Protection of the public shall be the highest priority for the California State Board of Pharmacy in exercising its licensing, regulatory, and disciplinary functions. Whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.

California Business and Professions Code section 4001.1
Regulatory Mandate

- The Board of Pharmacy regulates those who dispense, store, compound, ship and distribute prescription drugs and devices into, within or from California. This includes licensure of individuals and businesses, and oversight of the medication produced, distributed and destroyed.
Licensees

- 25 Major licensing Programs
  - Pharmacies – 7,100
    - Community – 6,600
    - Hospital – 450
    - Correctional Facility -- 60
    - Sterile Compounding Pharmacies – 900
    - Out of State Compounding Pharmacies -- 90
  - Pharmacists – 44,900
  - Advanced Practice Pharmacists -- 130
  - Pharmacist Interns – 6,800
  - Pharmacy Technicians -- 73,000
  - Clinics – 1,300
Licensees

- Wholesalers
  - In State
  - Outside CA
- Third-Party Logistics Providers
  - In State
  - Outside CA
- Outsourcing Facilities
- Automated Dispensing Machines
Board of Pharmacy

13 Board Members

- 7 professional members
- 6 public members
- Budget 2016/17: $22+ million
  Totally self-funded from fees assessed
- Staff: approximately 120

At least 4 public board meetings annually
Pharmacy and Pharmaceuticals

- It is all about drugs
  - Increasing numbers of individuals taking prescription medication
  - Increasing numbers of new drugs
  - Increasing numbers of drug shortages
  - Increasing recalls
  - Increasing numbers of pharmacies compounding
  - Increasing ways to make money (internet, low cost acquisition from diverted drugs)
Pharmacy and Pharmaceuticals

- Opioid epidemic
- More complex drug distribution
- Increasing forms of drug distribution
- Increased scrutiny of controlled drug distribution
- Greater need for multi-language labels and information
- Prescription drugs have high value on streets
And for the board . . .

- It is all about consumer protection
Education of Pharmacists

- Possess “PharmD” degree – typically 4 years post BS/BA degree
- Requires heavy experience of nearly one year working under supervision of pharmacists in diverse settings
- Passage of at least two exams— one national, one at state level
- Focus: drug management expertise
Advanced Practice Pharmacists

- CA one of first states to authorize
- Requires specialized training working under protocol with physicians typically doing drug management therapy
- CA pharmacists use APh denoting possession of this license
Regulations

- Highly regulated professions and businesses at state and federal levels
- US has the “gold standard” for prescription drug quality but drug prices are high in US
- HIPAA and a myriad of laws protect the health information of patients
Pharmacy Ownership

- Anyone can own a pharmacy, but only a pharmacist can be in charge of the pharmacy.
- Today, many of the board’s 7,000 pharmacies are corporations or limited liability companies. Growing number of trusts in ownership structure.
Complaints and Investigations

During 2016/17:

Complaints received: 2893
Complaints closed: 3116
Complaints pending: 2241
Types of Cases under Investigation

- Medication Errors
- Drug Losses
- Prescription Drug Abuse
- Compounding
- Unprofessional Conduct

BUT: Price/Cost of Drug Not Usually Within the Board’s Jurisdiction
What are Med Errors?

- Wrong Drug
- Wrong Strength
- Wrong Instructions
- Wrong Patient
- Wrong Medication Quantity
- Other Labeling Error
- Compounding/Preparation Error
- Refill Errors (frequency, timeliness)
- Uncertain and ambiguous prescription
Unprofessional Conduct includes:

- Incompetence, gross negligence, fraud, moral turpitude, dishonesty
- “Clearly” excessive furnishing of controlled substances to others or self
- Conviction of a crime substantially related to license
Outcomes of Investigations

- Inspection and Investigation

- Outcomes:
  - No violation
  - Correction ordered
  - Violation substantiated
    - Citations and Fines, Letters of Admonition
    - Formal Discipline for serious violations
Ways We Achieve Our Enforcement Aims Faster

- Seeking a “Penal Code 23” order at a time of criminal arraignment to ensure a pharmacist or other licensee cannot work until a serious matter has been adjudicated by the criminal court system.
- We also pursue interim suspension orders in CA’s administrative courts.
- Executive officer can issue a cease and desist for specific violations.
Prescription Drug Abuse

- 91.8 m adults used prescription pain relievers in 2015 – 1/3 of adults
- 11.5 m adults misused Rx pain relievers in 2015. Principal reason: to relieve pain
- 5.7 m adults misused tranquilizers in 2015, principally to relax, reduce tension or sleep
- 4.8 m adults misused stimulants, principally to be alert, stay awake or study
- 1.4 m adults missued sedatives, principally for sleep

SAMHSA CBHSQ Report, 7/27/17
Some Statistics

The two most commonly reported sources of the prescription pain relievers that were misused were:
(1) obtaining the drugs from a friend or relative and
(2) receiving the drugs through prescriptions or health care providers
We Have an Epidemic of Drug Overdose Deaths

- The majority of drug overdose deaths (more than six out of ten) involve an opioid.
- Since 1999, the number of overdose deaths involving opioids quadrupled.
- From 2000 to 2015, more than half a million people died from drug overdoses.
- 91 Americans die every day from an opioid overdose.
More Recently

August 8, 2017 WA Post

- Deaths from drug overdoses rose sharply in the first nine months of 2016 -- despite stepped-up efforts by public health authorities.

- Overdose deaths reached a record 19.9 per 100,000 population in the third quarter, a big increase over the 16.7 recorded for the same three months in 2015.
The first two quarters of last year showed death rates of 18.9 and 19.3, far greater than the corresponding periods for 2015.

The October issue of Medical Care journal puts the economic cost of opioid overdose, abuse and dependence at $78.5 billion.
What about Older Patients?

- Opioid abuse down in younger Americans, but up among older adults (UPI, 7/26/2017)

- New Report shows that Opioid Misuse Increases among Older Adults (SAMHSA, 7/26/2017)

- When Your Parents Are Addicted To Painkillers
Opioid Abuse in Older Patients

The high rates of comorbid illnesses in older populations and the potential for drug interactions has profound implications for the health and well-being of older adults who continue to misuse opioids.

These findings highlight the need for prevention programs for all ages as well as to establish improved evidence-based treatment, screening, and appropriate referral services.

Center for Substance Abuse Treatment, Dr. Kimberly Johnson, Director
More on OD Deaths

- Since 1999, the amount of prescription opioids sold in the U.S. nearly quadrupled, yet there has not been an overall change in the amount of pain that Americans report.

- Deaths from prescription opioids—drugs like oxycodone, hydrocodone, and methadone—have more than quadrupled since 1999.
Opioid Abuse

- Among young adults (18 to 25) decreased from 11.5 percent in 2002 to 8 percent in 2014.
- In adults 50 years and older, opioid abuse doubled, from 1 percent to 2 percent

U.S. Substance Abuse and Mental Health Services Administration (SAMHSA)
Incidence of Opioid Misuse by Age

- 18-25:
  - 2002: 4.8%
  - 2003: 5.2%
  - 2004: 4.9%
  - 2005: 4.9%
  - 2006: 5.7%
  - 2007: 5.4%
  - 2008: 5.1%
  - 2009: 5.4%
  - 2010: 5.5%
  - 2011: 5.1%
  - 2012: 5.8%
  - 2013: 5.2%
  - 2014: 4.7%

- 26-49:
  - 2002: 1.1%
  - 2003: 1.1%
  - 2004: 0.9%
  - 2005: 1.4%
  - 2006: 1.3%
  - 2007: 1.7%
  - 2008: 1.4%
  - 2009: 1.7%
  - 2010: 1.7%
  - 2011: 1.4%
  - 2012: 2.1%
  - 2013: 1.7%
  - 2014: 2.0%

- 50+:
  - 2002: 1.1%
  - 2003: 1.1%
  - 2004: 0.9%
  - 2005: 1.4%
  - 2006: 1.3%
  - 2007: 1.7%
  - 2008: 1.4%
  - 2009: 1.7%
  - 2010: 1.7%
  - 2011: 1.4%
  - 2012: 2.1%
  - 2013: 1.7%
  - 2014: 2.0%
Drug Diversion and Drug Losses
Drugs Are Worth More on Street than in the Pharmacy

Street value of common controlled substances; Supply & Demand Affect Price

- Dilaudid 4mg - $15.00-$20.00 per tablet
- Fentanyl - $10.00 per patch
- Hydrocodone - $2.00 - $10.00 per tablet
- Methadone - $10.00 per tablet
- Methyleneephedrine - $5.00 per tablet
- Morphine - $30.00 per/10 tablets
- MS Contin 60mg - $20.00 per dose
- Oxycodone 80mg - $12.00 - $40.00 per tablet
- Oxycontin 80mg - $35.00 - $50.00 per tablet
- Promethazine & Codeine – $1,600 +/ pint
- Diazepam 5mg - $1.00 - $2.00 per tablet
- Vicodin ES - $5.00 per tablet
- Xanax 2mg - $3.00-$5.00 per tablet
How Do Drugs Get on the Street

- Thefts from pharmacies
- Thefts from family members
- “Leftovers” from drug therapy
- Purchases from the Internet (eBay)
- Doctor shoppers
Drug Diversion & Doctor Shopping – what it looks like

- In about a four-year period:
  a patient obtained 636 prescriptions for various controlled substances (over 25 different drugs)
The Prescribers

- The patient saw a total of 116 prescribers (including dentists, physician assistants, and physicians).
- The patient saw 58 prescribers and obtained only a single prescription from each that was filled.
The Dispensers

- The patient used 76 pharmacies to fill the prescriptions for controlled substances
  - 17 pharmacies filled more than 15 prescriptions (22.4%)
  - 15 pharmacies filled between 5 and 10 prescriptions (19.3%)
  - 44 pharmacies filled 4 or fewer (57.9%)

636 Rxs, 25 controlled drugs, 116 prescribers
The Controlled Substances

- 44,423 doses obtained by the patient
- 11,850 hydrocodone doses (26.7%)
- 6,520 morphine sulfate (14.7%)
- 6,473 hydromorphone (14.6%)
- 3,025 oxycodone (6.8%)
- 2,574 alprazolam (5.8%)
- 1,440 zolpidem (3.2%)
Estimated street value

$821,785

- For 70 percent of the 44,400 drug doses obtained.
Another Doctor Shopper

- Adderall was obtained from a community’s pharmacies. The “patient” obtained prescriptions and then filled them on a rotating basis in his community where his family was known. He paid cash.

- Father turned in his son to get him to quit and into treatment.
How Else Do Drugs Leave Pharmacies?

- Thefts
- Thefts of any controlled substance must be reported to the Board of Pharmacy
- “Significant” losses reported to the DEA
- CA had more than 2m dosage units reported lost in 11 months of 2016/17
### Dosage Unit Losses and % by Loss Type

**FY 12/13 - FY 16/17 (through May)**

<table>
<thead>
<tr>
<th>Region</th>
<th>Dosage Units per Region and Loss Type</th>
<th>% Total Dosage Units per Region and Loss Type</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Southern</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Night Break-In</td>
<td>2,011,612</td>
<td>26.1%</td>
</tr>
<tr>
<td>Employee Pilferage</td>
<td>1,661,199</td>
<td>21.6%</td>
</tr>
<tr>
<td>Other</td>
<td>727,712</td>
<td>9.4%</td>
</tr>
<tr>
<td>Robbery</td>
<td>369,170</td>
<td>4.8%</td>
</tr>
<tr>
<td>Unknown</td>
<td>144,323</td>
<td>1.9%</td>
</tr>
<tr>
<td>Lost-in-Transit</td>
<td>102,283</td>
<td>1.3%</td>
</tr>
<tr>
<td>Customer Theft</td>
<td>22,290</td>
<td>0.3%</td>
</tr>
<tr>
<td><strong>Southern Total</strong></td>
<td><strong>5,038,589</strong></td>
<td><strong>65.4%</strong></td>
</tr>
<tr>
<td><strong>Northern</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Employee Pilferage</td>
<td>881,555</td>
<td>11.4%</td>
</tr>
<tr>
<td>Night Break-In</td>
<td>571,271</td>
<td>7.4%</td>
</tr>
<tr>
<td>Other</td>
<td>527,814</td>
<td>6.9%</td>
</tr>
<tr>
<td>Robbery</td>
<td>408,440</td>
<td>5.3%</td>
</tr>
<tr>
<td>Lost-in-Transit</td>
<td>157,085</td>
<td>2.0%</td>
</tr>
<tr>
<td>Unknown</td>
<td>86,429</td>
<td>1.1%</td>
</tr>
<tr>
<td>Customer Theft</td>
<td>38,155</td>
<td>0.5%</td>
</tr>
<tr>
<td><strong>Northern Total</strong></td>
<td><strong>2,670,749</strong></td>
<td><strong>34.6%</strong></td>
</tr>
<tr>
<td><strong>Grand Total</strong></td>
<td><strong>7,709,338</strong></td>
<td><strong>100.0%</strong></td>
</tr>
</tbody>
</table>

1. The Grand Total will not equal the total dosage units report in some previous tables since out-of-state licenses are not included here.
Drug Schemes Involving Pharmacies
Empty Containers in Pharmacy
Found in pharmacies
Drugs Sorted to Fill Empty Containers
Sorted drugs for dispensing
Sources of Drug Stock
Found in another pharmacy
Additional sources of drugs
Samples in Pharmacies
Why are drug take back programs necessary

- Get the unwanted/unneeded medications out of your home
Drug Take Back Programs

- Regulations recently approved in CA
- Two types
  - Mail back envelopes and packets
  - Deposit into collection receptacle
- Where can I find one:
  - Law enforcement
  - Some pharmacies
  - DEA does two annual collection days annually (April & October)
PHARMACEUTICAL WASTE ONLY

Programa de Reciclaje de Medicinas Solamente

It's Easy to Safely Dispose of Medications:
1. Remove, scratch off or black-out personal information from the prescription label.
2. Remove pills from original containers and place in a zip-up bag or dump into secured disposal bin. Keep liquids in original containers and place in secured disposal bin.
3. Recycle the empties pill containers in plastic recycling bin.

Programa de Reciclaje de Medicinas Solamente

Medicines that are accepted:
- Medications that are returned can be reused.
- Paracetamol
- Medicines in external form or cream
- Medicines that are expired
- Auto-injectors
- Bandages
- Emergency medical equipment
- Syringes and needles
- Dental products
- Medicines in liquid form

Medicines that are not accepted:
- Medical products
- Oral products
- Steroids
- Antiviral products
- Human growth hormone
- Prescription tablets
- Preventive care products
- Pain medications

ES FACIL DISPONER DE SU MEDICAMENTOS DE MANERA SEGURA:
1. Retire toda información personal del recipiente de la prescripción.
2. Retire medicamentos sólidos/tabletas de recipiente y coloque en una bolsa de plástico que tenga un cierre hermético.
3. Recicle los recipientes vacíos en casa o en la farmacia en los contenedores de reciclaje de plástico.
What Should I Do When I Go to a Pharmacy

- Talk to the pharmacist. Make certain you know what drug you are receiving, what it is for, precautions and relevant warnings, how to store it, what are side effects, how to destroy it.

- If the pill looks different that the last time you took it, ask the pharmacist, do not take it until you confirm what it is.
Make certain the name on the container is your name.

Don’t buy drugs from the Internet unless you are certain about the pharmacy. Look for .pharmacy suffixes.

Make certain you have no contraindications with other drugs you take or allergies.
Questions?

Thank you

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