COMPLIANCE ON THE FRONT LINES OF THE OPIOID EPIDEMIC

Matthew J. Landis MS, JD, CHC Vice President of Compliance Meridian Behavioral Health

DISCLAIMER

The information contained herein is for educational purposes only and the opinions expressed herein are my own and do not represent opinions of Meridian Behavioral Health or organizations I am affiliated with. Furthermore, this presentation and materials are not intended to be and should not be construed as legal advice.

AGENDA

- \bullet Define MAT/OTP services and general treatment approach
- Provide a public health perspective on the toll of opioid addiction
- Discuss how treatment services are accessed, the process of receiving treatment services, and the regulatory checks that are in place to control the process
- How we maintain compliance and address the challenges and opportunities of working with human beings in a highly regulated environment

MEDICATION ASSISTED TREATMENT FOR OPIOID DEPENDENCE AND ADDICTION

- SAMHSA defines medication assisted treatment (MAT) as "the use of medications in combination with counseling and behavioral the rapies for the $% \left(1\right) =\left(1\right) \left(1\right) =\left(1\right) \left(1\right) \left($ treatment of substance use disorders"
- Evidence points to a combination of medication and behavioral therapies as an effective approach to treating substance use disorders with a goal to help people sustain recovery
- \bullet Use of MAT is highly regulated: DEA, DHS 245G, CARF, SAMHSA
- This presentation will focus on use of Methadone and Suboxone in MAT, also called an Opioid Treatment Program (OTP)

| MA1 | r O1 | ים מי | T TRTI | | TRT | TATE OF |
|--------|--------|-------|--------|-----|-----|---------|
| IVIA I | I -O I | IP C | LINI | LOS | 111 | TATTA |

- Approximately 7,000 methadone patients in MN and 15 clinics
- Disease model view of addiction
 - Views addiction as a chronic and progressive medical condition, similar to other chronic diseases like Type II diabetes and cardiovascular disease
 - Medications like methadone and suboxone are prescribed by a physician to address the patient's unique needs
- · Individualized approach
 - All patients must receive counseling as a condition of participation: individual, group therapy, CBT, DBT, motivational interviewing, referrals and case management coordination with other social
 - . We employ harm reduction techniques to reduce stigma and sense of shame often associated with
- The goal is for patients to achieve and maintain sobriety
 - It is important that patients stick with the program, including other supportive therapy and recovery services

OPIOID DEPENDENCE AND ABUSE IS A PUBLIC HEALTH CRISIS

- Opioids can offer substantial relief to individuals in pain, but are also highly addictive
- Opioids affect the brain in two major ways:
 - bind to receptors in the brain and spinal cord, disrupting pain signals
 - · activate reward areas of the brain by releasing the hormone dopamine
- Over past 20 years, opioid consumption worldwide has tripled
- Synthetic opioids have increased their share of total opioid consumption from 31% in 2014 to 39% in 2016

Source: https://www.incb.org/documents/Publications/AnnualReports/AR2017/Annual_Report_chapters/Chapter_2_2017.pdf

| - | |
|---|--|
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |

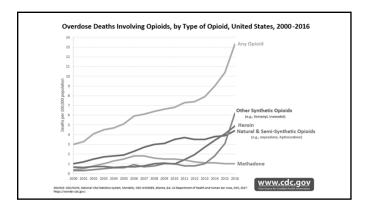


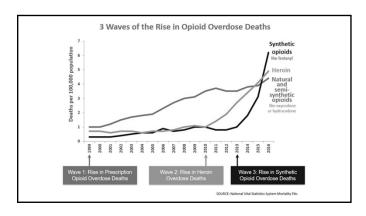
FENTANYL AND CARFENTANIL

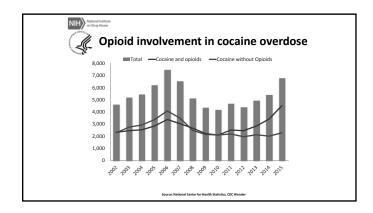


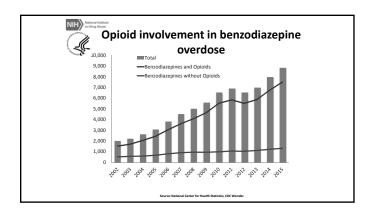
- Opiates with extremely high potency are beginning to be seen on the streets of Minnesota
- Fentanyl is 100 times more powerful than morphine; Carfentanil is 100 times more potent than fentanyl and 10,000 times more powerful than morphine. Furanylfentanyl is a fentanyl analogue about a fifth as potent as fentanyl.
- Used in black market pill production and can adulterate other drugs, making the risk of overdose much greater
 Star Tribune, Thursday, August 2: Minneapolis man received a 7 year sentence after pleading guilty to distributing highly potent opiate analogues
- "This is the first case in the District of Minnesota involving Carfentanil and one of the first involving furanyl
 fentanyl," U.S. Attorney Erica MacDonald said in her office's release. "Sadly, highly potent and extremely lethal
 opioid analogues such as these are becoming more common on the illegal drug market and the devastating
 societal impact of these substances, even in very small quantities, cannot be overstated."

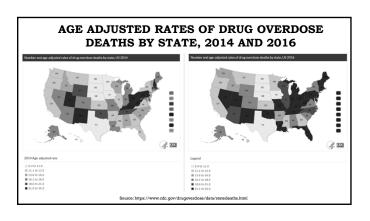
Sources: https://www.incb.org/documents/Publications/AnnualReports/AR2017/Annual_Report_chapters/Chapter_2_2017.pd

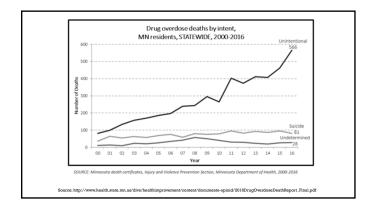


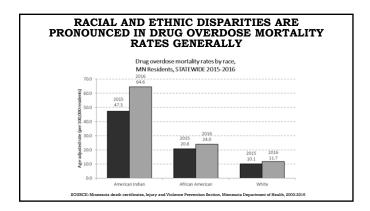


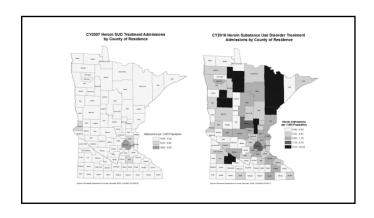














METHADONE AND SUBOXONE



- Methadone was first introduced in 1937 to treat opioid dependence
 - $\bullet \ \ Long\ acting\ opioid; full\ agonist; strong\ blockade\ effect, effective\ for\ reducing\ cravings\ and$ withdrawal effects
 - Prescribed by a physician and must be provided in a certified and licensed clinic
 - Cost effective but misuse can occur
- · Suboxone was approved by the FDA in 2002
 - · Mix of buprenorphine and naloxone
 - · Long lasting opioid; partial agonist; most effective for reducing physical withdrawal effects
 - Prescribed by a physician; can be prescribed in office
 - More costly but with lower potential for abuse

| ACCES | SING | TREAT | `MENT |
|-------|------|-------|-------|
|-------|------|-------|-------|

Step 1: Making the decision to break the cycle of addiction

Step 2: Receive an initial assessment, referral, walk-in or court order

Step 3: Come to the clinic and meet the counselor and medical staff

- Participate in the first session with their MAT/OTP counselor: Conduct Comprehensive Assessment to determine current state; biopsychosocial assessment; provide education and information on opioids
- Weekly counseling sessions for first 10 weeks, then monthly thereafter
- ${\scriptstyle \circ}\ \ \text{Treatment plan and goals with documentation of progress must reflect weekly/monthly therapy sessions}$

Step 4: Admit to the program

- o Complete program orientation
- o Check central registry: patient admits are submitted to DHS central registry for tracking
- Check Prescription Monitoring Program (PMP): State database for monitoring prescriptions of controlled substances
- o Patient photo and Baseline UA
- See the physician/PA: Conduct H&P, determine fitness for dosing and initial dose, submit signed order

Step 5: Patient receives their first dose

CENTRAL REGISTRY AND PRESCRIPTION MONITORING PROGRAM

Central Registry:

Patients in an OTP are required to register with the state as a condition of participation in the program.
 Statistical information is collected at intake and discharge and submitted to the drug and alcohol abuse normative evaluation system (DAANES).

Prescription Monitoring Program (PMP):

- The Minnesota Prescription Monitoring Program (PMP) is an online tool prescribers use to manage their
 patient's care and promote public health and welfare by detecting diversion, abuse and misuse of prescriptions
 for controlled substances.
- PMP contains information provided by Minnesota licensed pharmacies and prescribers and identifies individuals who have a recent history of multiple prescribers or multiple prescriptions for controlled substances (Schedule II, III, IV and V controlled substances, gabapentin and butalbital containing products) dispensed in
- The clinic checks patients against the PMP on admission, and at least quarterly thereafter. Patients who are identified on the PMP may have additional interventions, be monitored on a more frequent basis, or may be denied services.

| DOSING ST | EP 1: Q | UEUING | UP |
|-----------|---------|--------|----|
|-----------|---------|--------|----|



STEP 2: CLEARING FLAGS



STEP 3: ENTERING THE DOSING AREA



STEP 4: DISPENSING THE MEDICATION





STEP 5: UNSUPERVISED DOSING







ADDITIONAL DIVERSION CONTROL MEASURES







DUTY TO REPORT DIVERSION

- "Diversion crime" means diverting, attempting to divert, or conspiring to divert a scheduled drug on the program's premises
- To the fullest extent permitted under Code of Federal Regulations, title 42, sections 2.1 to 2.67, a program shall report to law enforcement any credible evidence that the program or its personnel knows, or reasonably should know, that a diversion crime has occurred on the premises of the program, or a threat to commit a diversion crime has taken place
- All employees are responsible for documenting the program's compliance with the statute's requirement in either a patient's record or an incident report
- Failure to comply can result in sanctions

HOW DO WE MAINTAIN COMPLIANCE AND PROMOTE QUALITY CARE?

Scalable Compliance Function

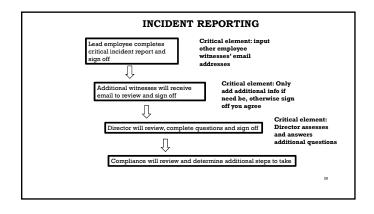
- Onsite safety and inventory compliance checklist completed each day
- Rotating site visits using standardized iPad based survey tool
- Prioritize auditing and monitoring based on business risk
- \bullet Feedback loops allow for real time monitoring
- Employing coding and programming talent allows scalability and customization
 - $\bullet\,$ Centralized reporting and resources allow for remote monitoring in real time
 - Peer review provides ongoing CQI and naturally aligns processes and expectations

USE AND OPTIMIZE AVAILABLE RESOURCES

- Intranet
- Security considerations
- Planning for standardization while realizing some level of customization is necessary
- Educating stakeholders on the ease of use

| | landatory Report Forms |
|---|---|
| | Oritical Incident Report Form Instructions |
| | Medication Error Report Form Instructions |
| | Upload a Geievance Form Reporting a Death in the Program Employee Incident Form Hospital Employee Injury Form Dushboard Access Director / Admin Access |
| C | hart Audit Forms |
| | Residential Chart Audit Form MAT Chart Audit Form |
| | |

Residential Outputient Medication Assisted Therapy Red River Serveily Acres Valley Vista DET Program Manual







| MERIDIAN BEHAVIORAL HEALTH | | | | Matt Land's VP of Qual Cpl and & Dashboar | Acred at Resource Center d | Back 🔸 |
|-------------------------------------|--|---------------------------------|----------------------------|---|----------------------------|-----------------------|
| All Facilities Data (Aggragated) | Facility Audit Results by Document Type | Individual Counselor Results | Hours Chart Residential | Second Step Review | Site Rankings | Counselor Rankings |
| Facility Location: | Discharge Status: | Star | t Date: | End Da | te: | |
| | ~~ | ****** | 142% 24% 47% 10% | 38 5X | 9.3% | 1175 |

OPPORTUNITIES AND CHALLENGES

- Compliance as a Customer Service
 - Creating intuitive and tailored systems to simplify employee processes
 - Encouraging a culture of compliance reporting and teamwork
- Compliance as a Business Partner
 - Using data to drive decision making
 - Informing performance on individual, facility and systems levels
 - $\bullet \ \ Data\ integrity\ and\ reliability\ (peer\ review\ challenges\ and\ implementing\ feedback\ loops)$
- $\bullet\,$ Getting buy-in from business partners
- Ongoing training and education

THANK YOU!

QUESTIONS?