COMPLIANCE ON THE FRONT LINES OF THE OPIOID EPIDEMIC

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AGENDA

- 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 therapies for the 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
- 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)

Source: https://www.integration.samhsa.gov/clinical-practice/mat/mat-overview

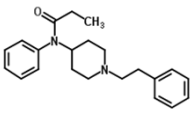
MAT-OTP CLINICS IN MN

- 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 services
  - We employ harm reduction techniques to reduce stigma and sense of shame often associated with addiction
- 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

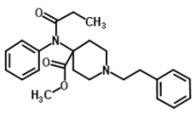
OPIOID DEPENDENCE AND ABUSE IS A PUBLIC HEALTH CRISIS

- 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

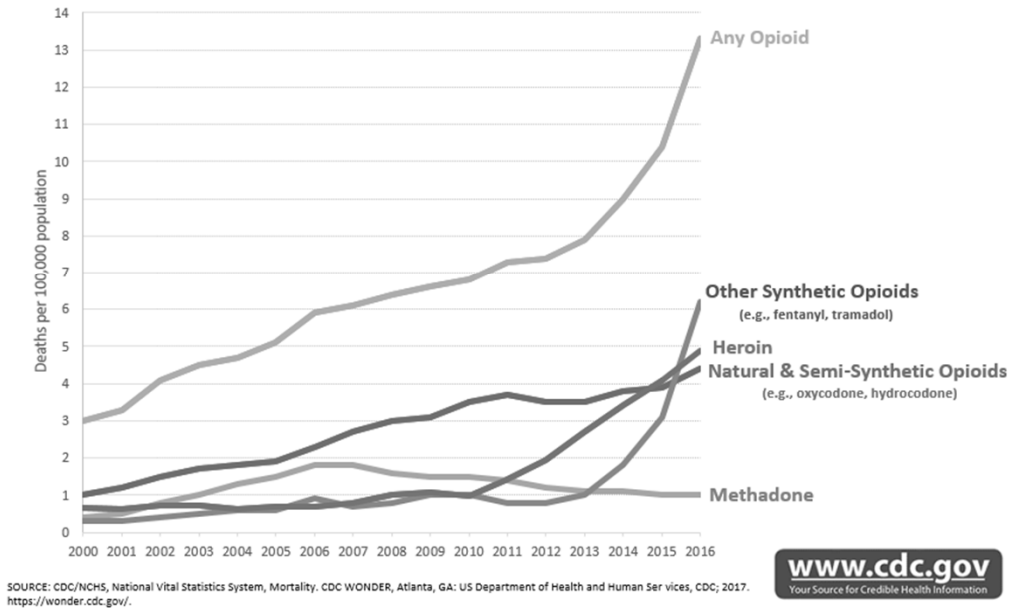


- Opiates with extremely high potency are beginning to be seen on the streets of Minnesota
- Fentanyl is 100 times more powerful than morphine; Carfentanil is 100 times more potent than fentanyl and 10,000 times more powerful than morphine. Furanylfentanyl is a fentanyl analogue about a fifth as potent as fentanyl.
- Used in black market pill production and can adulterate other drugs, making the risk of overdose much greater

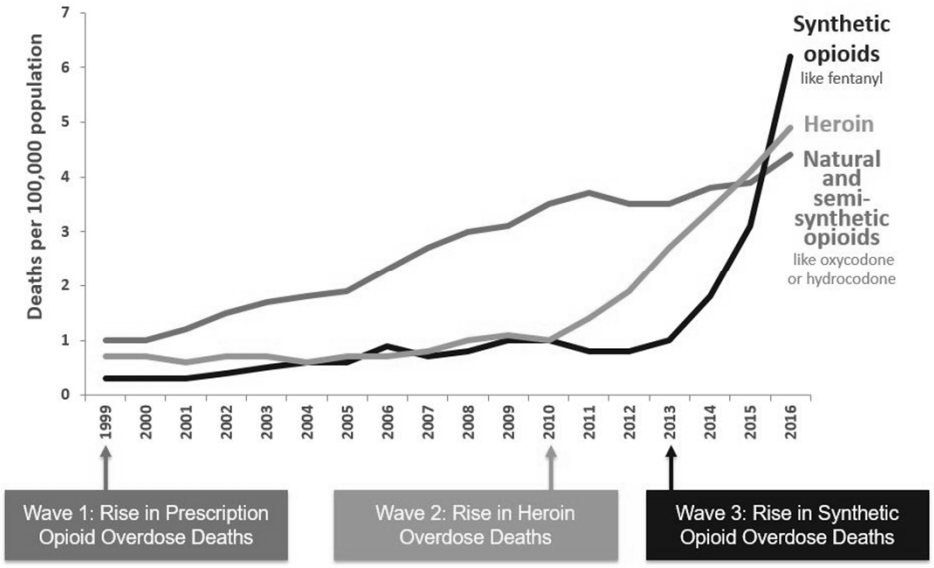
Star Tribune, Thursday, August 2: Minneapolis man received a 7 year sentence after pleading guilty to distributing highly potent opiate analogues

- "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.pdf; https://www.twincities.com/2018/08/02/minneapolis-man-sentenced-to-80-months-in-prison-for-opioid-distribution/



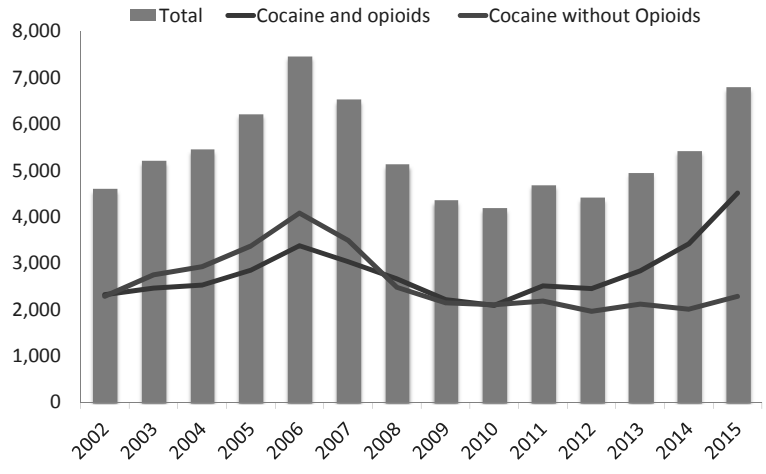
3 Waves of the Rise in Opioid Overdose Deaths



SOURCE: National Vital Statistics System Mortality File.

NIH National Institute on Drug Abuse

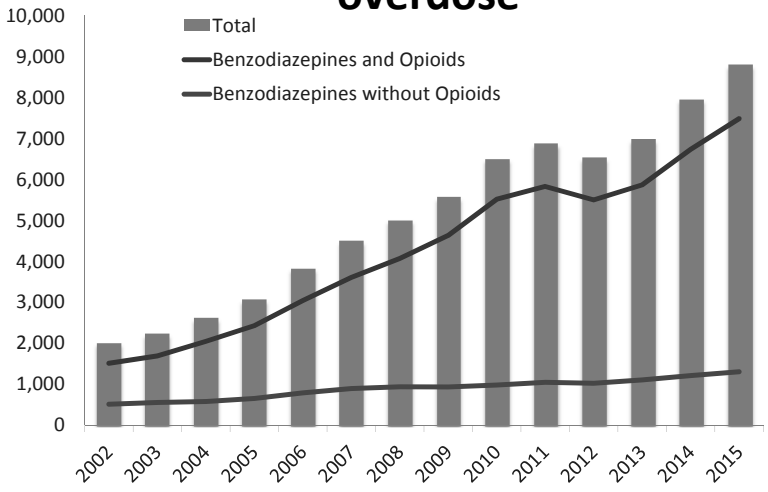
Opioid involvement in cocaine overdose



Source: National Center for Health Statistics, CDC Wonder

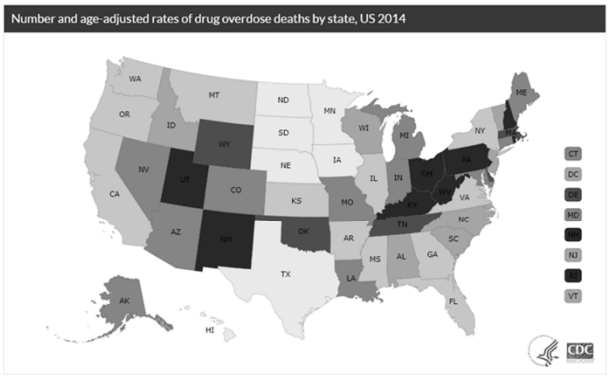
National Institute on Drug Abuse

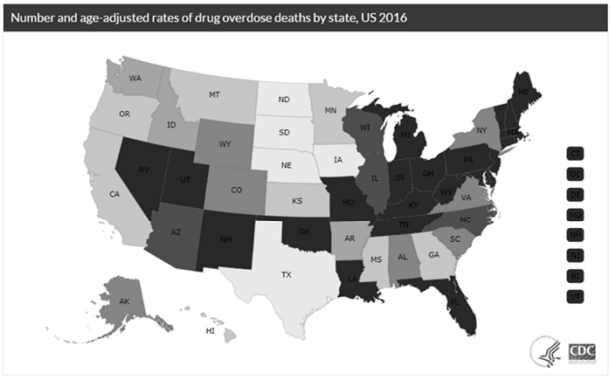
Opioid involvement in benzodiazepine overdose



Source: National Center for Health Statistics, CDC Wonder

AGE ADJUSTED RATES OF DRUG OVERDOSE DEATHS BY STATE, 2014 AND 2016





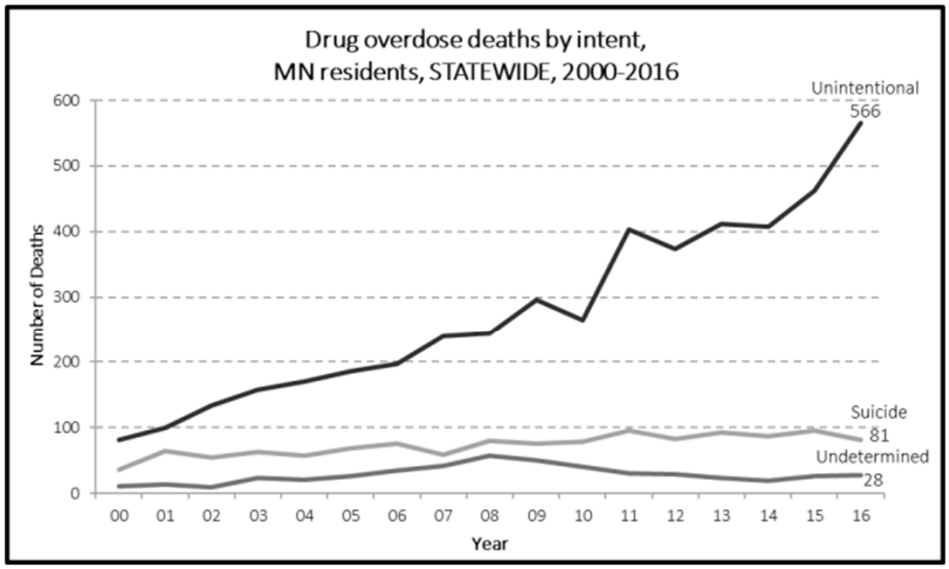
2014 Age-adjusted rate

- 6.3 to 11.0
- 11.1 to 13.5
- 13.6 to 16.0
- 16.1 to 18.5
- 18.6 to 21.0
- 21.0 to 35.5

Legend

- 6.9 to 11.0
- 11.1 to 13.5
- 13.6 to 16.0
- 16.1 to 18.5
- 18.6 to 21.0
- 21.1 to 52.0

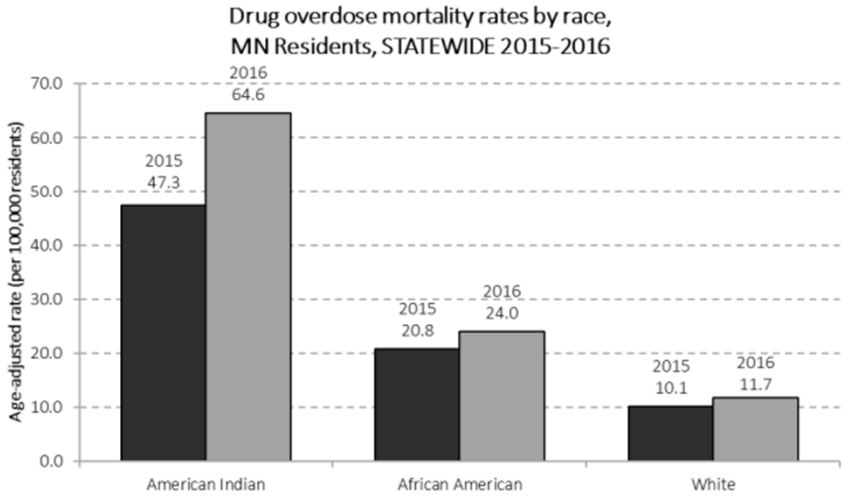
Source: https://www.cdc.gov/drugoverdose/data/statedeaths.html



SOURCE: Minnesota death certificates, Injury and Violence Prevention Section, Minnesota Department of Health, 2000-2016

Source: http://www.health.state.mn.us/divs/healthimprovement/content/documents-opioid/2016DrugOverdoseDeathReport_Final.pdf

RACIAL AND ETHNIC DISPARITIES ARE PRONOUNCED IN DRUG OVERDOSE MORTALITY RATES GENERALLY



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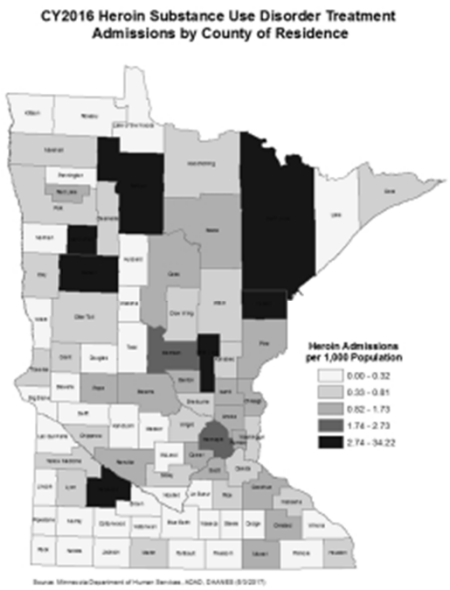
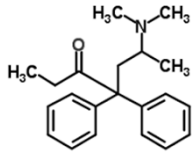
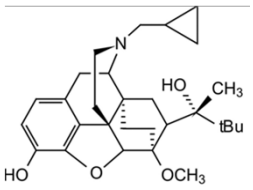




METHADONE AND SUBOXONE



- Methadone was first introduced in 1937 to treat opioid dependence
  - 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

ACCESSING TREATMENT

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
- Treatment plan and goals with documentation of progress must reflect weekly/monthly therapy sessions

Step 4: Admit to the program

- Complete program orientation
- 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
- 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

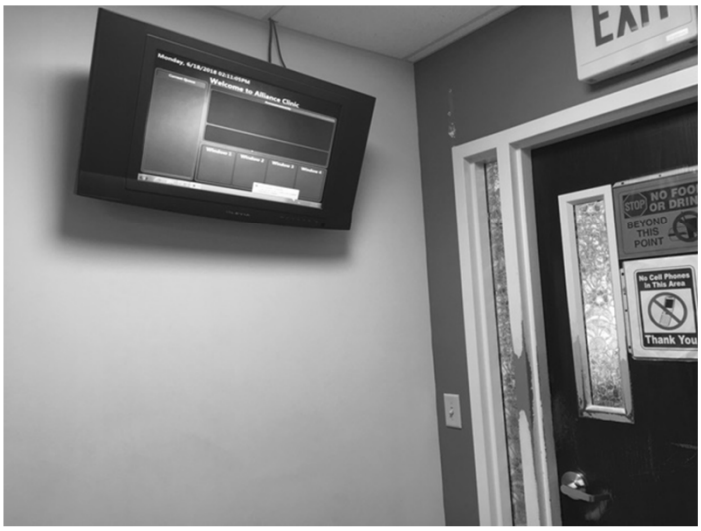
Central Registry:

- 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 Minnesota.
- 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 STEP 1: QUEUING UP



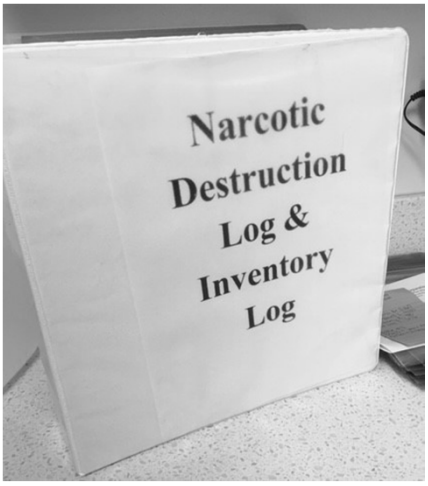
STEP 2: CLEARING FLAGS

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

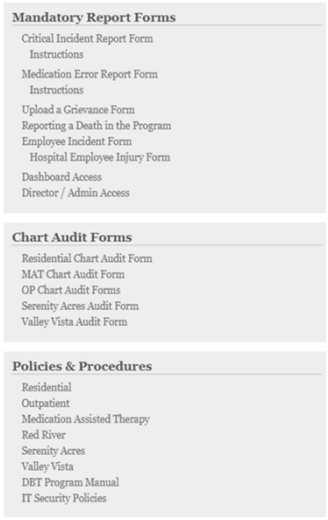
HOW DO WE MAINTAIN COMPLIANCE AND PROMOTE QUALITY CARE?

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
- Feedback loops allow for real time monitoring
- Employing coding and programming talent allows scalability and customization
  - 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



INCIDENT REPORTING

Lead employee completes critical incident report and sign off

Critical element: input other employee witnesses' email addresses

⇩

Additional witnesses will receive email to review and sign off

Critical element: Only add additional info if need be, otherwise sign off you agree

⇩

Director will review, complete questions and sign off

Critical element: Director assesses and answers additional questions

⇩

Compliance will review and determine additional steps to take

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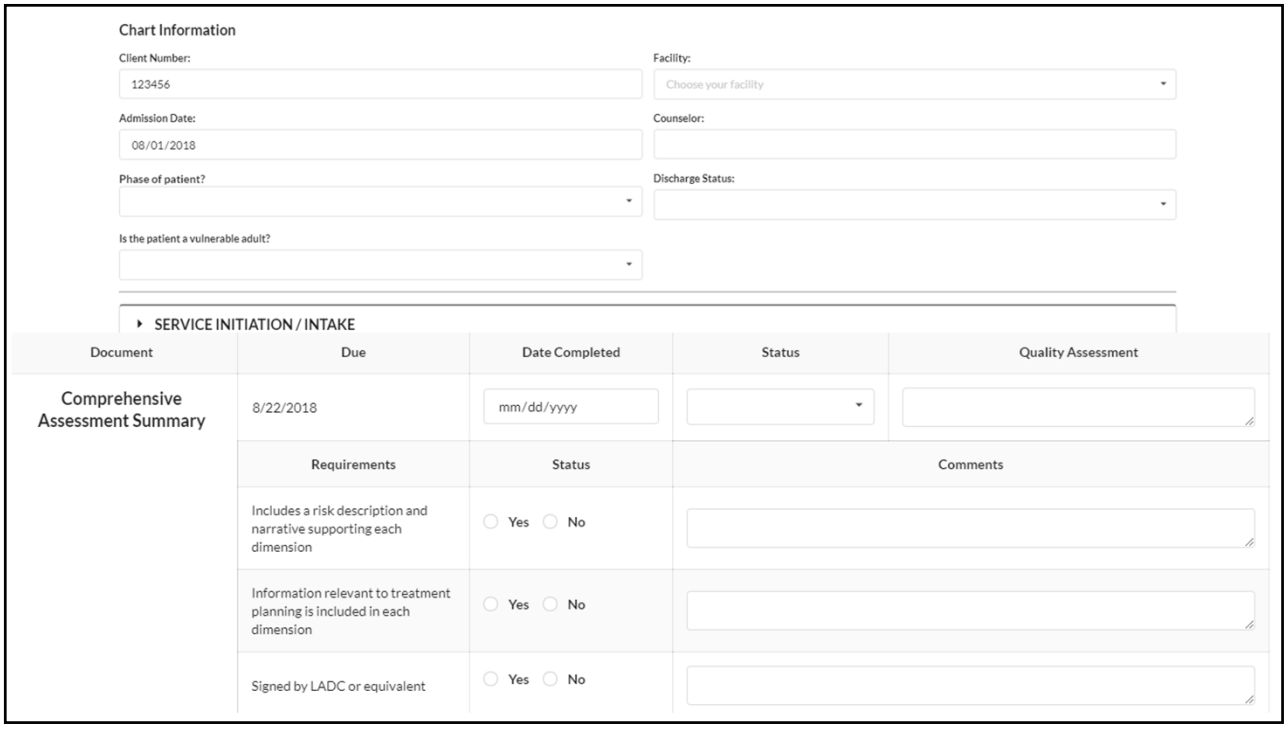
Chart Information
Client Number:
123456
Facility:
Choose your facility
Admission Date:
08/01/2018
Counselor:
Phase of patient?
Discharge Status:
Is the patient a vulnerable adult?
SERVICE INITIATION / INTAKE
MEDICAL
CLINICAL
SERVICE TERMINATION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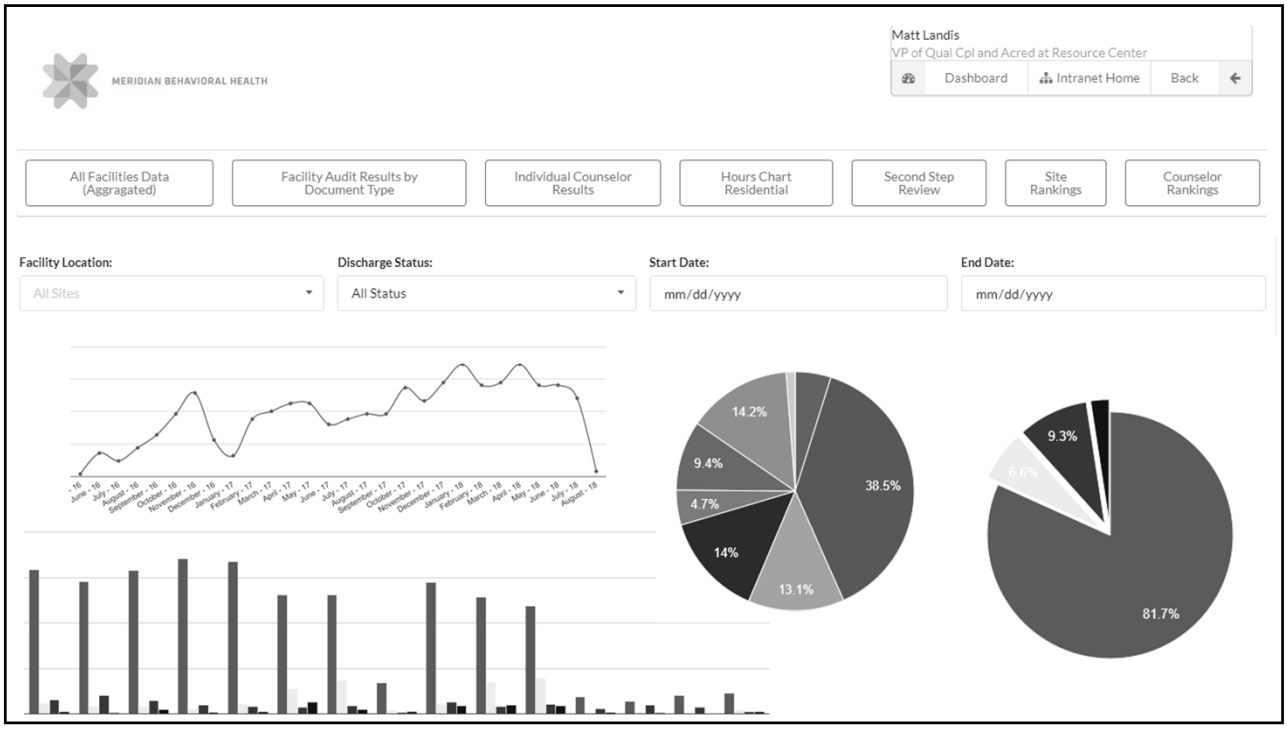
Counselor:
Phase of patient?
Discharge Status:
Is the patient a vulnerable adult?
SERVICE INITIATION / INTAKE
Document
Due
Date Completed
Status
Quality Assessment
Comprehensive Assessment Summary
8/22/2018
mm/dd/yyyy
Requirements
Status
Comments
Includes a risk description and narrative supporting each dimension
Yes
No
Information relevant to treatment planning is included in each dimension
Yes
No
Signed by LADC or equivalent
Yes
No



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
  - Data integrity and reliability (peer review challenges and implementing feedback loops)
- Getting buy-in from business partners
- Ongoing training and education

THANK YOU!

QUESTIONS?