Medications for opioid use disorder: overview of clinical, coverage, and parity issues

National Association of Insurance Commissioners National Meeting

March 17, 2024

Presented by Marcus Bachhuber, MD, FASAM

CENTER FOR EVIDENCE-BASED POLICY

Center for Evidence-based Policy

- Established in 2003 at Oregon Health & Science University
- We support states with evidence to guide decision making and improve health outcomes
- We are public university-based, nonpartisan, do not engage in lobbying, and our staff have no financial conflicts of interest

Disclosures

- No conflicts of interest

Outline

- What is opioid use disorder?
- What treatments are effective?
- Coverage considerations
- Parity considerations
- Resources

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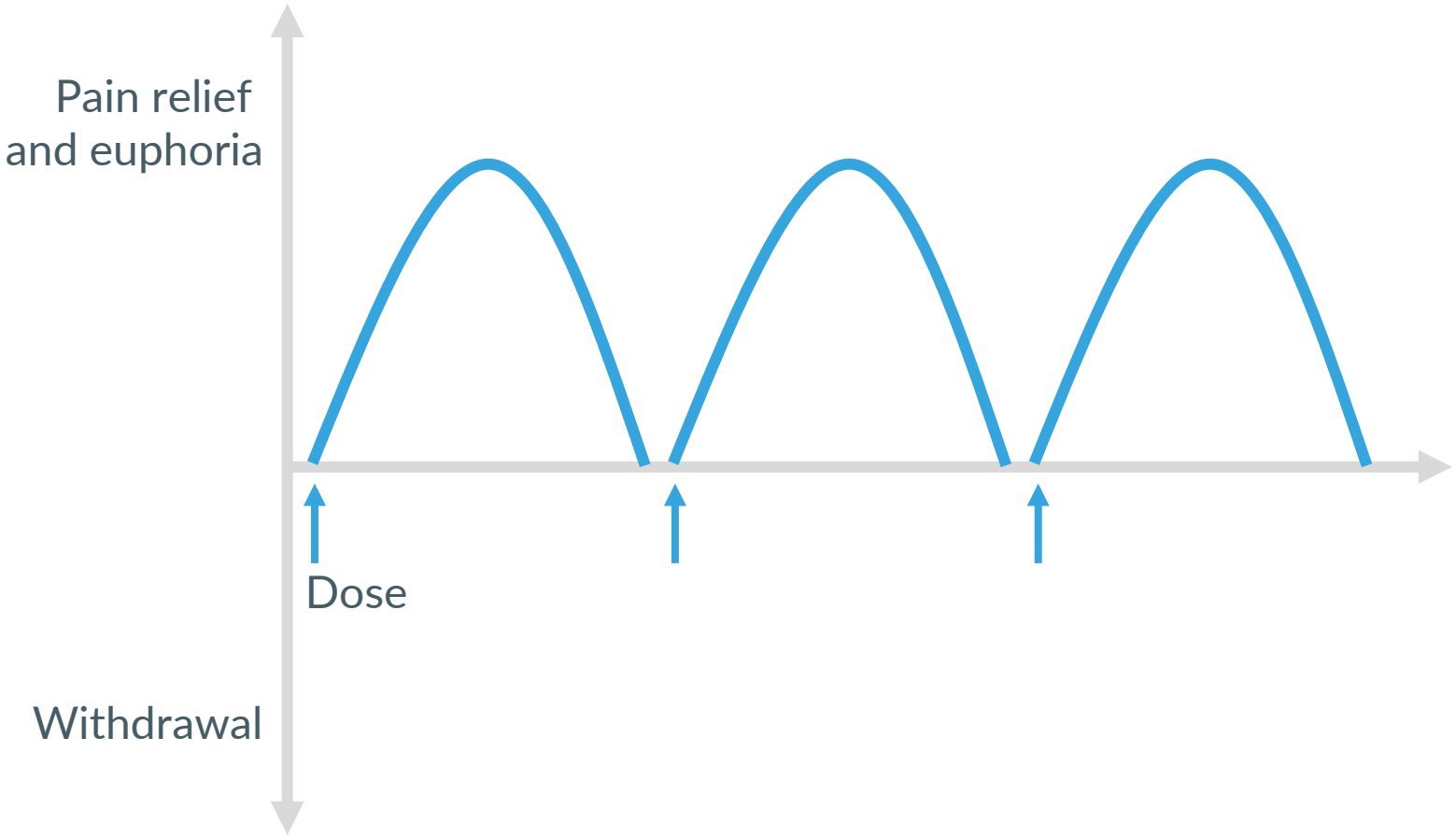
Background: Opioid Use Disorder (1 of 6)

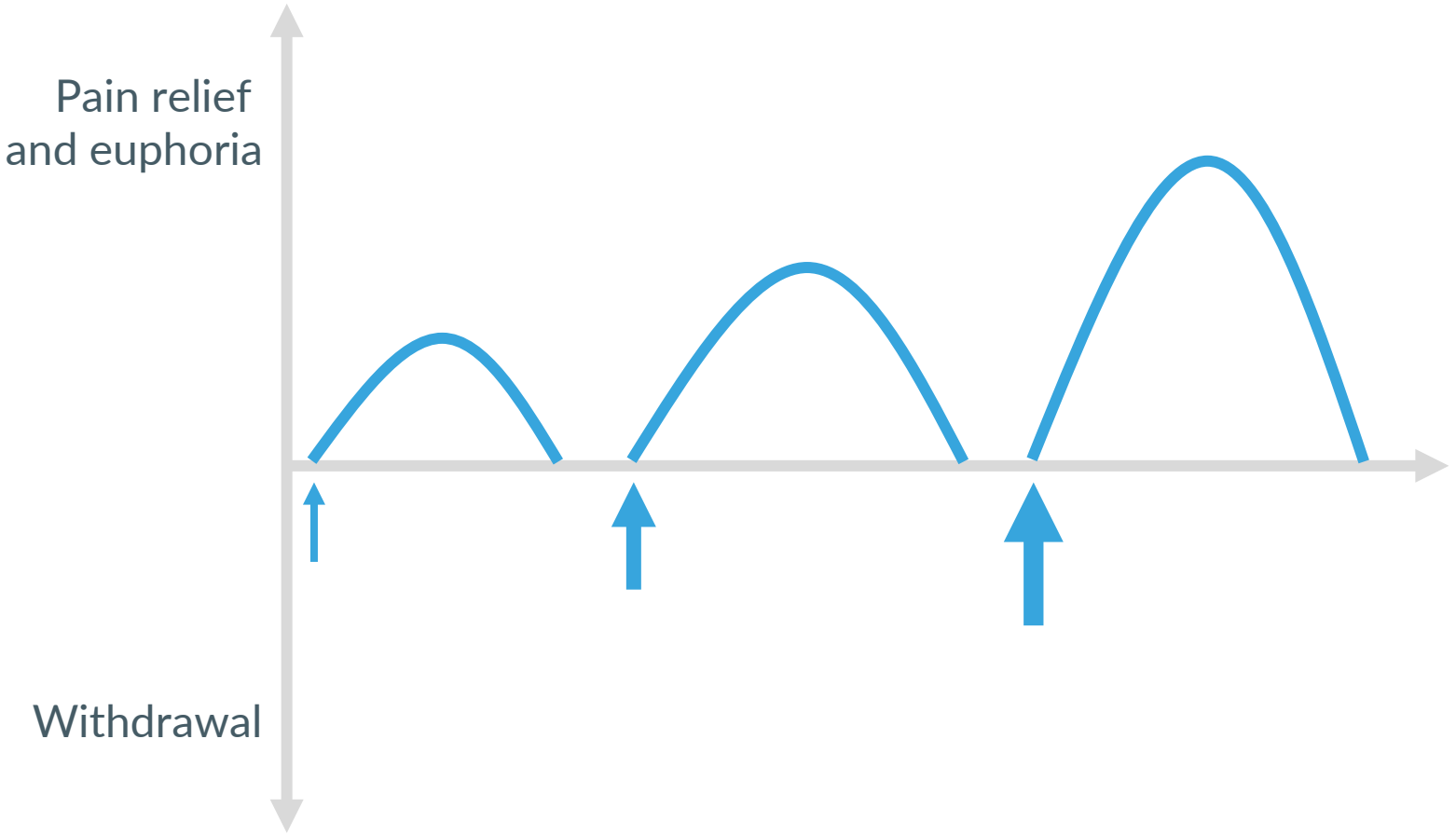
- Opioids are a class of drugs that affect the brain and body, resulting in pain relief (in medical doses) and euphoria (in higher doses)
- Includes morphine, oxycodone, hydrocodone, fentanyl, methadone, heroin, and others
- Activate the same pathways as hormones produced by the body (endorphins)

Background: Opioid Use Disorder (2 of 6)



Early use is mainly pleasurable

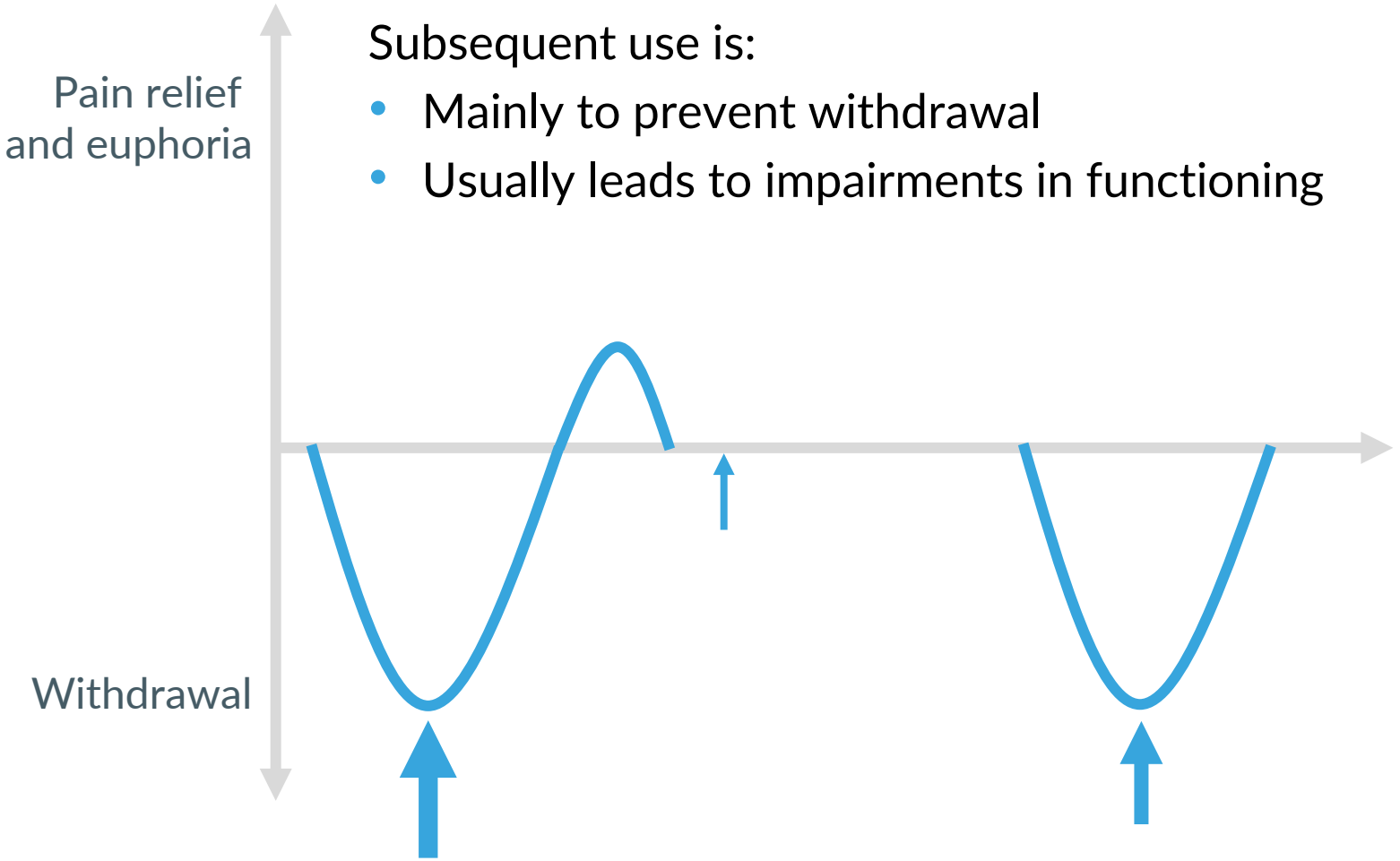
Background: Opioid Use Disorder (3 of 6)



Tolerance:

- The brain and nervous system become accustomed to opioid use
- The same dosage has a lesser effect
- Progressively increasing dosages are required to achieve effects

Background: Opioid Use Disorder (4 of 6)



Subsequent use is:

- Mainly to prevent withdrawal
- Usually leads to impairments in functioning

Withdrawal symptoms:

- Pain
- Nausea, vomiting, diarrhea
- Insomnia
- Feelings of unease (dysphoria)

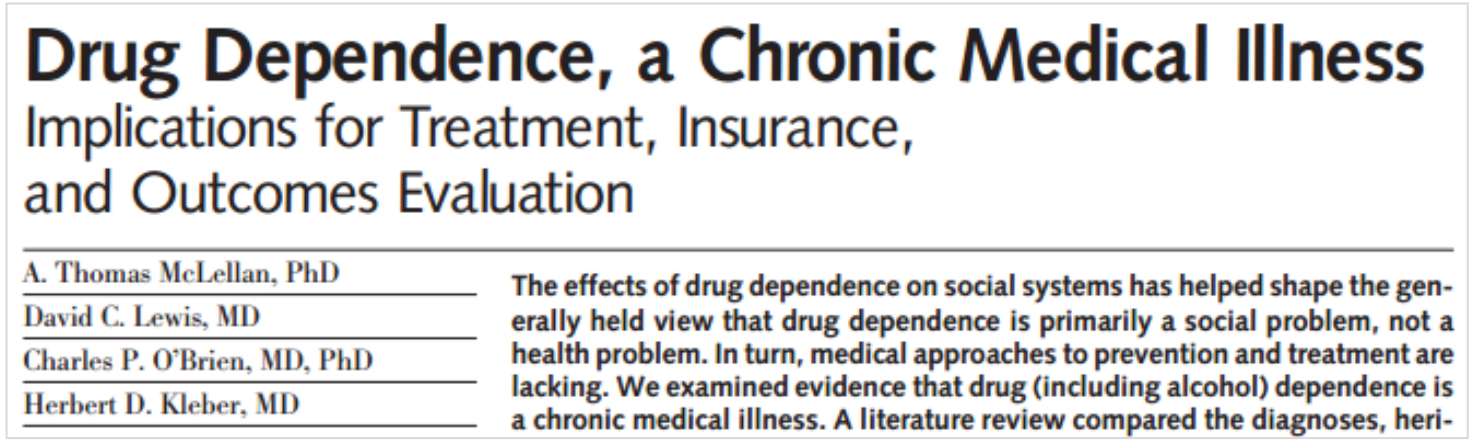
Symptoms are rapidly reversed by opioid use

Background: Opioid Use Disorder (5 of 6)

- Opioid use disorder is a “problematic pattern of opioid use leading to clinically significant impairment or distress”
- Characterized by:
  - Continued use despite consequences
  - Persistent desire to cut down
  - Tolerance
  - Withdrawal
- Name has changed, previously “opioid abuse” and “opioid dependence”
- “Addiction” is commonly understood but not medically precise

Source: Diagnostic and Statistical Manual of Mental Disorders (DSM-5)

Background: Opioid Use Disorder (6 of 6)



Drug Dependence, a Chronic Medical Illness

Implications for Treatment, Insurance, and Outcomes Evaluation

A. Thomas McLellan, PhD
David C. Lewis, MD
Charles P. O'Brien, MD, PhD
Herbert D. Kleber, MD

The effects of drug dependence on social systems has helped shape the generally held view that drug dependence is primarily a social problem, not a health problem. In turn, medical approaches to prevention and treatment are lacking. We examined evidence that drug (including alcohol) dependence is a chronic medical illness. A literature review compared the diagnoses, heri-

- Substance use disorders share many key features with other chronic medical illnesses
- Periods of remission and relapse
- Genetic heritability
- Diagnosis and treatment response

Source: McLellan, et al. (2002)

Overview

- What is opioid use disorder?
- What treatments are effective?
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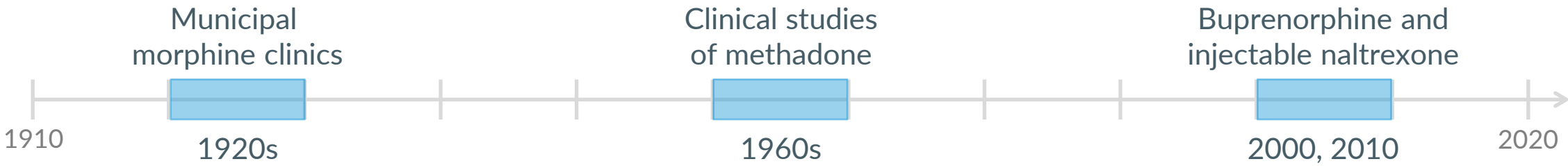
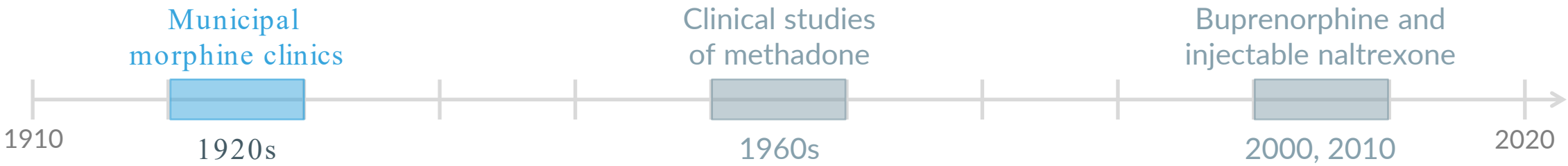
Treatments: Historical Overview

- Early recognition that opioid use disorder is different than other drug and alcohol use disorders
- Psychosocial treatments alone are generally ineffective, resulting in frequent relapse
- Short-term treatment to ease withdrawal was well established
- Long-term treatment with opioids was believed to be effective, but was controversial

Source: Institute of Medicine Committee on Federal Regulation of Methadone Treatment (1995)


Municipal morphine clinics
Clinical studies of methadone
Buprenorphine and injectable naltrexone
1910
1920s
1960s
2000, 2010
2020

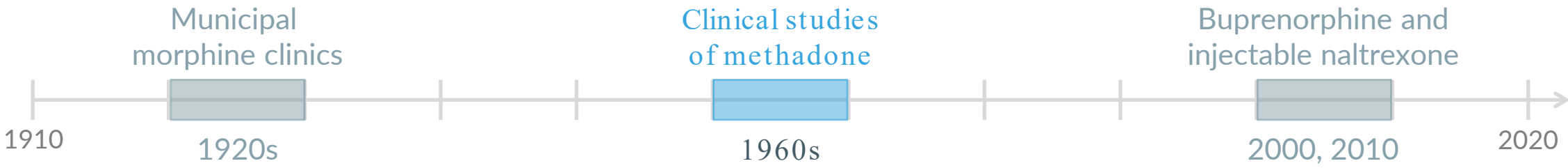


A Follow-up Study of the New Haven Morphine Maintenance Clinic of 1920

DAVID F. MUSTO, M.A., M.D., AND MANUEL R. RAMOS, J.D.

- Shut down under Harrison Narcotic Act:
  - Addiction was not recognized as a medical illness
  - Treatment with opioids in this context was considered non-medical

Source: Institute of Medicine (US) Committee on Federal Regulation of Methadone Treatment (1995)



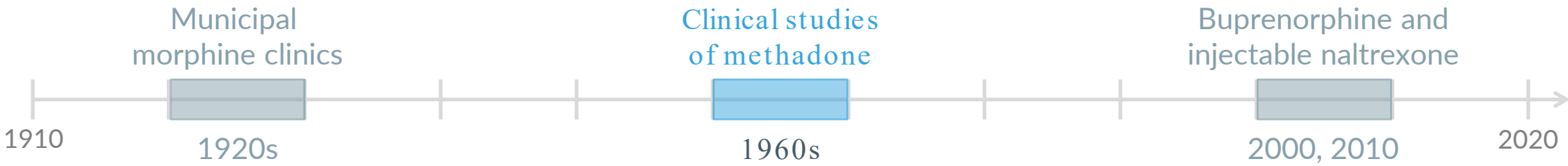
A Medical Treatment for Diacetylmorphine (Heroin) Addiction

A Clinical Trial With Methadone Hydrochloride

Vincent P. Dole, MD, and Marie Nyswander, MD

A group of 22 patients, previously addicted to diacetylmorphine (heroin), have been stabilized with oral methadone hydrochloride. This medication appears to have two useful effects: (1) relief of narcotic hunger, and (2) induction of sufficient tolerance to block the euphoric effect of an average illegal dose of diacetylmorphine. With this medication, and a comprehensive program of rehabilitation, patients have shown marked improvement; they have returned to school, obtained jobs, and have become reconciled with their families. Medical and psy-

ough review of evidence available in 1957,[1] concluded that "The advisability of establishing clinics or some equivalent system to dispense opiates to addicts cannot be settled on the basis of objective facts. Any position taken is necessarily based in part on opinion, and on this question opinions are divided." With respect to previous trials of maintenance treatment, the Council found that "Assessment of the operations of the narcotic dispensaries between 1919 and 1923 is difficult because of the



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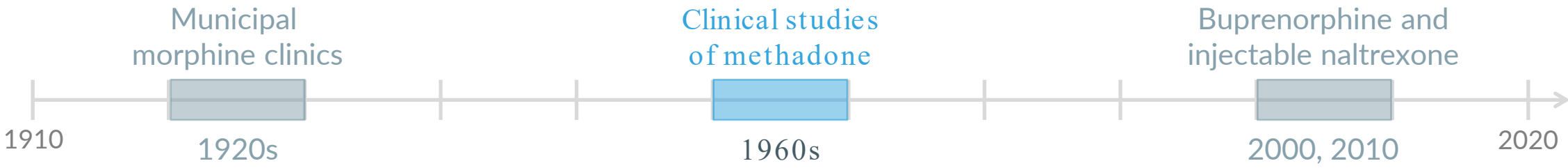

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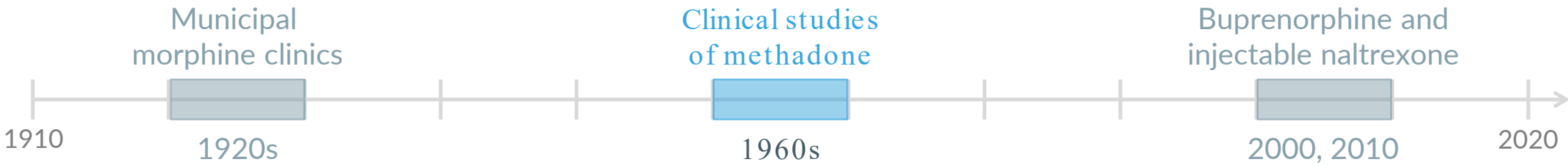

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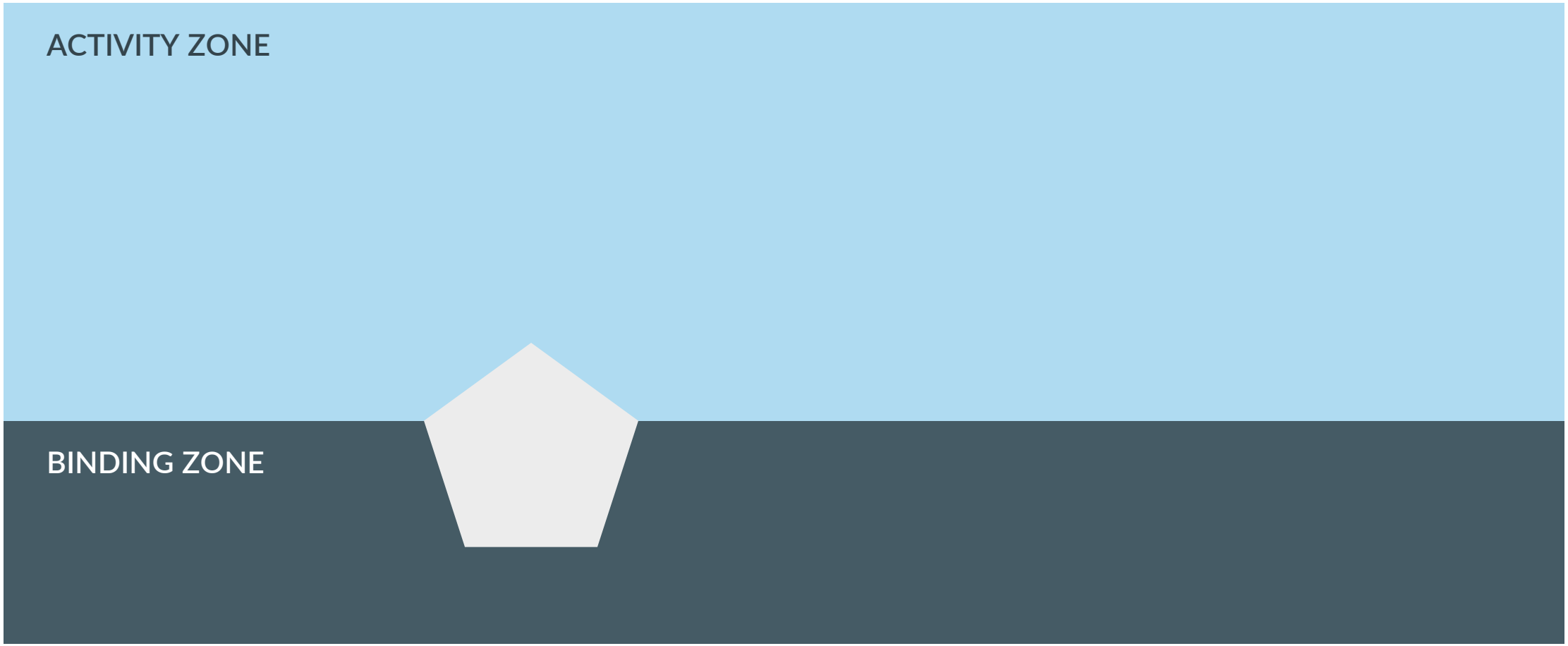
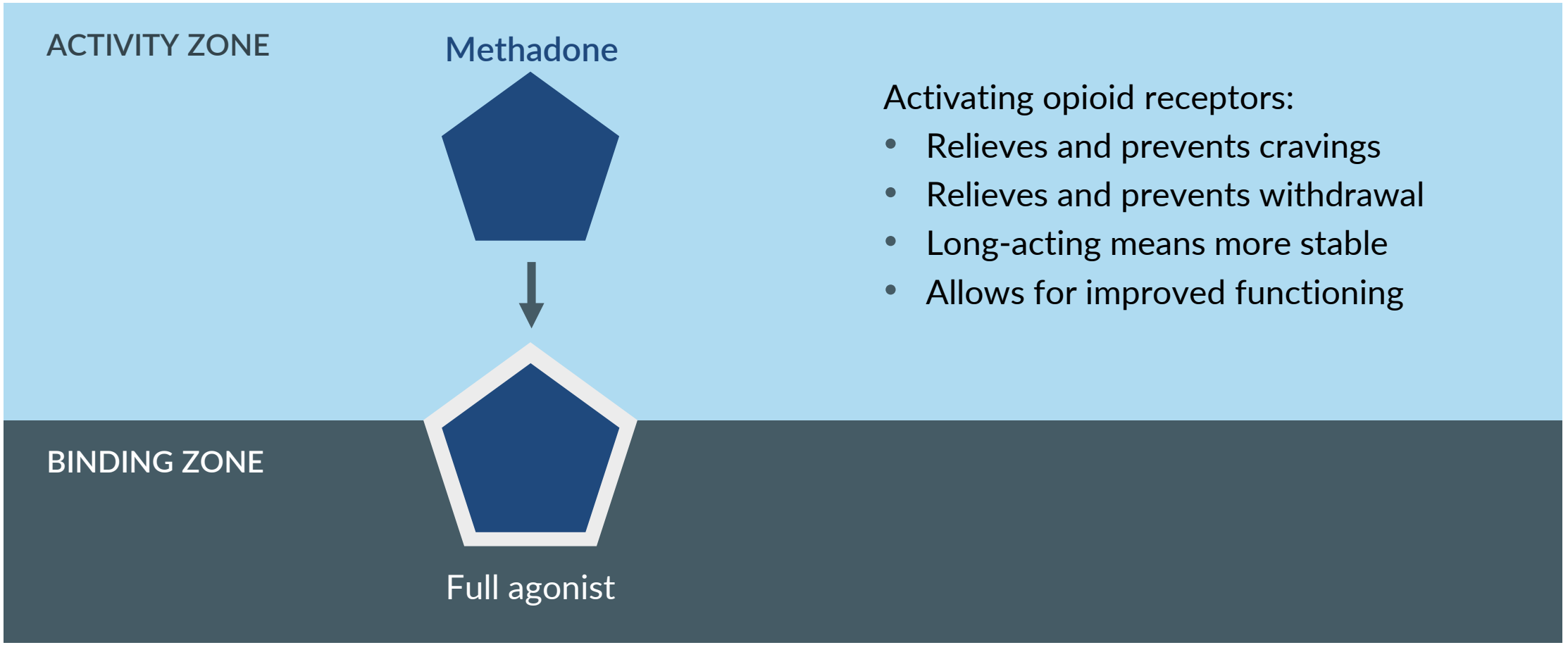
Opioid Receptor



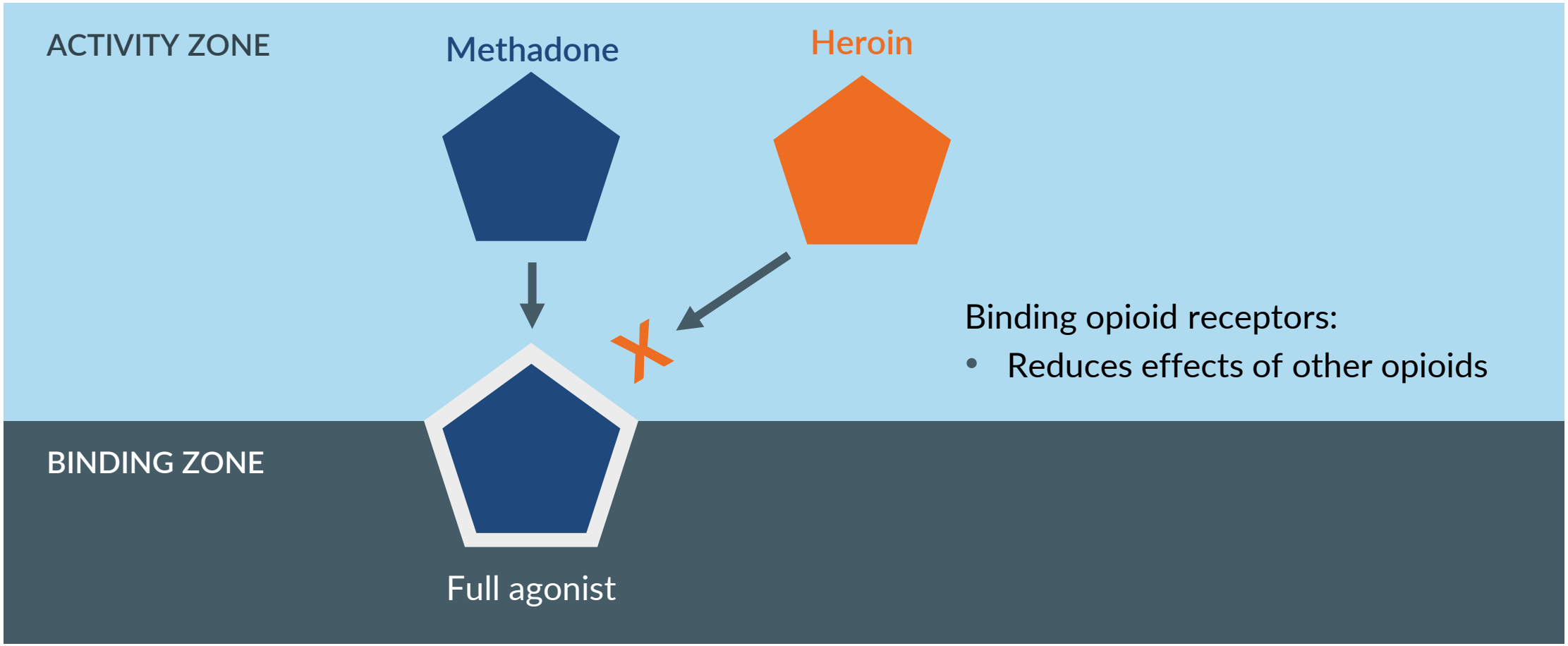
Opioid Receptor



Activating opioid receptors:

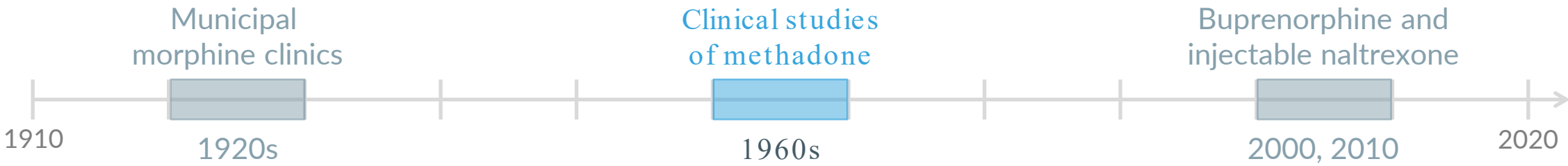
- Relieves and prevents cravings
- Relieves and prevents withdrawal
- Long-acting means more stable
- Allows for improved functioning

Opioid Receptor

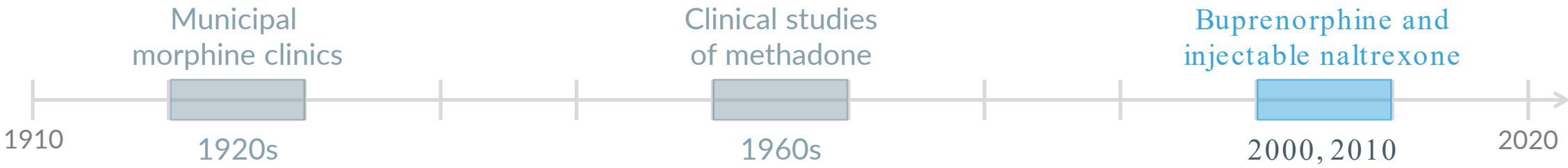


Binding opioid receptors:

- Reduces effects of other opioids

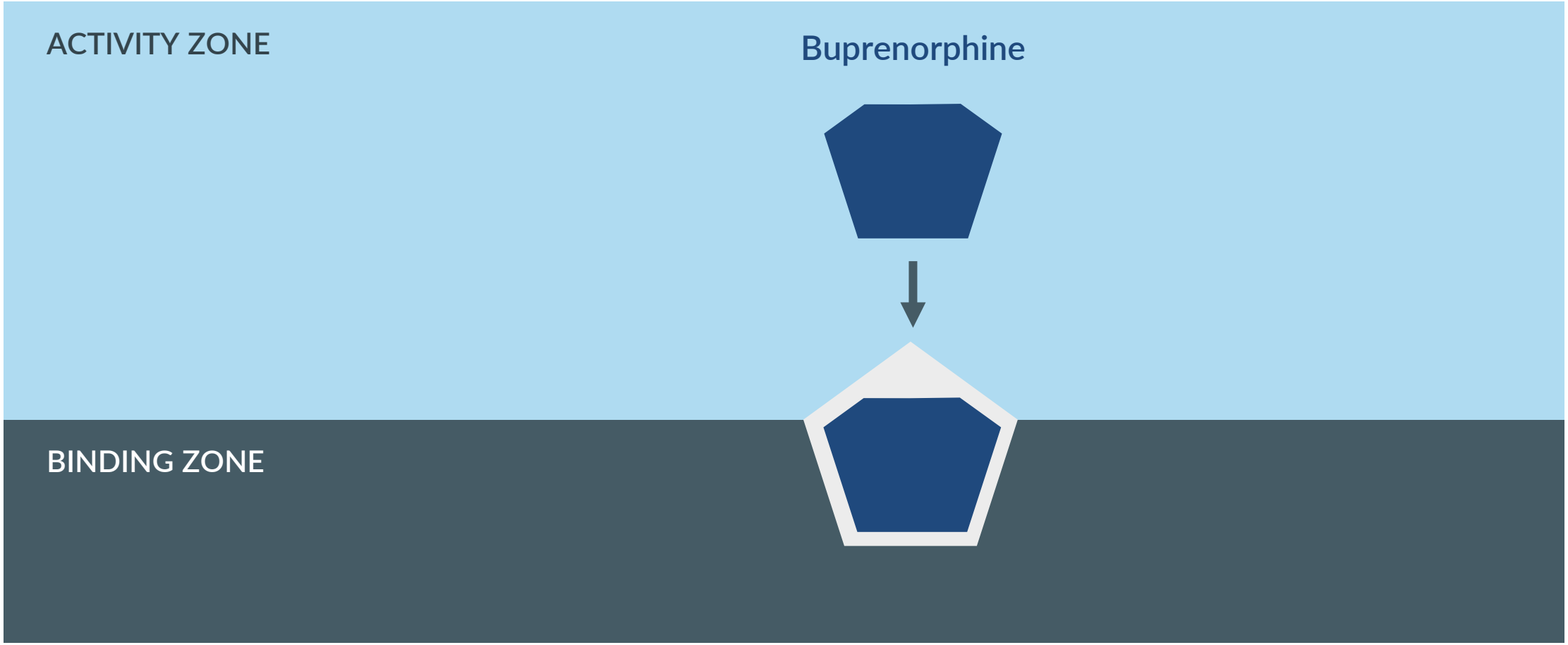


- Methadone treatment became an exception to previous prohibitions
- Was allowed in federally-regulated Opioid Treatment Programs
- Provide structured and supervised dispensing of medication
- Initial visits are frequent, decreasing over time



- Drug Abuse Treatment Act of 2000 created another exception for buprenorphine, allowing treatment in regular medical settings
- Created a waiver (X-waiver) to allow trained providers to prescribe buprenorphine
- Injectable long-acting naltrexone was approved by the FDA in 2010 for opioid use disorder

Opioid Receptor



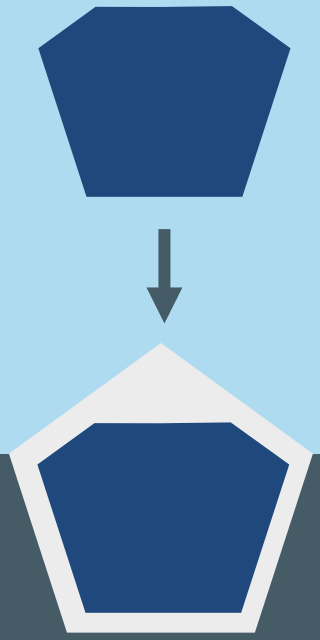
Opioid Receptor

ACTIVITY ZONE

Buprenorphine

Partial activation:

- Similar benefits to methadone
- Less risk of overmedication
- May not suffice for those with very heavy use



Binding:

- Reduces effects of other opioids
- Starting can require “induction”

BINDING ZONE

Partial agonist

Opioid Receptor

Opioid Receptor

ACTIVITY ZONE

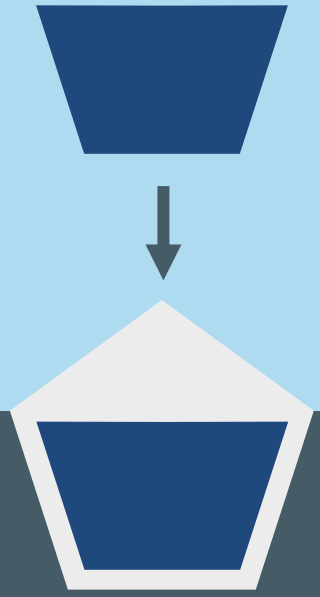
No activation:

- No pain relief
- Full withdrawal required prior to treatment
- Vulnerable to overdose if medication stopped

Binding:

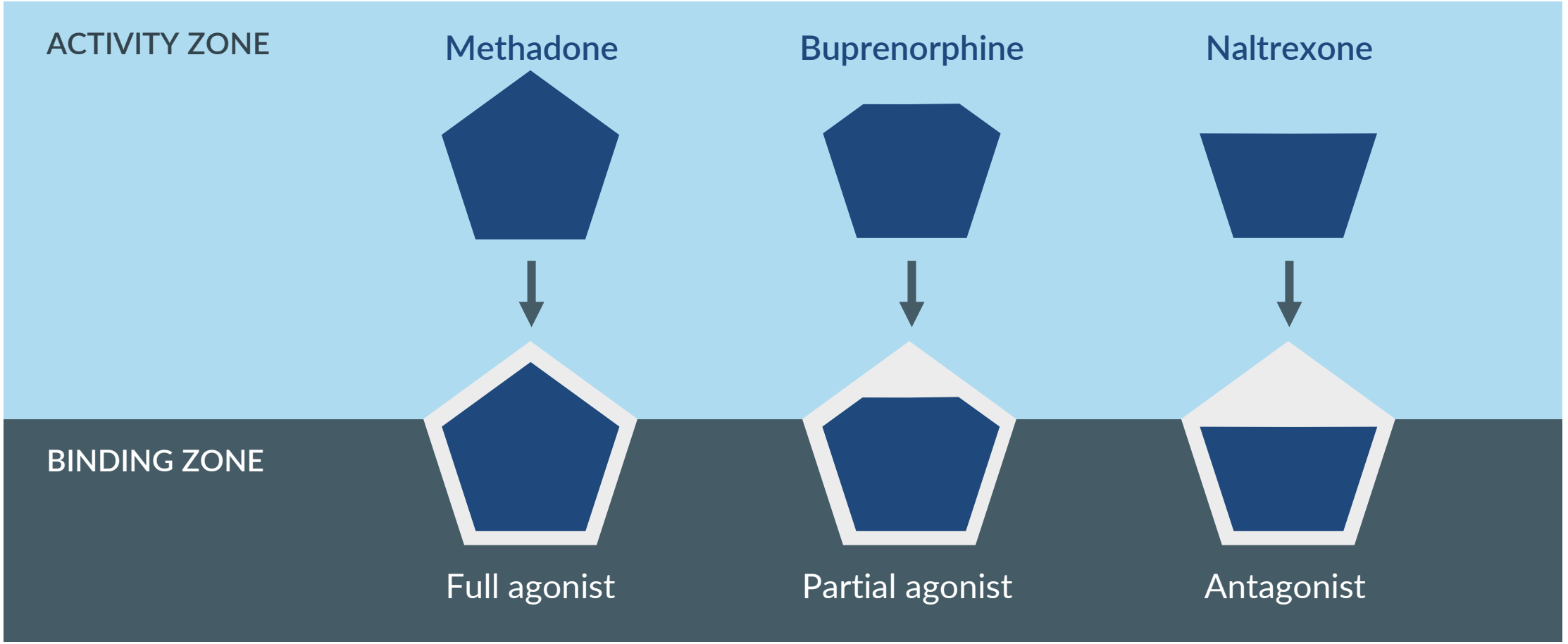
- Blocks effects of other opioids (including in emergencies)

BINDING ZONE



Opioid Receptor

“Medication-assisted treatment”, “medication for addiction treatment” (MAT), or “medications for opioid use disorder” (MOUD)



Medication and Form	Opioid Use Disorder	Pain	Brand Name (Notes)
Sublingual buprenorphine tablet	X		Subutex
Sublingual buprenorphine/naloxone tablet	X		Zubsolv
Sublingual buprenorphine/naloxone film	X		Suboxone
Buprenorphine buccal film		X	Belbuca (Bunavail for OUD was discontinued in 2020)
Buprenorphine transdermal		X	Butrans
Long-acting buprenorphine injection	X		Sublocade
Buprenorphine implant	X		Probuphine (discontinued in 2020)

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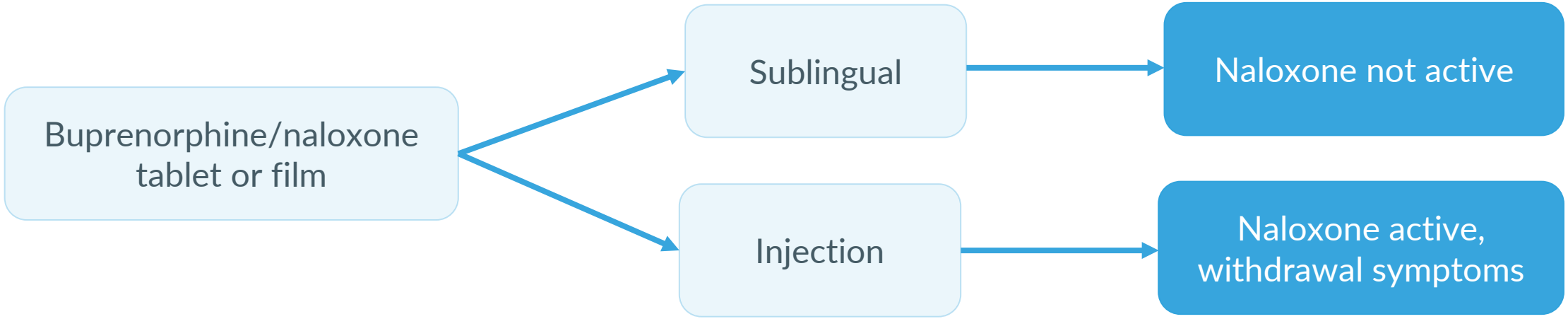

Treatments: Outcomes

- Broadly, medications for opioid use disorder:
  - Reduce drug use, overdose, and death
  - Reduce HIV and hepatitis C infection
  - Reduce crime
  - Prevent relapse
- Treatment is effective and lifesaving
- Treatment retention is similar to other chronic medical conditions (e.g., beta blocker treatment after a heart attack)

Sources: Center for Evidence-based Policy (2019); SAMHSA (2021); Butler, et al. (2002)

Treatments: Comparative Effectiveness (1 of 5)

Methadone

Buprenorphine

Naltrexone

Treatments: Comparative Effectiveness (2 of 5)

Methadone Buprenorphine Naltrexone

- Outcomes generally similar
- Methadone may have higher treatment retention
- Special considerations for pregnancy

Source: Center for Evidence-based Policy (2019)

Treatments: Comparative Effectiveness (3 of 5)

Methadone

Buprenorphine

Naltrexone

- No significant difference between film and tablet
- Long-acting injectable may result more days without drug use

Sources: Lintzeris, et al. (2013), Marsden, et al. (2023)

Treatments: Comparative Effectiveness (4 of 5)

Methadone

Buprenorphine

Naltrexone

- Injectable extended-release naltrexone
- Head-to-head comparisons are limited to special settings (i.e., release from inpatient treatment)
- For naltrexone, need to undergo withdrawal first is a limitation

Source: Lee, et al. (2018)

Treatments: Comparative Effectiveness (5 of 5)

Medication treatment is superior to treatment without medication

- The three medications are delivered to different patients in different settings, with different clinical protocols
- Patients often self-select based on their own history, values, and preferences (medication and setting)
- There is not one optimal treatment that will work for every patient
- Important to have several options for patients

Source: SAMHSA (2021)

Outline

- What is opioid use disorder?
- What treatments are effective?
- Coverage considerations
  - Who can prescribe?
  - Dose and quantity limits
  - Duration of therapy
  - Adjunctive services
- Parity considerations
- Resources

Coverage: Who Can Prescribe?

Methadone

- Only in federally-regulated Opioid Treatment Programs
- Governed by federal and state regulations and oversight

Buprenorphine

- X-waiver *eliminated* by the Consolidated Appropriations Act of 2023
- Schedule III controlled substance, no restriction on patient volume
- Long-acting injectable requires administration in the office

Naltrexone

- Not a controlled substance
- Injection requires administration in the office

Coverage: Dose and Quantity Limits

Methadone

- Dosing is flexible, evidence that higher doses are more effective than lower doses
- Frequency of clinic visits is dependent on patient progress and federal regulations

Buprenorphine

Sublingual: FDA package insert identifies 16mg/day as a target dose noting limited clinical evidence of efficacy for doses above 24mg/day

- Heavy use (i.e., fentanyl) may require daily dose of up to 32 mg/day (no evidence for any higher dose than 32 mg/day)
- Quantity supplied and refill schedule should be flexible, dependent on patient progress

Injection: fixed dose injections monthly (higher at first) administered in the office

Naltrexone

- Fixed dose monthly injection administered in the office

Coverage: Duration of Therapy

- In clinical research, longer duration is better than shorter duration, with no maximum or minimum established
- FDA package insert: “There is no maximum recommended duration of maintenance treatment. Patients may require treatment indefinitely and should continue for as long as patients are benefiting and the use … contributes to the intended treatment goals.”
- Limitations on duration of therapy can disrupt treatment and put patients at risk for overdose death

Source: Timko, et al. (2016); SAMHSA (2021)

Coverage: Adjunctive Psychosocial Counseling

- Foundational level of medication counseling required (as with any other medication)
- People with other behavioral health conditions should receive treatment (e.g., depression)
- There is little evidence of efficacy for psychosocial therapies as an addition to medication, but it may be beneficial for some
- There is no basis for requiring specialized psychosocial therapies or counseling as part of treatment
- Medication is the core component of treatment

Sources: Dugosh, et al. (2019); Rice et al. (2020); Zerden et al (2020); Wild et al (2021)

Coverage: Adjunctive Urine Drug Testing

- Widely used, although poorly studied
- There is little evidence on the value for managing patients and the optimal frequency of testing
- Guidelines generally recommend use in combination with other factors to gauge treatment response
- Continued drug use can indicate inadequate treatment, intensification of treatment may be necessary

Sources: McEarchern, et al. (2019); Dupouy, et al. (2014); ASAM (2017); SAMHSA (2021)

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Parity Considerations

- Medications for opioid use disorder are a target of parity enforcement efforts
- State actions have compared:
  - Medications for opioid use disorder treatment with opioids used for pain
  - Medications for opioid use disorder treatment with other medications

Source: Department of Labor (2020)

Parity Considerations: Examples of State Findings

- Excluding methadone
- Imposing prior authorization for opioid use disorder, but not chronic pain
- Requiring prior authorization every 6 months, as opposed to no prior authorization or a 1-year duration
- High tiering of all medications for opioid use disorder
- Quantity and dose limits

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Resources: Care Standards

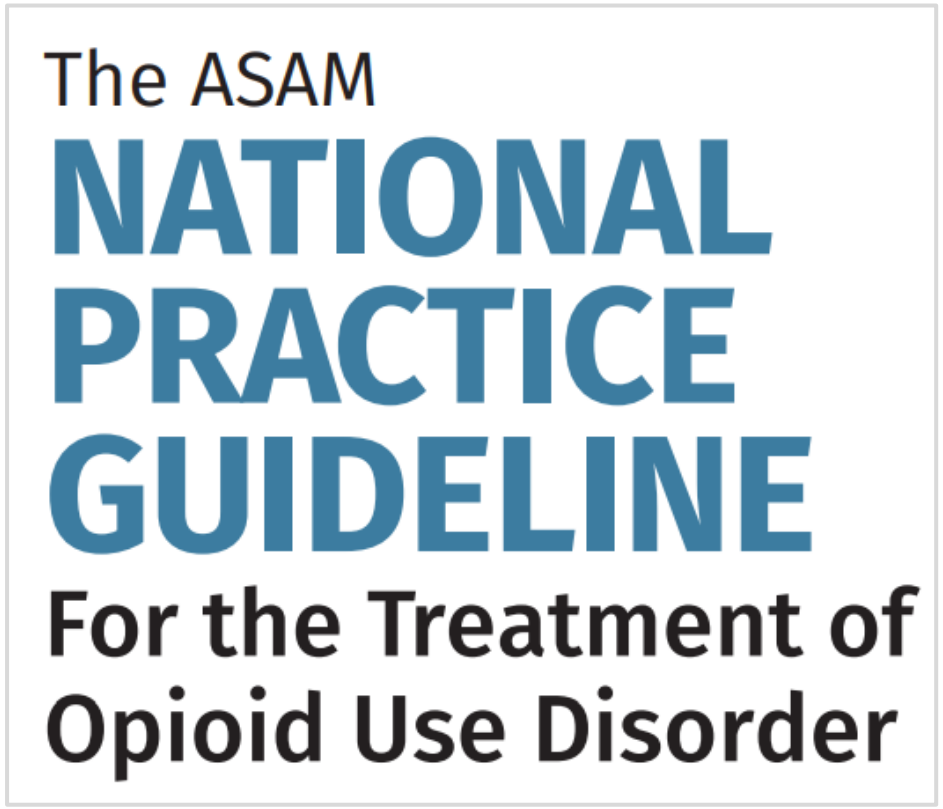
- Substance Abuse and Mental Health Services Administration

https://store.samhsa.gov/product/tip-63-medications-opioid-use-disorder/pep21-02-01-002

Resources: Care Standards

- American Society of Addiction Medicine (2020)

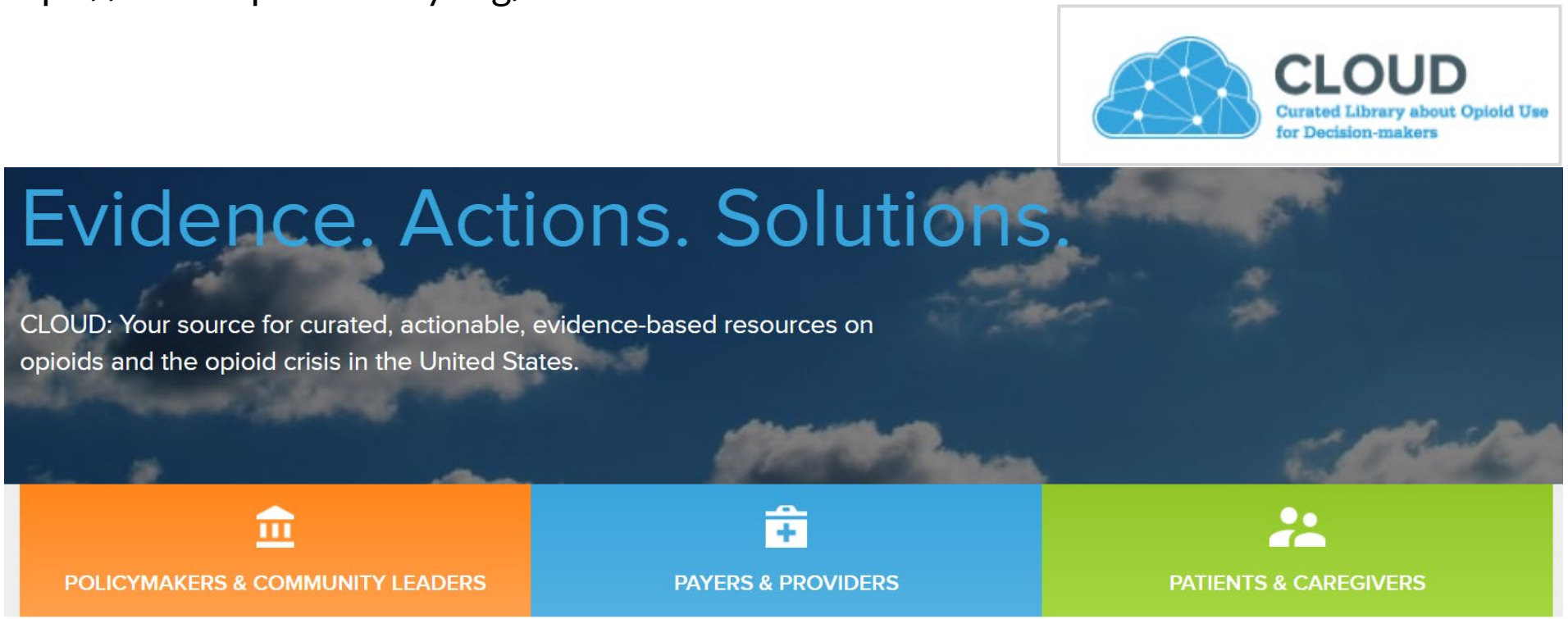
https://www.asam.org/quality-care/clinical-guidelines/national-practice-guideline



Resources: Center for Evidence-based Policy

- Curated Library about Opioid Use for Decision-makers (CLOUD)

https://www.opioidlibrary.org/



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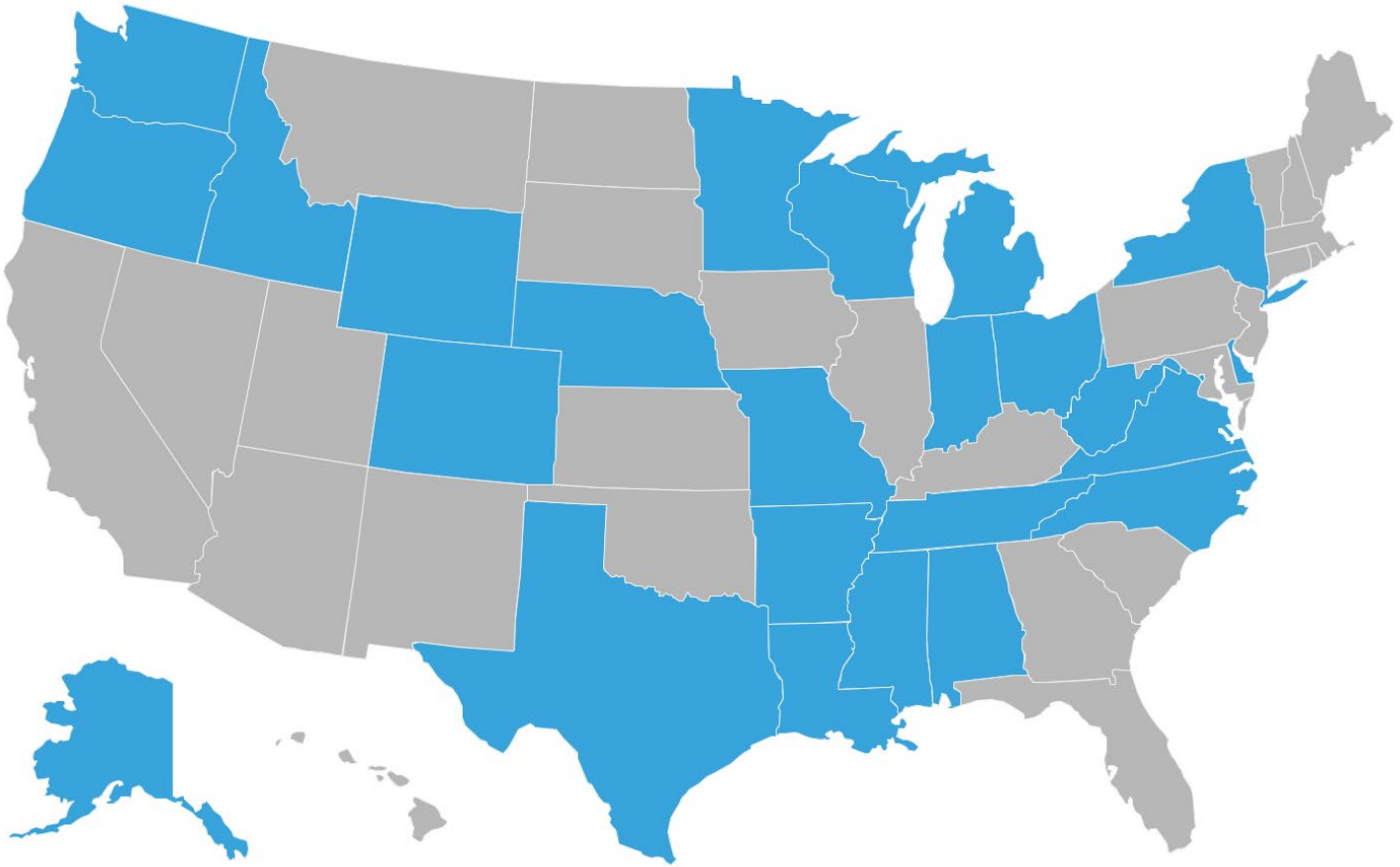
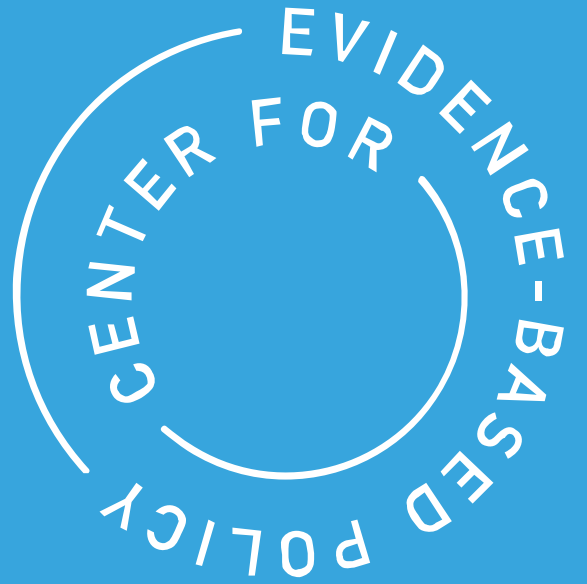


If you are one of the states in blue, you may already have access to some or all Center research and reports (most likely through the state Medicaid program)

Resources: Center for Evidence-based Policy

- Buprenorphine formulation coverage and criteria for treatment of opioid use disorder
- Management strategies to increase medication-assisted treatment access and utilization for opioid use disorder
- Efficacy and safety of extended-release injectable and implantable buprenorphine for opioid use disorder
- Comparative effectiveness and harms of buprenorphine and methadone for opioid use disorder
- Tapering or discontinuing opioid maintenance therapy in pregnancy: clinical evidence
- And more!

Questions?
Email: bachhmar@ohsu.edu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