Understanding of Terms

- **Opiate**: Natural, derived from opium such as Morphine and Codeine (Heroin is most often cut with other substances making it semi-synthetic)
- **Synthetic Opioid**: Manmade drugs that mimic the effects of natural opioids; includes legal (Fentanyl - 100 times more powerful than Morphine/50 times more powerful than Heroin, methadone, tramadol); available by prescription
- **Semi-Synthetic**: Partially derived from opium and codeine; legal, available by prescription - Oxycodone, Hydromorphone, Hydrocodone, and illegal – Heroin

The President’s Commission on Combating Drug Addiction and the Opioid Crisis

- Established 3-29-17 – Executive Order
- The Office of National Drug Control Policy (ONDCP) provides administrative and financial support
- 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
- Disbanded late 2017 after completing final report
- Report length 138 pages
- Leading cause of unintentional death in the U.S.
- “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. ”
- “…hundreds of parents who have buried their children, so these numbers are no longer simply statistics”
- “It is time we all say what we know is true: addiction is a disease.”
- “…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.”
- “…called for prescriber education and enhanced access to medication assisted treatment for those already suffering from addiction.”
- “…recommendation that the Department of Justice, which has already used successfully to stop the flow of illicit synthetic drugs into the country through the U.S. Postal Service, continue its efforts.”
The President's Commission on Combating Drug Addiction and the Opioid crisis

Summary of Recommendations:
1. Federal Funding and Programs
2. Opioid Addiction Prevention
3. Prescribing Guidelines, Regulations, Education
4. PDMP Enhancements
5. Supply Reduction and Enforcement Strategies
6. Opioid Addiction Treatment, Overdose Reversal, and Recovery
7. Research and Development

"Please read the report in detail."

CDC Update!

- 3-18 CDC Vital Signs:
  - Opioid OD ED visits rose 30% 7-16/9/17
  - Midwestern States hard hit, 70% increase
  - Increases in both sexes and all age groups
  - People who have had an OD more likely to have another
  - Repeat OD avoided thru treatment referrals during visit
  - Timely/coordinated response efforts better prevent OD in community
  - Learn about prevention and what to do – Save a Life!

- Federal Government:
  - Educate providers and public about pain management, addiction and opioid OD, equip states for safe prescribing practices, reduce access to prescription opioids, increase access naloxone, access to treatment and recovery services, increase access treatment, increase access naloxone

- States:
  - Maximize PDMP, improve prescribing practices, reduce access to prescription opioids, increase access medication-assisted treatment, increase access treatment and recovery services, increase access naloxone

- Health Insurers:
  - Refer to Guideline in prescription claims review, ID and address improper prescribing and use of opioids, increase access to treatment and recovery services, increase access naloxone

- Providers:
  - Follow CDC Guidelines, use opioids only after benefits outweigh risk, start lowest dose, prescriber only number of doses indicated for acute pain, monitor benefits and risks if considering non-medicines, stop prescription

- Patients:
  - Consider non-opioid options, store medications in secure place, dispose of medications properly as soon as treatment done, get help if having trouble controlling opioid use, 1-800-662-HELP (SAMHSA)
Media Update!

- **3-2-18** (NPR – National Public Radio): Surgeon General Jerome Adams on Morning Edition, “The majority of the public does not see the opioid epidemic as rising to the level of an emergency. It’s important that we continue to say at the highest levels, this is a problem in all communities and it’s getting worse.”

- **4-10-18** (The Washington Post):
  - Fatasties from heroin & black market synthetic opioids skyrocketed while nation saw decline in opioid painkiller prescriptions and the OD deaths contributed to them
  - People who became dependent on prescription opioids, when they became difficult to obtain, people turned to whatever alternative they could find
  - Root cause is dependency, in 2015 nearly 1 million people not working because of opioid dependency, employers unable to fill jobs because people not passing drug tests
  - Hundreds of municipalities across U.S. suing opioid manufacturers, distributors and down the supply chain – claim they knowingly peddled an addictive product that led to death and dependency

Media Update!

- **5-25-18** (Scientific American - Sewage Is Helping Cities Flush Out the Opioid crisis):
  - Sewage is information superhighway under your feet, according to Rolf Halden, Director of A.S.U. Biodesign Center for Environmental Health Engineering.
  - Examined sludge in more than 300 municipalities worldwide since 2008
  - Monthly data on residents’ collective intake of heroin, oxycodone, fentanyl and other opioids (toilet water tells the tale – poop studies)
  - Dealers lace drugs with fentanyl (50x more potent than heroin) and carfentanyl (5000x stronger than heroin)
  - Alert 1st responders to stock up on naloxone and prepare to administer in large doses

Media Update!

- **5-25-18** (The Wall Street Journal – The Heated Quest for Opioid Alternatives):
  - Rising abuse of prescription painkillers is intensifying search for alternatives to addictive opioids
  - 46 Americans/day according to CDC
  - Drug makers exploring and trialing growing number of alternatives designed to have little or no risk of abuse or addiction.
  - More than 23,000 Americans suffer from daily pain according to NIH (National Institutes of Health)
  - Opioids, activate specific receptors in brain/spinal cord and elsewhere, cause euphoria [trigger spike in dopamine] which leads to addiction. Also cause N/V and difficulty breathing
  - Drug makers targeting new molecules and avoiding opioid receptors – “Tanezumab” target nerve growth factor and prevent signaling pain neurons
  - New option: Zilretta, direct injection OA
  - Nektar company engineered opioid that enters brain slowly to reduce release of dopamine, drug was less likable to users!
Media Update!

• **6-2-18 (Time Magazine – Opioids Are Now Responsible for 1 in 5 Deaths Among Young Adults):**
  - 2016, 1 in 65 deaths in U.S. involved opioids
  - 1 in 5 among younger adults
  - According to CDC, nearly doubled since 2009, infiltrated all genders, demographics and geographic areas
  - JAMA Network Open put into perspective:
    - 2016 opioids involved in 28,496 deaths
    - More than 8400 between ages 25-34 (20%)
    - Nearly 3000 between ages 15-24 (12.4%)
    - Opioids involved in 1.5% of all deaths in 2016; more life years lost than high BP, HIV/AIDS & pneumonia. 1/10 of those lost to cancer

DEA Update!

• **7-11-18: Issued final ruling to consider the likelihood of whether a drug can be diverted for abuse when it sets annual opioid production limits**

• **8-16-18 (DEA – Justice Department, DEA Propose significant opioid manufacturing reduction in 2019):**
  - Consistent with President Trump’s “Safe Prescribing Plan”; seeking to cut opioid fills by 1/3 within 3 years
  - Applies to six most frequently misused opioids, average 10% over 2018 (National Prescription Audit)
    - Including more commonly prescribed schedule II opioids – oxycodone, hydrocodone, hydromorphone, morphine and fentanyl
  - 3rd straight year of reductions, which help to reduce amount of drugs diverted for trafficking and used to facilitate addiction

DEA Update!

• **8-16-18 (DEA – Justice Department, DEA Propose significant opioid manufacturing reduction in 2019): Continued**
  - Promotes greater involvement of U.S. Attorney Generals
  - Considers estimates of legitimate medical need from FDA, estimates from retail consumption based on prescriptions dispensed, manufacturer disposition history and forecasts, DEA’s own internal tracking system (past quota histories)
  - Revised limits encourage vigilance on part of opioid manufacturers, help DEA respond to drug threat environment, protect people from potential addictive drugs, ensure country has enough opioids for legitimate medical, scientific research and industrial needs
  - "We’ve lost too many lives to the opioid epidemic and families and communities suffer tragic consequences every day,” said DEA Acting Administrator Uttam Dhillon
  - Attty. General Jeff Sessions said, "The opioid epidemic that we are facing now is the worst drug crisis in American history. President Trump has set the ambitious goal of reducing opioid prescription rates by one-third in three years. We embrace that goal and are resolutely committed to reaching it."
CDC Update!

- **8-16-18: Preliminary Data 2017**
  - More than 72,000 Americans died of drug OD (may be under-estimated as all states data is not in)
  - Increased 7%
  - Twofold increase over a decade
  - Opioids, including prescription painkillers, along with illegal synthetic opioid drugs, contributed 49,068 to the total number of deaths (68%)
  - Nearly 30,000 were related to fentanyl and other synthetic opioids
  - Encompasses both intentional and unintentional OD
  - Majority of abused prescription drugs were obtained from family and friends, often from the home medicine cabinet
  - Efforts include Generation Rx Initiative (increase public awareness of prescription medication abuse) and National Prescription Drug Take Back Day (initiative to dispose of unused drugs in responsible way)
  - Increasing supply of naloxone to 1st responders
  - Some states limiting opioid prescribing

NIDA Update!

- **9-18 (NIH National Institute on Drug Abuse – NIDA's Role in the NIH HEAL Initiative)**
  - HEAL (Helping to End Addiction Long-Term): launched June 2018
  - Provide Scientific solutions to national opioid overdose crisis, including improved treatment strategies
  - Funded by Congress, focused on:
    - Opioid Medications Development Research Project
      - Ideally lead to about 15 Investigational New Drugs (INDs), produce 5 New Drug Applications (NDAs) submitted to FDA
      - Addiction treatments and opioid reversals
    - HEALing Community Studies
      - Determine if integrated set of evidence-based interventions within health/behavioral health/justice systems/community organizations can decrease opioid OD and prevent/treat OUD (buprenorphine)
    - Clinical Trials Network OUD Research Enhancement Project
      - Improve access to high-quality, evidence-based addiction treatment in justice settings
      - Study effectiveness and adoption of medications/interventions/technologies
      - Implement national survey of addiction treatment services in local and state justice systems
    - Justice Community Opioid Innovation Network
Actions

- According to DEA, 2mg fentanyl, about 4 grains of salt – DEADLY
- Chemical cousin, Carfentanil even more DEADLY
- $1.7 Million in Fentanyl from China Seized in Philadelphia 7-1-18
- President Trump would like Justice Department to pursue federal lawsuits against certain drug companies;
  Atty. General Sessions noted Justice Department in process of returning indictments against Chinese companies tied to fentanyl
  – 170 Physicians indicted for unlawfully prescribing opioids
- President Trump seeks 10% production cut for six opioids (Becker's Hospital Review)
  - Oxycodone
  - Hydrocodone
  - Hydromorphone
  - Methadone
  - Fentanyl
- DEA and Department of Justice proposal on heels of CDC estimate showing #48,612 deaths from opioid overdoses 2017

Regulatory and/or Legislative Help or Hinder?

- Joint Commission
  - PC.01.02.07: The identification and management of pain is an important component of patient-centered care. Both pharm and non-pharm strategies have a role
  - PC.02.03.01: Education and training are to be provided to the patient; include: safety, safe and effective use of meds, pain/risk for pain, importance of effective pain management, pain assessment, and methods for pain management
- CDC Guidelines-2016
- Professional Organization's Guidelines
- State Medical Boards, Boards of Registered Nursing and Pharmacy, FDA, REMS Programs, NIH
- President's Commission on Combating Drug Addiction and the Opioid crisis

Current State Summary

- According to CDC, the most common drugs involved in non-fentanyl overdose deaths include:
  - Methadone
  - Hydromorphone
  - Hydrocodone

- Anyone who takes prescription opioids can become addicted; 1 in 4 patients on long-term opioid therapy struggle with opioid addiction
- Providers must report a suspected opioid overdose on every American with a bottle of pills
- Overdose rates from prescription opioids involving an overdose death more than 1.7 Million 11-13-18
- According to CDC, the most common drugs involved in non-fentanyl overdose deaths include:
  - Methadone
  - Hydromorphone
  - Hydrocodone
Definitions

Addiction - Psychological dependence characterized by a continued use despite harm, impaired control over use, compulsive use, craving, using for wrong reason. APS, AAPM, ASAM 2001

Tolerance - Physiologic process characterized by decreasing effects of a drug (same dose) over time.

Physical Dependence - Physiologic response manifested by withdrawal syndrome with abrupt cessation, decreasing blood level and/or administration of an antagonist.

Pseudoaddiction - the difficult dilemma

PAIN SCALE FOR PATIENTS

<table>
<thead>
<tr>
<th>Scale</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severe</td>
<td>1. Activity limited by pain 2. Rest limited by pain 3. Cannot function normally 4. Numbness and paresthesia</td>
</tr>
</tbody>
</table>

Functional Pain Scale
Medicating to Numbers is NOT safe!

PAIN SCALE FOR STAFF

<table>
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<tr>
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</tr>
</thead>
<tbody>
<tr>
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</tr>
</tbody>
</table>

Functional Pain Scale for Provider/Staff
We have a responsibility to educate our patients on pain.
Standing in a doorway and asking a number is not in alignment with best practice.
PDMP: Prescription Drug Monitoring Program

- A prescription drug monitoring program (PDMP) is an electronic database that tracks controlled substance prescriptions in a state. PDMPs can provide health authorities timely information about prescribing and patient behaviors that contribute to the epidemic and facilitate a nimble and targeted response. (CDC)

- Provides decision makers with timely information that can save lives.
- Real-time data.
- Activity Managed.
- Easy to use and access.

- Alerts may be presented at the following therapy thresholds:
  - Patient is currently prescribed more than 90 morphine milligram equivalents per day
  - Patient has obtained prescriptions from 6 or more prescribers or 6 or more pharmacies during last 6 months
  - Patient is currently prescribed more than 40 morphine milligram equivalents of methadone per day
  - Patient is currently prescribed opioids more than 90 consecutive days
  - Patient is currently prescribed both benzodiazepines and opioids

Facts About Opioid Pain Medications

- Pain relief
- Oral
- Non-opioids
- Opioids
- Long-acting
- Short-acting
- Immediate-release
- Time-released
- Controlled-release
- Methadone
- Opioid agonists
- Opioid antagonist
- Opioid partial agonists
- Opioid receptor antagonists
- Naloxone
- Naltrexone
- Buprenorphine

Some Options Other Than Opioids

- Breathing exercises
- Ice
- Pet Therapy
- Massage
- Music
- Distraction
- Position change
- Relaxation
- Rest
- Cognitive Behavioral Therapy
- Breathing exercises
- Care channel
- Emotional support
- Heat
- Ice
- Pet Therapy
- Massage
- Music
- Distraction
- Position change
- Relaxation
- Rest
- Cognitive Behavioral Therapy
**Patient EDUCATION**

- **GOALS:**
  - Improve Pain Relief
  - Increase Knowledge
  - Decrease Misconceptions
  - Increase Adherence
  - Develop Patient skills
    - Cognitive-Behavioral
    - Self-Care
    - Family-centered Care

- **INCLUDE:**
  - Cause of Pain; if known
  - Types of Pain
  - Medications; names, why multiple medications, regimen
  - Side Effects and Management
  - Use of the Functional Pain Scale
  - Discussion of pain intensity
  - Getting mobile!
  - Activity Limitations
  - Follow-Up Care
  - Etc.

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**Let’s Manage Pain Together**

10/10 looks like this

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**NOT LIKE THIS!**

Everyone Must Change!