AGENDA

Florida Board of Pharmacy
Controlled Substance Standards Committee Meeting
August 14, 2017 – 9:00 a.m.

Embassy Suites Fort Lauderdale * 1100 SE 17th Street
Fort Lauderdale, FL 33316 * (954)315-1326

Committee Members:
Gavin Meshad, Chair
Debra Glass, BPharm
Jeenu Philip, BPharm
Michele Weizer, PharmD

Board Staff
C. Erica White, MBA, JD - Executive Director
Savada Knight, Regulatory Supervisor
Jessica Hollingsworth – Gov. Analyst II

Board Counsel:
David Flynn, Assistant Attorney General
Lawrence Harris, Assistant Attorney General

Note: Participants in this public meeting should be aware that these proceedings are being recorded.

1. **Opioid Epidemic and June 2017 Multi-Board Meeting Update**

2. **Role of the Board of Pharmacy; Pharmacies; and Pharmacist**
   a. How can the board and the profession contribute to solutions?
   b. Practical and Legal Barriers
   c. Patient Management and Addition Recognition – Available Resources
   d. for Legislation
   e. Education; Communication; Collaboration

3. **Collaborative** Practice related to the Prescribing of Controlled Substances and Patient Management

4. **National Response to Opioid Epidemic**

5. **Rule 64B16-27.831 – The Standards of Practice for the Filing of Controlled Substances Prescriptions; Electronic Prescribing; Mandatory Education.**
   a. Review to determine if there are any necessary updates
   b. ARNP and PA Prescribing of Controlled Substances (Need for Education of Rights and Limitation)

6. **Multi-Board Controlled Substance Workgroup** – *November 3, 2017*

7. **Public Comment**

8. **Adjourn**

TAB #1

STATE OF FLORIDA

OFFICE OF THE GOVERNOR
EXECUTIVE ORDER NUMBER 17-177
(Opioid Epidemic)

WHEREAS, the Centers for Disease Control and Prevention has declared a national opioid epidemic which poses a severe threat to the State of Florida and requires that measures are taken to protect the communities and the general welfare of this State; and

WHEREAS, on June 3, 2016 I issued executive order 17-146 declaring that the opioid epidemic threatens the State of Florida with an emergency, and as a consequence of this danger a state of emergency exists in the State of Florida.

WHEREAS, no state of emergency declared pursuant to the Florida Emergency Management Act may continue for more than 60 days unless renewed by the Governor; and

WHEREAS, the opioid epidemic continues to pose an immediate threat to the health, safety, and welfare of the State of Florida and its residents.

NOW, THEREFORE, I, RICK SCOTT, as Governor of Florida, by virtue of the authority vested in me by Article IV, Section 1 (a) of the Florida Constitution and by the Public Health Act, and all other applicable laws, promulgate the following Executive Order, to take immediate effect:

Section 1. The state of emergency declared in Executive Order 17-146 on June 3, 2016 will be extended for 60 days following the issuance of this order.

Section 2. Except as amended herein, Executive Order 17-146 is ratified and reaffirmed.

Section 3. This Executive Order will expire 60 days from this date unless extended within that time.

IN TESTIMONY WHEREOF, I have hereunto set my hand and caused the Great Seal of the State of Florida to be affixed, at Tallahassee, this 29th day of June 2017.

GOVERNOR

ATTEST:

SECRETARY OF STATE

FILED
2017 JUN 29 AM 9:32
DEPARTMENT OF STATE
TALLAHASSEE, FLORIDA

STATE OF FLORIDA

OFFICE OF THE GOVERNOR

EXECUTIVE ORDER NUMBER 17-178

(AMENDING EXECUTIVE ORDER 17-177)

WHEREAS, on June 29, 2017, Executive Order 17-177 was issued extending Executive Order 17-146, for sixty days. Executive Order 17-146 was issued declaring a state of emergency in the State of Florida as the opioid epidemic threatens this State; and

WHEREAS, a scrivener's error occurred in Executive Order stating that Executive Order 17-146 was issued on June 3, 2016; and

WHEREAS, Executive Order 17-146 was issued on May 3, 2017; and

NOW, THEREFORE, I, RICK SCOTT, Governor of Florida, in obedience to my solemn constitutional duty to "take care that the laws be faithfully executed," and pursuant to the Constitution and laws of the State of Florida, do hereby issue the following Executive Order effective immediately:

Section 1.

Executive Order 17-177, extending Executive Order 17-146, is hereby amended to reflect that Executive Order 17-146 was issued on May 3, 2017.

Section 2.

Except as amended herein, Executive Order 17-177 is ratified and reaffirmed.

IN TESTIMONY WHEREOF, I have hereunto set my hand and seal of the State of Florida to be affixed at Tallahassee, this 29th day of June 2017.

RICK SCOTT, GOVERNOR

FILED
2017 JUN 29 PM 4:21
DEPARTMENT OF STATE
TALLAHASSEE, FLORIDA

ATTEST:

SECRETARY OF STATE

STATE OF FLORIDA
SECOND AMENDED
DEPARTMENT OF HEALTH
DECLARATION OF PUBLIC HEALTH EMERGENCY
AND STATEWIDE STANDING ORDER FOR NALOXONE

WHEREAS, on May 19, 2017, Governor Rick Scott declared that the opioid epidemic threatens the State of Florida with an emergency, and that as a consequence of this danger a state of emergency exists in the State of Florida; and

WHEREAS, the Centers for Disease Control and Prevention has declared a national opioid epidemic which poses a severe threat to the State of Florida and requires that measures are taken to protect the communities and the general welfare of this State; and

WHEREAS, in 2015, opioids were responsible for nearly 3,900 deaths in Florida; and

WHEREAS, opioid abuse has required additional resources from local first responders such as law enforcement, firefighters, and emergency medical services; and

WHEREAS, in 2016, Florida enacted the "Emergency Treatment and Recovery Act" which authorized health care practitioners to prescribe and dispense opioid antagonists to patients, caregivers and first responders pursuant to a non-patient-specific standing order for the emergency treatment of known or suspected opioid overdoses occurring when a health care practitioner is not available; and

WHEREAS, pharmacists are authorized to dispense an appropriately labeled opioid antagonist based on a non-patient-specific standing order for an autoinjection delivery system or intranasal application delivery system, which must be appropriately labeled with instructions for use; and

WHEREAS, the Act authorizes emergency responders, including but not limited to, law enforcement officers, paramedics and emergency medical technicians, to possess, store and administer emergency opioid antagonists as clinically indicated; and

WHEREAS, immunity from civil liability is provided under section 768.13, Florida Statutes, the Good Samaritan Act, to any person, including health care practitioners and emergency responders, who possess, administer or store an approved opioid antagonist in accordance with the Act. A health care practitioner acting in good faith and exercising reasonable care is not subject to discipline under the applicable professional licensure statute and is also immune from civil or criminal liability for prescribing or dispensing an opioid antagonist in accordance with the Act.

NOW, THEREFORE, I, Celeste Philip, MD, MPH, Surgeon General of Florida and State Health Officer, by virtue of Executive Order Number 17-146 issued by Governor Rick Scott and the authority vested in me by section 381.00315, Florida Statutes, do hereby declare the following:

Section 1: A Public Health Emergency is declared statewide.

Section 2: As directed by Executive Order Number 17-146, the following Florida standing order for Naloxone is issued.

Naloxone Standing Order

This order authorizes pharmacists who maintain a current active license practicing in a pharmacy located in Florida that maintains a current active pharmacy permit to dispense one of the following naloxone formulations to emergency responders for administration to persons exhibiting signs of opioid overdose. Emergency responders include law enforcement officers, firefighters, paramedics and emergency medical technicians.

The pharmacy must maintain a copy of the naloxone Standing Order if dispensing naloxone pursuant to the order.

Incorporated in this Naloxone Standing Order is the expectation that the SAMHSA Opioid Overdose Prevention Toolkit Five Essential Steps for First Responders be followed.

Approved Options for Intranasal or Auto-Injector Administration:

Intranasal	Auto-Injector	Intranasal
Naloxone 2mg/2ml prefilled syringe, # 2 syringes SIG: Spray one-half of the syringe into each nostril upon signs of opioid overdose. Call 911. May repeat x 1. Mucosal Atomization Device (MAD) # 2 SIG: Use as directed for naloxone administration. Kit must contain 2 prefilled syringes and 2 atomizers and instructions for administration.	Naloxone 0.4 mg **or** 2mg #1 twin pack SIG: Inject one auto-injector into the outer thigh (through clothing if necessary) upon signs of opioid overdose Call 911 May repeat x 1 in 2 to 3 minutes No kit is required. Product is commercially available	Narcan Nasal Spray 4mg, #2 SIG: Administer a single spray intranasally into one nostril. Call 911. Administer additional doses using a new nasal spray with each dose, if patient does not respond or responds and then relapses into respiratory depression. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives. No kit is required. Product is commercially available.

Executed this 19th day of May, 2017, in Department of Health Offices, Tallahassee, Leon County, Florida.

Celeste Philip, MD, MPH
Surgeon General and Secretary

CONTROLLED SUBSTANCES

Presented by:
C. Erica White, MBA, JD
Executive Director
Florida Board of Pharmacy
June 2, 2017

OVERVIEW:

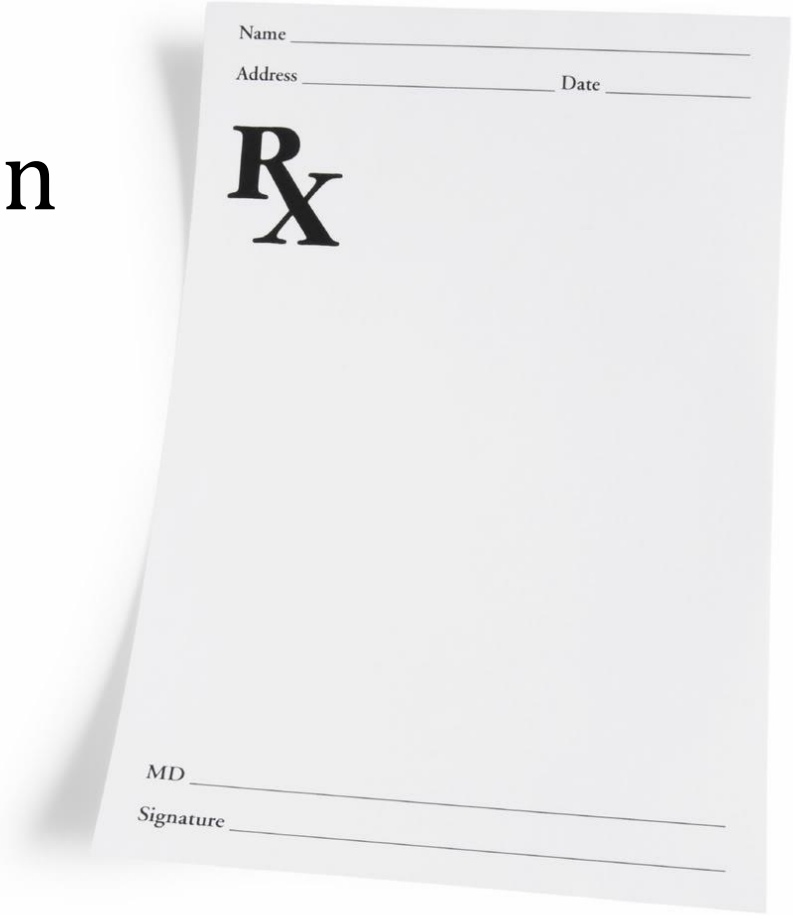
- There is a need for the use of controlled substances, through the use of properly prescribed medications, in order to provide the most effective patient care within various health care professions regulated by the Department.

GOALS:

- To ensure that all health care professions are compliant with Florida Statutes relating to the uses and distributions of controlled substances.

GOALS:

- To prevent fraudulent use or misuse of prescription drugs within regulated health care professions, by monitoring inventories and use of controlled substances by prescribing practitioners.

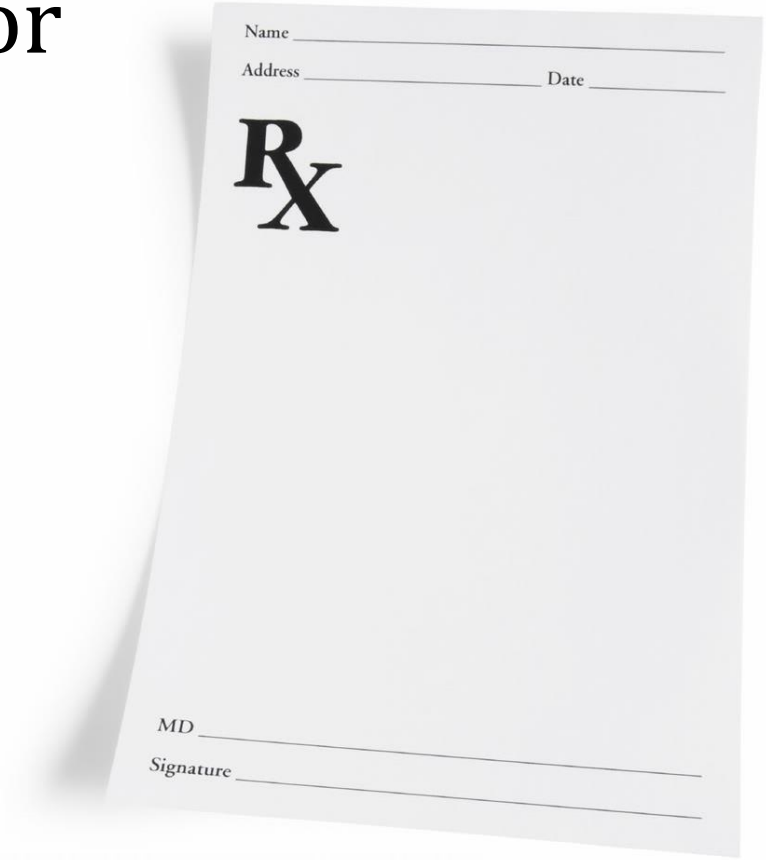


CONTROLLED SUBSTANCES

- Chapter 893, F.S., sets forth the Florida Comprehensive Drug Abuse Prevention and Control Act (Act).

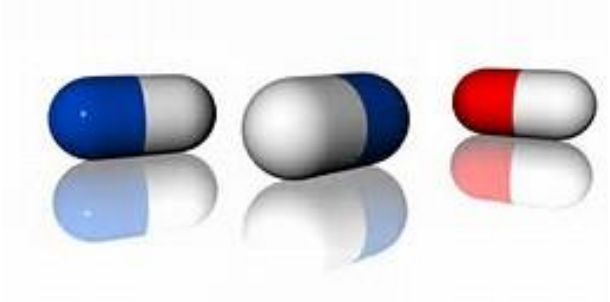
CONTROLLED SUBSTANCES

- The Act also provides requirements for the prescribing and administering of controlled substances by health care practitioners and proper dispensing by pharmacists and health care practitioners.



Drug Enforcement Administration

- Any health care professional wishing to prescribe controlled substances must apply for a registration number from the Drug Enforcement Administration (DEA), housed within the U.S. Department of Justice.



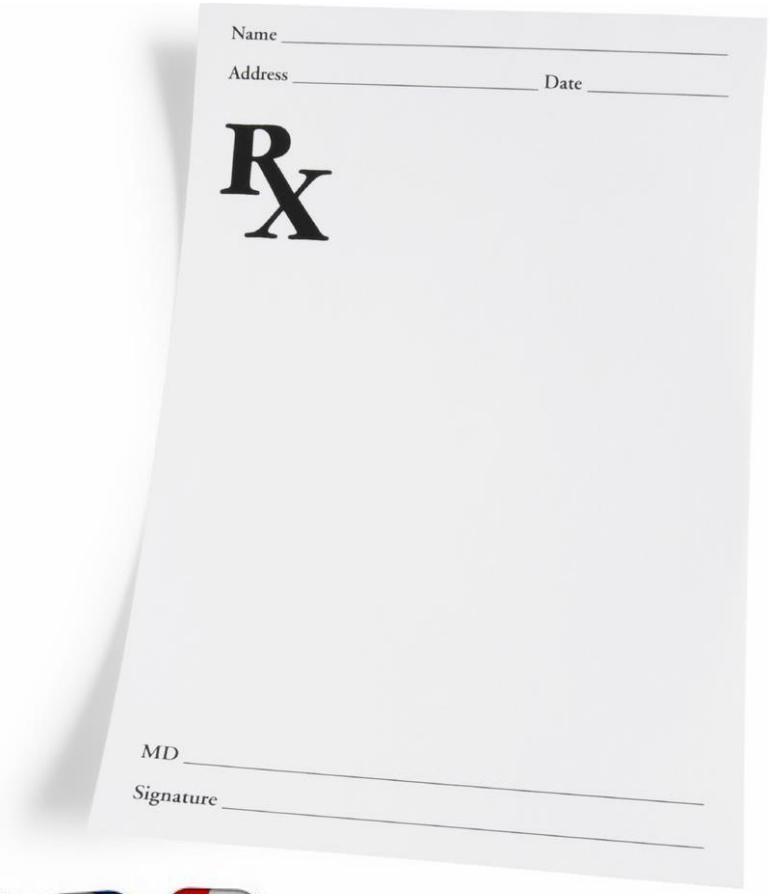
Drug Enforcement Administration

- Registration numbers are linked to state licenses and may be suspended or revoked upon any disciplinary action taken against a licensee.

PRESCRIBING PRACTITIONERS

Prescribing Practitioners

A Pharmacist, in good faith and in the course of professional practice only, may dispense controlled substances upon a written or oral prescription of a practitioner.



Section 893.04(1), F.S.

Prescribing Practitioners

A Physician licensed under Chapter 458, 459, 461, or 466, a PA licensed under Chapter 458 or 459, or an ARNP certified under Chapter 464 - Part I who prescribes any controlled substance, listed in Schedule II, III, or IV as defined, in Section 893.03, F.S.,…

Section 456.44(2), F.S.

Prescribing Practitioner

...Must designate himself or herself as a controlled substance prescribing practitioner on his or her practitioner profile, for the treatment of **chronic nonmalignant pain**.

Section 456.44(2), F.S.

PRESCRIBING PRACTITIONERS

- A Dentist shall have the right to prescribe drugs or medicine, subject to limitations imposed by law.
- Pharmacists licensed pursuant to Chapter 465, F.S., may fill prescriptions from licensed dentists in this state for any drugs necessary for the practice of Dentistry.

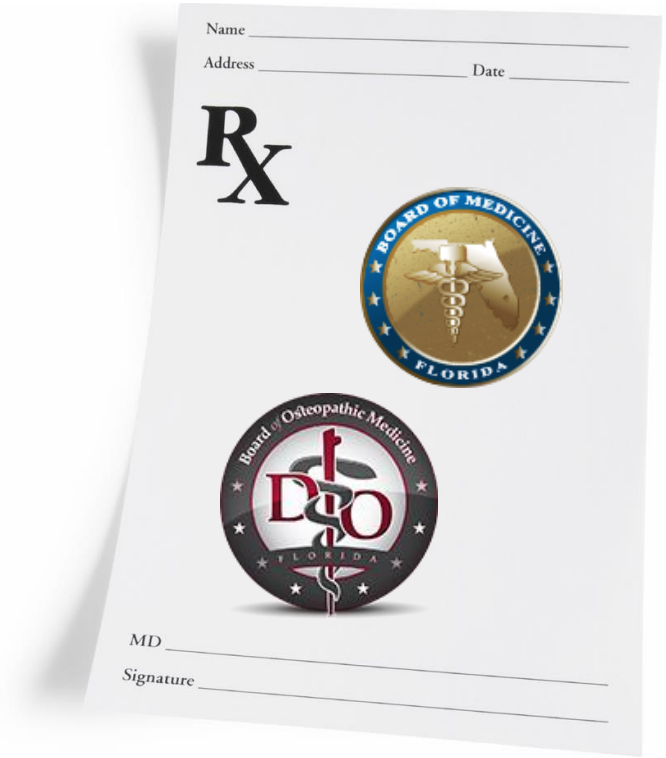
Section 466.017(1) -(2), F.S.

Pain Management Clinics

Pain Management Clinics

Florida HEALTH

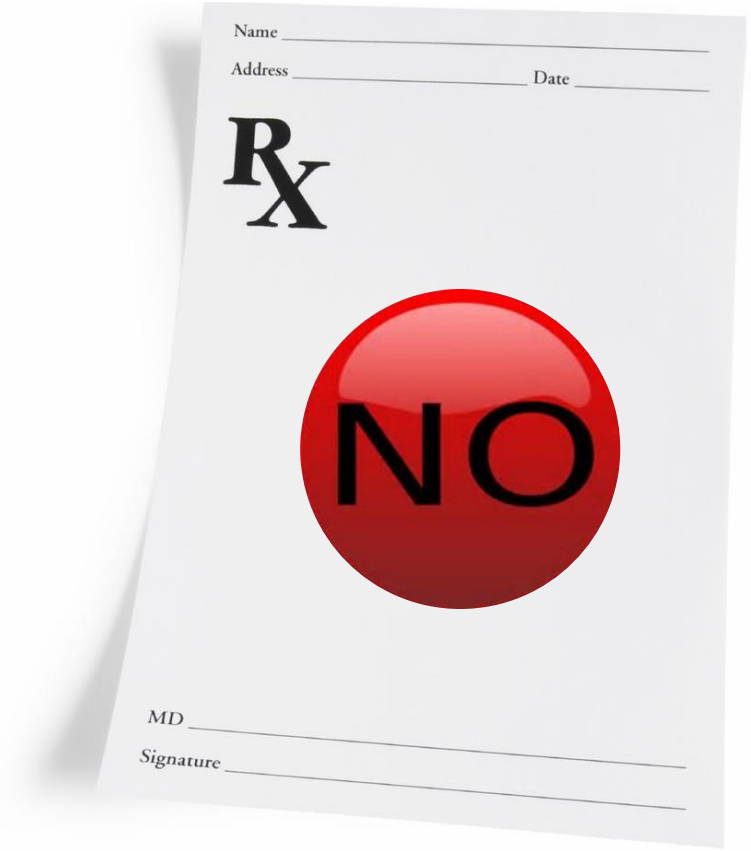
Only a Physician, licensed under Chapter 458 or 459, F.S. may dispense medication or prescribe controlled substances, regulated under Chapter 893, F.S., on the premises of a registered pain-management clinic.



Section 458.3265(2)(b), F.S.

Pain Management Clinics

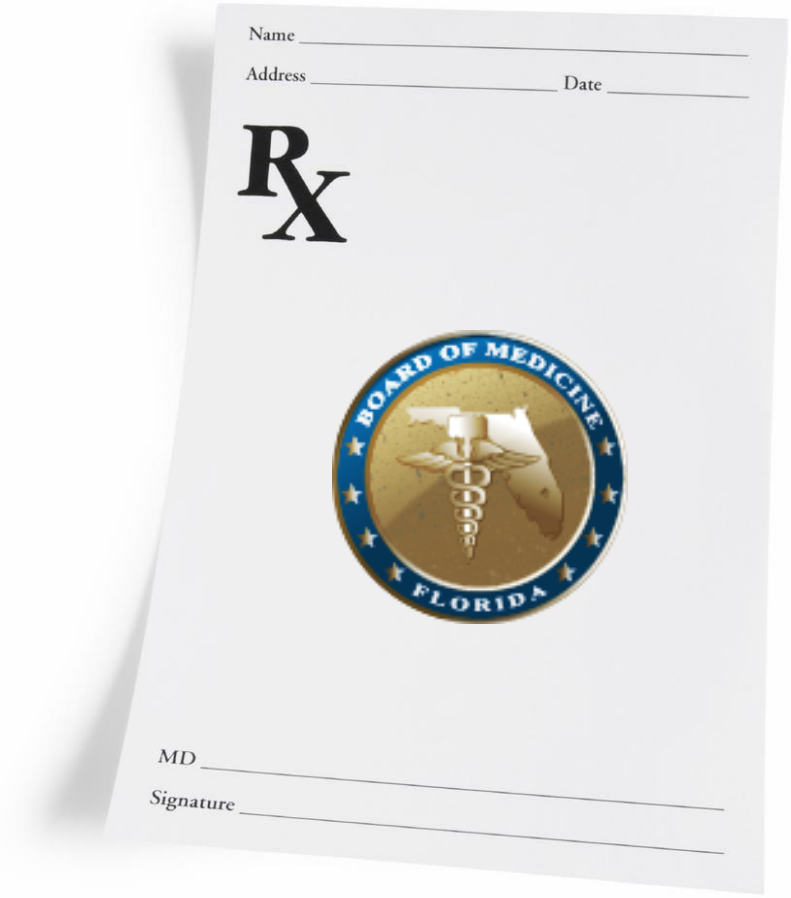
PAs and ARNPs are not allowed to prescribe Controlled Substances, regulated under Chapter 893, F.S., in pain-management clinics.



Physician Assistants

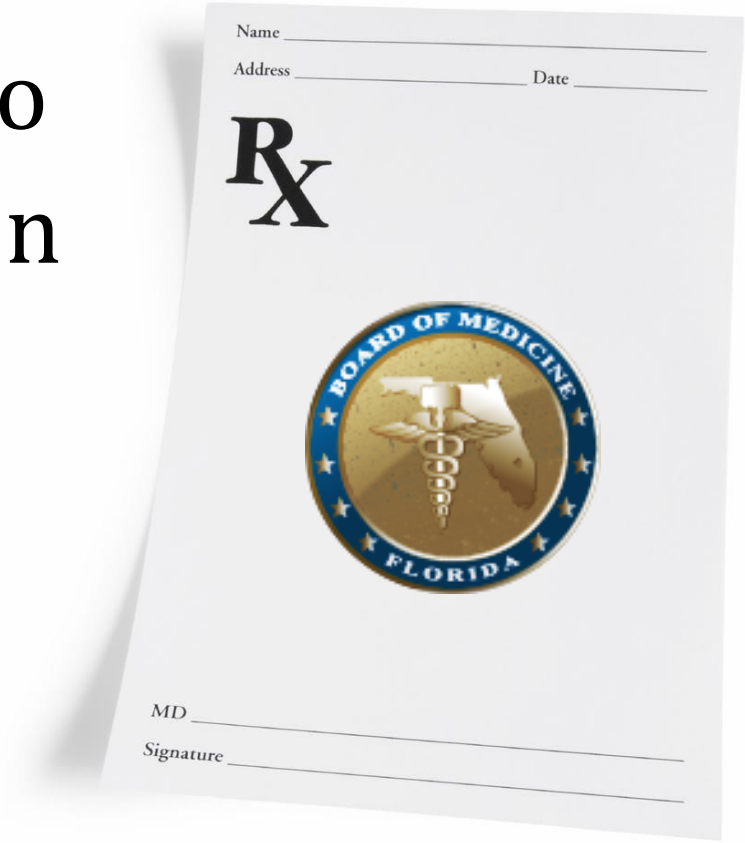
Physician Assistants (PA)

Effective January 1, 2017, PAs are authorized to prescribe controlled substances.



Physician Assistants - Supervision

A supervising physician may delegate to a fully licensed PA, the authority to prescribe or dispense any medication used in the supervising physician's practice unless such medication is listed a formulary established in Section 458.347(4)(f), F.S.



PA FORMULARY

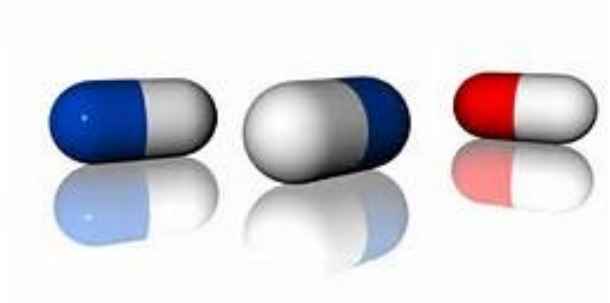
The Council of Physician Assistants shall establish a formulary of medicinal drugs that a fully licensed PA having prescribing authority under Section 458.347, F.S., or Section 459.022, F.S., may not prescribe.

PA FORMULARY

- The formulary must include general anesthetics and radiographic contrast materials.
- The formulary must also limit the prescription of Schedule II controlled as listed in Section 893.03, F.S., to a 7- day supply.

PA FORMULARY

- The bill also requires that the formulary must restrict the prescribing of psychiatric mental health controlled substances for children younger than 18 years of age.



Physician Assistants - Supervision

A fully licensed PA may only prescribe or dispense such medication under the following circumstances:

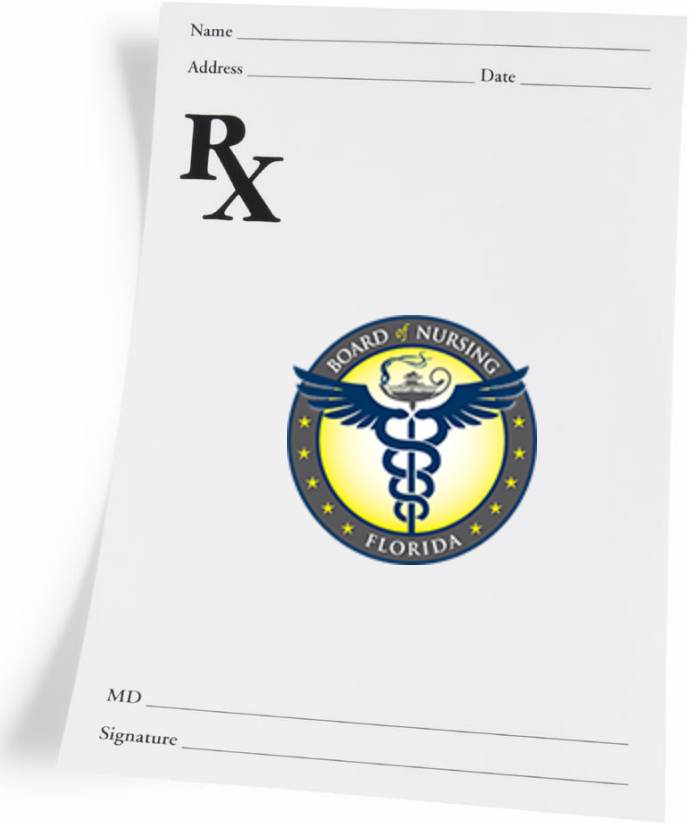
- A PA must clearly identify to the patient that he or she is a PA.
- The PA must inform the patient that he or she has the right to see a physician prior to any prescription being prescribed or dispensed by the PA.

Section 458.347(4)(e), F.S.

Advanced Registered Nurse Practitioners

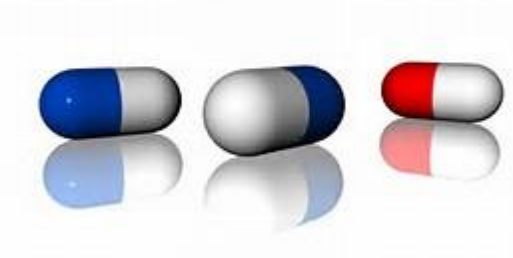
ARNP Prescribing

Effective January 1, 2017, ARNPs are authorized to prescribe, dispense, administer, or order any drug within an established supervisory protocol.



ARNP Prescribing

An **ARNP** may prescribe or dispense a controlled substance, as defined in (s) 893.03, F.S. only he or she has graduated from a program leading to a Master's or Doctoral degree in a clinical nursing specialty area with training in specialized practitioner skills.



ARNP – Formulary

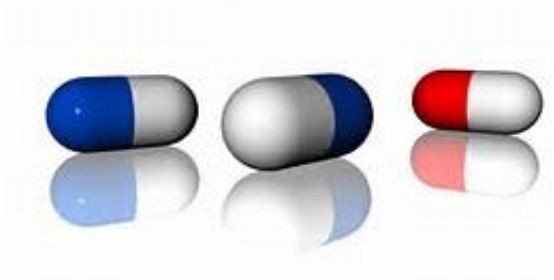
The Board of Nursing shall establish a committee to recommend a formulary of controlled substances that an ARNP may not prescribe or may prescribe only for specific uses or in limited quantities.

Section 464.012(6)(a), F.S.

CONTROLLED SUBSTANCE FORMULARY

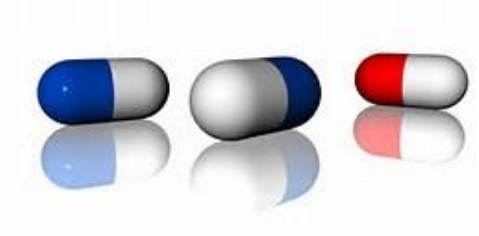
- Rule 64B9-4.016, F.A.C., became effective on October 16, 2016.

- The Rule provides:
  - ✓ ARNPs may only prescribe controlled substances pursuant to the individual's education, training, experience and protocol.



ARNP – Formulary

- ✓ ARNPs must restrict prescriptions of Schedule II controlled substances, listed in Section 893.03, F.S., to a 7-day supply.
- ✓ This does not apply to prescription of psychiatric medications prescribed by a psychiatric nurse as defined in Section 394.455, F.S.



Section 464.012(6)(a), F.S.

Rule 64B9-4.016, F.A.C.,

ARNP – FORMULARY

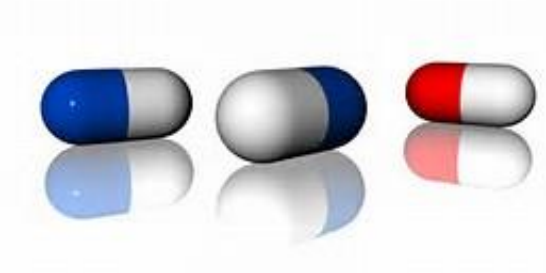
- ✓ Only ARNPs who meet the definition of a psychiatric nurse, as defined in Section 394.455, F.S., may prescribe psychiatric mental health controlled substances to children younger than 18 years of age.

Section 464.012(6)(a), F.S.

Rule 64B9-4.016, F.A.C.,

ARNP – Formulary

The formulary must also limit the prescribing of Schedule II controlled substances as listed in (s) 893.03, F.S., to a 7-day supply, except that such restriction does not apply to controlled substances that are psychiatric medications prescribed by psychiatric nurses as defined in s. 394.455, F.S.



Florida Prescription Drug Monitoring Program

FLORIDA PDMP / E-FORCSE®

The Florida Prescription Drug Monitoring Program, known as E-FORCSE® (Electronic-Florida Online Reporting of Controlled Substance Evaluation Program), was created by the 2009 Florida Legislature as an initiative to encourage safer prescribing of controlled substances and to reduce drug abuse and diversion within Florida.

FLORIDA PDMP / E-FORCSE®

The purpose of the PDMP is to provide the information that is collected in the database to health care practitioners to guide their decisions in prescribing and dispensing these highly abused prescription drugs.

FLORIDA PDMP / E-FORCSE®

Section 893.055, Florida Statutes, requires health care practitioners to report to the PDMP each time a controlled substance is dispensed to an individual. The information is reported through the system as soon as possible but not more than 7 days after dispensing.

FLORIDA PDMP / E-FORCSE®

In addition to practitioners and Pharmacists, a law enforcement agency may request confidential controlled substance dispensing information in the database during active investigations regarding potential criminal activity, fraud, or theft regarding prescribed controlled substances.

FLORIDA PDMP / E-FORCSE®

Florida HEALTH

Also the Department of Health Investigative Services Unit and Medicaid Fraud Unit investigators may request information in the database to aide in the investigation of cases involving controlled substances.

E-FORCSE
Electronic-Florida Online Reporting of Controlled Substances Evaluation

FLORIDA PDMP / E-FORCSE®

On February 14, 2017, a designee of a prescriber or dispenser may have direct access to the controlled substance dispensing information in the E-FORCSE® database by registering on the E-FORCSE® secure web portal.

FLORIDA PDMP / E-FORCSE®

In 2016, Florida Legislature passed SB 964 authorizing direct access to controlled substance dispensing information within the E-FORCSE® database to a designee of a prescriber or dispenser.

Rule 64K-1.003(3), F. A.C. sets forth the requirements for access.

FLORIDA PDMP / E-FORCSE®

The information collected in the system will be used by the PDMP to encourage safer prescribing of controlled substances and to reduce drug abuse and diversion within the State of Florida.

E-FORCSE
Electronic-Florida Online Reporting of Controlled Substances Evaluation

TAB #2

WHEN THE PRESCRIPTION BECOMES THE PROBLEM

Florida HEALTH

Your prescribed pain medication is only for you.

Health care providers prescribe pain medications based on a person's specific symptoms and medical history. That's why these medicines must not be shared with friends or family. Take your medication as prescribed, and follow your health care provider's instructions on using pain medication with other prescriptions and non-prescription drugs.

When pain medication is misused or abused, it does more harm than good.

Common signs of pain medication misuse or abuse are:

- Failing to take your medicine as prescribed by your health care provider.
- Sharing or selling your medication.
- Taking your medicine for reasons other than prescribed.
- Missing work or school, neglecting family and friends, or endangering yourself.
- Not being honest with your health care provider, family and friends about your medication use.

Know the difference between drug tolerance and drug addiction.

TOLERANCE: When the body becomes used to a drug, it has built a tolerance that makes the drug less effective at a given dose. This is a common occurrence for people with chronic pain who use opioid-based medication such as hydrocodone, oxycodone and morphine.

ADDICTION: A person is addicted when they use a drug compulsively despite the harmful consequences. Addiction is far more than a craving and can be characterized as a disease.

Pain medications should be safely stored and properly disposed.

STORAGE: Store pain medication safely and securely—away from people and pets. Avoid using common storage areas such as bathroom medicine chests, kitchen cabinets or bedroom night stands.

DISPOSAL: Always read and follow the disposal instructions on the drug label or patient information sheet that accompanies your medication. Never flush prescription drugs down the toilet. Get rid of expired, unwanted or unused pain medication as soon as possible to reduce the chance of others accidentally or intentionally taking your medicine.

Community drug take-back programs are your best option for drug disposal. These programs allow you to bring unused drugs to a central location for safe disposal. Call your pharmacist, local law enforcement department or your local government's household trash and recycling service to see if a take-back program is available in your community.

If your community does not offer a drug take-back program, follow these steps:*

1. Mix medicines with a substance that can't be eaten such as dirt, kitty litter or used coffee grounds—don't crush tablets or capsules.
2. Place the mixture in a plastic container or bag, and tightly seal.
3. Throw the container in your household trash.
4. Scratch out and make unreadable all personal information on the prescription label of your empty pill bottle or medicine packaging, and throw these items in your household trash.

Ask your provider about other options to treat your chronic pain.

Be involved, keep your health care team updated on how your treatment is going.

If you are struggling with addiction, help is available in your area.

BIG BEND COMMUNITY BASED CARE (BBCBC): 850-410-1020

CENTRAL FLORIDA BEHAVIORAL HEALTH NETWORK (CFBHN): 813-740-4811

CENTRAL FLORIDA CARES: 407-985-3560

LUTHERAN SERVICES OF FLORIDA: Access to Care Line, 1-877-229-9098

SOUTHEAST FLORIDA BEHAVIORAL HEALTH NETWORK, INC.: 561-203-2485

BROWARD BEHAVIORAL HEALTH COALITION: 877-698-7794

SOUTH FLORIDA BEHAVIORAL HEALTH NETWORK: 888-248-3111

DEPARTMENT OF CHILDREN AND FAMILIES: www.myflfamilies.com/service-programs/substance-abuse/get-help

*https://archive.epa.gov/region02/capp/web/pdf/ppcpflyer.pdf

GUIDELINE FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN

IMPROVING PRACTICE THROUGH RECOMMENDATIONS

CDC's *Guideline for Prescribing Opioids for Chronic Pain* is intended to improve communication between providers and patients about the risks and benefits of opioid therapy for chronic pain, improve the safety and effectiveness of pain treatment, and reduce the risks associated with long-term opioid therapy, including opioid use disorder and overdose. The Guideline is not intended for patients who are in active cancer treatment, palliative care, or end-of-life care.

DETERMINING WHEN TO INITIATE OR CONTINUE OPIOIDS FOR CHRONIC PAIN

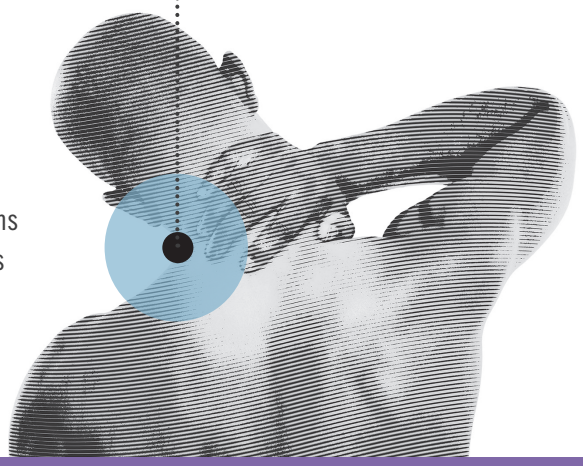
1. Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate.

2. Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients, including realistic goals for pain and function, and should consider how opioid therapy will be discontinued if benefits do not outweigh risks. Clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety.

3. Before starting and periodically during opioid therapy, clinicians should discuss with patients known risks and realistic benefits of opioid therapy and patient and clinician responsibilities for managing therapy.

CLINICAL REMINDERS

- **Opioids are not first-line or routine therapy for chronic pain**
- **Establish and measure goals for pain and function**
- **Discuss benefits and risks and availability of nonopioid therapies with patient**



U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

LEARN MORE | www.cdc.gov/drugoverdose/prescribing/guideline.html

OPIOID SELECTION, DOSAGE, DURATION, FOLLOW-UP, AND DISCONTINUATION

CLINICAL REMINDERS

- **Use immediate-release opioids when starting**
- **Start low and go slow**
- **When opioids are needed for acute pain, prescribe no more than needed**
- **Do not prescribe ER/LA opioids for acute pain**
- **Follow-up and re-evaluate risk of harm; reduce dose or taper and discontinue if needed**

4 When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids.

5 When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when considering increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day.

6 Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed.

7 Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids.

ASSESSING RISK AND ADDRESSING HARMS OF OPIOID USE

8 Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (≥50 MME/day), or concurrent benzodiazepine use, are present.

9 Clinicians should review the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose. Clinicians should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months.

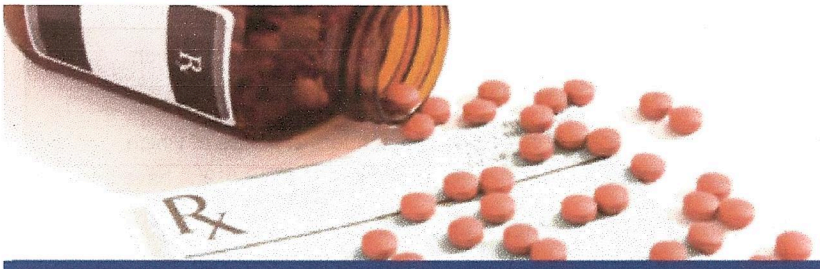
10 When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs.

11 Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible.

12 Clinicians should offer or arrange evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder.

CLINICAL REMINDERS

- **Evaluate risk factors for opioid-related harms**
- **Check PDMP for high dosages and prescriptions from other providers**
- **Use urine drug testing to identify prescribed substances and undisclosed use**
- **Avoid concurrent benzodiazepine and opioid prescribing**
- **Arrange treatment for opioid use disorder if needed**



E-FORCSE

Electronic-Florida Online Reporting of Controlled Substances Evaluation

Florida's Prescription Drug Monitoring Program

QUARTERLY DASHBOARD

PERFORMANCE MEASURE

P1 The number of controlled substance dispensing records that have been reported to the Prescription Drug Monitoring Program (PDMP) since it began collecting data on September 1, 2011.

March 31, 2017

216,187,278

P2 The number of prescriptions of the most commonly dispensed controlled substances.

As of March 31, 2017

TOP 10 CONTROLLED SUBSTANCES	NUMBER OF RX
HYDROCODONE/ACETAMINOPHEN	1,227,805
ALPRAZOLAM	1,116,105
OXYCODONE HCL/ACETAMINOPHEN	804,936
TRAMADOL HCL	758,493
ZOLPIDEM TARTRATE	605,916
CLONAZEPAM	548,950
LORAZEPAM	462,551
DEXTROAMPHETAMINE/AMPHETAMINE	459,522
OXYCODONE HCL	399,680
TEMAZEPAM	348,774

P3 The percentage of pharmacies that are reporting controlled substance prescriptions to the PDMP, as required by section 893.055, Florida Statutes.

During the period January 1, 2017 to March 31, 2017 5,878 pharmacies out of 6,286 (93.5%) pharmacies were found to be in compliance with reporting requirements.

P4 The number of health care practitioners who have requested access to the PDMP database and the number of authorized users who have requested and received controlled substance dispensing information by user type.

Among all licensed health care practitioners, pharmacists have the highest registration rate, 57.7 percent. Additionally, pharmacists have the highest utilization rate, 91.3 percent, and have queried the database 18,727,145 times.

Among all prescribers, osteopathic physicians have the highest registration rate, 37.3 percent. Overall 25.8 percent of all licensed health care practitioners have registered to use the database. In addition, 80.8 percent of all healthcare practitioners registered to use the database have queried 33,626,956 times.

License Type	Number Registered Users	Total Number Licensed	Percentage Registered	Number Users That Have Queried	Percentage Users that have Queried	Number of Queries
ARNP	3,013	23,442	12.9%	2,174	72.2%	875,791
Dentist	1,012	13,402	7.6%	619	61.2%	25,899
Medical Doctor	14,414	73,085	19.7%	10,614	73.6%	10,884,635
Optometrist	15	3,336	0.4%	4	26.7%	18
Osteopathic Physician	3,066	8,217	37.3%	2,388	77.9%	2,444,367
Physician Assistant	2,001	7,846	25.5%	1,570	78.5%	639149
Podiatric Physician	215	1,816	11.8%	132	61.4%	15,574
Pharmacist	17,449	30,247	57.7%	15,926	91.3%	18,727,145
Designee	396	N/A	N/A	182	46.0%	14,378
TOTAL	**41,581**	**161,391**	**25.8%**	**27,946**	**80.8%**	**33,626,956**

P5

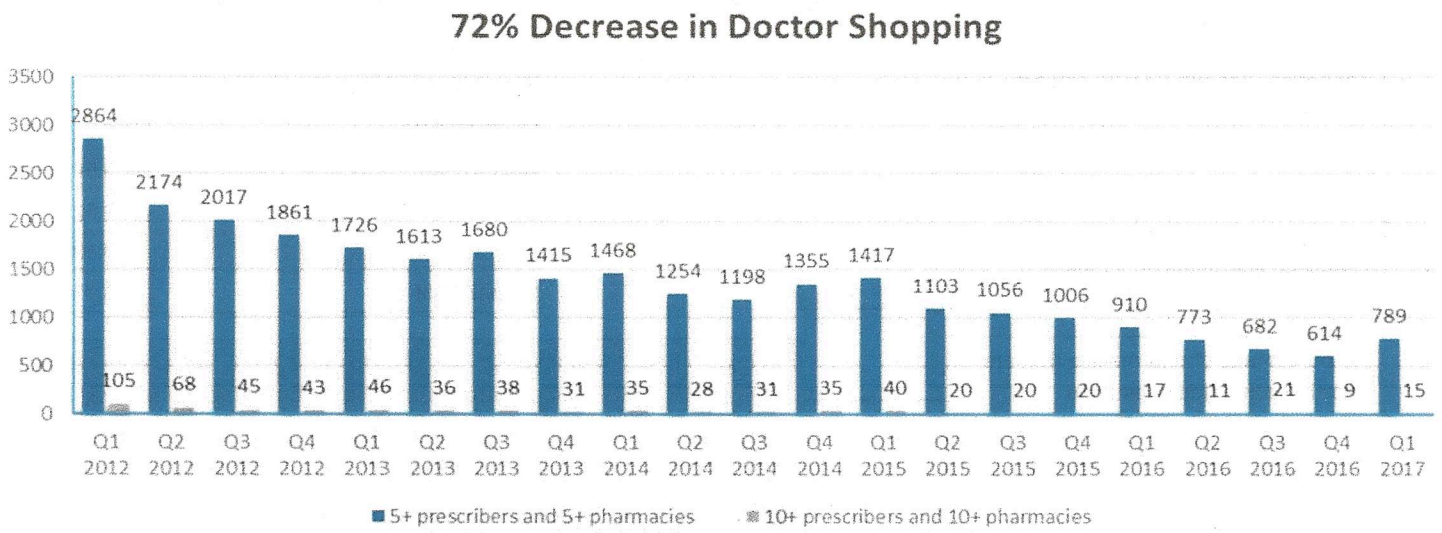
The percentage of the top 200 prescribers who are registered to access the PDMP database and percentage of those registered who have queried patient specific controlled substance dispensing information.

January 1, 2016 to March 31, 2016

- 170/200 (85%) of Top 200 prescribers registered of which 167/170 (98%) have queried
- 165/200 (82.5%) of Top 200 prescribers are MDs of which 1384/165 (84%) have registered and 136/138 (99%) have queried
- 35/200 (17.5%) of top prescribers are DOs of which 32/35 (91%) have registered and 31/32 (97%) of those registered have queried

P6

The number of individuals receiving a controlled substance prescription from five or more prescribers (or 10 or more prescribers) and having controlled substance prescriptions dispensed from five or more pharmacies (or 10 or more pharmacies) during a 90-day period.

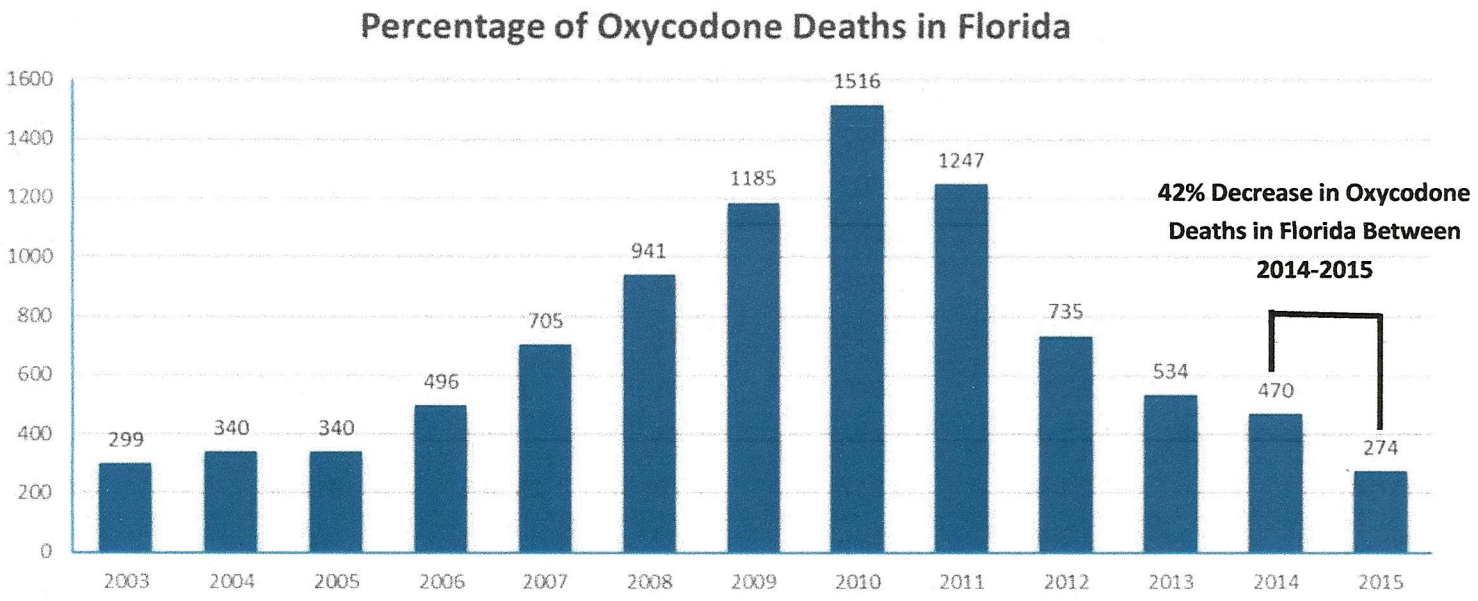


Source: Prescription Drug Monitoring Program

P7

The Drugs Identified in Deceased Persons by Florida Medical Examiners 2015 Report shows a 82 percent decrease in deaths caused by oxycodone since 2010.

The Drugs Identified in Deceased Persons by Florida Medical Examiners 2015 Report shows a 42 percent decrease in deaths caused by oxycodone when compared to 2014.



Source: Drugs Identified in Deceased Persons by Florida Medical Examiners 2015 Report

TAB #4

Dear Mr. President:

I am proud to present to you today the interim report prepared by your Commission on Combating Drug Addiction and the Opioid Crisis. This interim report is just a start; our work is ongoing and we will have more to share with you and the nation later in the Fall of 2017. We now recommend several actions for you to take as our nation's Chief Executive and someone who spoke passionately on this issue in the 2016 campaign.

Our nation is in a crisis. Your Executive Order recognized that fact. The work of your Commission so far acknowledges the severity of this national problem.

According to the Centers for Disease Control (CDC), the most recent data estimates that 142 Americans die <u>every</u> <u>day</u> from a drug overdose. Our citizens are dying. We must act boldly to stop it. The opioid epidemic we are facing is unparalleled. The average American would likely be shocked to know that drug overdoses now kill more people than gun homicides and car crashes combined. In fact, between 1999 and 2015, more than 560,000 people in this country died due to drug overdoses – this is a death toll larger than the entire population of Atlanta. As we have all seen, opioids are a prime contributor to our addiction and overdose crisis. In 2015, nearly two-thirds of drug overdoses were linked to opioids like Percocet, OxyContin, heroin, and fentanyl. This is an epidemic that all Americans face because here is the grim reality: Americans consume more opioids than any other country in the world. In fact, in 2015, the amount of opioids prescribed in the U.S. was enough for every American to be medicated around the clock for three weeks.

Since 1999, the number of opioid overdoses in America have quadrupled according to the CDC. Not coincidentally, in that same period, the amount of prescription opioids in America have quadrupled as well. This massive increase in prescribing has occurred despite the fact that there has not been an overall change in the amount of pain Americans have reported in that time period. We have an enormous problem that is often not beginning on street corners; it is starting in doctor's offices and hospitals in every state in our nation.

But, the challenge of reducing opioid supplies has evolved. As access to prescription opioids tightens, consumers increasingly are turning to dangerous street opioids, heroin, fentanyl alone or combined, and mingled with cocaine or other drugs. In 2016, specific states witnessed an escalating number of overdose deaths due to heroin and/or fentanyl(s), in some states vastly exceeding deaths due to prescription opioids.

In 2015, 27 million people reported <u>current</u> use of illegal drugs or abuse of prescription drugs. Despite this self-reporting, only 10 percent of the nearly 21 million citizens with a substance use disorder (SUD) receive any type of specialty treatment according to the most recent National Survey on Drug Use and Health. This is contributing greatly to the increase of deaths from overdose.

Over forty percent of people with a substance use disorder also have a mental health problem, but less than half of these people receive treatment for either issue. The reasons for these

treatment gaps are many, including lack of access to care, fear of shame and discrimination, and lack of motivation to seek treatment.

This Commission has been hard at work to meet the goals set for us in the Executive Order on March 29th, 2017. As a Commission, we have already met with leading national organizations in the addiction space, and we have received information and recommendations from countless individuals and groups, all of whom share in our commitment to beating this epidemic. The Commission thanks all the individuals and organizations, including Governors and representatives from Governors Offices from around the country, that have reached out to offer their experiences, expertise, and input.

In addition to conducting phone calls with Governors and their teams in all 50 states, we also held a listening session with bi-partisan members of Congress, and key cabinet members of your Administration. Individual Commission members have organized "listening sessions" and solicited recommendations from treatment providers, addiction psychiatrists and other physicians, data analysts, professional medical and treatment societies, medical educators, healthcare organizations, pharmacoepidemiologists, and insurance providers. Outreach also has been made to scientists with broad expertise in pain, addiction biology and treatment.

The first public meeting of the Commission was held on June 16th at the White House, and was a great success. The Commission members heard comprehensive public testimony by nine leading nonprofits, and have received more than 8,000 comments from the public, including comments from at least 50 organizations.

This information was reviewed by the Commission members and helped inform this interim report.

The first and most urgent recommendation of this Commission is direct and completely within your control. Declare a national emergency under either the Public Health Service Act or the Stafford Act. With approximately 142 Americans dying every day, America is enduring a death toll equal to September 11th <u>every</u> <u>three</u> <u>weeks</u>. After September 11th, our President and our nation banded together to use every tool at our disposal to prevent any further American deaths. Your declaration would empower your cabinet to take bold steps and would force Congress to focus on funding and empowering the Executive Branch even further to deal with this loss of life. It would also awaken every American to this simple fact: if this scourge has not found you or your family yet, without bold action by everyone, it soon will. You, Mr. President, are the only person who can bring this type of intensity to the emergency and we believe you have the will to do so and to do so immediately.

The Commission is additionally proposing the following recommendations for action:

- **Rapidly increase treatment capacity. Grant waiver approvals for all 50 states to quickly eliminate barriers to treatment resulting from the federal Institutes for Mental Diseases**

(IMD) exclusion within the Medicaid program. This will immediately open treatment to thousands of Americans in existing facilities in all 50 states.

The Commission has been urged by every Governor, numerous treatment providers, parents, and non-profit advocacy organizations to eliminate the IMD exclusion within the Medicaid program. This component of the Social Security Act prohibits federal Medicaid funds from reimbursing services provided in an inpatient facility treating "mental diseases" (including SUDs) that have more than 16 beds. This exclusion makes states entirely responsible for Medicaid-eligible patients in inpatient treatment facilities, including patients undergoing withdrawal management in addiction treatment facilities rather than hospitals. The Commission members that serve as Governors, as well as individuals and organizations that treat Medicaid patients, are intimately aware of how the IMD exclusion impacts the ability to serve patients with severe SUDs that are best served in an inpatient setting. The Commission recognizes that legislation would be necessary to repeal the exclusion in its entirety. However, certainly after an emergency declaration by the President (and arguably even without it) the Department of Health and Human Services (HHS) Secretary would be empowered to immediately grant waivers to each state that requests one. This is the single fastest way to increase treatment availability across the nation.

- **Mandate prescriber education initiatives with the assistance of medical and dental schools across the country to enhance prevention efforts. Mandate medical education training in opioid prescribing and risks of developing an SUD by amending the Controlled Substance Act to require all Drug Enforcement Administration (DEA) registrants to take a course in proper treatment of pain. HHS should work with partners to ensure additional training opportunities, including continuing education courses for professionals.**

According to a Substance Abuse and Mental Health Services Administration (SAMHSA) Center for Behavioral Health and Statistics Quality (CBHSQ) report, four out of every five new heroin users begin with nonmedical use of prescription opioids.

In other words, Mr. President, this crisis began in our nation's health care system. While we acknowledge that some of this inappropriate overprescribing is done illegally and for profit, we believe the overwhelming percentage is due to a lack of education on these issues in our nation's medical and dental schools and a dearth of continuing medical education for practicing clinicians. This can and must be solved by using Presidential moral and legal authority to change this lack of education leading to addiction and death.

There are several initiatives around the country aimed at ensuring that providers are aware of the potential for misuse and abuse of prescription opioids.

Governor Baker's administration in Massachusetts has worked with the medical and dental schools in that state and the Medical Society to develop core competencies related to opioids and SUDs that all graduating students are expected to learn and put into practice. Other states such as Arizona, Connecticut, Pennsylvania, New York, and Utah have expanded continuing medical education requirements for opioid prescribers and

dispensers. Alternatively, the American Society of Addiction Medicine (ASAM) has recommended implementing a requirement that clinicians who apply for a registration with the DEA to prescribe controlled substances demonstrate competency in safe prescribing, pain management, and substance use identification. In New Jersey, Governor Christie recently signed a law that requires providers themselves to take continuing education related to opioids, and requires prescribers to discuss the risks of opioid dependence with their patients prior to the first prescription. We urge national implementation of these initiatives.

In our first Commission meeting, we heard from several nonprofits about the need to promote expanded implementation of the CDC *Guideline for Prescribing Opioids for Chronic Pain* through increased prescriber education initiatives. The Office of National Drug Control Policy (ONDCP) estimates that, apart from federal prescribers who are required to be trained, fewer than 20% of the over one million prescribers licensed to prescribe controlled substances to patients have training on how to prescribe opioids safely. Similarly, it seems that many medical providers are not well-versed on how to screen for addiction, and what to do if a patient has become dependent on substances or presents with an SUD. We urge you to instruct the Department of Justice (DOJ) and the DEA to require continuing medical education for every physician requesting an initial DEA license or the renewal of such a license.

The CDC and the U.S. Food and Drug Administration (FDA) should finalize, review and recommend national training standards working with the Accreditation Council for Continuing Medical Education (ACCME) to ensure training courses are coordinated with other federal agencies, professional societies, medical schools, and residency programs to avoid discrepancies.

The FDA should also work with the ACCME to develop data analytics to determine whether courses change practices, increase patient referrals to treatment, and methods to improve compliance consistent with opioid prescribing education.

Clinicians need more detailed and specific guidance on drug choice, dose, and quantity to be dispensed in treating specific pain conditions. We also recommend a detailed analysis of, and solutions to clinical problems encountered in applying recommended guidelines.

- **Immediately establish and fund a federal incentive to enhance access to Medication-Assisted Treatment (MAT). Require that all modes of MAT are offered at every licensed MAT facility and that those decisions are based on what is best for the patient. Partner with the National Institutes of Health (NIH) and the industry to facilitate testing and development of new MAT treatments.**

MAT has proven to reduce overdose deaths, retain persons in treatment, decrease use of heroin, reduce relapse, and prevent spread of infectious disease. Expansion of MAT availability for qualified individuals and for short- or long-term treatment is an essential

component of treatment services. Yet approximately 10 percent of conventional drug treatment facilities in the United States provide MAT for opioid use disorder.

Individuals seeking SUD treatment, and even those currently enrolled in a treatment system, often find barriers to using MAT as a component of their treatment. Particularly for populations with opioid use disorders (OUDs) involved in the criminal justice system, there is often inadequate access to FDA-approved medications that are proven to improve outcomes as part of a full continuum of care. Multiple studies have shown that individuals receiving MAT during and after incarceration have lower mortality risk, remain in treatment longer, have fewer positive drug screens, and have lower rates of recidivism than other individuals with OUDs that do not receive MAT. The DOJ, in consultation with HHS and ONDCP, should be directed to increase the use of MAT for OUDs in these correctional settings.

In addition, the Centers for Medicare & Medicaid Services (CMS) should require all federally-qualified health centers (FQHCs) to mandate that their staff physicians, physician assistants, and nurse practitioners possess waivers to prescribe buprenorphine.

There are several barriers to the use of MAT, including a prevalent belief that use of MAT does not constitute true recovery or sobriety. The Federal Government, as a major purchaser of health care services, has a tremendous opportunity to increase the availability of MAT for individuals with OUDs. For example, across the Veterans Administration (VA) and Indian Health Services, there is a lack of providers able to prescribe/administer MAT. For Medicare patients, the Part B physician benefit does not cover methadone treatment and the Part D pharmaceutical benefit does not cover it either, as it is administered by a medical professional. CMS should send a letter to state health officials requesting that state Medicaid programs cover all FDA-approved MAT drugs for OUD.

Additionally, all FDA-approved MAT should be offered by authorized providers, not just one or two of these approved options. These decisions of which (if any) MAT to be used must be based upon what is best for the patient, not what is best for the provider. This can be mandated by the Executive Branch.

Finally, we urge you to instruct the NIH to begin to immediately work with the pharmaceutical industry in two areas; the development of additional MAT options and the development of new, non-opioid pain relievers based on research to clarify the biology of pain. The nation needs more options to treat those already addicted and can help to prevent addiction in the first place by avoiding the prescription of opioids. The NIH is best positioned, in our opinion, to lead this effort with industry partners.

- **Provide model legislation for states to allow naloxone dispensing via standing orders, as well as requiring the prescribing of naloxone with high-risk opioid prescriptions; we must equip all law enforcement in the United States with naloxone to save lives.**

Naloxone is a lifesaver that rapidly reverses opioid overdose. It is the first line of defense in many parts of our country; if we lose someone to overdose we obviously have no chance to

treat them and return them to a productive life. We urge you to mandate, with federal assistance, that naloxone be in the hands of every law enforcement officer in the United States. By declaring a national emergency, you can empower the HHS Secretary to negotiate reduced pricing for all governmental units. Forty-seven states have expanded access to naloxone in some form. The Federal Government should ensure that naloxone is made available when there is the greatest chance for an overdose. Accordingly, model legislation should include a requirement that naloxone is prescribed in combination with any CDC-defined high-risk opioid being prescribed.

An impediment to naloxone usage and people seeking help in the event of an overdose is the perceived threat of law enforcement involvement. Overly restrictive or punitive laws may prevent the uptake of naloxone or the seeking of aid in an emergency. In response, most state legislatures and some law enforcement agencies have created a variety of immunity and 'Good Samaritan' laws to ensure bystanders and those experiencing an overdose are not deterred from seeking immediate help. States vary widely in the content of 'Good Samaritan' laws, but they generally offer protection to people assisting at the scene of an overdose, or seeking care for their own or another's overdose, from civil or criminal prosecution. As of July 2017, 40 states and the District of Columbia have enacted some form of a 'Good Samaritan' or 911 drug immunity law. In addition to enacting legislation, it is crucial that states ensure the public fully understands the protections provided by the 'Good Samaritan' law and how it empowers them to call 911 in the case of an overdose.

HHS and other federal agencies should be directed by you or your cabinet to make recommendations on ways to identify persons who have overdosed and been revived with naloxone and the feasibility of notification of their primary care and other physicians caring for them. These primary care providers may be prescribing medications that increase future risks of another overdose.

- **Prioritize funding and manpower to the Department of Homeland Security's (DHS) Customs and Border Protection, the DOJ Federal Bureau of Investigation (FBI), and the DEA to quickly develop fentanyl detection sensors and disseminate them to federal, state, local, and tribal law enforcement agencies. Support federal legislation to staunch the flow of deadly synthetic opioids through the U.S. Postal Service (USPS).**

  Illicit fentanyl and fentanyl analogs are the next grave challenge on the opioid front and the awful news is that it is much, much more deadly than hydrocodone, oxycodone or even heroin. Since 2012, the nation has seen an alarming increase in the number of drug overdose deaths that involve fentanyl, a synthetic opioid many times more powerful than heroin, as well as heroin and cocaine laced with non-pharmaceutical fentanyl. Fentanyl defies detection at our borders, as the small quantities involved for psychoactivity of fentanyl and fentanyl analogs challenge Customs and Border Protection, USPS, and express consignment carriers' ability to detect and interdict. We are miserably losing this fight to prevent fentanyl from entering our country and killing our citizens. We are losing this fight predominately through China. This must become a top tier diplomatic issue with the

Chinese; American lives are at stake and it threatens our national security. Our inability to reliably detect fentanyl at our land borders and at our international mail handling facilities creates untenable vulnerabilities. Key federal agencies, including the DEA, DHS, FBI, and DOJ, should coordinate pursuant to the Controlled Substances Act to intercept fentanyl (and other synthetic opioids) in envelopes and packages at mail processing distribution centers, and increase detection efforts using enhanced technology, more manpower, and expanded canine deployment. Only a presidential directive will give this issue the top level attention it deserves from DOJ, DHS, and USPS.

- **Provide federal funding and technical support to states to enhance interstate data sharing among state-based prescription drug monitoring programs (PDMPs) to better track patient-specific prescription data and support regional law enforcement in cases of controlled substance diversion. Ensure federal health care systems, including Veteran's Hospitals, participate in state-based data sharing.**

  PDMPs are state-run electronic databases used to track the prescribing and dispensing of controlled prescription drugs. They are designed to give providers access to critical information regarding a patient's controlled substance prescription history, and can help health professionals identify patients who may be or are at risk of misusing prescription opioids or other prescription drugs. PDMPs are also used by professional licensing boards to identify clinicians with patterns of inappropriate prescribing and dispensing, and to assist law enforcement in cases of controlled substance diversion. Multiple published best practices for utilizing PDMPs, including guidelines from the Heller School for Social Policy and Management at Brandeis University, have identified interstate data sharing among PDMPs as a top priority to ensure that healthcare professionals and law enforcement have a complete picture of prescribing practices and controlled substances diversion. Numerous professional health organizations, including the American Medical Association (AMA) and the Association of State and Territorial Health Officials (ASTHO), agree that PDMPs are an effective and important clinical tool to combat the addiction crisis; however, they are being significantly underutilized in the vast majority of our states. Forty-nine states now have PDMPs but not nearly a majority of those are sharing their information. This is unacceptable. We urge you to direct the VA and HHS to lead an effort to have all state and federal PDMP systems to share information and to set a deadline of July 1, 2018 to achieve this data sharing.

  In addition to sharing data between states and the federal government, the PDMP needs to be improved with regard to its ease of use, and inclusion of other data to assist prescribing doctors. Ideally, clinicians should check their state PDMP before making the decision to prescribe either an opioid or benzodiazepine (several states already have this requirement in place), determine whether their patient has had an overdose, and other relevant information that can be summarized into categories of high to low risk.

- **Better align, through regulation, patient privacy laws specific to addiction with the Health Insurance Portability and Accountability Act (HIPAA) to ensure that information about SUDs be made available to medical professionals treating and prescribing medication to a**

patient. This could be done through the bipartisan Overdose Prevention and Patient Safety Act/Jessie's Law.

Providers and other advocates have found that certain privacy regulations, while well-intentioned patient protections, act as a barrier to communication between providers, can make it difficult for family members to be involved in a loved one's treatment, and limits the ability to use electronic health records to their full potential. 42 CFR Part 2, which requires addiction treatment professionals to acquire written patient consent before sharing any information with a patient's other health care providers, including when the addiction treatment facility is part of a larger health care system, is a particular hindrance to comprehensive health care. Making it administratively difficult for providers to share information has ill-effects on patients in both physical and behavioral health settings, by restraining physicians' ability to make informed healthcare decisions.

We urge you to direct that regulation be changed to permit the sharing of this type of information among health care providers and the loved ones of those suffering from SUDs. Otherwise, drugs with high abuse liability may be prescribed to people with OUD. That will lead to even more unnecessary and preventable deaths.

- **Enforce the Mental Health Parity and Addiction Equity Act (MHPAEA) with a standardized parity compliance tool to ensure health plans cannot impose less favorable benefits for mental health and substance use diagnoses verses physical health diagnoses.**

As Congressman Kennedy spoke eloquently about at the first Commission meeting, there has long been a difference in how individuals with health insurance receive treatment and medication for physical health diagnoses versus mental health and SUD diagnoses. The Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) prohibits health insurance plans that cover behavioral health from imposing benefit limitations on mental health or SUD treatment that are less favorable than limitations imposed on medical or surgical benefits. Benefit limitations can be quantitative, such as visit limits, or non-quantitative, such as pre-authorization requirements. But not providing real parity is <u>already</u> <u>illegal</u>. The Commission urges you to direct the Secretary of Labor to enforce this law aggressively and to penalize the violators.

The Commission heard from numerous organizations, including ASAM and the American Academy of Addiction Psychiatry, about the need to systematically monitor and enforce MHPAEA with a standardized tool, and actual penalties for non-compliance, to ensure parity in the coverage of mental health and addiction treatment services. The Labor Secretary, with appropriate direction from you, is the person to do this.

At this point, the largest outstanding issue is treatment limits. Patients seeking addiction treatment, including MAT, are often subjected to dangerous fail-first protocols, a limited provider network, frequent prior authorization requirements, and claim denials without a transparent process. The Commission applauds SAMHSA's work with multidisciplinary teams from states to improve parity enforcement and public education. However, we need

robust enforcement of the parity law by the state and federal agencies responsible for implementing the law. Regulators should be required to levy penalties against health plans that violate MHPAEA, and information about parity violations should be made available to the public.

It is not only critical that the Federal Government provide sufficient resources to prevent and combat this disease; it must also provide the easiest pathway for private providers and local and state governments to achieve success.

That is why the Commission, as a primary focus of the final report, is undertaking a full-scale review of federal programs, regulations, laws, and funding mechanisms targeted toward addressing addiction.

In addition to a full review of federal funding and programs and obstacles and opportunities for treatment, the final report will include, but not be limited to, a more thorough examination of the following issues:

- Development of a national prevention strategy using "big data analytics" to devise targeted prevention messages that employ cutting-edge methods of marketing and communications.
- Evidence-based prevention programs for schools, and tools for teachers and parents to enhance youth knowledge of the dangers of drug use, as well as early intervention strategies for children with environmental and individual risk factors (trauma, foster care, adverse childhood experiences (ACEs), and developmental disorders).
- The need for satisfaction with pain level as a satisfaction criteria through which health care providers are evaluated by HHS.
- Workforce access and training needs within the treatment community nationally, with a particular focus on the regions of the country with the highest overdose deaths.
- Improvements in treatment programs, based on adherence to principles of evidence-based treatment, continuum of care, outcome measures, and patient education on quality treatment.
- Research initiatives and opportunities to combat the epidemic and enhance treatment options, including alternative pain management strategies, and treatment for vulnerable populations such as pregnant women, and substance-exposed infants through work by the NIH, HHS, CDC, FDA, SAMHSA, and pharmaceutical partners.
- Opportunities to further the practice of substance use screenings and referrals through CMS quality measures.
- Opportunities for patient protections providing better information about the risks and benefits of taking prescription opioids.
- Supply reduction of heroin, fentanyl analogs and counterfeit pills through coordinated federal and state law enforcement initiatives.
- Targeted data collection and analytics needed to identify most effective prevention and treatment strategies, quality treatment access programs, reimbursements, and aid to law enforcement activities. The possibility of a behavioral health surveillance system run

through CDC that tracks prevalence rates, treatment modalities, and comorbidities with other illnesses in real-time.

- Regulatory or statutory changes to reduce commercial insurance barriers to MAT, such as dangerous fail-first protocols and onerous and frequent prior authorization requirements.

In our final report, we will provide an additional set of detailed recommendations that, if implemented, will ensure that the Federal Government operates as a strong partner in the fight against addiction and the opioid crisis.

Finally, our country needs you, Mr. President. We know you care deeply about this issue. We also know that you will use the authority of your office to deal with our nation's problems. The Commission looks forward to submitting its final report.

Sincerely,

Commission members

TAB #5

64B16-27.831 Standards of Practice for the Filling of Controlled Substance Prescriptions; Electronic Prescribing; Mandatory Continuing Education.

The Board of Pharmacy recognizes that it is important for the patients of the State of Florida to be able to fill valid prescriptions for controlled substances. In filling these prescriptions, the Board does not expect pharmacists to take any specific action beyond exercising sound professional judgment. Pharmacists should not fear disciplinary action from the Board or other regulatory or enforcement agencies for dispensing controlled substances for a legitimate medical purpose in the usual course of professional practice. Every patient's situation is unique and prescriptions for controlled substances shall be reviewed with each patient's unique situation in mind. Pharmacists shall attempt to work with the patient and the prescriber to assist in determining the validity of the prescription.

(1) Definitions: For purposes of this rule the following definitions shall apply:

(a) Valid Prescription. A prescription is valid when it is based on a practitioner-patient relationship and when it has been issued for a legitimate medical purpose.

(b) Invalid Prescription. A prescription is invalid if the pharmacist knows or has reason to know that the prescription was not issued for a legitimate medical purpose.

(c) Validating a Prescription. Validating a prescription means the process implemented by the pharmacist to determine that the prescription was issued for a legitimate medical purpose.

(2) General Standards for Validating a Prescription: Each prescription may require a different validation process and no singular process can fit each situation that may be presented to the pharmacist. There are circumstances that may cause a pharmacist to question the validity of a prescription for a controlled substance; however, a concern with the validity of a prescription does not mean the prescription shall not be filled. Rather, when a pharmacist is presented with a prescription for a controlled substance, the pharmacist shall attempt to determine the validity of the prescription and shall attempt to resolve any concerns about the validity of the prescription by exercising his or her independent professional judgment.

(a) When validating a prescription, neither a person nor a licensee shall interfere with the exercise of the pharmacist's independent professional judgment.

(b) When validating a prescription, the pharmacist shall ensure that all communication with the patient is not overheard by others.

(c) When validating a prescription, if at any time the pharmacist determines that in his or her professional judgment, concerns with the validity of the prescription cannot be resolved, the pharmacist shall refuse to fill or dispense the prescription.

(3) Minimum Standards Before Refusing to Fill a Prescription.

(a) Before a pharmacist can refuse to fill a prescription based solely upon a concern with the validity of the prescription, the pharmacist shall attempt to resolve those concerns and shall attempt to validate the prescription by performing the following:

1. Initiate communication with the patient or the patient's representative to acquire information relevant to the concern with the validity of the prescription;

2. Initiate communication with the prescriber or the prescriber's agent to acquire information relevant to the pharmacist's concern with the validity of the prescription.

(b) In lieu of either subparagraph 1. or 2., but not both, the pharmacist may elect to access the Prescription Drug Monitoring Program's Database to acquire information relevant to the pharmacist's concern with the validity of the prescription.

(c) In the event that a pharmacist is unable to comply with paragraph (a) due to a refusal to cooperate with the pharmacist, the minimum standards for refusing to fill a prescription shall not be required.

(4) Duty to Report: If a pharmacist has reason to believe that a prescriber is involved in the diversion of controlled substances, the pharmacist shall report such prescriber to the Department of Health.

(5) Electronic Prescriptions: All controlled substances listed in Schedule II through V may be electronically prescribed pursuant to the provisions of Section 456.42(2), F.S. (2015), and pursuant to applicable federal law. For more information related to the federal requirements, access http://www.deadiversion.usdoj.gov/ecomm/index.html.

(6) Mandatory Continuing Education: All pharmacists shall complete a Board-approved 2-hour continuing education course on the Validation of Prescriptions for Controlled Substances. The course content shall include the following:

(a) Ensuring access to controlled substances for all patients with a valid prescription;

(b) Use of the Prescription Drug Monitoring Program's Database;

(c) Assessment of prescriptions for appropriate therapeutic value;

(d) Detection of prescriptions not based on a legitimate medical purpose; and,

(e) The laws and rules related to the prescribing and dispensing of controlled substances. All licensed pharmacists shall complete the required course during the biennium ending on September 30, 2017. A 2-hour course shall be taken every biennium thereafter. The course shall count towards the mandatory 30 hours of CE required for licensure renewal. All newly licensed pharmacists must complete the required course before the end of the first biennial renewal period.

(7) Summary Record: Every pharmacy permit holder shall maintain a computerized record of controlled substance prescriptions dispensed. A hard copy printout summary of such record, covering the previous 60 day period, shall be made available within 72 hours following a request for it by any law enforcement personnel entitled to request such summary under authority of Section 893.07(4), F.S. Such summary shall include information from which it is possible to determine the volume and identity of controlled substances being dispensed under the prescription of a specific prescriber, and the volume and identity of controlled substances being dispensed to a specific patient.

Rulemaking Authority 456.013, 465.005, 465.0155, 465.009, 465.022(12) FS. Law Implemented 456.013, 456.42, 456.43, 465.0155, 465.003, 465.009, 465.016(1)(i), (s), 465.017, 465.022(12), 893.04 FS. History–New 8-29-02, Amended 2-24-03, 11-18-07, 12-24-15.