

# The Opioid Epidemic: Strategies and Tools for Compliance

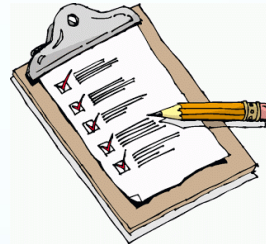
Eugenia (Genie) Stark Thomas  
Compliance Officer  
Ochsner LSU Health Shreveport  
April 26, 2019

1

1

## Today's Agenda

- Opioids: context and background
- The role of compliance in an opioid strategic initiative
- Increasing provider engagement
- Special opportunities with midlevel providers
- Measuring progress and improving compliance



2

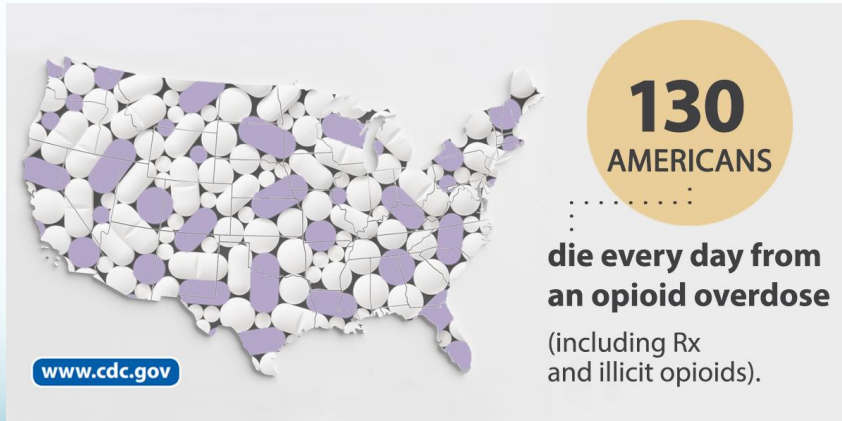
2

3



4

# Opioid Overdose Deaths



5

5

## CDC Opioid Categories

- **Natural opioids** (including morphine, codeine) and **semi-synthetic opioids** (oxycodone, hydrocodone, hydromorphone, and oxymorphone)
- **Methadone**, a synthetic opioid
- **Synthetic opioids** other than methadone (drugs like tramadol and fentanyl)
- **Heroin**, an illicit opioid synthesized from morphine

6

6

## Seismic Impact

- The USA utilizes 99% of hydrocodone prescriptions
- Approximately 50% of ED visits (1 in 7) are estimated to be substance-related
- 1 in 32 receiving chronic opioids will overdose and die
- About 21-29% of patients prescribed opioids for chronic pain misuse them
- Estimated 2.5M in the US addicted to opioids
- Estimated \$78.5B annual economic burden-some estimate the actual number is well over \$1 Trillion

7

7

## 2017 Opioid Prescribing Rates Per 100 People

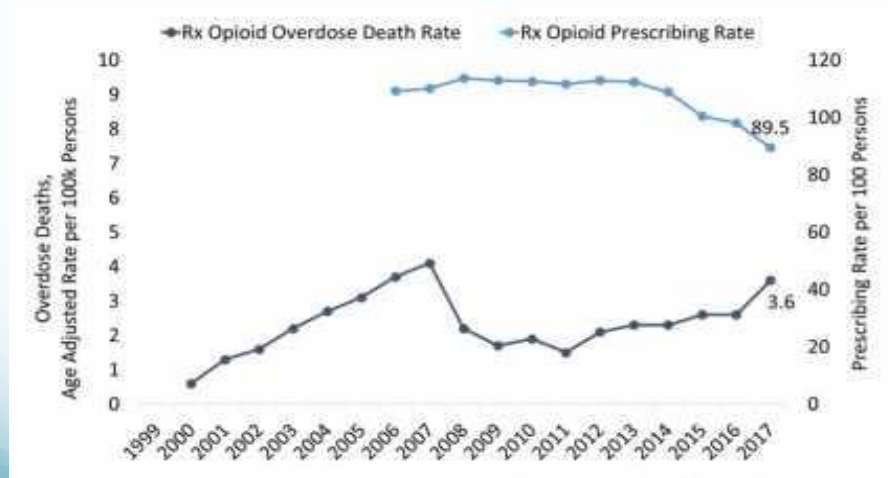
- 1. Alabama: 107.2
- 2. Arkansas: 105.4
- 3. Tennessee: 94.4
- 4. Mississippi: 92.9
- 5. Louisiana: 89.5
- 6. Oklahoma: 88.1
- 7. Kentucky: 86.8
- Contrast: Texas: 53.1, California: 39.5
- COMPARE: US rate of 58.7 prescriptions



8

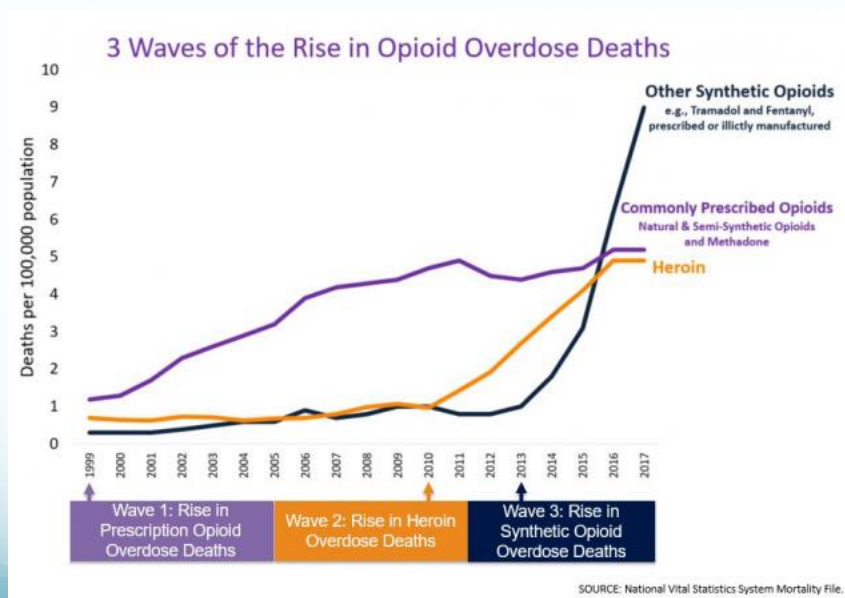
8

# 2017 Louisiana Data



9

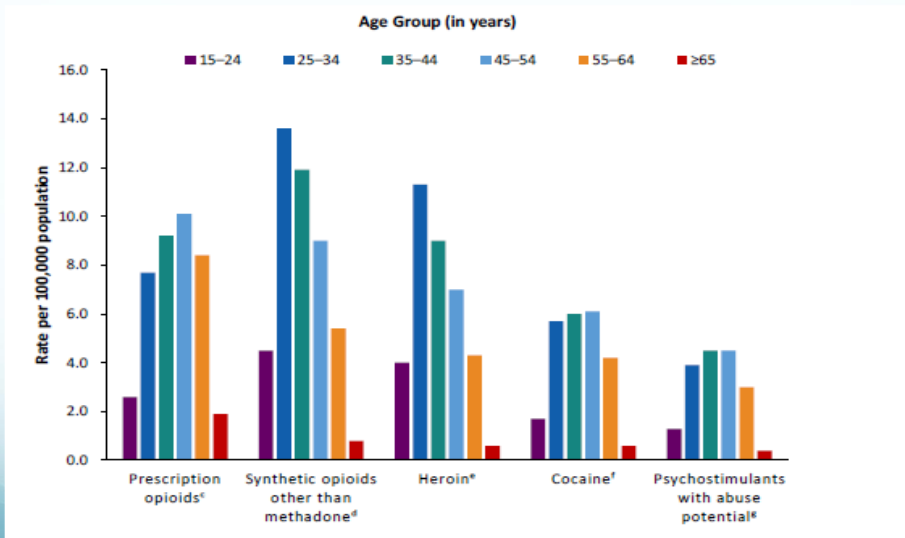
9



10

10

Rates of Overdose Deaths by Age and Drug Category- 2016



11

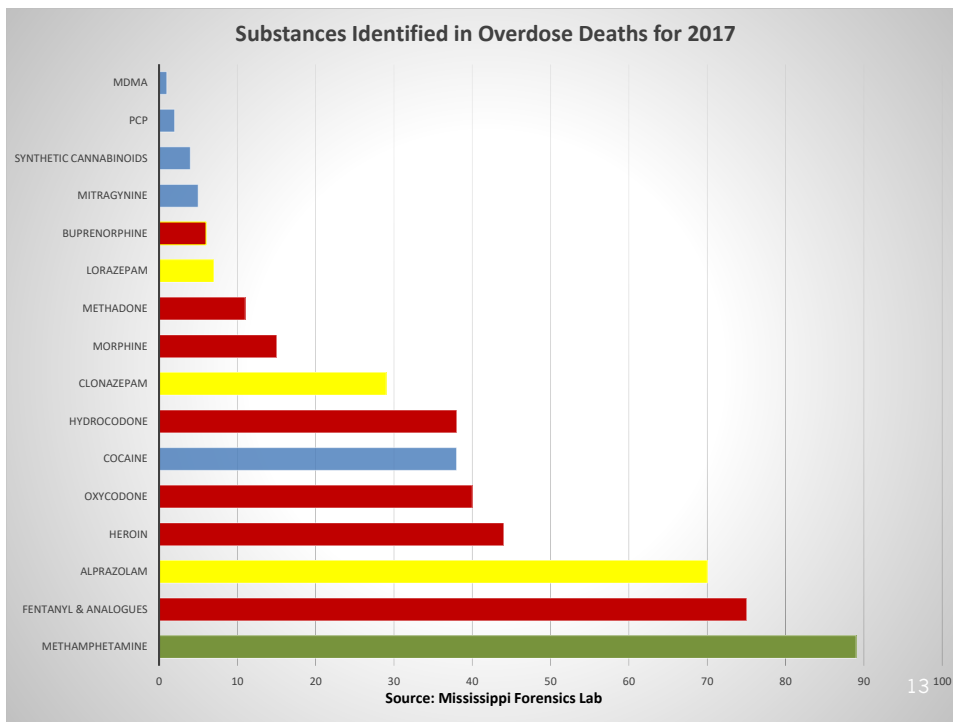
11

## Opioids, Addiction and Teens

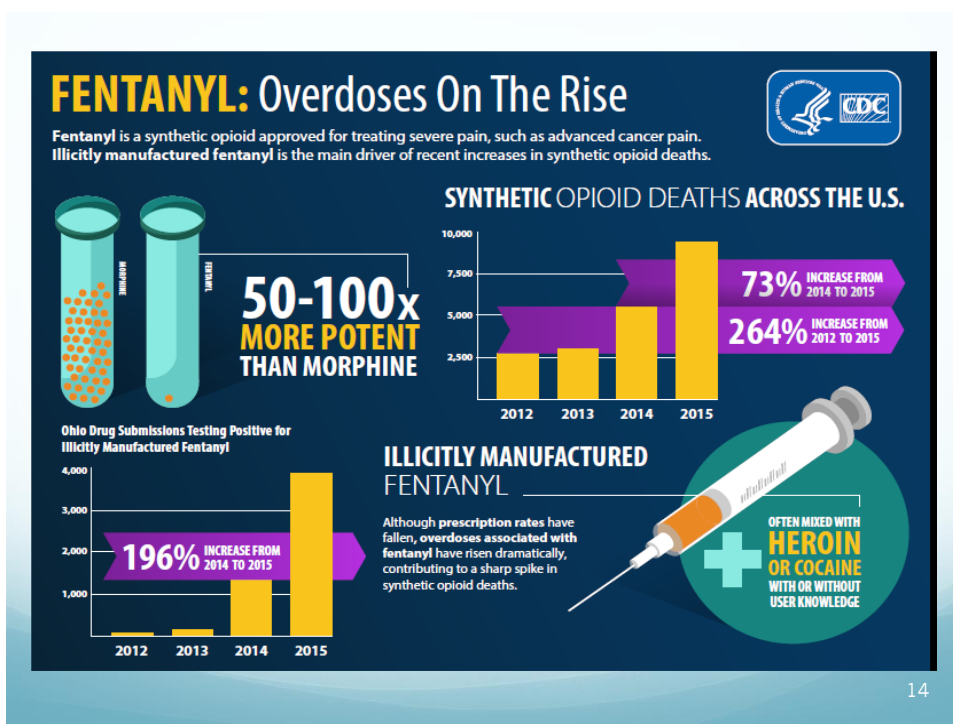
- Drugs, especially opioids, fundamentally change the brain in ways that make quitting hard
- Brain pathways are still being mapped through mid/late 20's, so teens and young adults are particularly vulnerable
  - The earlier that drug use begins, the more likely it will progress to addiction
- “Brain disease” model of addiction
- A combo of factors affects risk: biology, environment, development

12

12

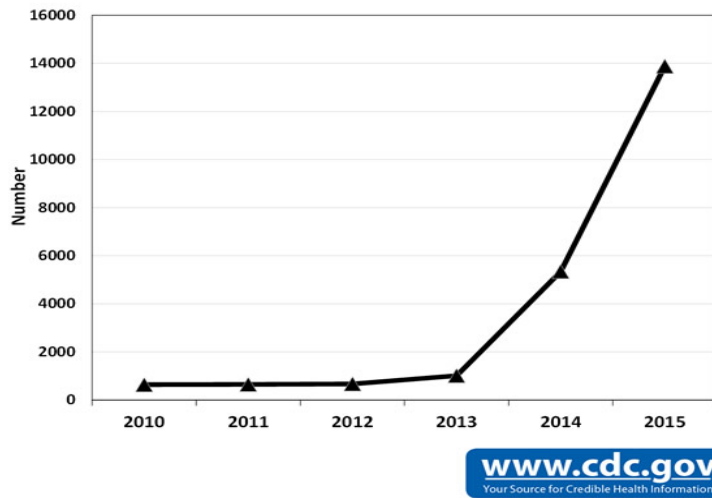


13



14

Number of Reported Law Enforcement Encounters  
Testing Positive for Fentanyl in the US: 2010 - 2015



15

15

## ● FENTANYL



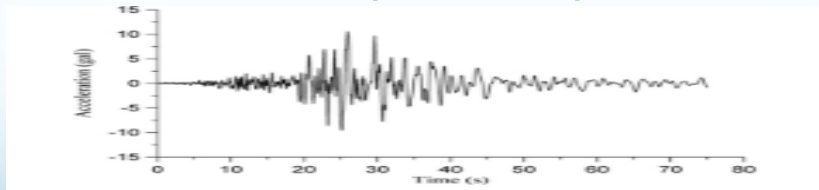
## Carfentanil

16

16



## The Ripple Effect: Other Collateral Damage from the Opioid Epidemic



17

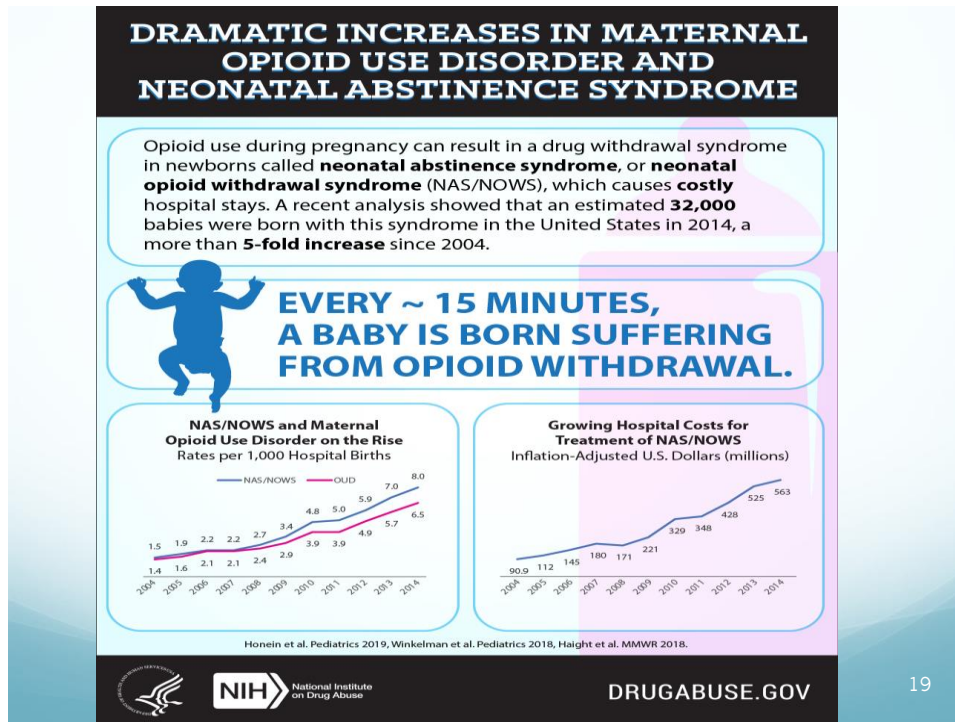
17

## Opioids and Human Trafficking

- Human Trafficking: traffickers use drugs to recruit and retain control of victims
  - Healthcare connection: 88% of victims have come into contact with a healthcare provider during their victimization, more than half coming to the ED
  - Familial sex trafficking resulting from parent's addiction
- Children entering foster care: up more than 10% from 2012-2016, believed due to opioid epidemic
  - These children are particularly targeted by sex traffickers
  - 60% of child sex trafficking victims have a history in child welfare system

18

18



19

## The Seismic Impact of Opioids on Healthcare

- The obvious: increases in opioid misuse, related healthcare treatment, addiction treatment, and related overdoses
- The less obvious:
  - Neonatal abstinence syndrome due to opioid use/misuse during pregnancy -> lifelong costs
  - Increase in IV drug use -> spread of infectious diseases such as HIV and HepC
  - Predisposition of teens to addiction, along with lifelong impact on brain function of early drug use
  - The hidden costs of foster care: perpetuating new generations of victims and addicts
  - Connection between addiction and sex trafficking

20

20

# The Role of Compliance in an Opioid Initiative



21

21

## Role of Compliance

- Compliance is uniquely positioned to address
  - Opioids are a multi-disciplinary problem that need a multi-disciplinary approach and playbook
  - Existing compliance infrastructure and tools can be leveraged to support the initiative
- Risk posed by an incomplete or inconsistent opioid strategy is unacceptably high
  - Need for consensus building and buy-in at all levels
  - Enforcement posture creates high-risk environment
    - Compliance with state regulatory requirements on prescribing –regardless of jurisdiction - must be a top priority
    - Risk of reputational harm elevated by enforcement environment

22

22

## Federal Response

- Aug. 2017: Then-AG Jeff Sessions: formation of the **Opioid Fraud and Abuse Detection Unit**
- **New DOJ pilot program** focusing on opioid-related health care fraud using data analytics
  - Which physicians are writing opioid prescriptions at a rate far exceeding that of peers
  - How many of their patients die within 60 days of a prescription
  - Average age of recipient
  - Pharmacies dispensing disproportionately large amounts of opioids
  - Identify regional hot spots
- First criminal indictment of physician (in PA) under this program announced 10/27/2017



23

23

## Federal Response: Themes

- **DATA: Use of PMP & data mining for initial tips/ investigation triggers**
  - Surrounding states are now all participating in the PMP
  - Data is the biggest weapon of the government
- **Increased emphasis on role of prescriber**
  - Targeting physicians, pharmacists, anyone with access, anywhere in the distribution chain
- **Joint operations—multi-agency, cross-border task forces, raids and enforcement operations**
  - DEA, state narcotics, FDA, OIG, USA, DOJ, etc.
  - 2018 was a year of “first and largest” actions related to opioid enforcement



24

24

# State Regulatory Response: Two States, Two Vastly Different Approaches



Mississippi State Board of Medical Licensure



*Louisiana*  
State Board of Medical Examiners

25

25

## State Response

- Across the nation, professional licensure boards have revised rules related to prescribing
  - Mississippi BOML: 2018 major overhaul and ongoing tweaks. See Part 2640 of MS BOML Admin Code.
  - Louisiana BME: 2017 major overhaul. See LA RS 40:978.
- With only a few exceptions, states now are all participating in the PDMP (PMP) and the trend is to require all prescribers to participate
- RISK: state rules vary widely in their requirements. Multi-state operations pose special challenges.

26

26

# Louisiana BME

## Overview of Changes

- Prohibits prescribing more than a 7 day supply
  - For opioid naïve adult patients with acute conditions
  - To a minor at any time and requires the practitioner to discuss with parent/ tutor/ guardian the risks associate with use and the reasons the prescription is necessary
- BUT, prescriptions for over 7 day supply may be exempted if, in the professional medical judgment of the practitioner, they are necessary to treat acute pain, or for palliative care



27

27

# Louisiana BME

## Overview of Changes

- Professional judgment underlying the exemption should be documented
  - Both in the record and on the prescription
  - Should include thought processes and plan of care
- Before issuing a prescription for an opioid, practitioners must:
  - Consult with the patient re the quantity and the patient's option to fill in a lesser quantity
  - Inform the patient of the risks associated with the opioid prescribed
  - Check the PMP (exceptions for hospice, cancer patients, and hospital inpatients)

28

28

# Louisiana BME

## Overview of Changes

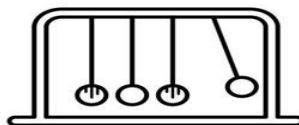
- If the patient's course of treatment exceeds 90 days, practitioners must access the PMP
- All prescribers of controlled dangerous substances are required to obtain 3 CME credits as prerequisite of license renewal after 1/1/2018.
- Content includes drug diversion training, best practices for prescribing, and appropriate treatment for addiction



29

29

## LA versus MS



Mississippi State Board of Medical Licensure

30

30

# Local Enforcement Posture

Mississippi:

- “[T]he ‘root of the problem’ is over-prescribing and the MBN (Mississippi Bureau of Narcotics) has made this a target of investigation.” – Marshall Fisher, Commissioner of DPS, July 20, 2017
- “If we find out that your prescription habits are causing addiction problems, we’ll come find you...If we have overdose deaths related to your prescribing habits, let this serve as notice to the health care professionals in this state, we’re not playing around anymore.”– John Dowdy, Director of MBN, 5/17/17

31

31

## Mississippi BOML Overview of Changes

- Use of the PMP- now mandated at most encounters where opioids, benzos, schedule II substances or controlled substances are prescribed
  - Requires repeating PMP at specified intervals and retaining documentation in the chart of the review
- Redefined chronic pain as > 3 months treatment with controlled substances
  - Significantly expands documentation requirements for treatment of these patients
  - Sets dosing standards at 50 mEq/day, with ability to exceed requiring justification. Required referrals to pain management over 100 mEq/day.
  - Review of treatment course every 3 months

32

32



## Mississippi BOML Overview of Changes

- Revised explanation of a good faith exam
- **With acute pain:**
  - Prohibits use of long-acting opioids for acute pain
  - Opioids must be prescribed in the lowest effective dose of immediate-release opioids.
- **Quantity limits:** prescribe no more than needed for expected duration of pain.
  - Discouraged from providing more than 3 days supply; must not provide more than 10 days
  - Additional 10 day supplies may be provided, but documentation and justification are required.

33

33

## Mississippi BOML Overview of Changes

- Highly discouraged: concurrent prescribing of opioids and benzos and/or Soma
  - Need must be extensively documented
  - Allowed only under limited circumstances
- Quantity limitations on benzo prescriptions
- Requires point of service drug testing (and PMP review) at least 3x/ calendar year:
  - For patients prescribed benzodiazepines for chronic medical and/or psychiatric conditions
  - When a schedule II medication is written for treatment of chronic non-cancer/ non-terminal pain

34

34

# Standard of Care: Criminal Liability

- *United States v. Moore*, 423 U.S. 122 (1975)
  - “a physician who knowingly or intentionally dispenses other than in good faith in the usual course of a professional practice and in accordance with a standard of medical practice generally recognized and accepted in the United States”
  - Criminal liability hinges on an intentional violation of the standard of care without a good faith basis.
- From the perspective of at least some in the US attorney’s office, the MS BOML Prescribing Rules will set (and were intended to set) a new standard of care!

(yes, you read that correctly!)

35

35

# Increasing Provider Engagement



36

36

# Increasing Provider Engagement

- Who wants to lead the way in the community? Leading a larger community initiative to help address the opioid epidemic
  - Physician-led steering committee
  - A joint effort of the hospital and medical staff, perhaps with a community partner
  - Community-based work group efforts led by physician champions
    - Identify and build on community resources to provide tools for providers
    - Facilitate physician-led community education series on addiction, adolescent risks, chronic pain, prescription alternatives
- Goal is to help improve the community response and reduce the overall impact on the community
- Regardless of specialty and practice location, all prescribers have a role to play

37

37

# Increasing Provider Engagement

- Consider an organizational task force
  - Board involvement and endorsement
  - Is this a subcommittee of the compliance committee?
  - Medical staff work groups by discipline
  - Developing strategies based on best practices
    - What is ortho's approach to prescribing? Family medicine?
    - Developing a consistent approach to prescribing through clinical practice guidelines
    - Physicians as drivers of self-regulation
    - Developing metrics to measure improvement and impact
- A "community compact" as a possible goal

38

38

# Increasing Provider Engagement

- The harsh realities of the enforcement environment
  - Responsibility of physicians for midlevels and for themselves
  - Prescribers as targets of enforcement
    - Use of PMP data as probable cause
    - Approach of USA, MS Narcotics and others in prescribing “hot spots”
    - Multi-jurisdictional, multi-agency efforts
  - “Regulate yourself or else” government position
- Unique position of physicians to significantly impact opioid use going-forward

39

39



## Opportunities with Midlevels



40

40

# Opportunities with Midlevels

- PA services:
  - LA Admin Code 46 XLV § 4505.A.: “The practice of a [PA] shall include the performance of medical services that are delegated by the supervising physician and are within the scope of the [PA’s] education, training and licensure. **A [PA] is considered to be and is deemed the agent of the supervising physician in the performance of all practice-related activities....**The level and method of supervision shall be at the supervising physician and [PA] level, shall be **documented in clinical practice guidelines, reviewed annually and shall reflect the acuity of patient care** and the nature of a procedure.”

41

41

# Opportunities with Midlevels

- PA services:
  - LA Admin Code 46 XLV § 4505.B.: “**In accordance with a written clinical practice guideline or protocol** (sic) medical services rendered by a [PA] may include:...[list omitted]; and, **to the extent delegated by the supervising physician**, prescribing legend drugs and controlled substances....”
  - § 4505.C.: “A [PA] may prescribe, order and administer drugs **to the extent delegated by the SP....** Drugs which may be prescribed, ordered and administered by a PA are those listed in schedules II, III, IV and V of R.S. 40:964 and legend drugs.”

42

42

## Opportunities with Midlevels

- NP services: LA Admin Code 46 XLV § 7911.A.:
  - “To be eligible to engaged in collaborative practice with an APRN **a physician shall: ... have signed a collaborative practice agreement ... with an APRN that complies with the standards of practice ....**”

43

43

## Opportunities with Midlevels

- NP services: LA Admin Code 46 XLV § 7903:
  - “*Collaborative Practice Agreement or CPA*– a formal **written statement addressing the parameters of the collaborative practice** which are mutually agreed upon by an APRN and one or more physicians which shall include but not be limited to the following provisions: a. availability of the [CP] for consultation or referral, or both; b. **methods of management of the collaborative practice which shall include clinical practice guidelines**; and c. coverage of the health care needs of a patient during any absence of the APRN or physician.”

44

44

## Opportunities with Midlevels

- NP services: LA Admin Code 46 XLV § 7903:
  - “*Clinical Practice Guidelines*—written or electronic documents, jointly agreed upon by the collaborating physician and APRN that **describe a specific plan, arrangement, or sequence of orders, steps, or procedures to be followed or carried out in providing patient care in various clinical situations.** These may include textbooks, reference manuals, electronic communications and Internet sources.”

45

45

## Opportunities with Midlevels

- NP services: LA Admin Code 46 XLV § 7911.A.:
  - In addition, a [CP] shall insure that the CPA includes:
  - a. a plan of accountability among the parties that addresses: i. prescriptive authority of the APRN and the responsibilities of the [CP]; ii. ...; iii. ...; iv. ...;
  - b. clinical practice guidelines ..., documenting the types or categories or schedules of drugs available and generic substitution for prescription by the APRN and be: i. ...; ii. ...; iii. ...; iv. reviewed and signed at least annually by the CP to reflect current practice....”

46

46

## Opportunities with Midlevels

- Leveraging the collaboration agreement
  - What is the prescriptive authority?
  - What guidelines should a midlevel follow re dosing, frequency?
  - Do you have sufficient informed consent?
  - Do you need a pain contract/ opioid contract?
  - Frequency of checking the PMP
  - Frequency of requiring a UDS
  - When a referral to pain management is warranted

47

47

## Opportunities with Midlevels

- Does the midlevel have sufficient education and training...
  - On diversion?
  - Detecting drug seeking behavior?
  - Identifying addiction?
  - Controlled substance and drug alternatives?
  - On the dangers of co-prescribing?
  - On when to make a referral to pain management?
  - To adequately obtain an informed consent for drug therapy involving opioids?

48

48



## Difficulties and Challenges

- Addressing the non-compliant patient
  - When and how to dismiss a patient from the practice
    - State law differences!!
    - Patients dismissed from other practices
- Access issues
  - Lack of mental health services
  - Lack of \$\$ to access mental health services or substance abuse treatment centers
  - Appointment backlogs and physician shortages- pain management
- Identifying available options

49

49

## Difficulties and Challenges

- How much of these social support resources can we as an organization provide...or can we afford to ignore?
  - Recent relaxation in some of the beneficiary inducement rules under AKS may provide an avenue
  - Can other, existing pathways be tapped into as a resource for providers?
- Is this part of our legal obligation as a 501(c)(3)? As a hospital? Is this part of our legal or ethical obligation as healthcare providers? As part of our community? If so...how far does that obligation extend?

50

50



# Measuring Progress and Improving Compliance

Bringing it All Together

51

51

## Improving Compliance: Education Opportunities

- Targeted CME/ education: prescribing habits and downstream implications
  - New provider training and refresher training on prescribing
  - State law but also best practices
- Development of tools and resources for physicians, NPPs, and hospital staff
  - Chronic pain patients, addiction treatment, drug alternatives
  - Social service options and other community resources
- Developing and using practice/specialty-specific guidelines for prescribing of controlled substances generally
  - What is the best practice? Has the evidence changed?

52

52

## Opportunity: All Prescribers

- Learn from what's already been done: developing best practices related to prescribing
  - Checking the PMP
  - Role of UDS
  - Prescribing parameters
  - Informed consent
  - Tailored pain contracts
  - When referrals to specialists are warranted
  - Documentation

53

53

## Opportunity: Midlevels

- With APPs, having an ongoing quality discussion as part of the MD-APP collaboration
  - How we best serve patients who are at high risk for overdose
  - How we identify addiction and how we address it
  - How we document having hard conversations with patients
- Revising/ updating practice guidelines and collaborative agreements to reflect practice changes on prescribing

54

54

# Developing Internal Controls

- Some EMR ideas:
  - Formulary defaults (dose and quantity limits)
  - Hard stops (co-prescribing or above MEq limit)
  - Require high alert/ secondary verifications
  - 100% reviews
- Monthly reviews of prescribing history (provider level) and PMP checks (chart level sampling) as part of routine compliance auditing/ monitoring function
  - Identify data outliers with PMP

55

55

# Developing Internal Controls

- Other compliance reviews/ controls: (note: MS and LA differences)
  - Adherence to state regulatory requirements in dosing, frequency of refills, and # of pills per script
  - Adherence to practice/specialty-specific standards as developed
  - Role of urine drug screen (N.B.: watch out on payment end!) and checking of the PMP
  - Informed consent for the opioid naïve
- And remember: chart documentation and all practice documentation (logs particularly) (DEA, FDA, state law) for prescribing, administering and dispensing controlled substances must be current and complete.

56

56

# Measuring Progress

- Is there an organizational report card? Consider:
  - Development of practice-specific guidelines and operational standards
  - Adherence to what has been peer-developed and reviewed
  - Reduction in NAS
  - Facilitation of mental health and addiction treatment
  - Facilitation of social service referrals and resource connections for trafficking victims
  - Community education
  - Physician and NPP education
- “Community compact” as part of a CHNA activity?

57

57



Eugenia (Genie) Stark Thomas  
Compliance Officer  
Ochsner LSU Health Shreveport  
[Eugenia.Thomas@ochsnerlsuhs.org](mailto:Eugenia.Thomas@ochsnerlsuhs.org)

58

58