	0	0	0	1	0	0	0	1
Wholesalers Nonresident (OSD)	7	5	3	6	3	4	2	5	6	6	5	7	59
Wholesalers Nonresident - Temp	2	2	1	1	1	1	3	0	10	2	0	1	24
Total	1063	1173	1838	1223	622	811	701	758	645	726	705	802	11067

PLICATIONS (continued)												
nding	JUL	AUG	SEP	ОСТ	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN
Designated Representatives (EXC)	307	338	333	347	348	326	318	327	337	331	324	327
Designated Representatives Vet (EXV)	3	3	1	1	1	1	1	1	1	1	1	1
Designated Representatives-3PL (DRL)	78	86	92	94	92	88	97	88	85	89	97	100
Intern Pharmacist (INT)	205	287	341	308	232	170	216	210	194	271	299	232
Pharmacist (exam applications)	1424	1435	1811	1351	1306	1121	1060	962	880	1071	1529	1272
Pharmacist (eligible exam(Status A))	2261	2107	1257	1457	1368	1471	1424	1367	1354	1335	1740	2487
Advanced Practice Pharmacist (APH)	148	138	143	146	151	159	141	141	164	174	162	174
Pharmacy Technician (TCH)	1407	1298	1266	1220	1325	1291	1361	1326	1173	1079	1006	1176
Centralized Hospital Packaging (CHP)	5	3	3	3	3	2	2	2	2	2	2	2
Clinics (CLN)	42	43	54	58	63	57	49	52	55	66	67	80
Clinics Exempt (CLE)	9	8	9	11	11	12	9	10	10	9	10	11
Emergency Medical Services Automated Drug Delivery System	N/A	N/A	N/A	N/A	N/A	N/A	0	0	0	0	0	0
Drug Room (DRM)	0	0	0	0	0	0	0	0	0	0	0	0
Drug Room Exempt (DRE)	0	0	0	0	0	0	0	0	0	1	1	1
Hospitals (HSP)	4	3	8	8	14	19	18	16	7	8	7	8
Hospitals Exempt (HPE)	1	0	0	0	1	1	1	1	1	1	1	0
Hospital Satellite Sterile Compounding (SCP)	N/A	2	1	3								
Hospital Satellite Sterile Compounding Exempt (SCE)	N/A	0	0	0								
Hypodermic Needle and Syringes (HYP)	7	10	9	8	8	14	17	18	18	17	20	24
Hypodermic Needle and Syringes Exempt (HYE)	0	0	0	0	0	0	0	0	0	0	0	0
Correctional Pharmacy (LCF)	1	1	1	1	2	2	2	2	2	2	0	1
Outsourcing Facility (OSF)	6	5	4	3	3	3	2	3	3	3	3	3
Outsourcing Facility Nonresident (NSF)	29	29	27	30	29	26	22	21	15	15	14	15
Pharmacy (PHY)	132	140	162	182	185	169	141	136	133	131	675	693
Pharmacy Exempt (PHE)	1	1	1	2	2	3	2	2	2	2	3	3
Pharmacy Nonresident (NRP)	105	103	111	105	112	88	75	82	84	79	79	91
Sterile Compounding (LSC)	34	35	49	56	75	70	69	70	69	65	70	69
Sterile Compounding - Exempt (LSE)	8	6	6	8	10	8	8	9	9	9	7	7
Sterile Compounding Nonresident (NSC)	16	17	18	19	20	15	16	18	19	18	20	22
Surplus Medication Collection Distribution Intermediary (SME)	0	0	0	0	0	0	0	0	0	0	0	0
Third-Party Logistics Providers (TPL)	8	8	8	8	7	7	9	9	9	9	9	9
Third-Party Logistics Providers Nonresident (NPL)	43	42	43	46	46	48	46	47	47	46	47	49
Veterinary Food-Animal Drug Retailer (VET)	1	1	1	1	1	1	1	1	1	1	1	0
Wholesalers (WLS)	37	40	38	42	42	48	47	47	46	47	45	43
Wholesalers Exempt (WLE)	0	0	0	0	0	0	0	0	0	0	1	1
Wholesalers Nonresident (OSD)	82	90	88	92	100	106	107	114	108	105	113	120
Total	6404	6277	5884	5607	5557	5326	5261	5082	4828	4989	6354	7024

APPLICATIONS (continued)													
Withdrawn	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Designated Representatives (EXC)	0	1	2	2	0	3	7	2	1	0	1	0	19
Designated Representatives Vet (EXV)	0	0	0	0	0	0	0	0	0	0	0	0	0
Designated Representatives-3PL (DRL)	0	1	0	1	0	0	1	0	0	0	0	1	4
Intern Pharmacist (INT)	0	2	0	1	0	0	0	1	1	0	0	0	5
Pharmacist (exam applications)	0	0	2	11	4	56	167	386	129	6	2	1	764
Advanced Practice Pharmacist (APH)	0	0	0	0	0	0	0	0	0	0	1	0	1
Pharmacy Technician (TCH)	8	8	4	5	7	18	13	8	241	141	35	52	540
-	FY 17/18 There wer	re 764 Pharmacist (exam) applications	withdrawn as a resu	ult of redirection of s	taff to identify aband	doned applications						
Centralized Hospital Packaging (CHP)	0	1	0	0	0	1	0	0	0	0	1	0	3
Clinics (CLN)	0	0	0	1	0	0	0	0	0	0	0	1	2
Clinics Exempt (CLE)	0	0	0	0	0	0	0	0	0	1	0	3	4
Drug Room (DRM)	0	0	0	0	0	0	0	0	0	0	0	0	0
Drug Room Exempt (DRE)	0	0	0	0	0	0	0	0	0	0	0	0	0
Emergency Medical Services Automated Drug Delivery System	N/A	N/A	N/A	N/A	N/A	N/A	0	0	0	0	0	0	0
Hospitals (HSP)	0	0	0	0	0	1	0	0	1	0	0	0	2
Hospitals Exempt (HPE)	0	0	0	0	0	0	0	0	0	0	0	0	0
Hospital Satellite Sterile Compounding (SCP)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	0	0	0
Hospital Satellite Sterile Compounding Exempt (SCE)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	0	0	0
Hypodermic Needle and Syringes (HYP)	0	1	0	0	0	0	0	0	0	0	0	0	1
Hypodermic Needle and Syringes Exempt (HYE)	0	0	0	0	0	0	0	0	0	0	0	0	0
Correctional Pharmacy (LCF)	0	1	0	0	0	0	0	0	0	0	1	0	2
Outsourcing Facility (OSF)	0	0	0	0	0	0	0	0	0	0	0	0	0
Outsourcing Facility Nonresident (NSF)	0	0	0	0	0	0	0	0	2	0	0	0	2
Pharmacy (PHY)	10	1	1	1	1	0	4	1	1	0	24	1	45
Pharmacy Exempt (PHE)	0	0	0	0	0	0	0	0	0	0	0	0	0
Pharmacy Nonresident (NRP)	2	2	1	15	1	4	2	0	0	0	2	0	29
Sterile Compounding (LSC)	0	0	0	0	0	0	0	0	0	0	1	0	1
Sterile Compounding Exempt (LSE)	0	1	0	0	0	0	0	0	0	0	0	1	2
Sterile Compounding Nonresident (NSC)	0	1	1	0	0	1	0	0	0	1	0	0	4
Surplus Medication Collection Distribution Intermediary (SME)	0	0	0	0	0	0	0	0	0	0	0	0	0
Third-Party Logistics Providers (TPL)	0	0	0	0	1	0	0	0	0	0	0	0	1
Third-Party Logistics Providers Nonresident (NPL)	0	0	0	0	0	0	1	0	1	0	0	0	2
Veterinary Food-Animal Drug Retailer (VET)	0	0	0	0	0	0	0	0	0	0	0	0	0
Wholesalers (WLS)	3	1	0	0	0	1	0	0	0	0	0	2	7
Wholesalers Exempt (WLE)	0	0	0	0	0	0	0	0	0	0	0	0	0
Wholesalers Nonresident (OSD)	0	0	0	0	0	4	3	0	0	2	0	1	10
Total	Total 23 21 11 37 14 89 198 398 377 151 68 63 1450												
	The number of tem	porary applications	withdrawn is reflec	ted in the primary lic	cense type.								

APPLICATIONS (continued)													
Denied	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Designated Representatives (EXC)	0	1	0	0	0	0	0	0	0	0	0	0	1
Designated Representatives Vet (EXV)	0	0	0	0	0	0	0	0	0	0	0	0	0
Designated Representatives-3PL (DRL)	0	0	0	0	0	0	0	0	0	0	0	0	0
Intern Pharmacist (INT)	1	1	1	0	0	1	0	1	0	0	0	0	5
Pharmacist (exam applications)	1	1	2	0	1	1	0	0	0	1	1	0	8
Pharmacist (eligible)	0	0	0	0	0	0	0	0	0	0	0	0	0
Advanced Practice Pharmacist (APH)	0	0	0	0	0	0	0	0	0	0	0	0	0
Pharmacy Technician (TCH)	1	3	2	8	1	5	0	2	3	4	7	1	37
Centralized Hospital Packaging (CHP)	0	0	0	0	0	0	0	0	0	0	0	0	0
Clinics (CLN)	0	0	0	0	0	0	0	0	0	0	0	0	0
Clinics Exempt (CLE)	0	0	0	0	0	0	0	0	0	0	0	0	0
Drug Room (DRM)	0	0	0	0	0	0	0	0	0	0	0	0	0
Drug Room Exempt (DRE)	0	0	0	0	0	0	0	0	0	0	0	0	0
Emergency Medical Services Automated Drug Delivery System	N/A	N/A	N/A	N/A	N/A	N/A	0	0	0	0	0	0	0
Hospitals (HSP)	0	0	0	0	0	0	0	0	0	0	0	0	0
Hospitals Exempt (HPE)	0	0	0	0	0	0	0	0	0	0	0	0	0
Hospital Satellite Sterile Compounding (SCP)	N/A	0	0	0									
Hospital Satellite Sterile Compounding Exempt (SCE)	N/A	0	0	0									
Hypodermic Needle and Syringes (HYP)	0	0	0	0	0	0	0	0	0	0	0	0	0
Hypodermic Needle and Syringes Exempt (HYE)	0	0	0	0	0	0	0	0	0	0	0	0	0
Correctional Pharmacy (LCF)	0	0	0	0	0	0	0	0	0	0	0	0	0
Outsourcing Facility (OSF)	1	0	1	0	0	0	0	0	0	0	0	0	2
Outsourcing Facility Nonresident (NSF)	0	0	0	0	0	0	1	1	2	0	0	0	4
Pharmacy (PHY)	4	0	1	1	1	1	2	1	0	0	3	0	14
Pharmacy Exempt (PHE)	0	0	0	0	0	0	0	0	0	0	0	0	0
Pharmacy Nonresident (NRP)	0	3	0	0	0	0	0	0	1	0	0	0	4
Sterile Compounding (LSC)	1	0	0	0	0	0	0	0	0	0	0	0	1
Sterile Compounding Exempt (LSE)	0	0	0	0	0	0	0	0	0	0	0	0	0
Sterile Compounding Nonresident (NSC)	0	0	0	0	0	0	0	0	0	0	0	0	0
Surplus Medication Collection Distribution Intermediary (SME)	0	0	0	0	0	0	0	0	0	0	0	0	0
Third-Party Logistics Providers (TPL)	0	0	0	0	0	0	0	0	0	0	0	0	0
Third-Party Logistics Providers Nonresident (NPL)	0	0	0	0	0	0	0	0	0	0	0	0	0
Veterinary Food-Animal Drug Retailer (VET)	0	0	0	0	0	0	0	0	0	0	0	0	0
Wholesalers (WLS)	0	0	0	0	0	0	0	1	0	0	0	0	1
Wholesalers Exempt (WLE)	0	0	0	0	0	0	0	0	0	0	0	0	0
Wholesalers Nonresident (OSD)	0	0	0	0	0	0	0	0	0	0	0	0	0
Total	9	9	7	9	3	8	3	6	6	5	11	1	77

DEC

NOV

RESPOND TO STATUS REQUESTS

A. Email Inquiries

Designated Representative Received Designated Representative Responded JUL

AUG

SEP

OCT

Pharmacist/Intern Received

Pharmacist/Intern Responded

Pharmacy Technician Received

Pharmacy Technician Responded

Pharmacy Received

Pharmacy Responded

Sterile Compounding/Outsourcing Received Sterile Compounding/Outsourcing Responded

Wholesale/Clinic/Hypodermic/3PL Received

Wholesale/Clinic/Hypodermic/3PL Responded

Pharmacist-in-Charge Received

Pharmacist-in-Charge Responded

Change of Permit Received

Change of Permit Responded

Renewals Received

Renewals Responded

N/A	N/A	N/A	N/A	97	98	201	147	144	159	159	129	1134
N/A	N/A	N/A	N/A	9	40	100	63	82	59	66	28	447
844	918	811	855	676	479	684	497	666	703	789	853	8775
630	759	608	682	487	355	665	452	446	532	464	372	6452
463	417	187	354	479	297	444	316	636	390	554	377	4914
620	295	226	144	505	225	290	261	402	336	380	332	4016
187	738	314	720	717	490	663	470	594	496	459	517	6365
148	420	314	657	596	578	773	502	641	571	450	533	6183
160	207	393	407	373	397	532	368	417	395	405	560	4614
40	238	225	173	201	269	862	454	457	383	433	340	4075
239	379	376	357	317	281	294	348	340	325	397	418	4071
175	293	250	453	160	217	205	282	261	390	361	400	3447
29	186	160	56	128	159	202	127	155	231	127	121	1681
53	141	117	31	90	138	197	101	88	177	127	51	1311
476	518	458	630	322	405	567	349	456	494	458	426	5559
338	346	383	424	242	423	603	303	365	384	326	378	4515
305	490	504	560	452	370	454	438	434	400	476	506	5389
294	378	489	511	345	272	353	358	338	342	368	364	4412

JAN

FEB

MAR

APR

MAY

JUN

FYTD

Telephone Calls Received

Designated Represenative

Pharmacist/Intern

Sterile Compounding/Outsourcing

Wholesale/Clinic/Hypodermic/3PL *

Pharmacist-in-Charge

Change of Permit

Renewals

JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
N/A	N/A	N/A	N/A	N/A	N/A	2	0	0	9	13	3	27
49	38	50	71	47	48	28	23	19	27	23	2	425
89	88	78	67	101	75	89	60	82	43	50	85	907
5	35	30	35	34	39	26	27	34	55	40	51	411
64	89	93	67	60	55	44	56	39	0	0	3	570
53	97	74	82	70	62	62	49	49	42	13	2	655
64	42	94	100	68	48	49	53	67	68	62	72	787
520	713	787	711	774	625	750	614	599	500	578	613	7784
*Phone calls for Ap	ril, May and June w	ere directed to wlss	tatus email for statu	us on applications.								

UPDATE LICENSING RECORDS													
A. Change of Pharmacist-in-Charge	JUL	AUG	SEP	ОСТ	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Received	175	156	164	230	185	187	215	159	171	173	190	188	2193
Processed	209	190	128	207	215	161	191	266	103	197	89	45	2001
Approved	178	193	160	190	215	161	193	263	157	184	111	32	2037
Pending	284	249	260	303	273	282	232	185	199	191	270	452	452
			,										
B. Change of Desig. Representative-in-Charge	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Received	8	13	9	8	12	12	4	12	14	10	7	11	120
Processed	8	17	9	8	12	13	4	13	14	11	4	1	114
Approved	7	11	12	7	7	14	5	12	7	13	5	1	101
Pending	28	30	28	28	33	31	30	31	38	35	37	48	48
C. Change of Responsible Manager	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Received	4	1	1	1	1	1	2	2	2	3	1	5	24
Processed	3	1	1	2	1	1	0	4	1	2	2	0	18
Approved	2	1	1	3	0	2	0	4	0	1	2	0	16
Pending	7	7	6	4	5	4	6	4	6	8	7	12	12
									-	-	_		
D. Change of Permits	JUL	AUG	SEP	ОСТ	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Received	152	118	141	178	105	90	126	110	168	368	82	98	1736
Processed	225	107	204	108	60	202	192	69	131	168	195	59	1720
Approved	122	153	181	117	115	82	167	172	45	180	156	128	1618
Pending	942	899	876	953	943	952	911	848	970	1168	948	930	930
E. Automotod Duna Politicana Suntanna		ALIC	CED	700	NOV	DEC	IANI	FED	MAD	ADD	MAN	ILINI	EVED
E. Automated Drug Delivery Systems	JUL	AUG	SEP	OCT	NOV	DEC	JAN 12	FEB 16	MAR	APR	MAY 10	JUN	FYTD
Received	34	87 312	26 334	215	12	4	13	16	13	0	10	2	240 950
Processed	0	209	334	212	9	44	15 15	9	11	1	0	0	844
Approved Pending	513	315	239	43	45	5	3	10	17	20	30	32	32
ronding	010	010	200	40	40	<u> </u>		10	.,,	20	50	02	02
F. Clinic Co-Location	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Received	N/A	N/A	N/A	N/A	N/A	N/A	0	0	0	0	0	1	1
Processed	N/A	N/A	N/A	N/A	N/A	N/A	0	0	0	0	0	0	0
Approved	N/A	N/A	N/A	N/A	N/A	N/A	0	0	0	0	0	0	0
Pending	N/A	N/A	N/A	N/A	N/A	N/A	0	0	0	0	0	1	1
G. Discontinuance of Business	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Received	23	50	22	47	32	23	44	23	31	32	34	48	409
Processed	18	66	33	28	26	47	31	30	9	52	15	2	357
Approved	25	53	42	21	23	43	23	24	12	41	16	4	327
Pending	120	118	100	125	134	114	120	123	141	136	154	199	199
U. Barranda Arranda		ALIC	CED	007	NOV	DEC	IANI	FED.	MAD	ADD	MAN	IUNI	EVED
H. Requests Approved Address/Name Changes	JUL 1215	AUG 1067	SEP 836	OCT 942	NOV 822	DEC 745	JAN 930	FEB 878	MAR 964	APR 959	MAY 1031	JUN 1022	FYTD 11411
Off-site Storage	1210	84	030	942	14	745	930	24	904	909	48	1022	170
Orr-site Storage Transfer of Intern Hours	10	3	1	اء	14 _A		اه		2	9	40	17	74
License Verification	163	217	153	102	175	241	202	153	89	192	222	325	2234
License venincation	103	21/	153	102	1/0	241	202	103	09	192	222	323	2234

<u>Licenses Renewed</u>													
	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Designated Representatives (EXC)	192	227	200	194	167	191	235	216	251	203	186	214	2,476
Designated Representatives Vet (EXV)	7	5	0	4	1	3	3	5	6	5	8	11	58
Designated Representatives-3PL (DRL)	17	22	25	17	12	16	9	10	13	10	26	25	202
Pharmacist (RPH)	1508	1749	2021	1725	1488	1762	1884	1384	1949	1476	1515	2202	20,663
Advanced Practice Pharmacist (APH)	3	1	7	6	6	13	8	7	8	10	5	17	91
Pharmacy Technician (TCH)	2443	2434	2776	2560	2184	2357	2922	1940	3038	2310	2230	2957	30,151
Centralized Hospital Packaging (CHP)	2	0	0	3	0	0	3	0	0	1	0	0	9
Clinics (CLN)	91	70	98	116	56	64	90	89	95	87	70	109	1,035
Clinics Exempt (CLE)	0	0	48	167	6	1	4	5	0	0	2	0	233
Drug Room (DRM)	3	1	1	3	2	1	1	2	4	2	2	2	24
Drug Room Exempt (DRE)	0	0	1	7	2	0	0	0	0	0	0	0	10
Emergency Medical Services Automated Drug Delivery System	N/A	0											
Hospitals (HSP)	28	21	21	82	20	25	38	37	33	21	28	36	390
Hospitals Exempt (HPE)	0	1	38	40	3	0	1	0	1	1	0	23	108
Hospital Satellite Sterile Compounding (SCP)	N/A	0											
Hospital Satellite Sterile Compounding Exempt (SCE)	N/A	0											
Hypodermic Needle and Syringes (HYP)	12	26	19	21	18	0	24	21	17	22	15	21	216
Hypodermic Needle and Syringes Exempt (HYE)	0	0	0	0	0	0	0	0	0	0	0	0	0
Correctional Pharmacy (LCF)	0	0	23	33	1	0	0	0	0	1	0	2	60
Outsourcing Facility (OSF)	0	0	0	0	0	0	0	0	0	0	0	0	0
Outsourcing Facility Nonresident (NSF)	0	0	0	0	0	0	0	0	0	0	0	3	3
Pharmacy (PHY)	222	185	761	1117	552	279	676	172	835	993	212	238	6,242
Pharmacy Exempt (PHE)	0	0	66	49	4	0	1	0	1	1	1	17	140
Pharmacy Nonresident (NRP)	23	26	39	33	32	43	47	44	46	36	39	41	449
Sterile Compounding (LSC)	58	41	40	148	45	38	48	63	48	68	51	61	709
Sterile Compounding Exempt (LSE)	0	6	0	98	1	2	0	0	1	1	4	30	143
Sterile Compounding Nonresident (NSC)	6	1	3	10	3	12	4	4	3	4	6	14	70
Surplus Medication Collection Distribution Intermediary (SME)	0	0	1	0	0	0	0	0	0	0	0	0	1
Third-Party Logistics Providers (TPL)	2	1	3	2	0	1	5	0	2	0	0	3	19
Third-Party Logistics Providers Nonresident (NPL)	2	6	5	7	1	9	6	3	1	0	9	3	52
Veterinary Food-Animal Drug Retailer (VET)	1	1	0	2	2	3	0	0	2	0	6	1	18
Wholesalers (WLS)	43	38	45	35	31	43	23	34	41	27	34	62	456
Wholesalers Exempt (WLE)	1	0	7	4	1	0	1	0	0	0	1	0	15
Wholesalers Nonresident (OSD)	52	49	69	43	48	39	57	37	48	45	56	58	601
Total	4716	4911	6317	6526	4686	4902	6090	4073	6443	5324	4506	6150	64644

<u>Current Licensees</u>													
	JUL	AUG	SEP	ОСТ	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Designated Representatives (EXC)	2963	2945	2984	2944	2935	2994	3021	2971	2967	2998	3004	3004	3004
Designated Representatives Vet (EXV)	72	72	74	73	72	72	72	71	70	70	69	69	69
Designated Representatives-3PL (DRL)	256	256	258	258	260	273	273	279	286	289	287	286	286
Intern Pharmacist (INT)	6719	6866	6778	6878	6941	6928	6927	6966	7008	7027	7045	6800	6800
Pharmacist (RPH)	44911	45052	45677	45890	45930	45984	4598	45969	45931	45957	45916	45988	45988
Advanced Practice Pharmacist (APH)	140	169	173	191	199	212	248	271	279	307	324	334	334
Pharmacy Technician (TCH)	72579	72568	72413	72412	72172	72069	71876	71698	71589	71587	71486	71360	71360
Centralized Hospital Packaging (CHP)	٥	ا	٥	11	11	11	11	10	10	10	10	10	10
Clinics (CLN)	1100	1099	1097	1106	1105	1105	1112	1112	1115	1110	1108	1109	1109
	239	238	238	238	239	239	242	242	242	242	242	242	242
Clinics Exempt (CLE)	239						242	242	242		23	242	
Drug Room (DRM)	11	23	23	23 10	23	23 10	10	23	23	23 10	23	23	23
Drug Room Exempt (DRE) Emergency Medical Services Automated Drug Delivery System	N/A	N/A	N/A	N/A	N/A	N/A	10	10	10	10	10	9	9
Hospitals (HSP)	395	394	392	393	393	391	201	385	386	384	383	383	383
Hospitals (HSF) Hospitals Exempt (HPE)	84	85	85	85	85	84	391 84	84	84	84	85	85	85
Hospital Satellite Sterile Compounding (SCP)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	65	65
Hospital Satellite Sterile Compounding (SCF)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	0	0
Hypodermic Needle and Syringes (HYP)	296	296	292	298	298	297	296	295	295	293	293	293	293
Hypodermic Needle and Syringes (TTF) Hypodermic Needle and Syringes Exempt (HYE)	290	290	292	290	290	297	290	293	293	293	293	293	293
Correctional Pharmacy (LCF)	59	59	59	59	58	58	57	57	57	57	58	58	58
Outsourcing Facility (OSF)	1	1	1	39	30	30	2	31	2	2	30	30	30
Outsourcing Facility Nonresident (NSF)	' '	' '		6	7	11	12	13	15	16	17	18	18
Pharmacy (PHY)	6471	6464	6459	6468	6474	6482	6498	6505	6519	6507	6513	6520	6520
Pharmacy Exempt (PHE)	124	124	124	124	124	124	125	125	125	126	126	126	126
Pharmacy Nonresident (NRP)	535	533	534	532	529	535	544	542	547	557	555	554	554
Sterile Compounding (LSC)	765	760	757	751	745	750	752	751	754	757	755	756	756
Sterile Compounding Exempt (LSE)	116	117	117	115	115	115	115		116	116	119	119	119
Sterile Compounding Nonresident (NSC)	92	92	89	89	87	86	86	85	82	79	77	77	77
Surplus Medication Collection Distribution Intermediary (SME)	1	1	1	1	1	1	1	1	1	1	1	1	1
Third-Party Logistics Providers (TPL)	23	22	22	21	21	22	22	22	22	22	23	23	23
Third-Party Logistics Providers Nonresident (NPL)	67	62	63	64	65	64	64	64	64	65	65	65	65
Veterinary Food-Animal Drug Retailer (VET)	23	23	23	23	23	23	23	23	23	23	23	20	20
Wholesalers (WLS)	533	533	537	536	536	537	539	541	544	547	548	540	540
Wholesalers Exempt (WLE)	16	16	16	16	16	16	16	16	16	16	16	16	16
Wholesalers Nonresident (OSD)	745	745	754	746	746	749	746	745	752	750	752	750	750
Total	139370	139638	140066	140363	140222	140267	98786	139994	139934	140032	139935	139640	139640
											-1	- 1	

Attachment 6

FDA News Release

FDA approves first drug comprised of an active ingredient derived from marijuana to treat rare, severe forms of epilepsy

For Immediate Release

June 25, 2018

Release

Español (/NewsEvents/Newsroom/ComunicadosdePrensa/ucm611724.htm)

The U.S. Food and Drug Administration today approved Epidiolex (cannabidiol) [CBD] oral solution for the treatment of seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome, in patients two years of age and older. This is the first FDA-approved drug that contains a purified drug substance derived from marijuana. It is also the first FDA approval of a drug for the treatment of patients with Dravet syndrome.

CBD is a chemical component of the Cannabis sativa plant, more commonly known as marijuana. However, CBD does not cause intoxication or euphoria (the "high") that comes from tetrahydrocannabinol (THC).

It is THC (and not CBD) that is the primary psychoactive component of marijuana.

"This approval serves as a reminder that advancing sound development programs that properly evaluate active ingredients contained in marijuana can lead to important medical therapies. And, the FDA is committed to this kind of careful scientific research and drug development," said FDA Commissioner Scott Gottlieb, M.D. "Controlled clinical trials testing the safety and efficacy of a drug, along with careful review through the FDA's drug approval process, is the most appropriate way to bring marijuana-derived treatments to patients. Because of the adequate and well-controlled clinical studies that supported this approval, prescribers can have confidence in the drug's uniform strength and consistent delivery that support appropriate dosing needed for treating patients with these complex and serious epilepsy syndromes. We'll continue to support rigorous scientific research on the potential medical uses of marijuana-derived products and work with product developers who are interested in bringing patients safe and effective, high quality

products. But, at the same time, we are prepared to take action when we see the illegal marketing of CBD-containing products with serious, unproven medical claims. Marketing unapproved products, with uncertain dosages and formulations can keep patients from accessing appropriate, recognized therapies to treat serious and even fatal diseases."

Dravet syndrome is a rare genetic condition that appears during the first year of life with frequent fever-related seizures (febrile seizures). Later, other types of seizures typically arise, including myoclonic seizures (involuntary muscle spasms). Additionally, status epilepticus, a potentially life-threatening state of continuous seizure activity requiring emergency medical care, may occur. Children with Dravet syndrome typically experience poor development of language and motor skills, hyperactivity and difficulty relating to others.

Lennox-Gastaut syndrome begins in childhood. It is characterized by multiple types of seizures. People with Lennox-Gastaut syndrome begin having frequent seizures in early childhood, usually between ages 3 and 5. More than three-quarters of affected individuals have tonic seizures, which cause the muscles to contract uncontrollably. Almost all children with Lennox-Gastaut syndrome develop learning problems and intellectual disability. Many also have delayed development of motor skills such as sitting and crawling. Most people with Lennox-Gastaut syndrome require help with usual activities of daily living.

"The difficult-to-control seizures that patients with Dravet syndrome and Lennox-Gastaut syndrome experience have a profound impact on these patients' quality of life," said Billy Dunn, M.D., director of the Division of Neurology Products in the FDA's Center for Drug Evaluation and Research. "In addition to another important treatment option for Lennox-Gastaut patients, this first-ever approval of a drug specifically for Dravet patients will provide a significant and needed improvement in the therapeutic approach to caring for people with this condition."

Epidiolex's effectiveness was studied in three randomized, double-blind, placebo-controlled clinical trials involving 516 patients with either Lennox-Gastaut syndrome or Dravet syndrome. Epidiolex, taken along with other medications, was shown to be effective in reducing the frequency of seizures when compared with placebo.

The most common side effects that occurred in Epidiolex-treated patients in the clinical trials were: sleepiness, sedation and lethargy; elevated liver enzymes; decreased appetite; diarrhea; rash; fatigue, malaise and weakness; insomnia, sleep disorder and poor quality sleep; and infections.

Epidiolex must be dispensed with a patient Medication Guide that describes important information about the drug's uses and risks. As is true for all drugs that treat epilepsy, the most serious risks include thoughts about suicide, attempts to commit suicide, feelings of agitation, new or worsening depression, aggression and panic attacks. Epidiolex also caused liver injury, generally mild, but raising the possibility of rare, but more severe injury. More severe liver injury can cause nausea, vomiting, abdominal pain, fatigue, anorexia, jaundice and/or dark urine.

Under the Controlled Substances Act (CSA), CBD is currently a Schedule I substance because it is a chemical component of the cannabis plant. In support of this application, the company conducted nonclinical and clinical studies to assess the abuse potential of CBD.

The FDA prepares and transmits, through the U.S. Department of Health and Human Services, a medical and scientific analysis of substances subject to scheduling, like CBD, and provides recommendations to the Drug Enforcement Administration (DEA) regarding controls under the CSA. DEA is required to make a scheduling determination.

The FDA granted <u>Priority Review (/ForPatients/Approvals/Fast/ucm405405.htm)</u> designation for this application. <u>Fast-Track (/ForPatients/Approvals/Fast/ucm405399.htm)</u> designation was granted for Dravet syndrome. <u>Orphan Drug (/ForIndustry/DevelopingProductsforRareDiseasesConditions/HowtoapplyforOrphanProductDesignation/default.htm)</u> designation was granted for both the Dravet syndrome and Lennox-Gastaut syndrome indications.

The FDA granted approval of Epidiolex to GW Research Ltd.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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Inquiries Media ✓ Michael Felberbaum (mailto:michael.felberbaum@fda.hhs.gov) • 240-402-9548 ✓ Sandy Walsh (mailto:sandy.walsh@fda.hhs.gov) • 301-796-4669 Consumers • 888-INFO-FDA

Related Information

- FDA and Marijuana (/NewsEvents/PublicHealthFocus/ucm421163.htm)
- NIH: Lennox-Gastaut Syndrome Information Page (https://www.ninds.nih.gov/Disorders/All-Disorders/Lennox-Gastaut-Syndrome-Information-Page)
- NIH: Dravet Syndrome Information Page (https://www.ninds.nih.gov/Disorders/All-Disorders/Dravet-Syndrome-Information-Page)
- NIH: Marijuana as Medicine (https://www.drugabuse.gov/publications/drugfacts/marijuanamedicine)
- FDA: Approved Drug Questions and Answers
 (/Drugs/ResourcesForYou/Consumers/ucm054420.htm)

Follow FDA			

Assembly Bill No. 710

CHAPTER 62

An act to add Section 26002 to the Business and Professions Code, and to add Section 11150.2 to the Health and Safety Code, relating to controlled substances, and declaring the urgency thereof, to take effect immediately.

[Approved by Governor July 9, 2018. Filed with Secretary of State July 9, 2018.]

LEGISLATIVE COUNSEL'S DIGEST

AB 710, Wood. Cannabidiol.

Existing law, the California Uniform Controlled Substances Act, classifies controlled substances into 5 designated schedules, with the most restrictive limitations generally placed on controlled substances classified in Schedule I, and the least restrictive limitations generally placed on controlled substances classified in Schedule V. Existing law designates cannabis in Schedule I. Cannabidiol is a compound contained in cannabis.

Existing law restricts the prescription, furnishing, possession, sale, and use of controlled substances, including cannabis and synthetic cannabinoid compounds, and makes a violation of those laws a crime, except as specified.

This bill, if one of specified changes in federal law regarding the controlled substance cannabidiol occurs, would deem a physician, pharmacist, or other authorized healing arts licensee who prescribes, furnishes, or dispenses a product composed of cannabidiol, in accordance with federal law, to be in compliance with state law governing those acts. The bill would also provide that upon the effective date of one of those changes in federal law regarding cannabidiol, the prescription, furnishing, dispensing, transfer, transportation, possession, or use of that product in accordance with federal law is for a legitimate medical purpose and is authorized pursuant to state law.

Existing law, the Medicinal and Adult-Use Cannabis Regulation and Safety Act, regulates the cultivation, processing, and sale of medicinal and adult-use cannabis within the state.

This bill would expressly exclude from regulation under that act, any medicinal product composed of cannabidiol approved by the federal Food and Drug Administration and either placed on a schedule of the federal Controlled Substances Act other than Schedule I, or exempted from one or more provisions of that act.

This bill would declare that it is to take effect immediately as an urgency statute.

Ch. 62 __2_

The people of the State of California do enact as follows:

SECTION 1. The Legislature finds and declares that both children and adults with epilepsy are in desperate need of new treatment options and that cannabidiol has shown potential as an effective treatment option. If federal laws prohibiting the prescription of medications composed of cannabidiol are repealed or if an exception from the general prohibition is enacted permitting the prescription of drugs composed of cannabidiol, patients should have rapid access to this treatment option. The availability of this new prescription medication is intended to augment, not to restrict or otherwise amend, other cannabinoid treatment modalities including, but not limited to, industrial hemp products and derivatives containing cannabidiol, currently available under state law.

- SEC. 2. Section 26002 is added to the Business and Professions Code, to read:
- 26002. This division shall not apply to any product containing cannabidiol that has been approved by the federal Food and Drug Administration that has either been placed on a schedule of the federal Controlled Substances Act other than Schedule I or has been exempted from one or more provisions of that act, and that is intended for prescribed use for the treatment of a medical condition.
- SEC. 3. Section 11150.2 is added to the Health and Safety Code, to read: 11150.2. (a) Notwithstanding any other law, if cannabidiol is excluded from Schedule I of the federal Controlled Substances Act and placed on a schedule of the act other than Schedule I, or if a product composed of cannabidiol is approved by the federal Food and Drug Administration and either placed on a schedule of the act other than Schedule I, or exempted from one or more provisions of the act, so as to permit a physician, pharmacist, or other authorized healing arts licensee acting within his or her scope of practice, to prescribe, furnish, or dispense that product, the physician, pharmacist, or other authorized healing arts licensee who prescribes, furnishes, or dispenses that product in accordance with federal law shall be deemed to be in compliance with state law governing those acts.
- (b) For purposes of this chapter, upon the effective date of one of the changes in federal law described in subdivision (a), notwithstanding any other state law, a product composed of cannabidiol may be prescribed, furnished, dispensed, transferred, transported, possessed, or used in accordance with federal law and is authorized pursuant to state law.
- (c) This section does not apply to any product containing cannabidiol that is made or derived from industrial hemp, as defined in Section 11018.5 and regulated pursuant to that section.
- SEC. 4. This act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of Article IV of the California Constitution and shall go into immediate effect. The facts constituting the necessity are:

3 Ch. 62

In order to ensure that patients are able to obtain access to a new treatment modality as soon as federal law makes it available, it is necessary that this act take effect immediately.