**Ethics and the Law**

**Session Outline**
**Session Speakers:**
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**Please note that none of the session or outline content is intended to be legal advice.**
**These materials are provided for board review only.**

- Ethical principles
    - Autonomy: self-determination
    - Beneficence: actions should promote patient well-being
    - Nonmaleficence: do no harm (or as little as necessary)
    - Justice: fairness in decisions, equal distribution of resources, uphold law
    - Respect for people: acknowledge people's intrinsic dignity
    - Truth-telling: honesty, sharing information
    - Clinical situations may place ethical principles at conflict
    - The goals of physicians and patients may result in ethical conflicts
- Informed consent = voluntariness + information disclosure + decisional capacity
    - Voluntariness: given freely
        - Consider coercion, persuasion, external influences, context
        - Addictions considerations: 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: what a reasonable person in the same situation would wish to know about condition/treatment
        - Addictions considerations: addictive medications, harmful medications (e.g., disulfiram), dangerous medications (e.g., methadone)
    - Decisional capacity: communicate a choice, understand relevant information, appreciation situation and its consequences, reason about treatment options
        - "Sliding scale" approach: greater risks, greater capacity required
        - Addictions considerations: intoxication, substance-related neurocognitive problems, dual diagnosis
    - Alternatives for patients lacking capacity
        - Durable power of attorney for healthcare decisions: form designating a surrogate decision-maker if one is incapacitated
        - Advanced directive/living will: written statement expressing specific wishes
        - Guardian/conservator of the person: appointed to make decisions when patient is incapacitated
- Privacy and confidentiality
    - **Pr**ivacy: **P**atient's **R**ight to protect sensitive information
    - **Co**nfidentiality: **C**linician's **O**bligation to protect sensitive information
    - 42 CFR Part 2: Confidentiality of Alcohol and Drug Abuse Patient Records
        - Original purpose was to protect patients' SUD records from disclosure to law enforcement, which could be used in criminal prosecutions (absent a viable court order)
        - Requires explicit patient consent to release records if the patient is receiving SUD treatment from a covered entity or provider, with limited exceptions
        - Know who is considered a 42 CFR Part 2 Program: Entities and/or providers which are federally assisted (i.e., certified Medicare/Medicaid provider, receiving federal funds, licensed to prescribe or dispense methadone/buprenorphine) and

meet the definition of a "program" (stand alone outpatient/inpatient SUD providers, a SUD treatment unit in a FQHC, SUD treatment centers within medical centers). Note, not all federally assisted providers delivering SUD treatment are Part 2 Providers (Is the provider's primary function to provide diagnosis, treatment and/or referral for SUD?)

    - Even if you are not a Part 2 provider, any lawful holder of Part 2 information is bound to Part 2 restrictions on confidentiality
    - Resource: https://www.samhsa.gov/about-us/who-we-are/laws-regulations/confidentiality-regulations-faqs
  - HIPAA, Privacy Rule: Health Insurance Portability and Accountability Act
    - All protected health information is protected
    - Exceptions to confidentiality under limited circumstances
    - SAMHSA is working to revise 42 CFR Part 2 to bring it in line with HIPAA
- Regulation of controlled substances
  - Controlled Substance Act of 1970
    - Regulates classification/regulation, manufacturing, distribution, exportation, and sale of controlled substances
    - Established DEA licensure requirement
    - Established controlled substance Schedules I (illegal, no medical use) through Schedule V
  - Ethical prescribing
    - Consider addiction risks, diversion, and exacerbation of comorbid conditions
    - Universal precautions in pain management provide a guideline
    - Legal consequences of misprescribing: state medical board sanctions, civil malpractice litigation, criminal charges (under CSA or state laws)
  - Prescription drug monitoring programs
    - Established in 49 states, DC, and Guam to mitigate abuse and diversion
    - Models: (1) non-mandated use, (2) proactive reporting, (3) mandated use
    - Mixed data on effectiveness across jurisdictions
- Adolescents & Addictions
  - Informed consent to treatment
    - Age of majority is 18 in most states
    - State law determines standards and ages for minor consent to treatment
      - Most states allow minors to consent to some substance services
      - Some states allow minors to consent to mental health
      - Most states require parental consent for general medical care
    - If legally emancipated, a minor is usually legally capable of providing informed consent
    - Mature Minor Doctrine (~14 states)
      - Recognition that some minors may be capable of providing informed consent if emotionally and psychologically mature
      - Physician may assess and determine if a "mature minor"
      - Physician still must document that the mature minor demonstrated adequate informed consent & decisional capacity, similar to an adult patient
  - Parental involvement in treatment
    - State laws
      - Parental consent alone required
      - Minor consent alone-most states
      - Parent or minor consent-most states

        - Parent and minor consent both required
    - Inpatient vs. detox vs. outpatient substance treatment may have differing requirements
    - Notification vs. Consent
        - Some states require notification but not informed consent from parents when a teen enters or receives SUD treatment
  - Autonomy & confidentiality
    - Laws which allow teens to access services without parental involvement are meant to increase access to treatment
    - Majority of teens though are justice-referred to SUD treatment
    - Parental involvement can actually be a good thing and is preferred. Confidentiality can still be preserved.
    - Beware of insurance issues and limits of privacy. Beware of Explanation of Benefits (EOBs) which may go to the parent and not the teen, depending on coverage.

    - Drug testing
        - Unless in an emergency or an incompetent adolescent, do not drug test a teen without consent and/or informing him or her
- Pregnancy, Substance use & the Law
  - Legal consequences
    - Criminal
        - Women can be prosecuted under existing feticide laws which prohibit intentional or unintentional harm or death of a fetus
        - Chemical endangerment laws: women can be prosecuted (particularly in Alabama) at any stage of pregnancy for using substances
        - Tennessee had a law, which expired in 2016, that specifically criminalized use of substances in pregnancy
    - Civil
        - Child welfare laws (23 states +DC)
        - Civil commitment (3 states)
    - Constitutionality
        - It is unconstitutional for health providers to drug test pregnant women without their informed consent if for the <u>sole</u> purpose of a criminal investigation
  - Provider reporting requirements to child welfare
    - Over half the states have reporting requirements for substance exposed newborns
    - Reporting for prenatal drug use is less clear
        - Is the provider required vs. discretionary reporting? Language is vague
        - Some states treat a positive urine tox at delivery as presumption of abuse/neglect and require reporting by the healthcare provider
        - Hospital policies may incentivize over reporting
    - Ethical & legal issues
        - Use does not necessarily equate to abuse, harm and/or impaired parenting
        - Does a positive urine toxicology= abuse or neglect?
        - Problematic “obligation” of the provider in reporting if no suspicion of abuse or neglect
    - ACOG recommends drug testing of the pregnant women <u>only</u> with informed consent, which includes notification of mandatory reporting requirements

    - Reporting of Child Abuse
        - Generally, the standard in most states is for a mandated reporter who has "reason to suspect or believe" abuse or neglect is occurring to report it
        - This is a low bar and subjective standard
        - Keep in mind that mandated reporting is an exception to confidentiality. Patients should be informed of the requirements to report (including other situations, such as imminent violence) at the outset of treatment
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- The Criminal Justice System
    - The U.S. is the top incarcerator in the world
    - Incarcerated population peaked from the 1980s onward due to a number of enhanced sentencing laws, "tough on crime" approach and the War on Drugs
    - Estimates are that 50-80% of prisoners have a substance use problem. ~60% with a SUD
    - Only ~10-15% receive treatment for addictions that is evidence based
    - Access to substance treatment in jails and prisons is inconsistent and may be extremely limited, especially in terms of MAT
    - Other barriers: restricted jail formularies, opinion that MAT is a drug of abuse/diversion, insurance stopped or suspended upon incarceration (county or state foots the bill); not enough qualified providers in the community to start or continue.
- Problem solving courts: Drug Courts
    - PSCs evolved as therapeutic alternatives to incarceration. They divert individuals from prison or jail back to the community and treatment while monitoring their progress
    - Participants enter and must:
        - Be under court supervision, commonly having a probation officer
        - Attend regular (often weekly in initial stages) court dates
        - Adhere to treatment recommendations
        - Comply with drug testing
        - Abstain from drugs/alcohol
    - In exchange for program completion, participants may have their charges reduced or dismissed, and/or avoid prison time
    - Treatment providers often communicate regularly with the drug court, with the participant's consent
    - Pros: Overall, drug courts work to reduce recidivism & decrease drug use
    - Cons: Participants may feel as if they have no choice but to enter a PSC, a treatment provider can feel conflicted regarding their duty to the patient and their "obligation" to provide information to the drug court/danger of becoming de facto probation officer, MAT may be under-utilized or not allowed (specifically, buprenorphine)
- Special Topics
    - Civil commitment
        - Every state allows under concept of parens patriae (state must protect those who cannot protect themselves)
        - You must be Mentally ill AND Dangerous
        - Legal process
            - Due to the loss of liberty involved, due process is required
            - This includes a judicial hearing with notice and attorney representation
            - Commitment is consistently reviewed by a judge to determine ongoing appropriateness
        - Substance use disorders
            - Most states allow substance use as the grounds for commitment
            - Two states only allow for "alcoholism" and do not mention drugs

            - Most states have laws that are separate for commitment of “standard” psychiatric disorders vs. addictions
- The ADA
    - Definitions
        - Disability is: a mental/physical impairment that limits one or more major life activities, a history of impairment, or someone regarded as having an impairment
        - Qualified individual: In the realm of employment, the person seeking a job must be, despite the disability, otherwise qualified for the job and able to perform the job with reasonable accommodations
        - Exception to ADA: Direct threat. If person poses direct threat, do not have to accommodate (i.e., showing up to work intoxicated, threatening others with violence, etc.)
    - Substance use
        - Alcohol use disorder is protected
        - Substance use disorder other than alcohol
            - Protected: Not using drugs, in treatment or has been in treatment, or erroneously regarded as a drug user
            - Not protected: Current user, casual user
    - Discrimination: Beware of ADA violations (Ex: person denied employment because she takes buprenorphine without consideration if buprenorphine actually causes her side effects that would inhibit performance)
- Social Security Disability
    - **Social security income** is a means tested benefit for elderly, blind or disabled individuals who meet general low income requirements
    - **Social security disability** insurance is an entitlement program for a disabled person to receive benefits based upon money they have paid into the system
    - Definition of disability
        - Inability to engage in substantial gainful activity due to a medically determinable physical or mental impairment that has lasted or is expected to last for at least 12 months or result in death
    - Addictions & Disability
        - Since 1996, an addiction cannot be the sole basis for a disability
        - SUD must be immaterial to the disability at hand
        - But-irreversible conditions caused by substance use may count (neurocognitive disorder, end stage liver disease)
        - Co-occurring disorder (schizophrenia with alcohol use disorder) should still be eligible
- Physician Licensing & Regulation
    - Medical practice acts (MPA)
        - Every state + D.C. has a MPA which defines the practice of medicine in the given state and delegates authority to enforce the law to the state medical board/licensing authority
        - State medical boards often have a contractual relationship with physician health programs, or even run the PHP themselves
    - Impaired physicians
        - Some estimates that up to 12% of physicians may develop a SUD during their career
        - Duty to report

                - Ethically, physicians have duty to report based upon the social contract
                - Legally, they may be required to report to the SMB
            - Be careful to not conflate presence of an illness with impairment
            - The ADA protects physicians, like other employees who are involved in substance treatment, who are not actively using drugs/alcohol but are discriminated against because of their substance use
        - Physician health programs
            - Voluntary track: “normal” confidentiality and privacy if self referred, although must comply with PHP recommendations or may be reported to the SMB
            - Mandated treatment: Results in license suspension, revocation or other penalties if don’t comply or finish treatment
            - The FSMB recommends monitoring for relapse for at least 5 years for an addictive illness
            - One area of controversy has been that PHPs have a fiduciary relationship with SMBs and this may lead to a conflict of interest in treating physician-patients. Physicians often have no way to directly appeal assessments of the PHP
    - Questions???
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