Pharmacy Law
Opioid Substance Use Disorder

UNMC

Comprehensive Drug Abuse Control & Prevention Act 1970

Consolidated 50 separate acts

Categorized drugs based on abuse & addiction potential

Intended to decrease diversion out of legitimate channels of drug distribution

Designed to improve the regulation of manufacturing, distribution, & dispensing of “controlled substances” by providing for a closed system for legitimate business

1973 – President Nixon signs Reorganization Plan No. 2

The DEA is established –

consolidating all the Federal government's drug control activities

History of Opioid Treatment Programs

Narcotic Addict Treatment Act of 1974

* Created Opioid Treatment Programs
* Defined treatment of “addiction” as a legitimate medical purpose under certain conditions

Original regulations were more concerned with diversion than with patient care

FDA Misstep

The FDA attempted to restrict the distribution of methadone to only a few pharmacies – to enforce that it could not be **DISPENSED** for detoxification or maintenance of opiate addiction.

APhA* v Weinberger* (1974) sued the FDA claiming that all pharmacies could stock methadone and the FDA had no standing to restrict distribution. The court agreed.

*American Pharmacists Association

*Casper Weinberger US Secretary of Health, Education & Welfare

Point of Confusion / Concern

Methadone is used for 2 things:

* Severe Pain

* Detoxification and maintenance of patients with opioid substance use disorder as a part of a registered opioid treatment program

Who may prescribe & provide methadone?

Depends on what it's for:

As an analgesic

* any licensed, DEA-registered, prescriber may prescribe
* any DEA-registered, licensed pharmacy may dispense.

Nebraska law does NOT require the prescription to say, "for pain", but it's a good idea

Who may prescribe & provide methadone?

In an Opioid Treatment Program* – methadone may be used for maintenance or detoxification of opioid addicted patients.

A prescriber must have a treatment DEA Registration

The drug may **only** be provided by the Licensed Opioid Treatment Program

*sometimes called Narcotic Treatment Programs

Opioid Treatment Programs

- Program must be registered with the DEA
- Each site must be registered separately
- Program must be certified by an accreditation body & have state authority to operate
- Only oral methadone is approved for use in opioid treatment programs
- May only handle those opioids for which they have received approval using
  DEA Registration Form (DEA Form 363)

Approved for treatment of addiction 1974

C-II: methadone
levomethadyl acetate (LAAM)

Controlled substances for the treatment of conditions other than opioid addiction cannot be administered, dispensed, or stored on the premises of an opioid treatment program unless the practitioner also possesses a separate dispenser registration.

Administration or Dispensing?

Any opioids administered or dispensed at an opioid treatment program must be administered **directly to the patient** either by the licensed practitioner, by a registered nurse, licensed practical nurse, or pharmacist under the direction of the practitioner.

May only be ordered via CHART ORDER, may not be ordered via prescription

Ordering methadone for use in Opioid Treatment Programs

Methadone is ordered using a DEA Form 222

Only a licensed practitioner employed by the program or other employee authorized in writing may sign for the receipt of “narcotic drugs”

21 CFR 1301.74(h)

Detoxification

Providing opioids in decreasing doses over a specified period-of-time to alleviate effects incident to withdrawal from continuous or sustained use of opioids

with the intent of bringing the individual to an opioid-free state within such period-of-time.

2 kinds of detoxification

Short-term detoxification:

Treatment not in excess of 30 days

Long-term detoxification:

Treatment for a period of more than 30 days, but not in excess of 180 days

Maintenance Treatment

Continued administration or dispensing of opiates for a period in excess of 21 days

Doses are stable – not decreasing as with detoxification

Goal is an eventual drug-free state, but there is recognition that the drug may be needed for an extended period-of-time.

Record Keeping

Extensive Record Keeping requirements:

Name and strength of drug
Dosage Form
Date Dispensed / Administered
Adequate identification of the patient
Amount of drug consumed
Amount and dosage form taken home by patient
Dispenser’s initials

Nebraska Statutes

Controlled Substances Act 28-412

Virtually identical to the Federal Requirements

Special Circumstances

A patient is suffering acute opioid withdrawal, the practitioner who is treating them is NOT a part of a treatment program.

That practitioner may ADMINISTER methadone to the patient to relieve the withdrawal symptoms while making arrangements to get the patient into an opioid treatment program.

Administration may only be 1 day at a time

This treatment cannot last longer than 3 days

This treatment may not be renewed or extended for any reason

Special Circumstances

An opioid addicted patient is admitted to a hospital for a medical condition other than the substance use disorder. The hospital does not have an opioid treatment program.

The hospital may ADMINISTER methadone to the opioid addicted patient to prevent withdrawal while the other medical issue(s) is(are) being taken care of

DATA 2000
Drug Addiction Treatment Act

Approved drugs with lower addictive potential for maintenance and detoxification

Buprenorphine – Controlled Substance Schedule III

Subutex: buprenorphine

Suboxone: buprenorphine + naloxone

sublingual tablets, oral film, buccal film

Drugs Approved for treatment of addiction

Prior to DATA 2000

C-II: methadone
levomethadyl acetate (LAAM)

After DATA 2000

C-II: methadone
LAAM
C-III: buprenorphine
buprenorphine + naloxone

DATA 2000

Allows for office-based treatment of opioid dependence – but only C-III through C-V

Before DATA, it was illegal to prescribe for the treatment of “narcotic” dependence

Prescribing for opioid dependence requires ”qualified” doctors.

DATA 2000

Physicians limited to a certain number of patients who were being treated for opiate addiction

- 30 patients for the first year
- 100 patients for the 2nd year
- May then increase to 275

this increase request is an on-line process

DATA Physician Requirements

Special DEA registration for the use of drugs associated with opiate addiction treatment. These DEA numbers start with X

Must have a risk management program to provide close monitoring of drug distribution channels and to deter abuse and diversion

Must hold a sub-specialty board certification in addition to medical or addiction certifications

Must complete >8 hour authorized training on treatment or management of opiate-dependent patients

Must agree to limit the number of patients as previously described

New Opioid Treatment Regulations 2001

Transferred enforcement to **SAMHSA**

Substance **A**buse & **M**ental **H**ealth **S**ervices **A**dministration

Concept of MAT is introduced:

Medication-Assisted Treatment combined with behavioral therapy

Requirements for the prescriber and the treatment program to be certified

CARA 2016

Comprehensive Addiction & Recovery Act

Allows nurse practitioners and physician assistants to apply for a DEA X waiver to prescribe buprenorphine

Must complete 24 hours of required training

May treat up to 30 patients

Comprehensive Addiction & Recovery Act {CARA} 2016

CARA Goals:

- To strengthen prevention, treatment and recovery efforts, by empowering medical professionals and law enforcement with funding & tools.
- Creates a Task Force on Pain Management
- Authorizes Community Awareness Campaigns
- Asks the Comptroller General (from the Government Accounting Office) to report on ”Good Samaritan Laws”

Nebraska “Good Samaritan” regarding naloxone

28-470

(2) A family member, friend, or other person who is in a position to assist a person who is apparently experiencing or who is likely to experience an opioid-related overdose, other than an emergency responder or peace officer, is not subject to actions under the Uniform Credentialing Act, administrative action, or criminal prosecution if the person, acting in good faith, obtains naloxone from a health professional or a prescription for naloxone from a health professional and administers the naloxone obtained from the health professional or acquired pursuant to the prescription to a person who is apparently experiencing an opioid-related overdose.

(3) An emergency responder who, acting in good faith, obtains naloxone from the emergency responder's emergency medical service organization and administers the naloxone to a person who is apparently experiencing an opioid-related overdose shall not be:

(a) Subject to administrative action or criminal prosecution

CARA 2016
Comprehensive Addiction & Recovery Act of 2016

Federal Law passed in July 2016

In order to reduce the number of doses available to the patient with a substance use disorder. C-II may be partial filled and the remainder may be supplied not later than 30 days after the prescription was written.

Nebraska Law was changed in 2017 to match the federal CARA law

Section 702 of CARA

Section 702: Partial Fills of Schedule II Controlled Substances This section amends section 309 of the Controlled Substances Act by adding that a prescription for a controlled substance in schedule II may be partially filled if:

(A) it is not prohibited by State law;

(B) the prescription is written and filled in accordance with this title, regulations prescribed by the Attorney General, and State law;

(C) the partial fill is requested by the patient or the practitioner that wrote the prescription; and

(D) the total quantity dispensed in all partial fillings does not exceed the total quantity prescribed. Remaining portions of a partially filled prescription may be filled within 30 days after the date on which the prescription is written.

In emergency situations, the remaining portions of a partially filled prescription may be filled within 72 hours after the prescription is issued.

NEBRASKA Law
Partial Fills

Schedule II:

28-414(5)(a)

Matches Federal Law for General Dispensing

28-414(5)(b)

Matches Federal Law for Long Term Care or Terminal Illness

Federal Regulations

Partial Filling of a C-II

Patient doesn’t want them all at one time

Can split prescriptions if allowed by the state

Partial Filling

Defined: Partial filling occurs when the quantity of drug dispensed to a patient is

LESS than the quantity of drug requested by the prescriber on the face of the original prescription.

Partial Filling IS NOT refilling

This is especially important for C-II’s

Partial Filling for Long Term Care Residents

C-II may be partially filled for residents of a long-term care facility (nursing home BUT not assisted living) up to 60 days on a single prescription.

Prescription MUST be written for 60 days

Prescription MUST note patient lives in a long-term care facility

Pharmacist MUST record quantity dispensed with each partial fill

Pharmacist MUST be identified for each partial fill

Partial Filling for terminally ill patients

The information is identical to long-term care, with the exception that the prescription MUST list that the patient is terminally ill

SUPPORT 2018
Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment

Requires Medicaid programs to have DUR and drug management programs for at-risk beneficiaries

Temporarily mandates coverage of medication-assisted treatment for substance use disorder

Allows for telehealth treatment of substance use disorder

Increases the number of patients who may be served under a buprenorphine waiver to 100

MAT* 2021

Mainstream Addiction Treatment Act of 2021

Passed as a part of the December 2022 Federal Omnibus bill

*Please note:
In patient care and pharmacotherapy MAT means:
Medication Assisted Treatment or Medication Assisted Therapy

MAT 2021

Removes DEA X waiver requirements for C-III, C-IV, or C-V

{Note: a separate DEA Registration continues to be required for methadone in Opioid Treatment}

Per SAMHSA

Removal of DATA Waiver (X-Waiver) Requirement

•Section 1262 of the Consolidated Appropriations Act, 2023 (also known as Omnibus bill), removes the federal requirement for practitioners to submit a Notice of Intent (have a waiver) to prescribe medications, like buprenorphine, for the treatment of opioid use disorder (OUD). With this provision, and effective immediately, SAMHSA will no longer be accepting NOIs (waiver applications).

•All practitioners who have a current DEA registration that includes Schedule III authority, may now prescribe buprenorphine for Opioid Use Disorder in their practice if permitted by applicable state law and SAMHSA encourages them to do so. SAMHSA and DEA are actively working on implementation of a separate provision of the Omnibus related to training requirements for DEA registration that becomes effective in June 2023. Please continue to check this webpage for further updates and guidance.

CDC Opioid Guidelines

Detoxification without medications, in patients with opioid use disorder is NOT recommended due to:

- Increased risk for resuming opioid use
- Increased risk for overdose and death

Dr. Sutera will focus on how we help patients with opioid substance use disorder

California initiative

California is exploring using long-acting hydromorphone (Dilaudid®) instead of methadone to avoid cardiac problems (QT prolongation) associated with methadone.

NOT currently allowed federally but used for maintenance in Canada.

Save a Life!

Naloxone in Nebraska

- Statewide protocol for dispensing
- Pharmacists may prescribe

- No liability for calling for help

2023 Unicameral Bills

LB 137 Senator Geist

Fentanyl contamination of illicit drugs, increased penalties for causing harm or death

LB 436 Senator Geist

Adds new illicit drugs to Nebraska statutes to match Federal Law

LB 521 Senator Walz

Provides immunity for School Personnel administering naloxone

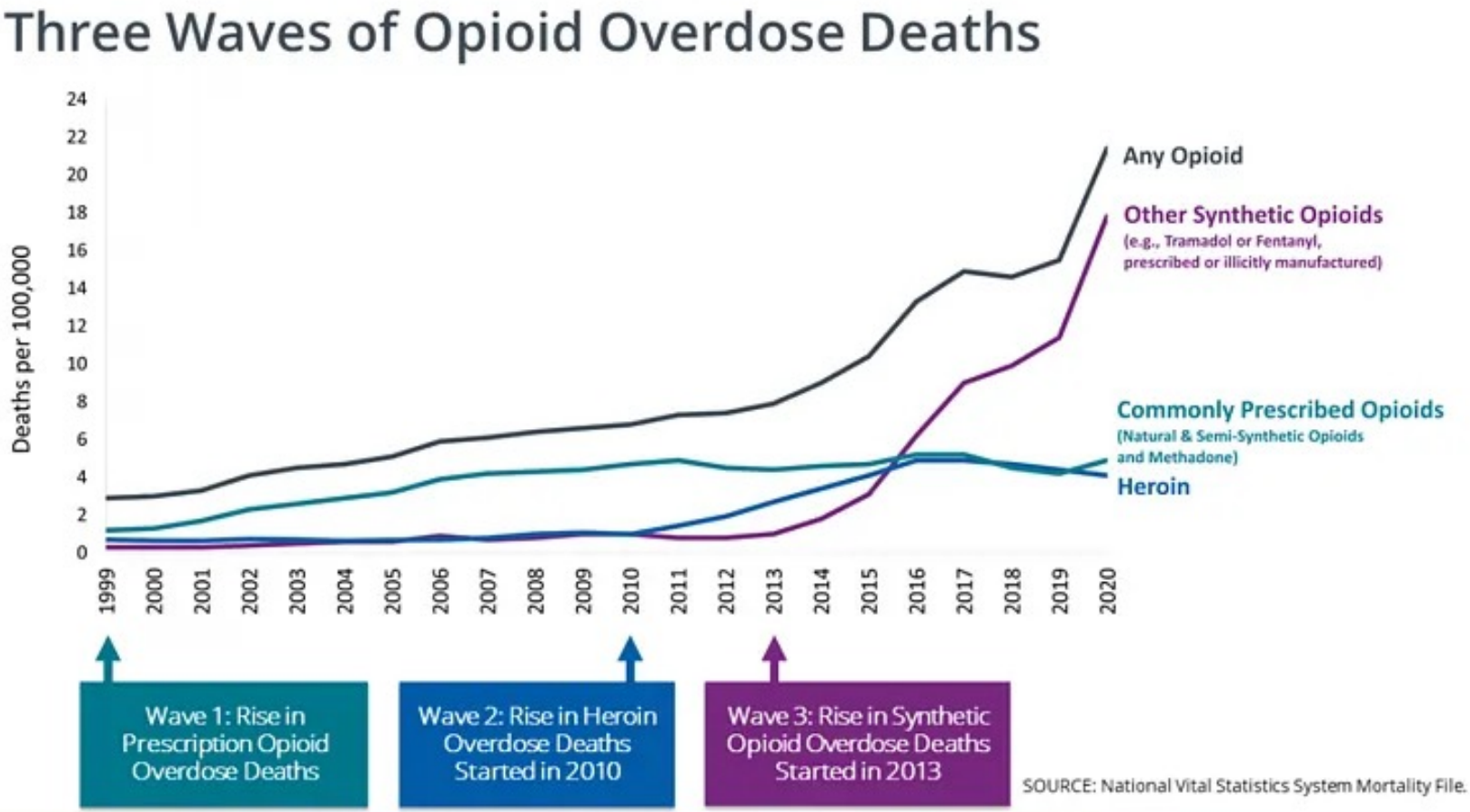
LB 570 Senator Vargas

Creates Overdose Fatality Review Teams

LB 795 Senator Wayne

Changes “naloxone” to “FDA approved opioid antagonists”

Perspective



What questions do you have for me?