The History and Politics of Opioid Maintenance Treatment

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Julie Kmiec, Disclosures

- I have no disclosures
- I will not be discussing any off-label use of medications
Target Audience

• The overarching goal of PCSS-O is to offer evidence-based trainings on the safe and effective prescribing of opioid medications in the treatment of pain and/or opioid addiction.

• Our focus is to reach providers and/or providers-in-training from diverse healthcare professions including physicians, nurses, dentists, physician assistants, pharmacists, and program administrators.
Educational Objectives

• At the conclusion of this activity participants should be able to:
  ▪ Discuss the rise in the use of and addiction to opiates in the 19\textsuperscript{th} and early 20\textsuperscript{th} centuries
  ▪ Cite legislation and case law that has shaped the treatment of opioid use disorder over the past century
  ▪ Describe the Dole & Nyswander (1965) clinical trial of methadone for treatment of heroin addiction
  ▪ Summarize how the Drug Addiction Treatment Act of 2000 further allowed treatment of opioid use disorder
  ▪ Discuss the Comprehensive Addiction Recovery Act of 2016 and its impact on treatment on opioid use disorders
Opium

- Obtained from opium poppies
- Commonly smoked, chewed, suspended in alcohol
- During the 19th century opium was prescribed to women with “female problems”
- There were 150,000 to 200,000 people addicted to opiates in the United States in the late 19th century
  - Between two-thirds and three-quarters were women

Morphine

- First extracted from the opium poppy plant in December 1805 in Germany
- Marketed as an analgesic in 1817, widespread use in U.S. by 1830s
- Also marketed for treatment for opium addiction (did not know it was addictive)
- Extensive use during the Civil War allegedly resulted in 400,000 with “Soldier’s Disease”

Introduction of Syringe

- Introduced to US possibly in 1856 or prior to Civil War
- Prior to syringe, opiates were taken orally, intranasally, rubbed into skin, rectally, put directly in wounds
- With syringe, used subcutaneously or IM
- No intravenous use until 1920s
- Claimed using via syringe decreased chance of addiction because using smaller amount

Heroin
(Heroisch – heroic & powerful)

- First synthesized in 1874 from morphine by an English chemist
- Was produced as a pain and cough remedy in 1898 by Bayer in Germany
- Gained widespread use by medical profession in early 1900s, marketed as a non-addictive
- Bayer stopped producing and selling heroin in 1913
- In 1924 the US banned production and sale of heroin (Anti-heroin Act)

Bayer heroin bottle 1920s, originally containing 5 g of Heroin. Image Public Domain.
Federal Laws Regarding Narcotics

• During the late 1800s, the Progressive Movement began with the purpose of improving the nation's morals

• In the early 1900s, there were no Federal laws limiting the domestic trade and exchange of narcotics

• 1906 Pure Food and Drug Act – defined foods and drugs, stated drugs had to be properly labeled with strength, purity

• 1909 Smoking Opium Exclusion Act – prohibited importation of opium prepared for smoking
International Opium Convention

- 1912 – First international drug control treaty in response to criticisms about opium trade
- "The contracting Powers shall use their best endeavours to control, or to cause to be controlled, all persons manufacturing, importing, selling, distributing, and exporting morphine, cocaine, and their respective salts, as well as the buildings in which these persons carry such an industry or trade."

There is no law in this State against the sale of morphine or its derivatives but the board is of the opinion that the pharmacy laws are not intended to provide a means for victims of drug habits to purchase drugs with immunity.

Heroin is said to produce a feeling that makes the user feel as though he owned the world and its users loose their appetite for food while their craving for tobacco in cigarette form increases. Increased doses are needed from time to time to satisfy the desires. The stuff is expensive and one young man who is employed in a West End factory recently went to New York and bought $18 worth of the stuff, spending his entire pay for a week in order to have a supply on hand.

Rarely a month passes without at least one death in this city directly traceable to the ravages of the drug habit.
Harrison Narcotic Act of 1914

- Attempt to carry out the International Opium Convention
- Any person dealing with derivatives of opium and cocaine was required to register annually and pay an annual tax of $1
- Made it illegal to sell or give away these drugs without a written order on a form issued by the commissioner of revenue

Harrison Narcotics Tax Act, 1914. 
Harrison Narcotic Act of 1914

• People who weren’t registered couldn’t partake in interstate trafficking of drugs
• People could not possess narcotics if they hadn’t registered or paid the tax
  ▪ Exception made for those prescribed medication in good-faith by a physician
• Penalty of up to 5 years in prison and up to $2000 fine

Harrison Narcotic Act of 1914

- "Nothing contained in this section shall apply . . . to the dispensing or distribution of any of the aforesaid drugs to a patient by a physician, dentist, or veterinary surgeon registered under this Act in the course of his professional practice only."

Harrison Narcotics Tax Act, 1914.
Harrison Narcotic Act of 1914

- Despite the above exception, from 1914-1938 about 25,000 physicians were indicted under the Harrison Act; about 3000 were imprisoned and 20,000 paid substantial fines for prescribing opiates to treat opiate addiction

Challenges to the Harrison Act
United States v. Doremus (1919)

- Doremus, a physician, distributed 500 one-sixth grain tablets of heroin to Ameris without using a form issued by the revenue service.
- The distribution of the medication was not in the course of the regular professional practice but to gratify Ameris’ “appetite for the drug.”

United States v. Doremus (1919)

• Supreme Court decided against Dr. Doremus, stating
  ▪ Doremus didn’t use the form he was supposed to use
  ▪ Doremus gave Ameris so many tablets that Ameris might have sold them and then did not pay the tax required by the Harrison Act
Webb v. United States (1919)

- Webb, a physician, prescribed morphine to “habitual users” in quantities the patient desired for the sake of continuing his accustomed use, not in aims of curing the habit.
- Goldbaum, a pharmacist, willingly filled the prescriptions knowing that they were to maintain an addiction.

Webb v. United States (1919)

- Court decided against Webb & Goldbaum stating that providing morphine to maintain a patient’s customary use is not in the course of professional practice

In 1916 Moy, a Pittsburgh physician, won a Supreme Court case in which he was charged with conspiring to provide “an addict,” Willie Martin, with morphine.

Dr. Moy wrote prescriptions for morphine to “professed morphine users” for the purpose of enabling them to continue their use of the drug, or to sell it to others, did cursory or no examination.

Prescriptions called for large quantities of morphine, 8 to 16 drams at a time, to be used “as directed”


United States v. Jin Fuey Moy (1920)

- Court decided against Dr. Moy, stating that the Harrison Act confines immunity to physicians strictly within the *appropriate* bounds of professional practice.
- It does not permit sales to dealers or distributions intended to satisfy the appetites or cravings of persons addicted to the use of such drugs.

- Jin Fuey Moy v. United States. **254 U.S. 189** (41 S.Ct. 98, 65 L.Ed. 214)  
Dr. Behrman prescribed Willie King, who was known to be addicted to opiates and cocaine, 150 grains of heroin, 360 grains of morphine, and 210 grains of cocaine (standard doses were 1/16-1/8 grain heroin, 1/5 grain morphine, 1/8-1/4 grain cocaine)

The drugs were not prescribed for any purpose other than to treat addiction

United States v. Behrman (1922)

- Court decided against Dr. Behrman, stating he gave Mr. King “enormous” quantities and that “such so-called prescriptions could only result in the gratification of a diseased appetite for these pernicious drugs or result in an unlawful parting with them to others in violation of the [Harrison] act”

Linder v. United States (1925)

- Dr. Charles Linder prescribed Ida Casey, who was known to suffer from addiction, 1 tablet of morphine and 3 tablets of cocaine.
- The drugs were not prescribed for any purpose other than to treat addiction.

Linder v. United States (1925)

• The court decided for Dr. Linder stating that despite the Behrman decision, a physician who acts according to fair medical standards may give people with addiction moderate amounts of drugs for self-administration in order to relieve conditions incident to addiction

Morphine & Heroin Clinics

- Open from 1912 to 1923
- Forty-four clinics were in existence by 1919
- Many opened in response to the Harrison Act and Supreme Court decisions
  - People were no longer able to get drugs OTC forcing them to go to physicians
  - Provide maintenance or detoxification with morphine

- Treatment Improvement Protocol (TIP) Series, No. 43. Center for Substance Abuse Treatment. Rockville (MD): Substance Abuse and Mental Health Services Administration (US); 2005.
City Breaking up Dope Traffic by Selling Drugs Itself.
TRUTH ABOUT CITY DRUG CLINIC.

Hearst-Assailed Institution for Control of the Traffic in Narcotics Reduces Crime, Pauperism, Suffering and Slavery to Peddlers, Experts Declare.

BY EDDIE SHIPPY.

[The Los Angeles Examiner recently printed a characteristic “expose” of the Los Angeles city drug clinic, an institution founded here recently at the request and with the assistance of the United States government, in which a wide variety of reckless and baseless charges were made against a really useful and sincere effort to deal with a grave and growing problem. Investigation by disinterested persons subsequently showed that each of the several charges made by the Examiner was without any foundation whatever. The most notable example of this was the chief count in the Examiner’s “indictment” of the clinic, viz.: that the drug sold by the city, purporting to be morphine, is in reality codein, a deadly narcotic. Expert analysis showed this to be as absolutely false as the rest of the malicious attack, whose only fruit was to give new hope to the vampires who baton unfortunate through illicit sales of drugs, and who have been well-nigh put out of business by the city clinic. The following, by a trained investigator, is an effort to get at the real truth about the institution and the work it is doing here.—Ed.]

The city of Los Angeles is engaged in the narcotic drug traffic. Every day it sells “shots in the arm” to several hundred “dope fiends.” Although it has been in operation only since March 8, already 364 drug addicts have registered at the city’s free clinic in the Temple Block. The number includes one Italian, one Belgian, six Englishmen, two Scotchmen, three Jews, eighteen negroes, sixteen Mexicans, three Frenchmen, one Canadian, six Irish people, one Dane, one Austrian, one Norwegian, one Indian, one Swede and 302 white Americans.

The clinic is not a hospital. It takes the ground that a drug addict is not vicious, but sick, and if cut off suddenly from the drug which has become a necessity to his body he will be an irresponsible creature, ready to take any risk, pay any price or even commit crime to get the narcotic. Its main effort is to give the addicts enough morphine to keep them in a normal state, an extent that treatment can cure them.

ITS RESULTS.

Of the 361 addicts who have registered at the clinic, some were transients and only 207 are “regulars.” Of those seven have quit the use of drugs entirely, sixteen others have left the clinic to take private cures, through the clinic’s efforts, 364 have been reduced, with their consent, from 10 to 80 per cent, and twenty have reduced the amount of morphine they use more than 50 per cent. All patients of the clinic are compelled to reduce the amount of the drug they use as soon as they are physically able to do so, but great care is taken to make the reductions gradual, so that the addicts are not thrown into a crisis and the ratios to which the number.

Los Angeles Times, May 2, 1920
AMA’s Position in 1921

• The Committee on Narcotic Drugs of the AMA reported its “firm conviction” that permitting a person addicted to narcotics to dose himself “begets deception, extends the abuse of habit-forming narcotic drugs, and causes an increase in crime”

Effect of Harrison Act

• Despite mixed findings by the Supreme Court, doctors stopped treating people with addiction with opioids for the next four decades due to the threat of legal prosecution

• All of the morphine and heroin clinics closed by 1923

Federal Narcotic Farms

- Two programs opened
  - Lexington, KY, 1935
  - Fort Worth, TX, 1938
- To rehabilitate people addicted to narcotics who were entering the federal prison system
- Some went for free, voluntary treatment for 6 months
- Program evaluations showed high relapse rates (70-95%)

Addiction Research Center

- Founded in 1935 at Lexington narcotic farm
- Pioneering research in addiction
- Became part of NIDA in 1973
- Relocated to Baltimore:
  - Clinical research unit in 1979
  - Basic science unit in 1984
- Senate Committee Hearing – 1977, former prisoners and research participants testified
  - Prisoners cannot provide informed consent

Opioid Related Achievements from ARC

• Studying methadone for treatment of heroin addiction
• Discovering and studying multiple opioid receptors
• Recognizing opioid antagonists as a possible treatment for opioid addiction
• Developing opioid antagonist as antidote for heroin overdose

Methadone

• Synthetic drug invented in Germany during World War II (when opium and morphine were scarce)
• After the war, the factory where methadone was invented came under U.S. control and clinical trials of methadone began in 1947
• New Drug Application was granted for Dolophine® to Eli Lilly & Company
• Used in Addiction Research Center in Lexington, KY

1940s

- During World War II heroin became scarce and purity was less than 1%
- Heroin addiction was at a record low
- In late 1940s more heroin was smuggled into the US and addiction rates again increased
Criminalizing Addiction

- Boggs Act (1951)
  - First Federal legislation to impose maximum penalties for drug related crimes; modification of the 1922 Import and Export Act

- Narcotic Control Act (1956)
  - Increased penalties for drug trafficking and dealing, added death penalty for certain offenses (e.g., selling heroin to minors)
  - Drug users had to register and get Treasury Department certificate before leaving country

1960s

- Heroin epidemic
- 1961 – joint report from the AMA and ABA (American Bar Association) questioned repressive drug policies and encouraged research on opioid maintenance

Civil Commitment

• 1966 Narcotic Addiction Rehabilitation Act (NARA) passed; Public Law 89–793
• Statement prepared in 1971 for the House Judiciary Committee stated there was underuse of Title I civil commitment by US Attorneys (179 from 1967-1970)

Dole & Nyswander (1965)

- Rockefeller Institute, New York
- Focused on addiction being a disease, not a character disorder
- Once one becomes addicted to heroin, there are changes in the brain that lead to craving and relapse
- Methadone should be effective in treating those addicted to heroin as it blocks euphoric effects and prevents withdrawal and craving

Dole & Nyswander (1965)

- 22 patients
  - Men
  - 19 – 37 years old
  - Heroin addiction
  - No other substantial addictions
  - Not psychotic
- Failed prior withdrawal treatment

Dole & Nyswander (1965)

- Phase I (6 weeks in hospital)
  - Stabilized on methadone
  - Medical work-up
  - Psychiatric evaluation
  - Review of family & housing problems
  - Job placement study
  - After 1 week allowed to leave unit
  - Those without diploma started GED classes
Dole & Nyswander (1965)

- Phase II (outpatient)
  - Present daily for medication
  - Drink methadone in front of nurse
  - Daily urine drug screen
  - Relaxed the daily requirement for reliable patients (e.g., weekend, short trips)
  - Provided services for obtaining jobs, housing, and education
- Phase III
  - “Ex-addict has become a socially normal, self-supporting person.”

Dole & Nyswander (1965)

• **Results**
  - Disappearance of “narcotic hunger”
    - Could resist drugs
    - Tolerated frustration without feeling like using
    - Stopped dreaming about drugs
    - Largely stopped talking about drugs
  - Four subjects injected heroin while on methadone and reported they did not get high
  - Functioning at work and school was normal
  - Adverse effects: sweating and constipation
  - Well-tolerated, only two patients were discharged

Dole & Nyswander (1965)

- Concluded that people addicted to heroin could stop using heroin and live law-abiding, productive lives
  - Decrease in heroin use
  - Decrease in criminal activity
  - Secured gainful employment
  - Showed improved health
  - Well tolerated by patients

Methadone: Getting Around the Harrison Act

- Following this publication, several treatment centers opened using Investigational New Drug (IND) applications by the FDA to get around policies by the Bureau of Narcotics.
- Of note, Dole and Nyswander did not submit an IND as methadone was approved as a therapeutic agent.
  - Contended their off-label use did not require an IND application.
Post-Dole & Nyswander Era

- 1967-1970: FDA liberally issued INDs for methadone research
- 1968: INDs were issued for study of levo-alpha-acetyl methadol (LAAM) in the use of heroin addiction
- 1968: Fewer than 400 people were enrolled in methadone maintenance treatment (MMT) research programs
- 1973: 73,000 people were enrolled in MMT

Initially No Regulations

- No rationale for number of INDs to issue
- No mechanism for preventing clinics from being used as a cover for running for-profit clinics
- No standards for treatment
- No rules about amount of methadone prescribed or taken home, or for whom treatment was appropriate
Comprehensive Drug Abuse Prevention and Control Act of 1970 (Public Law 91-513)

- Title I charges Secretary of Health, Education, and Welfare, to “determine the appropriate methods of professional practice in the medical treatment of the narcotic addiction of various classes of narcotic addicts.”
- Title II is Controlled Substances Act
April 1971 Regulations

- FDA IND regulations in response to concerns
- Strict requirements on
  - Starting dosage
  - Urinalysis
  - Recommendation for discharge
- Defined what efficacious treatment looks like

Nixon: June 1971

• “We must rehabilitate the drug user if we are to eliminate drug abuse and all the antisocial activities that flow from drug abuse.”
  • Requested $105 million in funds for treatment and rehabilitation, plus $14 million for veterans
• Asked Congress to amend the NARA 1966 to include methadone maintenance programs
  • “evidence indicates that methadone is a useful tool in the work of rehabilitating heroin addicts”
• Created the Special Action Office of Drug Abuse Prevention (SAODAP)
  • responsible for all drug related programs including education, treatment, and research

Early 1970s Criticism

- Methadone was being prescribed to those without serious addiction and thus created iatrogenic addiction
- Methadone was being diverted
- Children were being poisoned by methadone brought home by patients
- Just replacing one drug for another

Tighter Controls on Methadone

METHADONE, a powerful synthetic drug, has proved its worth as an effective weapon against the ravages of heroin addiction. Although the controversial narcotic is itself addictive, methadone users may often pursue normal occupations — work, study or other activities — without the crippling need for hard drugs.

Unfortunately, a supposedly benign substitute for heroin has been subverted to illicit usage by many addicts and pushers. Deaths from methadone overdose has risen to a frightening degree as the drug has become more accessible. (In Washington and New York, cities with large methadone maintenance programs, more deaths from methadone overdose have been recorded in the first two months of this year than in all of 1971.)

Accordingly, the government has moved to impose stringent controls on the dispensation of methadone. Proposed new federal regulations would remove methadone from private pharmacies and permit it to be dispensed only through government-approved methadone programs and through hospital pharmacies as a pain killer in certain types of afflictions.

In order to prevent the illegal diversion of methadone, 100 officers of the Food and Drug Administration will be trained to inspect methadone maintenance programs for efficient administration and the adequacy of measures to prevent illicit diversion. Under the new regulations, physicians would be permitted to prescribe methadone for narcotics addicts only through approved treatment programs and accurate records would be kept of all such use.

At the same time, Dr. Jerome H. Jaffe, director of the White House's Special Action Office for Drug Abuse Prevention, reemphasized the intention of the government to extend methadone treatment to all heroin users who really desire it. Dr. Jaffe estimates that roughly 20,000 applicants have requested treatment in government-approved programs.

A well-planned and adequately staffed federal inspection program would unquestionably stem the flow of much contraband methadone. Unhappily, the cunning of desperate human beings often outwits the best efforts of vigilant supervisors.

The success or failure of the tightened control program will greatly determine whether methadone will remain a promising means of combating heroin or become yet another pernicious destroyer of hapless human beings.
1972 Regulations  
(37 FR 26795, December 15, 1972)

- Methadone for treatment of opiate addiction can be dispensed only by federally licensed programs
- No dual enrollments
- Eligibility for treatment based on
  - Age
  - Length of addiction

1972 Regulations (37 FR 26795, December 15, 1972)

- Set maximum initial dose
- Set minimum amount of counseling
- Specified criteria for take-home methadone doses
  - Results of drug screens
  - Length of time in treatment
  - Dose under 100 mg

1972 Regulations

- Regulations were criticized as burdensome interference to the practice of medicine
  - Federal, state, and local regulations
- Departure from allowing physicians to use their own professional judgment guided by a drug’s labeling to determine how to prescribe a medication due to regulations

Narcotic Addict Treatment Act of 1974 (Public Law 93-281)

- Senate and House hearings in 1972 and 1973 regarding diversion
- Amended Controlled Substances Act of 1970
- Defined maintenance and detoxification periods
- Required separate DEA registration annually of practitioners
- Stated treatment privileges could be revoked if did not comply with standards of treatment

Changes since 1974

- **1980 & 1989**: The period of dependence to qualify for treatment (1 yr vs. 2 yrs), ability to use procedures other than urine toxicology for drug testing, expanded counseling for pregnant women, etc.

- **1993**: Interim maintenance treatment allowed – if clinic has a waiting list it could provide methadone without meeting other requirements, such as counseling, in response to HIV

- **2001**: Oversight for MMT switched from FDA to SAMHSA Center for Substance Abuse Treatment

MMT Over the Years

- Number of people treated
  - 1968: fewer than 400
  - 1976: more than 80,000
  - 2003: about 227,000
  - 2011: about 306,000
  - 2016: about 345,000

Levo-alpha-acetyl Methadonol (LAAM)

- Opioid agonist developed in 1948 that is similar to methadone with a longer half-life
- Able to dose 3 times weekly
- Approved by the FDA for treatment of opioid dependence in 1993
- Reports of adverse cardiac events led to an FDA Black Box warning stating it should only be used in patients who failed other treatment and baseline and periodic EKG monitoring is recommended
- LAAM was withdrawn from the market by its US manufacturer in 2003

Drug Addiction Treatment Act (DATA) 2000

- DATA amends Section 303(g)(2) of the CSA (21 U.S.C. 823(g)(2))
  - Physicians must complete appropriate training, certify they are qualified (state license/DEA), file notification of intent to Secretary of HHS
  - Physician assigned “X” DEA number
  - Can only prescribe/dispense Schedule III, IV, or V controlled substances that have been approved by the FDA for use in detoxification or maintenance treatment of opioid use disorder, without registering as an opioid treatment program

Suboxone® (buprenorphine/naloxone) and Subutex® (buprenorphine) were approved by the FDA for treatment of opioid dependence in 2002

- Schedule III
- Partial opioid agonist
  - High affinity for mu-opioid receptor
  - Slow dissociation from receptor
Amendments to DATA 2000

- **2005** – changed to allow physicians in groups could treat up to 30 patients (rather than per practice; Public Law 109–56)

- **2006** – changed so one year after filing notification of intent to treat, a physician can file another notice that he/she intends to treat up to 100 patients (Public Law 109–469)


More Products on Market

- 2009 - Buprenorphine generic tabs
- 2010 - Suboxone Film ® (bup/nx)
- 2013 - Buprenorphine/naloxone (bup/nx) tabs
- 2013 - Zubsolv ® tabs (bup/nx)
- 2014 - Bunavail ® buccal film (bup/nx)
- 2016 - Probuphine ® implant (buprenorphine)
- Long-acting injectable buprenorphine on horizon
Pharmacologic Treatment of OUD

Table 5.4a. Clients receiving medication-assisted opioid therapy provided at facilities with opioid treatment programs (OTPs) and other facilities, by facility operation: Number, March 31, 2016

<table>
<thead>
<tr>
<th>Facility operation</th>
<th>All clients receiving medication-assisted opioid therapy</th>
<th>OTP clients</th>
<th>Non-OTP clients</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Methadone</td>
<td>Buprenorphine</td>
<td>Injectable naltrexone</td>
</tr>
<tr>
<td>Total</td>
<td>345,443</td>
<td>61,486</td>
<td>10,128</td>
</tr>
<tr>
<td>Private non-profit</td>
<td>109,504</td>
<td>22,792</td>
<td>4,964</td>
</tr>
<tr>
<td>Private for-profit</td>
<td>215,576</td>
<td>31,804</td>
<td>3,336</td>
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<tr>
<td>Local, county, or community govt.</td>
<td>11,109</td>
<td>2,033</td>
<td>610</td>
</tr>
<tr>
<td>State government</td>
<td>6,739</td>
<td>1,169</td>
<td>201</td>
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<tr>
<td>Federal government</td>
<td>1,808</td>
<td>2,804</td>
<td>944</td>
</tr>
<tr>
<td>Dept. of Veterans Affairs</td>
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<td>Dept. of Defense</td>
<td>--</td>
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<tr>
<td>Indian Health Service</td>
<td>--</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Other</td>
<td>--</td>
<td>17</td>
<td>1</td>
</tr>
<tr>
<td>Tribal government</td>
<td>707</td>
<td>828</td>
<td>51</td>
</tr>
</tbody>
</table>

- Quantity is zero.

Injectable naltrexone = extended-release injectable naltrexone (Vivitol®).

NOTES: Methadone is available only at OTP facilities that are certified by SAMHSA’s Center for Substance Abuse Treatment. Buprenorphine may be prescribed by physicians who have received DATA 2000 specific training and received a waiver to prescribe the medication for treatment of opioid addiction; this report only includes clients receiving buprenorphine through physicians affiliated with substance abuse treatment facility, it does not include clients who receive buprenorphine through an independent DATA 2000 waivered physician.

SOURCE: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, National Survey of Substance Abuse Treatment Services (N-SSATS), 2016.
2015 Data from NSDUH

591,000 people aged 12+ had heroin use disorder
+ 2 million people aged 12+ had pill opioid use disorder
- 1,430,000 people received treatment for OUD

1,161,000 people did not receive treatment

Change in Patient Limit for Buprenorphine

- The Department of Health and Human Services published a Notice of Proposed Rulemaking on 3/30/16 to increase the highest patient limit for qualified physicians to treat opioid use disorder to 275
- Public comment until 5/31/16 (498 comments)
- Final rule 7/8/16
- Effective 8/8/16

Medication Assisted Treatment for Opioid Use Disorders: A Rule by the Health and Human Services Department on 07/08/2016
Who is eligible for 275 limit?

Licensed physicians who have had a waiver to treat 100 patients for at least 1 year can become eligible for the patient limit of 275 in one of two ways:

1. By holding additional credentialing
   - Board certification in addiction medicine or addiction psychiatry

2. By practicing in a “qualified practice setting”

Understanding the Final Rule for a Patient Limit of 275.
Qualified Practice Setting

- Provides emergency coverage after hours
- Provides access/referral to case management services (e.g., medical, behavioral, housing, employment, educational).
- Uses health information technology (EHR) if it is already required in the practice setting
- Is registered for their state PDMP where operational and in accordance with federal and state law
- Accepts third-party payment for some services
  - not necessarily for buprenorphine-related services
  - not necessarily all third-party payers

Understanding the Final Rule for a Patient Limit of 275.
To increase limit to 275

- You must attest to 8 statements when applying
  - Adhere to evidence-based treatment guidelines for OUD
  - Provide BH services directly or with formal agreement with another entity
  - Use appropriate releases of information to coordinate care
  - Use patient data to improve outcomes
  - Adhere to a diversion control plan
  - Have plan to ensure access to medication in event of an emergency
  - Notify patients above the 100 patient limit they will no longer be able to receive buprenorphine in the event request for higher limit is not renewed and make every effort to transfer these patients to other providers
  - Have documentation to demonstrate compliance as requested by SAMHSA
- Renew request for higher limit every 3 years,
  - Submit renewal at least 90 days before term expires

CARA

- Comprehensive Addiction Recovery Act of 2016
- Signed into law by President Obama 7/22/16 as Public Law 114-198
- Expands access to substance use treatment and overdose reversal medication, also focuses on prevention

Allows Additional Prescribers

- CARA gave qualifying APRNs and PA-Cs ability to prescribe buprenorphine for OUD until 10/1/21
- Have to complete 24 hours of training to be eligible for a waiver
  - 8 of the hours can be the course that physicians have traditionally taken
- Follow the 30 and 100 patient limits
- Works with, or is supervised by, a qualifying physician if required by state law

21st Century CURES Act
Signed 12/13/2016

- Provides $1 billion over 2 years for state grants to supplement prevention and treatment of opioid use disorder by
  - improving prescription drug monitoring programs
  - implementing prevention activities
  - training health care providers
  - expanding access to opioid treatment programs

State Laws to Address Epidemic

- Prescription drug time and dosage limit laws
- Doctor shopping laws
  - “no person shall obtain or attempt to obtain a narcotic drug…by fraud, deceit, misrepresentation, or subterfuge or…by the concealment of a material fact.”
- Laws requiring checking of PDMP prior to prescribing
- Laws requiring opioid prescribing education
- Physical exam requirements prior to prescribing opioids
- In PA – House Bill 932 “Fee.--A buprenorphine office-based prescriber shall pay a fee of $10,000 for licensure by the department.”

- https://www.cdc.gov/phlp/publications/topic/prescription.html
- http://www.legis.state.pa.us/CFDOCS/Legis/PN/Public/btCheck.cfm?txtType=PDF&sessYr=2017&sessInd=0&billBody=H&billTyp=B&billNbr=0932&pn=1088
Recommendation by commission to declare the opioid epidemic a national emergency

August 10, President Trump said he intended to declare the opioid epidemic a national emergency after a reporter asked him about it, saying, “We're going to draw it up, and we're going to make it a national emergency.”


What does a national emergency mean?

- We will have to see…
- Perhaps more money available to states?
- Public health workers could be deployed?
- Congress appropriate more money to treatment?
Thank you!

• Questions/Comments
References


References

References

- Treatment Improvement Protocol (TIP) Series, No. 43. Center for Substance Abuse Treatment. Rockville (MD): Substance Abuse and Mental Health Services Administration (US); 2005.
PCSS-O Colleague Support Program and Listserv

- PCSS-O Colleague Support Program is designed to offer general information to health professionals seeking guidance in their clinical practice in prescribing opioid medications.
- PCSS-O Mentors comprise a national network of trained providers with expertise in addiction medicine/psychiatry and pain management.
- Our mentoring approach allows every mentor/mentee relationship to be unique and catered to the specific needs of both parties.
- The mentoring program is available at no cost to providers.

For more information on requesting or becoming a mentor visit: [www.pcss-o.org/colleague-support](http://www.pcss-o.org/colleague-support)

- Listserv: A resource that provides an “Expert of the Month” who will answer questions about educational content that has been presented through PCSS-O project. To join email: pcss-o@aaap.org.
PCSS-O is a collaborative effort led by American Academy of Addiction Psychiatry (AAAP) in partnership with: Addiction Technology Transfer Center (ATTC), American Academy of Neurology (AAN), American Academy of Pain Medicine (AAPM), American Academy of Pediatrics (AAP), American College of Physicians (ACP), American Dental Association (ADA), American Medical Association (AMA), American Osteopathic Academy of Addiction Medicine (AOAAM), American Psychiatric Association (APA), American Society for Pain Management Nursing (ASPMN), International Nurses Society on Addictions (IntNSA), and Southeast Consortium for Substance Abuse Training (SECSAT).

For more information visit: www.pcss-o.org
For questions email: pcss-o@aaap.org

Twitter: @PCSSProjects

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