Ethics and the Law

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The ASAM Review Course of Addiction Medicine

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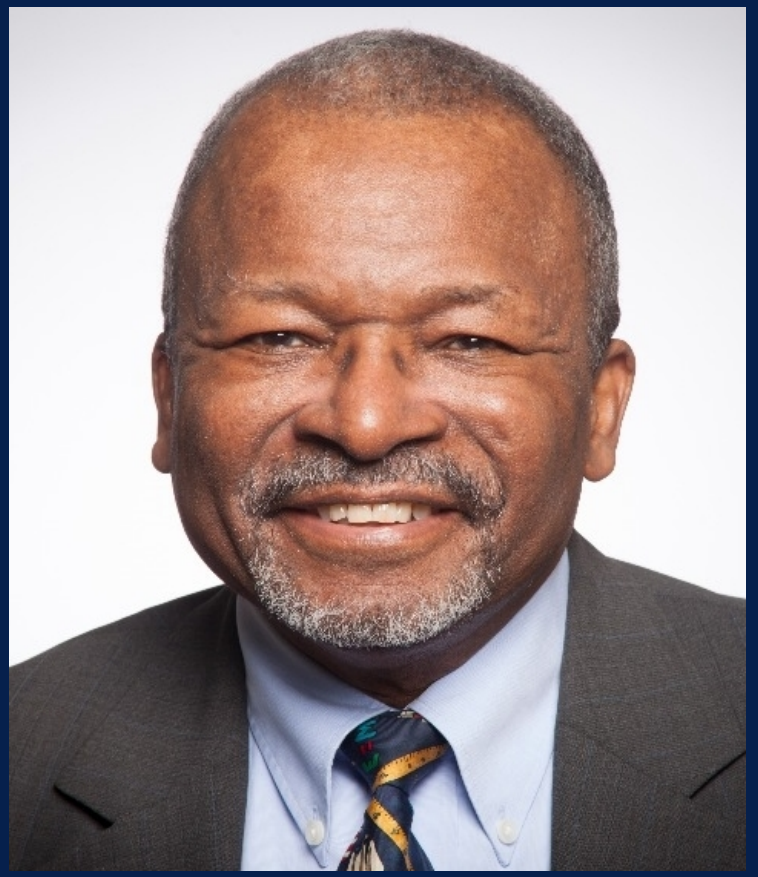
Financial Disclosures



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Disclosures:

- Consultant ABInBev Foundation
- Advisor, Responsility.Org
- Single Lecture for Indivior

Learning Objectives

Describe the ethical and legal considerations that impact treatment of patients with addiction.

Presentation Outline

Ethical Principles

Informed Consent

Privacy and Confidentiality

Ethical Prescribing

Special Topics

Ethical Principles

- Autonomy: self-determination, self-governance, moral independence
  - Example: Patient with recurrent upper GI bleed refusing voluntary inpatient addiction psychiatry admission

Ethical Principles

- Beneficence: actions should promote patient well-being
  - Example: A patient with a severe heroin use disorder sees PCP who offers him buprenorphine, referral to methadone treatment or inpatient withdrawal management and community recovery resources

Ethical Principles

- Non-maleficence: do no harm (or as little as necessary)
  - Examples: (1) Providing benzodiazepines for patients on high dose opioids or (2) prescribing buprenorphine without an exam for cash

Ethical Principles

- Justice:
  - Fairness in decisions
  - Equal distribution of resources and new treatments
  - Medical practitioners uphold laws
  - Examples: (1) Advocating for a patient rejected from inpatient addictions treatment when the insurance provider deems it “not clinically indicated” or (2) Accepting cash only for the use of buprenorphine or naltrexone, limiting access to treatment .

Ethical Principles

- Respect for people: treating people in a manner that acknowledges their intrinsic dignity
- Truth-telling: honesty, sharing information

Complex Ethical Scenario

- 40-year-old female anesthesiologist
- Taking opioid medications meant for patients, replacing with saline
- Has used oral opioids on the job but denies problems
- Asks you to notify nobody

Informed Consent

- Voluntariness
- Information disclosure
- Decisional capacity

Voluntariness

- Freely given
- Coercion: punishment or excessive rewards
- Persuasion
- Influence
- Context-dependent
- Risk of infringing
  - SUDs treatment in custody
  - Drug court
  - Inpatient treatment

Information Disclosure

- Nature of illness and proposed treatment
- Risks/benefits
- Alternatives
- Consequences of foregoing treatment
- “Reasonable person” standard
- High standard of disclosure
  - Addictive medications (opioids)
  - Medications with known adverse events (disulfiram)
  - Medication combinations that should be avoided with MAOIs (methadone, bupropion, tramadol, etc.)

Decisional Capacity

- Communicate a choice
- Understand the relevant information
- Appreciate the situation and its consequences
- Reason about treatment options
- “Sliding scale” approach
- Potentially impaired
  - Intoxication
  - Substance-related neurocognitive problems
  - Dual diagnosis

For Those Lacking Capacity

- Durable power of attorney for healthcare decisions (DPOAHC): form identifying surrogate decision-maker if one becomes incapacitated
- Advanced directive/living will: written statement expressing specific wishes, does not designate healthcare POA
- Guardian/conservator of the person: person appointed to make care decisions when patient is incapacitated

Pearls

- There are various ethical principles underlying medicine and addictions treatment that may come into conflict
- The process of informed consent requires voluntariness, information disclosure, and decisional capacity
- Certain treatment settings have the potential to infringe on voluntariness

Privacy and Confidentiality

- Privacy: patient's right to protection of sensitive information
- Confidentiality: clinician's obligation to protect sensitive information
- 42 CFR Part 2: Confidentiality of Alcohol and Drug Abuse Patient Records
- HIPAA

42 CFR Part 2 – Covered Programs

- Individual, entity, or identified unit within a general medical facility that provides SUDs diagnosis, treatment, or referral for treatment
- Medical personnel/staff in a general medical facility whose primary function is provision of SUDs diagnosis, treatment, or referral for treatment

42 CFR Part 2 – Federal Assistance

- Conducted in a federal department or agency
- Supported by federal funds
- Carried out under a license or registration from federal government
  - Medicare providers
  - Authorization to conduct maintenance treatment or withdrawal management
  - Registration under Controlled Substances Act to dispense a substance used in treatment of SUDs

Disclosure

- Part 2 programs may only release patient information with the patient's consent
- Exceptions include:
  1. Medical emergency
  2. Error in manufacture, labeling, or sale of a product under FDA jurisdiction
  3. Research
  4. Valid court order with subpoena
  5. Crimes committed on part 2 program premises
  6. Reporting suspected child abuse or neglect
- Failure can result in criminal penalty (a fine)

HIPAA (‘96), Privacy Rule (‘00)

- All PHI protected
- Exceptions related to medical operations and public interest/benefit
- SAMHSA working to revise 42 CFR Part 2

Controlled Substance Act (1970)

- Classification and regulation
- Manufacturing
- Distribution
- Exportation and sale

CSA Regulation/Classification

- DEA licensure requirement
- Schedule I: illegal, no medical use (cannabis, MDMA, methaqualone, gamma-hydroxybutyric acid (GHB), peyote)
- Schedules II-V: addictive potential
  - II: cocaine, methamphetamine, methadone, phencyclidine, oxycodone, fentanyl
  - III: ketamine, testosterone, buprenorphine, sodium oxybate
  - IV: benzos, zolpidem, tramadol,
  - V: diphenoxylate, pregabalin, *

* As of March 2022, gabapentin is not controlled under the CSA, but a number of states have made it a Schedule V drug. The DEA has been requested to reschedule gabapentin schedule V.

Ethical Prescribing

- Patient risks
  - SUDs
  - Diversion
  - Exacerbation of comorbid medical or psychiatric illness
- Practices to address
  - Urine drug testing
  - Medication contract
  - PDMPs

Universal Precautions

1. Make a diagnosis with appropriate differential, including a physical exam
2. Psychological assessment (risk of addictive disorders)
3. Obtain informed consent
4. Treatment agreement
5. Pre- and post-intervention assessment of pain level and function
6. Appropriate trial of opioid therapy +/- adjunctive medication
7. Reassess pain score and level of functioning
8. Regularly assess 4 A's: analgesia, activity, adverse effects, aberrant behavior
9. Periodically review diagnosis and comorbid conditions
10. Documentation

Legal Consequences

- Misprescribe: inappropriate rationale, dose, quantity, lack of physical examination
- CSA: “unlawful for any person to knowingly or intentionally… manufacture, distribute, or dispense, or possess with intent… a controlled substance”
- Knowingly or Intentionally
- Without legitimate medical purpose
- Outside the usual course of professional practice

  - State medical board sanctions
  - Civil: malpractice
  - Criminal: CSA, murder

Recent Case

- James Pierre, MD.
- From June 2015 through July 2016
- Unlawfully prescribing over 1 million pills of hydrocodone
- People paid cash $220 to $500 for each visit.
- Physician convicted by a jury

Prescription Drug Monitoring Programs

- 49 states (MO pending), D.C., Guam
- Mitigate abuse/diversion
- Models
  - Non-mandated use
  - Proactive reporting
  - Mandated use
- Criticisms
  - Inadequate information collection
  - Ineffective utilization in clinical settings
  - Limited interstate sharing
- Mixed data on effectiveness, differs by state

Pearls

- Confidentiality of substance abuse treatment is governed by 42 CFR Part 2, HIPAA, and the Privacy Rule
- The Controlled Substances Act of 1970 established the DEA regulation and classification of addictive drugs and criminal penalties for distribution of drugs
- There are various models of ethical prescribing that generally involve informed consent, regular assessment and dose planning, and appropriate clinical documentation
- PDMPs, though potentially helpful, differ in their implementation and effectiveness

Addiction & the Law: Special Topics

- Adolescents
- Pregnant patients
- Justice-involved populations
- Civil commitment & substance use
- Americans with Disabilities Act (ADA)
- Impaired Clinician

Adolescents, Addiction, & the Law

Legal Standards: Minor Informed Consent

- Age of majority
- Minor's ability to consent
  - General medical care
  - Mental health
  - Substance use disorders
- Emancipation
  - Legal
    - Marriage, military
  - Other forms
    - Mature minors
    - Have children
    - High school graduate

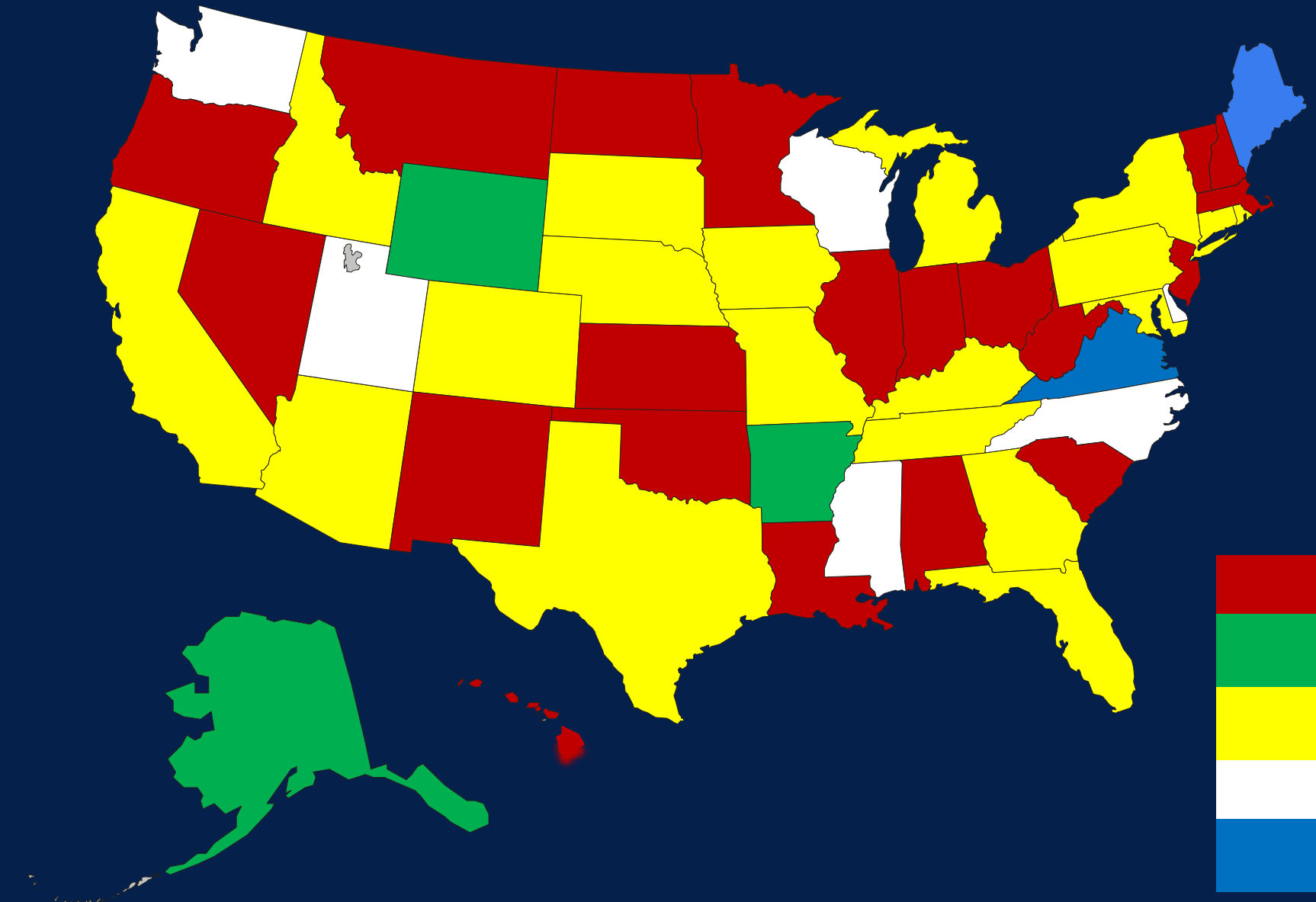
Mature Minor Doctrine

- Definition
- Assessment of maturity:
  - Age & maturity
  - Emotional capacity
  - Intelligence
  - Risk of procedure/treatment
  - Benefit to minor
- Informed consent assessment:
  - Risks of forgoing treatment
  - Long term consequences
- Brain development, impulsivity & “charged” environments

Minor Consent for SUD Treatment

- Laws vary by state
- Minimum age of consent can range from age 12-16
- May be able to consent to some services but not others
  - Withdrawal Management
  - Outpatient
    - Buprenorphine for those 16 -18
  - Inpatient
- Parental notification may still be required

Consent for Inpatient Substance Treatment
Kerwin et al. (2015)



Adolescent Autonomy, Privacy & Confidentiality

- Parental involvement
- Confidentiality can be preserved
- Insurance & privacy

Pearls

- State laws vary regarding minor consent requirements and may allow for a mature minor to consent
- Adolescents usually have the greatest autonomy to consent for substance use disorder treatment compared to other medical treatments
- When treating an adolescent patient, involve parents if possible while preserving the adolescent's confidentiality

Pregnancy, Substance Use, & the Law

Legal Consequences Of Substance Use In Pregnancy

- Criminal
  - Feticide laws (38 states)
  - Chemical endangerment of a child (Amnesty)
  - Direct criminalization of use during pregnancy
- Civil
  - Substance Use = Child Abuse (24 States +DC)
  - Reporting to Child welfare (25 states + DC)
  - Civil commitment (3 states)

Reporting Requirements to Child Welfare (Jarlenski, Guttmacher. Org)

- Mandated reporting of child abuse/neglect
  - Standard: Reasonable belief or suspicion for abuse
  - Prenatal drug use & Substance Exposed Newborns
- Clinical & ethical problems
- Guidelines
  - Inform of any mandated reporting requirements & limits of confidentiality
  - Obtain informed consent before drug testing (ACOG)

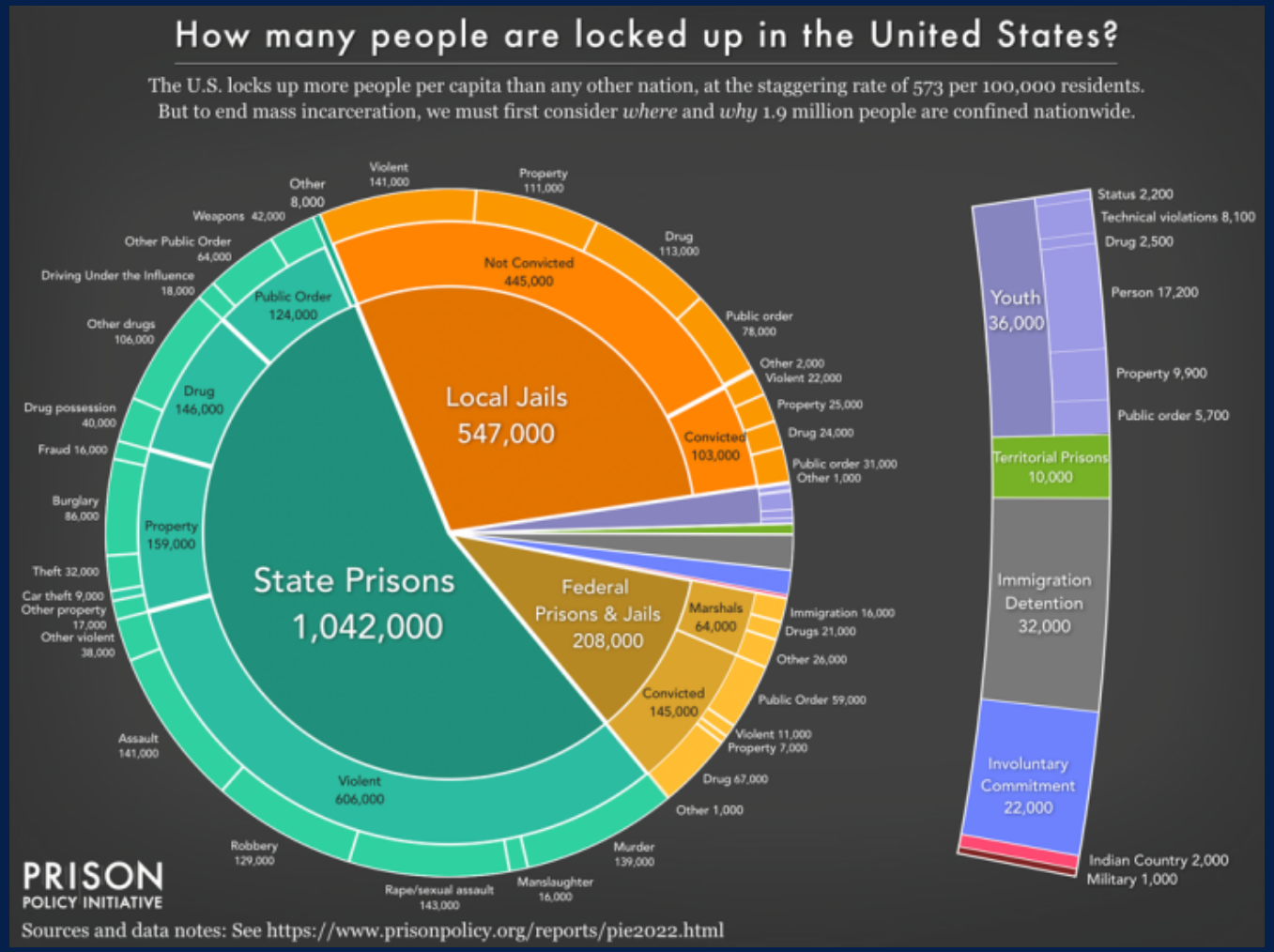
Pearls

- A person who uses substances during pregnancy can be subjected to civil or criminal penalties in many states
- Mandated reporting requirements of perinatal substance use vary across states
- Obtain informed consent before drug testing, including notification of reporting requirements

Justice-Involved Populations

Statistics

- In 2019, 6.3 million people under correctional supervision in the U.S.
- History of incarceration in the U.S.
- SUDs & incarceration
  - Over 50% with active SUD
    - >75% of women have SUD
  - ~10- 15% receive treatment



MAT in Corrections

- The Need
  - 75% will relapse within 3 months of release (SAMHSA)
  - 100x more likely to die of overdose within 2 weeks of release (BJS, Binswanger)
- Barriers
  - Lack of education
    - Substituting “one drug for another”/abstinence mentality
  - Diversion concerns
  - Cost
  - Lack of community providers to start or continue MAT
- BUT, more pilots across the US

Problem Solving (Treatment) Courts

- Drug, mental health, DUI, veteran's courts
- Therapeutic Jurisprudence
- Judge plays critical role
- Entry & Eligibility
- Structure & sanctions
- Efficacy (Logan)
  - Recidivism decreases
  - Future drug use reduced
- Treatment provider can be in dual role
- Some do not allow MAT (Matusow)

FINAL TOPICS

- Civil commitment
- The Americans with Disabilities Act (ADA)
- Impaired Physicians

Civil Commitment

- Standards
  - Mentally ill (or substance disorder, below) AND
  - Dangerous to self/others OR
  - Gravely disabled
- Substance use disorders
  - 37 states + DC (NAMSDL)
- Legal process
  - Due process required
  - Hearing occurs in timely manner
  - Committed for specified time by the judge

The Americans With Disabilities Act (ADA)

- Disability: Physical or Mental impairment which:
  - Limits in one or more major life activities
  - History of impairment
  - Regarded as having an impairment
- Substance use
  - Alcohol use disorder
  - Other substance use disorders
    - Protected: Not using now but is or has been in treatment for addiction or regarded by others as using drugs
    - Not protected: “Currently using drugs” or casual user
- Exceptions

Physician Regulation & Impaired Physicians

- Medical practice acts & state medical boards
- Physician health programs & impaired physicians
  - Exist in nearly every state
  - Goals
  - Voluntary vs. mandated treatment
  - High success rates
- Duty to report impaired physicians:
  - Impairment: physical, mental or substance-related disorder that interferes with abilities to safely and competently perform professional duties
  - Legal standards (have knowledge of or reason to believe) & options
  - Ethical and professional duties

Questions?

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- Complete bibliography available on request

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