AGENDA

Florida Board of Pharmacy
Controlled Substance Standards Committee Meeting
December 12, 2017 –9:00 a.m.

Rosen Plaza Hotel * 9700 International Drive
Orlando, FL 32819 * (407)996-9700

Committee Members:
Gavin Meshad, Chair
Jeenu Philip, BPharm

Board Staff
C. Erica White, MBA, JD - Executive Director
Irene Lake, Program Operations Administrator

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. **October 2017 Committee Meeting – assignment recommendations**

2. **Rule 64B16-27.831 – The Standards of Practice for the Filing of Controlled Substances Prescriptions; Electronic Prescribing; Mandatory Education.**

3. **Update from the Multidisciplinary Board Fact Finding Work Group on Controlled Substances** *(presented by Dr. Mark Mikhael)*

4. **Discussion of a letter of support of the Controlled Substance legislative proposals (***SB 8 by Benaquisto and HB 21 by Representative Boyd***) –** draft attached

5. **Old Business / New Business**

6. **Public Comment**

7. **Adjourn**

TAB #1

Controlled Substance Committee Research Items

(recommendations summary from October 2017)

PHYSICIAN ASKS: *(researched by Ms. Glass)*

1. Limiting physician prescribing through DEA restrictions.
2. Ensuring physicians follow CDC guidelines for the process in prescribing through FL adoption or adaptation.
3. Updating the mandatory Continuing Education (CE) for prescribers with the goal of more effective learning.
4. Limiting initial fills.
    a. Recommendations Follow specific guidelines
        i. Start slow
        ii. 3 days no more than 7 days
        iii. IR vs no SR
        iv. Mandatory CE for professions involved in CS
        v. Urinalysis

MANUFACTURER:

1. REMS aspect of pharmaceutical responsibility regarding manufacturing (*researched by Dr. Mesaros*)
2. Legal concerns and liability of pharmaceutical responsibility regarding manufacturing (*researched by Mr. Bisaillon*)
    a. No recommendations at this time
        i. Trend is for many states suing manufacturers regarding inappropriate marketing campaigns

BETTER USE OF PDMP:

1. Better use of PDMP, including mandatory checking of PDMP, funding of PDMP, and sharing PDMP data across state lines (*researched by Dr. Mikhael*)
2. Current balance of MQA Pharmacy trust-fund and how it can be utilized for the PDMP (*trust fund aspect researched by Ms. White*)
    a. Recommendations
        i. One log in sign in
        ii. Upgrades to PDMP for ease of use
        iii. Mandatory use
        iv. Better reciprocity in and out of state

MANDATORY COUNSELING:

1. Mandatory counseling by pharmacists of all patients prescribed opiates, including facilitation of take-back or disposal of unused medication (*researched by Dr. Alvarez*)
2. Mandatory Escribe for controlled substances (*researched by Mr. Philip*)
    Recommendations
        I. Support mandatory counseling
            1. Details not defined but feel it would be an impactful
                A. Disposal

B. Side effects
C. Signs of addiction
D. Appropriate use
E. Step down pain management

BETTER ACCESS TO REHAB:

1. Raising awareness and access to rehab for addicts, increasing qualified/certified providers of rehabilitation (*researched by Dr. Weizer*)
    a. Link placed on BOP website (Complete)

PHARMACY CS MANDATORY CE (*researched by Mr. Meshad and Mr. Flynn*)

1. Mandatory CE for pharmacy controlled substances, making this CE a "live" requirement and part of initial licensure.
2. Letters to the Deans of Florida Schools/Colleges of Pharmacy and Medicine.
    a. Open rule to look at CE requirements

499 DISPOSALS OF MEDICATION:

1. 499 drug take-back or disposal of unused medication (*researched by Mr. Philip*)
    a. No recommendations
        i. Important information regarding take back programs in the state

DEA Changes:

1. Research DEA rules for updates / changes (*researched by Dr. Mesaros*)
    a. No recommendations

last updated December 2, 2017

TAB #2

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) through (5) No Change

(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.

(f) _____

(g)_____

(h)_____

(i)_____

(j)_____

(7)~~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.~~

(8) ~~(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.

Commented [DF1]: The Committee should discuss whether the course title should be changed.

Commented [DF2]: The Committee needs to discuss what opioid course content shall be required.

Commented [DF3]: If the course content changes, this will be a new required course and the Committee needs to establish a time frame for when the course shall be completed.

TAB #3

MULTIDISCIPLINARY WORK GROUP STRATEGY DEVELOPMENT

OBJECTIVE #1: To increase awareness about the status of the opioid crisis.

Current Activities:

- EMS workers are engaging in community outreach efforts to educate about the effects of opioid use (preventative education).

- EMS workers are performing "wellness checks" in the community involving overdose patients – to ensure that patients are on the right path.

Future Strategies:

- Explore creating a marketing campaign such as "Opioid Overdose-Free Florida", patterning it after the concept of "Tobacco Free Florida". MQA will be collaborating with the Tobacco Free Florida /Cancer Programs Office to discuss valuable lessons/templates. Initial meeting scheduled for Tuesday, November 14th.

- Creation of a treatment plan that includes a component of patient education on opioids, as well as alternatives to opioid use.

OBJECTIVE #2: To increase knowledge about alternative therapies in addressing the opioid crisis.

Future Strategies:

- In conjunction with limiting prescription to 3-day supply, prescribing practitioners should also consider use of alternative treatments for pain management (not involving opioids).

- Use more integrated pain management training with other professions who specialize in alternative therapies.

- Invite insurance industry representatives to future multidisciplinary workgroup meetings to discuss reimbursement/coverage for utilizing alternative therapies.

MULTIDISCIPLINARY STRATEGY DEVELOPMENT (cont….)

OBJECTIVE #3: To increase knowledge about data and information resources regarding the opioid crisis.

Future Strategies:

- Consider the possibility of using telehealth in medication reconciliation with overdose patients.
- Educate practitioners regarding how to properly use the PDMP database.
- Make more use of webinars (or newsletters) and/or other efforts to better educate prescribing practitioners.
- Maximize data that is available from the PDMP database to see trends in prescribing habits.
- Practitioners should provide total upfront patient education – do more than just "check the box".
- Coordination of public education efforts across all disciplines.

OBJECTIVE #4: To identify strategies (collaborative and individual) for review, discussion, and implementation by individual regulatory boards on how to address the opioid crisis.

Current Activities:

- Law enforcement uses PDMP database to assist when conducting opioid investigations.
- Law enforcement interfaces with FDOH and utilizes Department knowledge base when conducting opioid investigations.
- Law enforcement encourages prescribing practitioners to check the PDMP when writing prescriptions.

MULTIDISCIPLINARY STRATEGY DEVELOPMENT (cont….)

OBJECTIVE #4: To identify strategies (collaborative and individual) for review, discussion, and implementation by individual regulatory boards on how to address the opioid crisis.

Future Strategies:

- Individual Boards will write letters in support of current legislative proposals (SB 8 / HB 21) for 3-day prescribing limits. Letters will be addressed to Governor Scott, House Speaker and Senate President.
- Find out what data is collected by or housed at AHCA on multidisciplinary collaboration efforts – specifically dealing with the opioid crisis.
- Look at removing technical obstacles to making access to the PDMP database more user-friendly (i.e. – changing password requirement from 6 weeks to a longer time, perhaps 3 months).
- Link the PDMP database to EHR database (future "wishlist" item).
- Require mandatory use of PDMP database.
- Require Mandatory post-licensure CE with "core topics" (i.e. – related to addiction). In lieu of eliminating the HIV CE requirement.
- Coordination of curriculum across all disciplines.
- Patient care plans must integrate alternative treatment modalities.
- Mandatory e-prescribing of controlled substances (will help to deter fraudulent prescriptions).
- Prescribing health care professions support prescribing limits as outlined in legislation and discuss guidelines for prescribing controlled substances for acute pain versus chronic pain.
- Allow or provide patients with the ability to request "opioid-free" medical treatment.
- Make the automatic software default prescription for opioids at a lower level (i.e. – 3-days) instead of higher dosage.

MULTIDISCIPLINARY STRATEGY DEVELOPMENT (cont….)

OBJECTIVE #5: To act as a "springboard" for future discussion regarding how to combat the opioid crisis from a multidisciplinary perspective.

Future Strategies:

- Schedule follow-up multidisciplinary workgroup meeting after 2018 legislative session.
- Form subgroup to build the modules and criteria for mandatory CE. Conference call is being scheduled.
- Multidisciplinary workgroup board representatives bring back workgroup outcomes and strategies for discussion and action at the full board level.

Work Group Outcome:
To see a reduction in opioid deaths in Florida because of strategies implemented by multidisciplinary health care boards.

AGENDA

Board Representatives:

- Mark Means, DC, Board of Chiropractic Medicine
- Lisa Bolhouse, LCSW, Board of Clinical Social Work, Marriage and Family Therapy, and Mental Health Counseling
- T.J. Tejera, DMD, MD, Board of Dentistry
- Jennifer Wakeman, LMT, Board of Massage Therapy
- Robert A. London, MD, Board of Medicine
- Derrick C. Glymph, DNAP, CRNA, ARNP, Board of Nursing
- Caylee J. Banta, OTD, OTR, Board of Occupational Therapy
- Michelle Mendez, DO, Board of Osteopathic Medicine
- Mark Mikhael, PharmD, Board of Pharmacy
- Gina Petraglia, PT, DPT, COS-C, CEEAA, Board of Physical Therapy
- Joseph Sindone, DPM, Board of Podiatric Medicine
- Catherine Drew, PhD, Board of Psychology

Call to Order and Introductions (estimated 20 minutes):

Moderator: Lucy C. Gee, MS, Director, Department of Health, Division of Medical Quality Assurance

Objectives: To increase awareness about the current status of the opioid crisis.

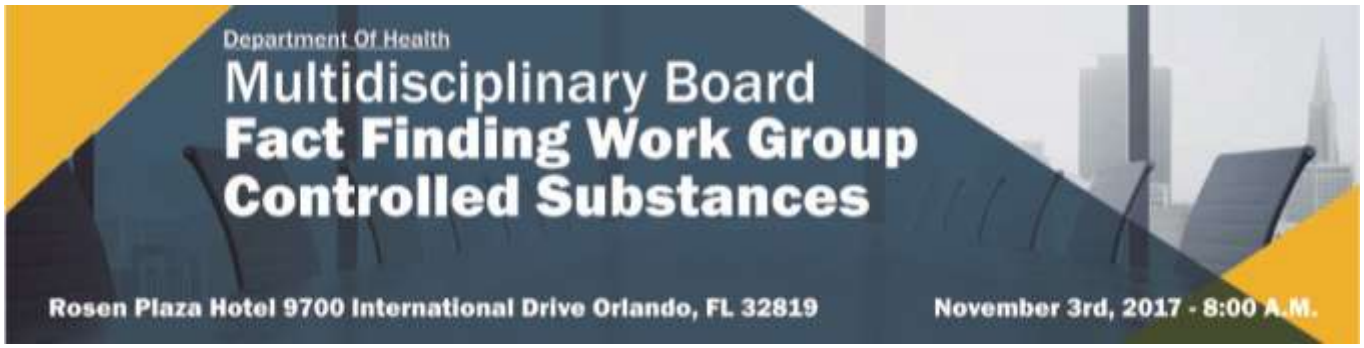
To increase knowledge about alternative therapies in addressing the opioid crisis.

To increase knowledge about data and information resources regarding the opioid crisis.

To identify strategies (collaborative and individual) for review, discussion, and implementation by individual regulatory boards on how to address the opioid crisis.

To act as a "springboard" for future discussion regarding how to combat the opioid crisis from a multidisciplinary perspective.

Outcome: A reduction in opioid deaths in Florida as a result of strategies implemented by multidisciplinary health care boards.



AGENDA (cont…)

Opening Remarks:
Celeste Philip, MD, MPH, State Surgeon General & Secretary

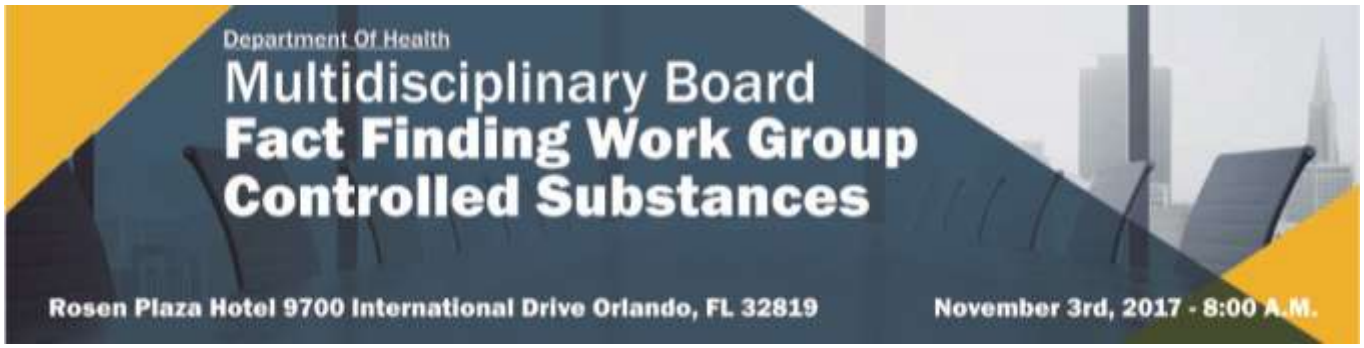
TAB 1: Prescribing and Dispensing Guidelines (estimated 45 minutes)
Presenter:
- Minda D. Reed, MD, MPH, CDC Fellow
  Reference Material: CDC Guideline for Prescribing Opioids for Chronic Pain- United States, 2016

TAB 2: Prescription Drugs: Ordering and Prescribing (estimated 20 minutes)
Presenter:
- Rebecca Poston, BPharm., MHL, Program Manager, E-FORCSE
  Reference Material: Prescription Drug Monitoring Program Annual Report 2015-2016

** BREAK ** (estimated 15 minutes)

TAB 3: Education: Pre and Post licensure (estimated 50 minutes)
Presenters:
- Phyllis L. Hendry, M.D., FAAP, FACEP, Professor, Department of Emergency Medicine, Division of Pediatric Emergency Medicine, University of Florida College of Medicine – Jacksonville
- Christopher W. Blackwell, PhD, ARNP, ANP-BC, AGACNP-BC, CNE, FAANP, University of Central Florida College of Nursing
- Steven Kaltman, DMD, Chair of the Oral and Maxillofacial Surgery Dept., Nova Southeastern University
- Venita Sposetti, DMD, Associate Professor, Associate Dean for Education, University of Florida, College of Dentistry, Department of Restorative Dental Sciences
- Scott Kjelson, PharmD, CPh, Director of Student Transitions/Assistant Professor, College of Pharmacy, Nova Southeastern University

  Reference Materials:
  AMA Opioid Task Force Progress
  Federation of State Medical Boards
  American Society of Anesthesiologist Task Force Acute Pain
  Rules: Florida, Georgia, Ohio, Washington, Utah



AGENDA (cont…)

TAB 4: Alternative Treatment Therapies (estimated 1 hour)
Moderator: Lucy Gee, Director, Division of Medical Quality Assurance
Presenters: Health Care Regulatory Board Representatives

** LUNCH ** (estimated 1 hour)

TAB 5: Multidisciplinary Strategy Development
Moderator: Lucy Gee, Director, Division of Medical Quality Assurance
Presenter: Gary White, MPH, CPH, Associate Director, Hillsborough County Anti-Drug Alliance

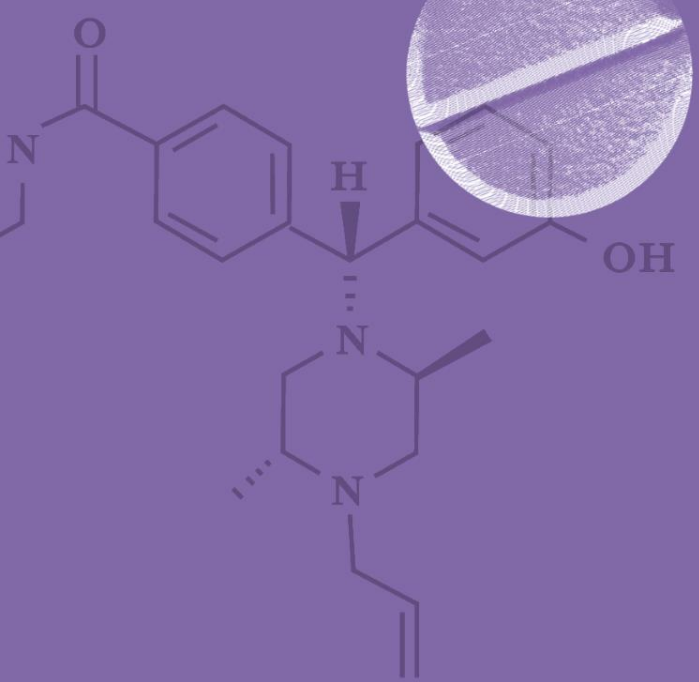
- Collaboration: Law Enforcement, Healthcare Industry, Other Partners
- Education: Practitioner and Public
- Regulatory Structure: Increased penalties, enhanced standards
  Reference Material:
  Drugs Identified in Deceased Persons by Florida Medical Examiners, 2016 Interim Report
  Statewide Drug Policy Advisory Council Annual Report 2016
  EMSTARs Report/Data

Adjourn

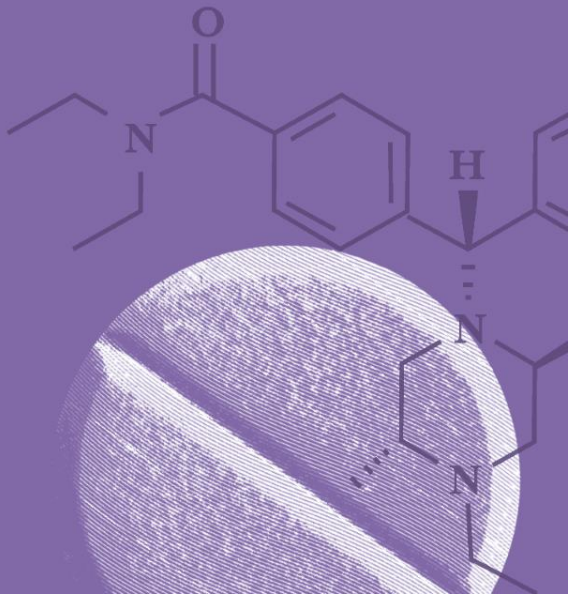
CDC Guideline for Prescribing Opioids for Chronic Pain

Minda D. Reed, MD, MPH
Health Scientist-Fellow, Division of Unintentional Injury Prevention

Florida Department of Health
Multidisciplinary Board Fact Finding Workgroup on Controlled Substances
November 3, 2017

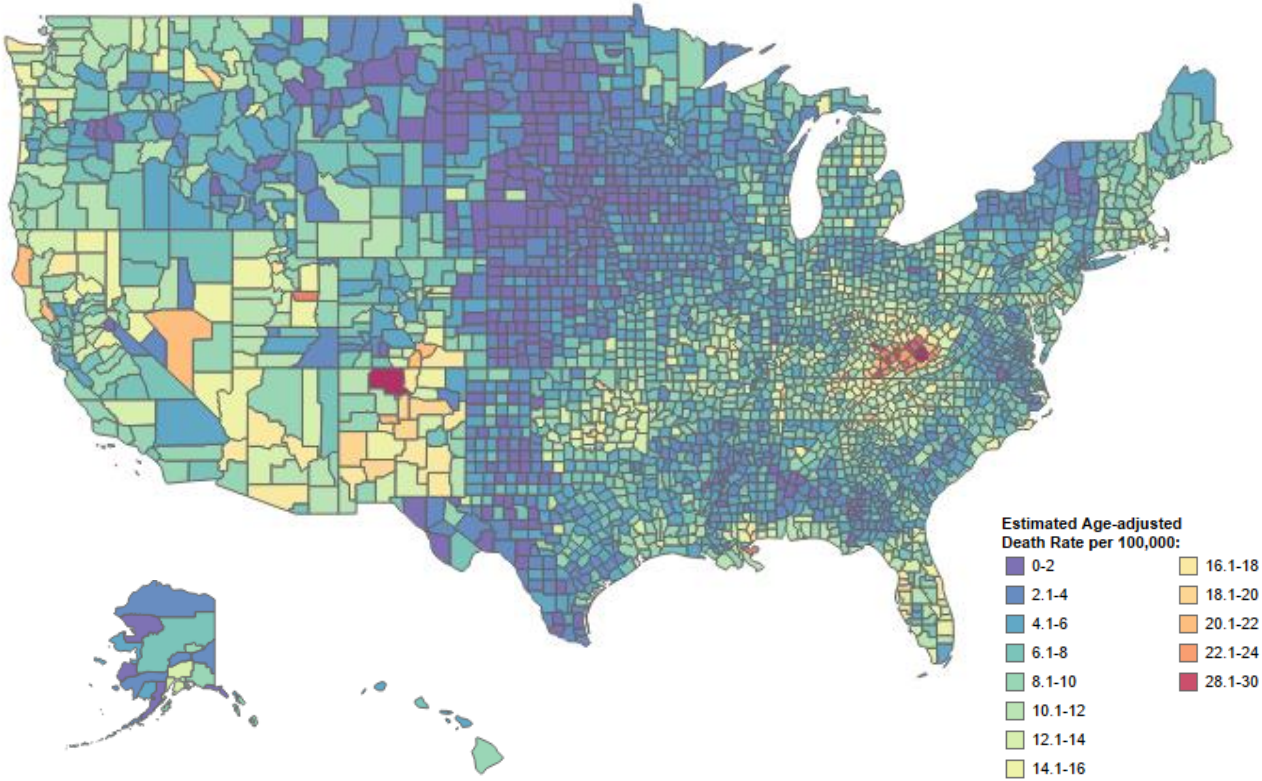


The Epidemic



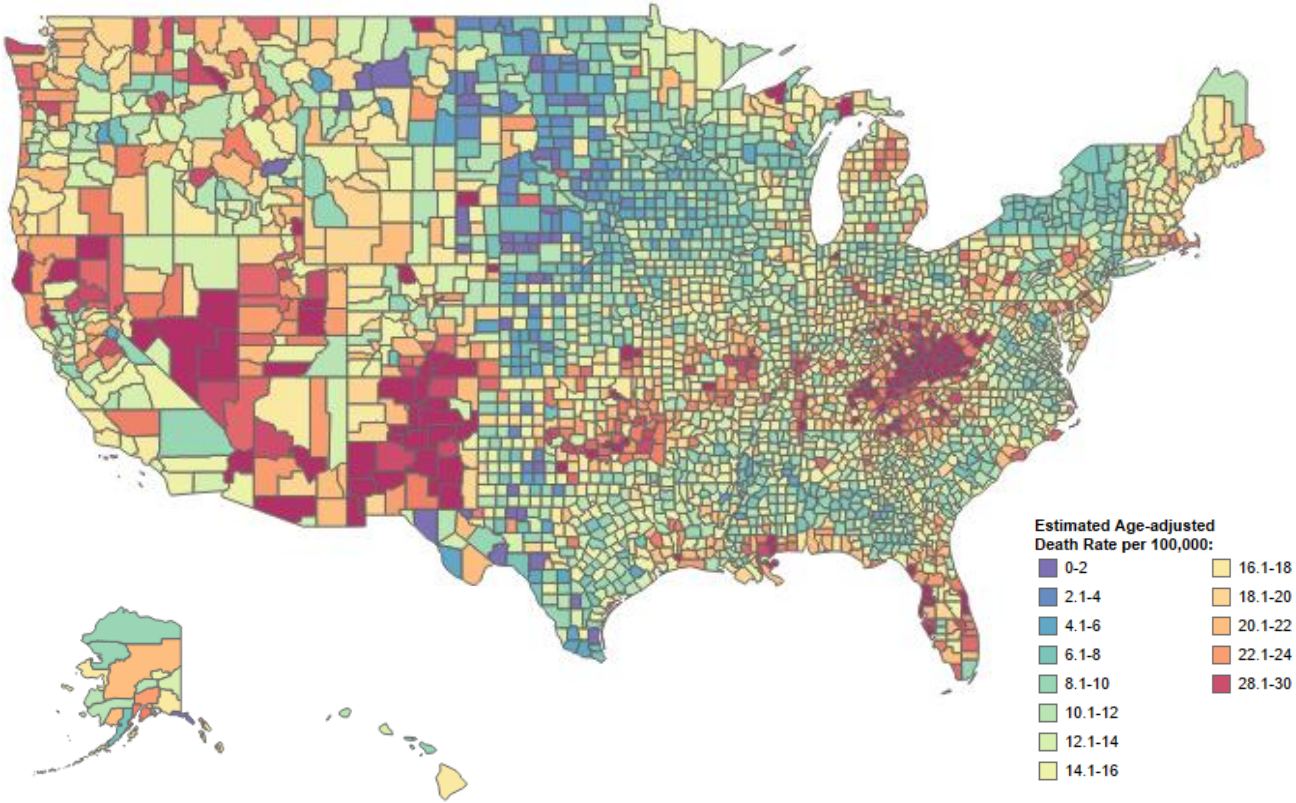
2005

Rapid Increase in Drug Overdose Death Rates by County



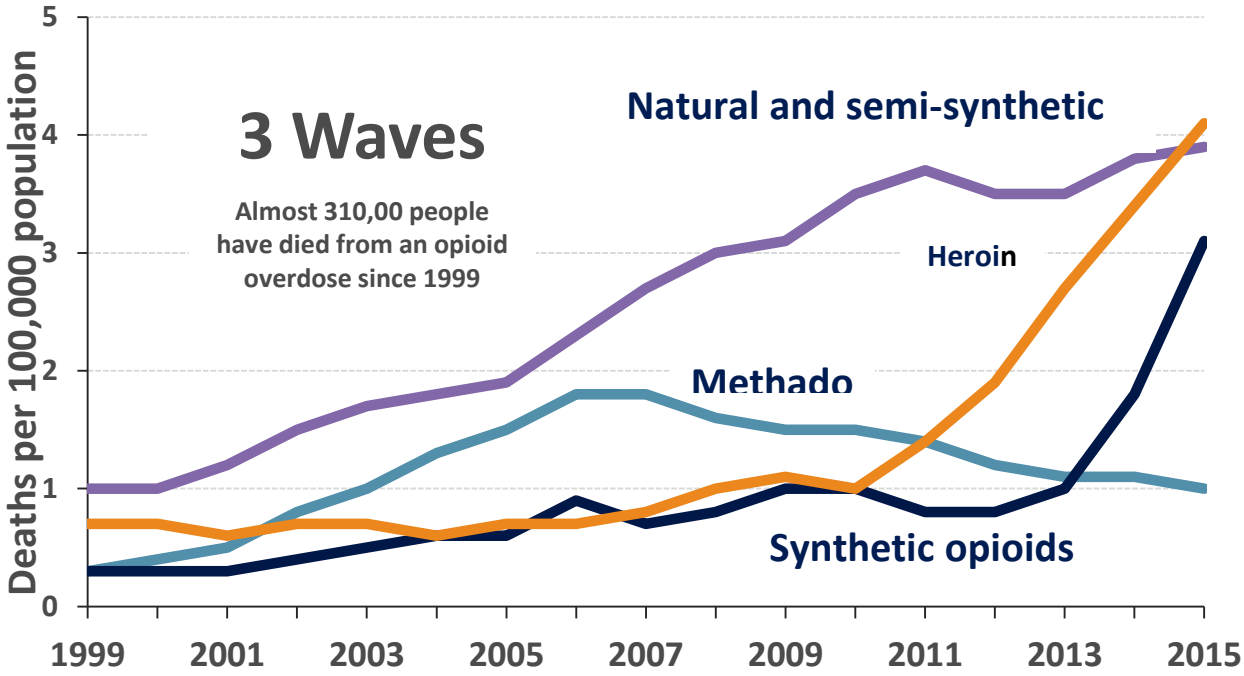
SOURCE: NCHS Data Visualization Gallery

2015 Rapid Increase in Drug Overdose Death Rates by County



SOURCE: NCHS Data Visualization Gallery

RISE IN OPIOID DEATHS | Overlapping, Entangled but Distinct Epidemics



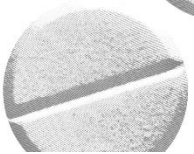
SOURCE: National Vital Statistics System Mortality File.

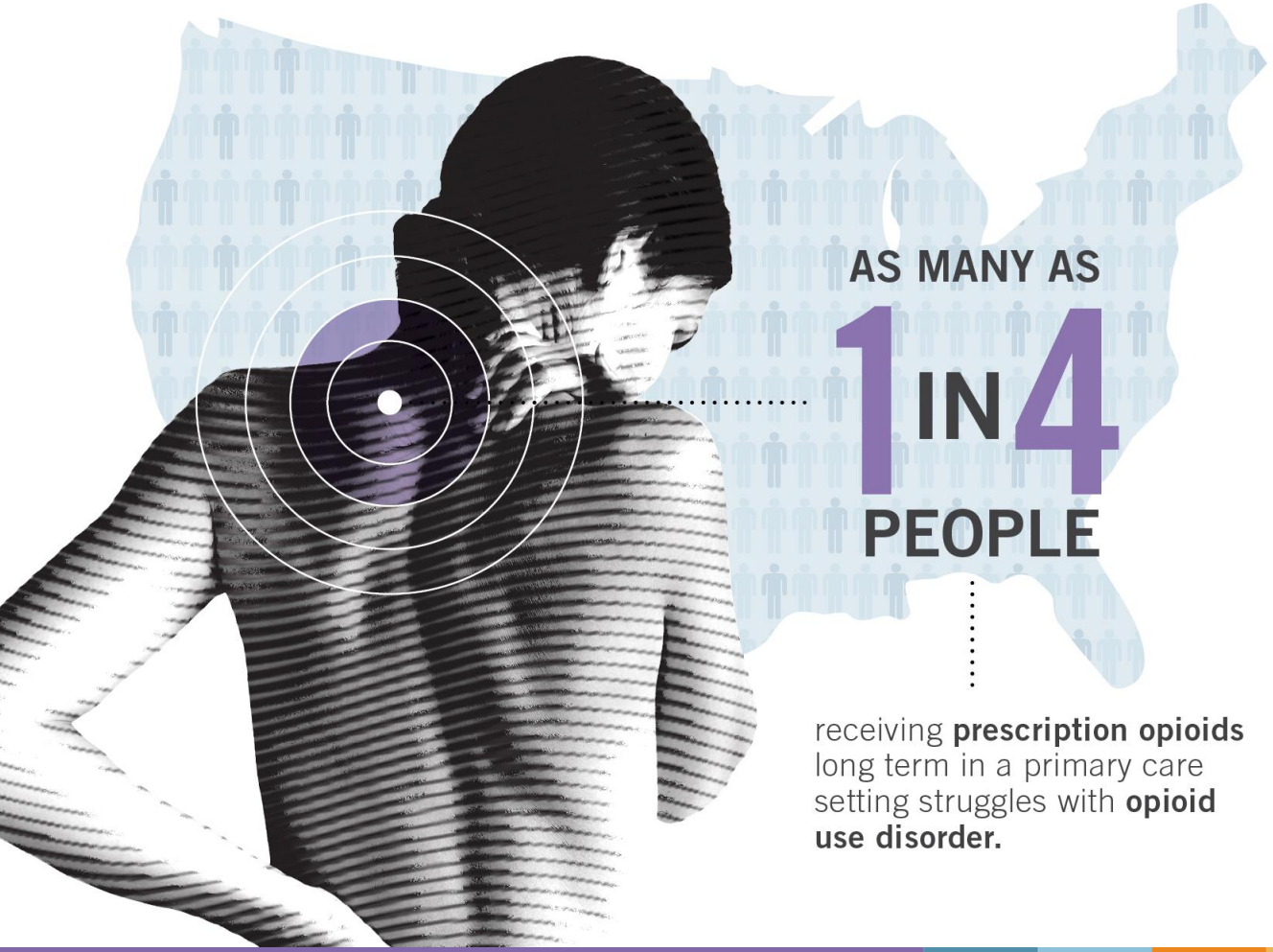
Chronic Pain and Prescription Opioids

- 11% of Americans experience daily (chronic) pain
- Opioids frequently prescribed for chronic pain
- Primary care providers commonly treat chronic, non-cancer pain
  - account for ~50% of opioid pain medications dispensed
  - report concern about opioids and insufficient training

The amount
of opioids prescribed has
QUADRUPLED
from 1999-2014,

but the pain that
Americans report remains
UNCHANGED

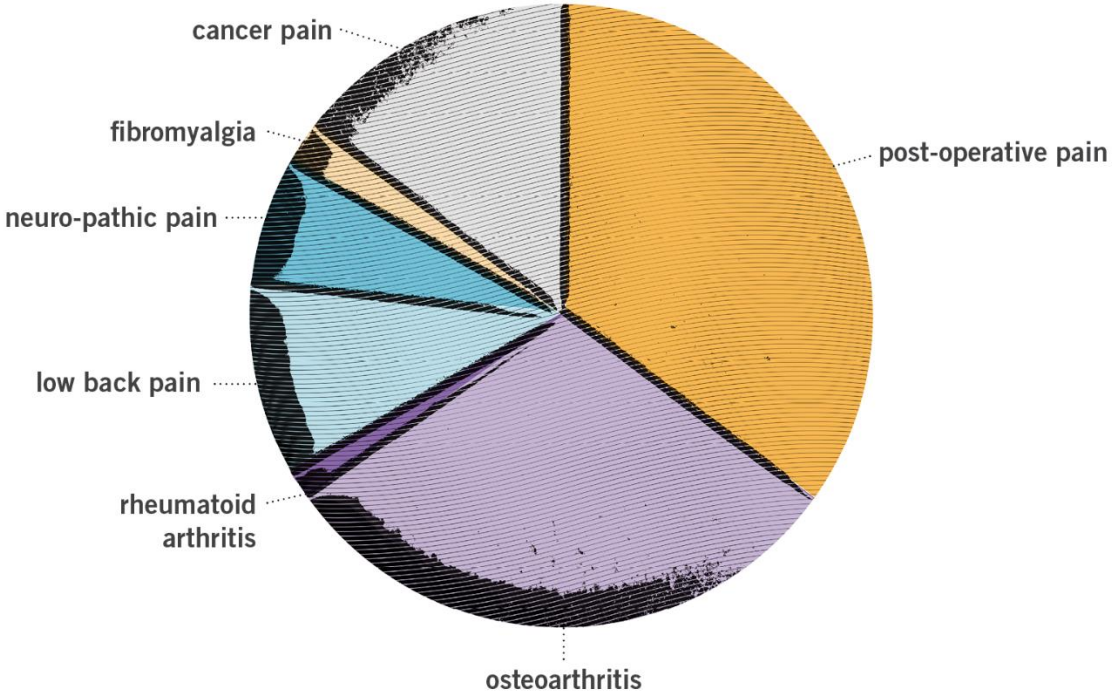



AS MANY AS
1 IN 4
PEOPLE
receiving **prescription opioids** long term in a primary care setting struggles with **opioid use disorder.**

Half of US opioids market is treatment for chronic, non-cancer pain

U.S. opioids market revenues for 7 leading indications, 2010

Source: GBI Research. Opioids Market to 2017. June 2011



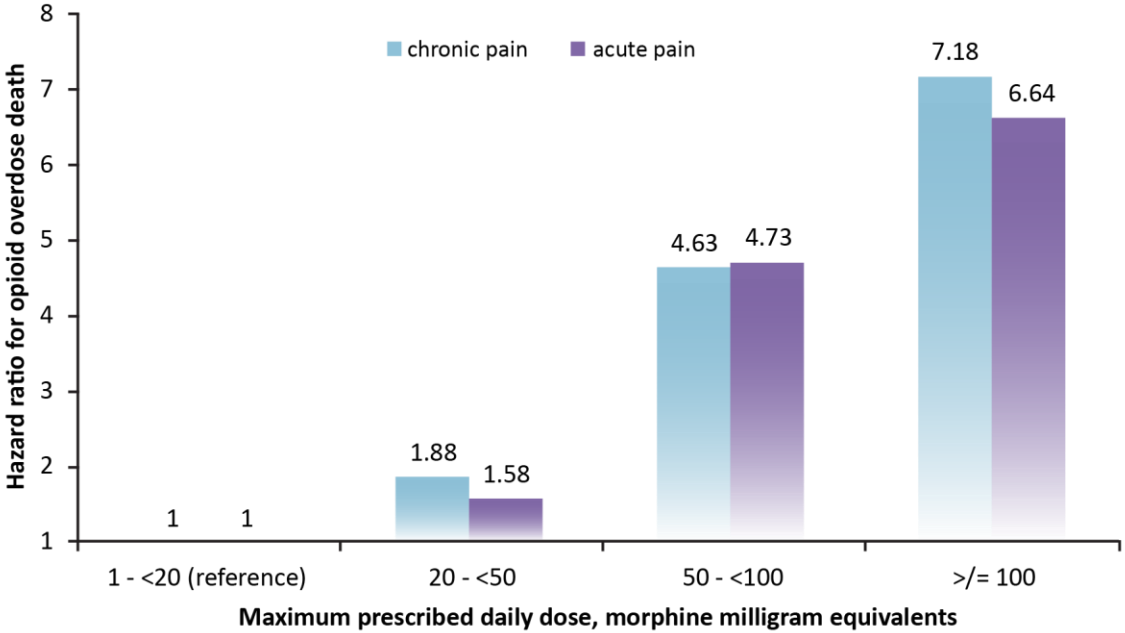
Longer duration and higher dosage

ORIGINAL CONTRIBUTION

JAMA 2011;305:1315-1321

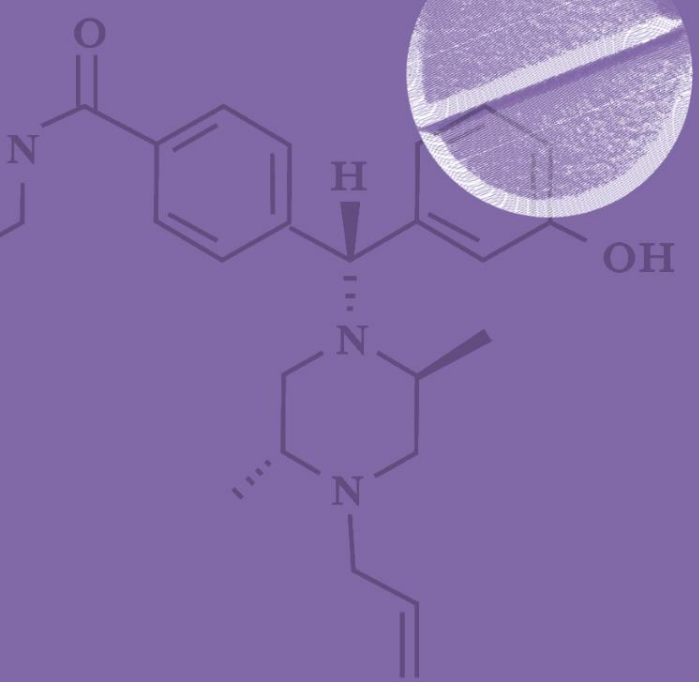
Association Between Opioid Prescribing Patterns and Opioid Overdose-Related Deaths

Amy S. Bohnert, PhD
Marcia Valenstein, MD
Matthew J. Bair, MD
Dara Ganoczy, MPH
John F. McCarthy, PhD
Mark A. Ilgen, PhD
Frederic C. Blow, PhD

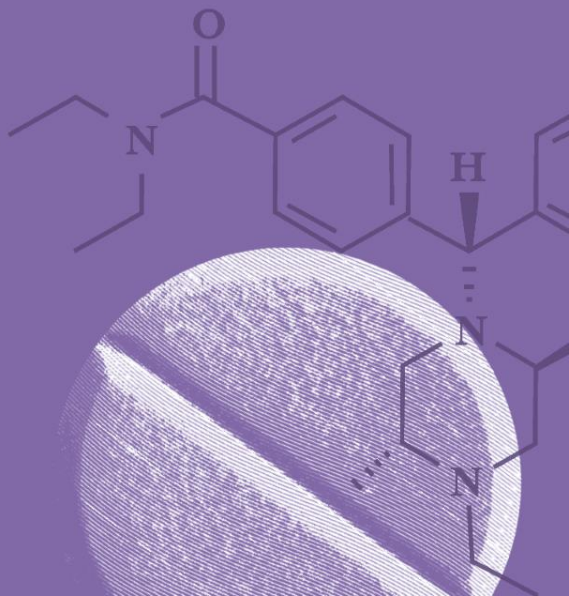


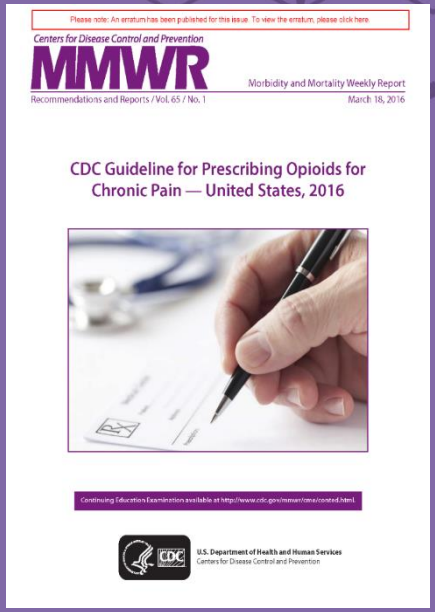
Need for Opioid Prescribing Guidelines

- Previous opioid prescribing guidelines have been developed by several states and agencies but were **inconsistent**
- Most recent national guidelines are **several years old** and don’t incorporate the most recent evidence
- Need for **clear, consistent** recommendations



Guideline for Prescribing Opioids for Chronic Pain





Please note: An erratum has been published for this issue. To view the erratum, please click here.

Centers for Disease Control and Prevention

MMWR

Morbidity and Mortality Weekly Report

Recommendations and Reports / Vol. 65 / No. 1

March 18, 2016

CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016

Continuing Education Examination available at http://www.cdc.gov/mmwr/cme/conted.html.

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

JAMA: The Journal of American Medical Association

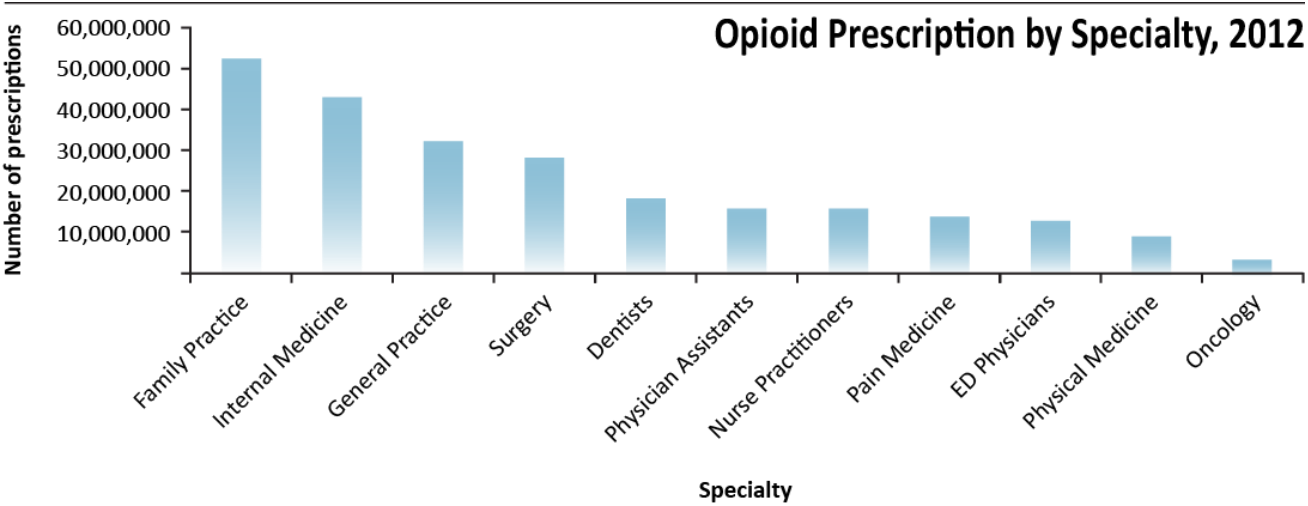
Deborah Dowell, Tamara Haegerich, and Roger Chou

CDC Guideline for Prescribing Opioids for Chronic Pain—
United States, 2016

Published online March 15, 2016

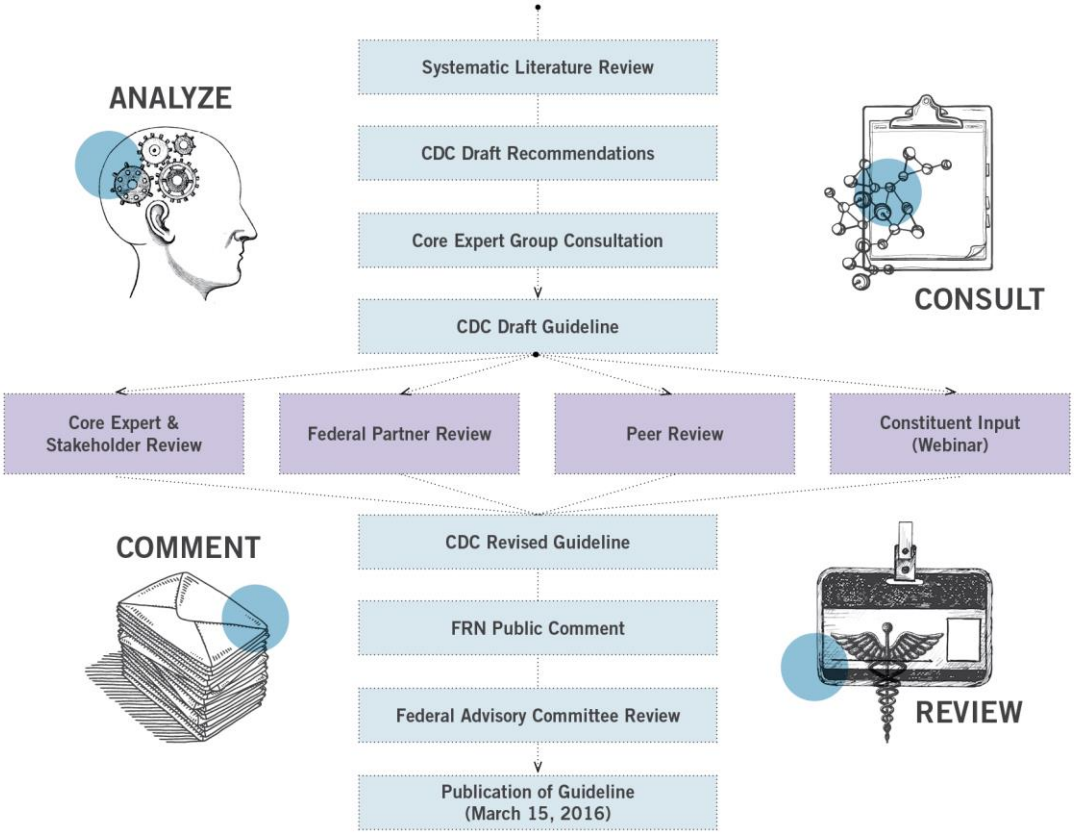
- Primary care providers
- Patients 18 years or older with chronic pain
- Outpatient settings
- Outside of active cancer, palliative, and end of life care

Why primary care providers?



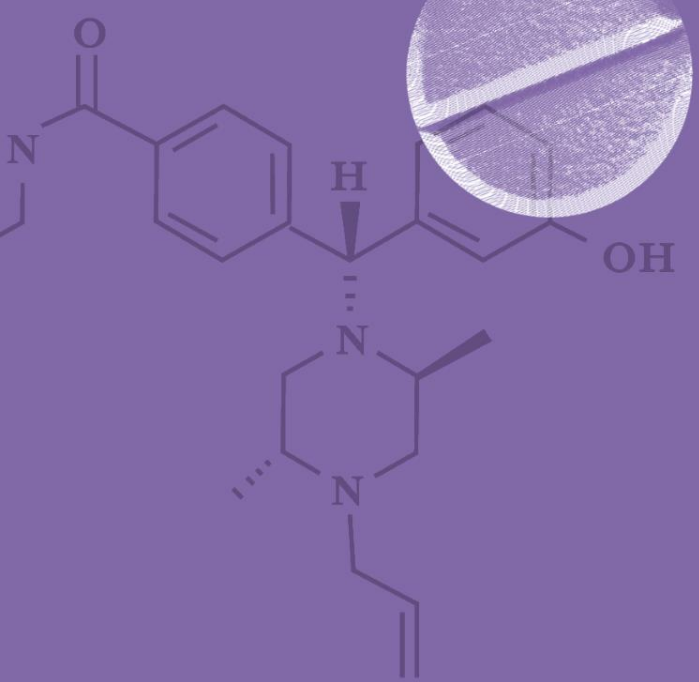
IMS Health, National Prescription Audit, United States, 2012

Guideline Development Process

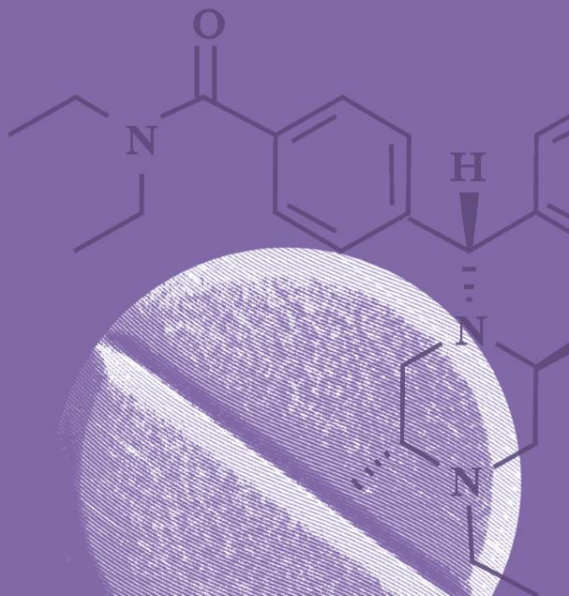


GRADE Method

- Standard for guideline development
- Transparent approach for conducting systematic review, rating quality of evidence, and determining strength of recommendations
- Used by > 100 organizations (including Advisory Committee on Immunization Practices)
- Recommendations based on:
  - Quality of evidence
  - Balance between benefits and harms
  - Values and preferences
  - Cost

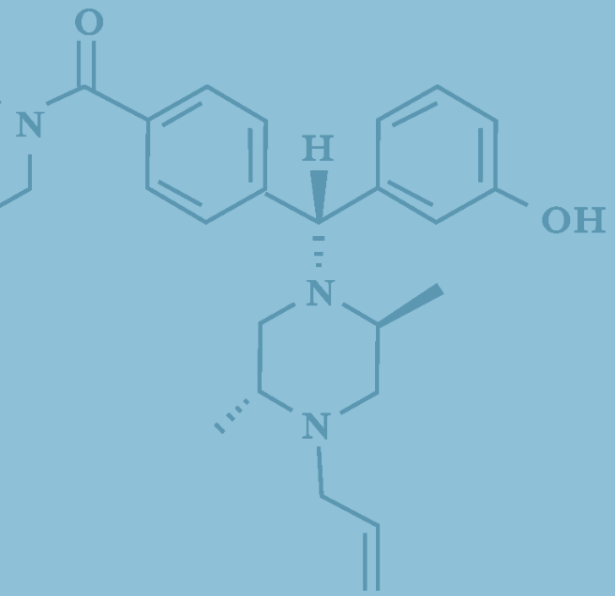


Guideline for Prescribing Opioids for Chronic Pain

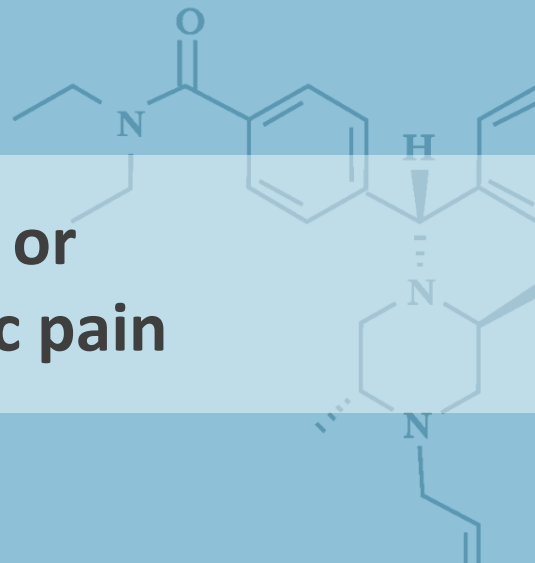


Organization of Recommendations

- **The 12 recommendations are grouped into three conceptual areas:**
  - Determining when to initiate or continue opioids for chronic pain
  - Opioid selection, dosage, duration, follow-up, and discontinuation
  - Assessing risk and addressing harms of opioid use



Determine when to initiate or continue opioids for chronic pain



Recommendation #1

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.

(Recommendation category A: Evidence type: 3)

Recommendation #2

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 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.

(Recommendation category A: Evidence type: 4)

Recommendation #3

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.

(Recommendation category A: Evidence type: 3)

Opioid selection, dosage, duration, follow-up, and discontinuation

Recommendation #4

4

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

(Recommendation category A: Evidence type: 4)

Recommendation #5

5

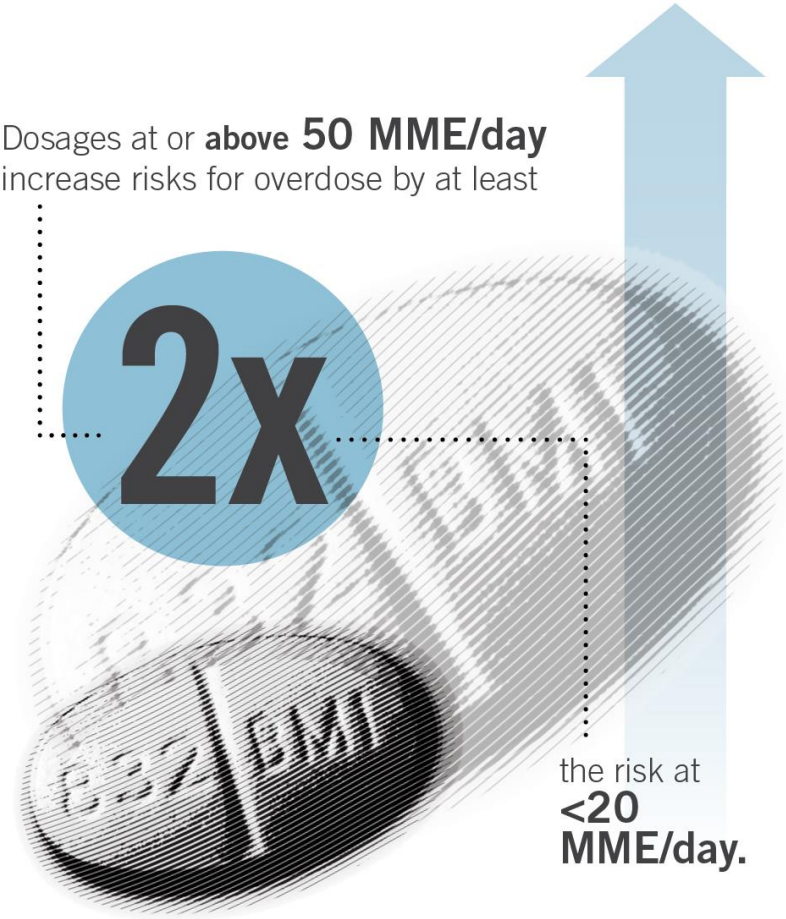
- When opioids are started, clinicians should prescribe the lowest effective dosage.
- Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and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

(Recommendation category A: Evidence type: 3)

Dosages at or **above 50 MME/day** increase risks for overdose by at least

2x

the risk at **<20 MME/day.**



Recommendation #6

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.
- 3 days or less will often be sufficient; more than 7 days will rarely be needed.

(Recommendation category A: Evidence type: 4)

Recommendation #7

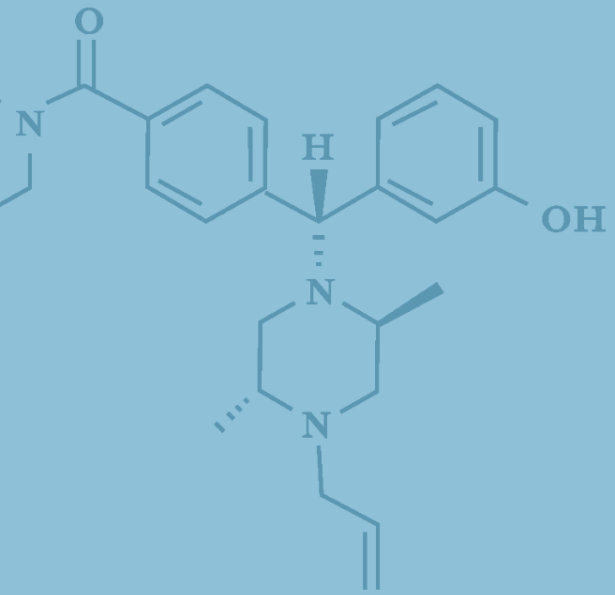
7

- 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.

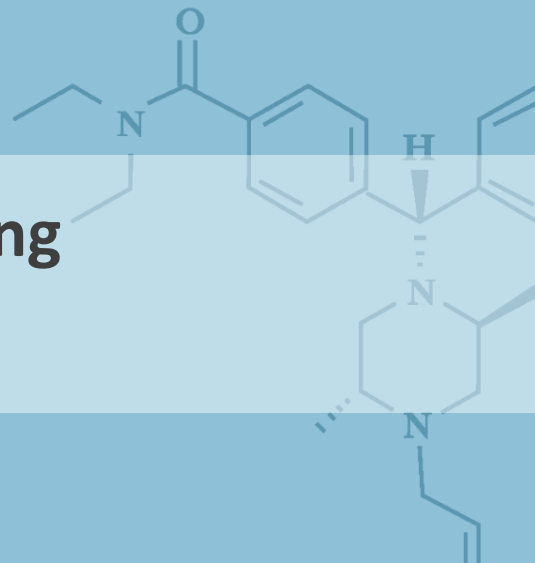
(Recommendation category A: Evidence type: 4)

Tapering Opioids

- Work with patients to taper opioids down or off when
  - no sustained clinically meaningful improvement in pain and function
  - opioid dosages ≥50 MME/day without evidence of benefit
  - concurrent benzodiazepines that can't be tapered off
  - patients request dosage reduction or discontinuation
  - patients experience overdose, other serious adverse events, warning signs.
- Taper slowly enough to minimize opioid withdrawal
  - A decrease of 10% per week is a reasonable starting point
- Access appropriate expertise for tapering during pregnancy
- Optimize nonopioid pain management and psychosocial support



Assessing risk and addressing harms of opioid use



Recommendation #8

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.

(Recommendation category A: Evidence type: 4)

Recommendation #9

9

- Clinicians should review the patient's history of controlled substance prescriptions using state PDMP data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him/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.

(Recommendation category A: Evidence type: 4)

Recommendation #10

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.

(Recommendation category B: Evidence type: 4)

Recommendation #11

11

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

(Recommendation category A: Evidence type: 3)

Recommendation #12

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.

(Recommendation category A: Evidence type: 2)

Implementation Activities

CDC Guideline Implementation

1

Translation and Communication

Develop tools and resources about the guidelines for a variety of audiences – including providers, health systems, and the general public.

2

Clinical Training

Educate providers through medical schools and ongoing continuing medical education (CME) activities.

3

Health System Implementation

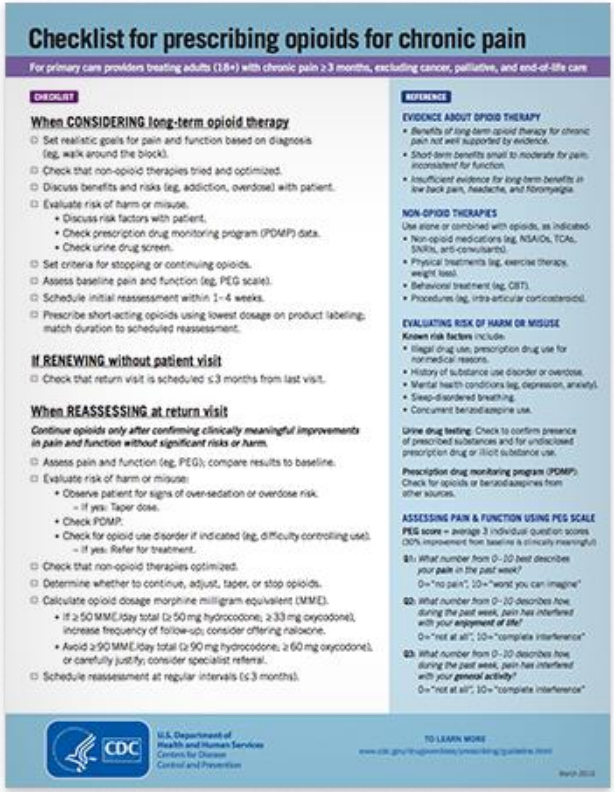
Educate providers, integrate into EHRs and other clinical decision support tools, adopt and use quality metrics, and leverage within broader coordinated care activities.

4

Insurer/Pharmacy Benefit Manager Implementation

Proactive use of claims information and improvement in coverage and service delivery payment models – including reimbursement for clinician counseling; coverage for non-pharmacological treatments; and drug utilization review or prior authorization.

Tools and Materials



Checklist for prescribing opioids for chronic pain

For primary care providers treating adults (18+) with chronic pain ≥ 3 months, excluding cancer, palliative, and end-of-life care

CHECKLIST

When CONSIDERING long-term opioid therapy

- ☐ Set realistic goals for pain and function based on diagnosis (eg, walk around the block).
- ☐ Check that non-opioid therapies tried and optimized.
- ☐ Discuss benefits and risks (eg, addiction, overdose) with patient.
- ☐ Evaluate risk of harm or misuse.
  - Discuss risk factors with patient.
  - Check prescription drug monitoring program (PDMP) data.
  - Check urine drug screen.
- ☐ Set criteria for stopping or continuing opioids.
- ☐ Assess baseline pain and function (eg, PEG scale).
- ☐ Schedule initial reassessment within 1–4 weeks.
- ☐ Prescribe short-acting opioids using lowest dosage on product labeling; match duration to scheduled reassessment.

If RENEWING without patient visit

- ☐ Check that return visit is scheduled ≤3 months from last visit.

When REASSESSING at return visit

Continue opioids only after confirming clinically meaningful improvements in pain and function without significant risks or harm.

- ☐ Assess pain and function (eg, PEG); compare results to baseline.
- ☐ Evaluate risk of harm or misuse:
  - Observe patient for signs of over-sedation or overdose risk.
    - If yes: Taper dose.
  - Check PDMP.
  - Check for opioid use disorder if indicated (eg, difficulty controlling use).
    - If yes: Refer for treatment.
- ☐ Check that non-opioid therapies optimized.
- ☐ Determine whether to continue, adjust, taper, or stop opioids.
- ☐ Calculate opioid dosage morphine milligram equivalent (MME).
  - If ≥ 50 MME/day total (≥ 50 mg hydrocodone; ≥ 33 mg oxycodone), increase frequency of follow-up; consider offering naloxone.
  - Avoid ≥ 90 MME/day total (≥ 90 mg hydrocodone; ≥ 60 mg oxycodone), or carefully justify; consider specialist referral.
- ☐ Schedule reassessment at regular intervals (≤ 3 months).

REFERENCE

EVIDENCE ABOUT OPIOID THERAPY

- *Benefits of long-term opioid therapy for chronic pain not well supported by evidence.*
- *Short-term benefits small to moderate for pain; inconsistent for function.*
- *Insufficient evidence for long-term benefits in low back pain, headache, and fibromyalgia.*

NON-OPIOID THERAPIES

Use alone or combined with opioids, as indicated:

- Non-opioid medications (eg, NSAIDs, TCAs, SNRIs, anti-convulsants).
- Physical treatments (eg, exercise therapy, weight loss).
- Behavioral treatment (eg, CBT).
- Procedures (eg, intra-articular corticosteroids).

EVALUATING RISK OF HARM OR MISUSE

Known risk factors include:

- Illegal drug use; prescription drug use for non-medical reasons.
- History of substance use disorder or overdose.
- Mental health conditions (eg, depression, anxiety).
- Sleep-disordered breathing.
- Concurrent benzodiazepine use.

Urine drug testing: Check to confirm presence of prescribed substances and for undisclosed prescription drug or illicit substance use.

Prescription drug monitoring program (PDMP): Check for opioids or benzodiazepines from other sources.

ASSESSING PAIN & FUNCTION USING PEG SCALE

PEG score = average 3 individual question scores (30% improvement from baseline is clinically meaningful)

Q1: *What number from 0–10 best describes your pain in the past week?*
0="no pain", 10="worst you can imagine"

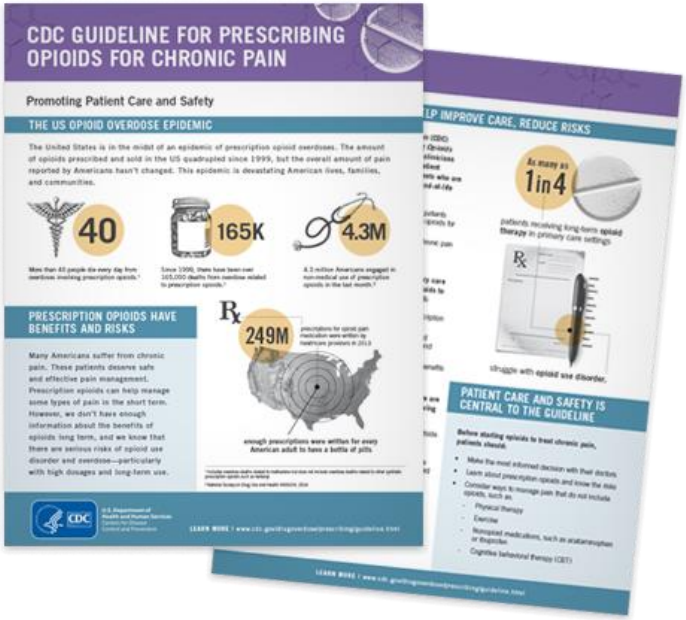
Q2: *What number from 0–10 describes how during the past week, pain has interfered with your enjoyment of life?*
0="not at all", 10="complete interference"

Q3: *What number from 0–10 describes how during the past week, pain has interfered with your general activity?*
0="not at all", 10="complete interference"

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

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

March 2016



CDC GUIDELINE FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN

Promoting Patient Care and Safety

THE US OPIOID OVERDOSE EPIDEMIC

The United States is in the midst of an epidemic of prescription opioid overdoses. The amount of opioids prescribed and sold in the US quadrupled since 1999, but the overall amount of pain reported by Americans hasn't changed. This epidemic is devastating American lives, families, and communities.

40 — More than 40 people die every day from overdoses involving prescription opioids.[1]

165K — Since 1999, there have been over 165,000 deaths from overdose related to prescription opioids.[1]

4.3M — 4.3 million Americans engaged in non-medical use of prescription opioids in the last month.[1]

PRESCRIPTION OPIOIDS HAVE BENEFITS AND RISKS

Many Americans suffer from chronic pain. These patients deserve safe and effective pain management. Prescription opioids can help manage some types of pain in the short term. However, we don't have enough information about the benefits of opioids long term, and we know that there are serious risks of opioid use disorder and overdose—particularly with high dosages and long-term use.

249M — prescriptions for opioid pain medication were written by healthcare providers in 2013

enough prescriptions were written for every American adult to have a bottle of pills

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

LP IMPROVE CARE, REDUCE RISKS

As many as **1 in 4** patients receiving long-term opioid therapy in primary care settings

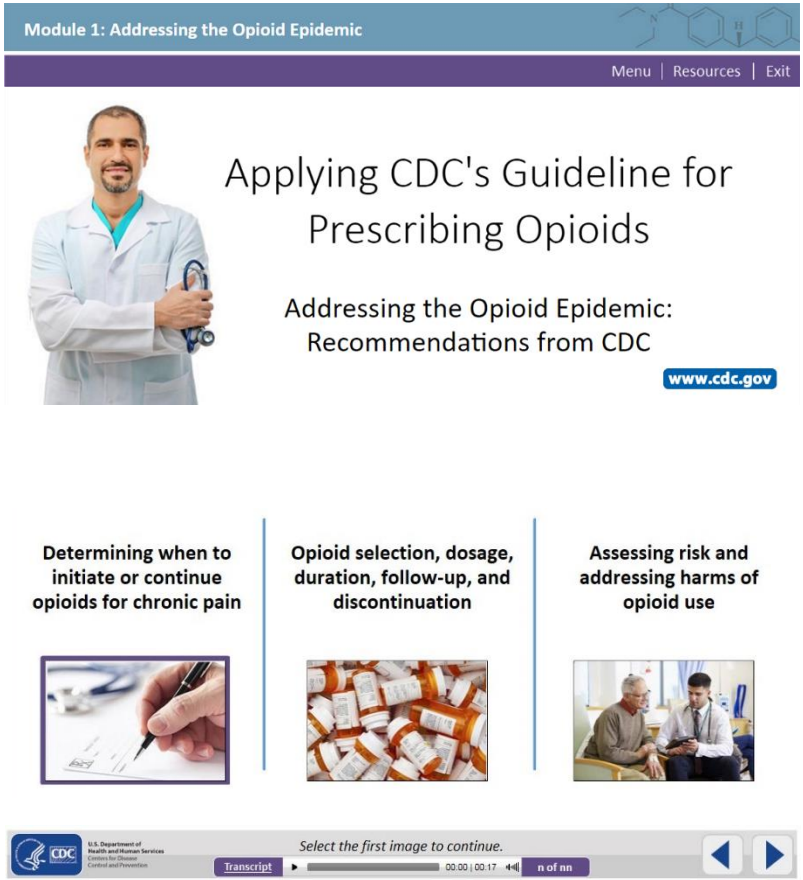
struggle with opioid use disorder.

PATIENT CARE AND SAFETY IS CENTRAL TO THE GUIDELINE

Before starting opioids to treat chronic pain, patients should:

- Make the most informed decision with their doctors
- Learn about prescription opioids and know the risks
- Consider ways to manage pain that do not include opioids, such as:
  - Physical therapy
  - Exercise
  - Nonopioid medications, such as acetaminophen or ibuprofen
  - Cognitive behavioral therapy (CBT)

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



Training

- Training modules for clinicians
  - Online modules
  - CME credits
- Guideline-concordant education
  - Medical schools
  - Nursing schools
  - Pharmacy schools

General Public Education

A COMMUNICATION TOOLKIT DESIGNED TO SUPPORT YOUR LOCAL WORK.

America's growing opioid epidemic impacts every state and every community. With the CDC *Rx Awareness Campaign Toolkit*, you can launch a campaign to raise awareness about the risks of opioids in your local community.

The toolkit features:

- Ready-to-use messaging and graphics about the risks of opioids
- Research tips for learning about key audiences
- Outreach and media placement strategies
- Tactics to get the most out of your campaign budget
- Campaign planning tools and media templates
- Methods to measure campaign success

Email **duipinquiries@cdc.gov** to learn more about the toolkit and when it will be available.

"ONE PRESCRIPTION CAN BE ALL IT TAKES TO LOSE EVERYTHING."

-MIKE

CHANGE YOUR COMMUNITY'S FUTURE FOR THE BETTER

TAKE PART IN THE CDC Rx AWARENESS CAMPAIGN.

Get ready-to-use, tested campaign materials and tips in the CDC *Rx Awareness Campaign Toolkit*.

CDC

CDC Resources

CDC Opioid Overdose Prevention Website
www.cdc.gov/drugoverdose

CDC Guideline for Prescribing Opioids for Chronic Pain
https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm

COCA Calls (clinician webinars)
https://emergency.cdc.gov/coca/calls/2016/index.asp

Online Training Series for Healthcare Providers
https://www.cdc.gov/drugoverdose/training/index.html

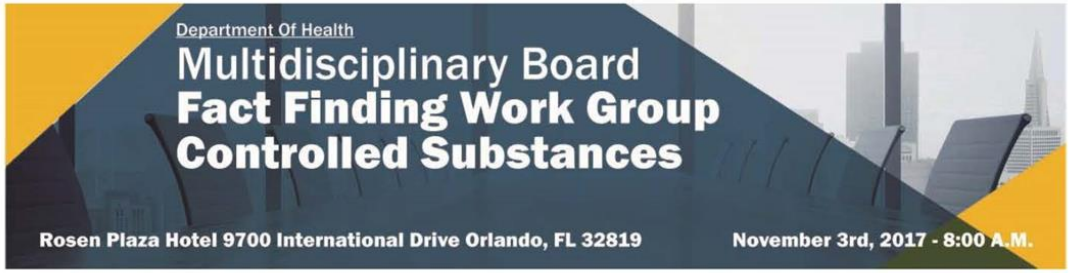
CDC Vital Signs, July 2017
https://www.cdc.gov/vitalsigns/prescription-drug-overdoses.html

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

Medical Education Competencies Regarding Pain, Opioids, and Addiction Risk: *Council of Florida Medical School Deans - Pain Management Working Group Report*

Phyllis Hendry, MD, FACEP, FAAP
University of Florida COM-Jacksonville
PI-Pain Assessment and Management Initiative (PAMI)



COUNCIL OF FLORIDA MEDICAL SCHOOL DEANS

Medical Schools' Pain Management Working Group Report: Overview

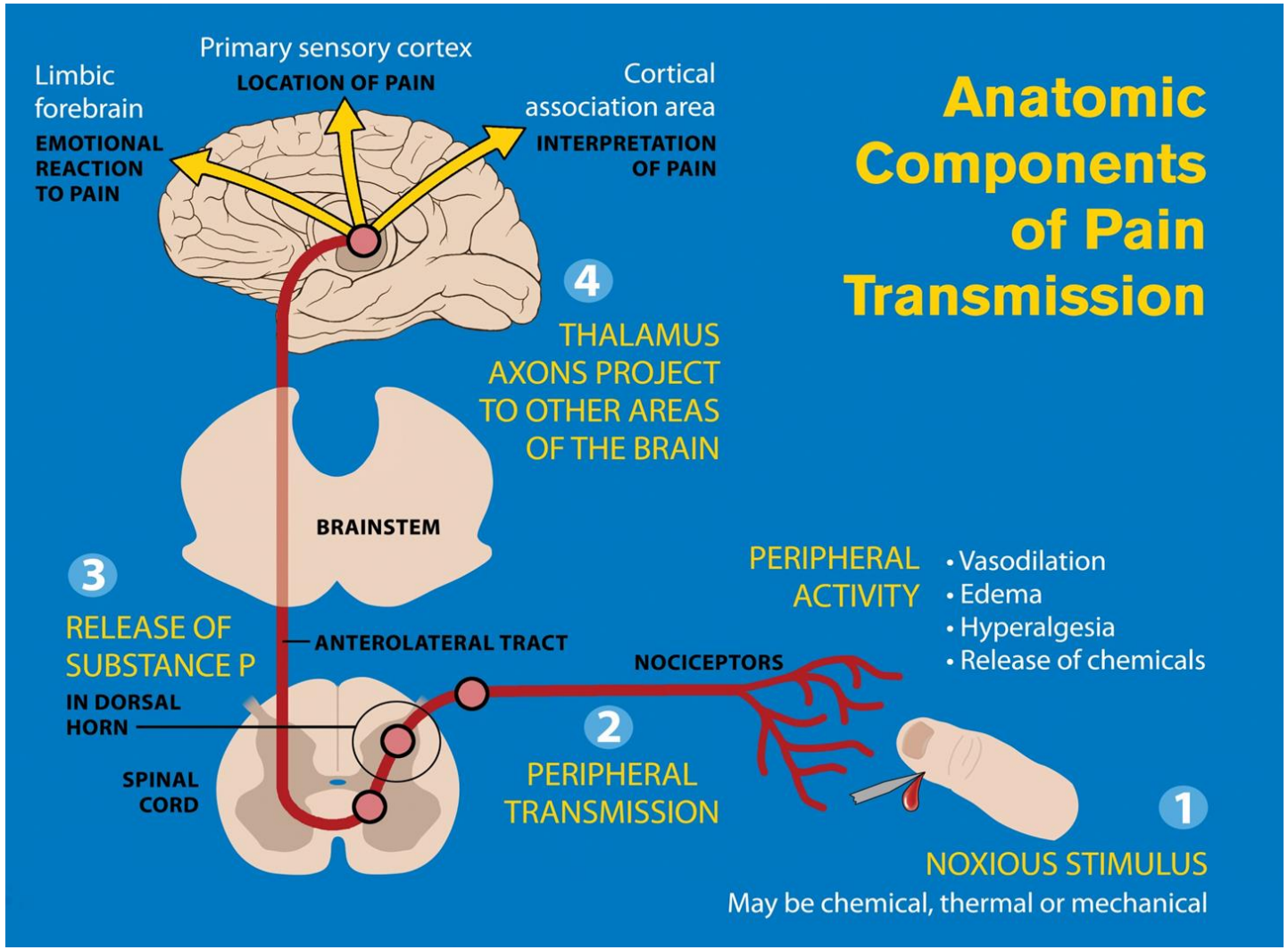
- Background
- Participation of Florida's Nine Allopathic and Osteopathic Schools
- Literature Search and Development of Sharing Platform
- Consideration of Existing Models for Medical Education
  - For Flexible Incorporation into Existing Curricula
    - Massachusetts
    - Pennsylvania
    - CDC
- Inclusion of Other Educational Initiatives: PAMI
- Coordination with State Surgeon General, Policymakers, FMA and FOMA, and others

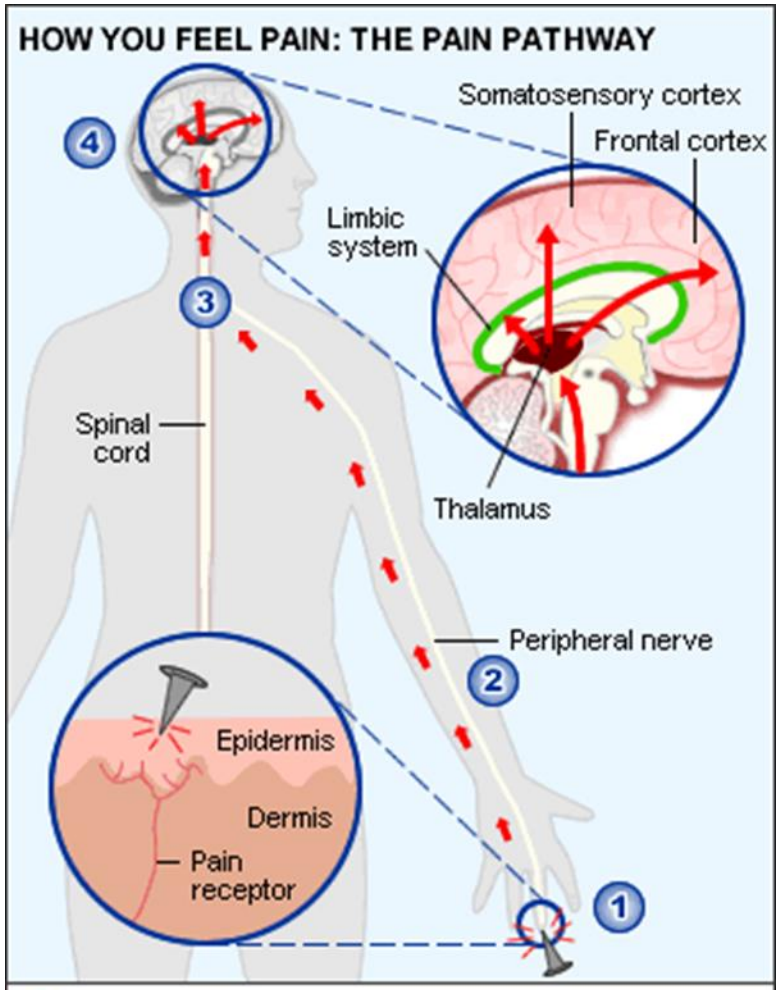
Guiding Principle: Pain Education is the Starting Point in Addressing the Opioid Epidemic

- Pain is the most common reason for seeking health care and as a presenting complaint accounts for up to 70% of ED visits
- Chronic pain alone affects more Americans than diabetes, cancer, and HD
- Early appropriate pain management (nonpharmacologic+/- pharmacologic) provides long-term benefits and decreased sequela
- Limited pain education in professional health related schools in general
  - But that is changing!

PAINWeek.org

Pain Management 101- Not! complicated, multifactorial





1. Pain receptors (nociceptors) in the skin are activated by tissue damage.
2. A signal travels up the peripheral nerve to the spinal cord.
3. Within the spinal cord, chemical messengers (neurotransmitters) are released. These activate other nerves that pass signals to the brain.
4. The thalamus relays the signals on to the somatosensory cortex (sensation), frontal cortex (thinking) and limbic system (emotional response).

Pain Management Balancing Act

- New research regarding the neurobiological/genetic complexity of pain and long term consequences of untreated acute pain
- New methods of treating pain
- Opioid addiction epidemic and need for change
- Joint Commission, HCHAPS surveys, readmission penalties, etc.

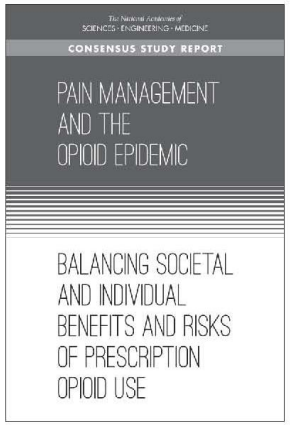
Consensus Study Report

July 2017

HIGHLIGHTS

Pain Management and the Opioid Epidemic

Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use



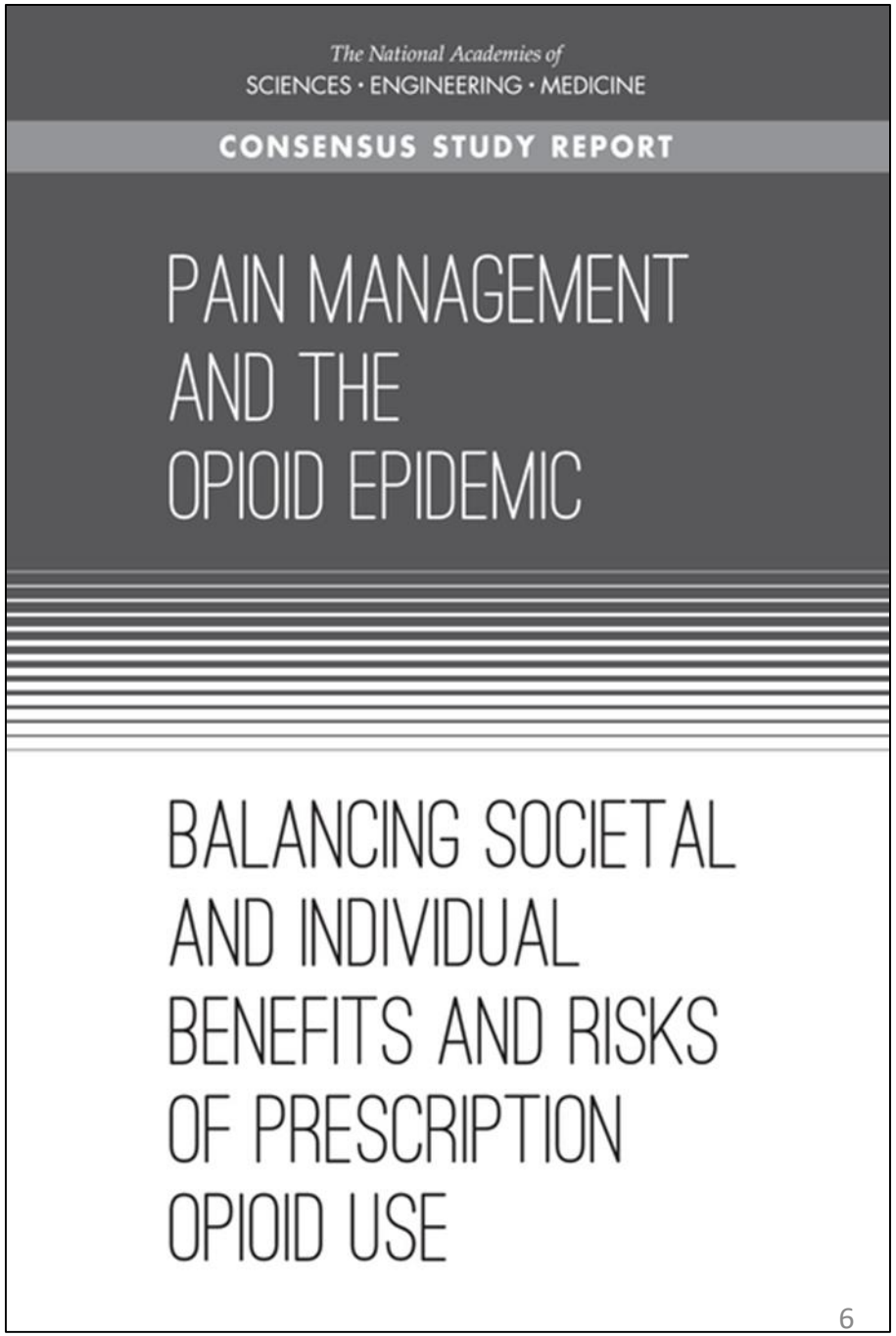
Drug overdose is now the leading cause of death from unintentional injury in the United States, and most of these deaths involve an opioid. The ongoing opioid crisis lies at the intersection of two public health challenges: reducing the burden of suffering from pain and containing the increasing toll of the harms that can arise from use of opioid medications.

On one hand, meeting the needs of tens of millions of U.S. residents suffering from pain (including acute pain, chronic pain, or pain at the end of life) requires access to a broad array of therapies for pain management. On the other hand, harms associated with use of prescription opioids, including misuse, opioid use disorder (OUD, a substance use disorder involving opioids), and overdose, affect not only patients with pain themselves but also their families, their communities, and society at large. Chronic pain and OUD both represent complex human conditions affecting millions of Americans and causing untold disability and loss of function.

Against this backdrop, the U.S. Food and Drug Administration (FDA) asked the National Academies of Sciences, Engineering, and Medicine to convene a committee to update the state of the science on pain research, care, and education and to identify actions the FDA and others can take to respond to the opioid epidemic.

The resulting report, *Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use*, states that a sustained, coordinated effort is necessary to stem the still-escalating prevalence of opioid-related harms, including a culture change in prescribing for chronic noncancer pain, aggressive regulation of opioids by the FDA, and multi-pronged policies by state and local governments. However, the committee also counsels against arbitrary restrictions on access to opioids by suffering patients whose health care providers have prescribed these drugs responsibly.

The National Academies of
SCIENCES · ENGINEERING · MEDICINE



Prescribing Medications for Chronic Pain Management: The State of Education in *Florida Medical Schools and Residency Programs*

Wyndham A. Bonett, BS; Katherine Perdomo, MPH, CHES; Suzanne C. Baker, MA; Marshall B. Kapp, JD, MPH

ABSTRACT

The purpose of this study was to assess the state of chronic, non-cancer pain management education in Florida medical schools and residency programs. Surveys were developed and distributed to Florida allopathic and osteopathic medical schools. One survey was specific to students and residents and one to faculty. Confidence in their general education, as well as in treating patients with chronic, non-cancer pain, was measured. ***A majority of medical students and residents (59.5%), in addition to a majority of faculty (58.1%), agreed or strongly agree that more clinical time needs to be dedicated to chronic, non-cancer pain management education.*** *Students, residents, and faculty suggested offering more lectures, online modules, workshops, and clinical scenarios as ways to improve the current educational environment. Results demonstrate that while Florida medical schools and residency programs provide education on chronic, non- cancer pain management, there is still room for improvement.* ***Increased communication between institutions and standardizing competencies related to pain management may prove beneficial.***

Florida Public Health Review, 2017; 14, 22-32.

Medical Education: State-Wide Collaboration in Florida

Council of Florida Medical School Deans' Pain Management Group

Nova Southeastern University
Florida International University
University of South Florida
Florida State University
University of Florida
Lake Erie College of Osteopathic Medicine
Florida Atlantic University
University of Central Florida
University of Miami

Representatives from Biomedical Sciences, Anesthesiology, Hospice, Law, Pediatrics, Internal Medicine, Psychiatry, Psychology, Family Medicine, Emergency Medicine, Pain Management, Addiction Medicine…..

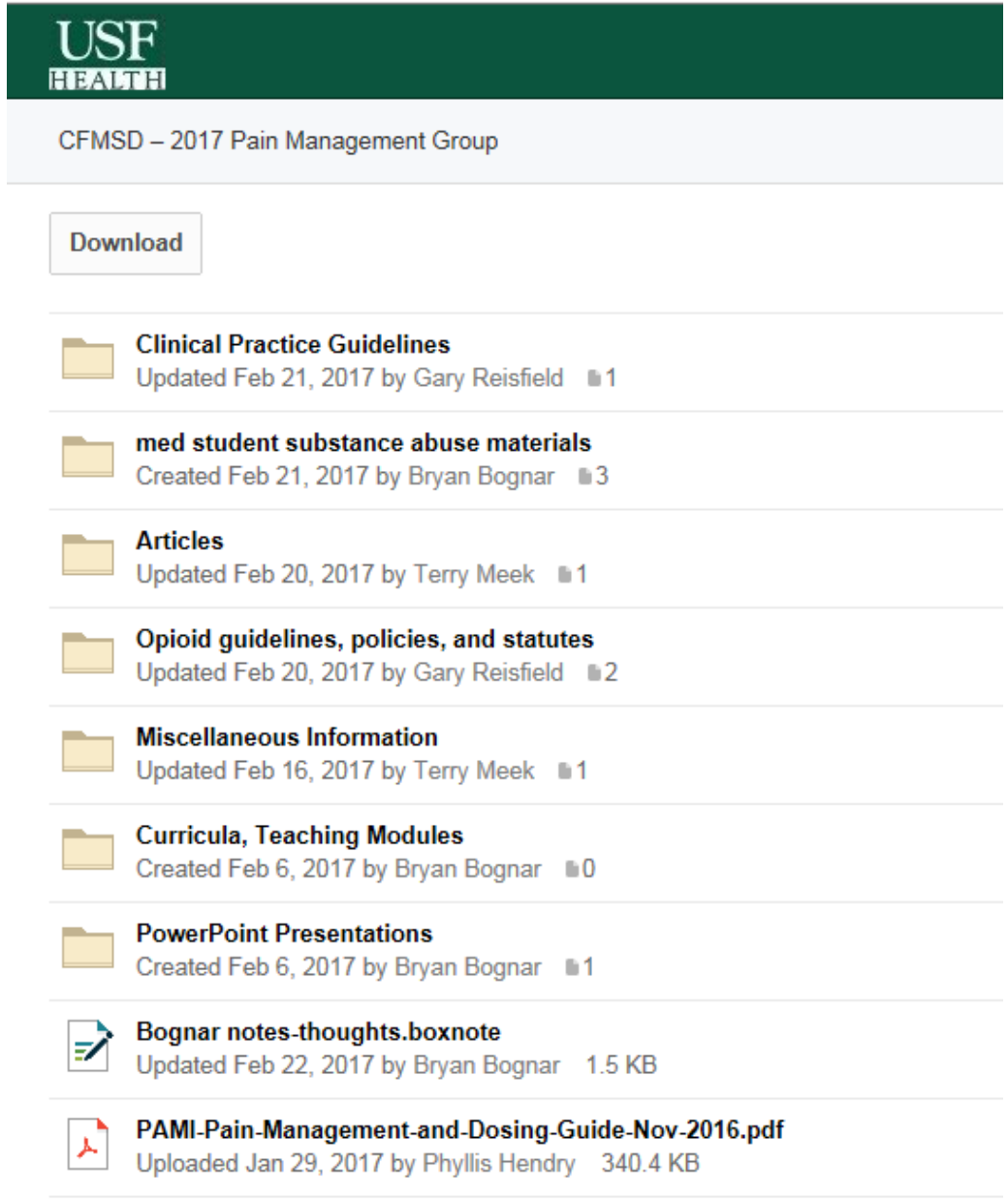
CFMSD Working Group Participants

- Diane McKay, LECOM*
- Bryan Bognar, USF*
- Deborah DeWaay, USF
- Sanaz Kashan, FIU
- Akiva Daum, FIU
- Marshall Kapp, FSU
- George Luck, FAU
- John Newcomer, FAU
- Marty Klapheke, UCF
- Janet Robishaw, FAU
- Phyllis Hendry, UF-Jax
- Rene Przokora, UF
- Gary Reisfield, UF
- Sigfried Schmidt, UF
- Steve Lucas, UF
- Costas Saranopoulous, UM
- Rebecca Cherner, NSU

***Co-chair**

Information Sharing Among Florida's Medical Schools

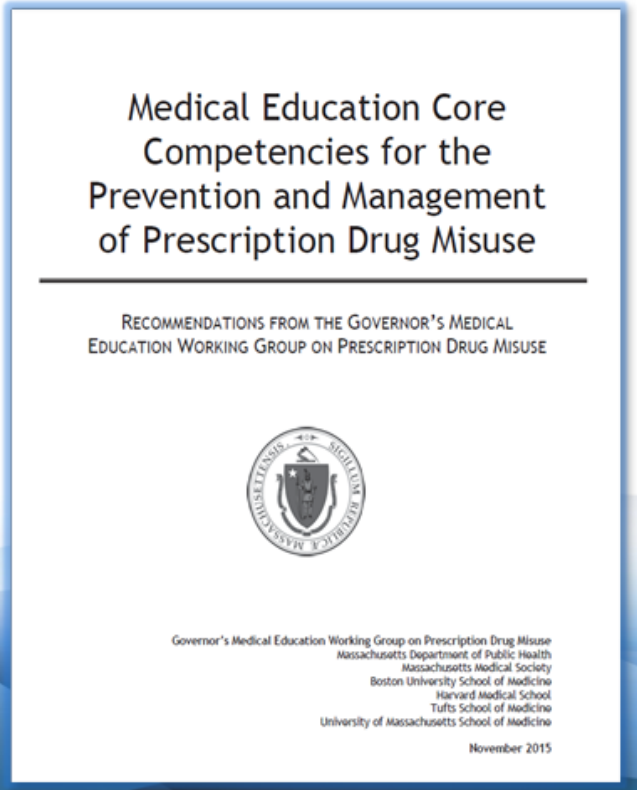
Online platform for working group to share curriculum modules, articles and other resources related to pain management and opioids.



Massachusetts:

#1: Identify shared core competencies

10 Core Competencies: Approved Nov 2016 became an interprofessional model for prescribers in training -- MD, APRN, DMD and PA



Medical Education Core Competencies for the Prevention and Management of Prescription Drug Misuse

RECOMMENDATIONS FROM THE GOVERNOR'S MEDICAL EDUCATION WORKING GROUP ON PRESCRIPTION DRUG MISUSE

Governor's Medical Education Working Group on Prescription Drug Misuse
Massachusetts Department of Public Health
Massachusetts Medical Society
Boston University School of Medicine
Harvard Medical School
Tufts School of Medicine
University of Massachusetts School of Medicine

November 2015

10 Competencies (Summary)

Prevent
- *Screen*
- *Evaluate*
- *Identify and Describe Options*

Treat At-Risk Patients
- *Patient Engagement in Patient Centered Treatment Plan*

Manage Substance Use Disorder
- *As a Chronic Disease*
- *Eliminate Stigma*
- *Build Awareness of Social Determinants*

University of Massachusetts Medical School
UMASS
umassmed.edu

MASSACHUSETTS MEDICAL SOCIETY
Every physician matters, each patient counts.

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Home > Physicians > Core Competencies

- Membership in the MMS
- Electronic Health Records
- Practice Management
- Legal & Regulatory
- Employed Physicians
- Residents & Fellows
- Boston Medical Library
- Personal and Financial Resources
- Volunteer Opportunities
- In Memoriam

Core Competencies

May 4, 2017

CORE COMPETENCIES FOR THE PREVENTION AND MANAGEMENT OF PRESCRIPTION DRUG MISUSE

In the appropriate setting, using recommended and evidence-based methodologies, the graduating medical student should demonstrate the independent ability and/or knowledge to:

Primary Prevention Domain – Preventing Prescription Drug Misuse:
Screening, Evaluation, and Prevention

1. Evaluate a patient's pain using age, gender, and culturally appropriate evidence-based methodologies.

2. Evaluate a patient's risk for substance use disordersbyutilizinage, gender, and culturally appropriate evidence-based communication skills

Massachusetts:

#2: Develop curriculum to share

Curriculum Development Highlights

- Addressed all 10 competencies using evidence-based tools and curricular methods (simulation)
- Partnered with experts across fields and professions (IM, Surg, Peds, OB, Family, Pharm, Behav Med, Psych, Pain Med, Pall Care, Nursing)
- Recruited community members
- Engaged students in curriculum development
- Created public website for all materials: http://umassmed.edu/opioid

University of Massachusetts Medical School
UMASS
umassmed.edu

Pennsylvania State Core Competencies for Education of Opioids and Addiction

- Objective and Methods
  - To develop core competencies on opioids and addictions to be used in Pennsylvania medical schools
  - Creation of task force; literature review; survey of graduating medical students
- Determination of Competencies
  - Specific competencies for developed for each of nine domains.
- Conclusions
  - Competencies will be incorporated into the education process at all Pennsylvania medical schools
  - Goal is to improve student knowledge and attitudes in this area, thus improving patient outcomes

Pennsylvania State Core Competencies Nine Domains

- Core Aspects of Addiction
- Screening for Substance Abuse Disorder
- Proper Referral for Specialty Evaluation and Treatment
- Proper Use of Multimodal Treatment Options for Acute Pain
- Patient Assessment when Treating Pain
- Use of Opioids for Treatment of Acute Pain (after consideration of alternatives)
- Role of Opioids in Treatment of Chronic Non-Cancer Pain
- Patient Risk Assessments
- Process for Patient Education, Treatment, Monitoring and Discontinuation of Therapy When Using Opioids to Treat Chronic Non-cancer Pain

CDC Guidelines for Prescribing Opioids for Chronic Pain

- Objectives
  - Improve communication between clinicians and patients – risk/benefits
  - Improve safety and effectiveness of pain treatment
  - Reduce risks associated with long-term opioid therapy
  - Provide guideline for primary care clinicians who are prescribing opioids outside of active cancer treatment, palliative care, and end-of-life care
- Methods
  - GRADE framework – Grading of Recommendations Assessment, Development and Evaluation
- Guidelines Address
  - When to initiate or continue opioids for chronic pain
  - Opioid selection, dosage, duration, follow-up and discontinuation
  - Assessing risk and addressing harms of opioid use

Checklist for prescribing opioids for chronic pain

For primary care providers treating adults (18+) with chronic pain ≥3 months, excluding cancer, palliative, and end-of-life care

CHECKLIST

When CONSIDERING long-term opioid therapy

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  - Check prescription drug monitoring program (PDMP) data.
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  - Check for opioid use disorder if indicated (eg, difficulty controlling use).
    - If yes: Refer for treatment.
- ☐ Check that non-opioid therapies optimized.
- ☐ Determine whether to continue, adjust, taper, or stop opioids.
- ☐ Calculate opioid dosage morphine milligram equivalent (MME).
  - If ≥50 MME/day total (≥50 mg hydrocodone; ≥33 mg oxycodone), increase frequency of follow-up; consider offering naloxone.
  - Avoid ≥90 MME/day total (≥90 mg hydrocodone; ≥60 mg oxycodone), or carefully justify; consider specialist referral.
- ☐ Schedule reassessment at regular intervals (≤3 months).

REFERENCE

EVIDENCE ABOUT OPIOID THERAPY

- *Benefits of long-term opioid therapy for chronic pain not well supported by evidence.*
- *Short-term benefits small to moderate for pain; inconsistent for function.*
- *Insufficient evidence for long-term benefits in low back pain, headache, and fibromyalgia.*

NON-OPIOID THERAPIES

Use alone or combined with opioids, as indicated:

- Non-opioid medications (eg, NSAIDs, TCAs, SNRIs, anti-convulsants).
- Physical treatments (eg, exercise therapy, weight loss).
- Behavioral treatment (eg, CBT).
- Procedures (eg, intra-articular corticosteroids).

EVALUATING RISK OF HARM OR MISUSE

Known risk factors include:

- Illegal drug use; prescription drug use for nonmedical reasons.
- History of substance use disorder or overdose.
- Mental health conditions (eg, depression, anxiety).
- Sleep-disordered breathing.
- Concurrent benzodiazepine use.

Urine drug testing: Check to confirm presence of prescribed substances and for undisclosed prescription drug or illicit substance use.

Prescription drug monitoring program (PDMP): Check for opioids or benzodiazepines from other sources.

ASSESSING PAIN & FUNCTION USING PEG SCALE

PEG score = average 3 individual question scores (30% improvement from baseline is clinically meaningful)

Q1: *What number from 0–10 best describes your **pain** in the past week?*
0 = "no pain", 10 = "worst you can imagine"

Q2: *What number from 0–10 describes how, during the past week, pain has interfered with your **enjoyment of life**?*
0 = "not at all", 10 = "complete interference"

Q3: *What number from 0–10 describes how, during the past week, pain has interfered with your **general activity**?*
0 = "not at all", 10 = "complete interference"

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

TO LEARN MORE
WWW.CDC.GOV/DRUGOVERDOSE/PRESCRIBING/GUIDELINE

March 2016

COUNCIL OF FLORIDA MEDICAL SCHOOL DEANS

Pain Assessment and Management Initiative (PAMI):

A Patient Safety Project

http://pami.emergency.med.jax.ufl.edu/

- Free access, online pediatric and adult pain management and sedation resources
- Began in 2014 with funding from Florida Medical Malpractice Joint Underwriting Association and University of Florida COM- Jacksonville, Dept. of Emergency Medicine
- Principal Investigators: Phyllis Hendry, MD, FAAP, FACEP and Sophia Sheikh, MD, FACEP
- Multidisciplinary program promoting safe alternatives to opioids, supplemental nonpharmacologic methods, safe dosing and discharge planning, education & research
- 7 online learning modules providing 14 hours of free pain management CME/CEUs

Basics of Pain Management	Acute Pain Management
Procedural Sedation and Analgesia	Nonpharmacologic Pain Management
Pharmacologic Pain Management	Pediatric Pain Management
Pre-hospital Pain Management	

FMMJUA
Florida Medical Malpractice Joint Underwriting Association

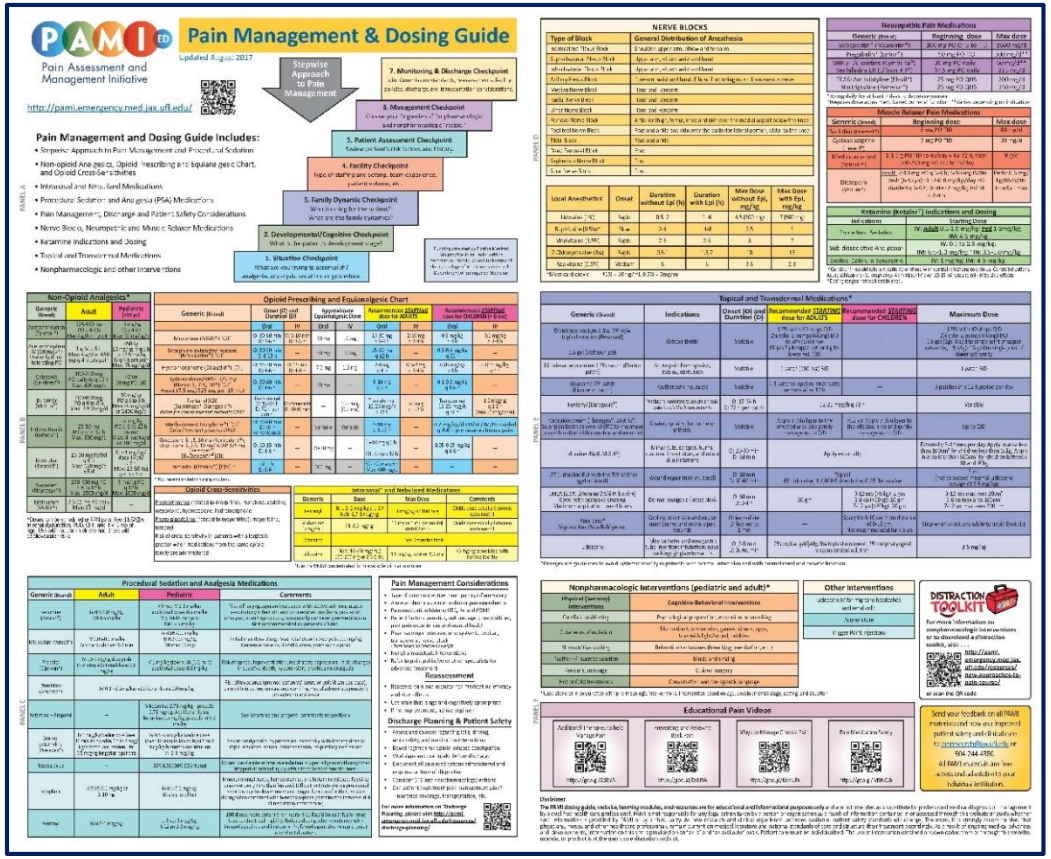
UF UNIVERSITY of FLORIDA
College of Medicine – Jacksonville
Department of Emergency Medicine

PAMI
Pain Assessment and Management Initiative

PAMI Resources and Toolkits

http://pami.emergency.med.jax.ufl.edu/

- PAMI Pain Management and Dosing Guide
  -Pediatric and adult dosages (oral, IV, nasal, topical), PAMI Stepwise Approach, Discharge tips, nerve blocks
  https://www.youtube.com/watch?v=rfwB1aoZblM&feature=youtu.be
- Nonpharmacologic, Child Life and Distraction Toolkit and course materials
- Discharge Planning Toolkit for Pain
  -Risk algorithm, instructions, patient videos
- Resources adaptable for individual institutions to use for clinical care or teaching
- Email: emresearch@jax.ufl.edu
- Stakeholders include FCEP, FHA and other state/national pain, EMS, and pediatric related organizations



January 2018- The Joint Commission's New Requirements for Pain

The Joint Commission

Perspectives®

The Official Newsletter of The Joint Commission

July 2017 • Volume 37 • Number 7

Joint Commission Enhances Pain Assessment and Management Requirements for Accredited Hospitals

Contents

1 Joint Commission Enhances Pain Assessment and Management Requirements for Accredited Hospitals

2 In Sight

https://www.jointcommission.org/assets/1/18/Joint_Commission_Enhances_Pain_Assessment_and_Management_Requirements_for_Accredited_Hospitals1.PDF

The Florida Model: Coming Soon to a School Near You!

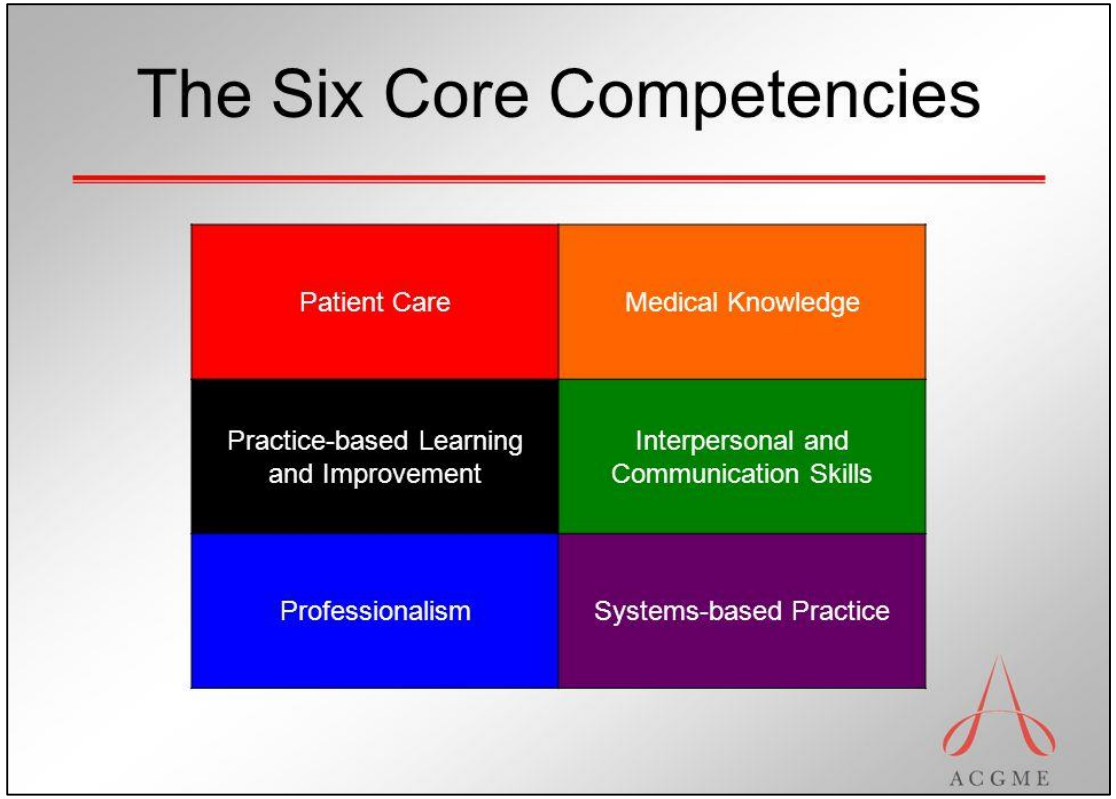
- Matrix that will incorporate components of PA and MA plans
- Different order proposed:
  - Pain basics, emphasis on *nonpharmacologic* and pharmacologic management and alternatives to opioids
  - Substance abuse/mental health/addiction basics
  - Opioid basics and safe prescribing
- Model that will allow for a changing landscape

Goals and Directions of CFMSDs Pain Management Working Group

- Provide core competencies in a manner that each medical school is able to flexibly incorporate into existing curriculum
- Ultimately address both UME and GME
- Utilize the best of existing resources
- Address pain, opioids and addiction as separate units. Then include a segment on the overlap of the three topics
- Include related psychiatric disorders
- Develop modalities for assessment of educational programs

Most Specialties Have Competencies or Milestones Related to Pain

- Family Medicine
- Internal Medicine
- Pediatrics
- Surgery/Trauma
- Psychiatry
- Radiology (procedures…)
- OB GYN
- Others



CFMSD Mid-Year Meeting Discussions on Pain Management and Opioids

August 5, 2017

The co-chairs of the CFMSD Pain Management Working Group met with Florida's medical school deans, State Surgeon General Celeste Philip and Representative Gayle Harrell, to determine desired directions and "next steps" in ensuring that Florida's medical students and residents are prepared to manage different types of pain, recognize the risk for addiction and safely prescribe opioids while keeping abreast of new pain management alternatives.

Questions and Comments

- Thank you for this opportunity to collaborate and work together!
- Special thanks to Claudia Kemp, JD and Siby Koshy
- Phyllis.Hendry@jax.ufl.edu

  904-244-4072

THE PRESIDENT'S COMMISSION ON COMBATING DRUG ADDICTION AND THE OPIOID CRISIS

Roster of Commissioners

Governor Chris Christie, Chairman
Governor Charlie Baker
Governor Roy Cooper
Congressman Patrick J. Kennedy
Professor Bertha Madras, Ph.D.
Florida Attorney General Pam Bondi

Table of Contents

Chairman's Letter.....5
Summary of Recommendations..... 12
The Drug Addiction and Opioid Crisis..... 19
Origins of the Current Crisis..... 19
Magnitude and Demographics..... 23
Newly Emerging Threats..... 26
Pathways to Opioid Use Disorder (Including Heroin) from Prescription Opioids..... 27
Health, Financial, and Social Consequences..... 29
Drug Overdose Deaths..... 31
Substance Use Treatment Availability..... 32
Systems Approach to Solutions..... 35
Federal Funding and Programs..... 37
Streamlining Federal Funding for Opioids and Consideration of State Administrators..... 37
Funding Effective Opioid-Related Programs..... 38
Opioid Addiction Prevention..... 40
Evidence-based Prevention Programs..... 42
SBIRT as a School Prevention Strategy..... 43
Mass Media Public Education Campaigns..... 44
Media Campaign Focusing on Opioids..... 46
Opioid Prescription Practices..... 48
Improving upon the CDC *Guideline for Prescribing Opioids for Chronic Pain* and Provider/Prescriber Education..... 48
Enhancing Prescription Drug Monitoring Programs (PDMP)..... 53
Prescription Take-Back Programs and Drug Disposal..... 55
Pain Level as an HHS Evaluation Criteria..... 56
Reimbursement for Non-Opioid Pain Treatments..... 57
Reducing and Addressing the Availability of Illicit Opioids..... 58
Improving Data Collection and Analytics..... 58
Disrupting the Illicit Fentanyl Supply..... 61
Interdiction and Detection Challenges..... 63
Protecting First Responders from Harmful Effects Resulting from Exposure to Fentanyl and other Synthetic Opioids..... 65

Opioid Addiction Treatment, Overdose Reversal, and Recovery 67
Drug Addiction Treatment Services 67
Increase Screenings and Referrals to Treatment through CMS Quality Measures 67
Evidence-based Improvements to Treatment 68
Insurance and Reimbursement Barriers to Accessing MAT 69
Enforcing the Mental Health Parity and Addiction Equity Act (MHPAEA) 71
MAT in the Criminal Justice System 72
Drug Courts and Diversion Programs 73
Addiction Services Workforce and Training Needs 74
Response to Overdose 77
Expanded Access and Administration of Naloxone 77
Overdose to Treatment and Recovery 79
Recovery Support Services 80
Impact on Families and Children 80
Supporting Collegiate Recovery and Changing the Culture on College Campuses 81
Employment Opportunities for Americans in Recovery 83
Support Recovery Housing 84
Research & Development 86
New Pain, Overdose, and MAT Medications 86
Medical Technology Devices 88
FDA Post-Market Research and Surveillance Programs 89
Conclusion 90
Current Federal Programs and Funding Landscape 93
Overview 93
FY 2018 Funding Specific to America's Opioid Crisis 93
The Comprehensive Addiction and Recovery Act (CARA) 96
21st Century Cures Act 96
FY 2018 Consolidated Federal Drug Control Budget 97
Prevention 97
Treatment and Recovery 98
Domestic Law Enforcement 101
Interdiction 102
International Efforts 103

Charter, President's Commission on Combating Drug Addiction and the Opioid Crisis 107
Appendices 110
Appendix 1. Acronyms 110
Appendix 2. History of Opiate Use and Abuse 113
Appendix 3. Interim Report, *President's Commission on Combatting Drug Addiction and the Opioid Crisis* 115
Appendix 4. Fentanyl Safety Recommendations for First Responders 125
References 126

Governor Chris Christie

Chairman

Governor Charlie Baker
Congressman Patrick J. Kennedy
Florida Attorney General Pam Bondi
Governor Roy Cooper
Professor Bertha Madras, Ph.D.

November 1, 2017

The Honorable Donald J. Trump
President of the United States
The White House
1600 Pennsylvania Avenue NW
Washington, DC 20500

Dear President Trump,

On behalf of the President's Commission on Combating Drug Addiction and the Opioid Crisis, we thank you for entrusting us with the responsibility of developing recommendations to combat the addiction crisis that is rampantly impacting our country.

Your speech in the East Room of the White House, along with the remarks of the First Lady, made it clear to the country that fighting this epidemic is a top priority of your Administration. On behalf of the Commission, we thank you for your leadership on this issue and on the clarity of your call to action.

When you declared the opioid crisis a national public health emergency under federal law on October 26, 2017, you acknowledged this crisis as one of epic proportion, impacting nearly every community across all 50 states. You signaled to the country that the force of the federal government should and will mobilize to reverse the rising tide of overdose deaths. You gave the millions of Americans fighting addiction hope that we can overcome this crisis, and we are prepared to win the fight.

Mr. President, as you acknowledged when you addressed the nation last week, the reason behind the urgent recommendations presented to you today by this Commission is that the leading cause of unintentional death in the United States is now drug overdose deaths.

Our people are dying. More than 175 lives lost every day. If a terrorist organization was killing 175 Americans a day on American soil, what would we do to stop them? We would do anything and everything. We must do the same to stop the dying caused from within. I know you will.

Without comprehensive action, including your national public health emergency, the death count will continue to rise. I know that is unacceptable to you. I know you will win this fight for the people who elected you.

You've met hundreds of parents who have buried their children, so these numbers are no longer simply statistics. Instead, they represent the injured student-athlete who becomes addicted after first prescription, ending her academic and athletic career, the newborn infant who is red and screaming from withdrawal pain, the grandparents using their retirement savings to raise young kids when the parents can't, the mom who just buried her only son, and the addict who cycles in and out of jail, simply because without access to treatment he is unable to stay sober and meet the terms of his parole.

It is time we all say what we know is true: addiction is a disease. However, we do not treat addiction in this country like we treat other diseases. Neither government nor the private sector has committed the support necessary for research, prevention, and treatment like we do for other diseases.

The recommendations herein, and the interim recommendations submitted by the Commission in July, are designed to address this national priority. These recommendations will help doctors, addiction treatment providers, parents, schools, patients, faith-based leaders, law enforcement, insurers, the medical industry, and researchers fight opioid abuse and misuse by reducing federal barriers and increasing support to effective programs and innovation.

Obviously, many of the recommendations that follow will require appropriations from Congress into the Public Health Emergency Fund, for block grants to states and to DOJ for enforcement and judicial improvements. It is not the Commission's charge to quantify the amount of these resources, so we do not do so in this report.

You have made fighting the opioid epidemic a national priority, Mr. President. And, the country is ready to follow your lead. Now, we urge Congress to do their constitutionally delegated duty and appropriate sufficient funds (as soon as possible) to implement the Commission's recommendations. 175 Americans are dying a day. Congress must act.

Here is what your Administration has already done:

- You acted to remove one of the biggest federal barriers to treatment by announcing the launch of a new policy to overcome the restrictive, decades-old federal rule that prevents states from providing more access to care at treatment facilities with more than 16 beds. This action will take people in crisis off waiting lists where they are at risk of losing their battle to their disease and put them into a treatment bed and on the path to recovery. We urge all Governors to apply to CMS for a waiver. This policy will – without any doubt – save lives. Governors across this nation thank you for listening to our call for help.
- In the interim report, the Commission also called for prescriber education and enhanced access to medication-assisted treatment for those already suffering from addiction. You acknowledged the need for these recommendations and directed all federally employed prescribers to receive special training to fight this epidemic. This is a bold step by you to deal with this issue.
- We recommended that the Department of Justice, which has already acted forcefully to stop the flow of illicit synthetic drugs into this country through the U.S. Postal Service,

continue its efforts. The aggressive enforcement action being taken by your Administration is critical in our efforts to reduce the rise of overdose deaths in this country.

- National Institutes of Health (NIH) Director Dr. Francis Collins has been partnering with pharmaceutical companies to develop non-addictive painkillers and new treatments for addiction and overdose. The Commission worked with Dr. Collins to convene a meeting with industry leadership to discuss innovative ways to combat the opioid crisis. The Commission also held a public meeting to highlight the progress and innovation occurring today resulting from the NIH's work. This type of scientific progress is a positive step to help free the next generation from the widespread suffering addiction is causing today.

Our interim recommendations called for more data sharing among state-based prescription drug monitoring programs and recognized the need to address patient privacy regulations that make it difficult for health providers to access information and make informed healthcare decisions for someone who has a substance use disorder. We recommended that all law enforcement officers across the country be equipped with life-saving naloxone.

Finally, we recommended full enforcement of the Mental Health Parity and Addiction Equity Act to ensure that health plans cannot provide less favorable benefits for mental health and substance use diagnoses than physical health ailments. You will see further recommendations in our final report regarding the Parity Act and calling for the Department of Labor to have enhanced penalty and enforcement powers directly against insurers failing those who depend on them for life-saving treatment.

All the interim recommendations remain extremely relevant today and are critical tools to reduce ever increasing overdose deaths plaguing our citizens. The Commission is grateful the Administration has begun the hard work of implementing these initiatives. We urge you to implement the others as soon as possible.

Today, the Commission, as one its most urgent recommendations among the more than 50 provided in the final report, is calling for an expansive national multi-media campaign to fight this national health emergency.

This campaign, including aggressive television and social media outreach, must focus on telling our children of the dangers of these drugs and addiction, and on removing stigma as a barrier to treatment by emphasizing that addiction is not a moral failing, but rather a chronic brain disease with evidence-based treatment options. People need to be aware of the health risks associated with opioid use, and they must stop being afraid or ashamed of seeking help when facing their addiction.

Today, only 10.6% of youth and adults who need treatment for a substance use disorder receive that treatment. This is unacceptable. Too many people who could be helped are falling through the cracks and losing their lives as a result.

Many states, including my State of New Jersey, have undertaken this media strategy with significant positive results. However, having a nation-wide campaign will serve to reinforce the message and ensure, for example, that youth and young adults no longer believe that experimenting with pills from a doctor is safer than experimenting with illegal substances from a drug dealer.

As part of its prevention recommendations, the Commission also calls for better educating

middle school, high school, and college students with the help of trained professionals such as nurses and counselors who can assess at-risk kids. Children have not escaped the consequences of addiction and our efforts to reduce overdose deaths must start early. Mrs. Trump's dedication and leadership in helping our nation's children will make this a top priority and help save innocent young lives.

One of the most important recommendations in this final report is getting federal funding support more quickly and effectively to state governments, who are on the front lines of fighting this addiction battle every day. Bureaucracy, departmental silos, and red tape must not be accepted as the norm when dealing with funding to combat this epidemic. Saving time and resources, in this instance, will literally save lives.

Accordingly, we are urging Congress and the Administration to **block grant federal funding for opioid-related and SUD-related activities to the states**. There are multiple federal agencies and multiple grants within those agencies that cause states a significant administrative burden from an application and reporting perspective. Money is being wasted and accountability for results is not as intense as it should be. Block granting them would allow more resources to be spent on administering life-saving programs. This was a request to the Commission by nearly every Governor, regardless of party, across the country. And as a Commission that has three governors as members, all of whom know the frustration of jumping through multiple hoops to receive the funding we need to help our constituents in this fight, we wholeheartedly agree.

Throughout the comprehensive recommendations of its final report, the Commission also identifies the need to focus on, deploy and assess evidence-based programs that can be funded through these proposed block grants. Many of the recommendations acknowledge a need for better data analysis and accountability to ensure that any critical dollars are spent on what works best to fight this disease.

From its review of the federal budget aimed at addressing the opioid epidemic, the Commission identified a disturbing trend in federal health care reimbursement policies that incentivizes the wide-spread prescribing of opioids and limits access to other non-addictive treatments for pain, as well as addiction treatment and medication-assisted treatment.

First, individuals with acute or chronic pain must have access to non-opioid pain management options. Everything from physical therapy, to non-opioid medications, should be easily accessible as an alternative to opioids. The Commission heard from many innovative life sciences firms with new and promising products to treat patients' pain in non-addictive, safer ways; but they have trouble competing with cheap, generic opioids that are so widely used. We should incentivize insurers and the government to pay for non-opioid treatments for pain beginning right in the operating room and at every treatment step along the way.

In some cases, non-addictive pain medications are bundled in federal reimbursement policies so that hospitals and doctors are essentially not covered to prescribe non-opioid pain management alternatives. These types of policies, which the federal government can fix, are a significant deterrent to turning the tide on the health crisis we are facing. We urge you to order HHS to fix it.

Second, as a condition of full reimbursement of hospitals, CMS requires that hospitals randomly survey discharged patients. HHS previously included pain question response information in calculations of incentive payment, but in 2017 thankfully abandoned this practice. However, all pain survey questions were not withdrawn from the surveys. The Commission recommends that CMS remove pain questions entirely when assessing consumers so that providers won't ever use opioids inappropriately to raise their survey scores. We urge you to order HHS to do this immediately.

The expectation of eliminating a patient's pain as an indication of successful treatment, and seeing pain as the fifth vital sign, which has been stated by some medical professionals as unique to the United States, was cited as a core cause of the culture of overprescribing in this country that led to the current health crisis. This must end immediately.

The Department of Labor must be given the real authority to regulate the health insurance industry. The health insurers are not following the federal law requiring parity in the reimbursement for mental health and addiction. They must be held responsible. The Secretary of Labor testified he needs the ability to fine violators and to individually investigate insurers not just employers. We agree with Secretary Acosta. If we do not get Congress to give him these tools, we will be failing our mission as badly as health insurance companies are failing their subscribers on this issue today leading to deaths.

Also contributing to this problem is the fact that HHS/CMS, the Indian Health Service, Tricare, and the VA still have reimbursement barriers to substance abuse treatment, including limiting access to certain FDA-approved medication-assisted treatment, counseling, and inpatient/residential treatment.

It's imperative that federal treatment providers lead the way to treating addiction as a disease and remove these barriers. Each of these primary care providers employed by the above-mentioned federal health systems should screen for SUDs and, directly or through referral, provide treatment within 24-to-48 hours. Each physician employee should be able to prescribe buprenorphine (if that is the most appropriate treatment for the patient) in primary care settings. As President, you can make this happen immediately. We urge you to do so.

A good example of this federal leadership occurred when Department of Veterans Affairs Secretary Shulkin, in response to the Commission's interim report release, immediately launched eight best practices for pain management in the VA health-care system. These guidelines included everything from alternatives and complimentary care, counseling and patient monitoring to peer education for front-line providers, informed consent of patients and naloxone distribution for Veterans on long-term opioid therapy. I had the opportunity to visit with doctors and patients at the Louis Stokes Northeast Ohio VA Healthcare System and witnessed first-hand the positive results of a hospital that has embraced a different continuum of care for pain management. The VA doctors, which included behavioral health specialists, acknowledge and treat those with addiction in the full complement of ways the medical community would tackle other chronic diseases. Let's use these VA practices as an example for our entire healthcare system.

As you will see in the Commission's recommendations, the Federal Government has a number of avenues through which it can ensure that individuals with addiction disorders get the

help they need; including changing CMS reimbursement policies, enforcing parity laws against non-compliant insurers, promoting access to rural communities through such tools as telemedicine, and incenting a larger treatment workforce to address the broad scope of the crisis.

For individuals with a substance use disorder, ensuring life-saving access to affordable health care benefits is an essential tool in fighting the opioid epidemic. Look at Indiana as an example. After Indiana used an insurance access program to rapidly respond to a rural, opioid-related health crisis, the Indiana Department of Health reported that such a program opened the door to life changing medical treatment.

We are recommending that a drug court be established in every one of the 93 federal district courts in America. It is working in our states and can work in our federal system to help treat those who need it and lower the federal prison population. For many people, being arrested and sent to a drug court is what saved their lives, allowed them to get treatment, and gave them a second chance.

Drug Courts are known to be significantly more effective than incarceration, but 44% of U.S. Counties do not have an adult drug court. DOJ should urge states to establish state drug courts in every county. When individuals violate the terms of probation or parole with substance use, they need to be diverted to drug court, rather than back to incarceration. Further, drug courts need to embrace the use of medication-assisted treatment for their populations, as it clearly improves outcomes. The criminal justice system should accept that medication, when clinically appropriate, can lead to lasting recovery; abstinence-only sobriety is not the only path to recovery.

Lastly, the Commission's recommendations identify multiple ways to reduce the supply of licit and illicit opioids and enhanced enforcement strategies. Recognizing the growing threat of synthetic opioids such as fentanyl, the Commission recommends enhanced penalties for trafficking of fentanyl and fentanyl analogues and calls for additional technologies and drug detection methods to expand efforts to intercept fentanyl before entering the country.

To help protect first responders, who are also on the front lines fighting this epidemic responding to overdoses sometimes multiple times a day, the Commission recommends the White House develop a national outreach strategy coordinating with Governors for the release and adoption of the Office of Homeland Security National Security Council's new Fentanyl Safety Recommendations for First Responders. The Commission thanks White House Homeland Security Advisor Tom Bossert for his support and hard work already on this initiative.

Many other thoughtful, vital recommendations are included herein. These recommendations were informed by expert testimony provided during the Commission's public meetings, which included treatment providers and experts, pharmaceutical innovators and insurers. They also were informed by thousands of written submissions accepted by the Commission as part of its public process.

The Commission acknowledges that there is an active movement to promote the use of marijuana as an alternative medication for chronic pain and as a treatment for opioid addiction. Recent research out of the NIH's National Institute on Drug Abuse found that marijuana use led to a 2 ½ times greater chance that the marijuana user would become an opioid user and abuser.

The Commission found this very disturbing. There is a lack of sophisticated outcome data on dose, potency, and abuse potential for marijuana. This mirrors the lack of data in the 1990's and early 2000's when opioid prescribing multiplied across health care settings and led to the current epidemic of abuse, misuse and addiction. The Commission urges that the same mistake is not made with the uninformed rush to put another drug legally on the market in the midst of an overdose epidemic.

The Commission extends our sincere gratitude to all of the individuals, organizations, families, companies, state officials, federal agency staff, and clinical professionals who provided personal stories, creative solutions, and thoughtful input to the Commission. The Commission members received thousands of letters, took hundreds of phone calls and meetings, and heard testimony from prominent organizations including non-profits, professional societies, pharmaceutical companies, health insurance providers, and most importantly, individuals and families that have been in the throes of addiction. These letters, conversations, and meetings were the impetus for the vast majority of recommendations made in this report.

The Commission is confident that, if enacted quickly, these recommendations will strengthen the federal government, state, and local response to this crisis. But it will take all invested parties to step up and play a role: the federal executive branch, Congress, states, the pharmaceutical industry, doctors, pharmacists, academia, and insurers. The responsibility is all of ours. We must come together for the collective good and acknowledge that this disease requires a coordinated and comprehensive attack from all of us.

The time to wait is over. The time for talk is passed. 175 deaths a day can no longer be tolerated. We know that you will not stand by; we believe you will force action.

Along with my fellow Commission members, and the thousands of people who contributed to this report by sharing their stories and ideas for solutions, I look forward to seeing these policy changes implemented. Thank you again for the opportunity to serve, and most of all thank you for your commitment to addressing this vital national public health emergency.

Sincerely,

Governor Chris Christie
Governor of New Jersey
Chairman, President's Commission on Combating Drug Addiction and the Opioid Crisis

Summary of Recommendations

Federal Funding and Programs

1. The Commission urges Congress and the Administration to block grant federal funding for opioid-related and SUD-related activities to the states, where the battle is happening every day. There are multiple federal agencies and multiple grants within those agencies that cause states a significant administrative burden from an application and reporting perspective. Creating uniform block grants would allow more resources to be spent on administering life-saving programs. This was a request to the Commission by nearly every Governor, regardless of party, across the country.

2. The Commission believes that ONDCP must establish a coordinated system for tracking all federally-funded initiatives, through support from HHS and DOJ. If we are to invest in combating this epidemic, we must invest in only those programs that achieve quantifiable goals and metrics. We are operating blindly today; ONDCP must establish a system of tracking and accountability.

3. To achieve accountability in federal programs, the Commission recommends that ONDCP review is a component of every federal program and that necessary funding is provided for implementation. Cooperation by federal agencies and the states must be mandated.

Opioid Addiction Prevention

4. The Commission recommends that Department of Education (DOE) collaborate with states on student assessment programs such as Screening, Brief Intervention and Referral to Treatment (SBIRT). SBIRT is a program that uses a screening tool by trained staff to identify at-risk youth who may need treatment. This should be deployed for adolescents in middle school, high school and college levels. This is a significant prevention tool.

5. The Commission recommends the Administration fund and collaborate with private sector and non-profit partners to design and implement a wide-reaching, national multi-platform media campaign addressing the hazards of substance use, the danger of opioids, and stigma. A similar mass media/educational campaign was launched during the AIDs public health crisis.

Prescribing Guidelines, Regulations, Education

6. The Commission recommends HHS, the Department of Labor (DOL), VA/DOD, FDA, and ONDCP work with stakeholders to develop model statutes, regulations, and policies that ensure informed patient consent prior to an opioid prescription for chronic pain. Patients need to understand the risks, benefits and alternatives to taking opioids. This is not the standard today.

7. The Commission recommends that HHS coordinate the development of a national curriculum and standard of care for opioid prescribers. An updated set of guidelines for prescription pain medications should be established by an expert committee composed of various specialty

practices to supplement the CDC guideline that are specifically targeted to primary care physicians.

8. The Commission recommends that federal agencies work to collect participation data. Data on prescribing patterns should be matched with participation in continuing medical education data to determine program effectiveness and such analytics shared with clinicians and stakeholders such as state licensing boards.

9. The Commission recommends that the Administration develop a model training program to be disseminated to all levels of medical education (including all prescribers) on screening for substance use and mental health status to identify at risk patients.

10. The Commission recommends the Administration work with Congress to amend the Controlled Substances Act to allow the DEA to require that all prescribers desiring to be relicensed to prescribe opioids show participation in an approved continuing medical education program on opioid prescribing.

11. The Commission recommends that HHS, DOJ/DEA, ONDCP, and pharmacy associations train pharmacists on best practices to evaluate legitimacy of opioid prescriptions, and not penalize pharmacists for denying inappropriate prescriptions.

PDMP Enhancements

12. The Commission recommends the Administration's support of the Prescription Drug Monitoring (PDMP) Act to mandate states that receive grant funds to comply with PDMP requirements, including data sharing. This Act directs DOJ to fund the establishment and maintenance of a data-sharing hub.

13. The Commission recommends federal agencies mandate PDMP checks, and consider amending requirements under the Emergency Medical Treatment and Labor Act (EMTALA), which requires hospitals to screen and stabilize patients in an emergency department, regardless of insurance status or ability to pay.

14. The Commission recommends that PDMP data integration with electronic health records, overdose episodes, and SUD-related decision support tools for providers is necessary to increase effectiveness.

15. The Commission recommends ONDCP and DEA increase electronic prescribing to prevent diversion and forgery. The DEA should revise regulations regarding electronic prescribing for controlled substances.

16. The Commission recommends that the Federal Government work with states to remove legal barriers and ensure PDMPs incorporate available overdose/naloxone deployment data, including the Department of Transportation’s (DOT) Emergency Medical Technician (EMT) overdose database. It is necessary to have overdose data/naloxone deployment data in the PDMP to allow users of the PDMP to assist patients.

Supply Reduction and Enforcement Strategies

17. The Commission recommends community-based stakeholders utilize Take Back Day to inform the public about drug screening and treatment services. The Commission encourages more hospitals/clinics and retail pharmacies to become year-round authorized collectors and explore the use of drug deactivation bags.

18. The Commission recommends that CMS remove pain survey questions entirely on patient satisfaction surveys, so that providers are never incentivized for offering opioids to raise their survey score. ONDCP and HHS should establish a policy to prevent hospital administrators from using patient ratings from CMS surveys improperly.

19. The Commission recommends CMS review and modify rate-setting policies that discourage the use of non-opioid treatments for pain, such as certain bundled payments that make alternative treatment options cost prohibitive for hospitals and doctors, particularly those options for treating immediate post-surgical pain.

20. The Commission recommends a federal effort to strengthen data collection activities enabling real-time surveillance of the opioid crisis at the national, state, local, and tribal levels.

21. The Commission recommends the Federal Government work with the states to develop and implement standardized rigorous drug testing procedures, forensic methods, and use of appropriate toxicology instrumentation in the investigation of drug-related deaths. We do not have sufficiently accurate and systematic data from medical examiners around the country to determine overdose deaths, both in their cause and the actual number of deaths.

22. The Commission recommends reinstituting the *Arrestee Drug Abuse Monitoring* (ADAM) program and the *Drug Abuse Warning Network* (DAWN) to improve data collection and provide resources for other promising surveillance systems.

23. The Commission recommends the enhancement of federal sentencing penalties for the trafficking of fentanyl and fentanyl analogues.

24. The Commission recommends that federal law enforcement agencies expressly target Drug Trafficking Organizations and other individuals who produce and sell counterfeit pills, including through the internet.

25. The Commission recommends that the Administration work with Congress to amend the law to give the DEA the authority to regulate the use of pill presses/tableting machines with requirements for the maintenance of records, inspections for verifying location and stated use, and security provisions.

26. The Commission recommends U.S. Customs and Border Protection (CBP) and the U.S. Postal Inspection Service (USPIS) use additional technologies and drug detection canines to expand efforts to intercept fentanyl (and other synthetic opioids) in envelopes and packages at international mail processing distribution centers.

27. The Commission recommends Congress and the Federal Government use advanced electronic data on international shipments from high-risk areas to identify international suppliers and their U.S.-based distributors.

28. The Commission recommends support of the Synthetics Trafficking and Overdose Prevention (STOP) Act and recommends the Federal Government work with the international community to implement the STOP Act in accordance with international laws and treaties.

29. The Commission recommends a coordinated federal/DEA effort to prevent, monitor and detect the diversion of prescription opioids, including licit fentanyl, for illicit distribution or use.

30. The Commission recommends the White House develop a national outreach plan for the *Fentanyl Safety Recommendations for First Responders*. Federal departments and agencies should partner with Governors and state fusion centers to develop and standardize data collection, analytics, and information-sharing related to first responder opioid-intoxication incidents.

Opioid Addiction Treatment, Overdose Reversal, and Recovery

31. The Commission recommends HHS, CMS, Substance Abuse and Mental Health Services Administration, the VA, and other federal agencies incorporate quality measures that address addiction screenings and treatment referrals. There is a great need to ensure that health care providers are screening for SUDs and know how to appropriately counsel, or refer a patient. HHS should review the scientific evidence on the latest OUD and SUD treatment options and collaborate with the U.S. Preventive Services Task Force (USPSTF) on provider recommendations.

32. The Commission recommends the adoption of process, outcome, and prognostic measures of treatment services as presented by the National Outcome Measurement and the American Society of Addiction Medicine (ASAM). Addiction is a chronic relapsing disease of the brain which affects multiple aspects of a person's life. Providers, practitioners, and funders often face challenges in helping individuals achieve positive long-term outcomes without relapse.

33. The Commission recommends HHS/CMS, the Indian Health Service (IHS), Tricare, the DEA, and the VA remove reimbursement and policy barriers to SUD treatment, including those, such as patient limits, that limit access to any forms of FDA-approved medication-assisted treatment (MAT), counseling, inpatient/residential treatment, and other treatment modalities, particularly fail-first protocols and frequent prior authorizations. All primary care providers employed by the above-mentioned health systems should screen for alcohol and drug use and, directly or through referral, provide treatment within 24 to 48 hours.

34. The Commission recommends HHS review and modify rate-setting (including policies that indirectly impact reimbursement) to better cover the true costs of providing SUD treatment, including inpatient psychiatric facility rates and outpatient provider rates.

35. Because the Department of Labor (DOL) regulates health care coverage provided by many large employers, the Commission recommends that Congress provide DOL increased authority to levy monetary penalties on insurers and funders, and permit DOL to launch investigations of health insurers independently for parity violations.

36. The Commission recommends that federal and state regulators should use a standardized tool that requires health plans to document and disclose their compliance strategies for non-quantitative treatment limitations (NQTL) parity. NQTLs include stringent prior authorization

and medical necessity requirements. HHS, in consultation with DOL and Treasury, should review clinical guidelines and standards to support NQTL parity requirements. Private sector insurers, including employers, should review rate-setting strategies and revise rates when necessary to increase their network of addiction treatment professionals.

37. The Commission recommends the National Institute on Corrections (NIC), the Bureau of Justice Assistance (BJA), the Substance Abuse and Mental Health Services Administration (SAMHSA), and other national, state, local, and tribal stakeholders use medication-assisted treatment (MAT) with pre-trial detainees and continuing treatment upon release.

38. The Commission recommends DOJ broadly establish federal drug courts within the federal district court system in all 93 federal judicial districts. States, local units of government, and Indian tribal governments should apply for drug court grants established by 34 U.S.C. § 10611. Individuals with an SUD who violate probation terms with substance use should be diverted into drug court, rather than prison.

39. The Commission recommends the Federal Government partner with appropriate hospital and recovery organizations to expand the use of recovery coaches, especially in hard-hit areas. Insurance companies, federal health systems, and state payers should expand programs for hospital and primary case-based SUD treatment and referral services. Recovery coach programs have been extraordinarily effective in states that have them to help direct patients in crisis to appropriate treatment. Addiction and recovery specialists can also work with patients through technology and telemedicine, to expand their reach to underserved areas.

40. The Commission recommends the Health Resources and Services Administration (HRSA) prioritize addiction treatment knowledge across all health disciplines. Adequate resources are needed to recruit and increase the number of addiction-trained psychiatrists and other physicians, nurses, psychologists, social workers, physician assistants, and community health workers and facilitate deployment in needed regions and facilities.

41. The Commission recommends that federal agencies revise regulations and reimbursement policies to allow for SUD treatment via telemedicine.

42. The Commission recommends further use of the National Health Service Corp to supply needed health care workers to states and localities with higher than average opioid use and abuse.

43. The Commission recommends the National Highway Traffic Safety Administration (NHTSA) review its National Emergency Medical Services (EMS) Scope of Practice Model with respect to naloxone, and disseminate best practices for states that may need statutory or regulatory changes to allow Emergency Medical Technicians (EMT) to administer naloxone, including higher doses to account for the rising number of fentanyl overdoses.

44. The Commission recommends HHS implement naloxone co-prescribing pilot programs to confirm initial research and identify best practices. ONDCP should, in coordination with HHS, disseminate a summary of existing research on co-prescribing to stakeholders.

45. The Commission recommends HHS develop new guidance for Emergency Medical Treatment and Labor Act (EMTALA) compliance with regard to treating and stabilizing SUD patients and provide resources to incentivize hospitals to hire appropriate staff for their emergency rooms.

46. The Commission recommends that HHS implement guidelines and reimbursement policies for Recovery Support Services, including peer-to-peer programs, jobs and life skills training, supportive housing, and recovery housing.

47. The Commission recommends that HHS, the Substance Abuse and Mental Health Services Administration (SAMHSA), and the Administration on Children, Youth and Families (ACYF) should disseminate best practices for states regarding interventions and strategies to keep families together, when it can be done safely (e.g., using a relative for kinship care). These practices should include utilizing comprehensive family centered approaches and should ensure families have access to drug screening, substance use treatment, and parental support. Further, federal agencies should research promising models for pregnant and post-partum women with SUDs and their newborns, including screenings, treatment interventions, supportive housing, non-pharmacologic interventions for children born with neonatal abstinence syndrome, medication-assisted treatment (MAT) and other recovery supports.

48. The Commission recommends ONDCP, the Substance Abuse and Mental Health Services Administration (SAMHSA), and the Department of Education (DOE) identify successful college recovery programs, including "sober housing" on college campuses, and provide support and technical assistance to increase the number and capacity of high-quality programs to help students in recovery.

49. The Commission recommends that ONDCP, federal partners, including DOL, large employers, employee assistance programs, and recovery support organizations develop best practices on SUDs and the workplace. Employers need information for addressing employee alcohol and drug use, ensure that employees are able to seek help for SUDs through employee assistance programs or other means, supporting health and wellness, including SUD recovery, for employees, and hiring those in recovery.

50. The Commission recommends that ONDCP work with the DOJ, DOL, the National Alliance for Model State Drug Laws, the National Conference of State Legislatures, and other stakeholders to develop model state legislation/regulation for states to decouple felony convictions and eligibility for business/occupational licenses, where appropriate.

51. The Commission recommends that ONDCP, federal agencies, the National Alliance for Recovery Residents (NARR), the National Association of State Alcohol and Drug Abuse Directors (NASADAD), and housing stakeholders should work collaboratively to develop quality standards and best practices for recovery residences, including model state and local policies. These partners should identify barriers (such as zoning restrictions and discrimination against MAT patients) and develop strategies to address these issues.

Research and Development

52. The Commission recommends federal agencies, including HHS (National Institutes of Health, CDC, CMS, FDA, and the Substance Abuse and Mental Health Services Administration), DOJ, the Department of Defense (DOD), the VA, and ONDCP, should engage in a comprehensive review of existing research programs and establish goals for pain management and addiction research (both prevention and treatment).

53. The Commission recommends Congress and the Federal Government provide additional resources to the National Institute on Drug Abuse (NIDA), the National Institute of Mental Health (NIMH), and National Institute on Alcohol Abuse and Alcoholism (NIAAA) to fund the research areas cited above. NIDA should continue research in concert with the pharmaceutical industry to develop and test innovative medications for SUDs and OUDs, including long-acting injectables, more potent opioid antagonists to reverse overdose, drugs used for detoxification, and opioid vaccines.

54. The Commission recommends further research of Technology-Assisted Monitoring and Treatment for high-risk patients and SUD patients. CMS, FDA, and the United States Preventative Services Task Force (USPSTF) should implement a fast-track review process for any new evidence-based technology supporting SUD prevention and treatments.

55. The Commission recommends that commercial insurers and CMS fast-track creation of Healthcare Common Procedure Coding System (HCPCS) codes for FDA-approved technology-based treatments, digital interventions, and biomarker-based interventions. NIH should develop a means to evaluate behavior modification apps for effectiveness.

56. The Commission recommends that the FDA establish guidelines for post-market surveillance related to diversion, addiction, and other adverse consequences of controlled substances.

The Drug Addiction and Opioid Crisis

The primary goal of the President's Commission on Combatting Drug Addiction and the Opioid Crisis is to develop an effective set of recommendations for the President to combat the opioid crisis and drug addiction in our nation. Many of the recommendations that follow will require appropriations from Congress into the Public Health Emergency Fund, for block grants to states and to DOJ for enforcement and judicial improvements. It is not the Commission's charge to quantify the amount of these resources, so we do not do so in this report.

The Commission urges Congress to respond to the President's declaration of a Public Health Emergency and fulfill their constitutionally delegated duty and appropriate sufficient funds to implement the Commission's recommendations. 175 Americans are dying every day. Congress must act. Notwithstanding this core mission, it is vital to address the influences that transformed the United States into the world leader of opioid prescribing, opioid addiction, and opioid overdose deaths.

Origins of the Current Crisis

The Current Crisis. In the mid- to late-19th century, the first national opioid crisis occurred; a detailed history is provided in Appendix 2. During this time, opioid use rose dramatically, fueled by physicians' unrestrained opioid prescriptions (morphine, laudanum, paregoric, codeine, and heroin) for pain or other ailments, and by liberal use of opioid-based treatments for injuries and diseases impacting Civil War combatants and veterans (see Appendix 2). In parallel with the current crisis, this nation-wide crisis extended across socio-economic statuses, and reached urban and rural areas. This first epidemic was eventually contained and reversed by physicians, pharmacists, medical education, and voluntary restraint, combined with federal regulations and law enforcement.

After the first crisis subsided, medical education emphasized the hazards of improper opioid prescribing, and by doing so, created a cultural mindset against the dangers of opioids. However, over 30 years ago, a sequence of events eroded fears of opioids, and the medical community once again relapsed into liberal use of medicinal opioids.

Triggered by excessive prescribing of opioids since 1999, the current crisis is being fueled by several factors that did not exist in the 19th century: the advent of large scale production and distribution of pure, potent, orally effective and addictive opioids; the widespread availability of inexpensive and purer illicit heroin; the influx of highly potent fentanyl/fentanyl analogs; the transition of prescription opioid misusers into use of heroin and fentanyl; and the production of illicit opioid pills containing deadly fentanyl(s) made by authentic pill presses. Prescription opioids now affect a wide age range, families both well-off and financially disadvantaged, urban and rural, and all ethnic and racial groups.

Historical precedent demonstrated that this crisis can be fought with effective medical education, voluntary or involuntary changes in prescribing practices, and a strong regulatory and enforcement environment. The recommendations of the Commission are grounded in this reality, and benefit from modern systematic epidemiological and large data analytics, evidence-based treatments, and medications to assist in recovery or rescue of an overdose crisis.

Contributors to the Current Crisis. A widely held and supportable view is that the modern opioid crisis originated within the healthcare system and have been influenced by several factors:

- **Unsubstantiated claims:** One early catalyst can be traced to a single letter to the Editor of the New England Journal of Medicine published in 1980, that was then cited by over 600 subsequent articles.[1,2] With the headline "Addiction Rare in Patients Treated with Narcotics," the flawed conclusion of the five-sentence letter was based on scrutiny of records of hospitalized patients administered an opioid. It offered no information on opioid dose, number of doses, the duration of opioid treatment, whether opioids were consumed after hospital discharge, or long-term follow-up, nor a description of criteria used to designate opioid addiction. Six years later, another problematic study concluded that "opioid maintenance therapy can be a safe, salutary and more humane alternative to the options of surgery or no treatment in those patients with intractable non-malignant pain and no history of drug abuse."[3] High quality evidence demonstrating that opioids can be used safely for chronic non-terminal pain did not exist at that time. These reports eroded the historical evidence (see Appendix 2) of iatrogenic addiction and aversion to opioids, with the poor-quality evidence that was unfortunately accepted by federal agencies and other oversight organizations.

- **Pain patient advocacy:** Advocacy for pain management and/or the use of opioids[4,5,6] by pain patients was promoted, not only by patients, but also by some physicians. One notable physician stated: "make pain 'visible'… ensure patients a place in the communications loop… assess patient satisfaction; and work with narcotics control authorities to encourage therapeutic opiate use… therapeutic use of opiate analgesics rarely results in addiction."[7]

- **The opioid pharmaceutical manufacturing and supply chain industry:** One pharmaceutical company sponsored over 20,000 educational events for physicians and others on managing pain with opioids, claiming their potential for addiction was low.[8] Yet, warning signs of the addictive potential of oxycodone and similar opioids long predated this period: in 1963, Bloomquist wrote that dihydrohydroxycodeinone (oxycodone, Percodan®), "although a useful analgesic retains addiction potential comparable to that of morphine. This fact should be considered when it is prescribed. Because of increasing numbers of addicts to this drug in the State of California, the California Medical Association Committee on Dangerous Drugs and the House of Delegates has recommended that oxycodone-containing drugs be returned to the triplicate prescription list as they were originally in 1949." This recommendation failed to pass the legislature.[9] Similar warnings followed.

  Aggressive promotion of an oxycodone brand from 1997-2002 led to a 10-fold rise in prescriptions to treat moderate to severe noncancer pain, and increases in prescribing of other opioids. Subsequently, the highest strengths permissible was increased for opioid-tolerant patients, likely contributing to its misuse. Extended-release (ER) formulations and delayed absorption were marketed as reducing abuse liability, but crushing the pills allowed users to snort or inject the drugs.[10,11] There are now at least five marketed opioids that carry abuse-deterrent labeling. It has been hypothesized that the marked rise in heroin and other illicit synthetic opioids is, in part, associated with unintended consequences of reformulation of OxyContin, and a reduced supply and greater expense of prescription opioids.[12,13]

  To this day, the opioid pharmaceutical industry influences the nation's response to the crisis.[14] For example, during the comment phase of the guideline developed by the Centers for Disease Control and Prevention (CDC) for pain management, opposition to the guideline was more

common among organizations with funding from opioid manufacturers than those without funding from the life sciences industry.[15]

- **Rogue pharmacies and unethical physician prescribing:** The key contributors of the large number of diverted opioids were unrestrained distributors, rogue pharmacies, unethical physicians, and patients whose opioid medications were diverted, or other patients who sold and profited from legitimately prescribed opioids.[16]

- **Pain as the 'fifth vital sign':** The phrase, "pain as the 'fifth vital sign,'" was initially promoted by the American Pain Society in 1995, to elevate awareness of pain treatment among healthcare professionals; "Vital Signs are taken seriously. If pain were assessed with the same zeal as other vital signs are, it would have a much better chance of being treated properly. We need to train doctors and nurses to treat pain as a vital sign. Quality care means that pain is measured and treated."[17]

  The Veteran's Administration (VA)[18] and then the Joint Commission on Accreditation of Healthcare Organizations (the Joint Commission) designated pain as a 'fifth vital sign.'[19,20] The Joint Commission accredits and certifies health care organizations. Certification has implications for objective assessment of clinical excellence, and for contracting and reimbursement. The Joint Commission's standards for pain assessment in 2000 "were a bold attempt to address widespread underassessment and undertreatment of pain,"[21] even though the health care community was not advocating for a regulatory approach to pain management.[22] The standards raised concerns that requiring all patients to be screened for the presence of pain and raising pain treatment to patients' rights issue could lead to overreliance on opioids.

  The Joint Commission received sponsorship for developing educational materials from an opioid pharmaceutical company, one of over 20,000 pain-related educational programs through direct sponsorship or financial grants. It was "unaware that the science behind their claims and the advice of experts in the field were erroneous."[23] This designation set in motion a growing compulsion to detect and treat pain, especially to prescribe opioids beyond traditional boundaries of treating acute, postoperative, procedural pain and end-of-life care. The surge in opioid supply escalated into opioid-related misuse, diversion, use disorder, and overdose deaths. Administrators, regulatory bodies, and insurers collectively pressured physicians to address patient satisfaction with aggressive pain management.[24] However, the concept that iatrogenic addiction was rare and that long-acting opioids were less addictive had been widely repeated, and studies refuting these claims were not published until years later. The Joint Commission has since eliminated the requirement that pain be assessed in all patients, except for patients receiving behavioral health care and established much stricter processes to review any corporate sponsorship of educational programs. In 2016, the Joint Commission began to revise its pain standards,[25] which will go into effect in January 2018.

- **Inadequate oversight by the Food and Drug Administration (FDA):** The FDA is the sole federal authority responsible for protecting public health by assuring the safety, efficacy, and security of human drugs, biological products, and medical devices. It approves medications to diagnose, treat, and mitigate illnesses, after assessing their safety and efficacy. It safeguards the nation's medications by setting standards for proper prescribing of approved drugs and post-approval surveillance. The FDA provided inadequate regulatory oversight. Even when overdose deaths mounted and when evidence for safe use in chronic care was substantially lacking, prior to 2001, the FDA accepted claims that newly formulated opioids were not

addictive, did not impose clinical trials of sufficient duration to detect addiction, or rigorous post-approval surveillance of adverse events, such as addiction.

The FDA also failed to assess the risks associated with deliberate diversion and misuse of opioids, risks that conceivably outweighed the intended benefits for patients if used as directed. They accepted the pharmaceutical industry's claim that iatrogenic addiction was "very rare" and that the delayed absorption of OxyContin reduced the abuse liability of the drug.[26] By 2001, the FDA removed these unsubstantiated claims from OxyContin's labeling. In March 2016, the FDA requested from the National Academies of Sciences, Engineering, and Medicine (NASEM) and received on July 13, 2017, a summary of the current status of science regarding prescription opioid abuse and misuse, and the role of opioids in pain management.[27] The current FDA Commissioner has stated a strong commitment to using the regulatory authority of the FDA to mitigate the adverse consequences of opioid use.[28]

- **Reimbursement for prescription opioids by health care insurers:** Sales of prescription opioids in the U.S. nearly quadrupled from 1999 to 2014,[29] largely paid for by insurance carriers. It is estimated that 1 out of 5 patients with non-cancer pain or pain-related diagnoses are prescribed opioids in office-based settings.[30] From 2007 to 2012, the rate of opioid prescribing steadily increased amongst specialists more likely to manage acute and chronic pain (pain medicine [49%], surgery [37%], physical medicine/rehabilitation [36%]). Insurance carriers, including Medicare Part D plans, did not serve as a stop-gap to the huge influx of opioid prescriptions.

- **Medical education:** Medical education has been deficient in pain management, opioid prescribing, screening for, and treating addictions.[31] During the 1990's, the pain movement should have alerted medical education institutions and creators of continuing medical education courses to address this issue. In some medical schools and some specialties, it remains inadequate to this day.[32] One strategy promoted 10 years ago to stratify patients' risk for opioid misuse and overdose was the screening of patients for substance use disorders (SUDs), especially pain patients.[33] Implementation of Screening, Brief Interventions, and Referral to Treatment (SBIRT) in healthcare systems was incentivized with billing codes.[34] SBIRT was mainstreamed into health care reform, but has yet to be incorporated nationally into medical curricula, or applied as routine care. Nor do core curricula necessarily address addictions, treatment options, or stress the need to screen for substance use and mental health.

- **Lack of patient education:** Patients and their families are not often fully informed regarding whether their prescriptions are opioids, the risks of opioid addiction or overdose, control and diversion, dose escalation, or use with alcohol or benzodiazepines.

- **Public demand evolves into reimbursement and physician quality ratings pegged to patient satisfaction scores:** Today, the use of opioids for chronic non-cancer pain remains controversial for the same reasons their use declined and was avoided at the turn of the 20th century: the potential for misuse and addiction, insufficient high-quality evidence of efficacy with long-term use, poor functional outcomes, overdose and death.

  Yet, a strong public demand for opioids continues to pressure clinicians to prescribe opioids persists. As an example, a recent survey of Emergency Department (ED) physicians indicated that 71% reported a perceived pressure to prescribe opioid analgesics to avoid administrative and regulatory criticism. Uniformly, they voiced concern about excessive emphasis on patient satisfaction scores by reimbursement entities as a means of evaluating their patient

management. The physician requirement to address pain as the "fifth vital sign" persists,[35] and reimbursement metrics based on patient satisfaction may have inadvertently created an environment conducive to exploitation by prescription opioid abusers.[36] There are legitimate circumstances for which opioids are an appropriate therapy. But many current institutional and societal issues continue to pressure physicians to prescribe opioids when they are not clinically appropriate.

Prior to this year, poor patient satisfaction with pain care could lead to reduced hospital reimbursement by Medicare through Value-Based Purchasing (VBP). There are often higher costs or no specific reimbursements for alternative pain management strategies, alternative pain intervention strategies, or spending time to educate patients about the risks of opioids. Further, failing to provide adequate pain relief can be grounds for malpractice claims or medical board action.

- **Lack of foresight of unintended consequences:** As prescription drugs came under tighter scrutiny and access became more limited (via abuse-deterrent formulations and more cautious prescribing), market forces responded by providing less expensive and more accessible *illicit* opioids. Increases in overdose death numbers due to prescription opioids have transitioned to overdoses largely due to heroin and, increasingly, fentanyl.[37] Locally, this trend may have been driven, in part, by tightening controls on prescription opioids. Physicians curtailed opioid prescriptions without guidelines on tapering and without determination of whether patients had developed an opioid use disorder (OUD), and if so, how to respond.[38]

  The availability of cheaper heroin also drove prescription opioid misusers to illicit opioids. Black market heroin is currently much less expensive than diverted prescription opioids, and fentanyl is even much less expensive per dose than heroin. Predictable from the economics of the two drug categories, the prescription drug overdose problem has decreased, but not the overall number of opioid-related deaths.

- **Treatment services insufficient to meet demand and to provide medication-assisted treatment (MAT):** As OUDs increased dramatically over the past 15 years, quality treatment services and the associated workforce did not expand in response to the growing crisis.

- **Lack of national prevention strategies:** Prevention strategies focusing on specific illicit drugs for vulnerable populations - adolescents, college age youth, pregnant women, unemployed men, and other - and for influencers, (parents, families) don’t exist or have not been tested adequately.

Magnitude and Demographics

National statistics on prescription opioid misuse and use disorder, 2016.[39] Weighted *National Survey on Drug Use and Health* (NSDUH) estimates suggested that, in 2016, 91.8 million (34.1%) or more than one-third of U.S. civilian, noninstitutionalized adults used prescription opioids; 11.5 million (4.3%) misused them. In 2015, 1.6 million (0.7%) had an OUD. Among adults with prescription opioid use, 12.2% reported misuse and 15.1% of misusers reported a prescription OUD.[40] The most commonly reported motivation for misuse was to relieve physical pain (63.6%). Misuse and use disorders were most commonly reported in adults who were uninsured, were

unemployed, had low income, or had behavioral health problems. Among adults with misuse, 62.2% reported using opioids without a prescription, and 40.6% obtained prescription opioids for free from friends or relatives for their most recent episode of misuse. The results suggest a need to improve access to evidence-based pain management and to decrease excessive prescribing that may leave unused opioids available for potential misuse.[41]

The NSDUH estimates that 3.4 million people aged 12 or older in 2016 were *current* misusers of pain relievers (1.2% of the population aged 12 or older).[42] In 2016, an estimated 239,000 adolescents aged 12 to 17 were *current* misusers of pain relievers (1.0% of adolescents) and 631,000 young adults aged 18 to 25 misused pain relievers in the past month (1.8% of young adults). Among adults aged 26 or older, 2.5 million are estimated to be current misusers of pain reliever (1.2%). Upwards of 1.8 million Americans harbor an OUD involving prescription opioids or 0.7% of people aged 12 or older. Among adolescents aged 12 to 17, 152,000 (0.6%) had a pain reliever use disorder in the past year, and 291,000 young adults aged 18 to 25 (0.8%) and 1.3 million adults aged 26 or older in 2016 (0.6%) had a pain reliever use disorder in the past year. These small percentages do not convey the massive personal and public health burden created by misuse of opioids.

National statistics on heroin use and use disorder, 2016.[43] The addictive and illegal opioid heroin has no accepted medical use in the United States. Past 30 day users of heroin (475,000) among people aged 12 or older or 0.2% of the population is probably an underestimate because NSDUH surveys households and does not capture heroin users in homeless shelters or transient populations with no fixed address, and the incarcerated. Despite its dangers heroin use continues to escalate and reflects changes in heroin use by adults aged 26 or older and, to a lesser extent, among young adults aged 18 to 25. Less than 0.1% of adolescents aged 12 to 17 were current or past year heroin users (3,000 and 13,000, respectively) and these numbers remained relatively stable. Among young adults aged 18 to 25, 0.3% were current heroin users (88,000) and this number rose since 2002. For past year and at minimum, 630,000 individuals have a heroin use disorder (HUD).[17] Among adults 26 and older 0.2% were current heroin users (383,000), a rise since 2015. About 626,000 people aged 12 or older reported an HUD (0.2%), an increase since 2002 to 2011. Less than 0.1% of adolescents aged 12 to 17 (1,000) had an HUD in the past year, but this rate was many times higher among 18-25-year-olds (152,000; 0.4%). Approximately 473,000 adults aged 26 or older had an HUD (0.2%)

Substance use disorder treatment needs, 2016.[44] For NSDUH, people are defined as needing substance use treatment if they had an SUD in the past year or if they received substance use treatment at a specialty facility in the past year. In 2016, 10.6% of people aged 12 or older (2.3 million people) who needed substance use treatment received treatment at a specialty facility in the past year. Among people in specific age groups needing substance use treatment, 8.2% of adolescents aged 12 to 17, 7.2% of young adults aged 18 to 25, and 12.1% of adults aged 26 or older received substance use treatment at a specialty facility in the past year. These percentages represent 89,000 adolescents, 383,000 young adults, and 1.8 million adults aged 26 or older who needed substance use treatment and received treatment at a specialty facility in the past year. Prior to 2016, NSDUH reported on the reasons people in need in treatment did not receive it. Approximately 90% self-reported they did not feel the need for treatment and did not seek it.

Special Populations. The Commission recognizes that, although many of the recommendations included in this report are generic for the population as a whole, subpopulations exist within our nation that conceivably require increased outreach, access to services, and more tailored or

intensive services. These special populations can be viewed from the perspective of race or ethnicity, residential location and population density, gender, age[45], mental[46] and physical health status (e.g. HIV-AIDS), income, employment, socio-economic status, education, veterans,[47,48] involvement in the criminal justice system (juveniles, parolees, incarcerated), family status (fetus[49], children of substance-using parents or other family members, pregnant women, living alone), healthcare insurance sources, behavioral health indicators[50] (other SUDs or history), type of opioid use (heroin/fentanyl, prescription opioid nonmedical or medical use, or combined use), and others.

According to the 2016 NSDUH, more males (4.8%) than females (3.8%) misused prescription opioid medications.[51] Young adults aged 18 to 25 years old had the largest proportion of misusers. In comparison to the national average for past year misuse of pain relievers by those 12 years and older, misuse was most common among Americans with two or more races (6.5%), American Indian or Alaska Natives (3.9%), Native Hawaiian or other Pacific Islanders (4.2%), and Hispanics (4.2%). The rate of non-medical use of prescription opioid medications was lowest among Asians (1.8%).

Scrutiny of the NSDUH and other data sources can reveal which populations are at highest risk. A recent study using 2010-2013 NSDUH data[52] revealed the prevalence of OUDs was highest among whites (72.29%), with lower prevalence among blacks (9.23%), Hispanics 13.82%, and others 4.66%. Other factors overrepresented among those reporting OUDs were adults aged 18–34 (55.95%), males (57.39%), low income (<$50,000; 67.12%), residents of large metropolitan areas (49.99%), with fewer privately insured persons (40.97%). Compared with whites, adolescents were overrepresented among mixed-race persons and Hispanics. In contrast, Native Americans included a higher proportion of older adults aged≥50.[53] Among mixed-race persons, the proportion of females was higher than males. The vast majority of blacks (83.78%), Native Americans (88.98%), and Hispanics (76.44%) were in the lowest income group. A high proportion of blacks, Native Hawaiians/Pacific Islanders/Asian Americans, and Hispanics resided in large metropolitan areas. A high proportion of native-Americans lived in nonmetropolitan areas. All non-white groups, except for Native Hawaiians/Pacific Islanders/Asian Americans, had higher proportions of public insurance than whites.

Among persons with OUD, the majority (80.09%) had another SUD, 28.74% had major depression, 53.02% had nicotine dependence, 40.93% had alcohol use disorder (AUD), and 43.22% had ≥1 other drug use disorder (cannabis 22.32%, tranquilizer 13.99%, cocaine 15.25%, stimulant 9.28%, hallucinogen 5.25%, sedative 3.51%, inhalant 2.22%), which was more prevalent among whites (83.39%) than Hispanics (72.04%). Major depressive episode was also common (28.74%). Most people with OUD report no use of OUD treatment, with only 26.19% using any alcohol or drug use treatment, 19.44% using opioid-specific treatment. Adolescents, the uninsured, blacks, Native Hawaiians/Pacific Islanders/Asian Americans, persons with prescription opioids only, and persons without depression episodes especially underutilized opioid-specific treatment. The treatment rate for adolescents among blacks with OUD was very low, unless they were involved with the criminal justice system. Among alcohol/drug use treatment users, self-help group and outpatient rehabilitation treatment were commonly used services.

Adolescent-onset OUD indicates a high risk for severe OUD. Low treatment rates, conceivably related to inadequate MAT data for adolescents, places this population at particular susceptibility. Native Hawaiians/Pacific Islanders/Asian Americans with OUD had the lowest prevalence of using alcohol/drug treatment (4.91%) or opioid-specific treatment (1.24%). Cultural-related

stigma toward addiction and a lack of culturally congruent addiction providers are unique barriers to seeking treatment. Residents in rural areas have relatively high rates of opioid overdoses, but they face substantial barriers to OUD treatment, including a shortage of mental/behavioral health providers.

Newly Emerging Threats

New Psychoactive Substances. The term "new psychoactive substances" (NPS) can be defined as individual drugs in pure form or in complex preparations that are not scheduled under the *Single Convention on Narcotic Drugs* (1961) or the *Convention on Psychotropic Substances* (1971). NPS may be categorized by chemical structure, by psychoactive properties, by biological targets, or by source (plant, synthetic, or combined). The emergence of NPS that target opioid sites in the body is challenging public health and drug policies globally. Their novelty, ambiguous legal status, ability to evade toxicological tests, swift adaptation to legal restrictions, global internet marketing, and scant public knowledge of their adverse effects are among the key drivers of this 21st century phenomenon.

The designation "new" is not necessarily limited to newly-designed compounds with no historical precedent, but may also include compounds modified from substances previously used. The majority are chemical analogs of drugs in restricted categories and may elicit effects similar to the parent drug, or a more amplified response. Others may evoke unique or complex sensations because of their hybrid structures, or because several compounds with differing pharmacological profiles are combined and sold as a unit. Although synthetic cathinone analogs and synthetic cannabinoids occupy a major share of this market, synthetic opioids, especially fentanyl analogs, are by far the most problematic substances because they are emerging as a leading cause of opioid overdose deaths in the United States.[54]

Drivers of NPS. The rapid expansion of NPS in the past decade is fueled by a convergence of the information revolution, vague legal status, uncertain detectability, and financial incentives combined with guileful marketing.

The internet is a "global neural network" that can be exploited to disseminate promotion and distribution of these drugs instantly. The venues are chat rooms, blogs, instant messaging sites, social networking, or multimedia sites. At minimal cost, descriptions of new drugs, their positive psychoactive effects, doses, synthetic routes, and purchasing sites are accessible world-wide on computers or mobile devices such as smart phones or smart watches. Many of the marketing sites are impervious to legal sanctions, as it takes time to deliberate the evidence and move newly emerging drugs into a legally restrictive zone, especially internationally.

Imperfect international agreements and a gradual dissolution of international resolve to attenuate drug use compromise effective solutions to this unique problem. Often, substances that imitate controlled drugs are unscheduled, unregulated, and not under the auspices of international law. Their nebulous legal status is an incentive for entrepreneurs to introduce new drugs quickly into the global market.

The allure of NPS is magnified by current limitations in detecting them. Identifying these drugs for forensic, workplace, legal, and policy purposes is constrained by a lack of reference materials and the need for sophisticated detection methods which are not routinely available (e.g., mass

spectroscopy). The chemical structures of NPS are designed to keep one step ahead of federal and international laws that restrict distribution and sale of specific chemicals. The Drug Enforcement Administration (DEA) has emergency powers to temporarily schedule a drug for 36 months, a time frame to accumulate evidence for/against long-term drug scheduling.

New Psychoactive Opioids. Novel opioid receptor agonists, some of which are much more potent than morphine, are of particular public health concern, as they can be mixed with or substituted for heroin, and are more likely to be deadly.[55] As these novel opioids emerge, emergency responders, medical professionals, law enforcement personnel, death investigators, medical examiners, toxicologists, and prosecutors face the challenge of treating and investigating intoxications and deaths from novel compounds whose identities are often unknown and for which analytical standards do not exist.

In 2013, the rapid ascent of the potent opioid agonist fentanyl compelled a rethinking of public health and regulatory approaches to the opioid crisis.[56] Fentanyl and fentanyl analogs, including carfentanil, are becoming a major contributor to opioid overdose fatalities in specific states, especially in the eastern half of the nation.[57] Many have been identified, with some fentanyl analogs found as contaminants of other drugs, e.g. furanyl fentanyl has been identified as a contaminant in crack cocaine.[58,59,60,61,62] As many do not cross-react in routine assays, a simple analytic device to identify whether a street drug is unknowingly contaminated with fentanyl analogs may yield a false negative and a false sense of security.

Other opioid NPS compounds include U-50488, desomorphine, tapentadol, salvinorin A, and its analog herkinorin.[63] 'Krokodil,' the street name for a homemade cheap heroin substitute in Russia, is synthesized from codeine, iodine, and red phosphorus, with esomorphine claimed as the end product. A total of 54 morphinans were detected after detailed chemical analysis, highlighting the possibility that additional morphinans may contribute to the psychotropic effects of krokodil.[64]

Pathways to Opioid Use Disorder (Including Heroin) from Prescription Opioids

Prior History of Prescription Opioid Misusers Who Seek Treatment. In 2016, 91.8 million people (ages 12 or older) in the United States use pain relievers in the past year.[65] Of these, 11.5 million people reported misuse of pain relievers.

In an analysis of more than 4,400 patients entering drug treatment for opioid abuse, of individuals initially exposed to opioids through a physician's prescription to treat pain, 94.6% had used a psychoactive substance non-medically prior to or coincident with their opioid prescription. Alcohol (92.9%), nicotine and/or tobacco (89.5%), and marijuana (87.4%) were used by nearly all patients prior to, or coincident with, their first opioid prescription. If one excludes these drugs, 70.1% (n=2,913) still reported some psychoactive drug use of licit or illicit stimulants (77.8%), benzodiazepines (59.8%) or hallucinogens (55.2%).[66] Similar findings were observed in a study restricted to women.[67] The findings are consistent with concerns that persons with prior use of addictive substances are at considerably higher risk for prescription opioid misuse, with addiction to one substance alone uncommon.[68] It highlights the need for clinicians to screen patients for prior drug use histories and judicious monitoring of and intervention with these at-risk patients prior to or during opioid prescribing. There is abundant evidence is that increased risk of iatrogenic

addiction or nonmedical use of prescription drugs overlaps consistently with problematic drinking, marijuana use, and other forms of substance use or a history of substance use or use disorder.

Prescription Opioids and Transition to Prescription OUD. Understanding the risks factors that drive transition to an OUD are critical for developing effective policies to attenuate the process.[69,70] The specific opioid, the dose, number of doses, duration, route of administration, formulation, ER, or immediate-release (IR) can influence misuse and progression to addiction. Some opioids engender greater likability or abuse liability than others. In patients dependent on heroin, oxycodone was ranked highest of several opioids, while buprenorphine scored lowest.[71] Overall, the risk of transition from medical use for pain relief to dependence is especially high for opioids, especially with longer use, and high doses.

One study found that the probability of long-term prescription opioid use increased markedly in the initial period of therapy, especially after five days or one month.[72] One causative factor of addiction is the development of rapid tolerance which can progress to OUD, without careful tapering.

In a small study of a single population, patients self-reported five common pathways to OUD: (1) inadequately controlled pain; (2) initial exposure to opioids during acute pain, which triggered a unique positive response; (3) relief from emotional distress; (4) relapse to a prior opioid addiction triggered by prescription opioids; and (5) misuse of prescription opioids solely for psychoactive purposes.[73] This survey highlights the need for prescribing clinicians to screen patients for prior history of substance use.

Prescription Opioids and Heroin Use Disorder. The vast majority of patients who use prescription opioids, either short or long term, do not progress to misuse and are unlikely to transition to heroin use. If transition occurs, the reverse (heroin to prescription opioids) is rare, as heroin is less expensive, more euphoric by the intravenous route, and more accessible. Overprescribing is still considered a driver of increases in opioid-related consequences, addiction, overdose, and infections, as it sustains nonmedical use of prescription opioids.[74,75] However, heroin initiation occurs in a relatively small subgroup of nonmedical users of prescription opioids,[76,77,78] but nonmedical use is a key risk for conversion to heroin use.[79,80] Although the percent of annual conversions from the large number of prescription opioid users to new heroin users is low, approximately 80% of heroin users are estimated to have transitioned from misuse of prescription opioids in recent years.[81,82]

Transition to heroin use among young prescription opioid users was predicted by prescription OUD, use of prescription opioids at an early age, and recreational use for psychoactive purposes. More specifically, a nationally representative sample of U.S. adolescents (2004-2011 NSDUH; n = 223,534; aged 12-21 years), showed that a prior history of nonmedical use of prescription opioids was strongly associated with heroin initiation, with the highest risk being nonmedical use of prescription opioids at ages 10-12 years, regardless of race/ethnicity or income group.[83] Moreover, because the peak period of heroin initiation occurs later, efforts to prevent heroin use may be most effective if they focus on young people who already initiated nonmedical use of prescription opioids.

An association between policies related to curtailing prescription opioids and heroin use or overdose mortality has yet to be definitively shown. Research has not yet shown whether restrictions on prescribing increased heroin use among those who had already initiated heroin. Yet,

past year heroin use among nonmedical opioid users has increased dramatically among young adults and emerging adults during the past six years.[84]

In one study of people in treatment, more persons (33.3%) in 2015 were experimenting with heroin as their first opioid exposure compared with 10 years prior (8.7%), although they may differ from the general population of opioid users.[85] In the same period, their endorsement of oxycodone and hydrocodone misuse declined. As supply side interventions reduce accessibility to commonly prescribed opioids, some initiates replace prescription opioids with heroin. Imprecise heroin dosing in users without a history of opioid use may contribute to overdose fatalities in novices. Fentanyl and analogues may be too strong for all but the most tolerant opioid users. Nearly half of patients entering treatment for OUD reported first exposure to opioids through a physician's prescription for pain management,[86] but these estimates may need revision in view of currently high availability of heroin and fentanyl.

Heroin Use. Heroin use also increased during the same period that witnessed a rise in prescription opioid misuse. Data from the 2001-2002 and 2012-2013 *National Epidemiologic Survey on Alcohol and Related Conditions-I and–III* (NESARC) showed prevalence of heroin use increased five-fold and use disorder tripled in the United States during the period between the two surveys.[87] The rise was greater among whites, unmarried respondents, males, young users, those with lower educational achievement, and those living in poverty. Prior exposure to nonmedical prescription opioids increased among white heroin users, reinforcing concerns and other reports that prescription opioid misusers were transitioning to heroin use. Evidence is accumulating that heroin is increasingly being used without prior to exposure to prescription opioids.[88]

Health, Financial, and Social Consequences

General Consequences of Opioid Misuse and Use Disorder. Heroin and other illicit opioids confer a high risk for medical consequences.[89] Nonmedical users of prescription pain relievers are 40 times more likely than the general population to use heroin or other injection drugs. Opioid addiction is a chronic difficult-to-treat disorder characterized by frequent relapses. Crude mortality rates and the risks of death of opioid users are substantially higher than the general population worldwide, although sample and country-level variables impact the extent and causes of mortality. Elevated causes of mortality among opioid users include overdose, traumatic and suicide deaths, and HIV-related mortality. Treatment, HIV-negative serostatus, and lower levels of injecting are protective factors against premature death.[90]

Powerful environmental factors can shape the course of heroin addiction. A study found that of the heroin-dependent soldiers who returned to the United States after the Vietnam War, only 12% were still drug dependent three years later.[91] Although more than half of the returning soldiers tried narcotics again, only a minority of them became re-addicted. These results illustrate that powerful environmental factors may influence the course of heroin addiction.[92]

Stable abstinence is less than 30% after 10-30 years, and even if abstinent, use of other drugs including alcohol is frequent.[93,94] Family, social support, and employment are associated with improved recovery rates, whereas a history of sexual or physical abuse and comorbid mental disorders correlate with persistent opioid use.[95,96,97]

A five-year abstinent period is associated with an increase in likelihood of stable abstinence. Mortality is 6-20 times higher than that of the general population, with deaths depending on country of origin. In the United States, the primary cause of mortality is overdose deaths.[98]

Medical Consequences. Opioid users are less healthy from the perspective of physical and mental health than drug users who do not use opioids.[99] They are also substantial users of medical services at higher costs than non-users and require chronic medical, psychiatric, and addiction care. Those using non-prescribed opioids differ from persons using opioids as prescribed, with more severe drug problems, as manifested by higher intravenous drug use and behavior that puts them at higher risk for HIV and Hepatitis C.

Opioid users have higher numbers of ED visits, more inpatient hospital stays, along with almost double the inpatient costs compared to their non-opioid using counterparts. Current data out of North Carolina indicates both a record number of overdose patients visiting EDs and that half, 49% of overdose survivors seen in the ED, do not have insurance.

Opioid users also have a higher mean number of outpatient medical visits and higher associated costs over the same time period. Their self-reported health status is lower, and they have a higher number of chronic medical comorbidities than their non-opioid using counterparts. They were also more likely to have been prescribed medication for psychological/emotional problems in their lifetime and to have a mental illness diagnosis.[100] Patients using opioids are more likely to be taking two or more illicit or non-prescribed drugs, to be taking non-prescribed benzodiazepines, and to report intravenous drug use. Compared to patients using opioids only as prescribed, those using any non-prescribed opioids were more likely to have been homeless, have more serious drug problems than those using opioids only as prescribed, engage in intravenous drug use, and have a higher HIV risk-taking score. Non-prescribed opioid users also had more problem alcohol use relative to their prescribed opioid user counterparts.

Infections and infectious diseases. Although overdose contributes most to drug-associated mortality, infections stemming from intravenous drug use are another major cause of death or an illness requiring hospitalization.[101,102,103] Injecting drug users are at risk for acquiring hepatitis C virus (HCV) and HIV, as well as invasive bacterial infections, including endocarditis.[104,105]

Brain Toxicity. Brain toxicity is a common finding for specific drugs of abuse.[106,107,108,109] Diagnostic imaging, especially magnetic resonance imaging (MRI) can detect a range of brain abnormalities associated with heroin use, including neurovascular complications related to inadequate blood supply such as stroke. A rare form of leukoencephalopathy has also been shown in people inhaling heroin vapors.

Children at risk. Children are at high risk in opioid-using environments. Pregnant women who continue to use opioids throughout the gestational period are likely to deliver a newborn with neonatal abstinence syndrome (NAS). The incidence of NAS is increasing in the United States, and carries an enormous burden in terms of hospital days and costs.[110] In comparing infants with a diagnosis of NAS with non-NAS infants between 2003 and 2012, NAS admissions increased more than fourfold, resulting in a surge in annual costs from $61 million and 67,869 hospital days in 2003 to nearly $316 million and 291,168 hospital days in 2012. For an infant affected by NAS, the hospital stay was nearly 3.5 times as long (16.57 hospital days compared with 4.98 for a non-NAS patient) and the costs more than three times greater ($16,893 compared to $5,610 for a non-affected infant).[111]

Children living in homes with drug abusers have numerous challenges, including the potential for exposure to drug production, chemicals, or equipment, neglect because the caregiver is using, abusive behavior towards the child,[112] risk of removal from their family, and/or exposure to the criminal sale or distribution of drugs.[113,114]

Labor Force. The Labor Force Participation Rate has declined since 2007, primarily due to an aging population and effects of the Great Recession. However, a recent Brookings Institution study examining the implications of the opioid crisis on the labor force suggests that the increase in opioid prescriptions could account for much of the decline in the labor force participation of "prime age men" (ages 25-54) during this same time.[115] The Bureau of Labor Statistics Time-Use Survey finds that 44% of prime age men not in the labor force acknowledged taking pain medications the previous day. The Brookings study found similar results (47% took pain medication the day before), however, nearly two-thirds of those men indicated it was *prescription* pain medication. Thus, on any given day, 31% of prime age men not in the labor force take prescription pain medication, most likely opioid based. These percentages are likely lower than the actual proportion of men who consume pain medication, due to the sigma and legal risk associated with narcotics.

Financial, Educational, Workplace, and Criminal Justice System. Prescription opioid overdose, abuse, and dependence carry high costs. In 2013, it was estimated that the total economic burden was $78.5 billion (in 2013 dollars).[116] Approximately one-third of the costs of the prescription opioid crisis are attributable to health care, and one-fourth of costs are borne by the public sector. Using data from various sources, the "monetized burden" of prescription opioid overdose, abuse, and dependence was estimated from a societal perspective, including direct healthcare costs, costs related to loss productivity, and costs to the criminal justice system. Total spending for health care and substance abuse was over $28 billion, most of which ($26 billion) was covered by insurance. In nonfatal cases, costs for lost productivity, including reduced productivity for incarcerated individuals, were estimated at about $20 billion. Fatal overdose costs related to healthcare and lost productivity were estimated at $21.5 billion. Approximately 25% of the economic burden was borne by public sector (Medicaid, Medicare, and veterans' programs) and other government sources for substance abuse treatment. Criminal justice-related costs were estimated at $7.7 billion expended by state and local governments in addition to lost tax revenue. The total estimated economic burden for prescription opioid abuse, addiction, and overdose death and heroin addiction would be approximately $111 billion (in 2013 dollars). Many costs are inestimable, including the social impact on opioid-dependent people, and the suffering of family members as witnesses to addiction or to fatal overdose.

Drug Overdose Deaths

The crisis in opioid overdose deaths has reached epidemic proportions in the United States (33,091 in 2015), and currently exceeds all other drug-related deaths or traffic fatalities. These data from the CDC are expected to rise even higher for 2016.[117] The risk of overdose resides primarily, but not exclusively, among those harboring a medical diagnosis of an OUD.[118] Of six risk markers (sex, age, race, psychiatric disorders, SUDs, urban/rural residence), SUDs have the strongest association with drug overdose death, followed by psychiatric disorders, white race, 35-44 year age group, and male sex.[119] Opioid-related death rates are higher among those who had recently been released from prison, those who doctor-shop and receive opioid prescriptions from multiple

pharmacies, and those who consume prescription opioids in combination with other scheduled medications, particularly benzodiazepines. From 1999 onwards, overdose deaths due to prescription opioids rose incrementally and consistently outpaced annual heroin death rates.

Heroin overdose deaths remained relatively low from 1999 onwards, and then escalated 4-fold from 2010-2015. Data from death certificates in 2015 revealed a disproportionate rise from the previous year in deaths attributable to fentanyl/analogs (72.2%) and heroin (20.6%), with prescription opioid-related deaths rising minimally (2.6%).

The overall death rate was higher for prescription opioids, but the most recent data show minimal increases in deaths involving prescription overdoses, while an increasing proportion now involves synthetic opioids, mainly fentanyl. Clearly, contamination of the heroin supply with fentanyl is currently driving recent increases in opioid-related overdose deaths. Reports from individual states in 2016 and 2017 confirm this emerging trend, as heroin and/or fentanyl currently account for more than 50% of the overdose deaths in specific states.[120]

Substance Use Treatment Availability

Among the many consequences of opioid misuse is the increasing need for SUD treatment services. SUD treatment facilities, particularly those providing MAT-enhanced opioid treatment programs (OTP), are uncommon in rural areas, as are physicians who can provide MAT from their offices.

Across all U.S. counties, 38% did not have a treatment facility for SUD in 2016 (Table 1).[121] Ten percent of large central metro counties did not have an SUD treatment facility. The data show that progressively larger proportions of counties did not have SUD treatment facilities as the level of urbanization decreased. Among the most rural counties, 55% did not have a substance use treatment facility.

Figure 1 below shows counties that did not have an SUD treatment facility as of 2014 by level of urbanization, and it is clear that the vast majority of counties is rural.

Table 1. Treatment Facilities for Substance Use Disorder by Level of Urbanization, 2016

Level of Urbanization	*Number of Counties*				*Percent of Counties in Level of Urbanization*			
	Total	*No Treatment Facilities for Substance Use Disorder (SUD)*	*No SUD Treatment Facilities with Opioid Treatment Programs*	*No SUD Treatment Facilities that accept Medicaid*	*Total*	*No Treatment Facilities for SUD*	*No SUD Treatment Facilities with Opioid Treatment Programs*	*No SUD Treatment Facilities that accept Medicaid*
Large Central Metro	68	7	8	7	100%	10%	12%	10%
Large Fringe Metro	368	88	259	104	100%	24%	70%	28%
Medium Metro	373	100	242	116	100%	27%	65%	31%
Small Metro	358	100	267	121	100%	28%	75%	34%
Micropolitan (non-metro)	641	157	586	204	100%	24%	91%	32%
Non-core (non-metro)	1,333	728	1,321	800	100%	55%	99%	60%
United States	*3,141*	*1,180*	*2,683*	*1,352*	100%	38%	85%	43%

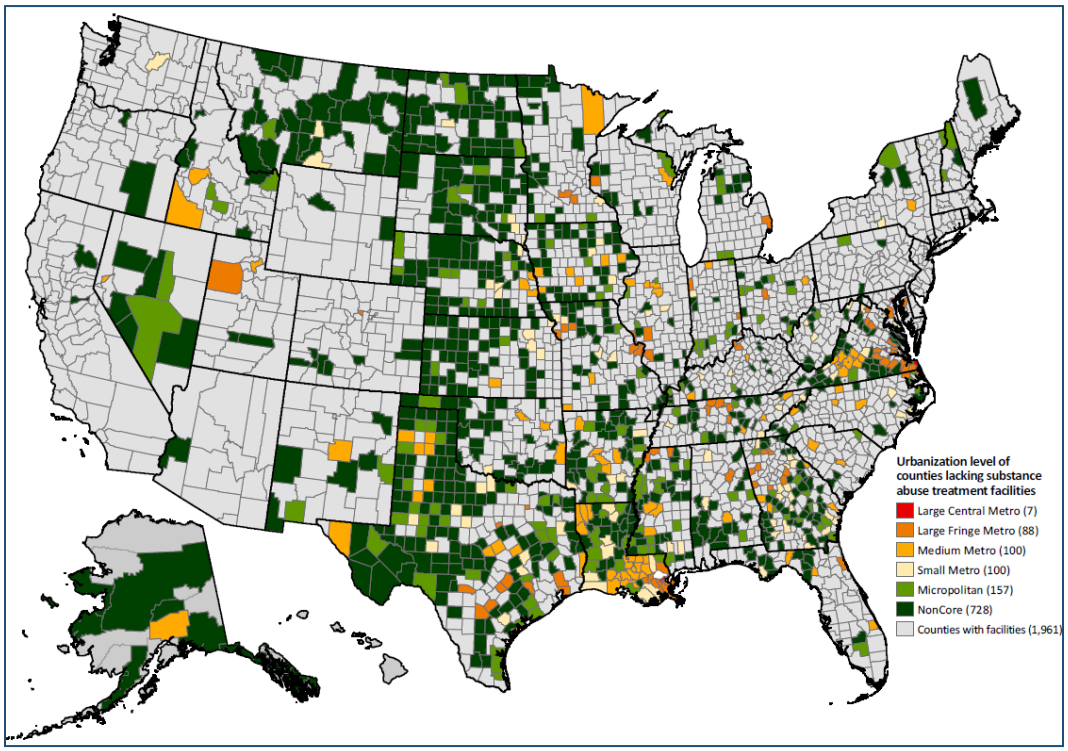


Figure 1. Counties with No Treatment Facilities for Substance Use Disorder by Level of Urbanization

Furthermore, 85% of all U.S. counties have no OTPs that provide MAT for people diagnosed with an OUD (Table 1). These facilities are concentrated in large central metropolitan areas, where 88% of these counties have at least one treatment facility offering OTP (only 12% of these central metropolitan counties do not have OTP facilities). For other metropolitan counties, 65 to 75% do not have OTP facilities, but among rural counties, almost all (91 to 99%) lack an OTP facility.

Figure 2 shows counties that did not have an OTP facility as of January 2016; as with SUD treatment facilities generally, the vast majority of these are rural counties. Many large fringe and medium metropolitan counties appear as doughnut-shaped areas around core locations where OTP facilities are located, but many rural counties are located far from OTP facilities.

Data were also obtained on the locations of physicians that can dispense buprenorphine from their offices.[122] Physicians can provide MAT for OUD treatment in settings other than OTP facilities, including dispensing buprenorphine from their offices. To prescribe or dispense buprenorphine for OUD treatment, qualified physicians must receive waivers from the DEA under the terms of the *Drug Addiction Treatment Act of 2000* (DATA 2000). As of February 2016, 47% of counties nationwide did not have a waived physician (Table 2). However, when classifying the county locations of waived physicians according to level of urbanization, the rural-urban disparities become clear. None of the large central metro counties, and 72% of the most rural counties, did not have a waived physician (Figure 3). The vast majority of counties without buprenorphine-waived doctors are rural. However, it is worth noting that the number of patients a physician can treat with buprenorphine is capped; so, having a waived physician within a geographic area is not necessarily indicative of sufficient access for county or city residents.

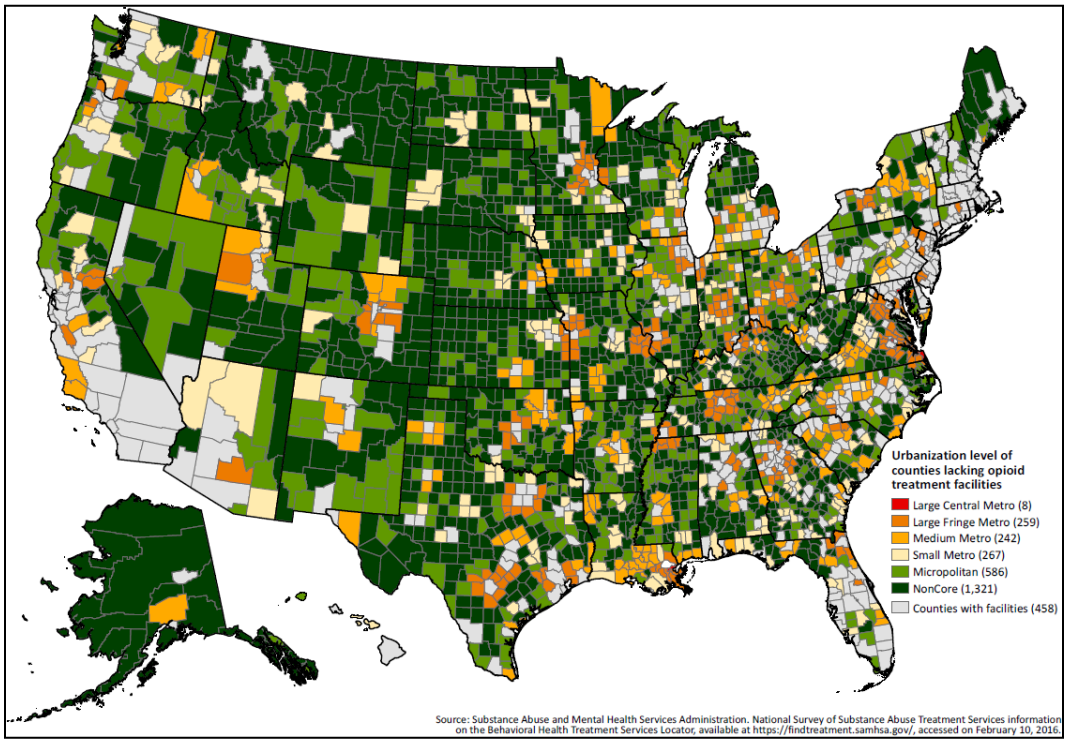


Figure 2. Counties with No Opioid Treatment Program Facilities by Level of Urbanization

While utilization of SUD treatment services in both rural and urban areas is challenged by many factors, the nature of these challenges varies. For example, findings from focus groups of counselors in rural areas noted a dearth of good facilities, poor access due to clients living far away from treatment centers, reliance on friends or family for transportation, and a need for basic medical and dental services. These factors were not mentioned by urban counselors.[123] A recent study of SUD treatment facilities that accept Medicaid also found that rural residents are less likely to have such a facility.[124]

Table 2. Physicians Waived to Dispense Buprenorphine by Level of Urbanization, 2016

Level of Urbanization	*Number of Counties*				*Percent of Counties in Level of Urbanization*			
	Total	*No Waived Doctors*	*1-5 Waived Doctors*	*More than 5 Waived Doctors*	*Total*	*No Waived Doctors*	*1-5 Waived Doctors*	*More than 5 Waived Doctors*
Large Central Metro	68	0	0	68	100%	0%	0%	100%
Large Fringe Metro	368	86	107	175	100%	23%	29%	48%
Medium Metro	373	107	86	180	100%	29%	23%	48%
Small Metro	358	113	103	142	100%	32%	29%	40%
Micropolitan (non-metro)	641	219	332	90	100%	34%	52%	14%
Non-core (non-metro)	1,333	964	340	29	100%	72%	26%	2%
United States	*3,141*	*1,489*	*968*	*684*	100%	47%	31%	22%

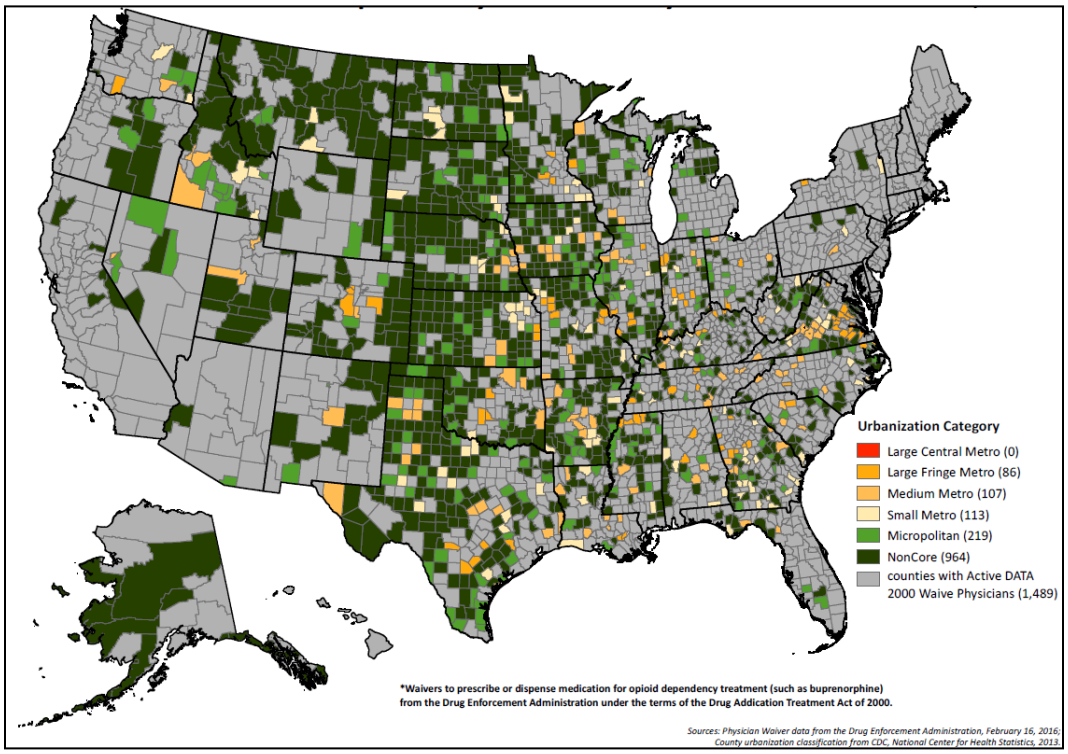


Figure 3. Counties with No Physicians with Buprenorphine Waivers by Level of Urbanization, 2016

Systems Approach to Solutions

There has never been a time more appropriate or opportune to develop effective and cost-effective policies for addressing substance use and disorders in our nation. A systems approach can facilitate development of recommendations and solutions to this dynamic and ever-shifting challenge. This report addresses solutions to each of the core components of the crisis, a trajectory which begins

with drug supply, attitudes towards drug use and knowledge of opioids, risk factors for misusing, and progresses to addiction, transition to heroin/fentanyl, situational factors in overdose, rescue, treatment, relapse prevention, recovery support, and continuum of care (Figure 4). Over the past decade, large databases have accumulated to inform policies and associated budgets.

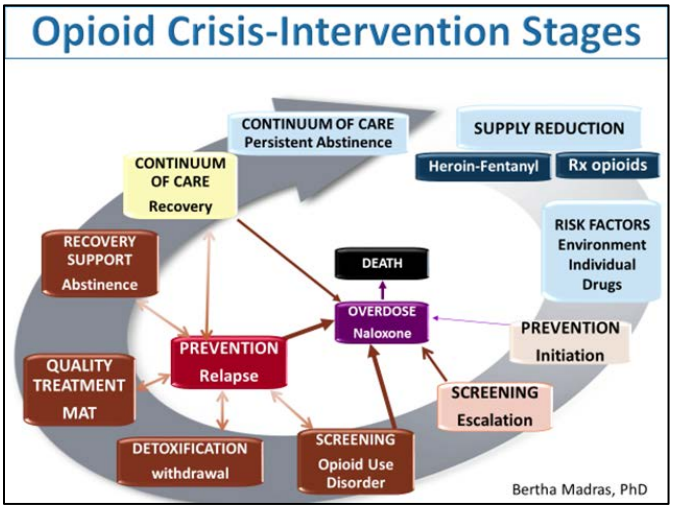


Figure 4. Opioid Crisis-Intervention Stages

The most urgent goals and readily quantifiable achievements will be a reduction in overdose episodes and deaths, increased entry into and adherence to high quality treatment, and a reduction in prescribed opioids. More complex models are needed to address whether prescribing policies result in time-dependent reductions in prescription opioid diversion or increase heroin/fentanyl use, who is at risk for transitioning to heroin or fentanyl, the incidence and prevalence of OUD, and others. The opioid epidemic defies standard medical and legal models for addressing addiction and trafficking. Limited data exists to track the crisis and identify weaknesses in current responses (e.g. prescribing practices, treatment availability, individuals at risk), but is held in different databases across a multitude of public and private organizations, and significant proportion is not in real-time.

Building a secure data foundation that promotes cross-entity collaboration while protecting privacy is a challenging but necessary step to save lives, expand treatment options, and effectively prevent further spread of this deadly epidemic. The data exists but resides in agency silos, or in the private sector providing analytics for specific industries (e.g. pharmaceutical or healthcare insurers), making it difficult to act upon the information. **The Federal Government should create an integrated data environment that brings together publicly available data with agency-specific data to help address this epidemic.** Often, the same data viewed through a different lens can support multiple parts of the problem. For example, doctors can use prescription drug monitoring programs (PDMPs) to check patient records, while law enforcement can use PDMPs to identify prolific opioid prescribers and public health agencies can use it to identify and intervene in a potential victim pool before overdoses occur – different, but all valuable uses of the same data.

This kind of effort would not require a new data warehouse or standardization initiative; the integrated data environment can immediately integrate existing data sources.

Federal Funding and Programs

On page 87 of the report, there is a full breakdown of federal funding sources for drug-related activities, including interdiction, prevention, and treatment. As shown in that section, the federal funding landscape is complex, exists in silos, potentially duplicative, and supports hundreds of on the ground programs.

Streamlining Federal Funding for Opioids and Consideration of State Administrators

One of the first activities the Commission Chair undertook was a series of calls with Governors' Offices in nearly all 50 states. A number of themes emerged from those calls that are reflected in this report and the recommendations. Regarding funding, many Governors and senior staff members expressed concern at how addiction and opioid-related funding coming from the Federal Government was fragmented; provided by many different agencies and funding sources which each had their own application requirements, reporting mechanisms, and preferred outcomes.

It is clear that each federal agency has goals related to reducing drug use and misuse and provides funding for such activities. However, from the vantage points of states, this funding is not well coordinated, and applying for funding from the many different agencies, is a tremendous administrative burden for states.

The SAMHSA block grants provide a formula-based grant to states for treatment activities; if additional funding opportunities could be rolled into the SAMHSA block grant, or combined to form larger block grants that required one application and one set of reporting requirements, that would free up state resources to focus on implementation activities, rather than paperwork.

Some states have identified a State Administrator to coordinate opioid and addiction activities. Others may use their Single State Authorities for substance abuse services to serve as an effective point of contact or liaison regarding most federally-supported demand reduction efforts in a state—although they may not always have up-to-date information on Department of Health and Human Services (HHS) or Department of Justice (DOJ) discretionary grant activities not directly involving the state. Regardless of the single entity that is identified by the state, the Federal Government should have a comparable single entity point of contact to help track activities related to discretionary grants with a demand reduction focus.

The Office of National Drug Control Policy's (ONDCP) core function is to develop and coordinate the implementation of national drug policy, but it does not have appropriate staff or organizational units to track federally supported demand reduction funding and activities at the program or grant level (versus the overarching policy level). The tasks of making and tracking grant awards fall squarely within the responsibility of the Departments and agencies that manage grant programs, including HHS's Regional Offices and the more recently established Substance Abuse and Mental Health Services Administration (SAMHSA) Regional Directors stationed in these offices. It therefore would seem reasonable for HHS to support ONDCP in this function by serving as an intermediary with Single State Authorities in the 50 states, the District of Columbia, and the territories. By so leveraging HHS and SAMHSA regional infrastructure, ONDCP could maintain timely accounting and ongoing awareness of the current allocation of federal demand reduction funding and the coordination of federally supported initiations, their contribution to activities

funded at the state and local level, duplication or inefficiencies that may need to be addressed, and timely scrutiny the program effectiveness of federally-or-state-funded programs. This would assist ONDCP to become aware of promising practices emerging at the state level.

1. **The Commission urges Congress and the Administration to block grant federal funding for opioid-related and SUD-related activities to the states, where the battle is happening every day. There are multiple federal agencies and multiple grants within those agencies that cause states a significant administrative burden from an application and reporting perspective. Creating uniform block grants would allow more resources to be spent on administering life-saving programs. This was a request to the Commission by nearly every Governor, regardless of party, across the country.**
2. **The Commission believes that ONDCP must establish a coordinated system for tracking all federally-funded initiatives, through support from HHS and DOJ. If we are to invest in combating this epidemic, we must invest in only those programs that achieve quantifiable goals and metrics. We are operating blindly today; ONDCP must establish a system of tracking and accountability.**

Funding Effective Opioid-Related Programs

As stewards of taxpayer dollars, the Federal Government must ensure that programs demonstrate effectiveness in achieving the desired policy outcomes. While various assessments have demonstrated that treating and preventing substance use are effective in reducing the costs associated with health care, the workplace, and criminal justice system, these costs-benefit analyses were done at the system, not program, level.

At the program level, the Federal Government has a long history of undertaking a variety of efforts, varyingly referred to as strategic planning, performance management, program evaluation, or performance budgeting, to inform management decisions for program and policy officials. These efforts have contributed to significant investments being made in the development of an evidence base for effective programs. However, comparing the effectiveness of programs has proven more elusive, and looking at system-wide cost effectiveness is rare. Research studies in addition to private and public-sector analyses may be of value to Federal efforts to develop and implement cost-benefit evaluations. For example, the Washington State Institute for Public Policy maintains a list of available, evidence-based public policy options and ranks them by return on investment.[125] While not a complete list, such ranked lists provide policymakers with a better understanding of the likelihood of which, of the many policy options available, are most likely to produce more benefits at lower costs.

Given the substantial challenges of the heroin and prescription opioid epidemic, it is critically important that the Federal Government maximize the impact of its response by supporting the most effective programs and policies to reduce the number of individuals affected by OUDs and end the nation's opioid epidemic. A thorough review of programs and policy options would assist the Director of ONDCP in making recommendations on how to best allocate scarce federal resources to achieve the objectives of the *National Drug Control Strategy*.

3. **To achieve accountability in federal programs, the Commission recommends that ONDCP review is a component of every federal program and that necessary funding is provided for implementation. Cooperation by federal agencies and the states must be mandated.**

Opioid Addiction Prevention

It is important to consider that the national crisis is not only about prescription or illicit opioids. We are focusing on this class of substances, but prevention efforts need to be broader because the removal of one substance conceivably will be replaced with another.

To address the opioid and addiction epidemic, it is vital to make substance use and misuse prevention a much higher priority and stop the pipeline into addiction. In the first Commission meeting, General Arthur Dean, speaking on behalf of Community Anti-Drug Coalitions of America, expressed the strong belief that prevention has been underutilized, relative to its importance and cost-effectiveness in preventing or reducing drug use and misuse and the related human and societal costs. The American Society of Addiction Medicine (ASAM) and the Addiction Policy Forum both recommended the launch of a national public education campaign, similar to the one developed for the AIDS epidemic in the 1980s, to raise awareness that addiction is not a moral failing, but rather a chronic brain disease, and that evidence-based treatment is available.

A generalized prevention campaign should address use of illicit drugs with abuse potential, as they can progress to addiction. Addiction is the most prevalent and costliest of neuropsychiatric disorders and the leading cause of premature, preventable deaths and disability in the United States. Of the ~2 million annual deaths in the United States, one-quarter are attributable to the consequences of tobacco, alcohol, opioids, and other drugs. Drugs impact every sector of society – individuals, families, communities, healthcare systems, educational environment, workplace, traffic safety, and the criminal justice system. Studies investigating the effects of drugs in the brain, body, and on behavior has yielded a vast base of information over the past twenty years, relevant and indeed critical information for public education. These research discoveries have outsized power and potential to heighten awareness and promote prevention, but their impact has been limited by discontinuities in translating research into effective prevention messages and broadcasting them widely. The current opioid crisis dramatically illustrates an unfulfilled need for expanded educational outreach to new generations of youth, their parents and the general population. Youth are more susceptible to addiction and are a key target cohort for prevention. The vast majority of users fall into 16-34 age category, a peak period for pregnancy, parenting, and for adverse consequences of drugs: addiction, underemployment, health issues, accidents, and trauma. It is well recognized that use rates are inversely correlated with perception of risk, yet effective state-of-the-art, credible, compelling, and comprehensible information on the risks and adverse health consequences of drugs has not been mounted to reverse these trends.

The National Institute on Drug Abuse's (NIDA) Drug Facts Chat Day website (http://drugfactsweek.drugabuse.gov/chat/) offers some insights into young people's curiosity for accurate information about drugs and the lack of accessibility to information. Teenagers from around the nation are offered a day-long session to ask NIDA staff their personal question about drugs. A sampling of questions is listed below:

- What is in drugs that make it so addictive?
- What should you do if a parent is doing drugs?
- Do drugs kill brain cells?
- Is drinking worse than smoking?

During this nation's worst drug crisis, there is no more opportune time to launch a national prevention campaign that highlights the hazards of substance use, but also focuses on the opioid crisis: (1) to educate the public on risks and consequences of drug use in general, with emphasis on opioids; (2) to focus on the vulnerable - adolescents, college age students, pregnant women, those harboring a psychiatric disorder, and the elderly - and highlight the detrimental effects of opioids; (3) to convey to parents their critical role in determining their children's use of drugs; (4) to show parents how to engage in crucial conversations with children about drugs; (5) to dispel common myths and misinformation on drugs; (6) to educate families on warning signs in family members and on reducing environmental risks for children; (7) to advance the concept of addiction as a treatable brain disease; and (8) to tailor messages to specific populations and communities in need. Many sources of information exist from government agencies (e.g. NIDA, SAMHSA, National Institute on Alcohol Abuse and Alcoholism [NIAAA], DEA) or on websites of non- and for-profit private organizations. The reach of these websites is limited, and their impact and value undetermined. Creative strategies are needed to engage much larger populations, with accountability on effectiveness.

Notably, recent surveys indicate that parents can be key contributors to a child's use or non-use of drugs**.** Youth alcohol or marijuana use was 5-7-fold lower if parents took a strong stance against use, compared with parents whose views were ambivalent. Systematic reviews have reinforced this conclusion.[126,127] Yet, parental knowledge is limited, as illustrated by examples from a recent survey:

a) Nine of ten parents do not think that teens spending time on social networking sites like Facebook are likelier to drink or use drugs. Yet, teens who spend time on a social networking site in a typical day are much likelier to use tobacco, alcohol, and other drugs than teens who don't spend time on a social networking site in a typical day; [128]
b) When asked, "do you consider it necessary to take steps to keep your child from having access to prescriptions for painkillers such as Oxycontin, Vicodin or Percocet in your home?," 57% of parents with prescription pain killers in their home did not consider it necessary to prevent their child from accessing the prescriptions,[129] even though more than 50% of people who misuse prescription pain killers obtained them for free from friends and family.[130] Yet, the 2016 national survey indicates that parental attitudes are critical in determining youth drug use.[131]
c) One-third of parents surveyed reported that it was "very likely" or "somewhat likely" that their teen would "try drugs (including marijuana or prescription drugs without a prescription to get high) at some point in the future." Yet, if parents are perceived to disapprove of marijuana use, use among youth is approximately 9 times lower. [132]

Parents have been under-represented in prevention programs, even though evidence is robust that parent-based prevention programs can play a pivotal role in delaying the onset and use of alcohol and other drugs, an influence that persists during adolescent development. Furthermore, universal prevention programs are enhanced with inclusion of parent-based components.[133] In a systematic review of studies which combined student- and parent-based programs to prevent or reduce adolescent alcohol, tobacco or marijuana use, effectiveness was shown in the majority of studies.

In summary, there is a compelling need to integrate evidence-based prevention programs in large scale outreach programs within schools. With tools for teachers and parents to enhance youth knowledge of the dangers of drug use, early intervention strategies can be implemented for

children with environmental and individual risk factors (trauma, foster care, adverse childhood experiences [ACEs], and developmental disorders).

Evidence-based Prevention Programs

Substance abuse prevention is a process which requires a shift in behavior, culture, and community norms. An investment in prevention requires meaningful outcome measures planned in coordination with the program. Demonstrated evidence of program effectiveness can include delaying the age of initiation of substance use, decreasing the number of new or current users, decreasing the frequency of use, reducing the adverse consequences of use (e.g. effect on school grades, employment, and others), decreasing use among contacts,[134] and duration of effect. When evidence-based programs are selected for specific populations and implemented with fidelity, they can be effective. Prevention programs need to be tested for scalability, fidelity, and sustainability after research champions are no longer present to drive programs. Prevention is most successful when messages are consistent, culturally-appropriate, repeated at home, reinforced in schools, workplaces, and community organizations, and delivered by influential adults and peers.

NASEM has described three categories of prevention interventions: universal, selective, and indicated. These interventions have been researched based on targeted populations and risk factors (e.g. schools, parents, or youth). Risk and protective factors are influential at different times during development, and they relate to changes that occur over the course of development. Risk factors can interrupt developmental patterns and it is therefore important to implement programs designed for early developmental periods by building on the strengths of the child or caregiver. Intervening early in childhood can alter the life course trajectory in a positive direction.[135]

Below is a description of the three categories of prevention interventions that target several risk factors and increase protective factors:

- Universal interventions attempt to reduce specific health problems across all people in a particular population by reducing a variety of risk factors and promoting a broad range of protective factors. Examples of universal programs include:
  - Good Behavior Game[136]
  - Nurse Family Partnership[137,138]
  - Life Skills Training (LST)[139]
  - Strengthening Families Program 10-14[140]
  - Communities that Care[141]

- Selective interventions are delivered to particular communities, families, or children who, due to their exposure to risk factors, are at increased risk of substance misuse problems. Selective interventions may include families living in poverty, the children of depressed or substance using parents, and children who have difficulties with social skills or may have experienced trauma. Examples of selective programs include:
  - Coping Power[142]
  - Focus on Families[143]

- Indicated interventions are directed to those who are already involved in a risky behavior, such as substance misuse, or are beginning to have problems, but who have not yet developed an SUD. Examples of individual intervention programs include:
  - Project Toward No Drug Abuse
  - BASICS
  - Keepin' it Real

School programs implementing environmental approaches targeting children focus on building a repertoire of positive competencies, including in the areas of academics, self-regulation, and social skills. Teachers can focus on interventions in the classroom for those who may need support with self-regulation and social skills. Increasing the capacity of teachers by training them in classroom management strategies (e.g. establishing clear rules and rewards for compliance, teaching interactively, and promoting cooperative learning) provides them with the skills for managing behaviors and teaching children self-regulation.[144] Risk and protective factors can be influenced by the choice of programs and policies at multiple levels, including federal, state, community, family, school, and the individual.

One advantage of a properly implemented universal prevention intervention is that it is likely to reach most or all the population (e.g. school-based interventions are likely to reach all students). Targeted (selective and indicated) approaches provide more intensive services to those who are reached. It is prudent for communities to provide a mix of universal, selective, and indicated preventive interventions.[145]

SBIRT as a School Prevention Strategy

SBIRT is an evidence-based systematic method to screen for problematic use of all substances and, depending on a cumulative score, follow up with a brief intervention or referral to specialty treatment. The service was catapulted more widely into healthcare systems following a report from the Federal Government demonstrating effectiveness in reducing substance use,[146] and the advent of billing codes to reimburse for these services.[147] Although traditionally developed for clinical care, SBIRT services have been increasingly offered in high schools and universities. School nurses and counselors are uniquely positioned to discuss substance use among young people.

In 2016, Massachusetts passed a bill enabling appropriately trained staff to reinforce prevention, screen for substance use, provide counseling and make referrals as necessary to all adolescents, including students in upper elementary grades. Adolescent SBIRT focuses on prevention, early detection, risk assessment, brief counseling and referral intervention that can be utilized in the school setting. Use of a validated screening tool (CRAFFT) focused on adolescents has enabled school nurses and counselors to detect risk for substance use-related problems and to address them at an early stage in adolescents. The bill requires all public-school districts in Massachusetts to screen seventh and 10th graders for potential drug use, and is viewed as a way to interrupt the potential use of drugs, including opioids, at an early stage. The screenings do not involve drug tests, but rather a screener (school nurse or psychologist trained in conversations on drug use with youth) to determine through a conversation/questionnaire if the student is engaged in risky substance use. The intent is to identify students who need help and to try to motivate them into treatment. Students or parents can opt out of the screening and parents are not immediately notified of the screening results to protect students' privacy. Parents are notified only in severe cases of addiction.

Previous research showed that 14.8% of adolescents had positive results on the CRAFFT screen. Prevalence rates differed significantly across practices after adjusting for demographic factors. The highest positive rates on the CRAFFT screen were at school-based health centers (29.5%) and the rural family practice (24.2%), the middle rate was at the adolescent clinic (16.6%), and lowest rates were at the health maintenance organization (14.1%) and pediatric clinic (8.0%). Sick visits had the highest rate (23.2%). Well-child care visits had a significantly lower rate (11.4%). Statistical modeling estimated that 11.3% of all patients had problematic use, 7.1% reported abuse, and 3.2% had an SUD. Substance abuse screening should occur whenever feasible, and not only at well-child care visits.[148] Recently the State of New Mexico has begun a program for universal screening,[149] the State of New York has initiated SBIRT trials,[150] and calls for universal screening using validated SBIRT screening tools are increasing.[151]

Ohio State University developed an SBIRT course with the goal of making SBIRT accessible for use on college and university campuses nationwide. To meet this goal, the Higher Education Center for Alcohol Drug Misuse Prevention and Recovery developed ScreenU, a web-based program that allows SBIRT to be implemented with college students either independently or together with a campus professional. ScreenU identifies students who are misusing alcohol or prescription drugs and provides feedback and strategies to reduce their risk for experiencing negative consequences from their use.

4. **The Commission recommends that Department of Education (DOE) collaborate with states on student assessment programs such as Screening, Brief Intervention and Referral to Treatment (SBIRT). SBIRT is a program that uses a screening tool by trained staff to identify at-risk youth who may need treatment. This should be deployed for adolescents in middle school, high school and college levels. This is a significant prevention tool.**

Mass Media Public Education Campaigns

Mass-media campaigns are one of the primary universal prevention strategies for delivering educational messages on health promotion to youth and adults. A review of the literature provides an overview of the lessons learned from research on mass-media campaigns. The literature is quite clear that mass media campaigns can increase awareness of messages but are not always successful in changing attitudes, beliefs, or behaviors.[152] Mass-media campaigns tend to work best when they are well-targeted and supported by comprehensive community-based efforts that coordinate clinical, regulatory, economic, and social strategies. In addition, funding for local prevention interventions that prevent initiation of a behavior and treatment programs that promote abstinence and recovery are important.

In addition to policies and strategies that help create environments that are less conducive to substance use, mass media campaigns can focus on either directly influencing individual level predictors or influencing an individual's behavior through targeting others within youths' social environment. The former strategy looks to increase knowledge about a particular drug, its negative health effects, self-efficacy in declining or stopping use, beliefs about the drug, and social norms about licit and illicit drug use. The latter includes messages which discourage young people from pressuring friends to use.[153]

Regardless of the approach, for a mass-media campaign to be effective, it is critical to develop coherent, credible, evidence based-messages that are grounded in behavioral science.[154] This is critical to counteract the meta-messaging that drug use in society is pervasive and normal.[155] Media messaging also must strategically target populations with culturally appropriate messages, take advantage of multiple media platforms, and have sufficient resources to provide broad exposure over a significant period of time to ensure an effect. Branding the campaign also has been shown to enhance the impact of public health messaging as has integrating a media literacy component that helps train youth and young adults to critically view messages about substance use, be they within television shows, movies, or advertising.

The literature is very limited on mass-media campaigns focusing on prescription opioids, and even less on heroin and other opioids. There is a more robust literature on lessons learned from mass-media prevention campaigns on alcohol and tobacco, which have been incorporated.

ONDCP's earlier paid advertising campaign, the *National Youth Anti-Drug Media Campaign*, targeted young people aged 9 to 18 years, their parents, and other influential adults. It used a combination of television, radio advertising, other media, and community programming with the goals to educate and enable youth to reject illegal drugs, prevent youth from initiating use of drugs, especially marijuana and inhalants, and convince occasional users of marijuana and other drugs to stop using. A comprehensive evaluation of the campaign[156] found substantial evidence that the campaign favorably impacted parents on measures such as thinking about and talking with their children about drugs, doing fun activities with their children, and beliefs about monitoring their children, but found little favorable direct effects of the campaign on youth. The evaluation found there were significant delayed unfavorable effects of exposure to the campaign on social norms and perceptions of use by youth; greater exposure was associated with weaker anti-drug norms. Additionally, greater exposure may have led to higher rates of initiation of marijuana use. Also, there was no evidence found to suggest that higher exposure to the campaign had any impact on quitting or reducing use.

Governor Otter shared with the Commission Chair the successes of the Idaho *Meth Project*, a large-scale prevention program founded in 2005 with the aim to reduce methamphetamine use through a comprehensive approach including public services messages, public policy approaches, community outreach, and in-school lessons. *The Meth Project* reports that 94% of teens that are aware of the anti-meth campaign ads say they make them less likely to try or use meth, and that Idaho has experienced a 56% decline in teen meth use since the campaign began in 2007. In a pooled analysis of sites, including from Colorado, Georgia, Hawaii, Idaho, Montana and Wyoming, no evidence was found of change in past month use among subjects aged 12-17.[157] However, there was evidence of reduction in past year use among this age group. In Idaho, this initiative was re-branded in 2016 as the *Idaho Prevention Project* to include opioids and prescription drugs.

Another study evaluated the impact of the SENsation seeking TARgeting approach (*SENTAR*) focusing on anti-heroin public service announcements (PSAs) on processing, affect, and anti-heroin attitudes in a sample of 200 young adults.[158] Building on previous work,[159] this study recruited subjects from communications courses at a large Midwestern University exposing them to 30-second anti-heroin PSAs selected from a larger pool of PSAs produced by the Partnership for a Drug Free America. It utilized data from the 5-year television-based media campaign using public service announcements targeting messages. They found that high-sensation seekers' anti-

heroin attitudes were largely influenced by narrative and sensory processes and low sensation seekers' anti-heroin attitudes were relatively unaffected by anti-heroin ads.

A national education campaign focused on opioids could be modelled after *The Real Cost*, an existing award-winning youth tobacco prevention campaign from the FDA. *The Real Cost* seeks to educate at-risk teens about the harmful effects of tobacco use with the goal of preventing youth who are open to using tobacco from trying it and reducing the number of youth who move from experimenting with tobacco to regular use. It was launched nationally in February 2014 across multiple media platforms including TV, radio, print, web, social media, and out-of-home sites, like billboards. Initial campaign advertising focused on reaching the nearly 10 million youth ages 12-17 in the United States who are either open to trying smoking or are already experimenting with cigarettes. Results from the first evaluation published in 2015 indicated that 9 out of 10 youth reported seeing *The Real Cost* ads seven months after the campaign launch and that the campaign positively affected tobacco-related risk perceptions and beliefs after 15 months. Further, from 2014-2016, the campaign was associated with a 30% decrease in the risk of smoking initiation which translates into preventing an estimated 350,000 youths aged 11-18 from smoking.[160]

Media Campaign Focusing on Opioids

A national prevention strategy with a comprehensive public health mass media campaign supported by evidence-based prevention programs is timely and essential. The goals would include: (a) universal drug prevention messages, as current or past SUDs predispose individuals to misusing opioids, and polysubstance use disorders are common; (b) youth-directed messages, as they are more susceptible to addiction and other adverse consequences; (c) prevention messages specific to opioids, to include patient and family education on what opioids are, the hazards of opioids, safeguarding of prescription medications, and disposing of unused pills; (d) the common hazards of illicit and prescription opioids; and (e) availability of treatment resources. Media campaigns are commonly used to deliver preventive health messages and to shape healthy behaviors and attitudes. There are several successful state, local government and grassroots media campaigns aimed at providing drug-related public education or assistance in locating appropriate help for children. During the first Commission meeting on June 16, 2017, the Commission heard about one such campaign from the Partnership for Drug-Free Kids, who have worked with national and local media partners, as well as private sector partners like Google and Facebook, to run public service announcements that inform parents on available help for their loved ones. Similarly, Commission Chairman Governor Christie has implemented a media campaign in New Jersey around opioid addiction and a help hotline and website.

A comprehensive public health mass media campaign should be conceived carefully, pilot tested on target audiences, quantitative goals established, and outcomes measured that are matched to goals. Initially, accurate, anonymous, and actionable national data can be collected by probing the internet about the opioid crisis and, more broadly, youth attitudes towards drugs. Data analytical industries are capable of uncovering the extent, locations, spread, who are most affected by specific drugs being used, and how they are obtained by surveying the web in real-time with keywords.[161] These probes can also identify treatment barriers, including shame, stigma, mistrust, cost, service availability, service preference, treatment avoidance, perceptions of service quality, and denial of service. Probes and interactive dashboards can scientifically test the potential success of public health video and other multi-media messaging on anti-drug campaigns, and shifts in sentiments, opinions, to provide continuous real-time survey data.

Since use of specific drugs is initiated in different age ranges, the campaign would need to be shaped according to various demographics. For example, alcohol, tobacco, marijuana, and inhalant use begins, on average, in early adolescence; the use of cocaine, methamphetamine, and hallucinogens in the later teen years; the misuse of prescription drugs (e.g., stimulants, tranquilizers, barbiturates, and pain relievers) and illicit opioids typically begins in early adulthood.

There is an unmet need to launch a portfolio of *comprehensible*, *compelling*, and *universal* information to educate our nation on drug-related vulnerabilities of youth and other populations. Audiences would include teens, parents, people with psychiatric disorders, older adults, and pregnant women. Information would be created for television and for the internet, with a portfolio of animated, visual, interactive, narrated material, or videos, with minimal text, and pop-ups to counter misinformation on drug. This form of communication has the advantage of fidelity, interactivity, feedback, and sustainability.[162] It can be dispersed on social networking sites, accessible via computers, iPad, smartphones or smartwatches. The internet is rapidly evolving as the most important medium for teens, where teen beliefs and perceptions are shaped, strengthened, and shared. Web-based digital, interactive, narrated, and animated materials should focus on: (a) the hazards of opioid use; (b) the risks of adolescent drug use; (c) the risks of opioid use during pregnancy; (d) the crucial role of parents in protecting children; (e) counter common myths and misinformation on drugs; and (f) educating youth and parents on signs of an emerging SUD. As mentioned above, parents can be major influencers on a child's use or non-use of drugs, as drug use is considerably lower among youth if parents deliver strong, clear messages disapproving of drug use, are involved with their children's school work, set clear limits on children's behavior by monitoring their time, friends, and supervising activities, and communicate and connect effectively with their children.

The media campaign's messaging will need to be amplified and extended by the integrative efforts of evidence-based prevention programs at the local level, many of which receive support from the Federal Government. To achieve the desired ultimate outcome — reduction in drug use — the campaign needs the support of locally implemented evidence-based prevention programming. The campaign's messaging needs to be integrated closely with local efforts and amplified by them. Local partners could include community coalitions, such as ONDCP's Drug-Free Community grantees, schools, hospitals, law enforcement, businesses, religious institutions, and local government. In this way, strong anti-drug abuse messages tightly focused on targeted audiences would serve to raise awareness of the problem and solutions to it and improve anti-drug attitudes, beliefs and intentions, driving parents, adult influencers and youth to the local evidence-based prevention resources available to achieve the desired behavioral outcomes.

Although the funding level for the recommended campaign has not yet been determined, the initial funding request in FY 1998 for the National Youth Anti-Drug Media Campaign was $200 million per year. Those entities receiving campaign funds to air/print its messages were required to match the funds received, thus doubling the purchasing power of the federal funds. The Commission believes that a coordinated media campaign that can be rolled out nationally with a consistent message about the dangers of both illicit and prescription drugs, including opioids could effectively educate youth, parents, pregnant women, remove stigma associated with the disease of addiction, and reduce drug use and misuse.

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5. **The Commission recommends the Administration fund and collaborate with private sector and non-profit partners to design and implement a wide-reaching, national multi-**

platform media campaign addressing the hazards of substance use, the danger of opioids, and stigma. A similar mass media/educational campaign was launched during the AIDs public health crisis.

Opioid Prescription Practices

More than 20 years ago, a growing compulsion to detect and treat pain set in motion the prescribing of opioids beyond traditional boundaries of treating acute, postoperative, and procedural pain and end-of-life care. The surge in opioid supply escalated into opioid-related misuse, diversion, use disorder, overdose deaths, and the advent of deadly fentanyl analogs. One of the areas which can have the greatest impact in the opioid crisis is reducing the rate of new addictions. This can be partly accomplished by aiming to prescribe opioids to appropriately indicated patients, and that prescription durations and doses match the clinical reason for which the drug is prescribed. Some states have set firm limits on the maximum number of days of prescribed opioids at initial encounters, irrespective of pain condition.

Improving upon the CDC *Guideline for Prescribing Opioids for Chronic Pain* and Provider/Prescriber Education

In March of 2016, the CDC developed and published a guideline for prescribing opioid pain medications for adults 18 years of age and older in *primary care settings*.[163] This guideline is "intended to improve the communication between provider and patient about the risks and benefits of opioid therapy for chronic pain, improve treatment safety and effectiveness of pain treatment, and reduce the risks associated with long-term opioid therapy, including OUD and overdose." The guideline focuses on three key areas: 1) determining when to initiate or continue opioids for chronic pain; 2) opioid selection, dosage, duration, follow-up and discontinuation; and 3) assessing risk and addressing harms of opioid use. Prescriptions by primary care clinicians account for nearly half of all dispensed opioid prescriptions, and the growth in prescribing rates among these clinicians have been above average. More importantly, use of prescription opioids for more than 90 days increases the risk of progression towards addiction.[164] A CDC "Morbidity and Mortality Weekly Report" published in July 2017 found that while prescriptions for opioid medications have decreased since 2010, substantial variation in opioid prescribing was observed at the county-level across the U.S.,[165] demonstrating "the need for better application of guidance and standards around opioid prescribing practices."

In the first Commission meeting, the Commission heard from various medical societies about the need to promote expanded implementation of the CDC opioid prescribing guideline. However, while many professional organizations encourage use of the CDC guideline, it is important to note the Commission received a substantial amount of correspondence from patients who currently use opioid medications for legitimate medical reasons and are worried about the guideline being too restrictive for their physicians to properly treat them. Clinicians have added their concerns about the CDC guideline, including the time required to discuss alternative forms of pain control, the difficulty in obtaining reimbursement for alternatives, how to address opioid tapering, and concerns with the prescribing guideline for specific forms of pain. Furthermore, it is important to point out that the CDC guideline is intended for *primary care clinicians*, who are treating patients

for chronic pain in outpatient settings, and more latitude in decision making should be given to physicians that have specialized training in pain management. The Commission also recognizes that the CDC guideline may not include specific recommendations regarding patient education and informed consent.[166] Patients are often ill-informed about the risks of taking opioid analgesics and, therefore, are not able to balance the potential benefits of opioid analgesics with the associated risks.

While progress has been made in training prescribers and fostering the adoption of prescribing guidelines such as the CDC guideline, the Commission has learned that not all states have adopted the guideline, not all physicians are aware of them, and sound opioid prescribing guidelines are far from universally followed. For example, while the CDC guideline, as well as guidelines from the VA and the Department of Defense (DOD), recommend clinicians use baseline and periodic urine testing as part of a comprehensive plan to ensure the safe and effective use of opioid therapies, not all states have placed sufficient emphasis upon the utility of medication screenings. In the current crisis, drug testing not only allows providers to assess proper use of prescribed medications in individual patients, but it would also be part of a broader solution in fighting the opioid crisis, as it can provide a snapshot of controlled prescription drugs and illicit drugs available in a community.

Consequently, the Commission recommended in the interim report that medical education and prescriber education initiatives in proper opioid prescribing and risks of developing an SUD be mandated (Appendix 3).

Stakeholders important to the adoption of prescribing guidelines include public and private payers, medical and dental schools, physician and pharmacy groups, insurers, and health care associations. Medical associations have developed courses for proper opioid prescribing practices, with support from federal grants and made them available online for free.[167,168,169,170] Federal agencies have also compiled lists of courses in compliance with the CDC guideline.[171,172] It is imperative that all DEA registrants prescribing scheduled drugs develop proficiency in pain management and opioid prescribing. In recognizing that OUD is associated with or preceded by other SUDs, training on diagnosis and office-based treatment of addictions should also be implemented for all stages of professional activity, including medical school, residency, practicing clinicians, and all others legally permitted to prescribe scheduled drugs.

Given that the practice of medicine, including prescribing, is regulated primarily at the state level, strategies for ensuring that prescribers are better informed and that patients are educated about the relative risks and benefits of opioid analgesics should incorporate state governments. Many states have acted to improve the safety of opioid prescribing. In July 2016, for example, 45 state governors signed the *Compact to Fight Opioid Addiction*[173] under which signatories agreed to update prescribing guidelines, require pain management continuing education for prescribers, improve monitoring of providers prescribing opioids, and increase access to treatment and recovery support services through state healthcare programs.[174] In March 2016, Massachusetts passed legislation[175] limiting opioid analgesic prescriptions to a seven-day supply for first-time adult users and for minors, mandating continuing medical education (CME) credits for effective pain management, and requiring prescribers to check the state PDMP before writing a prescription for a Schedule II or Schedule III narcotic.

Since January 2012, the State of Washington has required written treatment plans for use of opioid analgesics and a written agreement between patients and prescribers outlining patient responsibilities, including: taking the medications as prescribed; providing biological samples for

toxicology testing; releasing the agreement for treatment to local EDs, urgent care facilities, and pharmacies; authorizing the prescriber to notify authorities if there is reason to believe the patient has engaged in illegal activities; and, acknowledging that it is the patient's responsibility to safeguard all medications and keep them in a secure location.[176]

A recent survey in Massachusetts found that 50% of respondents felt that painkillers are prescribed too often or in larger doses than necessary; 47% felt that getting painkillers from those who save them is too easy. Only 36% of respondents who had been prescribed an opioid were informed of the addiction potential by their prescriber either before or while they were taking the medication.[177] In 2014, 4.4 million prescriptions for Schedule II or Schedule III opioids were written for Massachusetts residents, resulting in the dispensation of 240 million pills or tablets.[178] Together, these data point to the need to explore prescriber and patient education as a component of any strategy to address the current opioid epidemic. A review of the curricula at the four medical schools in Massachusetts revealed that, although they taught components of addiction medicine, no uniform standard existed to ensure that all students were taught prevention and management strategies for prescription drug misuse.

To fill this gap, Commission member Governor Baker and the Massachusetts Secretary of Health and Human Services invited the deans of the state's four medical schools to convene to develop a common educational strategy for teaching safe and effective opioid-prescribing practices. With leadership from the Department of Public Health and Massachusetts Medical Society, the deans formed the Medical Education Working Group in 2015. This group reviewed the relevant literature and current standards for treating SUDs and defined 10 core competencies for the prevention and management of prescription drug misuse. The medical schools have incorporated these competencies into their curricula and have committed to assessing students' competence in these areas. The members of the Medical Education Working Group have agreed to continue to work together on key next steps, including connecting these competencies to those for residents, equipping inter-professional teams to address prescription drug misuse, and developing materials in pain management and opioid misuse for practicing physicians. This first-in-the-nation partnership has yielded cross-institutional competencies that aim to address a public health emergency in real time.

The following themes emerged from a literature review and from national and local standards for treating SUDs. The core competencies are meant to enhance medical student training in primary, secondary, and tertiary prevention strategies for prescription drug misuse and to provide students with a strong foundation in prevention, identifying SUDs, and referring patients to appropriate treatment. These competencies are designed to serve as a vital bridge between undergraduate medical education and residency training.

1. Evaluate a patient's pain using age, gender, and culturally appropriate evidence-based methodologies.
2. Evaluate a patient's risk for SUDs by using age, gender, and culturally appropriate evidence-based communication skills and assessment methodologies, supplemented by relevant available patient information, including but not limited to health records, prescription dispensing records (e.g., the Prescription Drug Monitoring Program), drug urine screenings, and screenings for commonly co-occurring psychiatric disorders (especially depression, anxiety disorders, and posttraumatic stress disorder).
3. Identify and describe potential pharmacological and nonpharmacological treatment options, including opioid and nonopioid pharmacological treatments for acute and chronic

pain management, along with patient communication and education regarding the risks and benefits associated with each of these available treatment options.

- Secondary prevention domain: Treating patients at risk for SUDs (engaging patients in safe, informed, and patient-centered treatment planning)

4. Describe SUD treatment options, including MAT, as well as demonstrate the ability to appropriately refer patients to addiction medicine specialists and treatment programs for both relapse prevention and co-occurring psychiatric disorders.
5. Prepare evidence-based and patient-centered pain management and SUD treatment plans for patients with acute and chronic pain with special attention to safe prescribing and recognizing patients displaying signs of aberrant prescription use behaviors.
6. Demonstrate the foundational skills in patient-centered counseling and behavior change in the context of a patient encounter, consistent with evidence-based techniques.
   - Tertiary prevention domain: Managing SUDs as chronic diseases (eliminating stigma and building awareness of social determinants)
7. Recognize the risk factors for, and signs of, opioid overdose and demonstrate the correct use of naloxone rescue.
8. Recognize SUDs as a chronic disease by effectively applying a chronic disease model in the ongoing assessment and management of the patient.
9. Recognize their own and societal stigmatization and biases against individuals with SUDs and associated evidence-based MAT
10. Identify and incorporate relevant data regarding social determinants of health into treatment planning for SUDs.

Integrating the core competencies for the prevention and management of prescription drug misuse with any related competencies for residents is critical to ensuring that medical students are required to maintain and expand these skills as they enter residency training. Furthermore, the group recognized the need to expand inter-professional education opportunities designed to better equip collaborative teams for primary, secondary, and tertiary prevention of OUDs. As other practitioners, including nurses, pharmacists, dentists, and mental health providers, among others, also contribute to the provision of care, they too must demonstrate competence in this area. Finally, the group recognized the need for continuing medical education materials for current prescribers.

The level of urgency is greater than ever to develop creative solutions based on exploiting modern data mining and communication proficiencies. A more rational approach is to develop detailed and specific guidance for clinicians treating specific manifestations of pain. With modern data analytical techniques capable of interrogating vast prescribing databases, it is feasible to identify current patterns of opioid prescribing for specific conditions, recommend changes in practice patterns based on specific pain sources and medical specialties, and create active programs to educate practitioners on these recommendations. Combined with data from PDMPs, a simple electronic printout conceivably can assist in guiding a physician's decision on prescribing opioids or alternatives for pain management. Decisions on pain management can be fortified with additional information on a patient's physical and mental health status, as the complex causes of pain can arise from a confluence of biological, psychological, and social factors.

To advance this goal, providers need to be informed about suitable prescribing practices for opioids, a class of drugs which confer benefit, as well as high risk. Pharmacoepidemiology

research can facilitate improvements to the CDC guideline by initially defining existing patterns of opioid use and then developing condition-specific guidelines on optimal opioid dosing.[179,180]

To create a more useful foundation for interventions to reduce improper use of prescription opioids, much more needs to be known of existing patterns of prescription for specific conditions, including diagnosis, drug choice, dose, amount prescribed, and physician and patient characteristics. This work would draw on the extensive experience of pharmacoepidemiological analysis,[181] as well as extensive population-based datasets from both the public and private sector.[182] These studies will help to define which specific problems of opioid overuse are most prevalent in which settings in order to better focus public and private interventions on the areas of greatest need, in terms of clinical conditions, provider types, patient characteristics, and practice settings. The second and more important goal is to develop condition-specific guidelines on optimal opioid dosing. While CDC and other groups have set forth general guidelines on the principles of pain management, and some states have established uniform limits on the maximum number of tablets or capsules that can be prescribed for a first opioid prescription, clinicians need more detailed and specific guidance on drug choice, dose, and quantity to be dispensed in treating specific common conditions. Data analytics can build on the overall guidance documents prepared for pain management in general by: (a) reviewing the entire existing literature on evidence concerning condition-specific pain therapy, including recommended agents, doses, and quantities; (b) convening several expert clinician panels to generate condition-specific guidelines for managing the most common indications for pain medications; and (c) transforming that information into concise, clinically relevant, and actionable recommendations that can be disseminated to practitioners.

Pharmacists are under pressure to continue filling prescriptions from irresponsible providers. A recent study of Wisconsin pharmacists found that a not insignificant minority did not understand what is legitimate practice under federal and state laws about evaluating the legitimacy of a controlled substance prescription – also known as corresponding responsibility. Further, 36% of these pharmacists considered extended prescribing of opioids to be a violation of law or unacceptable medical practice. In the current crisis, it is critical that all pharmacists and pharmacy programs have the training necessary to responsibly dispense these medications while also not dispensing these powerful medications when the prescription is not legitimate or if it will harm the patient.[183]

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6. **The Commission recommends HHS, the Department of Labor (DOL), VA/DOD, FDA, and ONDCP work with stakeholders to develop model statutes, regulations, and policies that ensure informed patient consent prior to an opioid prescription for chronic pain. Patients need to understand the risks, benefits and alternatives to taking opioids. This is not the standard today.**

7. **The Commission recommends that HHS coordinate the development of a national curriculum and standard of care for opioid prescribers. An updated set of guidelines for prescription pain medications should be established by an expert committee composed of various specialty practices to supplement the CDC guideline that are specifically targeted to primary care physicians.**

8. **The Commission recommends that federal agencies work to collect participation data. Data on prescribing patterns should be matched with participation in continuing medical**

education data to determine program effectiveness and such analytics shared with clinicians and stakeholders such as state licensing boards.

9. **The Commission recommends that the Administration develop a model training program to be disseminated to all levels of medical education (including all prescribers) on screening for substance use and mental health status to identify at risk patients.**

10. **The Commission recommends the Administration work with Congress to amend the Controlled Substances Act to allow the DEA to require that all prescribers desiring to be relicensed to prescribe opioids show participation in an approved continuing medical education program on opioid prescribing.**

11. **The Commission recommends that HHS, DOJ/DEA, ONDCP, and pharmacy associations train pharmacists on best practices to evaluate legitimacy of opioid prescriptions, and not penalize pharmacists for denying inappropriate prescriptions.**

Enhancing Prescription Drug Monitoring Programs (PDMP)

State-based PDMPs are electronic databases that give prescribers and many pharmacists access to critical information regarding a patient's controlled substance prescription history, and which can help health professionals identify patients who may be misusing prescription opioids or other prescription drugs and who may be at risk for abuse or misuse. PDMPs are sometimes used by professional licensing boards to identify clinicians with patterns of inappropriate prescribing and dispensing. In most states, law enforcement may use them to investigate cases of controlled substance diversion. In the interim report, the Commission recommended that federal funding and technical support be provided to states to enhance data sharing among PDMPs to better track patient-specific prescription data and support regional law enforcement in cases of controlled substance diversion (Appendix 3). The commission believes the additional recommendations outlined below will further enhance the effectiveness and uptake of PDMPs across the nation.

Today, 49 states and the District of Columbia currently have legislation authorizing the operation of PDMPs in their jurisdictions. However, except in states with mandated PDMP use, providers who see patients and prescribe opioids, or have patients affected by opioids, don't routinely register for or use PDMPs. The national median PDMP registration rate among licensed prescribers is only 35%, per a report in the Journal of the American Medical Association published in 2015. Furthermore, a study by the Johns Hopkins Bloomberg School of Public Health found that patient history was not checked via a PDMP database by the prescriber in 86% of prescriptions for opioids written in 2015.

The Federal Government should leverage mechanisms to facilitate PDMP use. Congress should pass and the President should sign the Prescription Drug Monitoring (PDMP) Act of 2017, which would mandate the creation and use of PDMPs by states who receive federal funding to fight the opioid crisis. This Act would impose strict PDMP requirements, such as a 24-hour reporting requirement after dispensing a controlled substance, further centralize prescribing data, and would help to facilitate data sharing across the states.

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12. **The Commission recommends the Administration's support of the Prescription Drug Monitoring (PDMP) Act to mandate states that receive grant funds to comply with PDMP**

requirements, including data sharing. This Act directs DOJ to fund the establishment and maintenance of a data-sharing hub.

13. **The Commission recommends federal agencies mandate PDMP checks, and consider amending requirements under the Emergency Medical Treatment and Labor Act (EMTALA), which requires hospitals to screen and stabilize patients in an emergency department, regardless of insurance status or ability to pay.**

Providers often resist using PDMPs because these systems are not well integrated into the electronic health records (EHR) systems they currently use in practice, and for other reasons, including inadequate training on the use and complexity of some PDMP software programs. The Heller School at Brandeis University recommends simplifying the method of access to PDMPs for providers by integrating PDMP data into health information exchanges, increasing the likelihood that prescription history information will be used in clinical decision-making. Furthermore, many EHR systems also integrate electronic prescribing of controlled substances (EPCS). The American Medical Association (AMA) and the American College of Physicians both recommend EPCS as one of the top tactics to combat opioid abuse, as eliminating paper prescriptions will improve accuracy, reduce diversion and fraud, as well as improve data quality to PDMPs. However, only the States of Maine and New York have mandated the use of electronic prescribing for controlled substances (Minnesota has mandated e-prescribing since 2011, but no enforcement mechanism exists), and these states are using Medicaid reimbursement rates to incentivize providers to use EPCS. Other states have followed suit; Virginia passed legislation mandating statewide EPCS to take effect in 2020. More recently, Commission member Governor Cooper signed the Strengthen Opioid Misuse Prevention (STOP) Act which, as of July 1, 2017, requires electronic prescribing of certain schedule II and III controlled substances, including opioid medications, in North Carolina. Practitioner ability to electronically prescribe controlled substances in the United States is currently governed by an interim final rule, which would benefit from a revision so practitioners can take advantage of modern technology that would make registration and use of this service easier.

Practitioners are also hesitant to use PDMPs because they often do not know what to do when they identify patients with a potential SUD. Physicians and other health professionals often do not have adequate training in SUDs to assess patients and may need coaching on how to effectively address the issue of a potential SUD. This is especially relevant if the PDMP indicates a high-risk patient requiring tapering, alternatives for pain management, and specialty treatment for OUD. Inadequate patient support or treatment may compromise the value of the PDMP,[184] and promote a transition to illicit opioids if prescription opioids are eliminated. In addition, providers are typically pressed for time and often complain that if a patient is flagged by a PDMP they are either ill-equipped to screen for an SUD and/or unable to make a successful referral to specialty SUD treatment programs. ASAM strongly recommends that prescribers be trained in engagement strategies that result in linking patients to treatment when indicated. Integrated decision support tools, such as the screening tools used in SBIRT interventions, could also help practitioners make a quick determination about the likelihood of a SUD and to recommend appropriate specialty care or an appropriate specialty treatment provider at which to obtain an assessment.

There are a number of new and innovative tools for providers to determine which patients are at risk of adverse effects from prescription opioids, including accidental overdose or development of an SUD. Some are used at the provider level and some analytic tools are used at the payer level to flag certain patients for follow-up or interventions.

14. **The Commission recommends that PDMP data integration with electronic health records, overdose episodes, and SUD-related decision support tools for providers is necessary to increase effectiveness.**

15. **The Commission recommends ONDCP and DEA increase electronic prescribing to prevent diversion and forgery. The DEA should revise regulations regarding electronic prescribing for controlled substances.**

Organizations such as the Association of State and Territorial Health Officials (ASTHO) and Palantir recommend that multiple data sources should be integrated, accessible, and up-to-date in PDMPs to rapidly predict and detect outbreak "hot spots" and disease clusters for both public health and law enforcement purposes.[185] Medical providers would benefit from knowing if patients overdosed so they can adjust their treatment, but currently those records do not flow back to primary care from emergency rooms or emergency responders because, in many medical settings, the differing EHR systems are not sufficiently interoperable. Patient privacy laws, while well-meaning, can also hinder the ability to share this information between medical providers. However, the Department of Transportation (DOT) maintains a database of EMT responses for overdoses that could inform PDMPs about patients' level of risk and provide better decision-making tools for the prescriber.

16. **The Commission recommends that the Federal Government work with states to remove legal barriers and ensure PDMPs incorporate available overdose/naloxone deployment data, including the Department of Transportation's (DOT) Emergency Medical Technician (EMT) overdose database. It is necessary to have overdose data/naloxone deployment data in the PDMP to allow users of the PDMP to assist patients.**

Prescription Take-Back Programs and Drug Disposal

The National Prescription Drug Take Back Day, organized by the DEA with state and local partners, provides communities a safe and convenient way to dispose of their unneeded prescription drugs, while educating the public about the dangers for the public of abuse and misuse. Providers wrote nearly a quarter of a billion opioid prescriptions in 2013. This is enough for every American adult to have a bottle of prescription opioids.[186] Many misusers of prescription drugs have indicated they received prescriptions from their family and friends' medicine cabinets.[187]

DEA's Take Back Day, which is held twice a year, provides an opportunity for communities to dispose of their unneeded prescriptions. In addition, these events are often community driven and offers the public a venue to host community health fairs and provide information about drug screening and treatment services. Offering drug screening and treatment information and resources during Take Back events encourages friends and family of loved ones with a substance abuse problem to obtain information and support on a convenient walk in basis. There is also a need to leverage resources by collaborating with other health professionals that offer comprehensive health and substance use services.

States have also established year-round take-back programs in partnership with community stakeholders and local law enforcement agencies. North Carolina's 'Operation Medicine Drop' is

the largest take-back program in the U.S., and has collected nearly 89.2 million pills at more than 2000 events since 2010.

There is an opportunity to increase efforts by encouraging hospitals/clinics with onsite pharmacies and retail pharmacies to become authorized collectors. Authorized collectors provide a year-round opportunity for the public to properly dispose of their unused prescriptions. Onsite and retail pharmacies have a tremendous opportunity to aid in increasing collection rates by considering incentivizing the public to drop off their unneeded prescriptions by offering store rebates.

In addition, the Federal Government supported the development of drug deactivation bags to allow the safe disposal of old prescription opioids. Drug deactivation bags would be particularly useful in rural areas where an authorized collector may not be nearby. The use of such bags would complement Take Back Day events and give consumers more options. Furthermore, the Federal Government could explore a potential partnership with onsite and retail pharmacies to fund and include a drug deactivation bag with opioid prescriptions. This would provide an opportune moment at the time of drug dispensing to educate the patient on and encourage safe drug disposal.

17. The Commission recommends community-based stakeholders utilize Take Back Day to inform the public about drug screening and treatment services. The Commission encourages more hospitals/clinics and retail pharmacies to become year-round authorized collectors and explore the use of drug deactivation bags.

Pain Level as an HHS Evaluation Criteria

As a condition of full reimbursement of hospitals, the Centers for Medicare and Medicaid Services (CMS) requires that hospitals randomly survey discharged inpatients using the post-hospitalization survey *the Hospital Consumer Assessment of Healthcare Providers and Systems* (HCAHPS).[188] While hospitals must survey only a small percent of patients and response rates are not high (~18%), some elect to also use email to survey every patient and use these responses to improve their own internal processes. This information is reported as part of the program for hospital ratings, 'Hospital Compare,'[189] which offers a public data tool for prospective patients. The tool allows comparison of hospitals across the US on these and other metrics related to patient outcome. During Affordable Care Act (ACA) implementation, the survey became part of how CMS calculates the VBP Incentive, which gives hospitals maximal reimbursement when they reach certain targets. HHS previously included the pain question response information in calculations of incentive payments, but in 2017, CMS announced they would stop including the questions in the VBP program calculation. HHS's stated reason for removing the pain questions from the VBP calculation was to ensure there would not be any financial incentive or pressure to prescribe.[190] HHS has removed the former pain management questions and replaced them with pain management communication questions instead. Moving forward, they intend to continue to include them in HCAHPS.

However, providers and provider associations have expressed they are being required to treat pain with opioids to maintain high ratings. Recent published research since has shown that those with new opioid prescriptions post-discharge are more likely to report their pain was always well managed suggesting that savvy providers have figured out that opioids are a way to manipulate satisfaction.[191] This study also found a new opioid claim within seven days of discharge was likely

to be associated with an opioid claim 90 days post-discharge in Medicare.[192] Finally, other studies showed ratings of orthopedists performing knee and hip replacement were higher in patients reporting better pain control and orthopedist ratings and sometimes hospital ratings were also affected.[193,194] The research suggests that the current approach to pain treatment in the hospital that meets the highest level of response is iatrogenic for ongoing (90-day post-hospital) opioid use.

18. The Commission recommends that CMS remove pain survey questions entirely on patient satisfaction surveys, so that providers are never incentivized for offering opioids to raise their survey score. ONDCP and HHS should establish a policy to prevent hospital administrators from using patient ratings from CMS surveys improperly.

Reimbursement for Non-Opioid Pain Treatments

A key contributor to the opioid epidemic has been the excess prescribing of opioids for common pain complaints and for postsurgical pain. Although in some conditions, behavioral programs, acupuncture, chiropractic, surgery, as well as FDA-approved multimodal pain strategies have been proven to reduce the use of opioids, while providing effective pain management, current CMS reimbursement policies, as well as health insurance providers and other payers, create barriers to the adoption of these strategies. In the third Commission meeting, the Commission heard from several innovative pain management and pharmaceutical companies about the need for proper reimbursement of non-opioid pain medications to increase uptake among healthcare providers and limit the use of opioids. For example, the current CMS payment policy for "supplies" related to surgical procedures creates unintended incentives for those that prescribe opioid medications to patients for postsurgical pain instead of administering non-opioid pain medications. Under current policies, CMS provides one all-inclusive bundled payment to hospitals for all "surgical supplies," which includes hospital administered drug products intended to manage patients' postsurgical pain. This policy results in the hospitals receiving the same fixed fee from Medicare whether the surgeon administers a non-opioid medication or not. Any costs the hospital incurs for creating and administering a multimodal pain management strategy essentially get deducted from its fixed fee payment. Thus, purchasing and administering a non-opioid medication in the operating room increases the hospital's expenses without a corresponding increase in reimbursement payment. Dispensing and writing a prescription for postsurgical opioids, on the other hand, costs the hospital very little, especially since most opioids are generic. Inadequate reimbursement significantly hampers providers' ability to utilize non-opioid treatment for postsurgical pain.

A broader range of pain management and treatment services – including alternatives to opioids, physical therapy, computerized pain management educational programming, PDMP checking, evidence-based behavioral health treatment, tapering off opioids, and drug testing to confirm adherence – should be adequately reimbursed by payers, including CMS.

19. The Commission recommends CMS review and modify rate-setting policies that discourage the use of non-opioid treatments for pain, such as certain bundled payments that make alternative treatment options cost prohibitive for hospitals and doctors, particularly those options for treating immediate post-surgical pain.

Reducing and Addressing the Availability of Illicit Opioids

Along with reducing the supply of unnecessary prescription opioids, a major component of prevention is reducing the number of illicit opioids available on the streets, such as heroin, illicit fentanyl and fentanyl analogues, or diverted prescription opioids. In the Commission's interim report, the Commission recommended prioritizing funding and manpower to federal law enforcement agencies to develop fentanyl detection sensors, to disseminate them to federal, state, local, and tribal law enforcement agencies, and to support federal legislation to stop synthetic opioids from coming into the country through the U.S. Postal Service (Appendix 3). The Commission believes the recommendations outlined below will further address the availability of and staunch the flow of existing and newly emerging dangerous opioids crossing the border into our country.

Improving Data Collection and Analytics

The opioid crisis is both a national security and homeland security threat that impacts the health of individuals and the safety of communities. To respond effectively to this multi-faceted challenge, stakeholders need to access timely and accurate information that provides a comprehensive view of the drug environment at the federal, state, local, and tribal levels. Unfortunately, data on drug use, treatment, and public safety outcomes are managed in different agencies and are often not integrated in a comprehensive way that facilitates the needs of public safety and public health. There is also variability in the way key indicators are defined, collected, and reported across states making it difficult to monitor and assess regional and national trends. It is imperative that all levels of government develop a set of core public health and public safety indicators that can be standardized, collected, analyzed, and shared to inform local, regional, and national prevention, education, outreach, treatment, and enforcement initiatives.

The Federal Government has made considerable investments in capabilities that facilitate collaboration among federal, state, and local agencies to enhance our Nation's ability to address various threats affecting our communities. For example, the CDC has provided federal grant funding to select states to improve prevention and response efforts by supporting more timely public health data collection, disseminating public health surveillance findings to key stakeholders within states, and sharing data with the CDC to support improved multi-state public health surveillance. On the public safety side, the existing models of public health and public safety information sharing have largely been supported by federal grant programs and technical assistance administered through the DOJ's Bureau of Justice Assistance (BJA), and the CDC. Improved coordination among federal departments and agencies related to grant funding and technical assistance activities will expand models of public health, behavioral health, and public safety information sharing and collaboration at the state and local level.

Likewise, states have leveraged Department of Homeland Security (DHS) preparedness grant funding to effectively implement, in collaboration with federal partners, a decentralized and coordinated information sharing environment to identify, analyze, and share public safety information across all levels of government and first responder disciplines. Significant strides have also been made to enhance the Nation's capacity to collect, share, and analyze public safety information, and disseminate actionable and strategic intelligence to key stakeholders from all levels of government. A critical component of the national response to the 9/11 terrorist attacks was the development of a national-level, decentralized, and coordinated information sharing

environment that prioritizes information security and protects individual privacy, civil rights, and civil liberties. State and major urban area fusion centers, the *High Intensity Drug Trafficking Areas* (HIDTA) Program, and Regional Information Sharing Systems (RISS) Centers are some of the key field-based information sharing, analytic, and investigative entities that leverage this capability to enable interjurisdictional and multidisciplinary information sharing, and facilitate collaboration among federal, state, and local public safety partners to address both local and national threats. It is sensible to evaluate how investments in the national information sharing environment could be used to support public health and public safety information sharing and collaboration at all levels of government.

At the state and local levels, successful frameworks for public health and public safety collaboration are expanding. Several states have developed drug monitoring initiatives (DMIs) and overdose fatality review teams, while New York City has developed the RxStat initiative. These efforts integrate various public safety and public health data sets to include drug overdose deaths, non-fatal overdoses, naloxone administrations, prescriber data, drug arrests, drug seizures, and laboratory results. The analysis of these data enables public safety and public health stakeholders to develop and implement prevention, education, outreach, treatment, and enforcement initiatives that protect public safety and reduce drug use and its consequences. These data can be used to develop coordinated risk-reduction strategies tailored to local communities or specific regions.

20. The Commission recommends a federal effort to strengthen data collection activities enabling real-time surveillance of the opioid crisis at the national, state, local, and tribal levels.

In the United States, medicolegal death investigation (MDI) is conducted via a county-based system of medical examiners and coroners (ME/Cs). There are no national standards for conducting MDI in drug overdose cases; including when to investigate a death, any requisite accreditation of ME/C offices and the certification of their investigators, protocols for which drugs to test for and at what cut-off levels, the possibility of suicide, or how or to whom to report findings. The absence of shared standards and procedures prohibits the accurate and timely identification and prioritization of drug threats and the evaluation of the effectiveness of public health and safety policies implemented to abate them. The DOJ and the National Institute of Standards and Technology are currently leading an effort to standardize the process for forensic investigations. Consistency in the investigation and reporting procedures following fatal and nonfatal drug overdose events will permit improvements to the timeliness and completeness of mortality reporting statistics and is necessary to make better and more efficient use of limited state and federal funds.

21. The Commission recommends the Federal Government work with the states to develop and implement standardized rigorous drug testing procedures, forensic methods, and use of appropriate toxicology instrumentation in the investigation of drug-related deaths. We do not have sufficiently accurate and systematic data from medical examiners around the country to determine overdose deaths, both in their cause and the actual number of deaths.

Estimates of the extent of the opioid epidemic in the United States may be underestimated due to inadequate systems reporting information on the number, location, and degree of opioid

consequences. Surveys of chronic drug users and morbidity information could provide timely and in-depth insights into the opioid crises, but were defunded from the budgets of federal agencies. Current data systems do provide some level of measurement, but miss some important aspects of the opioid epidemic. Restoration of funding for these terminated programs is needed to obtain more detailed information on the opioid epidemic.

The unique aspects of opioid drugs exacerbate the issues of monitoring the misuse problem, unlike other illicit drugs such as marijuana, cocaine, or methamphetamine. Cocaine, for example, has been a drug of consequence for decades, is abused by millions of people in the United States, and has limited variations in composition. Data systems monitoring the extent of the cocaine problem have been standardized and institutionalized. Opioids, on the other hand, consist of many drug varieties, including prescription pain medications, heroin, and most recently, illicitly-manufactured fentanyl. Millions of people misuse prescription pain medications, but only a small fraction of that number abuse heroin. These fewer numbers present a challenge for estimating the prevalence of use by the standard federal survey.

For example, the NSDUH, a federal statistical survey of about 70,000 Americans annually (cited often throughout this report), estimated that 600,000 people used heroin in 2010.[195] A study conducted by the RAND Corporation on illicit drug expenditures in America estimated the number of heroin users in 2010 to be closer to 1.5 million.[196] This dramatic discrepancy has been discussed by the press.[197] Illicitly-produced fentanyl, another rapidly growing component of the opioid epidemic is not even routinely tracked by surveys such as NSDUH or drug seizure data systems.

Two discontinued data systems that would provide enhanced fidelity to measuring the extent of the opioid crisis are the *Arrestee Drug Abuse Monitoring* (ADAM) Program and the *Drug Abuse Warning Network* (DAWN). ADAM was a survey of current local high-risk arrestees in jails accompanied by a urinalysis test. Until its termination by the National Institute of Justice in 2003, over 30 jails in cities throughout the country were sampled and tested. These data would provide timely, geo-specific data on opioid use, supported with a confirmatory lab test. The lab analysis could also be adjusted to test for any new opioids appearing in the U.S. market. DAWN was a tabulation of drug mentions in hospital emergency rooms. SAMHSA funded the DAWN program until 2011. These morbidity data would provide a sentinel system, alerting decision makers of the consequences of opioid use before more serious overdoses would occur.

Existing data collection systems, including the major surveys, like the NSDUH and the *Monitoring the Future* study, need to be maintained and improved, and the data gaps need to be filled and revitalized using such novel approaches such as testing wastewater in highly circumscribed regions (e.g. a few blocks) for estimating drug metabolites. This innovative system has already collected biological specimens from high-risk populations for early indications of the changing drug landscape. Population-level data from toxicology screening can also provide a snapshot of drug use and misuse. Local information is essential to complement national data in informing public health and public safety responses to the opioid epidemic.

The possibility of a behavioral health surveillance system at sentinel sites across the country exists for 12+ sites currently under NIDA funding and additional resources have recently been awarded by CDC to 44 states and the District of Columbia to include better tracking of opioid-related overdoses. There is a need for an integrated system that, across the country, can track prevalence rates, treatment modalities, and comorbidities with other illnesses in real-time. Recognizing that there is variability across the United States, these surveillance or sentinel sites can be established for a multitude of local areas across the country.

22. The Commission recommends reinstituting the *Arrestee Drug Abuse Monitoring* (ADAM) program and the *Drug Abuse Warning Network* (DAWN) to improve data collection and provide resources for other promising surveillance systems.

Disrupting the Illicit Fentanyl Supply

The emergence of illicitly produced fentanyl and fentanyl analogues in the drug market has drastically compounded the illicit opioid problem. Increasingly, fentanyl and fentanyl analogues are combined with inert substances and pressed into pill form to be sold as counterfeit prescription opioid pills. To help deter these features of the illicit drug market, changes to sentencing guidelines are underway in many states and in various stages of maturity.

In Massachusetts, any person who traffics' in fentanyl, "by knowingly or intentionally manufacturing, distributing, dispensing or possessing with intent to manufacture, distribute or dispense or by bringing into the commonwealth a net weight of more than 10 grams of fentanyl" faces punishment of up to 20 years in state prison. The term "fentanyl" includes any derivative of fentanyl and any mixture containing more than 10 grams of fentanyl or a derivative of fentanyl. M.G.L.A. 94C § 32E (c ½).

As of July 2017, West Virginia law specifically criminalizes the unlawful manufacture, delivery, transport into state, or possession of fentanyl. W. Va. Code, § 60A–4–415. A violation is a felony, with the following prison terms: (1) if the net weight of fentanyl involved in the offense is less than one gram, such person shall be imprisoned in a correctional facility not less than two nor more than ten years; (2) if the net weight of fentanyl involved in the offense is one gram or more but less than five grams, such person shall be imprisoned in a correctional facility not less than three nor more than fifteen years; and (3) if the net weight of fentanyl involved in the offense is five grams or more, such person shall be imprisoned in a correctional facility not less than four nor more than twenty years.

New Hampshire law defines the term "fentanyl class drug" with reference to a listing of specific substances. N.H. Rev. Stat. § 318-B:1(XI-a.). These drugs are assigned the same criminal penalties as are heroin or crack cocaine. N.H. Rev. Stat. § 318-B:26.

While states consider laws that aim to reduce the supply of fentanyl, including harsher penalties for smaller quantities, given the potency, it is also important to consider whether users, who buy fentanyl unknowingly, could be unnecessarily punished for distribution. For individuals with OUD who are arrested with fentanyl, other factors beyond quantity should be considered to determine possession for personal use versus distribution.

23. The Commission recommends the enhancement of federal sentencing penalties for the trafficking of fentanyl and fentanyl analogues.

As mentioned above, illicit fentanyl and fentanyl analogues are increasingly being pressed into counterfeit prescription opioid pills, often mimicking the appearance of commonly prescribed opioid pain killers such as OxyContin, by Drug Trafficking Organizations (DTOs) and smuggled into the United States in large quantities. While fentanyl seizures are most typically in a powder, salt, or rock-like form, DEA's El Paso Intelligence Center (EPIC) reports an increase in the number of pills seized. In 2016 an estimated 15,632 domestically seized tablets and capsules were

identified by DEA forensic laboratories as containing some amount of fentanyl or fentanyl analogues with or without other illicit drugs and non-narcotic substances. This represents approximately 16 times the number of fentanyl tablets and capsules analyzed by DEA's laboratories in 2014.[198]

Fentanyl in pill form has enabled the development of a more diverse user population that is skewing younger and perhaps more opioid naïve. Moreover, the prototypical experienced intravenous drug user of previous illicit opioid crises has been joined by those who believe they are buying off-market prescription opioids, but are in fact buying fentanyl pressed into pill form.

Furthermore, the online marketplace and cryptocurrencies have empowered a "democratization of the drug trade," where the hierarchical DTOs the United States has effectively confronted for the past several decades no longer have a monopoly on supplying drugs. Rather, individuals can simply go online to one of many internet drug marketplaces and purchase illicit drugs for their own personal use or for further sale on a limited scale, creating a constellation of "micro-networks" across the country that are difficult to locate and nearly impossible to dismantle. The ability to easily purchase drugs like fentanyl online, which are subsequently shipped in a manner and at volumes that make them hard to detect, demonstrates a new pathway for these potent drugs to enter the domestic supply chain. This change carries enormous implications for the law enforcement and justice communities, and requires a framework of relationships, laws and regulations, and procedures to deal with an environment of drug trafficking and use the nation is just beginning to see.

The growing internet drug market, particularly for fentanyl and fentanyl analogues, is a clearly identified critical vulnerability in interrupting the supply of these drugs into the United States. Since the 2013 closing of the first well-known cryptomarket, Silk-Road 1.0, both the clear and the dark web have further expanded the illicit drug market, allowing individuals to purchase dangerous drugs directly from their manufacturers instead of through established trafficking organizations. Internet sales of fentanyl and other synthetic substances has evolved into a direct to consumer market generating large revenues. A Carnegie Mellon University study estimated that revenues from online illicit drug sales increased from between $15-17 million in 2012 to $150-$180 million in 2015.[199] The recent multi-agency and international effort, led by the DOJ, which resulted in the takedown of the Alphabay marketplace was a monumental step forward in this effort.

The dynamics of synthetic drugs and their availability online has the potential to permanently change the drug market. The Federal Government currently lacks a sustained, coordinated, and well-resourced effort to attack the illicit drug online purchase infrastructure to identify and target the network of actors involved, and limit the amount of fentanyl and fentanyl analogues entering the United States.

24. The Commission recommends that federal law enforcement agencies expressly target Drug Trafficking Organizations and other individuals who produce and sell counterfeit pills, including through the internet.

The importation of tableting machines (pill presses) is regulated by DEA. DEA has recently enhanced importation regulations by replacing paper reporting with an electronic process. However, the active use of pill presses remains unregulated. While DEA currently can inspect a registrant's use of controlled substances in their usable form to verify they are well stored and used

for their stated registered purposes, the DEA currently cannot inspect pill presses to verify that equipment is not being used to produce counterfeit drugs.

25. The Commission recommends that the Administration work with Congress to amend the law to give the DEA the authority to regulate the use of pill presses/tableting machines with requirements for the maintenance of records, inspections for verifying location and stated use, and security provisions.

Interdiction and Detection Challenges

The detection of fentanyl and its analogues shipped directly into the United States via international mail and express consignment presents a unique challenge. U.S. Customs and Border Protection (CBP) is responsible for interdicting and screening inbound international mail before all letters, parcels, and packages are released to the U.S. Postal Service (USPS) for domestic delivery.

The CBP operates within nine major USPS International Mail Facilities (IMF), inspecting international mail and parcels arriving from more than 180 countries. CBP partners with the U.S. Postal Inspection Service (USPIS) at each facility to target, detect, and seize international shipments of illicit narcotics, including fentanyl. International mail processing is primarily manual, requiring CBP officers to sort through large volumes of parcels to identify potential shipments of concern. CBP screens all international mail parcels for radiological threats, x-rays all international mail packages presented by USPS, and physically examines those deemed high-risk.

The USPS processed over 275 million international inbound mailings in FY 2016. Of those items, there were over ten million international express mail items and over four million air and surface parcels. In FY 2016, the USPIS initiated 2,439 cases involving drug trafficking and made 1,850 arrests which resulted in 1,571 convictions. Additionally, inspectors seized illegal assets valued at approximately $23.5 million, to include 89 pounds of heroin, 13,968 Oxycodone tablets, and fentanyl-family synthetic opioids on 36 occasions. In these cases, USPIS utilized intelligence derived from drug seizures, international partnerships, and strong relationships with federal, state, local and tribal law enforcement agencies.

Because of the increased threat of fentanyl, and the interagency focus on disrupting the fentanyl supply chain, CBP undertook a pilot program to train canines to detect fentanyl. Although training canines to detect synthetic drugs is a difficult undertaking, the CBP has already trained and fielded canines and placed them in critical locations in the United States to screen incoming parcels to indicate the presence of fentanyl and other synthetic opioids. Canine screening and detection, complemented by the deliberate targeting of shippers associated with fentanyl trafficking, has the potential to increase the likelihood that those containing illicit opioids are seized and removed from the supply chain.

The incredibly high volume of mail, fentanyl's ability to be shipped in very small quantities, a low number of available automated detection systems, and the relatively small number of trained canines make intercepting fentanyl and fentanyl analogues at IMF's monumentally difficult.

26. The Commission recommends U.S. Customs and Border Protection (CBP) and the U.S. Postal Inspection Service (USPIS) use additional technologies and drug detection canines

to expand efforts to intercept fentanyl (and other synthetic opioids) in envelopes and packages at international mail processing distribution centers.

The sheer volume of international mail and IMF infrastructure make interdiction efforts focused on illicit opioids and other drugs a monumental task. One method to address this issue is the increased use of Advanced Electronic Data (AED). Federal regulation requires express package operators to transmit AED prior to package arrival in the United States. AED consists of electronic data about the particulars of each shipment such as sender/receipt names and addresses, contents and quantity. AED's primary use is for advanced targeting for CBP inspections efforts. With AED, CBP can advance-target incoming shipments for additional examination based upon intelligence, prior violations, and other risk factors.

Over 90% of inbound international mail is sent from USPS's top-volume trading partners. USPS now receives AED on inbound packages from 20 countries, including China. International mail services are not required by International law to transmit parcel information prior to arrival in the United States and many do not have the capability to do so even if required. However, international law requires nations establishing such requirements to ensure they can be met by all nations.

To this end, the Commission recommends support of the Synthetics Trafficking and Overdose Prevention (STOP) Act of 2016 or the STOP ACT of 2016, which amends the Tariff Act of 1930 to make the Postmaster General the importer of record for non-letter class mail imported into the United States. The bill amends the Consolidated Omnibus Budget Reconciliation Act of 1985 to impose a duty of $1 on each item of non-letter class mail imported into the United States. The bill amends the Trade Act of 2002 to direct the Department of the Treasury to require the Postmaster General to provide for AED transmission to CBP of certain information on non-letter class mail imported into the United States.

27. **The Commission recommends Congress and the Federal Government use advanced electronic data on international shipments from high-risk areas to identify international suppliers and their U.S.-based distributors.**

28. **The Commission recommends support of the Synthetics Trafficking and Overdose Prevention (STOP) Act and recommends the Federal Government work with the international community to implement the STOP Act in accordance with international laws and treaties.**

DEA reports that diversion of licit fentanyl, either from theft or fraud, currently accounts for about 2-3% of fentanyl-related overdose deaths. However, as government agencies and international partners achieve success disrupting the illicit fentanyl supply chain, there is high confidence that the licit fentanyl, as well as other prescription opioids, stock and supply chain will experience an increased risk of diversion.

In 2011, Commission member Florida Attorney General Bondi fought for the passage of House Bill 7095 Florida Legislature, which aimed to regulate 'pill mills' by combating prescription drug diversion. Specific features of Florida's legislation included adding new criminal penalties, requiring wholesale distributors to credential customers and report on distribution of controlled substances, as well as funding state Regional Drug Enforcement Strike Forces. Within 18 months of the legislation passage, Florida achieved the largest-by an order of several magnitude-year-on-year recorded drops in prescription drug overdose deaths in the nation.

At any point in the manufacturing, distribution, and prescription process, fentanyl, like other prescription opioids, can be diverted for illicit use. The nation should re-examine its current procedures to track the licit supply chain to prevent the diversion of precursor chemicals, partially processed product, and finished material in manufacturing facilities. Additionally, there are few mechanisms to track fentanyl and prescription opioid diversion once the drug is issued by a medical professional to a patient for consumption. One such method could be a requirement for the recipients and users of legally prescribed fentanyl to provide proof, such as empty transdermal patch envelopes or lollipop sticks to a pharmacist before receiving their refills. Another control initiative could be placing restrictions on dispensing fentanyl through the mail, or requiring that packages containing fentanyl or other opioids must be signed for by the recipient.

The DEA must be able to successfully disrupt the diversion of prescription opioid at any and all points in the supply chain.

29. The Commission recommends a coordinated federal/DEA effort to prevent, monitor and detect the diversion of prescription opioids, including licit fentanyl, for illicit distribution or use.

Protecting First Responders from Harmful Effects Resulting from Exposure to Fentanyl and other Synthetic Opioids

The increased prevalence of fentanyl and other synthetic opioids in the illicit drug market requires law enforcement, fire, rescue, and emergency medical services (EMS) personnel to understand how to protect themselves from exposure to these substances. There have been reports nationwide of law enforcement professionals and EMS professionals experiencing opioid overdoses after unknowingly coming into contact with fentanyl residue. Similarly, crime labs do not always have updated policies and procedures for dealing with potentially deadly substances such as fentanyl.

Currently, fear and misinformation regarding potential health concerns to first responders are hindering response efforts and increasing the risk to first responders. To make the environment more challenging, fentanyl can be present in a variety of forms (e.g., powder, tablets, capsules, solution, etc.).

At the state and federal level, there is no systematic method of tracking and examining reports of first responder opioid intoxication due to inadvertent exposure to fentanyl. Establishing uniform data collection and sharing protocols across states, including conducting confirmatory testing and collecting specific information about each incident of suspected first responder opioid intoxication, would assist the first responder community in validating and refining safety recommendations.

The White House convened and coordinated an interagency working group that included medical, public health, law enforcement, and EMS subject-matter experts to develop a set of scientific, evidence-based recommendations for first responders to protect themselves from the harmful effects associated with fentanyl exposure.

As noted in Appendix 4, the *Fentanyl Safety Recommendations for First Responders* are included in this report to maximize awareness.

The Commission commends the Federal Government for providing unified recommendations to frontline personnel. We also acknowledge the interagency working group for recognizing the value

of incorporating feedback from stakeholder representatives from the medical, public health, occupational safety and health, law enforcement, and fire/EMS fields.

30. The Commission recommends the White House develop a national outreach plan for the *Fentanyl Safety Recommendations for First Responders*. Federal departments and agencies should partner with Governors and state fusion centers to develop and standardize data collection, analytics, and information-sharing related to first responder opioid-intoxication incidents.

Opioid Addiction Treatment, Overdose Reversal, and Recovery

Drug Addiction Treatment Services

In the interim report, the Commission reported that the use of MAT has been associated with reduced overdose deaths, retention of persons in treatment, decreased heroin use, reduced relapse, and prevention of the spread of infectious disease. The Commission recommended several steps to increase the use of and access to all forms of SUD treatment, including MAT for SUDs, including removing the federal Institutes of Mental Diseases (IMD) exclusion within the Medicaid program, establishing a federal incentive to enhance access to MAT, and requiring regulators to take enforcement action against health plans that violate the Mental Health Parity and Addiction Equity Act (MHPAEA) (Appendix 3). The Commission also expressed support for the Overdose Prevention and Patient Safety Act/Protecting Jessica Grubb's Legacy Act, and the need to update patient privacy laws, such as 42 CFR Part 2, to ensure that information about SUDs are made available to medical professionals treating and prescribing medication to patients. Building off the previous recommendations, the Commission supports implementation of the steps outlined below to remove additional barriers and further improve access to and quality of drug addiction treatment services across the nation.

Increase Screenings and Referrals to Treatment through CMS Quality Measures

There is a great need to ensure that health care providers are screening for SUDs and know how to appropriately counsel, or refer, a patient that presents with an SUD.[200] As Commission member Dr. Bertha Madras found in her analysis of a SAMHSA SBIRT program, training practitioners in hospitals and primary care settings in the SBIRT model can be effective in reducing rates of alcohol and illicit drug use. In this 2009 study, nearly 500,000 individuals were screened in six states across health care settings and those that demonstrated alcohol abuse and/or illicit drug use were given a brief intervention, brief treatment, or a referral to specialty treatment.[201] A variety of screening tools were employed, and study sites had differences in population demographics and substance use rates; however, across all sites and demographics, self-reported substance use was less at six months after the initial screen and a brief or more intensive intervention. This research demonstrates the effectiveness of addiction screening in a health care setting, as well as the potential to better utilize primary care medical professionals in areas where there is a shortage of specialty treatment providers.

There are opportunities to further the practice of substance use screenings and referrals through CMS quality measures. CMS has several quality measures throughout their programs (Medicaid, 1115 demonstrations, Innovation Accelerator Program, Medicare, etc.) that could help further the practice of substance use screenings and referrals to treatment. The Federal Government, in coordination with the private sector, has a process through which measures are identified, specified and implemented to assure good patient health outcomes. All federal programs have different purposes and authorities and the selection of measures will vary to reflect those differences. At the same time, federal programs strive to adopt measures that will have strong reach without overwhelming providers with reporting requirements. There are currently several substance use measures being used in federal and private quality assurance programs, and many more under

consideration for adoption. However, measures are not deployed across all programs and, in some cases, do not address some of the gaps in care.

Quality measures for substance use screenings and referrals to treatment should address immediate treatment (24-48 hours) at all points of care for individuals in need of an assessment and treatment for OUD, including hospital induction of MAT, strengthening coordination of care and referral efficacy/improved treatment linkage, follow-up monitoring, and adoption of 'hub-n-spoke' models where specialty providers provide clinical support for primary care-based high need patients. High rates of co-morbidity with mental health disorders also warrant substance use screenings when a mental health diagnosis has been made.

31. The Commission recommends HHS, CMS, the Substance Abuse and Mental Health Services Administration (SAMHSA), the VA, and other federal agencies incorporate quality measures that address addiction screenings and treatment referrals. There is a great need to ensure that health care providers are screening for SUDs and know how to appropriately counsel, or refer a patient. HHS should review the scientific evidence on the latest OUD and SUD treatment options and collaborate with the U.S. Preventive Services Task Force (USPSTF) on provider recommendations.

Evidence-based Improvements to Treatment

Addiction is a chronic relapsing disease of the brain which affects multiple aspects of a person's life. In addition to efforts to improve access to treatment, public policy should also seek to improve the efficacy of treatment. Effective treatment must address the needs of the whole person to be successful. Research by NIDA outlines 13 principles upon which effective treatment programs and practices are built.[202] Grounded in these principles, a growing body of evidence-based models guides the work of addiction treatment.[203] Models demonstrating the greatest outcomes tend to incorporate behavioral, psychosocial, and pharmacological elements, if available,[204] and are tailored to the individual client. The ability to adopt evidence-based models depends on provider ability to support skilled staff who are appropriately credentialed and/or licensed to implement necessary practices. Insurers and other payers can create pressure on treatment providers for a consistent, high-quality standard of care.

Treatment should include the following five elements:[205]

1. Complete evaluation for OUDs by a qualified medical professional including co-occurring other SUDs, psychiatric disorders, and medical disorders.
2. Access to MAT (e.g., methadone, buprenorphine/naloxone, naltrexone). Choice of medication should be made by a qualified professional in consultation with patient, and based on clinical assessment.
3. Simultaneous access to adjunctive psychosocial treatment that may include: group therapy, individual counseling, family therapy, relapse prevention, other psychosocial treatment. These services may be delivered in a variety of levels of care depending on what is clinically appropriate including inpatient, outpatient, intensive outpatient, residential, or partial hospitalization, depending on what is clinically appropriate for the client based on assessment.[206]

4. Treatment of co-occurring psychiatric disorders: The majority of patients with OUDs have co-occurring psychiatric disorders, especially trauma related disorders such as PTSD, depression, and anxiety disorders. Patients with OUDs who do not receive treatment for these mental health conditions generally have poor treatment outcomes.
5. Treatment of co-occurring medical conditions: Patients with OUDs may require treatment for the many medical conditions (e.g., cardiac, infectious, dermatologic, among others).

Connecting treatment to social supports, such as stable housing, employment/job training, education/vocational training, medical care, transportation, child care, etc. is also needed on an ongoing basis to help the individual be successful in their recovery and rebuild a lifestyle that is healthy and productive.[207,208] Reports by the Agency for Healthcare Research and Quality (AHRQ) at HHS endorsed process measures that emphasize treatment completion as key to achieving positive behavioral health outcomes. Similarly, the National Quality Forum, an organization that works to make improvements in healthcare, endorsed the adoption of process measures to count and increase the number of adults in MAT programs who receive at least 180 days of continuous treatment.[209] Subsequently, services that facilitate client retention and engagement to at least 180 continuous treatment days will improve client outcomes.

However, providers, practitioners, and funders often face challenges in translating such principles into practice to help individuals achieve positive long-term outcomes. Improving the quality of treatment programs will require increasing the number of skilled psychiatrists, medical practitioners, counselors, recovery coaches, and improving business practices of providers, which facilitates adoption of evidence-based practices such as MAT. Additionally, persons seeking care need user-friendly information on quality program and selection criteria to identify programs that match their needs. Use of evidence-based assessment tools and processes will help determine the appropriate level of care and configuration of services needed by the individual client. Adoption of ASAM's patient placement criteria should guide referral to the appropriate setting, frequency, and duration of services.

32. The Commission recommends the adoption of process, outcome, and prognostic measures of treatment services as presented by the National Outcome Measurement[210] and the American Society of Addiction Medicine (ASAM).[211] Addiction is a chronic relapsing disease of the brain which affects multiple aspects of a person's life. Providers, practitioners, and funders often face challenges in helping individuals achieve positive long-term outcomes without relapse.

Insurance and Reimbursement Barriers to Accessing MAT

There are currently three FDA-approved medications for the treatment of OUD: methadone (an opioid agonist), buprenorphine (an opioid partial agonist) and naltrexone (an opioid antagonist). MAT for OUD is associated with decreases in opioid use, opioid-related overdose deaths, criminal activity, and infectious disease transmission, while improving social functioning and retention in treatment.[212] Despite this, less than half of privately-funded SUD treatment programs offer MAT and only a third of patients with OUD at these programs receive it.[213] Though rural areas have high rates of OUD, treatment options, including those that utilize MAT, are minimal.[214] Furthermore, physicians that have the necessary training and DEA authorization to prescribe buprenorphine are limited in the number of patients they can treat.

There are commercial insurance barriers to MAT, such as dangerous fail-first protocols and onerous and frequent prior authorization requirements. Fail-first approaches require that a patient try counseling or other psychosocial approaches before being offered more intensive forms of treatment, or MAT. Families, consumers, and treatment providers have consistently identified these and other barriers to obtaining insurance coverage for opioid and other SUDs. These practices are not evidence-based and are not a tenable clinical protocol for individuals with OUDs, as they delay treatment and in doing so, open a window for renewed opioid use and potential death.

Prior authorizations may also serve as a barrier, as they can take a significant amount of time and can disrupt the clinical 'moment' when a patient has finally agreed to try treatment. A 2017 survey of physicians indicated that prior authorization requirements by third party payers were the most commonly reported barrier to prescribing.[215] In 2015, 48 Medicaid programs required prior authorization for buprenorphine.[216] With addiction, the initial goal is to rapidly and immediately engage a person in treatment. Rapid response is necessary to secure treatment before an individual goes into withdrawal and seeks drugs illegally in search of relief.

In addition, CMS policies regarding MAT for Medicare recipients are complex and create barriers for Medicare patients seeking access to MAT. Methadone is covered under Medicare Part D when prescribed for pain, but not when given as part of an OUD treatment program. Some MAT reimbursements are part of a bundled payment for inpatient care, but it has come to the attention of the Commission that bundled payments can be a barrier to providers offering an array of services and medications.

33. The Commission recommends HHS/CMS, the Indian Health Service (IHS), Tricare, the DEA, and the VA remove reimbursement and policy barriers to SUD treatment, including those, such as patient limits, that limit access to any forms of FDA-approved medication-assisted treatment (MAT), counseling, inpatient/residential treatment, and other treatment modalities, particularly fail-first protocols and frequent prior authorizations. All primary care providers employed by the above-mentioned health systems should screen for alcohol and drug use and, directly or through referral, provide treatment within 24 to 48 hours.

Reimbursement rates for SUD treatment services are typically lower than those for other health conditions. Private and public insurers complain that they cannot find enough quality providers for their networks. The provision of SUD treatment, often in the form of counseling and psychosocial services, has a different business and service model than other health conditions. Lack of sufficient reimbursement impedes the ability of professionals and practices to implement high-quality and consistent care, including but not limited to the use of EHRs, the implementation of evidence-based practices, and the routine use of quality metrics. Moreover, the disincentives are so significant that many practitioners no longer take insurance, diminishing access to care even when there appears to be sufficient capacity. Such differential reimbursement strategies exist in the hospital setting as well. Hospital chemical dependency units, for instance, are paid lower rates than inpatient psychiatric facilities.

34. The Commission recommends HHS review and modify rate-setting (including policies that indirectly impact reimbursement) to better cover the true costs of providing SUD treatment, including inpatient psychiatric facility rates and outpatient provider rates.

Enforcing the Mental Health Parity and Addiction Equity Act (MHPAEA)

Spearheaded by Commission member former Congressman Kennedy, MHPAEA aimed to build upon the patient protections enacted by the Mental Health Parity Act (MHPA) passed in 1996, which provided that large group health plans could not impose annual or lifetime dollar limits on mental health benefits that are less favorable than any such limits imposed on medical/surgical benefits. In other words, parity is a simple concept that requires health insurance plans to offer behavioral health coverage that is comparable, and equal to, the coverage for physical health. In reality, creating appropriate parity regulations, and enforcement of parity laws, is far from simple.

MHPAEA extended these parity requirements to SUDs, but legislation did not require large group health plans and health insurance carriers to cover mental health or SUD benefits. The Affordable Care Act changed this by requiring coverage of mental health and SUD services as an essential health benefit in individual and small group plans.

However, while parity is a legal requirement, the existing means of monitoring and enforcing the parity act are insufficient. The sole means of enforcement under the parity act is equitable relief against the buyer of the insurance plan; and for the employer-based plans that are self-funding, DOL is presently permitted to enforce MHPAEA against only the employer, rather than the insurance company administering the benefits. The Commission heard from numerous organizations, such as the Parity Implementation Coalition, the Partnership for Drug-Free Kids, the National Council for Behavioral Health, Shatterproof, ASAM, and the American Academy of Addiction Psychiatry, about the need to systematically monitor and enforce MHPAEA to ensure parity in the coverage of mental health and addiction services.

MHPAEA has been the impetus for much progress towards parity for behavioral health coverage; plans and employers have, by and large, done away with policies that are clear violations; provisions such as dollar-limits, visit limits, and outright prohibitions on certain treatment modalities that exist only on behavioral health benefits. However, what remains are violations that are murkier and harder for regulators to discern, for example, non-quantitative treatment limits (NQTLs). These hurdles include medical necessity reviews that are more stringent on the behavioral health side than the medical/surgical side, limited provider networks, and onerous prior-authorization requirements. In reality, it is often difficult to discern when a behavioral health benefit is “on par” with a medical/surgical benefit as different care settings and diagnoses have different policies regarding benefits, providers, and authorizations.

One goal of MHPAEA and other parity laws was to address cost-shifting from the commercial sector to the public sector for the financing of substance use and mental health treatment. Expanding the private sector share of expenditures could increase access to treatment for opioid and other drug use disorders. As of 2014, private cost-sharing did not increase in proportion to the private sector share of the insurance market. It financed only 18% of SUD treatment in 2014. Legislative changes providing DOL with the ability to impose a civil monetary penalty, such as those provided for violations of the Genetic Information Nondiscrimination Act (GINA), would encourage private insurance companies, and employers, to satisfy their legal obligations under MHPAEA and in turn, ensure they are adequately doing their part to address the country's opioid epidemic.

HHS has built an online portal to help individuals who have trouble accessing behavioral health services, including addiction treatment. This portal, available at https://www.hhs.gov/mental-health-and-addiction-insurance-help/index.html, directs individuals to different sites, including

DOL, depending on the type of insurance coverage. The Commission applauds this project as well as the other activities of the Federal Mental Health and Substance Use Disorder Task Force in working towards public education and full parity compliance.

Building upon the recommendations provided in the interim report, the Commission believes the following actions will help to ensure parity violations do not impede access to substance use treatment.

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35. Because the Department of Labor (DOL) regulates health care coverage by many large employers, the Commission recommends that Congress provide DOL increased authority to levy monetary penalties on insurers and funders, and permit DOL to launch investigations of health insurers independently for parity violations.

36. The Commission recommends that federal and state regulators should use a standardized tool that requires health plans to document and disclose their compliance strategies for non-quantitative treatment limitations (NQTL) parity. NQTLs include stringent prior authorization and medical necessity requirements. HHS, in consultation with DOL and Treasury, should review clinical guidelines and standards to support NQTL parity requirements. Private sector insurers, including employers, should review rate-setting strategies and revise rates when necessary to increase their network of addiction treatment professionals.

MAT in the Criminal Justice System

In the weeks following release from jail or prison, individuals with or in recovery from OUD are at elevated risk of overdose and associated fatality. MAT has been found to be correlated with reduced risk of mortality in the weeks following release and in supporting other positive outcomes. A large study of individuals with OUD released from prison found that individuals receiving MAT were 75% less likely to die of any cause and 85% less likely to die of drug poisoning in the first month after release.[217] Compared to approaches that do not include FDA-approved medications, MAT for OUD is associated with better treatment retention,[218] reductions in the spread of infectious diseases, such as HCV and HIV, and lower rates of criminal behavior.[219,220,221,222,223,224]

Despite the research evidence, a national survey of corrections staff in 14 states found very limited use of MAT. While 83% of prisons and jails offered some form of MAT, its use was limited mostly to detoxification or to maintenance treatment for pregnant women.[225,226] One study found that nearly 60% of jail personnel surveyed strongly disagreed with the statement that their tax dollars should support methadone treatment. The same survey found that nearly 55% of jail security personnel agreed with the statement that "people who overdose on heroin get what they deserve." Twelve percent of jail health services staff shared this perspective. The authors noted that negative attitudes regarding MAT appeared to be related to negative judgments about drug users in general and heroin users in particular.[227] While the National Institute on Corrections (NIC), the BJA, the National Association of Drug Court Professionals (NADCP), and other entities have made significant strides in educating correctional administrators and practitioners, much progress remains to be made.

Warranting special concern are pre-trial detainees involved in the criminal justice system. The population of pre-trial detainees is several times larger than the population of individuals sentenced

to jail. These individuals may be less likely to receive treatment and other services due to the fact that they may be released or transferred in a relatively short period of time. Increasing access to treatment, and especially MAT for OUD among these individuals is critically important. Doing so can save lives and reduce future public safety and public health costs associated with unchecked opioid addiction among these individuals.

37. The Commission recommends the National Institute on Corrections (NIC), the Bureau of Justice Assistance (BJA), the Substance Abuse and Mental Health Services Administration (SAMHSA), and other national, state, local, and tribal stakeholders use medication-assisted treatment (MAT) with pre-trial detainees and continuing treatment upon release.

Drug Courts and Diversion Programs

There is evidence that a large majority of individuals who have an SUD do not receive treatment.[228] Drug courts are a proven avenue to treatment for individuals who commit non-violent crimes because of their SUD. Drug courts have traditionally been a more effective response for non-violent, low-level offenders with SUDs, rather than lengthy prison sentences. A systematic review of drug courts in 30 states published by the Campbell Collaboration in 2012 found that a combination of comprehensive services and individualized care is an effective way to treat offenders with serious addictions. However, 44% of U.S. counties in 2014 did not have a drug court for adults.[229] The principal factors limiting drug court expansion are insufficient funding, treatment, and supervision resources, not a lack of judicial interest. The Commission heard from several organizations, including Advocates for Opioid Recovery, the Addiction Policy Forum, and Young People in Recovery, about the need to implement and oversee these problem-solving courts to create true 'recovery ready communities.'

The U.S. Pretrial Diversion Program diverts certain individuals involved in the justice system for a first or second felony offence to a program of supervision and services administered by the U.S. Pretrial or Probation Services. The U.S. Attorney's Office has the discretion to offer this alternative to eligible individuals. Under the program, diversion typically takes place before charging, although it is possible at any time before trial when a pretrial diversion agreement is executed. The period of supervision is up to 18 months. Drug, reentry, or veterans' courts can be a central component of the pretrial diversion process.

As of June 2015, the National Institute of Justice reported that there were 27 Federal District Courts that operated as drug courts as well as six federal veterans' courts. Generally, Federal District Courts adopting the drug court model or similar approaches for diversion and/or reentry support are designated as Federal Reentry Courts. These courts can encompass pre- and post-adjudication diversion as well as post-incarceration reentry/recovery support. Federal reentry courts concurrently engage probation, parole, the Federal Public Defenders, and U.S. Attorneys' Offices. They utilize a blend of treatment and sanction alternatives to address behavior, rehabilitation and community re-integration for non-violent, offenders who are seeking recovery from SUD.

As a rule, Federal Reentry Courts make MAT available to individuals participating in pre- and post-adjudication diversion and post-incarceration reentry programs. Studies have shown that MAT recipients remain engaged in treatment at higher rates, have fewer positive tests for illicit drugs, and reoffend at lower rates than individuals with OUD not receiving MAT. For incarcerated

individuals, these courts typically incorporate an early-discharge program to replace the final year of incarceration with strictly-supervised release into the drug court regimen. Federal Reentry Courts adopting the drug court model incorporate the 'Ten Key Components' of a drug court program in a voluntary contractual program lasting a minimum of 12-18 months. Court program participants returning to the community from incarceration are transferred to traditional parole supervision following graduation. However, they may continue to receive case management services voluntarily through the reentry court.

Jurisdictions that run drug courts continue to innovate and adjust their programs and policies based on experience and in light of the current opioid epidemic. In Buffalo, NY, the court found that some arrestees were suffering fatal overdose between arrest and their formal entry into drug court. Therefore, they established the first Opiate Intervention Court in the country. This court temporarily suspends adjudication of charges in order to get those at high risk of overdose into treatment. The program is relatively new, but the initial results are promising and other jurisdictions should consider adopting a similar strategy.

38. The Commission recommends DOJ broadly establish federal drug courts within the federal district court system in all 93 federal judicial districts. States, local units of government, and Indian tribal governments should apply for drug court grants established by 34 U.S.C. § 10611. Individuals with an SUD who violate probation terms with substance use should be diverted into drug court, rather than prison.

Addiction Services Workforce and Training Needs

By the year 2025, workforce projections estimate that there will be a workforce shortage in the fields of substance abuse and mental health treatment of approximately 250,000 providers across all disciplines. Workforce needs include addiction psychiatrists, physicians specializing in addiction medicine, counselors, recovery coaches, and other behavioral health providers. There are simply too few physicians and other clinicians with the requisite training to meet the demands of the estimated 19.4 million Americans suffering from untreated SUDs. Expanding the workforce to meet treatment demand will require a comprehensive federal, state, local, public and private effort to develop the workforce pipeline.

Opioid-related inpatient stays and ED visits have increased dramatically across the Nation.[230] Fourteen of the 18 states experiencing the highest rate of opioid overdose deaths have experienced an increase in opioid-related hospital admissions, ranging from 21.4% to 54.6%. Moreover, a recent analysis of private insurance data found that most privately insured patients do not receive recommended care following an opioid-related hospitalization.[231]

Hospital programs are emerging across the country to address these surges in overdoses and improve post-discharge outcomes. One method has been the use of peer recovery coaches and other types of community health workers (CHWs), such as health educators, medical assistants, and community health outreach workers. The American Public Health Association defines a CHW as a "frontline public health worker who is a trusted member of and/or has an unusually close understanding of the community served." These workers are increasingly employed in physician offices and other health settings as care extenders. As such, they are uniquely positioned to be trained to provide substance use screening, brief intervention, referral management, and health and

community linkages in primary care and emergency room settings, and to provide outreach and care to substance using homeless populations.

Peer recovery specialists/coaches are in recovery from an SUD. New programs are emerging across the country to use CHWs and recovery coaches in a range of settings, including hospitals, to provide immediate and ongoing support and treatment linkages to individuals who have overdosed from opioids, or support individuals newly in recovery. These programs can address alarming levels of readmissions due to overdose. In addition, recovery workers are supporting law enforcement, fire departments, and other community partners addressing the opioid overdose epidemic. The use of these types of care extenders can help address the workforce shortage, but more of them are needed.

Recovery coaches are often members of a recovery community organization (RCO), which can and do play unique rolls in helping individuals, families and communities respond to drug use, addiction, and their consequences; they are uniquely positioned to facilitate access to treatment, support retention and successful treatment completion, and provide ongoing services and support after treatment. Unfortunately, they exist in far too few communities. While states such as Vermont and Texas have developed and are expanding and enhancing statewide RCO networks, other states have no RCOs at all or only have RCOs in selected communities. RCOs play a critical role in engaging individuals addicted to opioids and other drugs, linking them to treatment and other needed services and supporting them as they pursue their recovery.

Integral in tackling this epidemic is the recognition that diverse communities experience different rates of mental disorders and/or SUDs, as well as challenges to treatment access. For example, in 2016, the rate of illicit drug use in the last 30 days among American Indians and Alaska Natives ages 12 and up was 15.7%, the highest among all racial demography.[232] Research has shown that integrating culturally-based solutions into evidence-based treatment and recovery programs is a best practice and improves treatment outcomes. RCOs are best positioned to develop and implement culturally-specific ways to address the crisis in their communities.

RCOs are innovators and collaborators, working with hospitals, treatment providers, law enforcement, courts, corrections, child welfare systems, and broader communities to reduce drug use, and helping people achieve and sustain recovery. Their flexibility allows them to rapidly adapt to changing circumstances and to identify and fill gaps in systems and services. To maximize the benefit accrued from RCOs, federal efforts should help better integrate RCOs into local and statewide systems, services and sectors, such as Drug-Free Communities, HIDTA, correctional systems, law enforcement, hospitals, primary care, specialty treatment, and child welfare.

DOL has established an apprenticeship program for CHWs and recovery coaches with standard competencies, a curriculum, educational training, and on-the-job learning components, and routinely provides grants to augment the workforce. Through this program, employers provide a stipend for entry-level CHWs to receive on-the-job learning, on-site supervision, and educational training with the intent to secure employment as a credentialed CHW. Once an apprentice completes the CHW certification program, his or her name is registered into a DOL database, issued a certificate of completion, and is considered certified. The Presidential Executive Order Expanding Apprenticeships in America published on June 15, 2017 encourages federal agencies to fund and provide other supports to expand the use of CHWs to provide critically needed services across the country.[233] Health entities such as hospitals and primary care offices can also sponsor training and employment.

39. The Commission recommends the Federal Government partner with appropriate hospital and recovery organizations to expand the use of recovery coaches, especially in hard-hit areas. Insurance companies, federal health systems, and state payers should expand programs for hospital and primary case-based SUD treatment and referral services. Recovery coach programs have been extraordinarily effective in states that have them to help direct patients in crisis to appropriate treatment. Addiction and recovery specialists can also work with patients through technology and telemedicine, to expand their reach to underserved areas.

Estimates suggest there are currently about 4,400 actively practicing certified addiction specialist physicians (addiction medicine and addiction psychiatry) in the country, but data on the specialty workforce is limited. About 8 years ago, an estimate was made of the need for 6,000 addiction specialists, but that number is now insufficient given the growth of the opioid epidemic.

Addiction medicine was only formally recognized as a medical subspecialty in 2016. Currently, 46 of the Nation's 160 accredited medical schools offer addiction medicine fellowships. The first-ever addiction medicine board exam was held in September 2017. By 2021, fellowships will be the only pathway for physicians to take the addiction medicine certification exam. Without an adequate number of fellowships producing at least two new fellows per year, the field will quickly atrophy. Therefore, it is important to quickly ramp up the numbers of fellowships to address the opioid crisis. The goal is to grow the fellowships to 125 over the next five years. Significant funding is needed to start and sustain fellowship programs.

The Health Resources and Services Administration (HRSA) provides unique vehicles for addressing the increasing trends in opioid use, overdose, and addictions across the United States. The agency funds health centers in urban, suburban, and rural areas, trains and strengthens the workforce, hosts the Federal Office of Rural Health Policy, and has grant programs for several high-need and underserved communities and populations. The 21st Century Cures Act included funding for HRSA for addiction medicine fellowships starting in 2018. Starting this year, fellowships will be accredited by the Accreditation Council for Graduate Medical Education, which is a significant step toward getting funding from the VA and others.

Federal agencies should also be considering where telemedicine can play a role in ensuring access to care for those in geographically isolated regions and underserved areas.

40. The Commission recommends the Health Resources and Services Administration (HRSA) prioritize addiction treatment knowledge across all health disciplines. Adequate resources are needed to recruit and increase the number of addiction-trained psychiatrists and other physicians, nurses, psychologists, social workers, physician assistants, and community health workers and facilitate deployment in needed regions and facilities.

41. The Commission recommends that federal agencies revise regulations and reimbursement policies to allow for SUD treatment via telemedicine.

42. The Commission recommends further use of the National Health Service Corp to supply needed health care workers to states and localities with higher than average opioid use and abuse.

Response to Overdose

Expanded Access and Administration of Naloxone

Naloxone is an opioid antagonist medication that can rapidly reverse opioid overdose. It has been available for over forty years, has an excellent safety profile, and can be easily administered by either intravenous or subcutaneous injection or via nasal absorption. In the interim report, the Commission recognized the importance of ensuring naloxone is made as widely available as possible to save lives. Consequently, the Commission recommended that all law enforcement in the United States be equipped with naloxone, model legislation be provided to states to allow naloxone dispensing via standing orders, and 'Good Samaritan' laws be enacted to empower the public to seek help (Appendix 3).

The Commission assessed the availability and accessibility of naloxone across the nation. Figure 5 below shows the means at which the public can access naloxone in community pharmacies widely differs between the states. While there is not necessarily a naloxone supply shortage, price increases of the various forms of naloxone continue to create affordability issues, preventing state and local governments, as well as community organizations, from stocking naloxone at the levels necessary to rescue more people from overdose.

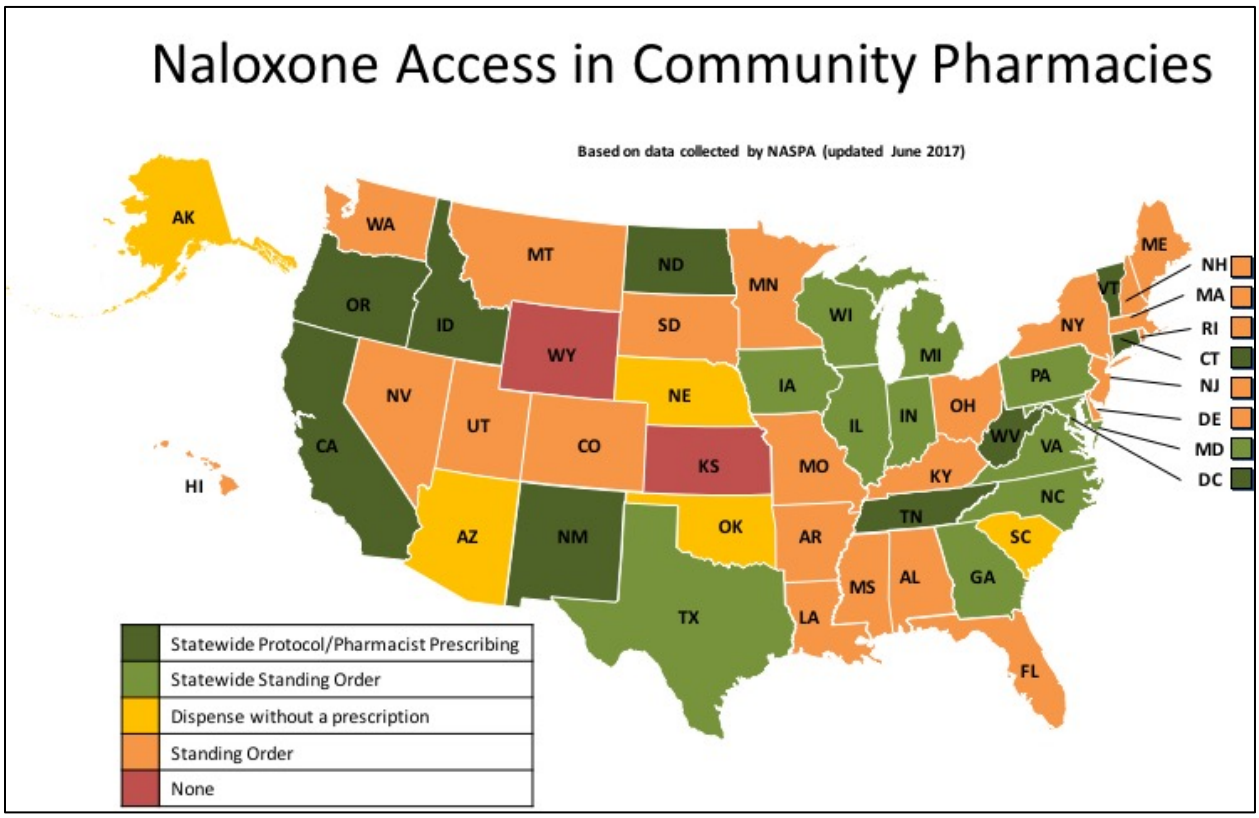

Figure 5. Naloxone Access (Source: National Alliance of State Pharmacy Associations)

To further ensure naloxone is made available when there is the greatest chance of an overdose, we must allow more first responders to be equipped with this life saving drug, including EMS personnel. In 2007, the National Highway Traffic Safety Administration's (NHTSA) issued its

National EMS Scope of Practice Model to provide guidance to states on the minimum skills and knowledge for licensure of each of four levels of EMS personnel; these four levels are:

- Emergency Medical Responder (EMR)
- Emergency Medical Technician (EMT)
- Advanced Emergency Medical Technician
- Paramedic

The *Model* suggests that the first two levels—EMR and EMT—not be approved for the administration of naloxone. Currently several states, following the NHTSA guidelines, prohibit EMRs and EMTs from administering naloxone in cases of opioid overdose. With the onset of the current opioid crisis, this prohibition has become problematic, especially in rural areas where the higher two levels—Advanced Emergency Medical Technician and Paramedic—are less common than in urban or suburban areas. Additionally, even in urban and suburban areas, EMS personnel in the two lower levels may be the first responders to incidents of opioid overdose. Given the critically narrow window that exists in which to administer naloxone to prevent overdose death, there may not be time to await arrival of higher level EMS personnel.

The *Model* has clearly become outdated with regard to its guidance on the ability to administer naloxone by EMS personnel in the two lower licensure levels, especially given the low risk of adverse effects of administering naloxone in either opioid overdose on non-opioid overdose conditions and the development of easily administered, pre-measured dose technologies.

Furthermore, in New Jersey, Commission Chair Governor Christie recently directed his Administration to revise EMS guidelines to allow for higher doses of intranasal naloxone to be administered, as the initial guidelines allowed for 2 mg of naloxone, which proved insufficient for some of the stronger opioids like synthetic fentanyl.

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43. The Commission recommends the National Highway Traffic Safety Administration (NHTSA) review its National Emergency Medical Services (EMS) Scope of Practice Model with respect to naloxone, and disseminate best practices for states that may need statutory or regulatory changes to allow Emergency Medical Technicians (EMT) to administer naloxone, including higher doses to account for the rising number of fentanyl overdoses.

Combination opioid products, especially those co-formulated with naloxone (e.g., oxycodone/naloxone and or buprenorphine/naloxone) have been associated with lower rates of misuse and nonmedical use compared with their single-entity counterparts.[234,235] In the interim report (Appendix 3), the Commission recommended a requirement that naloxone be prescribed in combination with any CDC-defined high-risk opioid being prescribed. Initial studies of the co-prescribing of naloxone with high morphine equivalent narcotic analgesics suggest that co-prescribing can reduce use and abuse of prescription opioids. The results from a 2016 study found a 47% reduction in opioid-related overdoses in the first six months after receipt of the prescription.[236] Initial best practice guidance should be provided based on currently available data and, further, a federally-funded pilot project should be developed to confirm initial findings and clarify the most effective strategies related to co-prescribing.

44. The Commission recommends HHS implement naloxone co-prescribing pilot programs to confirm initial research and identify best practices. ONDCP should, in coordination with HHS, disseminate a summary of existing research on co-prescribing to stakeholders.

Overdose to Treatment and Recovery

Effectively linking individuals who have survived an opioid overdose and those at risk for overdose remains a challenge. However, several promising approaches are emerging. These include, but are not limited to:

- Buprenorphine induction in the ED or other hospital departments followed by linkage with primary care and psychosocial services;
- Methadone induction for hospitalized patients followed by direct linkage to an opioid treatment program (OTP);
- An opioid urgent care unit adjacent to an ED that provides care coordination and linkage to office-based opioid treatment and psychosocial services;
- Overdose prevention training and naloxone distribution in the ED and other hospital settings;
- Post-overdose ED-based engagement, service linkage, and ongoing support and service coordination by recovery coaches and other peer workers who are on-call 24 hours per day, 365 days per year;
- Co-location of recovery coaches and other peer recovery support services workers at opioid treatment programs and primary care practices providing buprenorphine for the treatment of OUD;
- Community outreach and engagement of opioid users, their friends, and family by recovery coaches and other peer workers; and,
- Specialty bedside care for hospitalized patients from an inpatient addiction consult team.

In hospital settings, immediate engagement and initiation of treatment with an FDA-approved medication and/or recovery support services while the patient is still in the ED or is still in an inpatient hospital setting is critically important to increasing the number of Americans with opioid addiction who access treatment, decreasing overdose rates and related fatalities, and gradually lessening the burden the opioid crisis is creating for first responders, hospitals, and communities as a whole. To increase treatment participation, retention, and improve long-term recovery outcomes, a combination of clinical and recovery support services is necessary.

EMTALA requires EDs to stabilize and treat emergency medical conditions regardless of the patient's ability to pay. Medical stabilization language exists in other regulations as well. The general stabilization requirement is to resolve acute symptoms to avoid serious jeopardy to patient health. In the case of an individual with an OUD who has been revived after an overdose, initiation of MAT is often required to stabilize the patient prior to discharge. In addition, appropriate "health extenders," such as CHWs and recovery coaches, are also required to provide treatment engagement and follow-up services. Many emergency rooms and hospitals do not have sufficiently trained staff to diagnose an OUD or to provide the range of MAT and psychosocial services that

are needed to stabilize individuals. Thus, many overdose patients are being released without being appropriately stabilized and are at very high risk for subsequent overdose readmissions.

45. The Commission recommends HHS develop new guidance for Emergency Medical Treatment and Labor Act (EMTALA) compliance with regard to treating and stabilizing SUD patients and provide resources to incentivize hospitals to hire appropriate staff for their emergency rooms.

Recovery Support Services

Over the past decade or more, recovery has re-emerged as a key area of policy, practice, and advocacy. Recovery has many definitions. SAMHSA defines recovery from mental and SUDs as a process of change through which individuals improve their health and wellness, live a self-directed life, and strive to reach their full potential. Recovery support services (RSS) are non-clinical services designed to help individuals navigate the early stages of recovery and achieve stable, long-term recovery. Several organizations and programs exist to provide a structured and supportive environment for people in long-term recovery and are an emerging infrastructure with approximately 100 national organizations. However, national standards delineating the essential components, as well as financing and operation of state and local RSS, do not exist. The Recovery-Oriented Systems of Care framework identifies relevant values, principles, and strategies. It can be used as a starting point for development of standards.

While national peer RSS organizational accreditation standards have been developed and implemented by the Council on Accreditation of Peer Recovery Support Services, and national peer recovery support services specialist certifications have been developed by the two largest certification bodies in the addictions arena, states have not uniformly adopted these standards. Similarly, while the National Alliance for Recovery Residences has developed recovery housing certification standards that recognize levels of recovery housing, ranging from homes leased and operated by the residents (e.g., Oxford Houses) to residences with linked to clinical services, substandard recovery housing/sober living homes remains a problem in many jurisdictions.

46. The Commission recommends that HHS implement guidelines and reimbursement policies for Recovery Support Services, including peer-to-peer programs, jobs and life skills training, supportive housing, and recovery housing.

Impact on Families and Children

Addiction impacts each member of a family, affecting each member differently, but the most vulnerable are children. Children whose parents have an OUD may be neglected or even require removal to foster care. The developing fetus is vulnerable to substance use by the pregnant mother, as drugs readily cross the placenta and enters fetal blood circulation.

The opioid epidemic has impacted many states with increases in the number of children who have entered foster care due to parental drug use. Child welfare agencies have seen an increase in their

caseloads and are burdened with limited resources, e.g., funds to support drug treatment or parenting classes and community-based support for these children.

Stakeholders in the child welfare arena must collaborate to identify best practices to support families and intervene sooner. Successful treatment for parents can take multiple attempts and requires varied support from many agencies and community-based groups (e.g., treatment providers, counseling, supportive housing, drug courts, parenting classes, and transportation). Once a child enters foster care, the time frame for reunification with their parents or the termination of their parental rights begins. While this varies state by state, due to the scope of the problem it is critical that social workers and child protection staff are equipped to identify substance use early. In New Jersey, Commission Chair Governor Christie announced in September 2017 that the state's Department for Children and Families would be addressing these issues in a multi-prong approach; training Child Protection workers in SUDs, creating a program of peer-support for parents involved with the child welfare system, and increasing the investment in supportive house ("Keeping Families Together" program) for families involved in the child welfare system that experience parental SUD and housing instability.

Children who are in foster care are at greater risk for mental health problems, poor physical health, experience more adverse family experiences and more likely to be suspended from school.[237]

The number of children experiencing NAS increased 383% during the period 2000-2012 (1.2 cases per 1000 hospital births in 2000 to 5.8 cases per hospital births in 2012).[238] To address the number of children born with NAS, the passage of the Comprehensive Addiction and Recovery Act (CARA) of 2017 has modified state requirements related to how states must address SUDs, NAS and Fetal Alcohol Syndrome. Section 503 of CARA recommends that states implement a plan of safe care, yet the requirement does not identify a lead agency to oversee and ensure its implementation which continues to ensure a gap in leadership on this issue.

47. The Commission recommends that HHS, the Substance Abuse and Mental Health Services Administration (SAMHSA), and the Administration on Children, Youth and Families (ACYF) should disseminate best practices for states regarding interventions and strategies to keep families together, when it can be done safely (e.g., using a relative for kinship care). These practices should include utilizing comprehensive family centered approaches and should ensure families have access to drug screening, substance use treatment, and parental support. Further, federal agencies should research promising models for pregnant and post-partum women with SUDs and their newborns, including screenings, treatment interventions, supportive housing, non-pharmacologic interventions for children born with neonatal abstinence syndrome, medication-assisted treatment (MAT) and other recovery supports.

Supporting Collegiate Recovery and Changing the Culture on College Campuses

When American parents send their high school graduates to college, often at huge financial sacrifice, they hope to launch their children in pursuit of their American dream. Unfortunately, too many students get caught up in drug use and binge drinking, putting both their health, academic, extracurricular, and future prospects at risk. Many of these young people are unable to complete their studies. When they do achieve recovery, they are faced with the challenge of returning to the lion's den—a college or university campus where alcohol misuse and drug use may be the norm

for large portions of the student body. It is not surprising that researches have characterized higher education campuses as "abstinence-hostile environments." As more young people find recovery in their teens, they and their parents face the similar challenge of identifying a college or university that will not put their recovery at risk.

In face of this a growing number of colleges and universities have established collegiate recovery programs (CRP). These programs offer support and assistance to students in recovery and to students seeking help for alcohol and other drug problems. To join, some CRP's require treatment completion and/or a specified period of abstinence coupled with mutual aid participation while others are open to any student who believes they have an alcohol or other drug problem or who simply wishes to be part of a community for which alcohol or other drug consumption is not a part of social and recreational activities. Some CRPs provide a dedicated dorm or recovery residence for members and others do not.

Rutgers University, New Jersey's flagship state university system has the longest-running CRP in the nation. The Rutgers CRP began in 1983, with dedicated housing added in 1988. For the student residents, the program provides recovery support, a substance-free living environment, and a variety of extracurricular and enrichment activities such as outings and intramural sports. Students are expected to attend two 12-step meetings each week, and meetings are offered on campus. Rutgers staff regularly provides assistance to colleges and universities around the country who are looking to create or improve programs on their campuses.

To further these programs, New Jersey has passed legislation requiring all state colleges and universities with a significant portion of students living on-campus to have dedicated substance-free housing for students who wish to live in a substance-free environment.

CRPs are relatively small and inexpensive, and provide significant benefits to schools by encouraging degree completion, reducing drop outs, and promoting the health and safety of students. Programs vary, but they commonly include the following components: a coordinator or executive director and small staff; student volunteers; a gathering place, such as a recovery lounge, for students to drop by and support each other and for events; academic advice for those seeking to return to or stay in school; scholarships for those in need who are in recovery and maintain good grades; sponsorship of drug and alcohol free events open to all students on campus; leadership, professional development, and other opportunities to speak out about effective solutions to drug and alcohol problems.

In addition to helping students in recovery flourish and succeed academically, CRPs offer an attractive campus community for students who are not in recovery, but wish to avoid alcohol and other drugs. Through their alcohol- and other drug-free events, including football game tailgates and parties, movies, restaurants, music, and theater outings, they offer safer and healthier alternatives not only for members, but for a range of other students. While the number of collegiate recovery programs has grown significantly over the past decade, it has been estimated that only 3% of higher education institutions in the United States currently have a CRP.[239]

Although most of the costs associated with CRPs should be financed by the colleges themselves, government agencies can take some modest steps to accelerate adoption of these programs, as highlighted below.

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48. The Commission recommends ONDCP, the Substance Abuse and Mental Health Services Administration (SAMHSA), and the Department of Education (DOE) identify successful

college recovery programs, including "sober housing" on college campuses, and provide support and technical assistance to increase the number and capacity of high-quality programs to help students in recovery.

Employment Opportunities for Americans in Recovery

Americans who are in stable recovery from addiction deserve fair consideration for any job for which they are qualified. There are millions of Americans in recovery from all walks of life. Many of these individuals have past misdemeanor or felony drug-related criminal convictions that can impede or prevent them from securing employment for which they are qualified, even after having paid their debt to society and having achieved decades in recovery. When this occurs, it is not only those individuals who pay a price; their families and communities can be deprived of contributions these Americans might otherwise have been able to make. Laws and rules that impede or prevent employment for people in recovery can be counterproductive, making it more difficult to fully rejoin the community and sustain a life in recovery.

In addition to the barriers created by having a past criminal conviction, those in recovery can face long-lasting barriers to employment due to laws that prohibit the hiring of individuals with a past drug conviction in certain settings. For example, Section 1128 of the Social Security Act prohibits any entity receiving funding under federal health programs, such as Medicaid, Medicare, CHIP, TRICARE, or the VA, to employ individuals who have past felony convictions "relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance" (unless that conviction was related to an act that took place before the enactment of the Health Insurance Portability and Accountability Act of 1996) [42 U.S.C. 1320a–7 (4)]. This ban includes individuals with felony convictions related to the sale of illicit drugs outside of the context of a health care facility and covers not only health professionals, but all categories of staff, including custodians, drivers, administrative support staff, building engineers, mailroom personnel, etc.

Known as collateral consequences of conviction, laws of this kind apply restrictions to individuals that continue after they have completed their sentences. These laws can be found at the federal, state, and local levels. Collateral consequences of conviction can serve an important public safety function. However, to the extent that they impede successful recovery or reentry from incarceration without contributing significantly to public safety, they have the potential to actually undermine public safety, public health, and drug control policy goals. Under an award from DOJ, the American Bar Association created a publicly available comprehensive searchable online database cataloguing over 45,000 collateral consequences and civil disabilities and identifying remedies in instances where they are available.[240,241]

Ultimately, private sector employers are well positioned to play a central role in supporting the hiring and ongoing employment of those in recovery, identifying rules and laws that may impede hiring people in recovery, and increasing treatment access for employees with active addiction.

Employment for those with past drug use is a critical part of the solution to this drug crisis. The State of Florida has decoupled felony convictions and eligibility for certain business or occupational licenses with great success, expanding access to the wide arrays of jobs with licensing requirements.

49. **The Commission recommends that ONDCP, federal partners, including DOL, large employers, employee assistance programs, and recovery support organizations develop best practices on SUDs and the workplace. Employers need information for addressing employee alcohol and drug use, ensure that employees are able to seek help for SUDs through employee assistance programs or other means, supporting health and wellness, including SUD recovery, for employees, and hiring those in recovery.**

50. **The Commission recommends that ONDCP work with the DOJ, DOL, the National Alliance for Model State Drug Laws, the National Conference of State Legislatures, and other stakeholders to develop model state legislation/regulation for states to decouple felony convictions and eligibility for business/occupational licenses, where appropriate.**

Support Recovery Housing

There is a critical shortage of recovery housing for Americans in or pursuing recovery. Recovery residences (also known as "sober homes" or "recovery homes") are alcohol- and drug-free living environments for individuals seeking the skills and social support to remain free of alcohol or other drugs and live a life of recovery in the community. Generally, recovery residences do not offer treatment, although some are affiliated with, or are arms of treatment provider organizations that offer counseling or other services to residents, onsite or at a nearby location. Recovery residences strongly encourage attendance at 12-step groups or other mutual aid groups (e.g., SMART Recovery, Women for Sobriety, Celebrate Recovery, etc.) and are generally self-funded through resident fees, or in the case of Oxford Houses or other resident-run homes, shared rent, utility, and food payments. Benefits associated with staying in a recovery residence include decreases in alcohol and drug use, psychiatric symptoms, and arrests as well as increases in employment.[242]

Recovery residences can play a critical role for individuals in outpatient treatment, those exiting residential treatment, homeless individuals in early recovery, those involved in drug courts, those returning to the community from incarceration, and those who may not require residential treatment if they have a living environment that is supportive of recovery, outpatient treatment and/or mutual aid groups. Many who cannot return to a home where there is active drug use or a community where they used drugs find a safe haven in a recovery residence. Importantly, like peer RSS generally, recovery residences can help maximize the public and private investments in treatment by ensuring better long-term outcomes, by sometimes making a lower, less costly level of care possible and, in some instances, by making treatment unnecessary.

Unfortunately, unethical operators have cast suspicion on recovery residences generally and have complicated the efforts of families, treatment centers, and court systems to identify safe, supportive, well run, and affordable recovery housing. Quality recovery residences operate in accordance with accepted national guidelines, such as the standards developed by the National Alliance for Recovery Residents (NARR) or the charter Oxford Houses must follow. Residences that do not meet these or state-established standards can place those they serve at risk. While some states have defined recovery residence licensing criteria and or required their treatment providers to only refer patients to certified recovery residences and Oxford Homes, many have no mechanism for ensuring quality and accountability.

51. **The Commission recommends that ONDCP, federal agencies, the National Alliance for Recovery Residents (NARR), the National Association of State Alcohol and Drug Abuse**

Directors (NASADAD), and housing stakeholders should work collaboratively to develop quality standards and best practices for recovery residences, including model state and local policies. These partners should identify barriers (such as zoning restrictions and discrimination against MAT patients) and develop strategies to address these issues.

Research & Development

For too long addiction and pain research have been conducted and led by separate research communities and suffered from silos and in some cases excessive pressure from industry at the cost of patient health. The *National Drug Control Strategy* has never included a pain management emphasis despite the fact that prescription opioid misuse still is responsible for most opioid misuse in this country and providing better pain management is essential to preventing prescription opioid misuse and diversion that starts so many people down the path to heroin use. Several federal agencies are best suited for shepherding research initiatives and opportunities to combat the epidemic[243] and enhance treatment options, including alternative pain management strategies, and treatment for vulnerable populations such as pregnant women, and substance-exposed infants. Addressing the gaps with basic, applied research, and development can conceivably expand the range of alternatives to imperfect medications currently used to mitigate pain or treat addiction.

52. The Commission recommends federal agencies, including HHS (National Institutes of Health, CDC, CMS, FDA, and the Substance Abuse and Mental Health Services Administration), DOJ, the Department of Defense (DOD), the VA, and ONDCP, should engage in a comprehensive review of existing research programs and establish goals for pain management and addiction research (both prevention and treatment).

New Pain, Overdose, and MAT Medications

The bounties of scientific research are essential to mitigate the opioid crisis, drug addiction and associated morbidity and mortality. The most practical basic research goals for the current epidemic[244] are to develop: (1) effective analgesics with limited or no abuse liability, i.e. alternatives to opioids; (2) drugs to reverse overdose capable of surmounting newly emerging fentanyl analogs or new psychoactive opioids; and (3) medications that do not engender abuse liability or physical dependence to assist in treating opioid addiction. Each of these areas requires short-, intermediate-, and long-term research strategies. The research goals have been charted and led by the NIDA Director, with support and coordination among the NIH institutes and the NIH Director. NIH has also recruited pharmaceutical companies to develop public-private partnerships in pursuit of these goals. This initiative offers great promise to improve the range of choices for pain management, medications assistance, and overdose reversal. As an example, a NIDA partnership with a pharmaceutical company successfully developed a user-friendly intranasal naloxone formulation that results in blood naloxone levels equivalent to those reached with injection. The FDA approved it in 2015.

Alternatives to Opioid Pain Medications. μ-opioid signaling is among the most effective system to dampen or block pain. The same system also produces pleasurable sensations, even euphoria which drives addictive behaviors. For over a century, medicinal chemists have pursued safer opioids to disconnect pain relief from pleasurable sensations. Opioid over-prescribing in part reflects the limited number of effective medications to treat moderate to severe pain and the compelling need for alternatives. Among the candidate solutions are development of abuse-deterrent formulations, new opioids that trigger "biased" μ-signaling pathways, or target other opioid receptors subtypes, or drugs that modify other receptors, and ion channels involved in

processing or modifying pain sensations, including transient receptor potential vanilloid (TRPV) channels, non-psychoactive cannabinoids, inflammatory pathways, or other modifiers of signaling pathways.

Novel therapeutics are also likely to emerge from a better understanding of pain biology, enabled in part by transformative technologies such as the ability to solve the three-dimensional crystal structure of target proteins or assess pharmacology by computer simulations. Adoption of other transformative technologies, including induced stem cells and CRISPR, can result in more efficient validation of novel compounds through the development of models with better translational fidelity. Clinical studies can also be improved by patient selection and stratification.[245]

Overdose Reversal Interventions. Over 140 Americans die daily from opioid overdoses. The primary reason is that overactivated μ-opioid receptors in brainstem neurons stop natural breathing. Naloxone targets the μ-opioid receptor, but unlike oxycodone, heroin, or fentanyl, instead of activating it, it prevents it from functioning and reverses and overdose, if administered in sufficient time. It has saved thousands of lives, but is ineffective if the person overdosing is alone during a narrow window of time, or if requiring multiple doses to surmount a highly potent opioid.[246] This new challenge is reflected in the rapid rise in overdose fatalities driven by the highly potent drug fentanyl, or even more potent fentanyl analogs. Private partnerships are engaging with NIH to develop higher affinity longer-acting formulations of antagonists, including naloxone, to counteract the very-high-potency synthetic opioids that are now claiming thousands of lives.

Treatments for Opioid Addiction. Research and development are needed to improve the range of medications to assist in treating OUD. Currently, three medications are approved for treating OUD: methadone, buprenorphine, and ER naltrexone. Along with psychosocial support, they comprise the current standard of care for reducing illicit opioid use, relapse risk, and overdoses, while improving social function.[247] Each of these medications has important strengths, but some shortcomings. Methadone is full agonist at the μ-opioid receptor, while buprenorphine is a partial agonist. Both methadone and buprenorphine can be reinforcing and thereby diverted, unlike naltrexone which, like naloxone, blocks the receptor. Compliance with treatment is higher with methadone than with buprenorphine or naltrexone,[248] but overall success in abstinence is imperfect.[249] There is a clear need to develop new treatment strategies for OUDs, including new pharmacologic approaches that focus on modulating activity of the reward circuit through other targets (e.g. neurokinin-1 receptor antagonists or κ-opioid receptors antagonists). Other target receptors and vaccines to prevent brain entry of opioids are under investigation.

Over a longer time-frame, prevention and treatment of opioid addiction will require more exquisite knowledge of the mechanisms underlying pain, reward, loss of control, and how biological and social factors shape the attractiveness of opioids. Treating chronic pain while avoiding misuse is problematic for patients with a prior history of SUD, and more research conceivably will reveal the degree of risk for OUD when people with serious pain are undertreated. Other research voids include brain research imaging of people who overdose one or more times. Recent reports have documented cases of amnesia after an overdose. The extent to which opioids cause significant and possibly irreversible brain damage warrants investigation.

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53. The Commission recommends Congress and the Federal Government provide additional resources to the National Institute on Drug Abuse (NIDA), the National Institute of Mental Health (NIMH), and National Institute on Alcohol Abuse and Alcoholism (NIAAA) to fund the research areas cited above. NIDA should continue research in

concert with the pharmaceutical industry to develop and test innovative medications for SUDs and OUDs, including long-acting injectables, more potent opioid antagonists to reverse overdose, drugs used for detoxification, and opioid vaccines.

Medical Technology Devices

Research and development in new technologies/devices to assist in the opioid crisis are emerging. Their development should be encouraged. A few examples are offered, with a caveat that few have received FDA approval, while others are in various stages of research and development and have yet to undergo FDA scrutiny or even be sufficiently developed for clinical trials.

- Detection of real-time substance use is a critical step for optimizing behavioral interventions and feedback to prevent drug abuse. Traditional methods based on self-reporting or rapid result urine screening are inefficient or intrusive for drug use detection, and inappropriate for timely interventions. Methods for real-time substance use detection are severely underdeveloped. A new real-time drug use event detection method is being developed that uses data obtained from wearable biosensor. Biosensors are designed to detect and establish thresholds of parameters in a real-time drug use event and to produce wearable biosensor data streams.[250]
- Wearable devices that sense respiratory depression (rings, ear pieces) that can alert the user, a family member, or wirelessly report to a first responder to intervene, or automatically inject naloxone when blood oxygenation levels become dangerously low.
- Apps on electronic devices (phones, watches) that can function as behavioral coaches and reminders.
- Technology devices that transmit findings from smartphones directly into the medical record.
- In home monitoring of vital signs with transmission capability
- Transcranial magnetic stimulation (TMS) for treatment of pain.
- Monitoring appropriate consumption/compliance with medications that contain a transmitter to relay a signal as soon as a drug enters the digestive system. A similar transmitter can be adapted for naloxone use.
- Behavioral monitoring feedback apps that can be as, or more effective than face-to-face behavioral training for addiction.
- Pain reduction devices such as subcutaneous field stimulators, dorsal column stimulators, dorsal root ganglion stimulators, multifidus muscle stimulators, implantable infusion pumps, and sensory cortex stimulators.
- Detection of drug consumption use (drugs/metabolites) in neighborhoods using a waste water collection system positioned in drains within small regions (two block radius) to identify hot zones of distribution and/or use.

54. The Commission recommends further research of Technology-Assisted Monitoring and Treatment for high-risk patients and SUD patients. CMS, FDA, and the United States Preventative Services Task Force (USPSTF) should implement a fast-track review

process for any new evidence-based technology supporting SUD prevention and treatments.

55. **The Commission recommends that commercial insurers and CMS fast-track creation of Healthcare Common Procedure Coding System (HCPCS) codes for FDA-approved technology-based treatments, digital interventions, and biomarker-based interventions. NIH should develop a means to evaluate behavior modification apps for effectiveness.**

FDA Post-Market Research and Surveillance Programs

The FDA is a key federal agency designed to safeguard public health and safety, including opioids. Of all the drugs approved by the FDA, opioids are causing more illnesses and deaths than any other drug class currently on the market. FDA's timeline of regulatory oversight of opioids from 1911-onward shows a rapid expansion of approval of opioids starting in the mid-1990's and continuing to this day. In 2001, as concerns of addiction and overdoses emerged, the FDA took steps to develop public education regarding prescription drug abuse, packet inserts for patient education, and stronger warnings. Other discrete steps taken to rein in their adverse consequences proved equally ineffective.[251]

In 2016, the FDA once again initiated assessment and implementation of its policies to constrict unfettered prescribing practices. These policies included expanded use of advisory committees, development of warnings and safety information for IR opioid labeling, strengthening post-marketing requirements, updating the Risk Evaluation and Mitigation Strategy (REMS) Program that requires sponsors to fund continuing medical education to providers, at low or no cost, on appropriate use of opioids, expanding access to abuse-deterrent formulations to discourage abuse, and reassessing the risk-benefit approval framework for opioid use.[252] In 2017, the FDA brought IR opioids under its REMS program authorities, along with ER long-acting opioids; however, prescriber education in this program is currently optional for prescribers. Currently, more than 20 opioid analgesic formulations are approved by the FDA and an additional 52 applications for approval are being considered.[253]

The evidence base to guide the use of opioid medications, particularly in the setting of long-term use, is substantially lacking. Over decades, opioids were approved by the FDA with two significant gaps in vigilance: lack of concern of misuse, tampering, and diversion from a legitimate prescription and inadequate post-market surveillance of efficacy for long-term use, addiction, and other long-term consequences (e.g. depression or transition to heroin). The FDA is strengthening the requirements for drug companies to generate post-market data on the long-term impact of using ER/long-acting opioids and accumulate better evidence on the serious risks of misuse and abuse associated with long-term use of opioids, predictors of opioid addiction, and other important issues.

56. **The Commission recommends that the FDA establish guidelines for post-market surveillance related to diversion, addiction, and other adverse consequences of controlled substances.**

Conclusion

The origins of the current opioid crisis can be traced to a sequence of at least twelve converging events and movements that catalyzed the most devastating drug epidemic in our nation's history. A five-sentence letter to a biomedical journal in 1980, followed by other low-quality articles claiming that opioid narcotics are safe to use universally for chronic pain, bolstered advocacy by pain patients and professional societies to treat pain with opioids. It also instigated the opioid pharmaceutical industry to embrace and exploit the flawed claims with aggressive marketing and "educational outreach." Government agencies and accreditation organizations then designated pain as a fifth vital sign. Without a counterbalancing force appearing in the medical community to question the evidence or conclusions, pain assessment became a preoccupation of healthcare practices and opioid prescribing became an accepted solution.

Prescriptions for opioids surged, now fueled by financial and performance pressures on physicians to satisfy patients using opioids, insurers' unrestrained reimbursements for opioids, an insufficient response of federal regulators, and lack of public unawareness of the hazards of this class of drugs. Poor medical education on pain management, on opioid prescribing, and on screening for high risk patients undermined the ability of conscientious physicians to safely treat pain or addiction.

A nation awash with prescription opioids became fertile ground for diversion by acquisition from medicine cabinets, through rogue pharmacies, rogue physicians, and for opportunistic sellers of illicit heroin, fentanyl, and other deadly opioids. The Commission has reflected on this history, for it is a compelling source for solutions to contain this national nightmare, solutions that are complex and multi-dimensional.

By the very nature of our federal-state-local governance, most solutions require responses at all levels of government. Some need the cooperation and the support of private institutions, such as commercial insurers, companies engaged in data analytics, academic institutions, or individuals who have inadvertently contributed to this crisis. Unintentional contributors to the crisis are recognizing earlier missteps and devising strategies to 'reverse engineer' decisions with prudence.

The goals of the recommendations included in this report are to promote prevention of all drug use with effective education campaigns and restrictions in supply of illicit and misused drugs. To achieve supply reduction, we recommend shaping prescribing practices by improved medical education, by alternatives to pain management, as appropriate, by enhancing physician awareness of high risk patients though substance use, mental, and medical screenings and interrogation of PDMPs, insurance company oversight, and by interdiction of deadly opioids. Treatment and overdose rescue are both distinct and inextricably linked efforts. Overdose rescue procedures need to be opportunistic and include access to trained personnel, to medications, and to treatment services. Administering naloxone to a person who has overdosed and then abandoning them without offering medication and same-day entry to treatment is short-sighted and inadequate.

Treatment services need to be improved, foremost by developing thoughtful national evidence-based standards of care, record-keeping, and long-term support. In view of the need, expansion of services is imperative and so are surmounting barriers – to medications, limited healthcare workforce, to insurance reimbursement – and ensuring high-quality care and long-term recovery support services.

The Commission strongly supports research and development of alternatives to opioids for pain management, treatment and rescue, and of modern medical devices essential to improving our

responses. The Commission also strongly recommends real-time data analytics to inform our mission and accomplishments. Above all, each recommendation should have accountability built-in and be subjected to measurable goals, quantitative solutions, and measurable outcomes. The Federal Government now must develop a level of accountability that has not been imposed rigorously in the past.

Lessons learned. A catalog of lessons learned can guide our nation in devising current solutions and alerting future generations on how to avoid inevitable emerging and potentially devastating drug-related crises. Important lessons can be extracted from earlier imprudence. The current focus on opioids is driven by the devastatingly high death rates. While death is the ultimate catastrophe, many psychoactive drugs with abuse potential do not precipitate an overdose crisis nor death as dramatically as do opioids. Nonetheless, other drugs can be markedly detrimental to the brain, body, and behavior.

- Low quality evidence that opioids are innocuous for chronic pain management was accepted without scrutiny, by the healthcare system, by physicians, medical schools, regulatory bodies, and insurers. High-quality assessment of the addictive potential of orally bioavailable opioids should have been imposed by the FDA.
- Constant vigilance is necessary to recognize if marketing efforts are suppressing scientific evidence (e.g. addiction) and common sense. Early scientific scrutiny of dubious claims should be a key priority of regulatory agencies and physicians.
- Engage all stakeholders when creating standards and actionable outcomes. Do not restrict input to those who passionately favor a substance. Advocates may be less willing or able to see unintended consequences than others.
- The approval process of medications with abuse liability should not be restricted to drug safety and efficacy in short term clinical trials. The drug approval process should expand its oversight and consider the number of doses and duration of a prescription for specific indications, the possibility of misuse, diversion, and tampering, and other consequences not traditionally a component of evidence required in the approval process.
- Anticipate unintended consequences and devise effective data analytics, monitoring, and responses at the outset of a trend. A small, but significant portion of patients and other users or misusers of diverted prescription opioids transitioned to heroin. Screening for OUD when reducing opioid supply or creating a tamper-resistance formulation, and implementing procedures to assist treating OUD patients conceivably could have avoided the transition for some people.
- Apply the lessons learned to current movements to medicalize and legalize other Schedule 1 drugs. The catalyst of the opioid crisis was a denial of its addictive potential.
- Pharmaceutical sponsorship of medical society events needs rigorous oversight and review.
- Without adequate training in pain management and in addiction diagnosis and treatment, the medical establishment was caught off guard and unprepared for iatrogenic opioid addiction. Training in these disciplines should be mainstreamed into every level of medical education, to address the current crisis and to prepare for inevitable iterations.
- Healthcare insurers have a significant role in attenuating this public health crisis. They can reduce opioid supply by declining reimbursement for unnecessary opioid prescriptions, and

facilitate recovery by seamless reimbursement for medications and treatment services. Federal oversight on insurance company practices was inadequate as the crisis expanded.

Current Federal Programs and Funding Landscape

Overview

Congress has not enacted full year appropriations for fiscal year (FY) 2018, which began October 1, 2017. The Federal Government is operating under a Continuing Resolution (CR) that will expire in December 2017. The funding levels presented in this report are consistent with the funding levels represented in the FY 2018 President's Budget, including FY 2018 Request levels and FY 2017 CR (annualized) estimates.

The President's FY 2018 Budget Request supports $27.8 billion for drug control efforts spanning prevention, treatment, interdiction, international operations, and law enforcement across 14 Executive Branch departments, the Federal Judiciary, and the District of Columbia. This represents an increase of $279.7 million (1.0%) over the annualized CR level in FY 2017 of $27.5 billion.

Within this total, the Budget supports $1.3 billion in investments authorized by the *Comprehensive Addiction and Recovery Act* (CARA), the *21st Century Cures Act*, and other opioid-specific programs to help address the opioid epidemic.

FY 2018 Funding Specific to America's Opioid Crisis

Reducing Overdoses. Reducing opioid overdoses, to include identifying those at risk of overdose, the signs of overdose, and expanding the use of naloxone, are key pieces of the Administration's strategy to address the opioid overdose epidemic.

The FY 2018 Budget request for SAMHSA includes $12.0 million for *Grants to Prevent Prescription Drug/Opioid Overdose Related Deaths*. This program will provide continuation grants to 10 states to significantly reduce the number of opioid overdose-related deaths by helping states purchase naloxone, equipping first responders in high-risk communities, supporting education on the use of naloxone and other overdose death prevention strategies (including covering expenses incurred from dissemination efforts), and providing the necessary materials to assemble overdose kits. This program was appropriated $12 million in FY 2016 and $12 million in the FY 2017 CR.

The FY 2018 Budget request for the CDC includes $70.0 million for the *Prescription Drug Overdose Prevention for States* program to cover overdoses from opioids and other drugs, the same level as the FY 2017 CR. This program, which advances and evaluates comprehensive state-level interventions for preventing prescription drug overuse, misuse, abuse, and overdose, is expanding to all 50 states and the District of Columbia in FY 2017. Funds in FY 2018 will support state efforts as well as rigorous monitoring, evaluation, and improvements in data quality at the national level. Funds will also be used to increase uptake among providers of the CDC's *Guideline for Prescribing Opioids for Chronic Pain*, as well as implementation of a coordinated care plan that addresses both opioid and heroin overdose prevention by improving care for high-risk opioid patients.

The FY 2018 Budget request also includes $5.6 million in funding for the CDC to address the rising rate of heroin-related overdose deaths by working to collect near real-time ED data and

higher quality and timely mortality data by rapidly integrating death certificate and toxicology information. This is a small increase above the FY 2016 appropriation and level with the FY 2017 CR. Apart from these programs, the FY 2018 budget request continues to provide funding for expansion of electronic death reporting to provide faster, better quality data on deaths of public health importance, including prescription drug overdose deaths.

Enhancing Prescription Drug Monitoring Programs. PDMPs are an important state-based health care tool. They provide information to health care providers so they can better understand what is being prescribed and intervene before a prescription drug abuse disorder becomes chronic. Currently, PDMPs exist in 49 states.

The FY 2018 request for DOJ's PDMP activities includes $12.0 million for state grants to enhance the capacity of regulatory and law enforcement agencies to collect and analyze controlled substance prescription data. The FY 17 CR level for PDMP activities was $13.0 million, level with the FY 2016 final budget. The purpose of DOJ's PDMP effort is to enhance the capacity of regulatory and law enforcement agencies to collect and analyze controlled substance prescription data. In coordination with HHS, the program aims to assist states that want to establish or enhance a PDMP. Objectives of the program include building a data collection and analysis system at the state level, enhancing existing programs' ability to analyze and use collected data, facilitating the exchange of collected prescription data between states, and assessing the efficiency and effectiveness of the programs funded under this initiative.

The FY 2018 Budget for SAMHSA includes $58.4 million for the *Strategic Prevention Framework*. Within this amount, SAMHSA will target $10 million to address prescription drug (including opioids) abuse and misuse, use PDMP data for prevention planning, and implement evidence-based practices and/or environmental strategies aimed at reducing prescription drug abuse and misuse. The final spending level for the *Strategic Prevention Framework* program was appropriated $119.5 million in FY 2016; in FY 2017, the CR level was $119.3 million.

Medication-Assisted Treatment Programs. MAT is an evidence-based treatment for individuals with OUDs. However, it is underutilized and often not available to those who could benefit from its administration. Expanding access to MAT, in combination with other behavioral health care, will help address this issue and help more individuals sustain their recovery from OUDs.

The FY 2018 Budget includes $25.0 million for SAMHSA, to support the *MAT for Prescription Drug and Opioid Addiction* program for states, level with funding for FY 2016 and the FY 2017 CR. In FY 2018, SAMHSA plans to expand and enhance its program to improve access to MAT services for treating OUDs. SAMHSA anticipates 22 new states that have demonstrated a dramatic increase in treatment admissions for OUDs will be funded under the FY 2018 request.

Medication-Assisted Treatment in the Criminal Justice System. The Bureau of Prisons' (BOP) budget contains $1.0 million in new resources to expand the MAT Pilot. The pilot provides an opportunity to evaluate whether MAT should be expanded in the corrections setting.

Residential Substance Abuse Treatment. The Office of Justice Program's budget contains $12.0 million for the Residential Substance Abuse Treatment (RSAT) program for state prisoners, level with funding for FY 2016 and the FY 2017 CR. The program was established to help state and local governments develop, implement, and improve residential substance abuse treatment

programs in correctional facilities, and establish and maintain community-based aftercare services for probationers and parolees. It is intended improve public safety and reduce criminal recidivism by helping offenders become drug-free and learn the skills needed to sustain themselves upon return to the community.

Enhanced Drug Enforcement Efforts. The Budget provides increases to federal law enforcement agencies aimed at reducing the flow of illicit drugs into the country and increasing investigations of transnational criminal organizations, violent gangs, and drug traffickers. Specifically:

The FY 2018 Budget includes funding to maintain and expand capacity to fight against heroin and other illicit drugs at the DOJ. This includes a total of $2.6 billion for the DEA, including $21 million in new discretionary resources are requested for DEA and $32 million in new mandatory resources for the DEA's Diversion Control Program to reduce the diversion and abuse of pharmaceutical controlled substances and listed chemicals, including prescription opioids. The overall DEA request for FY 2018 is an increase of $158.1 million over the FY 2016 level and $150.3 million over the FY 2017 CR level. The FY 2018 Request for the DOJ also includes $526.0 million for Organized Crime and Drug Enforcement Task Force (OCDETF) to support heroin enforcement efforts, address transnational organized crime, and to reduce violent crime in cities across the nation. The request is an increase of $14.0 million above the FY 2016 and $15.0 million more than the FY 2017 CR and will enhance heroin enforcement efforts, address transnational organized crime, and reduce violent crime in cities across the nation.

Drug Prevention. The *Drug Free Communities (DFC) Support Program* is built upon the idea that local problems require local solutions. DFC funding provides for the bolstering of community infrastructure to support environmental prevention strategies to be planned, implemented, and evaluated in communities across the United States, Territories and Protectorates. The DFC Program is guided by local communities who identify and develop evidence-based strategies to reduce drug use and its consequences. For FY 2018, $91.8 million will fund approximately 659 DFC grants and continue the DFC National Cross-Site Evaluation. This program received $95.0 million in FY 16 and $94.8 million in FY 2017 through CR.

Addressing Domestic and Transnational Organized Crime. The Administration will employ tools to disrupt the flow of illicit drugs into our country, and reduce drug trafficking domestically.

In an effort to enhance security at the Southwest Border, in the FY 2018 President's Budget, CBP requests $260.5 million to fund acquisition, delivery, and sustainment of prioritized border security capabilities. This is a new activity, reflecting the President's commitment to border security.

The *HIDTA* program, created by Congress with the Anti-Drug Abuse Act of 1988, aids federal, state, local, and tribal law enforcement agencies operating in areas determined to be critical drug-trafficking regions of the United States. A total of $246.5 million is requested for the HIDTA program in FY 2018, a decrease from the FY 2016 funding level of $250.0 million and the FY 2017 CR funding level of $249.5 million.

The Comprehensive Addiction and Recovery Act (CARA)

The *Comprehensive Addiction and Recovery Act* (CARA) authorized new programs to help fight the scourge of opioid abuse plaguing our Nation, and authorized appropriations for existing programs to continue their work. Highlights of these programs are below:

In FY 2018, SAMHSA is requesting $12.0 million for the *Preventing Prescription Drug/Opioid Overdose-Related Deaths* (PDO II) program, authorized in CARA. FY 2018 is the first-time appropriations for this newly-authorized program will be requested. The purpose of this program is to reduce the number of prescription drug/opioid overdose-related deaths and adverse events among individuals at risk for OUD. Applicants will train first responders and members of other key community sectors at the state, local government, and tribal levels to implement secondary prevention strategies, such as the administration of naloxone through FDA-approved delivery devices to reverse the effects of opioid overdose.

SAMHSA is also requesting $1.0 million to support a new cohort of grants through the *Building Communities of Recovery* program. This program mobilizes resources within and outside of the recovery community to increase the prevalence and quality of long-term recovery support for people with SUDs. These grants support the development, enhancement, expansion, and delivery of recovery support services, as well as promotion of and education about recovery.

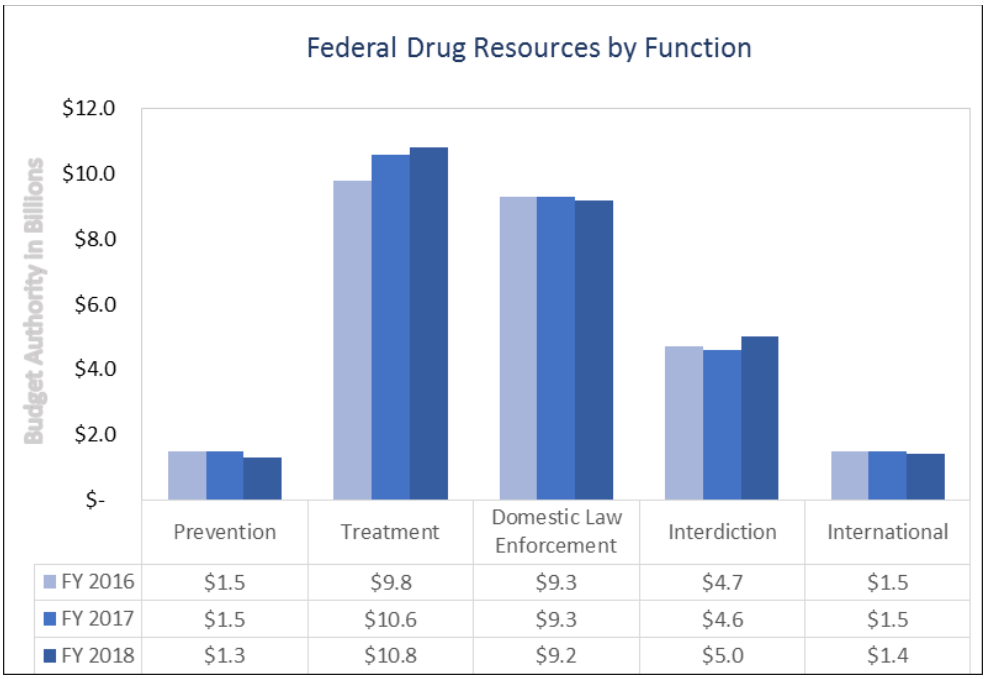
At the DOJ, the Office of Justice Programs is requesting $20.0 million for grants under the *Comprehensive Opioid Abuse Program*. This new program aims to support cross-system collaboration; develop and implement strategies to reach survivors of non-fatal overdoses and their loved ones; provide treatment and recovery support services; expand diversion and alternative to incarceration programs; expand services in rural or tribal communities; implement and enhance PDMPs; and assess the impact of new strategies.

At the VA, $50 million authorized under CARA is being requested for activities to increase opioid safety practices and improve care for Veterans within the Veterans Health Administration. VA began implementation of these activities with CR funds in FY 2017.

21st Century Cures Act

The *21st Century Cures Act* provides a total of $970 million over two fiscal years (FY 2017 and FY 2018) to HHS to address the opioid crisis by increasing treatment, reducing unmet treatment need, and reducing opioid overdose related deaths through the provision of prevention, treatment, and recovery activities for OUD (including prescription opioids, as well as illicit drugs such as heroin).

SAMHSA is administering the *21st Century Cures Act* funding through the *State Targeted Response to the Opioid Crisis Grants*. The President's Budget requests $500 million for state grants under this program. Grantees use epidemiological data to drive decision-making, rapidly address gaps in their systems of care, implement prevention strategies, deliver RSSs, and report progress on expanding treatment and reducing opioid overdose deaths.



	Prevention	Treatment	Domestic Law Enforcement	Interdiction	International
FY 2016	$1.5	$9.8	$9.3	$4.7	$1.5
FY 2017	$1.5	$10.6	$9.3	$4.6	$1.5
FY 2018	$1.3	$10.8	$9.2	$5.0	$1.4

Figure 6. Drug Resources by Function

FY 2018 Consolidated Federal Drug Control Budget

The consolidated National Drug Control Budget details agency resources by function. Functions categorize the activities of agencies into common drug control areas. Figure 6 details funding by function.

Prevention

Preventing drug use before it starts is a fundamental element of a comprehensive approach to drug control. Federal resources totaling $1.3 billion in support of education and outreach programs has been requested to educate young people about the consequences of drug use and prevent youth initiation. This represents a decrease of $167.5 million (11.1%) over the FY 2017 level; the major efforts are highlighted below:

Substance Abuse Prevention and Treatment Block Grant ($370.9 million)
Department of Health and Human Services – Substance Abuse and Mental Health Services Administration
Twenty percent of the $1.9 billion (i.e., $370.9 million) Substance Abuse Prevention and Treatment Block Grant is the minimum set aside to support prevention services. State Substance Abuse Administering Agencies use these funds to develop infrastructure and capacity specific to SUD prevention. Some State Substance Abuse Administering Agencies rely heavily on the 20% set-aside to fund prevention, target gaps in prevention services, and enhance existing program efforts.

Education's Prevention Efforts ($48.9 million)
Department of Education
The $48.9 million request includes $46.3 million for School Climate Transformation Grants and related technical assistance. These funds help create positive school climates through multi-tiered decision-making frameworks that guide the selection, integration, and implementation of the best evidence-based behavioral practices. A key aspect of this multi-tiered approach is that it provides differing levels of support and interventions to students based on their needs. In schools where these frameworks are implemented well, there is evidence that youth risk factors are improved; improved risk factors are correlated with reduced drug use, among other improved behaviors.

***Prevention* Research ($331.9 million)**
Department of Health and Human Services – National Institutes of Health
NIH's NIDA invests in genetics, neuroscience, pharmacotherapy, and behavioral and health services research, producing innovative strategies for preventing SUDs. In addition, NIDA is supporting research to better understand the impact of changes in state policies related to marijuana. Through NIAAA, the NIH helps to develop strategies to prevent the short- and long-term consequences of alcohol use among youth.

Drugged Driving ($2.72 million)
Department of Transportation, National Highway Traffic Safety Administration
NHTSA's FY 2018 request supports the Drug-Impaired Driving Program, which provides public information, outreach efforts, and improved law enforcement training to help reduce drugged driving. Funding will also allow NHTSA to continue to conduct research designed to reduce the incidence of drug-impaired driving.

Anti-Doping Activities/World Anti-Doping Agency Dues ($11.8 million)
Office of National Drug Control Policy
Anti-doping activities focus on efforts to educate athletes on the dangers of drug use, eliminate doping in amateur athletic competitions, and rely on standards established and recognized by the United States Olympic Committee. Funding for both efforts promotes an increased awareness in the United States and internationally of the health and ethical dangers of illicit drug use and doping in sport. Funding and participation in the Anti-Doping Activities/World Anti-Doping Agency is necessary to compete in international events. These activities support state-of-the-art research within the scientific and public health communities, while striving to protect athletes' fundamental rights to participate in drug-free sports, and thus promote the health and safety of athletes at all levels.

Treatment and Recovery

Treatment and recovery support services are essential elements of reducing drug use and its consequences. The FY 2018 Budget proposes $10.8 billion, an increase of $202.6 million (1.9%) over the FY 2017 annualized CR level in federal funds for early intervention, treatment, and recovery services. SUD treatment services need to be integrated better into primary care settings, made more widely accessible, and made eligible for insurance coverage on par with other medical conditions. The major efforts in this area include the following:

Medicare- & Medicaid-funded Substance Abuse Treatment Services ($5,840.0 million)
Department of Health and Human Services – Centers for Medicare & Medicaid Services
SUD treatment is usually financed through a variety of-public and private sources (i.e., private health insurance, Medicaid, Medicare, state and local funds, and other federal support). The Federal Government makes its largest contribution to the payment for treatment through the Medicaid and Medicare programs. The Medicaid estimate is based on federal reimbursement to states for SUD treatment services. Medicare supports treatment for SUDs in both inpatient and outpatient settings.

Substance Abuse Treatment for Veterans ($721.7 million)
Department of Veterans Affairs – Veterans Health Administration
The Department of Veterans Affairs (VA) operates a national network of SUD treatment programs located in the Department's medical centers, residential rehabilitation facilities, and outpatient clinics. It provides effective, safe, efficient, recovery-oriented, and compassionate care for Veterans with SUDs and mental illness.

Substance Abuse Prevention and Treatment Block Grant ($1,483.8 million)
Department of Health and Human Services – Substance Abuse and Mental Health Services Administration
Up to 80% of the $1.9 billion Substance Abuse Prevention and Treatment Block Grant (i.e., $1,483.8 million) is estimated to support treatment services and related activities. This formula-based funding to states supports the provision of SUD treatment services, providing maximum flexibility to states to respond to their local and/or regional emergent issues impacting health, public health, and public safety through a consistent federal funding stream. The grant allows states to provide a range of clinical and recovery support services to clients during treatment and recovery, and supports planning, coordination, needs assessment, and quality assurance.

Screening, Brief Intervention, and Referral to Treatment ($46.8 million)
Department of Health and Human Services – Substance Abuse and Mental Health Services Administration
The SBIRT program, funded via Public Health Service Evaluation funds, provides grants to health care providers to intervene early in the disease process before individuals achieve dependency, and to motivate the clients with SUDs to engage in SUD treatment. Grant funds will further integrate Screening, Brief Intervention, and Referral to Treatment within medical treatment settings to provide early identification and intervention to at-risk individuals within the context of their primary care provider.

Treatment Research ($575.8 million)
Department of Health and Human Services – National Institutes of Health
NIH's NIDA invests in genetics, neuroscience, pharmacotherapy, and behavioral and health services research, producing innovative strategies for treating SUDs. For example, NIDA supports a large research network for conducting studies related to treatment of SUDs in the criminal justice system, including studies that pertain to the implementation of MAT and seek, test, treat, and retain for individuals with SUDs at risk for HIV. Through NIAAA, the NIH helps to develop strategies to treat the short- and long-term consequences of alcohol misuse among youth.

Substance Use Disorders Treatment for Military Service Members/Families ($76.7 million)
Department of Defense – Defense Health Program
DOD's Defense Health Program provides medical and dental services, including treatment for SUDs, for all members of the armed forces to include all eligible beneficiaries, including military family members. In addition to treatment services, the Defense Health Program also conducts alcohol and SUD research.

Homeless Assistance Grants - Continuum of Care ($494.2 million)
Department of Housing and Urban Development
The *Strategy* calls for federal support for reducing barriers to recovery from SUDs, including lack of housing. For persons in recovery, structured and supportive housing promotes healthy recovery outcomes. The Department's Continuum of Care—Homeless Assistance Grants support efforts to eliminate homelessness by financing local solutions to locate, intervene, and house the homeless population. These programs provide housing and supportive services on a long-term basis.

Drug Courts ($99.9 million)
Department of Health and Human Services - Substance Abuse and Mental Health Services Administration
Department of Justice - Office of Justice Programs
Drug courts help reduce recidivism, provide treatment to individuals with SUDs, and improve the likelihood of successful rehabilitation through early, continuous, and intense judicially supervised treatment, mandatory periodic drug testing, community supervision, appropriate sanctions, and other rehabilitation services. HHS ($59.9 million) and DOJ ($40.0 million), work together to enhance court services, coordination, and the SUD treatment capacity of juvenile, family and adult drug courts.

Bureau of Prisons Drug Treatment Efforts ($119.1 million)
Department of Justice, Bureau of Prisons
BOP continues to develop evidence-based treatment practices to manage and treat incarcerated individuals with SUDs. BOP's strategy includes early identification through psychological screening of individuals entering prison. According to the severity of the disease, BOP provides drug education, treatment for those within the general population, separate intensive residential SUD treatment and community transition treatment. The request includes $1.0 million to expand BOP's MAT field trial program, which provides medication during the last two months of incarceration and for four to six weeks after release in community custody, a residential reentry center, or home confinement.

Judiciary Treatment Efforts ($172.8 million)
Federal Judiciary
The Federal Judiciary provides for court-ordered drug testing, drug treatment, and supervision of federal defendants, probationers, parolees, and those on supervised release after incarceration. Funding is used by the probation and pretrial services offices for drug testing and treatment of federal defendants and offenders. Probation and pretrial services officers have primary responsibility for enforcing conditions of release imposed by the courts and for monitoring the behavior of persons placed under their supervision. With Executive Office of the U.S. Attorneys oversight, officers administer a program of drug testing and treatment for persons on pretrial release, probation, supervised release after incarceration, and parole. The goal is to eliminate

substance use by persons under supervision and to remove violators from the community before relapse leads to recidivism.

Domestic Law Enforcement

Maximizing federal support for interagency law enforcement drug task forces is critical to leveraging limited resources. A total of $9.2 billion in federal resources are requested in FY 2018 to support domestic law enforcement efforts (including state and local assistance, as well as federal investigation, prosecution, and corrections), a decrease of $62.7 million (0.7%) below the FY 2017 annualized CR level. The major efforts are highlighted below.

Methamphetamine Enforcement and Lab Cleanup Grants ($11.0 million)
Department of Justice
These grants aid state, local, and tribal law enforcement agencies in support of programs to address methamphetamine production and distribution. Working with the DEA, funding also supports assistance to state and local law enforcement in removing and disposing of hazardous materials generated by clandestine methamphetamine labs, and providing training, technical assistance, and equipment to assist law enforcement agencies in managing hazardous waste.

Federal Law Enforcement Training Center ($48.8 million)
Department of Homeland Security
The Federal Law Enforcement Training Center (FLETC) is a law enforcement training facility that provides training and technical assistance to federal, state, local, tribal, territorial, and international law enforcement entities. As part of its curriculum, FLETC provides training programs comprised of drug enforcement activities and drug-related investigations to enhance the qualifications of law enforcement personnel.

Federal Drug Investigations ($3,359.8 million)
Multiple agencies
Federal law enforcement personnel—including those from DOJ ($2,582.2 billion), DHS ($490.9 million), Treasury ($60.3 million), Interior ($14.9 million), and Agriculture ($14.6 million) - prepare drug cases for the arrest and prosecution of leaders and traffickers of illegal drug organizations, seize drugs and assets, and enforce federal laws and regulations governing the legitimate handling, manufacturing, and distribution of controlled substances.

Federal Prosecution ($842.4 million)
Multiple agencies
Several agencies— (including DOJ's Organized Crime Drug Enforcement Task Force Program ($161.3 million), U.S. Marshals Service ($129.8 million), Executive Office of the U.S. Attorneys ($78.1 million), Criminal Division ($37.7 million), and the Federal Judiciary ($435.5 million)—conduct Federal criminal proceedings against drug trafficking and money laundering organizations. The related costs include salaries for attorneys and other court personnel, defender services, judicial and courthouse security, prisoner security, and other administrative costs.

Corrections ($4,410.4 million)
Department of Justice/Federal Judiciary
The BOP ($3,284.7 million), the Federal Judiciary ($597.0 million), and the U.S. Marshals Service ($528.6 million) conduct activities associated with the incarceration and/or monitoring of drug-related offenders. The request includes funding for the costs associated with inmate care, security and facility maintenance, contracted confinement, and general management and administration.

Interdiction

The United States continues to face a serious challenge from the large-scale smuggling of drugs from abroad that are distributed to every region of the Nation. In FY 2018, the Administration's request includes $5.0 billion to support the efforts of federal law enforcement agencies, the military, the intelligence community, and our international allies to support collaboration to interdict or disrupt shipments of illegal drugs, their precursors, and their illicit proceeds. The FY 2018 request represents an increase of $453.4 million, (9.9%) above the FY 2017 annualized CR level. The major efforts are highlighted below.

Customs and Border Protection ($3,118.7 million)
Department of Homeland Security
CBP implements border enforcement strategies to interdict and disrupt the flow of narcotics and other contraband across our Nation's borders. The comprehensive interdiction strategy includes the border security personnel at and between ports of entry, detection and monitoring provided by aviation assets, and border security infrastructure and technology.

United States Coast Guard ($1,452.7 million)
Department of Homeland Security
One facet of the United States Coast Guard's (USCG) mission is maritime interdiction. The USCG functions as the maritime counternarcotics presence in the source, transit, and arrival zones. Their maritime interdiction activities disrupt the flow of drugs into the United States.

Federal Aviation Administration Interdiction Support ($13.2 million)
Department of Transportation/Federal Aviation Administration
Air traffic controllers staffing Air Route Traffic Control Centers monitor the Air Defense Identification Zones to detect possible suspicious aircraft movement. When suspicious movement is identified, the Federal Aviation Administration (FAA) notifies the DEA and USCG of such activity. Upon confirmation of suspicious aircraft movement, FAA controllers support interdiction efforts by providing radar vectors to track the time of arrival, traffic advisory information, and last known positions to intercept aircrafts of interest.

Department of Defense Drug Interdiction ($413.2 million)
Department of Defense
DOD's counterdrug programs detect, monitor, and support the disruption of drug trafficking organizations. Additionally, DOD coordinates interagency resources and force requirements of air and surface assets in the Western Hemisphere Transit Zone.

International Efforts

Illicit drug production and trafficking generate huge profits and are responsible for the establishment of criminal enterprise networks that are powerful and corrosive forces that destroy the lives of individuals, tear at the social fabric, and weaken the rule of law in affected countries. In FY 2018, $1.4 billion is requested for international drug control efforts, a decrease of $146.1 million (9.6%) below the FY 2017 annualized CR level. These funds are requested to support the efforts of the United States Government and our international partners around the globe to meet the challenges of illicit trafficking of all drugs, including synthetics and precursors, and illicit substance use. The major efforts in this area include the following.

DEA's International Efforts ($470.4 million)
Department of Justice
The focus of DEA's international enforcement program is to disrupt or dismantle the most significant international drug and precursor chemical trafficking organizations around the world. Personnel in DEA's foreign country offices focus their investigative efforts on the most significant international command and control organizations threatening the United States. DEA coordinates all programs involving drug law enforcement in foreign countries, and provides intelligence to assist the interagency community in determining future trends in drug trafficking and evaluating their long-term impact. DEA works closely with the United Nations, Interpol, and other organizations on matters relating to international drug and chemical control programs.

Bureau of International Narcotics and Law Enforcement Affairs ($290.3 million)
Department of State
In support of the *Strategy*, Bureau of International Narcotics and Law Enforcement Affairs (INL) works closely with partner nations and source countries to disrupt illicit drug production, strengthen criminal justice systems and law enforcement institutions, and combat transnational organized crime. INL is comprehensive in its approach to the counterdrug mission and provides training and technical assistance for prevention and treatment programs.

United States Agency for International Development ($83.6 million)
Department of State
The United States Agency for International Development (USAID) provides foreign assistance funds to develop holistic alternatives to illicit drug production by providing agricultural assistance, improving small scale infrastructure, increasing market accessibility, and incentivizing licit crop production. USAID's alternative development programs foster economic growth, local governance and civil society strengthening, and enhanced security of impacted communities.

DOD International Counternarcotics Efforts ($491.1 million)
Department of Defense
The international support programs of DOD's Combatant Commands detect, interdict, disrupt, or monitor activities related to drug trafficking organizations and transnational criminal organizations. In the Western Hemisphere Transit Zone, DOD functions as the command and control support for counterdrug activities for federal, state, local and international partners.

Table 3. Federal Drug Control Spending by Function, FY 2016 – FY 2018 (Budget Authority in Millions)

	FY 2016 Final	FY 2017 CR	FY 2018 Request	FY17 - FY18 Change Dollars	Percent
Function					
Treatment	$9,845.1	$10,580.8	$10,783.4	$202.6	*1.9%*
Percent	*36.6%*	*38.5%*	*38.9%*		
Prevention	1,486.4	1,507.4	1,339.9	-167.5	*-11.1%*
Percent	*5.5%*	*5.5%*	*4.8%*		
Domestic Law Enforcement	9,282.8	9,298.6	9,235.8	-62.8	*-0.7%*
Percent	*34.5%*	*33.8%*	*33.3%*		
Interdiction	4,734.7	4,569.0	5,022.4	453.4	*9.9%*
Percent	*17.6%*	*16.6%*	*18.1%*		
International	1,524.9	1,521.0	1,375.0	-146.1	*-9.6%*
Percent	*5.7%*	*5.5%*	*5.0%*		
Total	**$26,874.0**	**$27,476.8**	**$27,756.5**	**$279.7**	***1.0%***
Supply/Demand					
Demand Reduction	$11,331.5	$12,088.2	$12,123.3	$35.1	*0.3%*
Percent	*42.2%*	*44.0%*	*43.7%*		
Supply Reduction	15,542.5	15,388.6	15,633.2	244.6	*1.6%*
Percent	*57.8%*	*56.0%*	*56.3%*		
Total	**$26,874.0**	**$27,476.8**	**$27,756.5**	**$279.7**	***1.0%***

Table 4. Federal Drug Control Spending by Agency (Budget Authority in Millions)

	FY 2016 Final	FY 2017 CR	FY 2018 Request
Department of Agriculture			
U.S. Forest Service	12.3	12.9	15.6
Court Services and Offender Supervision Agency for the District of Columbia	55.4	55.3	56.1
Department of Defense			
Drug Interdiction and Counterdrug Activities[1] (incl. OPTEMPO, DSCA, and OCO)	1,302.8	1,299.4	1,127.8
Defense Health Program	76.7	75.8	76.7
Total DoD	**1,379.5**	**1,375.1**	**1,204.6**
Department of Education			
Office of Elementary and Secondary Education	50.3	49.1	48.9
Federal Judiciary	1,147.8	1,166.7	1,210.9
Department of Health and Human Services			
Administration for Children and Families	18.5	18.6	20.0
Centers for Disease Control and Prevention	75.6	75.4	75.4
Centers for Medicare & Medicaid Services[2]	5,390.0	5,550.0	5,840.0
Health Resources and Services Administration	119.0	121.0	171.0
Indian Health Service	104.7	104.9	105.1
National Institute on Alcohol Abuse and Alcoholism	55.2	55.2	42.7
National Institute on Drug Abuse	1,049.0	1,075.4	865.0
Substance Abuse and Mental Health Services Administration[3]	2,533.7	3,052.1	2,943.2
Total Health and Human Services	**9,345.7**	**10,052.7**	**10,062.5**
Department of Homeland Security			
Customs and Border Protection	2,687.2	2,663.7	3,118.7
Federal Emergency Management Agency	8.3	8.3	6.2
Federal Law Enforcement Training Center	44.1	43.9	49.3
Immigration and Customs Enforcement	508.9	514.7	524.6
United States Coast Guard	1,597.1	1,456.0	1,452.7
Total Homeland Security	**4,845.6**	**4,686.4**	**5,151.5**
Department of Housing and Urban Development			
Community Planning and Development	490.5	489.5	494.2
Department of the Interior			
Bureau of Indian Affairs	9.7	9.7	9.3
Bureau of Land Management	5.1	5.1	5.1
National Park Service	3.5	3.3	3.3
Total Interior	**18.3**	**18.1**	**17.7**

	FY 2016 Final	FY 2017 CR	FY 2018 Request
Department of Justice			
Assets Forfeiture Fund	258.4	230.1	227.5
Bureau of Prisons[4]	3,532.6	3,526.0	3,403.8
Criminal Division	39.0	38.0	37.7
Drug Enforcement Administration	2,425.5	2,433.4	2,583.6
Organized Crime Drug Enforcement Task Force Program	512.0	511.0	526.0
Office of Justice Programs	278.2	297.7	240.2
U.S. Attorneys	72.6	72.6	78.1
U.S. Marshals Service	771.3	792.8	812.8
Total Justice	**7,889.7**	**7,901.7**	**7,909.7**
Department of Labor			
Employment and Training Administration	5.7	6.0	6.0
Office of National Drug Control Policy			
High Intensity Drug Trafficking Areas	250.0	249.5	246.5
Other Federal Drug Control Programs	109.8	109.6	103.7
Salaries and Expenses	20.0	20.0	18.4
Total ONDCP	**379.9**	**379.1**	**368.6**
Department of State[5]			
Bureau of International Narcotics and Law Enforcement Affairs	405.3	404.5	290.3
United States Agency for International Development	70.5	70.4	83.6
Total State	**475.8**	**474.9**	**373.9**
Department of Transportation			
Federal Aviation Administration	30.4	31.6	31.7
National Highway Traffic Safety Administration	3.5	2.7	2.7
Total Transportation	**33.8**	**34.3**	**34.4**
Department of the Treasury			
Internal Revenue Service	60.3	60.3	60.3
Department of Veterans Affairs			
Veterans Health Administration	683.4	714.6	741.7
Total Federal Drug Budget	**$26,874.0**	**$27,476.8**	**$27,756.5**

1. Due to statutory changes included in the FY 2017 National Defense Authorization Act that consolidated the DOD's security sector assistance authorities, funding for building foreign partner counter-drug enforcement capacities is now included in DOD's Defense Security Cooperation Agency's budget request.
2. The estimates for the CMS reflect Medicaid and Medicare benefit outlays (excluding spending under Medicare Part D) for substance use disorder treatment; they do not reflect budget authority. The methodology for Medicaid estimates has been refined from prior years to more accurately reflect spending. The estimates were developed by the CMS Office of the Actuary.
3. Includes budget authority and funding through evaluation set-aside authorized by Section 241 of the Public Health Service (PHS) Act.
4. Funding for the FY 2018 column excludes a proposed rescission of unobligated balances.
5. Funding for 2017 column is a mechanical calculation that does not reflect decisions on funding priorities.
6. Detail may not add due to rounding

PRESIDENT'S COMMISSION ON COMBATING DRUG ADDICTION AND THE OPIOID CRISIS

Commission Charter

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1. **Committee's Official Designation:** President's Commission on Combating Drug Addiction and the Opioid Crisis (Commission).

2. **Authority:** The Commission is being established in accordance with Executive Order No. 13784 of March 29, 2017, and the provisions of the Federal Advisory Committee Act (FACA), as amended, 5 U.S.C. App. 2.

3. **Objectives and Scope of Activities:** The Commission is established in the interest of obtaining advice and recommendations for the President regarding the opioid crisis. The Commission will function solely as an advisory body and will make recommendations regarding policies and practices for combating drug addiction with particular focus on the current opioid crisis in the United States. The heads of executive departments and agencies shall, to the extent permitted by law, provide the Commission with information concerning drug addiction and the opioid crisis when requested. To achieve this goal, the Commission shall:
    a. identify and describe the existing Federal funding used to combat drug addiction and the opioid crisis;
    b. assess the availability and accessibility of drug addiction treatment services and overdose reversal throughout the country and identify areas that are underserved;
    c. identify and report on best practices for addiction prevention, including healthcare provider education and evaluation of prescription practices, collaboration between State and Federal officials, and the use and effectiveness of State prescription drug monitoring programs;
    d. review the literature evaluating the effectiveness of educational messages for youth and adults with respect to prescription and illicit opioids;
    e. identify and evaluate existing Federal programs to prevent and treat drug addiction for their scope and effectiveness, and make recommendations for improving these programs; and
    f. make recommendations to the President for improving the Federal response to drug addiction and the opioid crisis.

4. **Description of Duties:** The duties of the Commission are solely advisory.

5. **Agency or Official to Whom the Committee Reports:** The Commission shall provide its formal interim and final findings and recommendations to the President. The Commission shall report to the President, directly at meetings with the President and also through the Director of National Drug Control Policy.

6. **Agency Responsible for Providing Necessary Support:** The Office of National Drug Control Policy (ONDCP) within the Executive Office of the President will provide necessary administrative support for the Commission with the approval of the Director of ONDCP and will maintain staff and quarters to meet the needs of the Commission. The Director of ONDCP will be responsible for ensuring that the requirements of §6(b) of FACA are fulfilled.

7. **Estimated Annual Operating Costs and Staff Years:** To be determined.

8. **Designated Federal Officer:** The Designated Federal Officer (DFO) will be a full-time officer or employee of the Federal Government appointed by the Director of ONDCP or the President. The DFO will approve or call all of the Commission's meetings, prepare all meeting agendas, attend all meetings, and adjourn any meeting when the DFO determines adjournment to be in the public interest. Should the Commission Chair designate any subcommittees, the DFO will similarly approve or call any/all subcommittee meetings, prepare all subcommittee meeting agendas, attend all such meetings, and adjourn any subcommittee meeting when the DFO determines adjournment to be in the public interest.

9. **Estimated Number and Frequency of Meetings:** The Commission shall meet as frequently as needed and called and approved by the DFO. As required by FACA, the Commission will hold open meetings unless it is determined by the Executive Director that a meeting or a portion of a meeting may be closed to the public in accordance with subsection (c) of section 552b of Title 5, United States Code. Interested persons may attend meetings, appear before the Commission, and file statements with the Commission.

10. **Duration and Termination:** Within 90 days of the date of the Executive Order establishing this Commission, the Commission shall submit to the President a report of the Commission's interim findings and recommendations regarding how the Federal government can address drug addiction and the opioid crisis. The Commission shall submit to the President a report of final findings and recommendations on or before October 1, 2017, unless the Commission Chair provides written notice to the President that an extension of time is necessary. The Commission shall terminate thirty (30) days after it presents its final report to the President, unless the Commission's term is extended by the President prior to that date.

11. **Membership:** The Commission shall be composed of members appointed by the President. As required by FACA, the membership of the Commission will be fairly balanced in terms of the points of view represented and the functions to be performed by the Commission. The advice and recommendations of the Commission will be the result of the Commission's independent judgment. The President shall designate a Chair of the Commission (Commission Chair or Chair) from among the Commission's members. The Director of ONDCP will designate an Executive Director of the Commission who is a full-time employee from ONDCP who will supervise staff and coordinate administrative support for

the Commission. The Executive Director will work at the direction of the Chair on all Commission related matters and will attend each meeting of the Commission. Members serve at the pleasure of the President.

12. **Subcommittees:** Subcommittees composed of members designated by the Chair may be established by the Chair in consultation with the Executive Director and the DFO to perform specific functions within the Commission's jurisdiction. The Chair will notify the Executive Director and the DFO upon the establishment of each subcommittee and will provide the Executive Director and the DFO with information on its name, membership, function, and estimated frequency of meetings. Subcommittees must not incur costs or expenses without prior consultation with the Executive Director and express written authorization of the Chair. Subcommittees must not provide any information to any entity without written authorization of the Chair. Subcommittees are required to report any findings, conclusions, or recommendations to the Commission and must not provide any information directly to the President.

13. **Recordkeeping:** The records of the Commission and its subcommittees will be handled in accordance with General Records Schedule 6.2 and approved agency records disposition schedules. These records will be available for public inspection and copying, subject to the Freedom of Information Act, 5 U.S.C. § 552.

14. **Filing Date:** The filing date of this charter is April 24, 2017.

Approved on this 24th day of April, 2017

Richard J. Baum, Acting Director

Office of National Drug Control Policy

Appendices

Appendix 1. Acronyms

ACA:	Affordable Care Act
ADAM:	Arrestee Drug Abuse Monitoring Program
AED:	Advanced Electronic Data
AUD:	alcohol use disorder
AHRQ:	Agency for Healthcare Research and Quality
ASAM:	American Society of Addiction Medicine
BJA:	Bureau of Justice Assistance
BOP:	Bureau of Prisons
CARA:	Comprehensive Addiction and Recovery Act
CBP:	U.S. Customs and Border Protection
CDC:	Centers for Disease Control and Prevention
CHW:	community health worker
CME:	continuing medical education
CMS:	Centers for Medicare and Medicaid Services
CRP:	collegiate recovery programs
DAWN:	Drug Abuse Warning Network
DEA:	Drug Enforcement Administration
DHS:	Department of Homeland Security
DOD:	Department of Defense
DOE:	Department of Education
DOJ:	Department of Justice
DOL:	Department of Labor
DOT:	Department of Transportation
DTO:	Drug Trafficking Organization
ED:	Emergency Department
EHR:	electronic health records
EMR:	emergency medical responder
EMS:	emergency medical services
EMT:	emergency medical technician
EMTALA:	Emergency Medical Treatment and Labor Act
EPCS:	electronic prescribing of controlled substances
ER:	extended-release
FAA:	Federal Aviation Administration

FDA:	U.S. Food and Drug Administration
FLETC:	Federal Law Enforcement Training Center
HCAHPS:	Hospital Consumer Assessment of Healthcare Providers and Systems
HCPCS:	Healthcare Common Procedure Coding System
HCV:	hepatitis C virus
HHS:	U.S. Department of Health and Human Services
HIDTA:	High Intensity Drug Trafficking Areas
HIV:	human immunodeficiency virus
HRSA:	Health Resources and Services Administration
HUD:	heroin use disorder
IMD:	Institutes of Mental Disease
IMF:	USPS International Mail Facilities
INL:	Bureau of International Narcotics and Law Enforcement Affairs
IR:	immediate-release
MAT:	Medication-Assisted Treatment
MDI:	medicolegal death investigation
ME/C:	medical examiners and coroners
MHPAEA:	Mental Health Parity and Addiction Equity Act
NARR:	National Alliance for Recovery Residents
NASEM:	National Academies of Sciences, Engineering, and Medicine
NAS:	neonatal abstinence syndrome
NHTSA:	National Highway Traffic Safety Administration
NIAAA:	National Institute on Alcohol Abuse and Alcoholism
NIC:	National Institute on Corrections
NIDA:	National Institute on Drug Abuse
NIH:	National Institutes of Health
NQTL:	non-quantitative treatment limits
NSC:	National Security Council
NSDUH:	National Survey on Drug Use and Health
NPS:	new psychoactive substances
ONDCP:	Office of National Drug Control Policy
OTP:	opioid treatment programs
OUD:	opioid use disorder
PDMP:	prescription drug monitoring program
RCO:	recovery community organization
RSS:	recovery support services

SAMHSA:	Substance Abuse and Mental Health Services Administration
SBIRT:	Screening, Brief Intervention, and Referral to Treatment
SUD:	substance use disorder
USAID:	United States Agency for International Development
USCG:	United States Coast Guard
USPS:	United States Postal Service
USPIS:	United States Postal Inspection Service
USPSTF:	United States Preventative Services Task Force
VA:	Department of Veteran Affairs
VBP:	Value-Based Purchasing

Appendix 2. History of Opiate Use and Abuse

The opium poppy was a medicinal plant used by ancient civilizations. It blunted pain; elevated mood; relaxed; dulled stress, melancholy, and anxiety; and induced sleep. With the dawning of modern chemistry in the early 1800's, morphine, codeine, and thebaine were purified from the opium poppy *Papaver somniferum*, and their chemical structures identified. Scientific curiosity or optimization of medicinal properties drove chemists to synthesize variations of these naturally occurring opioids. The end products included heroin, oxycodone, oxymorphone, hydrocodone, hydromorphone, and others.

To avoid reliance on the poppy plant for opioids, *de novo* compounds such as methadone, meperidine, fentanyl, tramadol, U47700, were subsequently created. These drugs were structurally distinct from morphine yet targeted the same pain-reducing/pleasure-inducing receptors/circuits as plant-derived morphine analogs to engender pain relief, suppression of cough and intestinal function and chemical coping of psychological distress. Susceptible individuals, whether medical or non-medical users discovered the euphoriant properties of potent opioids delivered rapidly into the brain, especially by smoking or injection.

Opioid mechanisms. Opioid analgesics target opioid signaling systems within circuits engaged in diverse homeostatic mechanisms, especially management of pain, anxiety, stress, intestinal motility, cough mechanisms and hedonic pleasure. Opioid signaling is comprised of endogenous chemical neurotransmitters (small and large mobile peptides such as endorphins that transmit signals) and their corresponding opioid receptors (large anchored proteins that interpret signals). These signaling systems are widely distributed throughout the human brain and body. Three major opioid receptors (μ or mu, κ or kappa, and δ or delta), their subtypes and splice variants have been identified. Opioids activate one or more of these G-protein–coupled transmembrane molecules, to trigger diverse responses governed by splice variants, post-translational modifications, and receptor heterodimer or homodimer formation.[254] All exogenous opioids that target the μ-opioid receptor suppress pain perception, slow gastrointestinal motility, attenuate cough, and induce pleasurable sensations or intense euphoria. At sufficiently high doses, activation of μ-opioid receptors in the brain stem can depress respiration, leading to reduced blood flow and oxygen in the brain and even death. Frequent exposure to opioids leads to tolerance, a diminution of specific signaling functions of the mu opioid receptor (e.g., euphoria and respiratory depression), which may drive the user to escalate drug doses to levels that can be fatal in the drug-naïve or in abstinent former users. If high dose opioids are reintroduced during abstinence (e.g. released prisoners or in long term recovery), the risk of a lethal overdose is grave as tolerance to opioids wanes during abstinence.

Historical Origins of Iatrogenic Opioid Addiction. In the mid- to late-19th century, opioid use rose dramatically, fueled by physicians' unrestrained opioid prescriptions (morphine, laudanum, paregoric, codeine, heroin) for pain or other ailments, by inclusion of opioids in aggressively promoted patent medicines, and by liberal use of opioid-based treatments for injuries and diseases gnawing at Civil War combatants and veterans. Opioids were undoubtedly more effective and reliable medications for a variety of ailments, compared with existing alternatives. During this first wave, physicians were largely responsible for iatrogenic addiction to opioids among patients. By 1900, 1 in 200 people were addicted in the United States. In parallel with clinicians and pharmacists issuing unrestrained opioid supplies to treat medical ailments and addiction, profiteers organized clandestine, illicit opioid distribution networks. Powered by unregulated international

production and shipments of opium, opium dens proliferated in the United States and created a non-medical, addicted population among denizens of these sites.[255,256,257] The steep rise in consumption of medical opioids or smoked opium led to an alarming surge of addictions, either medically-induced, or resulting from opium smoking. The two populations did not "cross-over," nor merge regarding drug sources, types of opioids, or routes of administration. This nation-wide crisis extended across socio-economic strata, and reached urban and rural areas. Thereafter, smaller scale waves of heroin addiction surfaced periodically during the 20th century, but these were confined to large cities.

Response to the First Crisis. Medical professionals, federal, local, and international regulatory bodies awakened to the epidemic of iatrogenic and situationally-based opioid addiction. One physician James F.A. Adams wrote compellingly on the adverse side effects of these medicinal drugs - depression, constipation, and the "opium habit," (addiction). Eventually, the first epidemic of opioid addiction was contained and then reversed by physicians, pharmacists, medical education, voluntary restraint, combined with federal regulations and law enforcement. In 1890, the U.S. government began taxing opium and by 1906, the Pure Food and Drug Act was passed, which required manufacturers to disclose the contents of their medicinal products to consumers. Three years later Congress passed the Opium Exclusion Act, banning its import for opium smoking. The International Opium Convention in the Hague and the Harrison Act of 1914 taxed and regulated the sale and distribution of opium and cocaine-based products, the first broadly based prohibition in American history. Opioids remained available for short-term medical use, but not for maintenance of addiction. Doctors and pharmacists who violated the Act, which discouraged morphine use to sustain addiction, were arrested. The United Nations Single Convention on Narcotic Drugs in 1961 and the Controlled Substances Act (CSA) of 1970 (Title II of the Comprehensive Drug Abuse Prevention and Control Act) established federal U.S. drug policy on regulating the manufacture, importation, possession, use and distribution of certain substances. The CSA was the national legislation for implementing the Single Convention on Narcotic Drugs. The DEA, the enforcement branch of the CSA, was charged with registration of physicians, stringent annual production quotas, chain-of-custody and other regulatory oversight.

Appendix 3. Interim Report, *President's Commission on Combatting Drug Addiction and the Opioid Crisis*

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 immediate 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 Agency (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 state health official letter 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

FENTANYL†

SAFETY RECOMMENDATIONS FOR FIRST RESPONDERS

† For the purposes of this document, fentanyl, related substances, and synthetic opioids (herein after referred to as fentanyl†) includes fentanyl analogues (e.g., acetylfentanyl, acrylfentanyl, carfentanil, furanylfentanyl), novel synthetic opioids (e.g., U-47700), and other drugs that may be laced with these substances.

- **The abuse of drugs containing fentanyl† is killing Americans. Misinformation and inconsistent recommendations regarding fentanyl† have resulted in confusion in the first responder community.**
- You as a first responder (law enforcement, fire, rescue, and emergency medical services (EMS) personnel) are increasingly likely to encounter fentanyl† in your daily activities (e.g., responding to overdose calls, conducting traffic stops, arrests, and searches).
- This document provides scientific, evidence-based recommendations to protect yourself from exposure.

WHAT YOU NEED TO KNOW

- Fentanyl† can be present in a variety of forms (e.g., powder, tablets, capsules, solutions, and rocks).
- Inhalation of airborne powder is MOST LIKELY to lead to harmful effects, but is less likely to occur than skin contact.
- Incidental skin contact may occur during daily activities but is not expected to lead to harmful effects if the contaminated skin is promptly washed off with water.
- Personal Protective Equipment (PPE) is effective in protecting you from exposure.
- Slow breathing or no breathing, drowsiness or unresponsiveness, and constricted or pinpoint pupils are the specific signs consistent with fentanyl† intoxication.
- Naloxone is an effective medication that rapidly reverses the effects of fentanyl†.

Actions to take . . .

To protect yourself from exposure

- Wear **gloves** when the presence of fentanyl† is suspected.
- **AVOID actions that may cause powder to become airborne.**
- Use a properly-fitted, NIOSH-approved **respirator ("mask")**, wear **eye protection**, and minimize skin contact when responding to a situation where small amounts of suspected fentanyl† are visible and may become airborne.
- Follow your department guidelines if the scene involves large amounts of suspected fentanyl† (e.g., distribution/storage facility, pill milling operation, clandestine lab, gross contamination, spill or release).

When exposure occurs

- Prevent further contamination and notify other first responders and dispatch.
- Do not touch your eyes, mouth, nose or any skin after touching any potentially contaminated surface.
- Wash skin thoroughly with cool water, and soap if available. **Do NOT use hand sanitizers as they may enhance absorption.**
- Wash your hands thoroughly after the incident and before eating, drinking, smoking, or using the restroom.
- If you suspect your clothing, shoes, and PPE may be contaminated, follow your department guidelines for decontamination.

If you or other first responders exhibit

- **Slow Breathing or No Breathing**
- **Drowsiness or Unresponsiveness**
- **Constricted or Pinpoint Pupils**

- Move away from the source of exposure and call EMS.
- Administer naloxone according to your department protocols. Multiple doses may be required.
- If naloxone is not available, rescue breathing can be a lifesaving measure until EMS arrives. Use standard basic life support safety precautions (e.g., pocket mask, gloves) to address the exposure risk.
- If needed, initiate CPR until EMS arrives.

Collaborative Support From:

- American College of Emergency Physicians
- American College of Medical Toxicologists
- American Industrial Hygiene Association
- Association of State and Territorial Health Officials
- Association of State Criminal Investigative Agencies
- Fraternal Order of Police
- International Association of Chiefs of Police
- International Association of Fire Chiefs
- International Association of Fire Fighters
- Major Cities Chiefs Association
- Major County Sheriffs of America
- National Alliance of State Drug Enforcement Agencies
- National Association of Counties
- National Association of County and City Health Officials
- National Association of Emergency Medical Technicians
- National Association of EMS Physicians
- National Association of State EMS Officials
- National Governor's Association
- National HIDTA Directors Association
- National Narcotic Officers' Associations' Coalition
- National Sheriffs' Association
- National Volunteer Fire Council
- Police Executive Research Forum
- Police Foundation

https://www.whitehouse.gov/ondcp/key-issues/fentanyl

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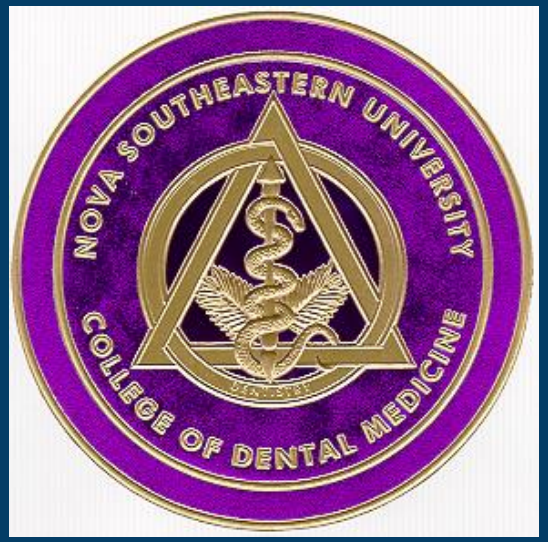
ADDRESSING FLORIDA'S OPIOID CRISIS

"THE NSU-CDM PLANNED APPROACH"



NSU
NOVA SOUTHEASTERN UNIVERSITY
College of Dental Medicine

SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION

- Dental Schools Addiction Education Summit for SAMHSA Region III (DC,DE,MD,PA,VA,WV) and Region IV (NC,SC,GA,FL,KY,TN,MS,AL)

OBJECTIVES OF SUMMIT

- Discuss factors Contributing to the Rise in Substance Abuse in the United states
- Identify Prescribing Practices and Guidelines That Can Be applied in Dental Schools
- Compare Experiences in Assessing and Implementing Prescription Practices in the Dental School setting
- Develop a Plan for Future Engagement and Collaboration Amongst Participating Institutions

PRE-DOCTORAL CURRICULUM (ELEMENTS)

- How to Evaluate Patient’s Pain
- Patients Risk for Abusing Drugs
- How to Discuss the “Pros” and “Cons "of Pain Treatments
- How to Recognize the Signs of Inappropriate Drug Use and to Practice Pain Management
- Train and Encourage Students to Counsel Patients
- Collaborate With Other health Professionals

PRE-DOCTORAL CURRICULUM

- New Material will be Incorporated into Existing Courses
- Building Longitudinally Across the Curriculum

COLLABORATIVE INTERDISCIPLINARY APPROACH

- School of Pharmacy
- College of Osteopathic Medicine
- College of Allopathic Medicine
- School of Psychology
- School of Nursing
- College of Law

D-2 YEAR

- Pharmacology
- Anesthesia 1& 2
- Oral Medicine
- Oral and Maxillofacial Surgery 1

D-3 YEAR

- Oral and Maxillofacial Surgery 2
- Behavioral Science
- Evidenced-Based Dentistry in Clinical Practice
- Temporomandibular Dysfunction
- Oral Medicine
- Clinic (interdisciplinary with Clinical Psychology)
- Urgent Care Clinic
- OMFS Clinic

D-4 YEAR

- Advanced Techniques in Pain and Anxiety Control
- Oral Medicine
- Clinic
- Urgent-Care Clinic
- OMFS Clinic

PRE-DOCTORAL AND ADVANCED EDUCATION PROGRAMS

Establishment of Core Competencies

- Throughout the Course of their Dental Education and Advanced Specialty Training
- With the Goal of Providing Necessary Skills and a Foundational Knowledge
- In the Prevention of Prescription Drug Misuse and Effective Pain Management

PRE-DOCTORAL AND ADVANCED EDUCATION PROGRAMS

Core Competencies over three areas of Prevention

A) ***Primary***

Preventing Prescription Drug Abuse

B) ***Secondary***

- Treating Patients at Risk for substance use disorders
- Learning Prevention skills

C) ***Tertiary***

- Develop knowledge in the methods of screening, evaluation, treatment planning and referral

PRIMARY PREVENTION (PREVENTING PRESCRIPTION DRUG MISUSE)

- Screening
- Evaluation
- Prevention of Substance Misuse During the Diagnosis of Dental and Oro-Facial Pain

SCREENING

Evaluation of Patient's Pain

- Utilizing age, gender and culturally appropriate evidence based methodologies
- History and Physical Examination
- Relevant Imaging Studies
- Develop Differential diagnosis

STRATIFICATION OF RISK FOR SUBSTANCE ABUSE DISORDERS

- Learn to Utilize Standardized assessment Methodologies
- Review of Health Records, Family History, Prescription Dispensing Records (E-FORCSE)
- Screenings for Co-Morbid Psychiatric Disorders (Depression, Anxiety Disorders and PTSD
- Communication with other treating Physicians

PRIMARY PREVENTION

- Learn to Identify and Describe Potential Pharmacological and Non-Pharmacological Treatment Options (opioid and Non-Opioid) for Acute and Chronic pain
- Develop Communication Skills to Educate Patient and Family Risks and Benefits of Treatment Options, Securing and Proper Disposal of Medication to Prevent Diversion

SECONDARY PREVENTION
(TREATING PATIENTS AT-RISK FOR SUBSTANCE ABUSE DISORDERS)

- ***Referral***- Demonstrate the ability to appropriately refer patients for consultation and collaboration

  a) primary care physician,

  b) mental health specialist

  c) Substance use treatment programs

SECONDARY PREVENTION
(TREATING PATIENTS AT-RISK FOR SUBSTANCE ABUSE DISORDERS)

- Learn to practice evidence-based and patient centered pain management for patients with acute and chronic pain
- Focus on safe prescribing
- Recognize patients displaying signs of drug seeking behavior
- Demonstrate the basic skills in patient centered counseling and behavior change in the context of a patient encounter, consistent with evidence- based techniques

TERTIARY PREVENTION
(MANAGING SUBSTANCE USE DISORDERS AS A CHRONIC DISEASE)

- Advance Interdisciplinary and Inter-professional Collaborative Efforts to Reduce Substance misuse
- Eliminate the stigma and false stereotypic biases associated with substance misuse

TERTIARY PREVENTION
(MANAGING SUBSTANCE USE DISORDERS AS A CHRONIC DISEASE)

- Recognize the role and learn to utilize available screening tools for at risk patients (SBIRT) ***S***creening, ***B***rief, ***I***ntervention and ***R***eferral to ***T***reatment)
- Develop models across the University of inter-professional education engaging dentists, physicians, nurses, pharmacists, psychology and mental health specialists
- These disciplines can work in concert to develop training of students and post-graduate students collaboratively to facilitate a best practices environment for the University

POST- LICENSURE (COMMUNITY PRACTITIONERS)

- Nova Southeastern University Health Professions Division recognizes the need to “Change Ingrained Medical Minds”
- Nova Southeastern University Health Professions Division is committed to Educating Community Dentists Through Continuing Education Courses on the Abuse of Controlled Substances and Safe Prescribing Practices
- Courses are Being Designed to be Interdisciplinary and Inter-Professional

SUGGESTIONS FOR THE BOARD TO PONDER??

- Mandatory checking of (E-FORCSE) before writing for any Opioid Prescription
- Mandatory Continuing Education Course of at least 2 hours designed specifically to address prescribing practices. **The course will include, but not be limited to, instruction on controlled substance prescribing practices and controlled substance prescribing for chronic pain management.**
- ***Online Training***

  SAMSHA – "Safe Opioid Prescribing for Acute Dental Pain"

  CDC – "Guideline for Prescribing Opioids for Chronic Pain"

GOAL: TRAIN THE NEXT GENERATION OF DENTISTS

- How to Prescribe Opioids Appropriately
- How to Think About Pain Differently
- Able to Demonstrate That They Know How to Consider Non-Opioid Treatment Options
- Become ***Engaged*** to Participate as Part of the Solution to ***Eradicate*** the Opioid Crisis in Florida and Nationally

THANK YOU !!

SECONDARY PREVENTION (TREATING PATIENTS AT-RISK FOR SUBSTANCE ABUSE DISORDERS)

Engaging Patients in Safe, Informed Patient Centered Treatment Planning

Opioids

Pharmacist Education: Pre and Post Licensure

Scott Kjelson, Pharm.D., CPh.
Director of Student Transitions
Assistant Professor
Nova Southeastern University College of Pharmacy

NSU NOVA SOUTHEASTERN UNIVERSITY
College of Pharmacy

Objectives

- **Opioid safety and efficacy education**
- **Explain education regarding controlled substances in the Doctor of Pharmacy Curriculum**
- **Describe post-licensure education requirements for pharmacists for controlled substances**
- **Essential roles for pharmacists to mitigate the opioid epidemic**

NSU NOVA SOUTHEASTERN UNIVERSITY
College of Pharmacy

Evolution of Pharmacy Education

- 1907 • 2 years (Graduate in Pharmacy)
- 1925 • 3 years (Graduate in Pharmacy or Pharmaceutical Chemist)
- 1932 • 4 years (B.S. or B.S. in Pharmacy)
- 1960 • 5 years (B.S. or B.S. in Pharmacy)
- 2000 • 6 years (Pharm.D.)

Minimum Education Requirements for Pharmacist Education in the United States

NSU NOVA SOUTHEASTERN UNIVERSITY
College of Pharmacy

Evolution of Pharmacy Education

Joe Pharmacist
Graduate – 1993

1 year pre-pharmacy course work

Didactic curriculum focusing on basic sciences

400 hours of clinical rotations

Less than 500 pharmacists entering into post-graduate residencies

Evolution of Pharmacy Education

Jane Pharmacist
Graduate - 2013

6 to 8 years

At least 2 years pre-pharmacy curriculum

60% enter with bachelor degrees

3 years of pre-clinical course work including intro clinical experiences

2 years body-system focused pharmacotherapy

1440 hours (36 weeks) of clinical rotations

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Pharmacy Post-Graduate Training

PGY-1

- Pharmacy Practice
- Managed Care (Ex. primary care)
- Community Practice

PGY-2

- Specialty Practice
- Ambulatory Care, **Pain Management and Palliative Care** Infectious Disease, Cardiology, Critical Care, Pediatrics, etc.

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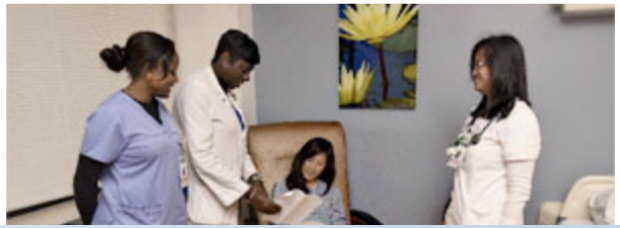
Welcome
About the Department
Patient Care
Residency Programs
- Pharmacy Residency (PGY–1)
- Ambulatory Care (PGY–2)
- Critical Care (PGY–2)
- Drug Information (PGY–2)
- Emergency Medicine (PGY–2)
- Pain Management and Palliative Care (PGY–2)
  - Pain Management and Palliative Care Faculty

Residency Programs: Pain Management and Palliative Care (PGY–2)

The PGY-2 Pain and Palliative Care Residency Program at UF Health Jacksonville offers a diverse experience in patient-focused care. Residents are integrated in both outpatient and inpatient practice, including acute and chronic pain management, oncology, and hospitalist medicine. Elective rotations may occur in a variety of settings such as academia, cardiothoracic surgery, clinical research, emergency medicine, medical critical care, neurology, neuroscience critical care, OB/Gyn oncology, psychiatry, or our skilled nursing facility. Numerous teaching opportunities at the hospital and the University of Florida College of Pharmacy are available. In addition, a teaching certificate program is available.

Program



The Pain and Palliative Care residency provides the resident the education, training, and experience necessary to actively participate in a comprehensive pain and palliative care setting. In collaboration with the medical staff, the resident provides

Today's Pharmacy Curriculum

- American Council for Pharmaceutical Education (ACPE) 2016 standards emphasize that pharmacy graduates must be "**practice-ready" and "team-ready."**
  - Practice-ready = provide direct-patient care in a variety of healthcare settings
  - **Team-ready = contribute as a member of an interprofessional collaborative patient care team**
- Emphasize earlier exposure to clinical care through:
  - Practice skills laboratory
  - Introductory pharmacy practice experiences
  - **Intensive courses focusing on optimal use of medications**

ACCREDITATION COUNCIL FOR PHARMACY EDUCATION

Key Elements:

2.1. Patient-centered care – The graduate is able to provide patient-centered care as the medication expert (collect and interpret evidence, prioritize, formulate assessments and recommendations, implement, monitor and adjust plans, and document activities).

2.4. Population-based care – The graduate is able to describe how population-based care influences patient-centered care and the development of practice guidelines and evidence-based best practices.

3.3. Patient advocacy – The graduate is able to represent the patient's best interests.

3.4. Interprofessional collaboration – The graduate is able to actively participate and engage as a healthcare team member by demonstrating mutual respect, understanding, and values to meet patient care needs.

3.5. Cultural sensitivity – The graduate is able to recognize social determinants of health to diminish disparities and inequities in access to quality care.

3.6. Communication – The graduate is able to effectively communicate verbally and nonverbally when interacting with individuals, groups, and organizations.

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Pharmacists' Patient Care Process

Pharmacists use a patient-centered approach in collaboration with other providers on the health care team to optimize patient health and medication outcomes. An essential first step is the establishment of a patient–pharmacist relationship that supports engagement and effective communication with patients, families, and caregivers throughout the process. In addition, at the core of the process, pharmacists continually collaborate, document, and communicate with physicians, other pharmacists, and other health care professionals in the provision of safe, effective, and coordinated care. This process is enhanced through the use of interoperable information technology systems that facilitate efficient and effective communication among all individuals involved in patient care. (Figure 1).

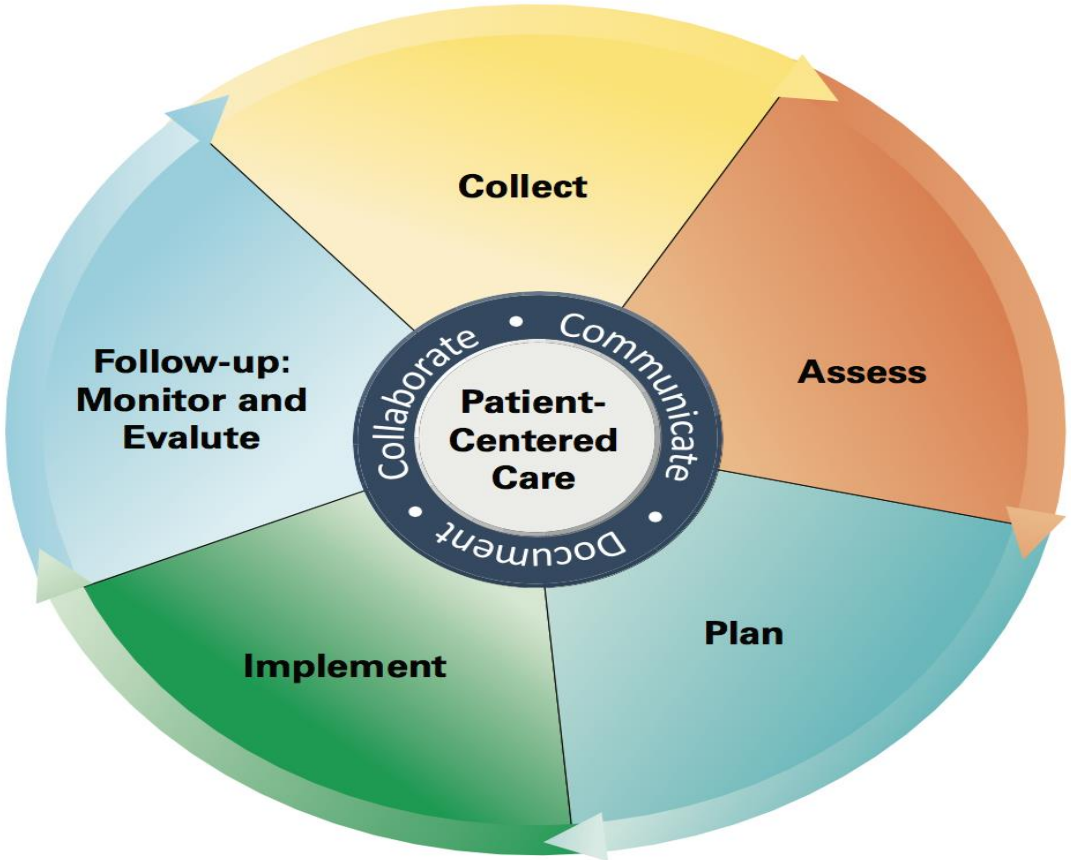

Figure 1: Pharmacists' patient care process

Pharmacists' Patient Care Process
Pharmacists use a patient-centered approach in collaboration with other providers on the health care team to optimize patient health and medication outcomes.

Using principles of evidence-based practice, pharmacists:

Collect
The pharmacist assures the collection of the necessary subjective and objective information about the patient in order to understand the relevant medical/medication history and clinical status of the patient.

Assess
The pharmacist assesses the information collected and analyzes the clinical effects of the patient's therapy in the context of the patient's overall health goals in order to identify and prioritize problems and achieve optimal care.

Plan
The pharmacist develops an individualized patient-centered care plan, in collaboration with other health care professionals and the patient or caregiver that is evidence-based and cost-effective.

Implement
The pharmacist implements the care plan in collaboration with other health care professionals and the patient or caregiver.

Follow-up: Monitor and Evaluate
The pharmacist monitors and evaluates the effectiveness of the care plan and modifies the plan in collaboration with other health care professionals and the patient or caregiver as needed.

Today's Pharmacy Curriculum
(Medication Safety Specialists)

- **Pain management**
- Appropriate selection
  - Monitoring
  - Pharmacodynamics
    - (Once medication is taken, what happen next. Distribution, Metabolism, Excretion)
  - Pharmacokinetics
    - Conversion
      - Opioid rotations to reduce tolerance and side affects with chronic use
  - Toxicology
  - Alternative (Non-Opioid) pain medications or modalities
    - Physical Therapy
    - Anti-inflammatory

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Today's Pharmacy Curriculum

- **LAW**:
  - **E- Force/ PDMP**
    - Validation and resources for communication
    - Interstate Communication
  - DEA Regulations
    - Special guests and relationships
  - Multistate Pharmacy Jurisprudence Examination (MJPE)
  - Attendance at BOP disciplinary meeting as part of curriculum
  - **Naloxone (Narcan)** (which states, Open order vs Individual)
  - **Advocacy –** Florida Pharmacy Association, promotion for public health, legislation, collaborations with medical associations

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Today's Pharmacy Curriculum

- **Patient Education/Counseling Training**: (Cultural Sensitivity- Community)
  - Select monitor and screen for risks of improper use
  - Better ways to engage dialogue without blame
  - Plan as interprofessional team
  - Implement care plan through collaboration - (in-person, sim lab, telehealth)

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Post Licensure Education Requirements for Pharmacists
RE: Controlled Substances

- **(6) <u>Mandatory Continuing Education</u>: 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.

Post Licensure Education for Pharmacists
RE: Controlled Substances

- **APhA** - American Pharmacists Association
- **AACP** - American Association of Colleges of Pharmacy (*Ex. Substance Abuse SIG*)
- **FSHP** - Florida Society of Health-System Pharmacists
- **FPA** - Florida Pharmacy Association
- **Other pharmacy orgs** (*state and nationally*)

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Todays Pharmacist (**NARCAN)**

GOV. SCOTT DIRECTS STATEWIDE PUBLIC HEALTH EMERGENCY FOR OPIOID EPIDEMIC

On May 3, 2017, in News Releases, by Staff

TAMPA, Fla. – Today, following the Centers for Disease Control and Prevention (CDC) declaring a national opioid epidemic, Governor Rick Scott signed Executive Order 17-146 directing a Public Health Emergency across the state. By signing the Emergency Order, it will allow the state to immediately draw down more than $27 million in federal grant funding from the United States

communities. In addition to declaring a Public Health Emergency, Surgeon General Dr. Celeste Philip will issue a standing order for Naloxone, an emergency treatment for opioid overdose. This will ensure first responders have immediate access to this lifesaving drug to respond to opioid overdoses.

Education and opportunities for pharmacists to assist in the opioid epidemic.

- **Narcan training** and dispensing as discussed
  - (Ex. Walgreens is now requiring their pharmacists to offer NARCAN upon dispensing

    Methadone, Oxycodone (such as OxyContin®), Hydrocodone (such as Vicodin®)
- **Screening and referral for substance abuse**
- **Safe Needle programs** (reduction of Hepatitis and HIV. Allows for follow-up)
- **Drug Take back program** (lead and encourage with local Law Enforcement)
- **Clinical Education** (Automation support)
- **Engaging with legislators** (also getting into legislation) and other health care providers as we are here to provide health to our public as a health care "SYSTEM" which up until now has failed many families.
  - Engage pharmacists to be more proactive and references for legislators.

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Venita J. Sposetti, DMD, Associate Dean for Education
John H. Hardeman, DDS, MD, OMFS Residency Program Director

What do we teach @ UF?

- DMD Curriculum
  - Didactic & Clinical Instruction
  - What's new?
- Advanced and Graduate Programs
- Continuing Education

DMD Courses (Handout)

	Professional DMD Curriculum		Year			
Course Number	Course Name	Course Type	1	2	3	4
DEN 5120C	Physiology	Didactic	x			
DEN 6251	Science & Clinical Management of Dental Pain	Didactic		x		
DEN 6250C	Pain and Anxiety Control in Dental Patients	Didactic		x		
DEN 6260	Oral Medicine and Pharmacotherapeutics	Didactic		x		
DEN 6262	Principles of Pharmacology	Didactic		x		
DEN 7016	Professionalism: Patient Care and Practice Management II	Clinical			x	
DEN 7017	Professionalism: Patient Care and Practice Management III	Clinical			x	x
DEN 7422	Periodontal Surgery for the General Practitioner	Didactic			x	
DEN 7443L	Hospital Dentistry	Clinical			x	x
DEN 7735L	Clinical Endodontics 1	Clinical			x	
DEN 7736L	Clinical Endodontics 2	Clinical			x	
DEN 7761L	Oral Diagnosis/Medicine & Treatment Planning I	Clinical			x	
DEN 7766L	Oral Diagnosis/Medicine & Treatment Planning 2	Clinical			x	x
DEN 7805L	Clinical Oral Surgery I.	Clinical			x	
DEN 7834L	Comprehensive Periodontal Treatment 1	Clinical			x	
DEN 7835L	Comprehensive Periodontal Treatment 2	Clinical			x	
DEN 7836L	Comprehensive Periodontal Treatment 3	Clinical			x	
DEN 8018	Professionalism: Patient Care and Practice Management IV	Clinical				x
DEN 8263	Advanced Oral Medicine and Clinical Pharmacology	Didactic			x	x
DEN 8737L	Clinical Endodontics 3	Clinical				x
DEN 8738L	Clinical Endodontics 4	Clinical				x
DEN 8739L	Clinical Endodontics 5	Clinical				x
DEN 8768L	Oral Diagnosis/Medicine & Treatment Planning 3	Clinical				x
DEN 8809L	Advanced Oral Surgery	Clinical				x
DEN 8837L	Comprehensive Periodontal Treatment 4	Clinical				x
DEN 8838L	Comprehensive Periodontal Treatment 5	Clinical				x
DEN 8839L	Comprehensive Periodontal Treatment 6	Clinical				x

DEN8263: Advanced Oral Medicine and Clinical Pharmacology

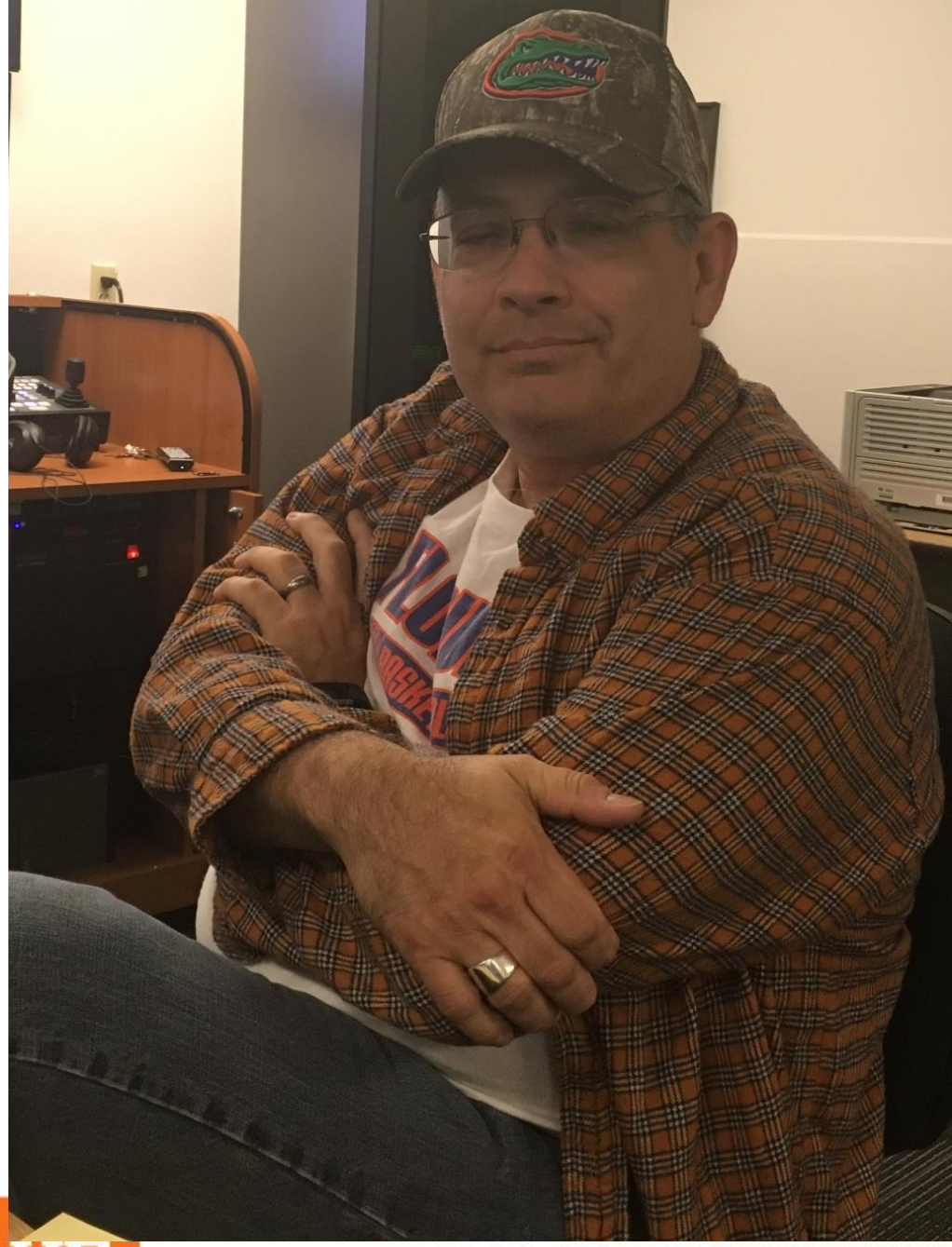
- May 2017

  Implemented a joint case based capstone with the College of Pharmacy

  4th year Dental & 2nd year PharmD students

  'Doc, My Tooth Hurts'

- In ‘Doc, My Tooth Hurts’
- DMD & PharmD students interviewed a standardized patient with acute dental pain and a H/O substance abuse treatment for opioid addiction.



Clinical Patient Care

- Daily clinical team huddles & bi-weekly team meetings
- Annual seminar Professionals Resource Network (PRN) & recovering addict dentists
- Risk Management invited speaker. The opioid crisis and legal aspects of prescribing were cited examples.

UF

UF Health Interprofessional Education

In discussion phase of creation of interprofessional class on opiod issues across the UF Health center.

Follows a model we already have in place for tobacco and community public health.

New Commission On Dental Accreditation (CODA) Standard

- Standard 2-23 e.
  - At a minimum, graduates **must** be competent in providing oral health care within the scope of general dentistry, as defined by the school, including:
    - e. local anesthesia, and pain and anxiety control, <u>including consideration of the impact of prescribing practices and substance abuse.</u>

UF

Advanced and Graduate Education

- Oral and Maxillofacial Surgery program
- Graduate Endodontics
- Graduate Periodontology
- Graduate Prosthodontics
- AEGD – Hialeah & Seminole, FL
- Graduate Pediatric Dentistry – Gainesville & Naples

Advanced and Graduate Education

- DEN 6678 Advanced Oral Medicine and Dental Pharmacology – Course Director: Dr. Joseph Katz

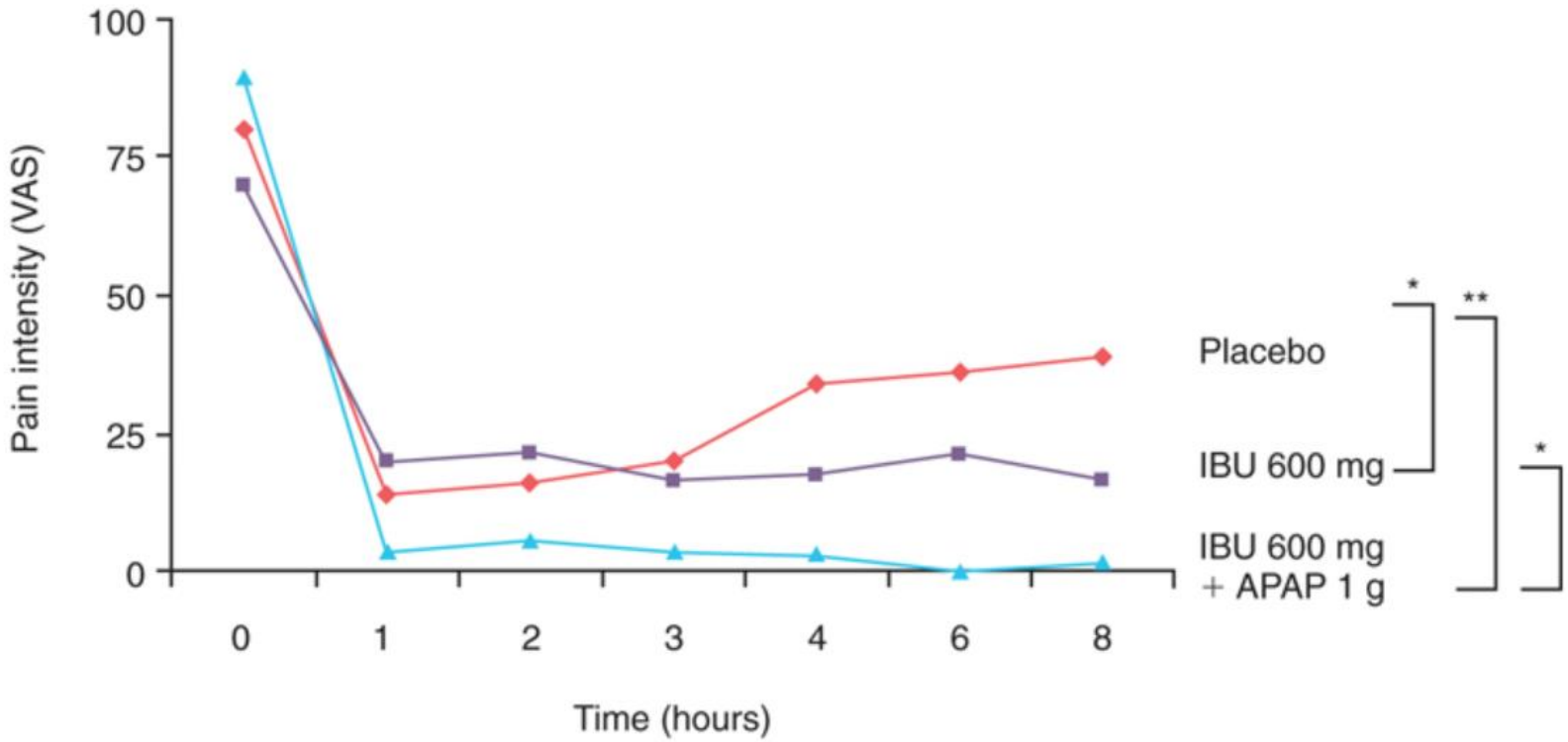
Flexible Analgesic Strategy – Endodontics, Periodontology

- Mild pain –**600mg of ibuprofen 3 times a day, usually for 2-3 days.**

- Severe pain - **600mg of Ibuprofen with 650mg of acetaminophen.**

- the residents know that the flexible analgesic treatment with NSAIDs and AAA is more efficient than the narcotics.
- However if the patients are allergic to NSAIDs, we might need to prescribed narcotics. But, In general in those cases if there is not an infection we use corticosteroids rather than narcotics, and if narcotics are prescribed it is not for more than 2-3 days.

Mild pain - 600mg of ibuprofen 3 times a day
Severe pain - 600mg of Ibuprofen with 650mg of acetaminophen.
2-3 days.



From Menhinick KA, Gutmann JL, Regan JD, et al: The efficacy of pain control following nonsurgical root canal treatment using ibuprofen or a combination of ibuprofen and acetaminophen in a randomized, double-blind, placebo-controlled study, *Int Endod J* 37:531, 2004.

Continuing Education for Practicing Professionals

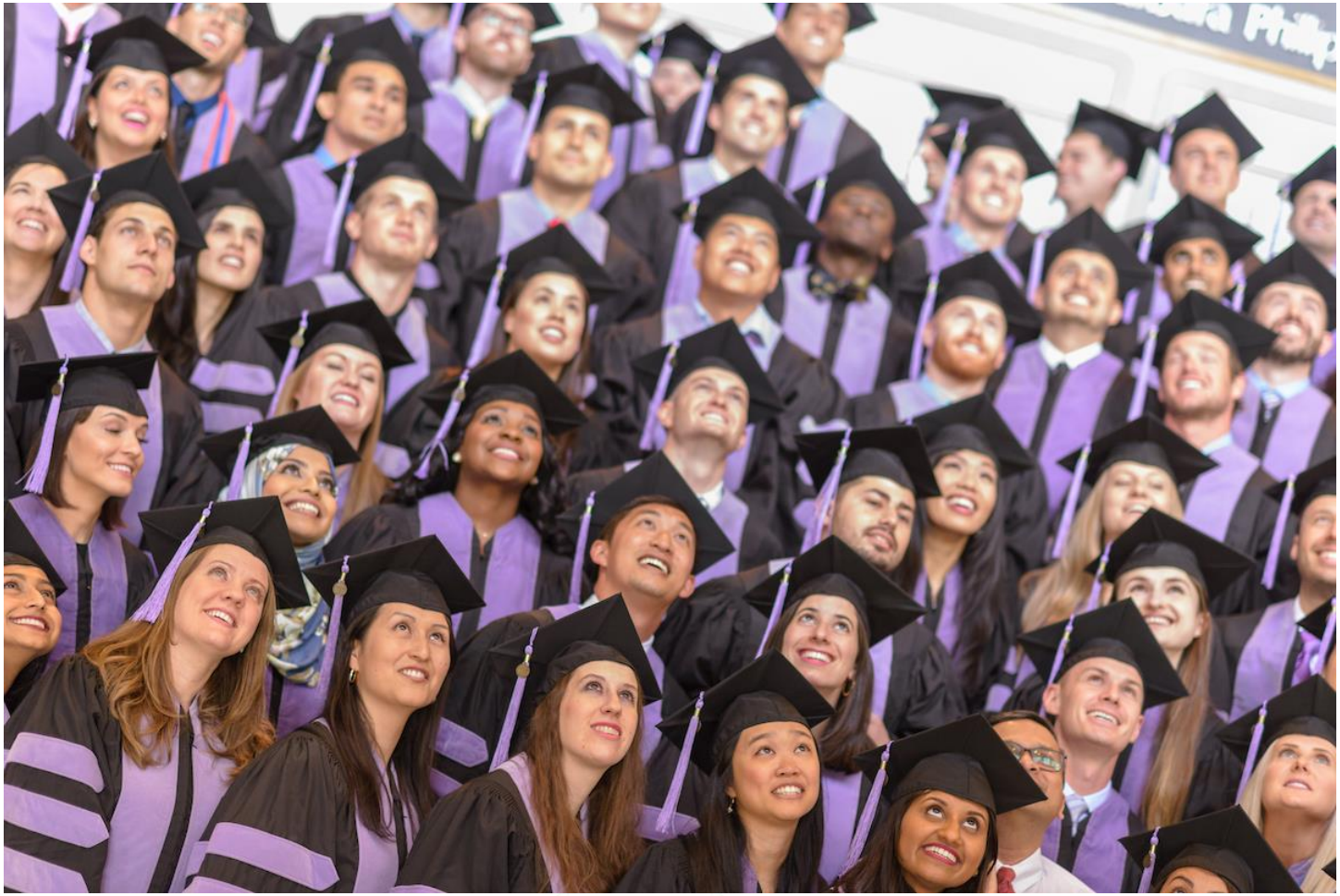
- **Pharmacology course given every two years and is next scheduled in November 2018:**

- **"Drugs in Dentistry Update: including conventional drugs, herbals and natural supplements" by Dr. Richard Wynn, lead author of the textbook, Drug Information Handbook for Dentistry**.

- **Here are the courses over the past couple of years where we cover pain management, with and without opioid medication:**
- • July 2015 – Occlusion, MPD and TMD Level II
- • August 2015 – Surgical Periodontics
- • November 2015 – Oral Surgery Level II
- • February 2016 – Surgical Endodontics
- • September 2016 – Pharmacology
- • November 2016 – Oral Surgery for the General Dentists
- • January 2017 - Occlusion, MPD and TMD Level I
- • July 2017 - Surgical Periodontics
- • August 2017 - Occlusion, MPD and TMD Level II
- • September 2017 - Oral Surgery Level II
- • October 2017 - Oral Surgery for the General Dentists

UF

Educating Dentists for Florida's Future



UF

Thank you

Opioid Epidemic: A Collaborative, Comprehensive Strategy

Gary White, MPH, CPH
Associate Director - HCADA

HCADA Vision and Mission

- **Vision:** A community where youth and families are safe, healthy and free of substance abuse and addiction.

- **Mission:** To plan and implement strategies to prevent and reduce youth and adult substance use/misuse by promoting healthy communities in Hillsborough County through **education, collaboration and advocacy**.

Our Process – Strategic Prevention Framework (SPF)

…through **education, collaboration and advocacy**.

Our Plan ...

Comprehensive Coalitions Implement Multiple Strategies

1. Provide information
2. Build skills
3. Provide social support
4. Reduce barriers/enhance access
5. Change consequences/incentives
6. Alter the physical design of the environment
7. Change policies and rules

Examples of Individual Strategies

Examples of Environmental Strategies

Our Plan …

Practitioner/Provider Impact:

1. Addiction Medicine Specialty– Incentivize

2. **Mandate additional Opioid use and addiction training**

3. Mandate checking of Prescription Drug Monitoring Program (PDMP) by medical practitioners before prescribing opioids
4. …

Our Plan …

Public/Communities Impact:

1. Early Recognition/Intervention: Provide SBIRT training to school systems. SBIRT is SAMHSA endorsed & evidence-based.
2. **Fund and promote high-quality drug abuse primary prevention initiatives in school, <u>higher education</u>, and community settings.**
3. Public Awareness Campaigns
4. …

Our Plan …

Foster Collaboration (LEO, Healthcare Industry, etc.):

1. Insurance coverage for the full range of Medication Assisted Treatment (MAT)

2. **Establish guidelines to screen for substance use in all health care settings. (SBIRT)**

3. ER Departments: “Warm” hand-off protocol following an overdose.
4. …

Our Plan …

Regulatory Structure: Increased penalties, enhanced standards:

1. Encourage courts and jails to create pilot programs for the use of MAT
2. **Diffuse innovations that have resulted in a reduction of opioid deaths.**
3. Expand drug courts, diversion alternatives, etc. to provide access to substance use disorder treatment and monitoring
4. …

Opioid Epidemic: A Collaborative, Comprehensive Strategy

HCADA
Hillsborough County Anti Drug Alliance

Questions?

Gary White, MPH, CPH
Associate Director - HCADA

Gwhite@HCADA.com
813-238-4034

Opioid Epidemic: A Coalition Response

- **Vision: A community where youth and families are safe, healthy and free of substance abuse and addiction.**

- **Mission: To plan and implement strategies to prevent and reduce youth and adult substance use/misuse by promoting healthy communities in Hillsborough County through education, collaboration and advocacy.**

Case Statement:

HCADA is committed to a community relationship and planning process that continues to make Hillsborough County a healthier and safer place for all of us to live. Working together with our community partners we have seen a reduction in harmful results related to alcohol, tobacco, and drug use. It is important to sustain the work of the coalition that has produced a decrease in substance abuse and made significant strides in making a safer Hillsborough County. We Need YOU to continue the progress made by community volunteers, community leaders, and our dedicated staff.

Key Areas of strategy focus:

Practitioner/Provider Impact:

• Create incentives for medical practitioners to obtain a specialty in addiction medicine; fund fellowships in addiction medicine.
• Require additional training on opioid use and addiction for all professionals prescribing controlled substances.
• Require mandatory checking of Prescription Drug Monitoring Program (PDMP) by medical practitioners before prescribing opioids.
• Require mandatory education for physicians on opioid prescribing as part of the licensure renewal process.
• Identify and implement best practice policies that hospitals could use to intervene with overdoses and link overdose patients with Substance Use Disorder (SUD) treatment.

Public/Communities Impact:

• Create/implement multi-faceted public awareness campaigns to inform the public of the dangers/consequences of substance abuse, drug trends, effective drug policy, preventing substance abuse among youth, how to safeguard and properly dispose of medications including lock boxes, drug disposal pouches, and continued expansion of permanent take back sites, and 911 Good Samaritan Law.
• Provide prevention resources to the community including substance abuse prevention toolkits.
• Fund and promote high-quality drug abuse primary prevention initiatives in school, higher education, and community settings.
• Provide Community Conversations (aka Town Hall Meetings) in local communities

• Provide training to teachers, school professionals, and school nurses to recognize and respond to children in need of services utilizing Screening, Brief Intervention & Referral to Treatment (SBIRT). SBIRT is SAMHSA endorsed, evidence-based.

Foster Collaborations: Law Enforcement, Healthcare Industry, And Other Partners:

• Develop and distribute a toolkit that hospital emergency departments can use to assist drug overdose patients with treatment options; institute a warm hand-off protocol following an overdose.
• Establish guidelines to screen for substance use in all health care settings. (SBIRT)
• Require all commercial health insurance carriers and managed care plans to cover the full range of Medication Assisted Treatment (MAT) services including ***medication, counseling and naloxone***; ensure all plans fully cover cost of MAT medications; remove prior authorization tied to MAT.
• Create statewide shared real-time data and early warning system that provides real-time information on drug use trends and risks to public safety and public health. Establish rapid/reliable lines of communication about
drug trends, overdose deaths, arrests, data treatment trends, EMS response, and use of naloxone. Identify legal, administrative, and operational barriers to obtaining real time overdose trends/data.
• Issue public health alerts to warn law enforcement, first responders, providers and the public when surges of contaminated drugs are known.

Regulatory Structure: Increased penalties, enhanced standards:

• Examine policies being utilized across the country regarding involuntary, court-ordered commitments of overdose victims. Explore the role of family, friends, courts, and physicians play in this process.
• Promote additional training for law enforcement in recognizing and effectively dealing with addiction.
• Encourage courts and jails to create pilot programs for the use of MAT.
• Document and replicate efforts between law enforcement and local community groups and/or coalitions that have resulted in a reduction of opioid deaths.
• Expand drug courts, diversion alternatives and alternatives to incarceration for non-trafficking drug offenses; provide access to substance use disorder treatment and monitoring.

Existing Resources / Termination Dates:

1. $125,000 ~ DFC (Federal – Drug Free Communities) ~ Expires 9/30/2018 ~ Funds 2 Staff, Office Space, Utilities, Phone
2. $347,000 ~ BTFF-Exp. 6/30/21 ~ Funds 2.50 Staff/Supplies, Office Space, Utilities, Phone
3. $78,000 ~ DCF (State - Florida Dept. of Children & Families) ~ Expires Annual Recurring ~ Funds 1 Staff, Office Space, Utilities, Phone, Youth Programs Staff and Supplies.

Sources and Strategies:

1. Raise Revenue through Local Business Support
2. Enlist Board of Directors in Fundraising Efforts
3. Apply for Foundation Support and Grant Opportunities
4. Request local budget allocation and state legislative budget request (LBR)
5. Expand Fee for Service activities Charge (Mental Health First Aid

Awareness, SBIRT Training, Technical Assistance, Consultation, etc.)

6. Enlist Community Support for In-Kind Services

Timeline for Action(s): Ongoing

Contact Information:

Hillsborough County Anti-Drug Alliance (HCADA)
2815 E Henry Ave, Ste B1
Tampa FL 33610
813-238-4034
www.HCADA.com
Ellen Snelling, Board Chair
Cindy Grant, Director
Gary White, Associate Director

TAB #4

FLORIDA BOARD OF PHARMACY

Mark Mikhael, PharmD
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Orlando, FL

Blanca R. Rivera, MPharm, MBA
Orlando, FL

David Wright, BPharm
Fort Pierce, FL

December XX, 2017

Office of Governor Rick Scott
State of Florida
The Capitol
400 South Monroe Street
Tallahassee, Florida 32399

Dear Governor Scott:

On behalf of the Florida Board of Pharmacy, we would like to express our support of both Senator Benaquisto's legislative proposal in Senate Bill 8, and Representative Boyd's legislative proposal in HB 21 regarding the prescribing of controlled substances. During our December XX, 2017 meeting, the Florida Board of Pharmacy voted unanimously in support of this legislation, as we feel safe and standardized practices are necessary to combat overprescribing of controlled substances.

As you know, the misuse and abuse of controlled substances has reached epidemic proportions. Since our profession holds a key role because we are responsible for filling controlled substance prescriptions, we are committed to help in the fight against this emerging and very present epidemic.

Sincerely,

Mark Mikhael, PharmD
Chair, Board of Pharmacy

Florida Board of Pharmacy
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