

Trends in Behavioral Health

Webinar Series



**Office-Based Opioid Treatment:
What You Need to Know**

April 4, 2019

presented by



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Agenda

1. Policy and Clinical Context
2. Legislative Context
3. Models for OBOT Delivery
4. OBOT in California
5. Regulatory and Policy Risks and Opportunities
6. Q&A

Policy and Clinical Context



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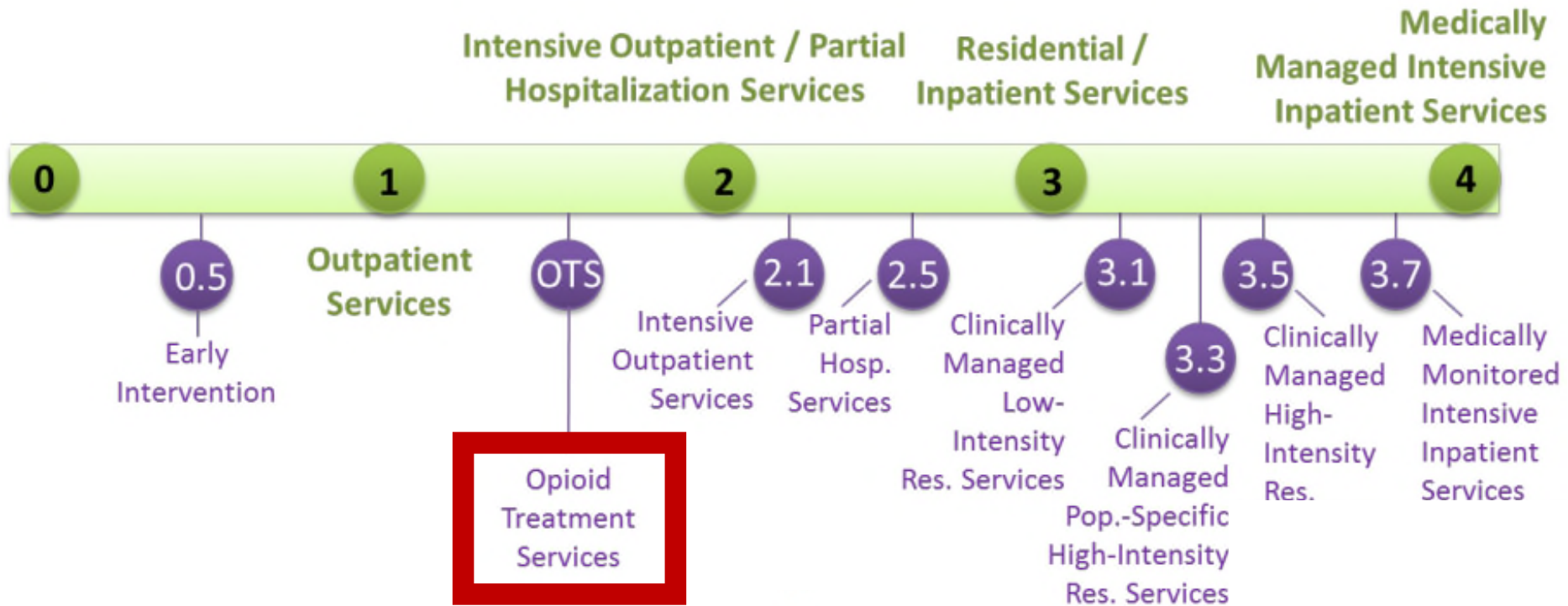


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American Society of Addiction Medicine (ASAM)

Levels of Care



Rationale for Medication Assisted Treatment (MAT)

Decrease overdose and death

Retain people in SUD addiction treatment

Reduce compulsive behavior, illicit opioid use, criminal behavior

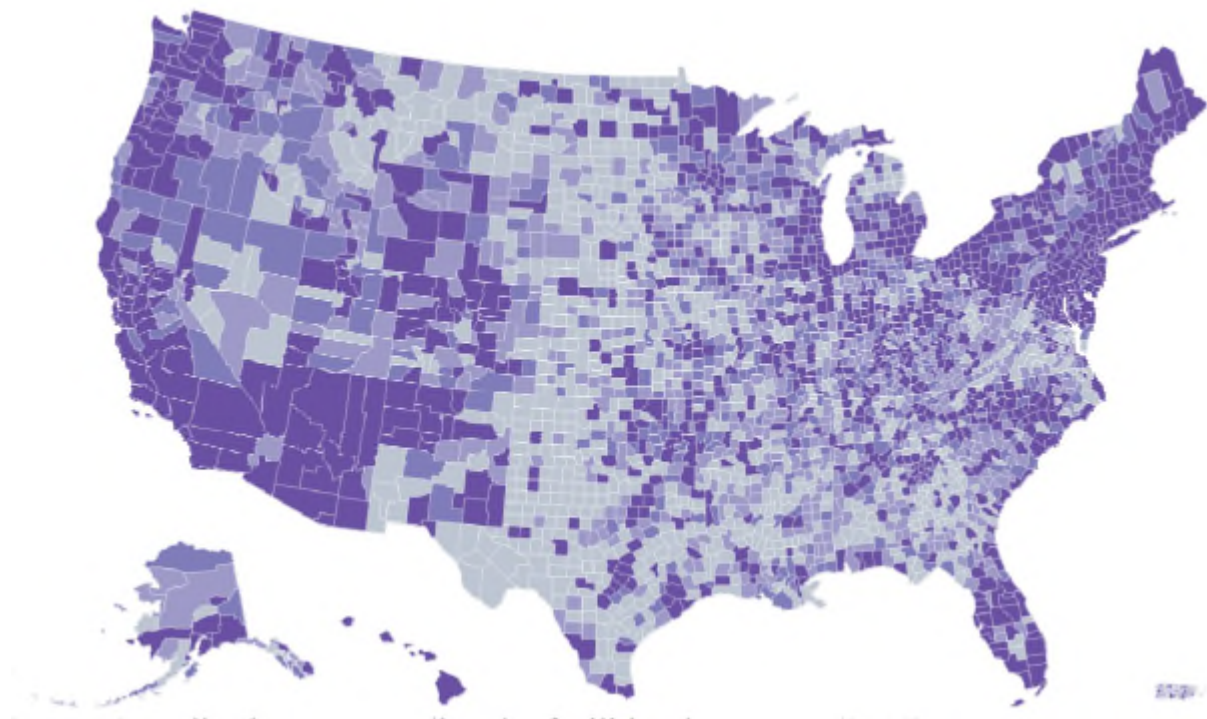
Reduce transmission of hepatitis C, HIV

Reduce sexual risk behaviors (e.g., trading sex for money/drugs)

Improve physical and mental health

Improve social functioning

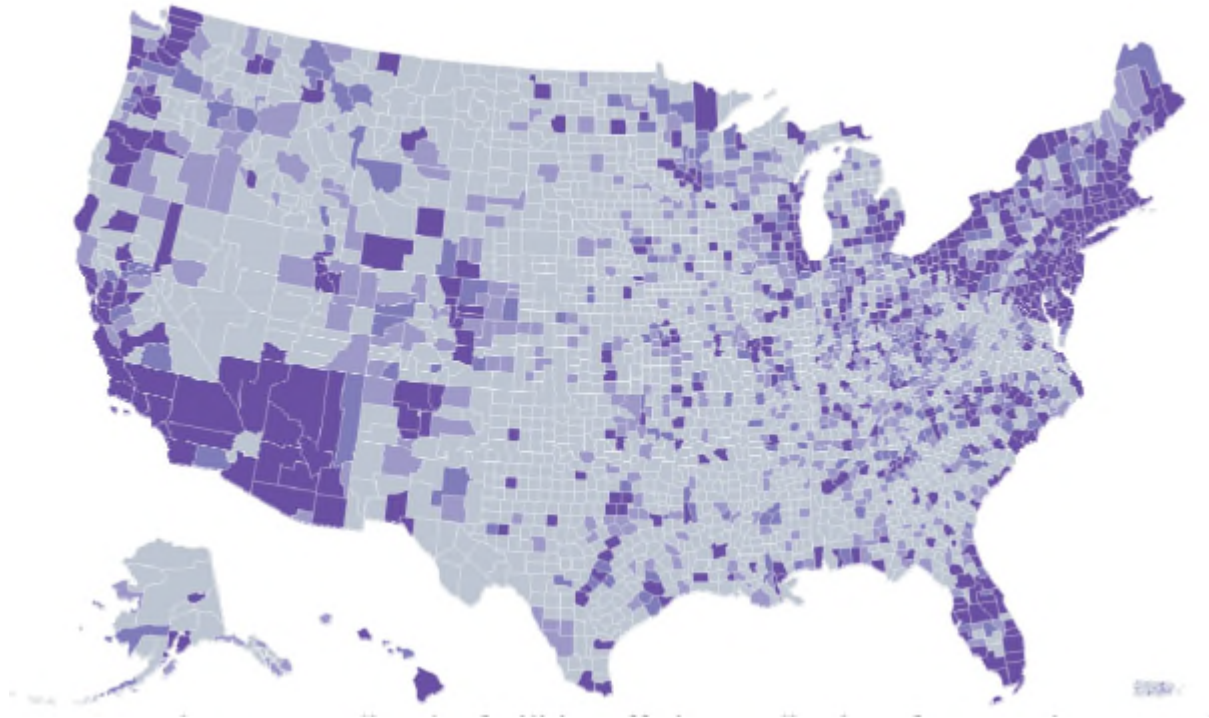
All substance use disorder (SUD) facilities



Gray = no facilities; light purple = 1 facility; medium purple = 2 facilities; dark purple = 3 or more facilities.

National Academies of Sciences, Engineering, and Medicine 2019. *Medications for Opioid Use Disorder Save Lives*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25310>.

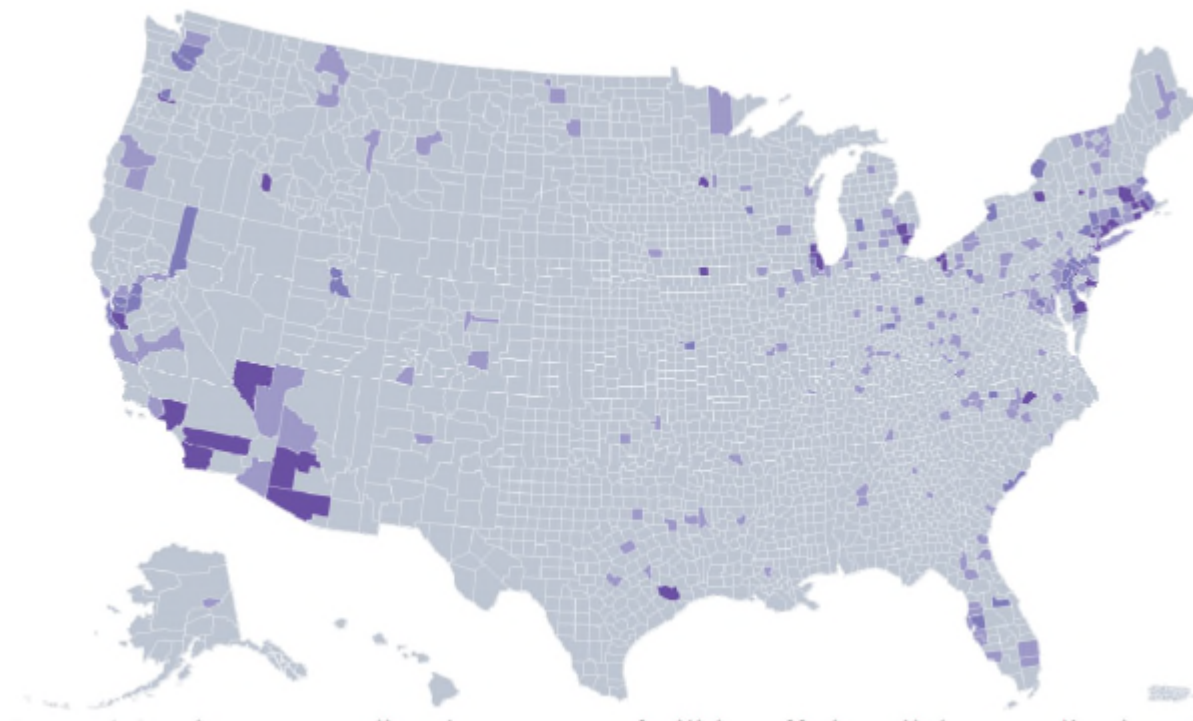
SUD facilities offering MAT



Gray = no facilities; light purple = 1 facility; medium purple = 2 facilities; dark purple = 3 or more facilities.

National Academies of Sciences, Engineering, and Medicine 2019. *Medications for Opioid Use Disorder Save Lives*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25310>.

SUD facilities offering all three MAT drugs



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National Academies of Sciences, Engineering, and Medicine 2019. *Medications for Opioid Use Disorder Save Lives*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25310>.

Tradeoffs among MAT drugs

Methadone

- Effective at overcoming cravings and withdrawal
- Higher risk of abuse
- High physical dependency
- Dangerous risk of interactions
- Low cost
- Stigmatized
- Dispensed by OTP

Buprenorphine/naloxone (Suboxone)

- Easy transition from illegal drug dependency
- Less severe dependency than methadone.
- Lower overdose risk
- Higher cost
- Still stigmatized
- Prescribed by OBOT

Naltrexone (Vivitrol)

- Blocks analgesic and euphoric effects of all opioids
- Cannot be used until after detox and patient is opioid-free
- Limited research on efficacy and relapse
- Preferred by abstinence-focused treatment providers

Opioid Treatment: Changing Approach

Methadone Clinic (OTP)

- Criteria:
Withdrawal
12 months use
- Dose regulated
- Age > 18
- Limited take homes
- Services “required”

Buprenorphine (OBOT)

- Criteria:
DSM IV
No time criteria
- MD sets dose
- Age > 16
- Take homes (30 days)
- Services must be “available”

Advantages of Office-Based Opioid Treatment (OBOT)

- Fewer than 20% of opioid dependent persons are receiving treatment in traditional settings
- Poor clinic retention for OTPs
 - Environment inhibits recovery
 - Highly regulated doses & take homes
- Infrastructure of care
 - High turnover of staff
 - Ability to get to treatment may be limited

Legislative Context



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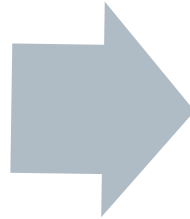
DATA 2000: The Shift from OTPs to MD Offices

- Until DATA 2000, methadone and buprenorphine could only be distributed via DEA-registered, state-licensed Narcotic Treatment Programs (NTPs) (*e.g.* Narcotic Addict Treatment Act of 1974).
- DATA 2000 opened up the possibility for DEA waivers for MD office-based prescribing and dispensing for opioid use disorders.
- MDs must qualify for and get DEA waiver based on approved addiction certification, clinical trial participation, or 8-hour approved course.
- 30-patient limit; then could increase up to 100 patients

Expansion of Office-Based MAT

CARA (2016):

- Increase patient limits to 275 (per HHS rule; renewal every three years)
- Allows NP and PA prescribing (until 2021), with 24-hour initial training; 30 patients
- Requires ability to refer for behavioral treatment



SUPPORT (HR 6) (2018):

- Codifies physicians who have been authorized to treat 100 patients for 1 year to treat up to 275 patients
- Makes permanent NP and PA prescribing
- Further expands MAT authorization for practitioner types beyond MDs
- And more

Further, the Federal **21st Century Cures Act (“Cures Act”)**, enacted in 2016, increases federal funding for states to develop and implement initiatives to reduce the opioid epidemic.

SUPPORT Act Section 2005: Medicare coverage

Medicare coverage of MAT via Opioid Treatment Programs (OTPs) for Medicare beneficiaries.

Historically, OTPs are not recognized as Medicare providers, meaning that beneficiaries receiving MAT at OTPs for their OUDs must pay out-of-pocket.

Section 2005 provides Medicare will pay the outpatient OTPs via bundled payments made for holistic services, including necessary medications, counseling, and testing

SUPPORT Act Section 3201: MAT Expansion

- **Authorizes** clinical nurse specialists, certified nurse midwives, and CRNAs to prescribe MAT for 5 years.
- Makes **permanent** NP and PA prescribing
- **Allows waived MDs to immediately treat** up to 100 patients if board-certified in addiction medicine or addiction psychiatry, or if the practitioner provides MAT in a qualified practice setting.
- **Codifies physicians authorized** at 100 for 1 year to apply for authority up to 275 patients.
- HHS Secretary, in consultation with DEA, to **report on care provided** by 100+ MDs and 30+ other qualifying practitioners

SUPPORT Act Section 3202

- Authorized D.O. physicians (i.e. from an accredited school of allopathic or osteopathic medicine) to obtain a waiver to prescribe MAT (*e.g.* with the 8-hour course)

OUD Funding under CARA and Cures Act

- **Comprehensive Addiction and Recovery Act of 2016 (CARA)**
 - Did not appropriate funding but authorizes \$181 million in new funding for programs designed to reduce the impact of OUD, including prevention and treatment, including connecting patients with outside entities providing MAT
 - also authorizes HHS to allocate a total of \$25 million per year (between 2017 and 2021) for expansion of MAT
 - HHS Secretary may award additional grants for states to “implement an integrated opioid abuse response initiative,” which may include expanding availability of MAT and behavioral therapy
 - In 2017 SAMHSA announced grants totaling \$2.6 million
- **21st Century Cures Act**
 - Authorized appropriations of \$500 million per year in 2017 & 2018 plus additional grant opportunities and Medicaid policy changes

Recent California Legislation



- In 2018, California Legislature considered more than 20 bills addressing opioid crisis.
- **AB 349**
 - DHCS to adopt new regulations and update reimbursement rates for Drug Medi-Cal Treatment Program
- **SB 992**
 - Includes MAT non-discrimination
- **SB 1228**
 - Prohibition on patient brokering: giving/receiving anything of value to induce a referral seeking SUD services

Models for OBOT Delivery



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Keys to Success

- Provider and community education
- Integration (or at minimum collaboration) with medical and mental health providers and systems
- Coordination with wraparound and social services and supports
- Adapted to local health system capacity
- Leverages multi-payer coverage and reimbursement strategies

Vermont – Hub and Spoke

- “Hubs” are regional OTPs that care for more complex patients or stabilize as needed, dispense methadone, support tapering off MAT, and provide consultative services to the spokes
- “Spokes” include an array of primary and BH providers that provide MAT for less complex patients using an OBOT approach
- Patients may transfer between a hub and a spoke on the basis of changing care needs, coordinated by RN or case manager
- State funds online DATA waiver training and BH specialists for hubs
- Financed through Medicaid Health Home authority and SAMHSA block grant
- Model is suited to areas with rural populations where access to hub-level services is limited

Maryland – Baltimore Buprenorphine Initiative

- Centralized initial intake, buprenorphine induction, and stabilization in an OTP
 - Case worker involved from the start, helps with health insurance, MCO and PCP selection, and care transitions and patient tracking
- Once patient meets transfer criteria, transfer to primary care for ongoing MAT
 - OTP provides ongoing psychosocial services and care management for six months after transfer
- Requires geographic proximity of primary to OTP
- Collaboration of BH Systems Baltimore, Health Care Access Maryland, and Baltimore City Health Department
- Opt-in patient enrollment and low participation by OTPs have led to lower program enrollment

Massachusetts – Collaborative Care Model

- Central role for nurse care managers—screening, intake, and education of patients, coordinate scheduling with physician prescriber for MAT, and collaborate with pharmacist (refills management)
 - FQHC or CHC based
 - Urgent drop-in hours also available
- The prescribing physician confirms the OUD diagnosis and appropriateness of MAT and co-manages the patient
- Psychosocial and support services are integrated on-site or nearby, including housing, employment, and health insurance (including prior auth)
- Patients who require a higher level of care receive expedited OTP referral
- Training and technical assistance provided by state Medicaid agency

OBOT in California



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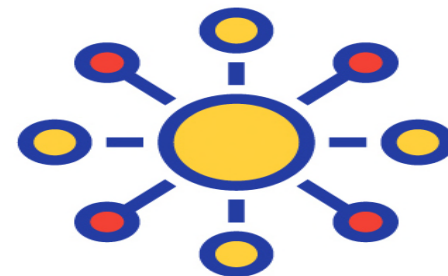


Drug Medi-Cal Organized Delivery System (DMC-ODS)

- Medicaid Section 1115 waiver
- Expand MAT options under DMC-ODS
- Other goals: Improve SUD services for California beneficiaries; select quality providers; access Level of Care based on ASAM model; coordination and integration
- Counties that choose to participate in DMC-ODS must:
 - Use a benefit design modeled after the American Society for Addiction Medicine (ASAM) criteria, covering a broad continuum of SUD treatment and support services
 - Specify standards for quality and access
 - Require providers to deliver evidence-based care
 - Coordinate with physical and mental health services
 - Act as a managed care plan for SUD treatment services

California Hub and Spoke System

- California's Hub and Spoke System (H&SS) as part of MAT Expansion program – modeled after Vermont Hub and Spoke model
- Goals: Build OUD and MAT treatment network that meets community needs; increase availability of buprenorphine and naloxone; increase waived providers; improve MAT access for tribal communities
- Focus regions: Counties with high overdose rates, including but not limited to: Modoc, Humboldt, Lake, Mendocino, Yuba, Del Norte
- Focus populations: American Indians & Alaska Natives, Perinatal Clients, Service Members & Veterans, Uninsured/Underinsured, Youth
 - *Source: California DHCS*



Provider licensure and certification

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

(1) By holding additional credentialing; or

(2) By practicing in a qualified practice setting.

Additionally, practitioners must not have had their Medicare enrollment and billing privileges revoked and must not have been found to be in violation of the Controlled Substances Act (CSA).



Risks and Opportunities



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Risks and Opportunities

Telemedicine

- Ryan Haight Online Pharmacy Consumer Protection Act of 2008 governs the prescription of controlled substances via telemedicine
 - 2018 guidance clarifies that DATA-waivered practitioners are exempt from the in-person medical evaluation requirement
 - SUPPORT Act requires final rules from Attorney General by October 24
- The SUPPORT Act permits providers to be reimbursed for providing eligible SUD services to Medicare beneficiaries in their homes via telehealth at same rates as in-person services
- California AB 2861 expands Medicaid reimbursement for individual counseling services delivered via telehealth by SUD providers

Risks and Opportunities

Stigma

- Recent (2019) DOJ settlement based on a complaint alleging disability discrimination on the basis of disability where a medical facility refused to accept patient for a new family practice appointment because he was being treated with Suboxone



Risks and Opportunities

Treatment limits under the Mental Health Parity and Addiction Equity Act

- MHPAEA requires frameworks for utilization management (UM) limits for MAT to be no more restrictive than UM for medical and surgical benefits
- Many payers impose dosage limits on prescriptions for buprenorphine or Suboxone, some as low as 16 mg/day
- Payers also impose a variety of limits on the duration of treatment and/or the ability to renew treatment within a given timeframe (or lifetime)
- Where these limits deviate from national standards, payers must ensure that the process and evidence used to develop them are no more restrictive than the process and evidence used to impose limits on drugs used for medical/surgical conditions

Risks and Opportunities

MAT drug diversion

- Many providers cite fear of diversion as a barrier to providing MAT
- Buprenorphine/naloxone formulation blocks the rewarding effects of opioids and triggers withdrawal if injected
- Rates of both misuse and diversion decline as buprenorphine availability increases
- Diversion rates for MAT are lower than for prescribed antibiotics and allergy medications

Questions?



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