Medical Law and Ethics
Handout 2.2
Professional Liability and Medical Malpractice Part II

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In the previous handout (Handout 2.1), we discussed medical malpractice and its facets in greater detail. In this handout, we will take a look at how liability affects the health professions.

Each individual is **liable** for his or her actions which mean that he or she has a legal responsibility for the decisions and resulting consequences arising from those decisions. Whether he or she is a healthcare professional, a patient, or an owner of a medical device business, they are all responsible for any accidents or injuries that occur within the premises of their work environment or due to their own actions.

We had extensively discussed the doctrine of *respondeat superior* (Handout 1.6 p. 4; Handout 2.1 p. 12) in which employers are responsible for their employees' actions even if the employer was not the one responsible for injuring the patient. *Respondeat superior* tilts in favor of the patient rather than an employee. Although it may seem that the blame can be shifted to the employer in the event that the employee is responsible for the negligent act, it does not mean that the employee will be protected under this doctrine. On the contrary, the patient (or other party acting as the plaintiff) may choose to take both the employer and employee to court and sue for damages from both parties.

If the employee is at fault (but not the employer) and the employer ends up paying the plaintiff due to employee's negligent behavior, the employer may collect those damages by suing the employee (or a responsible third party such as an insurance company). In the case of *St. John's Regional Health Center. v. American Casualty Company of Reading, Pennsylvania* 980 F.2d 1222 (8th Cir. 1993), a nurse from St. John's Regional Health Center named Ruth Lierz was sued for malpractice. Ruth Lierz asked both St. John's and American Casualty to defend her in court in which American Casualty refused. St. John's covered the $375 000 settlement, but then demanded reimbursement from American Casualty, the insurance company where nurse Ruth Lierz had to purchase a policy to cover liabilities.

A **settlement** is an official agreement between the involved parties to resolve a dispute. This resolution may take the form of a monetary payment (like the case we are currently discussing) or another means to satisfy each party. Also, a settlement does not provide any indication or admission of innocence or guilt. It just means that the defendant agreed to pay the plaintiff after going through the negotiations in order to "settle" the legal dispute.

American Casualty argued that the clause in Ruth Lierz's policy stated that they would only cover the liability if the "other insurance" funds were utilized (in this case, the $375 000 paid by St. John's came from a pooled liability fund that was set up for hospitals under a health system which St. John was part of). American Casualty stated that they would cover the liability after the "other insurance" (the pooled liability funds).

The court then stated that the purpose of requiring nurse Lierz to purchase the insurance was to have it take precedence when covering the liability costs. As a result, the court found American Casualty responsible for covering the cost of the payment that St. John's handled regarding nurse Lierz's settlement suit and had to pay St. John's back. (*p. 35 Essentials of Nursing Law and Ethics, Westrick & Dempski*)

Issues in the Healthcare Environment

Drugs

In the United States, the **Food and Drug Administration** (FDA) manages the sale and distribution of medications which includes prescription and over-the-counter drugs. We began discussing the role of the FDA as a federal agency in Handout 1.3 (p.2).

Many healthcare professionals have access to medications including controlled substances in their workplace. As a result, potential employees undergo a thorough screening and background check to ensure that there are no prior drug related offenses in their history (e.g. drug possession or abuse) prior to being hired. Issues related to drugs offenses include the theft of controlled substances for personal use, redistribution, or resale. These drugs carry a risk of abuse, addiction, or habituation.

Addiction is an acquired physical or psychology dependence on a drug. Individuals who are addicted to a drug have a compulsion or strong craving for that specific drug.

Habituation is when an individual develops an emotional dependence on a drug as a result of repeated use. Individuals who are in a state of habituation continue to use a drug, but do not have the irresistible urge to take it (compared to those who are addicted).

Licensed healthcare professionals (e.g. physicians) are required to have a DEA registration number assigned by the Drug Enforcement Administration (DEA) which permits them to prescribe controlled substances. Registration must be renewed every three years.

The **Controlled Substances Act (CSA) of 1970** is an act enforced by the DEA to oversee and regulate the manufacture, distribution, and dispensing of drugs which can have a potential to cause dependence. The controlled drugs are categorized into five schedules: I (one) through V (five). Schedule I controlled substances have the highest potential for abuse and addiction while Schedule V has the lowest potential for abuse.

Currently, **Schedule I drugs are not allowed to be prescribed and used medically in the United States**. They may only be used for research purposes by authorized entities. Examples of Schedule I drugs are heroin and LSD. There is also an exemption to allow the Native American Church to use peyote (classified under Schedule I) for religious purposes under the American Indian Religious Freedom Act Amendments of 1994 (codified 42 U.S.C. § 1996a - Traditional Indian religious use of peyote).

Controlled substances under Schedules II through V may be prescribed by licensed and registered practitioners in the United States.

Schedule II drugs have a high potential for abuse, but are medically accepted for use in the United States. Prescribers must write out the prescription by hand and may not fax or provide the order by phone unless it is an emergency. **Drugs under Schedule II may not be refilled**. A new prescription has to be written out each time. Examples include codeine, opium, and morphine.

Schedule III drugs have a moderate to low potential for abuse. In a six month period, 5 refills are allowed. After that (the 6 month period or after 5 refills) the prescriber may renew the prescription. Examples include Tylenol with Codeine and anabolic steroids.

Schedule IV drugs have a low potential for abuse. Similar to Schedule III, 5 refills are allowed within a six month period. Examples include diazepam (brand name: Valium) and phenobarbital.

Schedule V drugs have a low potential for abuse. Some drugs under this schedule need a prescription while others may be requested at the pharmacy counter by individuals who are 18 years of age or older. Examples include cough syrups with codeine and pregabalin (brand name: Lyrica).

Any violations related to controlled substances can result in a suspension or loss of license to practice, monetary fines, or jail sentences.

The CSA also regulates the compounding, dispensing, and retailing of drugs. **Compounding** is the process of preparing specific medications (such as those ordered by a physician for a patient) by mixing ingredients for the drug whose final form will

have the specified dosage form and strength. Pharmacists and technicians usually perform this when compounding IVs or when a pharmacist has to adjust an adult dose of a drug for a child.

Dispensing is the labeling, distribution, delivery, disposing, or transfer of a drug. For example, pharmacists dispense prescriptions to the patient or individual. There are also automatic dispensing cabinets (ADCs) which track the distribution of drugs and improve medication safety for the patient. The ADC can document the drugs that had been dispensed, log who accessed it, and help the pharmacy and nursing teams provide the correct dose and the correct drug to the patient. Dispensing is generally performed by the pharmacy. States will have their own laws, but in general, nurses may only dispense a drug under the order of a legal prescriber (e.g. physician or nurse practitioner).

Retailing is the legal act of selling or trading medications and prescriptions. Additionally, retail pharmacies also sell over the counter (OTC) medications, supplements, and medical supplies such as blood glucose monitors and bandages.

The **Drug Enforcement Administration (DEA)** enforces the law and prosecutes those who are found manufacturing or distributing controlled substances. On a global scale, the DEA works with international governments to handle individuals or groups responsible for violence and crime related to illegal drug activities. The DEA also provides the public with information to educate them regarding current issues involving drugs.

A few key issues to consider under this point:

- Administration of drugs classified as a controlled substance to the patient
    - Ensure that patient receives the medication and not falsified as administered by a healthcare professional who end up keeping it for themselves
- Proper safekeeping of controlled substances
    - Only licensed and authorized individuals can access these drugs
    - Controlled substances are properly locked up by the healthcare professional (e.g. the pharmacist)
    - Prescription blanks should only be accessed by the prescriber and kept away from unauthorized personnel
- Accurate record keeping of controlled substances inventory
    - Controlled substances must be accurately accounted for in an inventory log which must be kept for two years
    - Information such as who the controlled substance was administered to (e.g. the patient), who administered the controlled substance (e.g. the physician or nurse) as well as their signature, and the date the controlled substance was administered should be recorded
- Federal laws vs. State laws
    - Each state may have their own laws when managing controlled substances

- States may have stricter regulations compared to their federal counterparts; if this is the case, health professionals should follow state law
- If you recall, state laws can be stricter than federal laws, but state laws cannot be more lenient or less stringent than federal laws (Handout 1.3 p. 2)

Medical Records

Medical records are documents containing the historical information related to a patient's care. This information includes medical and family history, test results, any observations and findings by the physician and healthcare team, and any procedures performed to name a few.

Accuracy when documenting information on a medical record is crucial.

Under Rule 803 of the Federal Rules of Evidence, medical records are an exception to the Rule Against Hearsay **(Please see 4A and 4B under Rule 803 under additional readings)**. **Hearsay** is an "out of court" statement made during court proceedings to provide evidence in order to prove that what is being stated is true.

An example of hearsay is "Kevin told me that Matt stole the money." This differs from "I saw Matt steal the money." Since Kevin is not present in court to be cross examined on his statement, it is hearsay.

From 4A and 4B under Rule 803 (Statement Made for Medical Diagnosis or Treatment), the person who originally made the statement (referred to as the declarant) **does not have to be present** as a witness.

Under the Uniform Business Records As Evidence Act, the **Federal Rules of Evidence** permit medical records to be introduced in court as evidence.

(State example) Under the Washington State Legislature Chapter 5.45 Section 5.45.020 Business Records as Evidence:

"*A record of an act, condition or event, shall in so far as relevant, be competent evidence if the custodian or other qualified witness testifies to its identity and the mode of its preparation, and if it was made in the regular course of business, at or near the time of the act, condition or event, and if, in the opinion of the court, the sources of information, method and time of preparation were such as to justify its admission.*"

A few key issues to consider under this point:

- Staff should ensure the patient's confidentiality
    - This includes not discussing a patient's information where unauthorized individuals may hear it (e.g. the waiting room or lunch area)
    - Patient charts and information should not be placed in areas where they may be seen by the public or by unauthorized personnel
- Medical records should display accurate and updated information related to a patient's care.
    - The documentation should include patient's appointments, prescription history, signed consent forms for procedures and treatments, documentation regarding the termination of a patient's care (whether by the patient or by the physician), notes signed by healthcare professionals (e.g. nurses, pharmacists, social workers, physical therapists, etc.), and advance directives to name a few.
- Physicians should initial diagnostic test scans and reports
- Medical records should not be altered (this includes making improper corrections to errors); follow the procedures set by your employer, but in general the following guidelines are used:
    - When an error has been made, cross it out with a single line and note "correction" followed by the corrected entry; include the date and your name or initials for your entry
    - Don't correct another person's entry. Notify them or the supervisor regarding the error in the medical record so that it can be reexamined and corrected by those responsible for entering the original information.
    - For electronic medical records, follow similar guidelines. Type "correction" and refer back to which entry you are correcting. Usually electronic medical records are dated by default and will have the healthcare professional's name from logging on to the system.
    - Entries should be inputted into the system (or written) promptly. For example, a social worker will note a session he or she had with a patient or a nurse will enter that medication ordered by the physician had been administered to the patient.

(Please read *Medical Record Documentation Standards* courtesy of Carefirst in the additional readings on the main website)

Law of Agency

The **law of agency** is the legal relationship in which a contract is formed between two parties (the principal and the agent) in regards to managing responsibilities. The principal (e.g. physician or supervisor) allows the agent (the individuals working under them) to perform duties and handle third party interactions (e.g. patient interactions). As the principal and agent work to establish a relationship, both parties must be clear on what is expected in terms of agreed upon duties.

The principal should outline the necessary qualifications and job responsibilities for the position. This should provide the healthcare professional (agent) with a foundation to apply the standard of care when working with third parties as well as follow the rules and terms set by the principal.

A few key issues to consider under this point:

- The doctrine of *respondeat superior* applies (the principal is responsible for the actions of the agent should any injury occur as a result of the agent's negligent behavior)
- Healthcare professionals (agents) should only perform duties that are within their scope of practice
- Employers should provide training detailing the standard of care and professionalism that is expected throughout the employees' work.
- In the event that agents do not fulfill their duties as required, the principal may choose to terminate the relationship to prevent injuries from happening. However, please note that the principal may terminate the relationship at his or her discretion (as noted in the reading specified below)

(Please read *What is the law of "agency"?* courtesy of the Rottenstein Law Group LLP for the specifics of this point under additional readings)

Safety and the Environment

The standard of care in medical environments such as hospitals, clinics, and offices are similar to those in public environments. This means that employees must exercise careful judgment to ensure the safety of individuals entering the facility. If there are any changes to the condition of the premises (e.g. a wet floor, remodeling/construction), then the visitors (e.g. patients) should be given notice by the employees to prevent any accidents from occurring. Should any unexpected incidents occur, incident reports should be documented promptly by the employee.

(Please read Melanie L. Goodman's article on Medscape *How Should Incident Reports Be Handled?* under additional readings)

Employers must also maintain a safe work environment for their employees. Examples include maintaining proper receptacles for discarding biohazardous waste, ensuring that equipment are inspected and safe to use, and complying with the Occupational Safety and Health Administration's (OSHA) regulations and guidelines.

Insurance

There are two types of insurance relevant to the medical field: liability and malpractice insurance.

Liability insurance

Physicians and other healthcare professionals carry liability insurance to protect them from litigation in the event they are sued

For an additional cost, a **rider** is a component added on to an insurance policy to cover extra benefits. For example, physicians may add on a rider to their current policy to cover the employees working in his or her clinic (in the event the employees are held liable for negligence).

Claims-made insurance is a type of liability insurance where the insured parties are only covered for claims made during the time period the policy was in effect. For example, the insured party was covered in 2015 and the insured individual was injured in June 2015. However, if the insured individual then decides to file a claim in January 2016 for the injury, the claim would be denied. Because of this, claims must be filed as soon as possible before the end of the policy.

Occurrence insurance, on the other hand, is a type of liability insurance where the insured parties are covered for any injuries or accidents that occurred during the period when the policy was valid regardless of when the claim is made or reported to the insurer. For example, the insured individual was covered in 2014 and he or she gets injured in March 2014 (or any month during 2014). If the insured individual files a claim at a later time period (e.g. September 2015 or February 2016), the claim would be covered. Since occurrence insurance depends on the time when the injury or incident took place (i.e. the incident occurred at the time period the policy was in effect), it is important to maintain accurate documentation of when and where the incident occurred. As long as the injury occurred at the time the policy was valid and in effect, the claim would be covered.

Malpractice Insurance

Physicians and other healthcare professionals also carry malpractice insurance to pay for damages as a result of losing a malpractice lawsuit.

Since physicians and other healthcare professionals have a risk of being taken to court, many of them practice **defensive medicine** in which more tests and procedures are ordered than are medically necessary to prevent litigation. However, this process can have negative consequences. For example, having patients undergo more tests and procedures may be inconvenient, result in pain and discomfort, and most importantly, it can become very expensive.

According to the National Conference of State Legislatures (NCSL), 33 states have placed a cap on the amount of damages that can be awarded. **Medical malpractice reform** (also referred to as tort reform) focuses on restructuring this system by

- Reducing medical errors so that there will be fewer negligence cases; this in turn can reduce the damages that need to be paid out due to the healthcare professional or facility's negligent actions
- Reducing situations where physicians may practice defensive medicine; by reducing medical errors and having fewer cases against negligence or malpractice, the physician can focus more on assisting the patient with their healthcare needs instead of having unnecessary tests done to avoid a lawsuit

With the increasing costs of healthcare related expenses, states working on medical malpractice reform are working on improving patient safety while examining strategies to efficiently streamline the awarding of damages in the legal system (e.g. settlements and judgments by the court).

(Please also see the NCSL's brief on Health Cost Containment under additional readings)

Alternative Dispute Resolution

Alternative dispute resolution (ADR) refers to methods in which civil disputes are handled outside of the court setting. A third party may or may not be chosen to get involved with settling the dispute.

Arbitration is an example of this. **Arbitration** refers to the process in which a dispute for resolution is submitted to an individual other than a judge. The individual(s) is/are referred to as the **arbitrator(s)**. The arbitrator is the selected individual/party who examines and hears the facts and evidence presented by both sides (e.g. a physician and a patient). Afterwards, the arbitrator issues a binding decision.

There are a few key components regarding arbitration to keep in mind. First, both parties must agree in advance on who will act as the arbitrator. Second, both parties must agree that they will accept the arbitrator's decision once it is given.

Mediation is another form of ADR which refers to the process in which a neutral third party provides their opinion and utilizes techniques to assist the disputing parties with resolving their dispute.

The book also discusses **Med-Arb** which utilizes a combination of arbitration and mediation. The arbitrator begins the process as a mediator to assist both parties in reaching a resolution. Should the mediation process fail, the arbitrator will issue a binding decision.