WHEN LAW AND ETHICS COLLIDE . . .
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AGENDA

- Privacy laws
- Prescription monitoring laws
- Ethics implications under both

SOURCES OF PRIVACY RULES

- Federal Law
  - HIPAA – really quite limited law (permissive – may disclose)
  - 42 USC § 290 dd-2 – quite restrictive law
- State Law – hidden source of privacy issues
  - Medical Privacy
  - Mental Health Privacy
- Ethics
  - Section 4.2 (confidentiality)
CONFLICTS IN PRIVACY RULES

HIPAA:
- Disclose for treatment/payment purposes without consent
  - Medication prescription/monitoring
  - Start/stop times
  - Modalities and frequencies of treatment
  - Test results
  - Summary of diagnosis, functional status, treatment plan, symptoms, progress to date
- Applies only to those electronically submitting information

Psychotherapy notes need express authorization:
- What
- To whom (or class)
- Purpose
- Dates
- Signature

NOT producible in response to subpoena unless do not keep separate.

42 USC §290DD-2
If any program or activity is
- conducted regularly, directly or indirectly; and
- assisted by any U.S. department or agency, then records of identity, diagnoses, prognoses, or treatment of any patients which are maintained in connection with any program or activity relating to substance abuse can only be disclosed:
  - in bona fide medical emergencies; or
  - within a program on a need to know basis; or
  - to authority with administrative control over program
NB: Legislation being considered to eliminate in favor of HIPAA
OCR ADVISORY ON MENTAL HEALTH

- Family, Friends or others involved in Patient’s care:
  - Permission to disclose
  - Inform of intent to disclose and opportunity to object
  - Infer from circumstances using professional judgment that patient does not object

- Patient with capacity objects:
  - Disclose consistent with law and ethics
  - Good faith belief serious risk to health and safety of self or others

OCR ADVISORY ON MENTAL HEALTH

- Patient without capacity:
  - Patient cannot give agreement or object
  - In patient’s best interest to disclose
  - Person is the appropriate person to share it with all determined in exercise of physician’s professional judgment

  **Hint:** Document, document, document

  **NB:** Legislation in Congress to relax further

DISCLOSURE UNDER HIPAA

**MINIMUM NECESSARY** standard applies, **except**:

- Disclosure to individual, personal representative, or subject of the information
- Disclosure to HHS for complaint investigation or compliance review
- Disclosure required by law
HIPAA VS. MINNESOTA STATE LAWS

Preemption: Federal rules apply when MN laws are contrary to HIPAA – meaning it would be impossible to comply with both, or if MN law is obstacle to satisfying HIPAA.

Exceptions:
- When MN law provides greater privacy protections or rights with respect to patient’s health information
- When reporting of disease or injury, child abuse, birth, or death, or for public health surveillance, investigation, or intervention
- When required for certain health plan reporting, such as management or financial audits

MN DIFFERENCES FROM HIPAA

1. Mental health records and psychotherapy notes are part of medical record to assure greater access to patients
   - But allows clinical judgment in release of all medical records, e.g. may cause harm to patient or others
2. MN Statutes §144.291-298: Patients are entitled to records, without charge unless it would be detrimental to patient or others to give them to patient
3. Does not only apply to those transmitting information electronically
4. Must get consent for transmission for payment purposes
5. Express not implied authorization to share with family

Minimum necessary disclosure allowed to law enforcement agency allowed when:
- Patient is involved in emergency interaction with agency; and
- Disclosure is necessary to protect health or safety of patient or other
SUGGESTION: AUTHORIZATION FORM FOR PATIENTS

• Express authorization AND consent for specific information for specific uses
• Permission if doctor judges them to be incapacitated and identify person to tell
• Include all requirements from state laws
• Extend from beginning of relationship until terminated
• Signature and date required
• Should solve issues raised by conflicting rules
• Let patient know if you intend to disclose or after

“TARASOFF RULE” IN MINNESOTA

• Minnesota Statutes §148.975
• Duty to warn and liability arises only when patient has communicated a specific, serious threat of physical violence against a specific, clearly identified or identifiable potential victim
• No duty to warn of threat by patient to commit suicide or inflict self harm, or threat by a patient who is adjudicated “mentally ill and dangerous” under chapter 253B.

ETHICS PRINCIPLES

• Section 1 – physician shall be dedicated to providing competent medical care, with compassion and respect for human dignity and rights.
• Section 3 – physician shall respect the law and also recognize a responsibility to seek changes in those requirements that are contrary to the best interest of the patients.
• Section 4 – physician shall safeguard patient confidences and privacy within the constraints of the law
• Section 8 – responsibility to the patient is paramount
ETHICS

• Can only release confidential information under proper authorization of the patient or under proper legal compulsion
  • Authorization: Is HIPAA implied consent “proper authorization”?  
  • Legal Compulsion: subpoena, mandatory laws “shall”

• Conflicts with HIPAA, not with many state or with SUD disclosure requirements

ETHICS vs. LAW:
WHAT IS A POOR DOC TO DO?

• Hospital system requires use of electronic health records.
  • What is proper authorization?  
  • Job requires it, is it legal compulsion?

ETHICS OPINION

• Hospital system uses electronic health records, patients sign hospital privacy form
  • Answer: psychiatrist should include limited HIPAA information and inform patient during the course of treatment that he is using EHR and who has access and let patient know when he speaks to another health care provider.

• Patient has lucid and non lucid moments. Concern that he will not take medications. Has told you he does not want kids to know his condition
  • Can you tell them under HIPAA? 
  • Is it ethical?

• Answer: HIPAA allows psychiatrist to speak to patient’s family if implied consent.

• Ethics: Express consent except emergency/incapacity
**Ethical Issues:**

- Competent care
- Patient autonomy
- Trust relationship
- Confidentiality

**BACKGROUND**

**Increasing problem of drug diversion:**

- Unlawful channeling of regulated pharmaceuticals from legal sources to illicit marketplace
  - "Doctor shopping" – requesting care from multiple physicians simultaneously to get more prescriptions
  - Illegal internet pharmacies
  - Drug theft
  - Prescription forgery
  - Redistributing to friends and relatives
  - Opioid analgesics are most widely prescribed and abused
**PRESCRIPTION DRUG MONITORING PROGRAMS – WIDELY USED**

- 48 states have mandatory reporting requirements –
- Maintain statewide electronic database of designated information on specified prescription drugs dispensed within the state
- Data is available to prescribers, law enforcement officials, licensing boards, and practitioners who have been granted access
- Interstate data sharing
- Ethical Concerns for inputting patient data??

**REPORTING REQUIREMENTS – WHAT?**

State statutes vary greatly:
- 15 states require reporting for Schedules II-V controlled substances
- 20 states require reporting for Schedules II-IV and Drugs of Concern
- 12 states require reporting for Schedules II-IV only
- 4 states require reporting for Schedules II-IV and Drugs of Concern

**REPORTING EXEMPTIONS**

States differ greatly in exemptions from reporting:
- Generally, drug samples and controlled substances administered directly to patients in healthcare facilities are exempt
- Other common exemptions:
  - Pharmacies dispensing to prisoners, assisted living facilities
  - Wholesale distributors
  - Veterinarians
REPORTING REQUIREMENTS

State statutes vary greatly:

- At the very least, in-state pharmacies are required to report.
- The most inclusive laws require reporting from any person or entity licensed, registered, or otherwise permitted to prescribe, distribute, dispense, conduct research with respect to, or to administer or use in teaching or chemical analysis a controlled substance in the course of professional practice or research in the state.

ACCESSING THE PDMP DATABASE

31 states REQUIRE that prescribers access the database (11 of these also require query by dispensers):

- Based in part of the prescriber’s judgment about the patient’s motive for seeking the prescription; or
- If objective triggers are met
  - E.g., if treatment extends longer than three months
  - Generally, use of the database shall occur upon the initial prescribing or dispensing of a controlled substance and at a designated period thereafter if controlled substances remain part of the patient’s treatment.

19 states and District of Columbia DO NOT REQUIRE prescribers and pharmacists to check the database before prescribing or dispensing a controlled substance.
PENALTIES FOR FAILURE TO REPORT DATA

- Criminal penalties:
  - Many states impose criminal charges, from Class 2 misdemeanor to Class 1 felony, in addition to civil fines
- A few states only impose civil penalties
- Practitioners and dispensers who violate reporting requirements are subject to disciplinary action by the state’s licensing board

PENALTIES FOR WRONGLY OBTAINING, USING, OR DISCLOSING DATA

- Most states impose criminal charges for negligently or fraudulently obtaining, using, releasing, or disclosing information from the database in a manner or for a purpose in violation of state laws
  - Range in level of offense from misdemeanor to Class C felony.
  - Very few states only impose civil fines
- Violators are further subject to disciplinary action from the state’s licensing agencies and boards

PENALTIES FOR FAILURE TO ACCESS DATABASE

- 26 states and D.C. have laws that provide some immunity from civil liability for not accessing or using the database

- Some states, such as Idaho and Illinois, provide protection when information is accessed and used negligently but do not provide immunity for failing to access the database at all
DRUG MONITORING IN MINNESOTA

• Minnesota Prescription Monitoring Program  (operational since 2010)
  • Minnesota Statute § 152.126
  • http://pmp.pharmacy.state.mn.us/
• Who must report: Dispensers
  • Daily reporting required
  • Hospital pharmacies dispensing for inpatient use are exempt
• What prescriptions reported: Schedule II-V Controlled substances and butalbital containing products dispensed in or into MN.

What information is reported:
• Prescriber and NPI number
• Dispenser and NIP number
• Patient name, address, DOB
• Prescription drug, quantity, strength, days of supply
• Date prescription written and prescription number

Reported information is protected by HIPAA and Minnesota state privacy laws

• Reporting dispenser must provide to the patient for whom the prescription was written a conspicuous notice of the reporting requirement.
  • e.g. Sign posted visible to the patient, an insert in the prescription package, or a label on the prescription container.
WHAT ABOUT YOU?

Who may access data:

- Prescribers and their agents and employees for current patients, in emergencies, or with patient consent
- Dispensers or their agents and employees when considering dispensing a drug
- Licensed pharmacist
- Boards and their personnel and agents in investigating a licensee
- Law enforcement with search warrant
- HHS
- Vendor who runs the database

DISCIPLINARY ACTION

- Dispenser who are required to report and do not do not... Licensing board referral
- Prescribers or dispensers who knowingly disclose data in violation of laws relating to health care privacy do not... Civil penalties and licensing board referral
- If make a report to the program in good faith, immune from liability.
- If accessed in good faith, physicians, prescribers, etc. who access the data are immune from liability for receiving and using the information
- Immunity from civil and criminal liability if report and use data in good faith

Should you report or review data before prescribing from an ethical standpoint?
WHAT WOULD YOU DO?

• State encourages but does not require look up and reporting

• You suspect patient is doctor-shopping and addicted to the medication, but patient denies it

• What will you do?

ETHICAL?

• You look you look up the patient and find they have prescription for controlled substance from another physician

• Patient tells you he not longer is seeing that physician

• You call the other physician to discuss patient’s situation