Legal Fundamentals of Healthcare Law

LEGAL FUNDAMENTALS OF HEALTHCARE LAW

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INTRODUCTION

Healthcare, a field dedicated to the well-being of individuals and communities, operates within an intricate web of legal principles. Understanding these laws is not simply a professional necessity for doctors, nurses, administrators, and researchers; it's also an ethical imperative for anyone who interacts with the healthcare system. This book is your compass, guiding you through the labyrinth of legal fundamentals that shape the landscape of healthcare.

We begin by demystifying the financial framework that underpins healthcare delivery. We explore the diverse players, from hospitals and insurers to pharmaceutical companies, and delve into the complex regulations that govern their interactions. You'll gain insights into the challenges and opportunities presented by healthcare reform initiatives, understanding their impact on access, cost, and quality of care.

The heart of healthcare law lies in the fundamental principles of torts and contracts. Next, we unveil the legal framework that governs negligence, malpractice, and other forms of harm to patients. You'll learn how contracts bind healthcare providers and patients, ensuring informed consent and defining the scope of care.

Innovation is the lifeblood of healthcare, but it raises critical

questions about ownership and access. We explore the legal landscape of patents, copyrights, and trade secrets, examining how they incentivize research and development while ensuring equitable distribution of medical breakthroughs. Healthcare decisions are not merely legal matters; they are often fraught with ethical dilemmas. We navigate the intricate terrain of informed consent, end-of-life care, and resource allocation, highlighting the principles that guide ethical decision-making in a complex system.

Healthcare professionals face unique workplace hazards and legal responsibilities. We delve into the legal framework surrounding occupational safety and health, exploring issues like worker exposure to hazardous materials, infectious diseases, and workplace violence. You'll gain insights into the legal landscape of liability for healthcare providers and institutions. The fight against fraud and abuse in healthcare is crucial to maintaining system integrity. We unravel the intricate web of regulations that govern billing, coding, and other financial practices, ensuring you understand the legal boundaries and ethical considerations that underpin responsible healthcare delivery.

This book is not merely a legal manual; it's your invitation to engage critically with the legal framework that shapes healthcare. Through accessible explanations, real-world examples, and thought-provoking questions, you'll gain a deeper understanding of the legal principles that govern everything from patient care to scientific advancements. So,

whether you're a seasoned healthcare professional, an aspiring student, or simply a curious citizen, turn the page and embark on a journey through the essential elements of healthcare law. Together, let's navigate the labyrinth, ensuring a future where healthcare is not only accessible but also ethical, efficient, and just.

ABOUT THE AUTHOR: BEYOND THE PAGES, IGNITING MINDS

Author Photo: Dr. Tiffany C. Jackman

Dr. Jackman isn't just a wordsmith; she is a passionate advocate for education and a champion for student success. She believes that every student, regardless of background, deserves the chance to thrive. This conviction fuels their work, both within the classroom and beyond the pages of her books. Dr. Jackman's dedication to student success isn't just theoretical. She boasts a remarkable track record, spearheading initiatives that empower young minds. Her commitment has created tangible results, including the creation of several Open Educational

Resources (OER). Her impact extends far beyond individual programs. In her words,

> Having dedicated my career to healthcare and academia, I am deeply committed to preparing the next generation of healthcare leaders. I have taught these concepts since 2017 and found that many books either do not focus enough on healthcare as it relates to the legal realm or are too in depth for a introductory course. I wanted to combine the information I have found to support the concepts taught in my course into something that was easy to read and more palatable to novice learners. Every student deserves the opportunity to succeed, and I am committed to creating an environment where all students can thrive. Therefore, I wanted to design a textbook at no cost that would complement any undergraduate law course for healthcare administration and health science students. I encourage faculty users to explore the topics and concepts that may help teach the fundamentals of healthcare law. Feel free to tailor this material to your needs in the learning environment.

PART I
THE BUSINESS OF MEDICINE

Introduction

Healthcare is a business that drives innovation and growth. While most consider healthcare strictly in terms of physicians, nurses, and patients, the business of healthcare needs careful management to continue achieving its health-related mission. The healthcare industry is different from others in some very fundamental ways. The business side monitors the bottom line, which directly affects the quality of patient care and the

cost of services. Therefore, the bottom line needs to be positive to invest in equipment, technology, and competitive staff compensation. Another definitive difference between healthcare and other industries is that large segments of healthcare are dominated by nonprofit providers, and payments are made by third parties, including private insurers and the government.

Learning Objectives

- Describe the distinctive elements of health as a business enterprise
- Identify professional norms in healthcare
- Summarize the rise of for-profit medicine through the lens of specialty hospitals and hospice providers

Healthcare Priorities

Whether an organization is a for-profit or a non-profit entity, it cannot stay in business if it is unable to generate income

to keep the lights on and make payroll. Organizations must balance financial solvency with the well-being of patients. In healthcare, patients are the primary stakeholders. However, one critical difference is the asymmetry of information, where a patient may never have a complete understanding of their medical condition or the costs associated with treatment. Trust between the patient and provider is critical. The complex patient-physician relationship creates a unique transaction experience with few comparables.

A. For-Profit Hospitals

There are approximately 1,000 proprietary hospitals in the US that provide short-term care. Almost half are owned by large corporations that specialize in hospital management, while the other half are owned by groups of private investors. Proprietary hospitals are for-profit and characterized by having 250 beds or less and offering inpatient and outpatient services. Most are located in small or medium towns, and virtually none are found in states with strong commissions or certificate-of-need policies. Proprietary hospitals are considered to have more efficient management and use fewer employees per bed. Patients in proprietary hospitals are typically not lower-income or covered through Medicaid. Proprietary hospitals generally have per diem rates comparable to voluntary hospitals; however, ancillary charges are higher.

The COVID-19 pandemic, as well as cost escalations related

to the nationwide shortage of nurses, resulted in inflating labor costs. HCA Healthcare, one of the biggest operators of for-profit healthcare facilities, manages an 182-hospital system based in Nashville, TN. HCA reported $6.94 billion in expenses tied to salaries and benefits in the first quarter of 2022, a 10.1 percent year-over-year increase (Ellison, 2022).

B. Proprietary Nursing Homes

Nursing home residents account for one percent of the US population (Warraich, 2021). Several legislative changes were created during the COVID-19 pandemic to support the 36 percent increase in federal expenditures for healthcare expenses associated with the COVID response (Hartman et al., 2021). Due to the lack of personal protective equipment (PPE) and nursing-patient ratios, six studies showed that the risk of infection and death from COVID-19 was significantly higher in for-profit nursing homes (Warraich, 2021). Contrarily, these studies also found that the quality of care improved

when ownership changed to not-for-profit. Further encouraging health disparities, these proprietary homes are more likely to care for Black and Hispanic patients. While many states began to lobby for legislation that protected nursing homes from lawsuits during the pandemic, the delivery of care began to suffer as for-profit nursing homes received millions in government funding (Warraich, 2021). Some unscrupulous practices ensued, with investors buying nursing homes and then renting these spaces back to operators with excessive management fees.

C. Home Health & Hospice Care

A variety of home services are provided by for-profit entities. Services include nursing care, homemaking assistance, respiratory therapy, occupational and physiotherapy, and hospice care. These services generate a multi-billion-dollar profit. Approximately half the total cost of home health care is covered by Medicare. As Medicare and private third-party coverage expand, the rapidly growing expenditures for care continue to increase.

Two-thirds of hospice providers in the US are for-profit. Correspondingly, the cost of hospice care has increased while the quality of care has decreased. The need for elderly care, like patients with dementia, has increased convergence between for-profit nursing homes and hospices. Over 20 percent of nursing homes and hospice providers have common

ownership (Department of Health and Human Services, 2018). This relationship has increased the cost of care. While many have been charged with fraud, many lobbyists are recommending the elimination of immunity provisions (Warraich, 2021).

The Centers for Medicare & Medicaid Services (CMS, 2022a) issued updates to the Medicare payment policies and rates for skilled nursing facilities under the Skilled Nursing Facility Prospective Payment System (SNF PPS) for fiscal year 2023, which aims to ensure the safety of both nursing home residents and staff and improve the quality of services. By 2025, $265 billion worth of care services for Medicare could shift to the home (Bestsennyy et al., 2022).

D. Laboratory & Emergency Services

The global laboratory services market is expected to grow 4.21% over the forecast period, from $365.690 billion in 2019 to $468.249 billion by 2025 (CMS, 2022b). Almost a third of these laboratories are owned by for-profit companies. Some operate laboratories in not-for-profit hospitals as well. Other ancillary services sold by these companies include cardiopulmonary testing, CAT scans, industrial health screening, weight-control clinics, dental care,

alcohol and drug programs, rehabilitation counseling, and prepaid HMO programs. Two additional markets are emergency room services and long-term hemodialysis for end-stage renal disease.

The Emergency Medical Treatment & Labor Act (EMTALA) passed by Congress in 1986, ensures public access to emergency services regardless of ability to pay. As part of this legislation, Medicare-participating hospitals must offer medical screening examinations for emergent medical conditions such as active labor (CMS, 2022b). Combined with the decline in general practice providers making house calls, the dependency on emergency room visits has skyrocketed over the past few decades. Additionally, third-party payers reimburse at higher rates for emergency care than the same care provided in a doctor's office. These actions coalesce in an industry that specializes in emergency services. Services can include the facility, emergency care packages, and professional staffing. Locum tenens, temporary physicians work in varying locations, allowing physicians and training residents to provide medical services often without board certification. The average hospitalist working 15 shifts a month makes around $280K/year. Working 15 shifts/month as a locum tenens hospitalist makes a minimum of $350K annually (todayshospitlaist.com, 2023). While locum tenens can relieve burnout or fill a temporary void left by departing physicians, the costs are significantly higher. Several studies have shown that there is limited empirical evidence to support

the assumptions about the quality and safety of locum practice (Ferguson & Walshe, 2019). In other words, there appears to be no greater risk of harm to patients when staffing is provided by locum tenens. This is specifically important in rural areas with physician staffing issues.

E. Hemodialysis

Dialysis patient by Mishu57 CC BY-NC-SA Wikipedia

The Social Security Act of 1972 was amended to expand Medicare funding for end-stage renal disease. The number of patients requiring dialysis has grown exponentially over the decades. According to the National Institute of Diabetes and Digestive and Kidney Disease, nearly 786,000 Americans have end-stage renal disease, 71% are on dialysis, and 29% will receive a kidney transplant (2023). As of August 2022, 89,931 people were on the waiting list for a kidney transplant, while only 20,663 transplants had been performed, according to the U.S. Organ Procurement and Transplantation Network. Medicare spending per person for those with chronic kidney disease was more than double the amount for those without, according to the USRDS 2020 annual report.

The number of proprietary dialysis facilities has continued to trend upward in parallel with the needs of patients. Free-standing facilities typically have lower expenses in comparison to dialysis units located in hospitals. Some proprietary companies have expanded their services to include the sale of dialysis equipment and supplies. The national dialysis market is controlled by two for-profit organizations, one is DaVita, which controls 37% of the market (Childers et al., 2019). US kidney dialysis clinics form a profitable $24 billion industry, with four large proprietary firms capturing more than 85% of the revenues (LaRosa, 2019).

F. Technology

The new healthcare industry is expanding rapidly and is highly profitable. The expansive nature of healthcare and the displacement of patients during Hurricane Katrina sparked a governmental push to increase the role of technology in healthcare with the use of electronic medical records (EMR), also called electronic health records (EHR). Two of the most used companies in the US, Epic and Cerner, are cloud-based software development companies with a large market share across the healthcare industry. Epic covered almost 31%, and Cerner held around 25% of the total EHR market share in 2020. Epic's revenue hit $3.8 billion in 2021 (Dyrda, 2022) while Cerner's 2021 revenues pulled in $5.765 billion, up 5% from 2020 (Jercich, 2022). Costs for technologies range from

$15K-$70K per provider. Electronic health records not only improve efficiency but also increase the portability of medical records and decrease medical errors, thereby improving patient safety. Costs to consider include the purchase of the software package subscription, implementation/development, ongoing upgrades, and optimization. In addition to those costs are expenses for IT personnel and provider training. Many of these expenses were offset by Medicare and Medicaid EHR Incentive Programs to promote interoperability between EHR systems. Between 2011 and 2017, financial incentives were provided to healthcare organizations through "**Meaningful Use**." As US healthcare payments shifted from a "fee-for-service" model to focus on quality outcomes, many payment models require EHRs that are meaningful use compliant, further pushing the requirements placed on technology that follows governmental guidelines for interoperability.

Healthcare as a Private Business

Considering the aforementioned revenues generated from healthcare combined with the growing complexity and need for healthcare services, the healthcare industry is inevitably attractive to businesses (Perry & Thompson 2017). Healthcare's growing need for technology is a massive investment of capital, which presents a problem for nonprofit institutions. Private entrepreneurs come with the capital needed to build and equip new hospitals, nursing homes, and

laboratories and to start new healthcare businesses. With profits ensured, consumers expect improved efficiency and quality of healthcare. Two major differences in healthcare that make it a unique market are the goods and consumers. Because most people consider it a basic right, healthcare differs from other businesses. Public funds pay for most of the research needed to develop new medications and new medical technology. Additionally, more US citizens are receiving tax-supported medical care through Medicare and Medicaid and other types of public programs. A second unique feature of the healthcare market is that most consumers (i.e., patients) are not "consumers" at all. Patients who are seriously ill do not have the ability to "shop around" for the best price; therefore, the laws of supply and demand do not apply the same to healthcare. Assumptions about a competitive free market do not apply to healthcare, considering the dependence of patients on the judgment of the providers. Typically, the healthcare expenditures are based on the decisions of providers. Patients with lower **health literacy** were associated with increased reports of poor physical functioning, pain, limitations in daily activities, and poor mental health status. All these special characteristics of the healthcare market conspire to produce an atypical situation when a private business enters the equation. A private corporation in the healthcare business uses technology often developed at public expense, and it sells services that most Americans regard as their basic right but are heavily subsidized by public funds,

largely allocated through the decisions of physicians rather than consumers, and almost entirely paid for through third-party insurance (Perry & Thompson 2017). The possibilities for abuse are obvious.

A. The Uninsured

Currently, 1 in 10 (approximately 8.0%) of Americans are uninsured, according to the U.S. Census Bureau Household Pulse Survey data from March 2022. While this percentage has fallen from 10.5% since 2020, rates tend to be higher in the Southern regions: Mississippi (14.4%), Texas (13.0%), Oklahoma (12.4%), and Georgia (12.0%). Other large disparities exist, with 13% of uninsured reported being between the ages of 18 and 24, and the second largest uninsured demographic being 11.8% between the ages of 25 and 39. Education was a large predictor of health insurance status, with 20.9% of insureds reporting not having a high school diploma. In contrast, only 3.3% with a bachelor's degree or higher reported being uninsured (Festa, 2022). 17.0% of the uninsured reported being Hispanic/Latino while 9.5% were Black Americans. This stands in contrast to 6.0% of Asian Americans and 5.4% of white Americans who reported being uninsured. Two other large predictors of insurance status are household size and income. Families with children under 18 (10.2% vs. 6.7% without children) and whose income was less than $25K annually reported being uninsured more than

individuals with higher income (7.0% under $60K annually, 2.4% at $100K annually) (Festa, 2022). Most Americans obtain insurance through their employers, which further complicated coverage during the COVID-19 pandemic when many Americans (specifically Latinos) lost coverage. The unregulated market approach in healthcare fails to resolve social inequalities and injustices that arise when the market fails to provide access to uninsured or underinsured patients.

B. Role of the Medical Professional

Because healthcare is a unique market for the aforementioned reasons, the answer to overuse may fall on the medical provider acting on behalf of the patients. Providers can help patients navigate cost-effective options for treatment, pharmaceutical discounts, and determine the necessity of each option. The provider should shop for goods and services that are the most cost-effective for the patients. Physicians should have no economic conflict of interest when providing care; however, physicians with proprietary hospitals and nursing homes, diagnostic laboratories, dialysis units, and many small companies represent the stockholders of these corporations.

Currently, there are no principles adopted by the American Medical Association's (AMA) Principles of Ethics regarding the declaration of physicians' financial interests. A statement about practicing physicians deriving no financial benefit from the healthcare market except their own professional services should become part of the ethical code of the AMA. It would have no legal force but would be accepted as a standard for the behavior of practicing physicians throughout the country (Perry & Thompson, 2017). In the Opinions and Reports of the Judicial Council, it states that "It is not in itself unethical for a physician to own a for-profit hospital or interest therein," confirming that there is nothing inherently improper in physicians' owning or investing in healthcare businesses. However, acting in their own financial interests by overusing services or obtaining kickbacks and rebates would be considered improper. This stance only addresses abuse and ignores physicians' responsibilities to evaluate drugs, devices, diagnostic tests, and therapeutic procedures in the public interest. (Opinions and Reports, Section 4.40(2)). "If the AMA took a strong stand against any financial interest of physicians in healthcare businesses, it might risk an antitrust suit," according to Perry & Thompson (2017). This is specifically concerning when the physician is acting as the

purchasing agent for the patient while the public pays the majority of the bill.

Another critical problem emerging from the increasing commercialization of healthcare is the so-called "**cream-skimming**" phenomenon. Proprietary hospitals can concentrate on providing the most profitable services to the best-paying patients, thereby skimming the cream off the market. According to Perry & Thompson (2017), this can be achieved in two ways: the elimination of low-frequency and unprofitable services and the exclusion of unprofitable patients (e.g., uninsured patients or those with complex and chronic illnesses). The not-for-profit healthcare facility could not employ such practices. Another form of skimming in the proprietary hospitals' is the lack of residency and other training programs. To provide an adequate and up-to-date range of experiences that are often expensive, large teaching hospitals are obliged to maintain services that are not necessarily economically viable.

The tendency of the profit-making sector to emphasize procedures and technology that are heavily automated and highly profitable, particularly when applied on a mass scale, creates more issues. Combining the aforementioned with the omission of relatively inefficient and unprofitable services, regardless of medical or social need, leads to the exacerbation of problems with excessive fragmentation of care and overemphasis on expensive technology. One final concern is

that the private healthcare industry could hold powerful political influence on national health policy, which could hinder rather than facilitate rational debate on national healthcare policy (Perry & Thompson, 2017).

When pondering the ethical connections between medicine and business as well as policy and regulation, it is important to consider the concept of autonomy. This notion that patients are engaged in their healthcare decisions is foundational to healthcare as well as health law and policy developments. However, without appropriate access to healthcare, ethical concerns over shared decision-making with one's physician become moot.

Type of Healthcare Organization

Healthcare organizations are responsible for providing patients with a wide range of services, including preventive care, diagnosis, treatment, and rehabilitation. The specific services that they offer and the populations that they serve can vary widely.

- **Hospitals:** Hospitals are the most complex and comprehensive type of healthcare organization. They provide a wide range of services, including inpatient care, outpatient care, and emergency care.
- **Clinics and medical offices:** Clinics and medical offices are typically smaller than hospitals and offer a more

limited range of services. They may specialize in a particular area of medicine, such as primary care, pediatrics, or surgery.

- **Nursing homes:** Nursing homes provide care for people who need assistance with daily living activities. They may offer short-term or long-term care.
- **Mental health and addiction treatment centers:** Mental health and addiction treatment centers provide care for people with mental health disorders or substance abuse problems.
- **Home health agencies:** Home health agencies provide care to people who are unable to leave their homes for medical reasons. They may provide nursing care, physical therapy, or other services.
- **Public health organizations:** Public health organizations work to improve the health of the population as a whole. They may focus on prevention, education, or research.
- **Health insurance companies:** Health insurance companies provide financial protection for people who need medical care. They may reimburse patients for services or pay hospitals and other healthcare providers directly.

Now, let's take a closer look at the differences between for-profit and not-for-profit healthcare systems and what implications these differences have for the quality and

accessibility of healthcare.

A. For-Profit vs. Not-for-Profit

For-profit healthcare organizations are owned by investors and shareholders (either public or private), whereas not-for-profit organizations are managed by either a state or local government entity. What does this mean exactly? Any profits obtained by a for-profit entity can be distributed among investors, who then pay income and property taxes. Not-for-profits are legally obligated to invest any profits generated back into the organization to benefit the community.

Many patient advocates, labor unions, and bioethicists believe that with this configuration, for-profit healthcare providers' interests lie with shareholders and investors rather than the patient. Some go further to accuse for-profit providers of denying care to patients who are not insured or have Medicaid (Perry & Thompson, 2017).

B. Physician-Owned Specialty Hospitals

Physician-owned hospital means any hospital in which a physician, or the immediate family member of a physician, has an ownership or investment interest. These entities are either partially or fully owned by physician-investors. They also limit the number of services offered to only a few that

provide high-profit margins, like cardiology, orthopedics, or outpatient surgical procedures. These specialty hospitals cherry-pick patients who are typically not severely ill. By limiting access to healthier patients, costs are reduced in relation to technology and personnel needed for treatment. Additionally, the costs at these facilities are higher (Perry & Thompson, 2017).

It is important to note that healthcare legislation drives trends in all areas of healthcare. Decades ago, drastic reductions in Medicare reimbursements forced a mass exodus to physician-owned specialty hospitals. Further exacerbating these disgruntled departures was the dissatisfaction of physicians with administrators and government bureaucrats. Decreasing physicians' salaries fueled by profit motivation, physician-owned specialty hospitals were propelled by the physicians' frustrations concerning efforts to exercise control of their clinical practices. In doing so, many physicians actively pursued the more lucrative patient population for higher profits; notably, there were fewer, if any, Medicaid patients. This action ultimately resulted in damage to the healthcare industry for both the system and the patients. Some private health systems responded by destabilizing the threat of administrators for physicians who remained affiliated with the hospitals. Physicians referred their least costly and most healthy patients to facilities in which they had an ownership interest while sending the more complex cases to general hospitals. However, many of these physician-owned specialty

hospitals were not in compliance with the Centers for Medicare & Medicaid Services (CMS) Conditions of Participation, including having an on-site emergency department and patient safety standards. In March 2010, Congress passed the largest legislative healthcare reform with the Affordable Care Act (or Obamacare). A portion of this legislation was dedicated to curbing the expansion of physician-owned specialty hospitals (Perry & Thompson, 2017).

C. For-Profit Hospice

The earliest considerations of hospice care arose in the 1960s but didn't emerge as the concept as we know it until the 1980s. The growth of hospice care spread rapidly in the 1970s, with mostly small volunteer-dominated, community-based programs that provided spiritual support and palliative care. By the late 1970s, there were approximately 60 hospice providers in America. That number exploded in the early 1980s to over 400. Policymakers began to take notice, and Congress created Medicare hospice benefits in 1982 for patients deemed terminally ill with less than 6 months to live. These federal benefits pay a fixed per diem rate, which includes routine home care, continuous home care, inpatient respite

care, or general inpatient care. The per diem rate covers services that include nursing care, physician services, pain management, medical social services, counseling (including bereavement services), physical therapy, occupational therapy, speech-language pathology, dietary counseling services, and homemaking services, whether they are provided or not. Throughout the 1990s, the per diem rates paid by Medicare steadily increased, and by 2006, 40% of Medicare beneficiaries had received hospice care prior to death. Between the years 1992 and 2002, Medicare payments for hospice care increased fivefold, as did the number of Medicare-participating hospice providers. Within the next 6 years, hospice expenditures exceeded $11 billion. Concurrently, the for-profit hospice industry grew by 128%, while the nonprofit sector only grew by 1% (Perry & Thompson, 2017). Based on this information, it is reasonable to predict that the rising availability and awareness of hospice care could lead to more Medicare beneficiaries choosing it for end-of-life care.

Marketing For-profit Hospice Services

Marketing Strategy by Nick Youngson CC BY-SA Alpha Stock Images

Some of the largest hospice providers successfully grow their business by sending patient recruiters into nursing homes to market hospice services and recruit patients. As expected, many of these practices have become unethical and warrant investigation. In 2009, the Medicare Payment Advisory Commission exposed this conflict of interest between the financial relationships of hospice providers and long-term care facilities. Given the heightened emotions and vulnerability of these dying patients and their caregivers, potential informed decision-making is susceptible to unscrupulous marketing that overpromises the services that will be provided. Medicare found hospice providers maximize the length of stay for profits. The initial costs of transitioning patients to hospice care are higher in the first four days as well as the last four days prior to death. Although costs in between those times are lower, the longer the duration of the patient's stay, the higher the overall profits. Studies found that for-profit hospices selectively admitted patients with primary diagnoses and younger ages than religious or non-profit hospices, which corresponds with higher profits (Perry & Thompson, 2017).

Compromised Quality of Care by Hospice Providers

Holistic end-of-life care with a coordinated interdisciplinary care team is the hallmark of hospice. Federal law mandates care pursuant to an individual patient's written plan, including access to physician services, skilled nursing care, dietary or nutritional services, psychological counseling, spiritual care, and medical social services (Perry & Thompson, 2017). Other services include occupational therapy, speech therapy, physical therapy, continuous home care, and homemaker services. Basic hospice services include:

- Providing patient care, including pain management
- Coordinating care with the family or nursing home
- Ordering medications
- Grief counseling
- Support for caregivers
- Education to family members on caregiving
- Religious or community resources
- Burial arrangements assistance

For-profit hospice providers were noted to use less-skilled nursing staff. For-profit hospice patients received significantly fewer services than non-profit hospice patients. Hence the name for-profit, the financial bottom line is driving the creation of profits for its investors. Although quality is difficult to measure in hospice care, new quality self-reporting metrics

show that for-profit hospice providers are scoring lower than not-for-profit.

Key Takeaways

- Distinctive elements of health as a business enterprise include monitoring the bottom line, which directly affects the quality of patient care and the cost of services. The bottom line needs to be positive to invest in equipment, technology, and competitive staff compensation. Large segments of healthcare are dominated by nonprofit providers, and payments are made by third parties, including private insurers and the government.
- Professional norms in healthcare include the medical provider acting on behalf of the patients. Providers can help patients navigate cost-effective options for treatment, pharmaceutical discounts, and determine the necessity of each option. The provider should shop for goods and services that are the most

cost-effective for the patients. Physicians should have no economic conflict of interest when providing care; however, physicians with proprietary hospitals and nursing homes, diagnostic laboratories, dialysis units, and many small companies represent the stockholders of these corporations.

- Physician-owned hospitals are hospitals in which a physician, or an immediate family member, has an ownership or investment interest and are either partially or fully owned by physician investors. By limiting access to healthier patients, costs are reduced. For-profit hospice patients receive significantly fewer services and have lower-skilled caregivers. However, little evidence is provided to support a difference in quality between for-profit versus not-for-profit hospice providers.

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PART I
HEALTHCARE REFORM

Healthcare reform by Nick Youngson CC BY-SA 3.0 Pix4free

Introduction

Business has become a powerful force in medicine. The future of health care cannot escape that reality. "The US recently experienced the most devastating recession since the Great Depression" (Wicks & Keevil, 2021) and a global crisis with

the COVID-19 epidemic. As healthcare costs rise, the pressure to rein in healthcare spending is ever-present. New legislation could make a significant shift in how healthcare is provided and who has access to care.

In 2010, the Affordable Care Act (ACA) was the largest piece of legislation to pass regarding healthcare in America. It aimed to reduce healthcare costs by providing affordable insurance to the underinsured and uninsured. It encompassed individuals making between 100% and 400% above the national poverty level. However, it was not embraced by states equally. More conservative states in the southern regions did not adopt Medicaid Expansion and did little to ensure the ACA's success. The array of issues facing the US healthcare system urges the need for new health reform to address rising costs, reduce medical errors, strengthen patient rights, build public health infrastructure, and confront the costs of medical malpractice insurance. Pollard (2022) provides several factors that deter significant social/health reform in this country, including:

- **Political gridlock:** The US political system is highly polarized, with two major parties that often have very different views on social and health policy. This makes it difficult to pass major reforms that require bipartisan support.
- **The influence of special interests:** Powerful special interests, such as the healthcare industry, often oppose reforms that would threaten their profits. They can use

their financial resources and political influence to block or weaken reform efforts.

- **Public apathy:** Many Americans are not well-informed about social and health policy issues, and they may not see reform as a priority. This can make it difficult to build public support for reform efforts.
- **The complexity of the issue:** Social and health policy issues are often complex and difficult to understand. This can make it difficult to reach a consensus on the best course of action.
- **The cost of reform:** Social and health reform can be expensive, and there is often disagreement about who should pay for it. This can be a major obstacle to reform efforts.

Learning Objectives

- Summarize the implications of reform for health professionals, such as physicians, nurses, or pharmacists
- Describe the increased complexity of relationships between physicians, healthcare institutions, and drug and device manufacturers

- Articulate how healthcare is different from other industries based on policies and regulations
- Determine how to find an acceptable equilibrium between market and professional service paradigms for healthcare

Business

Clarifying the Definition of Business

Business, in terms of healthcare, is about being an employer who offers opportunities that are more attractive than others, provides a chance to develop the employee's abilities, and does work that has value. Businesses should start with a realistic view of what they do, particularly if the right kinds of conditions are present. Business is defined in two ways:

1. The practice of making one's living by selling a product or service; or
2. An organization engaged in commercial, industrial, or professional activities.

Businesses can be for-profit entities or non-profit

organizations. Business types range from limited liability companies to sole proprietorships, corporations, and partnerships.

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https://pressbooks.uwf.edu/healthcarelaw/?p=44#h5p-6

Measuring Impact and Performance

Metrics used to determine the success of healthcare are different from those used for other types of businesses, which solely focus on financial returns in the form of profits. A broader set of metrics around "value creation" for stakeholders (employees, suppliers, managers, financiers, customers, and the local community) should be how organizational performance is evaluated.

Stakeholders are individuals who have an interest in decisions made in the healthcare industry and its subsidiaries. Businesses need to find ways to engage stakeholders, clarify their purpose beyond profits, clarify to whom they are accountable, and clarify how they are going to treat others to foster the kind

of cooperation they need to generate and sustain value over time. Stakeholder Theory is a view of capitalism that stresses the interconnected relationships between a business and its customers, suppliers, employees, investors, communities, and others who have a stake in the organization. The ultimate purpose of any healthcare entity is to provide a service to the community it serves.

Stakeholder Theory in Healthcare

Healthcare systems' hallmarks are things like quality, access, innovation, and prevention. However, affordability and fiscal limits are also important. With the soaring costs of US healthcare, importance is placed on financing care, creating a system that is sustainable and maintains high quality, and innovation. Markets provide a powerful mechanism for aligning the interests of organizations and patients and ensuring that new innovations align with the community's needs. Properly functioning markets have great efficiency, create powerful connections between patients and providers, generate new innovations that continue to improve the quality of care, and help reduce waste. Waste comes from a variety of sources and patterns of behavior, not only via replication of services and unnecessary treatment but also administrative costs, as well as irresponsible and wasteful behavior by patients.

There remains a need to create a system that better serves the interests of a variety of key stakeholders.

Identifying Stakeholders and Their Interests

Stakeholders have a vested interest in the changes within the healthcare sector. Whether they are community patients, providers, payors, policymakers, donors, or investors, they are affected by the operational performance of the organization. The principles of engaging stakeholders include:

- Know who the stakeholders are, both internally and externally
- Build trust with stakeholders through open communication, transparency, and data
- Define ways to serve stakeholders
- Execute a stakeholder strategy (financial impact) to build creditability
- Build a sustainable long-term operating model that creates value for stakeholders through standardization, metrics, and providing feedback

The ACA Responsibility

The Affordable Care Act of 2010 (ACA) increased health insurance coverage for the uninsured and underinsured

through health insurance markets. The delineated principles of this reform included:

1. Protect citizens' financial health (bankruptcy due to catastrophic illnesses)
2. More affordable insurance (reducing administrative costs, removing unnecessary testing, and limiting premium charges for certain populations)
3. Aim for universality
4. Made coverage portable
5. Guaranteed choice of plans and providers (allowing individuals to keep their current plans)
6. Focused on prevention and wellness
7. Improve safety and quality
8. Long-term financial sustainability (reducing costs, improving productivity, and adding new revenue sources)

Changes from the ACA required stakeholders to alter normative behaviors. First, an individual mandate required minimal essential health coverage with penalties. Those who were of a lower socioeconomic status but not qualified for Medicaid received federal subsidies under the law. Second, it prohibited insurance providers from considering pre-existing conditions when determining an applicant's coverage. Third, it created a marketplace for online shopping for health insurance. Last, it expanded existing Medicaid programs.

Places where ACA improved access include:

1. Children are allowed to stay on their parent's health insurance policies until they turn 26 years old.
2. Children 19 and under cannot be turned down for coverage due to a pre-existing condition.
3. Preventative services are provided without cost-sharing.
4. Coverage can no longer be rescinded by the insurance company for any reason other than fraud.
5. Incentives are provided for providers who work in underserved areas.
6. Lifetime limits cannot be placed on any essential health coverage.
7. Small businesses can provide health coverage and receive tax credits (up to 35%).
8. Seniors who are Medicare Part D eligible can receive a tax-free $250 rebate check.
9. Insurance companies must justify unreasonable rate increases (10% or more).
10. Consumers can appeal a denied claim with an outside reviewer.

ACA Medicaid expansion by state by Kurykh CC BY-SA Wikimedia

Many contend that the ACA falls short in its reform. However, many of the shortcomings of the ACA were due to the lack of commitment by the states. There were 12 states (Alabama, Florida, Georgia, Kansas, Mississippi, North Carolina, South Carolina, South Dakota, Tennessee, Texas, Wisconsin, and Wyoming) that chose not to expand Medicaid coverage, thereby negating the ability to advance health equity. For example, Mississippi chose not to expand using federal matching funds under the American Rescue Plan Act of 2021, despite having more than 300,000 individuals who could not afford health insurance and were not qualified for Medicaid. Although former Attorney General Jim Hood was in favor of the expansion, former Governor Phil Bryant sued the federal government, claiming the ACA was unconstitutional. Despite losing millions of dollars caring for uninsured Mississippians each year, the governor chose to "...look at health care as an economic driver...like the automobile industry." There was also a troubled debut of the federally run insurance marketplaces and state-run programs (Campbell, 2018). The Mississippi marketplace offered very few options that were accepted by very few healthcare entities and often did not reimburse claims for long periods. This poorly supported

model would lead one to believe that the ACA was a failure; however, the fault lies with the states that did not support it and the political parties that refused to put citizens before political alliances.

The Patient Protection and Affordable Care Act

Partisan Elements of the PPACA

"Beyond analyzing the rhetoric used to describe healthcare reform," importance should be placed on examining the legislation bill itself for clues as to its partisan or bipartisan nature. "The Patient Protection and Affordable Care Act (PPACA) contains progressive insurance reform and increased fees and burdens on employers, but the bill also incorporates some forward-thinking delivery-side reforms that received bipartisan support (Frakes, 2012)."

A. Insurance Reform

Patient Protection and Affordable Care Act with stethoscope by Marco Verch CC BY Flickr

Democrats have publicly denounced the payer community for focusing on profits rather than patients and simultaneously producing barriers to achieving universal coverage. Democratic control of both Congress and the Presidency after the 2008 elections finally offered some opportunity to pass massive insurance industry reforms. The PPACA contained several partisan provisions aimed at negating the market power of insurance companies. Some provisions included severe taxes on insurers and allowed adult dependents to remain on their parent's coverage until the age of 26. It also established the minimum essential benefits that plans must provide. The White House and Congressional Democrats drafted the bill, which targeted health insurance reform, and this legislation made a strong partisan statement (Frakes, 2012).

B. Employer Penalties

While the PPACA subjects businesses to increased restrictions, requirements, and fees, it allowed the Democrats to reshape employer participation within the insurance industry. Shifting

employer participation away from the old model of voluntary, flexible employer-sponsored coverage, a mandate was also added that required employers to provide health insurance coverage to their employees. Section 9006 of the PPACA required businesses to issue 1099 IRS tax forms to any individual or corporation from whom they purchased a good or service worth over $600 within a given tax year. This provision was criticized for being burdensome and time-consuming. However, Congress repealed the provision in early 2011 before President Obama signed the measure into law (Frakes, 2012).

C. Bipartisanship Reform

The trending bipartisan goal that unites both sides of the aisle is the focus on increasing healthcare quality at a lower cost, which is inextricably linked. The promotion of the accountable care shared savings program has gained bipartisan support. Providers are incentivized to produce specific health outcomes and high patient satisfaction. Alternatively, increases in cost resulting from care are the financial responsibility of the provider. The PPACA includes a shared savings model in the form of Accountable Care Organizations ("ACOs"), a shared savings structure for Medicare beneficiaries, and has gained bipartisan support. Lastly, strong bipartisan support exists for the inclusion of health information technology within healthcare delivery. Large-scale political conflicts are brutal, and every congressional member's votes and statements are

available online. These factors present challenges to crafting a piece of healthcare legislation representative of varying opinions and bipartisan support (Frakes, 2012).

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The Affordable Care Act

Effect on Availability of Affordable Health Insurance and Access to Care

Doctor writing on clipboard by Marco Verch CC BY Flickr

Years after the ACA was signed into law on March 23, 2010, it has had its clearest and most measurable effects on the availability of health insurance for the American people and access to care. According to the US Department of Health & Human Services (2022), the Centers for Medicare & Medicaid Services (CMS) show a "record-breaking 21 million people in more than 40 states and territories gained healthcare coverage thanks to the ACA's expansion of Medicaid to low-income adults under 65. The total enrollment for Medicaid expansion, Marketplace coverage, and the Basic Health Program in participating states has reached an all-time high of more than 35 million people as of early 2022."

The ACA has improved the availability of health insurance and access to care by providing states with the option to expand Medicaid programs to include all adults with incomes at or below 138% of the federal poverty level (that translated to $17,130 for a single person and $35,245 for a family of four in 2021). States that chose not to expand cited concerns about funding once federal funds were withdrawn. Several issues that originally plagued the ACA rollout have been improved. The federal marketplaces now seem to be functioning adequately. The number of canceled policies has declined, and marketplaces have offered accessible and affordable alternatives. Lastly, some new marketplace plans restrict access to providers to control costs. While good efforts to improve the process are making strides, many who purchased marketplace plans have substantial deductibles and copayments to minimize premiums, leaving participants with large out-of-pocket expenses and limited access to services (Blumenthal et al., 2015).

The ACA and the Health Care Delivery System

The most aggressive efforts in the history of the nation to address the problems of the delivery system need to focus on approaches to improving healthcare delivery, including:

1. changes in the way the government pays for health care,

2. changes in the organization of health care delivery,
3. changes in workforce policy, and
4. changes intended to make the government more nimble and innovative in pursuing future healthcare reforms.

Changes in Payment

The ACA embraced efforts to move away from volume-based, fee-for-service reimbursement and push towards outcome-driven payment models with compliance incentives.

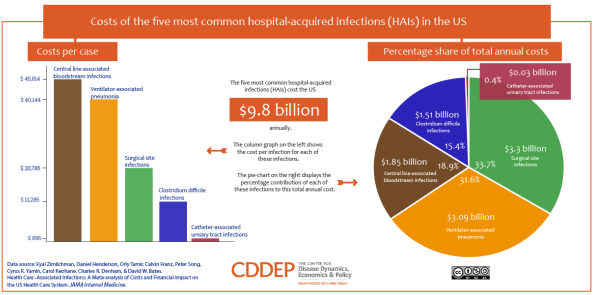
- ***Reduce Medicare Readmissions***

Hospitals were subjected to financial penalties for higher-than-expected rates of readmissions of Medicare beneficiaries within 30 days, starting in October 2012. Healthcare entities were frustrated because the cause of readmission was not taken into consideration in many cases. For example, a patient who is recovering from being discharged the previous week has an automobile accident and is readmitted. The cause of readmission had no bearing on the initial incident. However, since the inception of this program,

30-day readmission rates nationally have declined drastically among Medicare beneficiaries. According to Blumenthal et al. (2015), "the appropriateness of current readmission measures has been questioned because of evidence that safety-net hospitals and large teaching hospitals may be unfairly penalized under the program owing to the social and medical complexity of their patient populations."

- ***Reduce Hospital-Acquired Conditions***

The ACA expanded a previous CMS program that penalized hospitals for avoidable threats to the safety of Medicare patients, coined *never events*. Under the ACA program, a hospital may lose 1% of Medicare payments if it performs in the lowest quartile regarding rates of hospital-acquired conditions, including avoidable infections, adverse drug events, pressure ulcers, and falls. This payment program strives to improve patient safety. The Department of Health and Human Services (DHHS) noted a documented decline in composite rates of hospital-acquired conditions nationally and estimates that these safety improvements prevented deaths and saved healthcare costs.



Costs of the Five Most Common Hospital-Acquired Infections (HAIs) in the US by CDDEP CC BY-NC-SA One Health Trust

- ***Value-Based Payment Programs for Hospitals and Physicians***

Since the passage of the ACA, value-based payment models have revolutionized the way healthcare systems receive payments. Value-based programs provide incentives for hospitals and physicians to improve their performance on a variety of quality and cost metrics other than hospital-acquired conditions and readmissions.

CMS's five original value-based programs have the goal of linking provider performance of quality measures to provider payment:

- End-Stage Renal Disease Quality Incentive Program (ESRD QIP)

- Hospital Value-Based Purchasing (VBP) Program
- Hospital Readmission Reduction Program (HRRP)
- Value Modifier (VM) Program (also called the Physician Value-Based Modifier or PVBM)
- Hospital Acquired Conditions (HAC) Reduction Program

There are other value-based programs:

- Skilled Nursing Facility Value-Based Purchasing (SNFVBP)
- Home Health Value-Based Purchasing (HHVBP)

LEGISLATION	PROGRAM
ACA: Affordable Care Act	APMs: Alternative Payment Models
MACRA: Medicare Access & CHIP Reauthorization Act of 2015	ESRD-QIP: End-Stage Renal Disease Quality Incentive Program
MIPPA: Medicare Improvements for Patients & Providers Act	HACRP: Hospital-Acquired Condition Reduction Program
PAMA: Protecting Access to Medicare Act	HRRP: Hospital Readmission Reduction Program
	HVRP: Hospital Value-Based Purchasing Program
	MIPS: Merit-Based Purchasing System
	VM: Value Modifier or Physician Value-Based Purchasing Program
	SNFVBP: Skilled Nursing Facility Value-Based Purchasing Program

- ***Bundled Payments***

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) encourages clinicians to participate in alternative payment models (APM), such as bundled payments. Bundled payments shift the financial risk to providers, further urging them to focus on cost-efficient care and reduced waste. Under the bundled payment model, providers receive a single

payment for a specified set of hospitalization, physician, and post-acute care services related to a given procedure or condition (Franco, 2017).

Changes in the Organization of Health Care Delivery

- ***Accountable Care Organizations***

The ACA encourages healthcare providers to form new organizational arrangements called accountable care organizations (ACOs). It intends to promote the integration and coordination of ambulatory, inpatient, and post-acute care services and to take responsibility for the cost and quality of care for a defined population of Medicare beneficiaries. It was perceived that ACOs would serve as a bridge from fragmented fee-for-service care to integrated, coordinated delivery systems. However, challenges with the early implementation of ACO caused over 100 people to drop out of Medicare and commercial plans.

- ***Primary Care Transformation***

One of the ACA's focuses is to improve the delivery of primary care by supporting a variety of programs, like the Comprehensive Primary Care Initiative. It is an innovative payment and organization model designed to control expenses and improve the quality of care through emphasized care coordination, improved chronic disease management, greater access to primary care, and administrative simplification. It has shown a significant reduction in emergency department visits and inpatient hospitalizations.

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The Patient Protection and Affordable Care Act

The Patient Protection and Affordable Care Act was a comprehensive healthcare reform law enacted in 2010 and also known as the Affordable Care Act (ACA). The ACA had three primary goals.

- Improving access to healthcare coverage through more affordable options and subsidies ("premium tax credits").
- Expand the Medicaid program to cover all adults with income below 138% of the FPL. Despite federal funds to support the Medicare expansion, several states did not

adopt the expansion (Texas, Wyoming, Kansas, Wisconsin, Mississippi, Alabama, Tennessee, Georgia, Florida, North Carolina, and South Carolina).
- Support initiatives designed to lower the costs of healthcare.

Initially, one initiative under the ACA provided increased Medicare reimbursements to pay primary care physicians for two years. This helped increase the number of primary care appointments for Medicare patients (U.S. Department of Health and Human Services, 2022). In addition to extending coverage and improving preventative healthcare access, the ACA also enforced:

- Requirements for employee coverage for companies with 50 or more full-time employees
- Eliminated rejection of coverage based on preexisting conditions for children
- Create a state-based Health Exchange for individuals to gain coverage
- Create essential health benefits packages providing comprehensive coverage for a set of services
- Eliminated lifetime capitations for coverage
- Shifted focus on quality outcomes and reduced waste

An individual mandate requiring US citizens to maintain healthcare coverage or be penalized (KFF, 2013). Penalties

were increased annually. All of the ACA requirements can be found here.

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Single-Payer Healthcare

With the insurgent campaign of Bernie Sanders during the 2016 Democratic Primary, advocates for a single-payer system gained momentum. The revival of support for single-payer health insurance on the public agenda was the platform for Senator Bernie Sanders's 2020 presidential campaign (Oberlander, 2016). Many questions exist as to whether or not it is a realistic option for the United States or a political impossibility. There are currently 17 countries that offer single-payer healthcare: Norway, Japan, the United Kingdom, Kuwait, Sweden, Bahrain, Canada, the United Arab Emirates, Denmark, Finland, Slovenia, Italy, Portugal, Cyprus, Spain, and Iceland. The United Kingdom has both universal healthcare and a single-payer healthcare system. Canadian residents receive government coverage for medically necessary hospital and physician services but also have the option to obtain private coverage for services not covered by the Canadian National Health Insurance to the British National Health Service (NHS). Canada's single government-operated insurance plan greatly reduces administrative costs and the complexity of healthcare. Canada has had its fair share of issues with controlling costs, providing access and timely

service, and grappling with growing public dissatisfaction; all its problems pale in comparison to those in the United States (Oberlander, 2016).

Healthcare reform by Nick Youngson CC BY-SA 3.0 Pix4free

The first bill proposing a single-payer system in the U.S. was endorsed by President Harry Truman in 1943 and would be funded through payroll taxes. Although the bill did not come to fruition, Medicare was enacted in 1965 and embodied the single-payer model. The architects of Medicare saw it as the cornerstone of a national health insurance system and believed it would eventually expand to cover the entire population. Support for the single-payer system gained momentum again in the early 1970s among liberal Democrats such as Senator Ted Kennedy (D-MA). While policymakers were able to pursue incremental expansion through Medicaid, Medicare expansion has yet to happen. Groups such as Physicians for a National Health Program support the single-payer approach (Oberlander, 2016).

Although the ACA was the largest piece of healthcare reform with considerable achievement, healthcare coverage continues to be out of reach for many Americans, specifically those in poorer states, due to a lack of marketplace choices. According

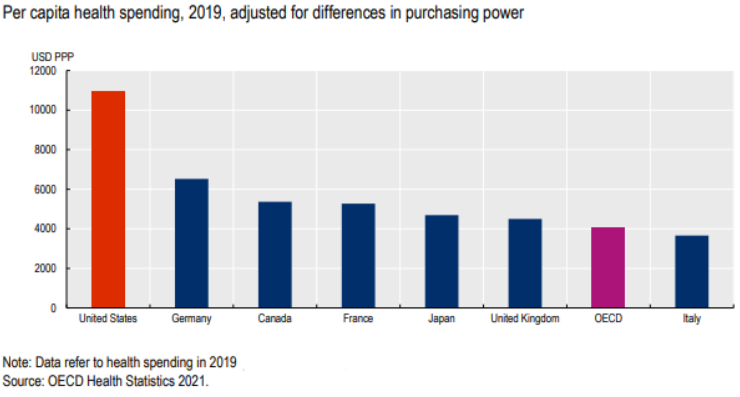
to the U.S. Department of Health and Human Services Centers for Disease Control and Prevention National Center for Health Statistics, there were 31.6 million people of all ages without healthcare coverage in 2020, and 31.2 million were under the age of 65 (Cha & Cohen, 2022). While the allure of reducing healthcare spending is enticing, one of the biggest drawbacks to a U.S. single-payer program is the fierce resistance from conservatives that charge these programs to be "socialized medicine" with "death panels." There is a belief that large-scale tax increases would need to fund a single-payer program rather than trim government spending on military defense. The combination of prevailing anti-tax sentiment with the required substantial overhaul of the current system leaves the task of adopting a single-payer system daunting. Not to mention the needed support from the U.S. Senate to secure enough votes to overcome a filibuster. With each election comes uncertainty concerning healthcare reform and ongoing support. Preserving and strengthening the ACA and Medicare while addressing the underinsurance and affordability of coverage could be just as difficult as establishing a single-payer system.

Based on the current lack of federal funding for healthcare and the exorbitant costs associated with it, the question remains whether or not the government could absorb the costs of a single-payer system. Although Senator Bernie Sanders proposed a single-payer bill in 2016, estimating $14 trillion over a decade, economists estimate costs to be much higher.

According to the Committee for a Responsible Federal Budget (2019), economists estimated that a single-payer healthcare system would cost the federal government $27.7 trillion through 2026, the Urban Institute estimated a $32 trillion cost over the same period, and the American Action Forum calculated that it would cost the federal government $36 trillion through 2029. On average, the estimated cost to the federal government would roughly be $28–32 trillion over a decade. Representative Pramila Jayapal's Medicare for All Act proposed in 2019 and 2021, has failed to pass. Medicare for All is supported by 69 percent of registered voters, including 87 percent of Democrats, the majority of Independents, and nearly half of Republicans. Additionally, over 50 cities and towns across America have passed resolutions endorsing *Medicare for All*.

Future Healthcare Law

Trends in healthcare spending have followed a steep upward trajectory accompanied by a global pandemic, rapidly growing scientific precision, and technical sophistication. According to the Centers for Medicare & Medicaid Services National Health Expenditure Data (2021), the U.S. healthcare system spent upwards of $4.3 trillion, or 18.3% of the Gross Domestic Product (GDP). Not only did Medicare and Medicaid spending grow by 21% and 17%, respectively, but private health insurance and out-of-pocket expenditures also grew by 28% and 10%, respectively. National health spending is projected to grow to reach $6.2 trillion by 2028 (CMS, 2021). Sadly, U.S. spending is comparatively high in relation to other developed countries, yet outcomes are not superior to these other countries.



OECD Health Statistics, 2021

In 2023, Speaker of the House Kevin McCarthy vowed to avoid raising the debt limit on entitlement programs like Social Security and Medicare without first issuing budget cuts to the programs. Reforms to these programs are likely to come, including cuts that would decrease reimbursements for services and are expected to impact the quality of care patients will receive. The House Freedom Caucus is a group of 50 Republicans that is tackling excessive government spending, including healthcare. McCarthy granted them significant concessions to secure his seat as Speaker of the House. Republicans propose converting Medicaid and Affordable Care Act subsidies to block grants, which would cut spending by $3.6 trillion over 10 years (Lalljee, 2023). Some Republicans have called for the complete elimination of Social Security. In 2023, Florida Senator Rick Scott proposed a plan to require Congress to renew Social Security and Medicare every five years. However, Senate Republican Leader Mitch McConnell stated, "Unfortunately, that was the Scott plan; that's not a Republican plan (Bailey, 2023)." While funds for entitlement programs stay at the forefront of budget concerns, other areas of the national federal budget seem to be increasing with no opposition. For example, the 2023 National Defense Authorization Act defense budget was increased by 8%. President Joe Biden has signed the Fiscal 2023 National Defense Authorization Act into law, allotting $816.7 billion to the Defense Department. Funding for this increase is not yet clear (Harris, 2022). This is important to note when budget

cuts are being made to the national federal budget. Comparatively speaking, defense spending is over half of the U.S. discretionary spending budget, while healthcare remains at an average of 5% (not including the 8% allocated for veterans' benefits). This continues to transfer healthcare costs for services back to those not covered by Medicare/Medicaid. The majority of healthcare spending went towards in-patient hospital care (over 30%) (Kurani et al., 2022). To lower healthcare costs, the focus has heavily shifted to preventative care.

Preventative Care

One way to prevent the enormous costs associated with treatment for acute illnesses and chronic healthcare events is to shift the focus from treatment to prevention and early intervention (Sage & McIlhattan, 2014). Healthcare demands that we "do more with less." Throwing money at a problem no longer suffices, and patients expect quality. Trends in unhealthy behaviors and chronic disease have enhanced the need for population health. The COVID-19 pandemic has also pushed the government to be more involved in healthcare. Inventing and funding new technologies could alleviate some of the financial burdens. Unfortunately, most of what is considered "healthcare law" is anchored in legal issues relating to professionals, facilities, private insurance, public programs, corporate structures, and the use or withdrawal of life-giving

technology. Health policy needs to reevaluate and accommodate changing geographic and service boundaries, new professional settlements, and evolving financial practices.

A. Dyadic care

"The physician-patient relationship is a member of a special class of legal relationships called *fiduciary relationships.* Through the creation of fiduciary duties, the law recognizes that there are relationships in which the parties inherently have unequal power (*Witherell v. Weimer*, 1981)." This relationship's foundation is based on the theory that the physician-patient relationship has the following structure: the physician is skilled and experienced in those subjects about which the patient is not, but may depend on their health or even their lives. Therefore, the patient places great confidence and faith in the professional advice and acts of the physician. The physician is expected to recommend treatments based only on the patient's medical and psychological needs. *Witherell v. Weimer*, 421 NE2d 869 (1981).

The physician-patient relationship is fiduciary, and the patient's interests must be a priority. This stands in contrast to the legal rule of ***caveat emptor*** ("let the buyer beware"). Typically, the law assumes the buyer and seller have knowledge of and access to the same information and possess bargaining power. Fiduciary duty extends to all aspects of the physician-patient relationship. This includes breaching the financial

aspects of the fiduciary duty to a patient, which can subject the physician to liability under the law.

B. Physician control

Power and accountability in healthcare reside mainly within the self-regulating medical profession. This indicates that physicians decide what treatments patients will receive. The healthcare practitioner who generates a medical record after making a physical or mental examination of, or administering treatment to, any person is considered the owner of the medical record. This is especially the case when medical charts are kept on paper in a file cabinet. Physicians serve as gatekeepers by determining the scope and intensity of healthcare services. As a result of this structure, medical services are low in variety, accessibility, and measurable benefit. Physicians most often bear moral and financial responsibility in the event that something goes wrong, which can breed bias and fear in the profession.

Information and authority are more diffused with the evolution of electronic medical records. Displaced individuals during Hurricane Katrina, along with destroyed medical records, encouraged the widespread adoption of interoperable electronic systems and allowed a patient's medical history to be accessed anywhere. Electronic health records (EHR) expenditures in the US grew an annual average of 5.4% from 2015 to 2019, totaling $14.5 billion in 2019 (Jercich, 2020).

US expenditures on EHRs are forecast to total $19.9 billion in 2024 (Jercich, 2020). However, according to Huynh and Dzabic (2020), interoperability of EHRs would cut health costs by $30 billion through streamlined patient-centered care.

C. Hospital walls

Hospitals are confined settings where patients receive treatment for serious illnesses. They have specialized technology and a clear professional hierarchy. Patients are considered vulnerable, and their care is considered crucial, but the history of hospitals is more focused on charity than business, despite the large number of resources and financial benefits they generate. Therefore, hospitals often have a feudal-like community structure rather than a business-like structure, including in terms of safety and quality.

Hospitals represent a closed environment in which the sickest patients live as well as receive care, with captive technology and a strict hierarchy of professional authority. Hospitalized patients are assumed to be vulnerable, and the care they receive is seen as life-saving. However, the hospital's history is more charitable than corporate, notwithstanding the considerable resources the sector consumes and the financial rewards it generates. As a result, the hospital often functions as a feudal community rather than an industrial organization, including with respect to safety and quality. Historically, independent physician decision-making has taken precedence over

administrative efficiency, leading to decentralized governance among clinical departments, which is delegated to medical staff committees and verified through compliance with private accreditation standards. Physicians do not hold positions as owners, managers, employees, or suppliers, but instead form an internal nobility with their own power dynamics and methods for distributing rewards and resolving conflicts. However, health services obtained through schools, faith organizations, workplaces, and community groups are different. Physicians are not typically in charge in these settings. Other professionals, such as nurses, pharmacists, social workers, and clergy, exercise their authority and follow their own preferences. Health can also be a significant aspect of social networks that lack a clear hierarchy or leadership but still require oversight to prevent harm and misuse of resources.

D. Third-party payment

Healthcare coverage typically falls into three categories: governmental, employer-provided, or private plans.

1. Government plans:
    1. Medicare- Individuals 65 years and older
    2. Medicaid- state-run plan for low-income families, qualified pregnant women, children, and individuals with disabilities
    3. TRICARE- federal program for military personnel
    4. CHAMPVA- federal program for disabled veterans

and their dependents

2. Employer-provided plans are provided to employees who work 30 or more hours per week
3. Private plans are provided by the private health insurance industry and are not run by the government but are regulated at the state and federal levels.
    1. COBRA allows eligible former employees and their dependents the option to continue group health insurance coverage at their own expense for a period of time, usually up to 36 months. It is also available for individuals turning 26 and no longer covered by their parent's insurance plan, part-time workers, and the self-employed.

Hospital care, services provided by licensed health professionals, and treatments that require a physician's prescription are typically covered by health insurance, while areas such as nutrition, fitness, and stress management are often excluded. The justification for these fixed categories is practical, as they tend to be more expensive and less flexible, making insurance both necessary and manageable. For companies offering health coverage as an employee benefit, this aligns with providing financial security. For publicly funded programs like Medicare and Medicaid, this reduces the potential for abuse. However, these arguments can be circular, as insurance may contribute to high prices, and reactive care may be more costly and less effective than proactive prevention

and early treatment. Only a few health insurance plans, known as health maintenance organizations, attempt to address these issues. The rest reinforce the medical establishment through provider contracts in private coverage and reimbursement systems in public coverage.

Healthcare law will require a more adaptable approach to easing the financial strain of healthcare. Most transactions will not be covered by traditional insurance. Healthcare law must determine the responsibilities of these intermediaries to end-users based on the contracts they offer to the public and the impact they have on service providers. Instead of offering fixed coverage categories, insurance may provide fixed subsidies in case of illness or injury, giving policyholders more control over how the funds are used (similar to disability insurance). This approach is more attractive because insurers can no longer rely on physician judgment as a necessary proxy.

E. Physician-extending technology

Many "mid-level" providers have been seen as *physician extenders* rather than independent professionals. However, this assumption is disrespectful to their skill set and knowledge-based. The objective of employing mid-level providers is to enhance or supplement the services provided and billed by physicians, not to diminish their skills or replace them. When new devices, treatments, or drug formularies are created, physicians act as "learned intermediaries" for patients

regarding the product's risks. However, the US pharmaceutical market is unique in its ability to market directly to consumers. Combined with the push to engage the patient as part of the healthcare decision-making team, it is unclear who possesses "prescriptive authority" under the law.

With emerging new technologies being "reimbursable" by health insurance, access to third-party payment creates incentives for providers to use new products/devices but high additional costs for the patient. However, many modern technologies are extensions of the physician's practice, such as the ability to access hospital and clinic notes or diagnostic laboratory results.

With the emergence of COVID-19, one technology service that has rapidly expanded is telehealth services. Telehealth involves utilizing digital technologies and information to access healthcare services from a distance and manage one's health. This may be done through personal devices such as computers or mobile phones from the comfort of the home or through healthcare professionals using telehealth

technology from a medical office or mobile van, particularly in rural areas. Telehealth can also be utilized by healthcare providers to enhance and support their services.

F. Self-monitoring

Patients are able to easily obtain a home pulse oximeter, a home blood pressure monitoring system, a wristband blood pressure monitor to be worn when exercising, and a home defibrillator. A compact device can be attached to an individual's inhaler, which records each time the inhaler is used and its location. The recorded data is then wirelessly transmitted to the individual's smartphone. Similar devices enable people with chronic conditions to self-monitor various health parameters, such as blood glucose levels, ECG data, body temperature, heart rate, and blood pressure. Electronic platforms, smartphone apps, and computerized systems are becoming increasingly prevalent, empowering individuals to take a more proactive role in managing their health and wellness. There is a wide range of informational and educational tools available, each performing diverse functions. Symptom checkers from WebMD and Aetna allow individuals to learn about potential causes of symptoms. A drug interaction checker through CVS informs individuals about potential drug interactions with prescription and over-the-counter medications.

There are countless other applications that encourage healthier

habits, track pregnancy, customize fitness and weight-loss plans, as well as track sleep patterns, physical activity, and calories burned. Most apps are downloaded to personal smartphones and can offer a mobile-connected recordkeeping service for individuals. Individuals can access their medical records, such as Epic Systems' MyChart, through digital portals, allowing them to view lab/test results, immunization history, prescription lists, family medical histories, and data from self-monitoring.

G. Communication and consultation

Some apps allow patients to search for physicians, hospitals, and other healthcare providers, schedule appointments, and check in remotely. Some apps allow individuals to consult a physician on demand for a nominal fee of $40. The ability to access medical records also allows for real-time communication between the patient, office staff, and physician via patient portals. Patients can leave messages directly for the nurse or provider and receive responses without communicating with office personnel. Eliminating this link in the process makes communication more efficient.

H. Retail Medical Clinics

Retail medical clinics offer accessible and affordable health services, typically provided by mid-level practitioners, without the need for appointments and at fixed prices. Clinics are

commonly located in chain drug stores like Walgreens and CVS, supermarkets like Publix, or big-box retailers like Walmart and Target. Although they are not yet a major source of primary care, they have had a significant impact on COVID vaccination coordination and distribution. Retail clinics provide basic medical services for minor illnesses and injuries at a lower cost and without the need for appointments. While they may provide similar services to what a private physician's office would offer, they are typically not considered a replacement for a traditional doctor-patient relationship.

Sentinel Legal Issues

Sentinel issues in the healthcare industry involve various aspects of the healthcare workforce, such as restrictions on licenses for primary care providers, obstacles to telehealth, and limitations on community health workers. Other issues encompass approvals of medical products, liability, and malpractice risks, insurance coverage and payment, and privacy and security of health information. Several issues have exacerbated the need for providers, including the aging baby boomer population, the COVID-19 pandemic, and the number of people obtaining mandated healthcare coverage. According to predictions by Heiser (2021) from the Association of American Medical Colleges (AAMC), the United States could see an estimated shortage of between 37,800 and 124,000 physicians by 2034. The global pandemic

highlighted severe disparities in access to healthcare services and revealed weaknesses in the healthcare system.

A. Nurse Scope of Practice

Licensing laws in most states limit the independent delivery of primary care by nurse practitioners (NPs). To provide care, some states mandate that NPs enter into collaboration agreements with physicians. For instance, in New Jersey, NPs must establish a joint protocol with a collaborating physician to prescribe medication. In other states, NPs require formal supervision, delegation, or physician-led management. Restrictive practice laws usually outline the ratio of physicians to NPs, require supervising physicians to be present on site (e.g., at a retail clinic) for a certain number of hours, or limit the number of sites that a single physician can oversee. While some states have loosened these restrictions or allowed NPs full autonomy to practice, it has been met with great opposition from medical professional organizations.

B. Community Health Centers

Community health workers (CHWs), who are not necessarily medical professionals, serve as bridges between community members and healthcare providers. Health centers, such as Federally Qualified Health Centers (FQHCs), that receive funding from the HRSA Bureau of Primary Health Care are responsible for providing comprehensive primary care services

to underserved communities and populations. Most patients are treated either for free or charge a nominal fee on a sliding scale based on their income. These centers are crucial in rural areas, as they serve as a safety net for those in need. FQHCs, which are outpatient clinics, are eligible for specific reimbursement systems under Medicare and Medicaid, including Health Center Program award recipients and look-alikes, as well as clinics connected with tribal organizations (Rural Health Information Hub, 2021).

C. Over-the-Counter (OTC) Drugs

It's important to note that not all OTC drugs are appropriate for everyone, and some conditions may require a prescription. It's always a good idea to talk to a doctor or pharmacist before taking any new medication. Over-the-counter (OTC) drugs can generate cost savings in several ways:

1. Avoiding the need for a doctor's visit: By allowing consumers to purchase and self-medicate with OTC drugs, they can avoid the cost of a doctor's visit, which can be substantial.
2. Lower cost of medication: OTC drugs are typically less expensive than prescription drugs because they do not require a prescription and can be sold directly to consumers.
3. Reduced health insurance costs: Using OTC drugs can reduce the burden on the healthcare system and lower

the overall cost of healthcare, which can result in lower health insurance costs for consumers.

4. Increased competition: The availability of OTC drugs creates competition in the marketplace, which can lead to lower prices for consumers.
5. Improved health outcomes: By allowing consumers to treat common illnesses and conditions at home, OTC drugs can improve health outcomes and prevent the need for more costly medical interventions.

D. Home Testing

Home testing options have expanded rapidly in the last two decades. Many consumer diagnostics are regulated by the U.S. Food and Drug Administration (FDA) using the risk-based approach to classifying medical devices authorized by the FDA Modernization Act of 1997. However, testing is being heavily marketed directly to consumers, sometimes without proper FDA clearance. Home testing kits can provide information about DNA genealogy, potential allergies, illegal drug use, fertility, pregnancy, STDs, colorectal cancer, and the inheritance of breast or cervical genes. Home testing kits were revolutionized by the free COVID-19 kits provided to American citizens.

Without proper FDA clearance, the FDA warns of accuracy flaws in processing results and the estimates of disease risk for customers. However, its availability provides access to

consumers without the need for an appointment or insurance approval. The results are also private and owned by the consumer. If the consumer purchases genetic testing from a home kit, there is no medical record validating that diagnosis. If that individual decides to upgrade their cancer policy after receiving at-home kit results, there is no confirmed medical diagnosis to disclose as a pre-existing condition. A medical diagnosis is typically made by a licensed healthcare provider based on a comprehensive evaluation of a patient's symptoms, medical history, and results from various diagnostic tests, including laboratory tests.

It's important to note that at-home medical kits can be useful tools for monitoring health, but they should not be used in place of a formal medical evaluation by a licensed healthcare provider. If the results of an at-home test are positive or concerning, it's recommended to follow up with a doctor or healthcare professional for a more complete evaluation and to receive an accurate diagnosis.

Privacy and Security of Personal Health Data

The Health Insurance Portability and Accountability Act (HIPAA) is a federal law in the United States that was enacted in 1996. It provides a set of national standards to protect the privacy and security of individuals' protected health information (PHI). The Department of Health and Human

Services was given the authority to enforce HIPAA compliance.

HIPAA requires healthcare providers, health plans, and healthcare clearinghouses to implement administrative, physical, and technical safeguards to ensure the confidentiality, integrity, and availability of electronically protected health information (ePHI). HIPAA also gives individuals the right to access and receive a copy of their health information, as well as the right to request that their information be amended if it is inaccurate or incomplete. HIPAA is important for maintaining the privacy and security of individuals' health information, as well as ensuring that this information is only used for authorized purposes. Failure to comply with HIPAA can result in significant fines and legal penalties. The largest HIPAA settlement in 2021 was against Excellus Health Plan for a penalty of over $5 million for a breach of over 9K patient records in 2015 (HIPAA Journal, 2022). A study from the University of Minnesota and the University of Florida measured attacks on healthcare delivery organizations from 2016 to 2021, and the results suggest ransomware attacks on healthcare delivery organizations are increasing in frequency and sophistication, further exacerbating HIPAA violations. Attacks have doubled while personal health information exposure increased more than 11-fold, from approximately 1.3 million in 2016 to more than 16.5 million in 2021 (McKeon, 2023)

The HIPAA Right of Access standard, specified in 45 C.F.R. § 164.524(a), grants individuals the privilege to examine, obtain, and receive a copy of their own protected health information kept in a designated record set. Within 30 days of receiving a request from an individual or their authorized representative, the health records must be provided. A reasonable fee, based on the cost of reproduction, may be charged for the copies requested. Although a request for access to health records may be declined, this can only occur under specific and rare circumstances. Some of these circumstances include:

1. Psychotherapy notes: A covered entity may deny an individual's request for access to psychotherapy notes, which are separate from the rest of the individual's medical record.
2. Information compiled for legal proceedings: A covered entity may deny an individual's request for access to PHI if it was compiled in anticipation of, or for use in, a civil, criminal, or administrative proceeding.
3. Information that could cause harm: A covered entity may deny an individual's request for access to PHI if the disclosure of the information could cause serious harm to the individual or another person.
4. Information that is subject to law enforcement or national security restrictions: A covered entity may deny an individual's request for access to PHI if the information is restricted by law enforcement or national

security requirements.

5. Information that is protected by a privilege: A covered entity may deny an individual's request for access to PHI if the information is protected by a privilege, such as attorney-client privilege or physician-patient privilege.

Other general privacy laws include the Computer Fraud and Abuse Act of 1986 and the Electronic Communications Privacy Act of 1986. The Computer Fraud and Abuse Act of 1986 prohibits unauthorized access to protected computers and networks as well as unauthorized damage to computer systems. It also criminalizes the unauthorized distribution of malicious software and the unauthorized interception of electronic communications. The Electronic Communications Privacy Act of 1986 governs the interception of electronic communications, including unauthorized access to stored electronic communications. Health information technology is governed by various federal and state laws and regulations, including the Health Insurance Portability and Accountability Act (HIPAA), which provides specific protections for electronically protected health information. However, the Computer Fraud and Abuse Act of 1986 and the Electronic Communications Privacy Act of 1986 were enacted before the widespread use of telehealth and mobile medical apps and may not fully address the privacy and security risks associated with these types of apps.

Therefore, while the Computer Fraud and Abuse Act of

1986 and the Electronic Communications Privacy Act of 1986 may provide some protections for individuals using mobile medical apps, they may not be sufficient to fully address the privacy and security risks associated with these apps. It's important for individuals to be aware of the privacy and security risks associated with mobile medical apps and to carefully review the privacy policies and terms of use for these apps before using them.

Conclusion

Innovations in healthcare are being leveraged to help curtail the excessive costs of healthcare delivery. It's worth noting that the healthcare system is a complex and constantly evolving area, and there are many different opinions on the best way to reform it. There is no quick fix. The global pandemic put urgency on healthcare reform. The newest legislative reform will ensure no individual or family pays more than 8.5 percent of their total household income for their health care insurance. The Health Care Improvement Act of 2021 was an amendment to the Patient Protection and Affordable Care Act to reduce healthcare costs and expand healthcare coverage to more Americans, requiring the Secretary of Health and Human Services to create a low-cost public healthcare option. It aims to reduce healthcare costs and protect citizens with preexisting conditions. The *Health Care Improvement Act of 2021* would lower costs for working families by:

- Capping healthcare costs on the ACA exchanges
- Establishing a low-cost public health care option
- Authorizing the federal government to negotiate prescription drug prices
- Allowing insurers to offer health care coverage across state boundaries
- Supporting state-run reinsurance programs
- Incentivizing states to expand Medicaid
- Expanding Medicaid eligibility for new moms
- Simplifying enrollment
- Increasing Medicaid funding for states with high levels of unemployment
- Funding rural healthcare providers
- Reducing burdens on small businesses

Key Takeaways

- The Affordable Care Act (ACA): The ACA, also known as Obamacare, was signed into law in 2010 and aimed to increase access to healthcare and reduce costs. Some of the key

provisions of the ACA include the expansion of Medicaid, the creation of health insurance exchanges, and the requirement that all individuals have health insurance coverage.

- Drug pricing: There has been a growing concern about the high cost of prescription drugs in the United States. In response, there have been efforts to increase transparency in drug pricing and to allow the government to negotiate drug prices directly with pharmaceutical companies.
- Mental health and addiction services: Mental health and addiction services have long been underfunded and stigmatized in the United States. There have been recent efforts to increase access to mental health and addiction services, including the expansion of telemedicine and the integration of mental health services into primary care.

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PART I
TORTS

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Introduction

Within the intricate tapestry of law, torts occupy a significant space, representing civil wrongs that inflict harm upon an individual. Among the diverse landscape of tortious acts, a prominent category emerges in the healthcare realm: medical malpractice. This tort absorbs the concept of negligence, where a healthcare provider's deviation from the expected

standard of care results in patient harm. In other words, it embodies the failure to act with the prudence and skill that a reasonably competent healthcare professional would demonstrate in similar circumstances. Here we begin to dissect the legal framework surrounding negligence within the healthcare context and meticulously navigate the definitions of duty, breach, causation, and damages, elucidating the elements necessary to establish a successful claim.

Learning Objectives

- Explain the requirements to prove a tort by negligence, known in healthcare as medical malpractice
- Explain issues related to proof of medical malpractice
- Develop business implications related to medical malpractice

What is a tort?

A tort is a civil wrong committed upon an individual or as

typically termed in healthcare, **medical malpractice** which falls under the legal doctrine of **negligence**. **Strict liability** (like medically defective products) is a legal doctrine that causes someone to be liable for the damages their actions or product causes regardless of fault. Tort liability is determined by the premises that: (1) one individual should not intentionally injure another person or their property. (2) Everyone should exercise reasonable care and caution in the conduct of their affairs. The main difference between intentional torts and negligence is **intent** which is present in intentional torts but not in negligence.

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https://pressbooks.uwf.edu/healthcarelaw/?p=283#oembed-1

What is Torts? And What Torts is Not. [YouTube]

Negligence

Negligence is a lesser form of fault than intentional torts, so damages in negligence cases are limited to actual damages, not punitive damages. It can be carelessness resulting from a

deviation from the standard of care. Unlike the intentional tort, negligence rests on a spectrum of lesser faults. Negligence claims are generally restricted to the redress of "actual damages," as opposed to the punitive damages reserved for more egregious misconduct. At its core, it stems from a failure to uphold a requisite standard of care, resulting in foreseeable harm.

Table 1. Types of Negligence

Types of Negligence	Definition	Example
Slight Negligence	Minor deviation from the expected standard of care	A doctor forgets to order a routine blood test.
Ordinary Negligence	Failing to do what a reasonably prudent person would do	A driver rear-ends another car while distracted.
Gross Negligence	Intentional disregard for safety or a reckless act	A surgeon leaves an instrument inside a patient.

Proof of Negligence

Proof of negligence is determined by four elements: duty, breach, causation, and damages.

- **Duty:** The defendant has a duty or obligation to act reasonably to avoid harming others. This duty is based on the relationship between the defendant and the plaintiff. *Did a physician-patient relationship exist?*
- **Breach:** The defendant breached their duty of care by failing to act reasonably. This means that the defendant did not take the precautions that a reasonable person would have taken in the same situation. This is a deviation from the standard of care or failure to adhere to an obligation. *Did the physician fail to meet the standard of care?*
- **Causation:** The defendant's breach of duty must have caused the plaintiff's injuries. This means that the plaintiff's injuries would not have happened if the defendant had not breached their duty. *Did the physician fail to meet the standard of care?*
- **Damages:** The plaintiff must have suffered actual damages (foreseeable injury) as a result of the defendant's negligence. This means that the plaintiff must have suffered some type of financial or physical loss. *Did the patient incur actual damages as a result of*

the breach?

In addition to these four elements, other factors, including the patient's age, health, and medical history, as well as the severity of the patient's injuries, may affect the liability of a physician in a negligence case. Furthermore, strong incentives are provided to take reasonable care and prevent injury.

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An Overview of Tort Law: Intentional Torts, Neg

A. Duty

To determine negligence, the first question is whether or not a duty is owed. This is established by the fact that the actions of a **tortfeasor** can lead to a foreseeable risk of injury (Perry & Thompson, 2017). Examples of tortfeasors include a driver, doctor, landlord, babysitter, business, etc. Regular citizens are not required to assist someone in foreseeable danger unless they create the danger. For example, if a child is drowning, you

do not have a legal duty to save the child unless you have a duty to protect the child, such as a parent, lifeguard, or caregiver, or if you created the danger by allowing a hose to drain water filling a public area.

- In a negligence lawsuit, the plaintiff must demonstrate the defendant owed him or her a **duty of care**.
- The duty of care can be highly specific or applied more generally to the public.
- If the court decides that the defendant did not meet his or her duty of care, the defendant can be found in "breach of duty of care."

1. The Carrol Owing Rule

To determine whether or not standard duty or reasonable care is provided depends on the circumstances. In the case *United States v. Carrol Towing* ***United States v. Carrol Towing***, the judge determined negligence by using an algebraic function of three variables: if the probability is called P; the injury is L; and the burden is B; liability depends upon whether B is less than L multiplied by P. **B<PL** Using this equation, the expected benefit should exceed the cost and reduce the probability of an accident (Perry & Thompson, 2017). Healthcare providers may be sued for negligence if an individual is injured when the provider fails to exercise the appropriate standard of care. However, the claimant must show:

1. a duty existed for the provider to conform to a certain standard of care,
2. the provider breached that duty of care,
3. the claimant sustained actual loss or damage from the conduct or omission by the provider, and
4. that the loss or damage suffered was proximately caused by the provider's breach of duty.

In general, duty is always owed under

- Common law (duty owed by provider): reasonably foreseeable plaintiff
- Statutory duty (mandated by laws such as the **EMTALA**)

2. Standard of Care

Typically, the standards of care have been determined by asking what a similar individual would do in this circumstance. For physicians, the nature of medicine requires a comparison with similar skill sets of similar physicians. To determine the standard of care, courts need to determine two key items:

- **The skill and knowledge ordinarily possessed by a reasonably competent practitioner in the same medical specialty.** This means that the court will consider the level of training, experience, and knowledge that is typically possessed by other doctors in the same

specialty as the defendant doctor.

- **The degree of care and skill that a reasonably prudent practitioner would exercise under the same or similar circumstances.** This means that the court will consider the specific facts and circumstances of the case, such as the patient's condition, the risks and benefits of the treatment, and the available alternatives.

3. Location

An additional consideration of the court when determining what a "reasonable physician" would do is the locality. Previous courts used a strict locality standard in medical malpractice cases, but recently courts have moved away from this standard due to the difficulty of getting local physicians to testify against other local physicians and the increasing nationalization of the medical community. This meant that the standard of care was set by the practices of other doctors in the same community as the defendant doctor. However, several factors have led recent courts to move away from the strict locality standard. One factor is the difficulty of getting local physicians to testify against other local physicians. Another factor is that the medical community is becoming increasingly national and specialized. This means that the practices of doctors in one community may not be the same as the practices of doctors in another community. Additionally, in smaller communities, specialists may be limited, and the standard of care for that specialty should be reviewed by the

same type of specialist; however, this may not be true in all states.

B. Breach

The second element in a negligent action is proof of breach of duty. Once duty has been established and a party fails to provide reasonable care, which may include taking a particular action or not doing some other action, a breach is proven. Typically, medical expert testimony is used to prove medical malpractice. The expert must be able to show that the physician departed from the standard of care. There are cases where experts are not necessary to prove **breach** of care. For example, an injured patient can claim ***negligence per se***. With this argument, a plaintiff must show that the statute was violated and that the violation was an actual and proximate cause of the accident. An example would be an ER provider refusing a critically ill patient, directly violating the **EMTALA**.

Additionally, accreditation bodies and regulatory standards can specify standards of treatment. These are referred to as "never events" or "adverse events." To better prevent their occurrence, the **[pb_glossary id="394"]National Quality Forum**[/pb_glossary] has published a list of "Serious Reportable Events" ("SRE"s). The list of serious reportable events, or "never events," includes:

- Surgical or invasive procedure events

    - Wrong site
    - Wrong patient
    - Wrong procedure
    - Retention of foreign body
    - Postoperative death
- Product or device events
    - Patient death associated with contaminated drug or device
    - Death or serious injury associated with the use of a device
    - Death or serious injury associated with IV air embolism
- Patient protection events
    - Discharge of patient who is unable to make decisions (to an unauthorized person)
    - Death or serious injury associated with patient elopement (disappearance)
    - Patient suicide, self-harm, or attempted suicide resulting in injury
- Care management events
    - Patient death or serious injury associated with a medication error
    - Patient death or serious injury associated with unsafe administration of blood products
    - Maternal death or serious injury associated with labor or delivery in a low-risk pregnancy
    - Death or serious injury of a neonate associated with

labor or delivery in a low-risk pregnancy
    - Patient death or serious injury associated with a fall
    - Any Stage 3, Stage 4, and unstageable pressure ulcers acquired after admission
    - Artificial insemination with the wrong donor sperm or the wrong egg
    - Patient death or serious injury resulting from the irretrievable loss of an irreplaceable biological specimen
    - Patient death or serious injury resulting from failure to follow up or communicate laboratory, pathology, or radiology test results
- Environmental events
    - Patient or staff death or serious injury associated with an electric shock
    - Incident where a system designated for oxygen or other gas to be delivered to a patient contains no gas, the wrong gas, or is contaminated by toxic substances
    - Patient or staff death or serious injury associated with a burn incurred from any source
    - Patient death or serious injury associated with the use of physical restraints or bedrails while being cared for
- Radiologic events
    - Death or serious injury of a patient or staff associated with the introduction of a metallic

object into the MRI area

- Potential criminal events
  - Any care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider
  - Abduction of a patient
  - Sexual abuse/assault on a patient or staff member
  - Death or serious injury of a patient or staff member resulting from a physical assault (i.e., battery)

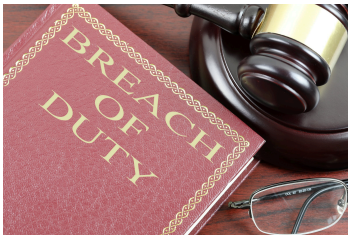
Additionally, plaintiffs can prove breach without evidence of a deviation from the standard of care if it satisfies *res ipsa loquitur*, Latine for "the thing speaks for itself.***res ipsa loquitur*** Three elements are needed to show *res ipsa loquitur,* which include:

1. The accident generally would not have occurred unless negligence was provided.
2. Harm was under the exclusive control of the defendant.
3. The accident was not caused by the plaintiff.

What defense is needed to prove breach?

- Expert Testimony
- Negligence per se
- Serious reportable events
- *Res Ipsa Loquitur*

C. Causation



Breach of duty by Nick Youngson CC BY-SA 3.0 Pix4free

The second element in a negligent action is **causation**. It is a necessary element of many legal claims, including negligence, product liability, and intentional torts. There are two main types of causation in law:

- **Factual causation,** also known as actual causation, meaning "but for" breach of duty, the injury would not have occurred.
- **Proximate causation** means the injury must be a foreseeable outcome.

However, causation can be difficult to prove, especially in cases where harm could be the result of many causes. The burden of proof rests on the plaintiff. Proof of causation includes expert testimony and is most difficult to prove in the medical context. If the defendant can show that the injury would likely have happened regardless of their direct care, the defendant is not liable. Meaning the outcome was inevitable.

Analougus duty is used to describe the relationship between causation and duty of care. To determine if an **analogous** duty already exists, the following are needed:

- **Foreseeability**
- **Proximity**

Arguments in favor of the existence of an analogous duty in causation:

- The law of torts is based on the principle of fairness. It is unfair to allow someone to cause harm to another person without any legal liability.
- The concept of analogous duty is already used in other areas of law, such as the law of negligence.
- There is a growing trend in the law to recognize the importance of preventing harm, even if there is no explicit duty of care.

Arguments against the existence of an analogous duty in causation:

- The law of torts is based on the principle of fault. It is unfair to hold someone liable for harm that they did not intend to cause.
- The concept of analogous duty is too vague and uncertain. It would be difficult to apply it in practice.
- The law of torts should not be used to create new duties of care. This would lead to increased litigation and uncertainty.

Table 2. Negligence Defenses

Defenses	
Contributory/ Comparative Negligence	Did the Plaintiff fail to take proper care?
Assumption of Risk	Did the plaintiff agree to assume the risks?
Informed Consent	Did the plaintiff consent to the risks of medical treatment?
Statutes of Limitations	Did the plaintiff file their claim in time?

D. Damages

The final element of proof of negligence is to show damages suffered as a result of the breach of duty by the defendant. This can be as straightforward as economic salary loss, pain/suffering, or death. Reform attempts have been made to limit the amount of pain and suffering damages awarded in tort litigation. The purpose of tort litigation is to compensate victims for injuries incurred by the fault of another party. Victims typically hire attorneys to collect damages, and attorneys are compensated through a contingent fee system, which means they receive a percentage of the recovery. Contingent fees make the legal system accessible to all, regardless of their ability to pay. However, some people believe that contingent fees are unfair when the injuries are very

substantial and liability is easily established. For example, in a case where a victim is awarded $15 million for the loss of two legs, it may be difficult to justify an attorney's fee of $5 million.

1. Compensatory Damages

Compensatory damages are intended to compensate the victim for their actual losses, such as medical expenses, lost wages, and pain and suffering. They are meant to make the victim whole as if the injury had never happened. Compensatory damages can be awarded in a variety of cases, including personal injury, property damage, and wrongful death. The amount of compensatory damages awarded will vary depending on the specific facts of the case. No amount of money can replace an arm, eye, or life, but monetary damages can help with the costs of damage to property or hospital bills. Experts use life expectancy tables to compute compensatory damages with a degree of accuracy.

2. Punitive Damages

Punitive damages are intended to punish the defendant for their wrongful conduct and to deter others from engaging in similar behavior. They are not meant to compensate the victim for their losses. Punitive damages are not awarded in all cases. They are typically only awarded in cases where the defendant's conduct was particularly egregious, such as in cases of intentional torts or gross negligence. Punitive damages can be

subject to limitations. Courts suggest that these damages cannot exceed a 10:1 ratio with the initial award amount. Many states have been more aggressive with punitive damage limits for personal injuries, with fixed caps starting at $250,000 in some states and up to $10,000,000 in others.

3. Limitation of Damages

Limitation of damages refers to laws that restrict the amount of damages that can be awarded in certain types of cases. These laws are often put in place to protect defendants from excessive liability. Limitation of damages laws can vary from state to state. Some states have no limitations on damages, while others have strict limits on the amount of damages that can be awarded. Limitation cap amounts can range from $250,000 to $800,000; however, all make exceptions for cases involving death and serious injuries like the loss of a limb during surgery. Cases that provide these exceptions either permit a higher damage cap or eliminate the cap altogether. Few states have placed damage caps for personal injury claims.

Malpractice

Malpractice is a type of negligence that occurs when a hospital or professional, such as a doctor, lawyer, or accountant, fails to provide the care that a reasonably competent professional would have provided in the same circumstances. Malpractice

can result in harm to the patient or death, and it can lead to a lawsuit. Four elements must be proven to establish medical malpractice:

- The healthcare professional has a duty of care to the patient.
- The healthcare professional breached that duty of care.
- The patient suffered damages as a result of the breach.
- The damages were caused by the breach of duty.

In medical malpractice cases, even though the standard of care is determined by experts, the question of whether negligence occurred is ultimately decided by a jury. In many cases, juries find that liability exists, even when members of the profession contend that the care provided was reasonable.

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UAE Medica Liability & Malpractice Law Expla

The number of malpractice suits against doctors and hospitals has increased rapidly in recent years, and the size of the verdicts

has also increased. This has had a significant impact on the practice of medicine and the cost of malpractice insurance. Many doctors have been unable to obtain adequate malpractice insurance coverage, and some have been reluctant to attempt medical procedures that could result in a malpractice suit. As a result, many doctors are practicing defensive medicine, which is more costly. Malpractice cases against lawyers have also increased significantly, but the impact on the cost of legal services is not as great as it is on medical services. Malpractice litigation against accountants is another area of growing significance.

Defensive medicine is the practice of ordering tests or procedures that are not strictly necessary to protect oneself from a malpractice lawsuit. Defensive medicine can be costly for both patients and healthcare providers. The cost of malpractice insurance has increased significantly in recent years, which has passed on costs to patients through higher medical bills. Some doctors have changed their practice patterns in response to the threat of malpractice lawsuits. For example, some doctors may be less likely to perform risky procedures or to admit patients who are considered to be high-risk. Additionally, some states have had a shortage of specific specialties due to the costs associated with malpractice insurance for those providers.

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How Can Doctors Avoid Malpractice Suits? Be Nic

Strict Liability

In tort law, **strict liability** is a legal doctrine that holds someone responsible for the harm they cause, even if they did not intend to cause harm or were not negligent. This doctrine is based on the idea that certain activities are inherently dangerous and that the people who engage in these activities should be held responsible for the harm that they cause, regardless of their intentions or level of care. The law of strict liability began with owning dangerous animals and has since expanded to include other types of activities, such as the manufacturing of fireworks, toxic chemicals, and explosives. In healthcare, this can extend to defective medical products and equipment. These activities are also considered to be inherently dangerous, and the people who engage in them should be held responsible for the harm that they cause. Under

strict liability, the plaintiff does not need to prove that the defendant was negligent. Instead, the plaintiff only needs to prove that the defendant engaged in the dangerous activity, that the activity caused the harm, and that the plaintiff suffered damages. This means that even if the defendant took all reasonable precautions, they can still be held liable for the harm caused by their dangerous activity.

Restatement (Third) of Torts shows product liability through three avenues: manufacturing defect, design defect, and warning defect. The Restatement of the Law (Third) of Torts is a multi-volume treatise on tort law published by the American Law Institute (ALI). It is a revision of the Restatement of the Law of Torts, published in 1934. The Third Restatement is still under development, but it has been published in several volumes, including:

- Liability for Physical and Emotional Harm (2010/2012)
- Apportionment of Liability (2000)
- Products Liability (1998)
- Liability for Economic Harm (2020)

The Third Restatement is a comprehensive and authoritative source of tort law. It is used by judges, lawyers, and scholars to interpret and apply tort law. The Third Restatement also guides legislators and policymakers who are considering changes to tort law. The Third Restatement has been criticized by some for being too complex and for departing from

traditional tort principles. However, it is still considered to be an important work of legal scholarship. The Restatement (Third) of Torts 47 is a section that deals with the issue of emotional harm. It provides that a plaintiff may recover for emotional harm alone if the harm is severe and the defendant's conduct is extreme and outrageous. This is a significant departure from the traditional rule, which required plaintiffs to prove that they had also suffered physical harm to recover for emotional harm. The Restatement (Third) of Torts 47 has been cited by courts in several cases, and it is likely to have a significant impact on the law of emotional harm.

A plaintiff must show that medical products depart from the intended design to prove a manufacturing defect. A design defect is determined by providing an alternative design that provides similar benefits but a lower risk of harm. A warning defect is a product defect that occurs when the manufacturer fails to provide adequate warnings about the dangers of using the product. examples include:

- A power tool that does not have any safety instructions.
- A children's toy that does not have a choking hazard warning.
- A medication that does not have a warning about its side effects.
- A car that does not have a warning about its blind spots.
- A lawnmower that does not have a warning about the dangers of operating it near children.

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https://pressbooks.uwf.edu/healthcarelaw/?p=283#oembed-5

What is Strict Liability Crime? [YouTube] 2015

Intentional Torts

Intentional torts involve (1) interference with the personal freedom of an individual, (2) interference with property rights, (3) interference with economic relations, and (4) wrongful communications.

1. **Assault**
2. **Battery** is defined as the harmful touching of someone without their consent.
3. **False imprisonment** is the unlawful physical restraint of a patient. For example, when a patient is locked in a room and not permitted to leave.
4. **Invasion of privacy** which occurs with improper disclosure of medical treatment information and violations protected under HIPAA. All patients have a

right to the reasonable expectation of privacy. Other circumstances also exist outside of the medical industry, including phone tapping and the use of photos or images without permission.

5. **Mental Distress** is a tort that occurs when someone intentionally or recklessly causes another person severe emotional distress. It can be caused by the high-pressure tactics of collection agencies, including violent cursing and accusations of dishonesty. However, it is not a tort when someone simply insists on their legal rights, even if they know that it will cause emotional distress.

Table 3. Theory of Liability

Theory of Liability	Description
	Interference with Personal Freedoms
Assault	Causing harm or offensive contact with a person's body
Battery	Intention and unpermitted physical contact with a person's body
Assault and battery	A combination of assault and battery
False imprisonment	A wrongful restraint of a person's freedom of movement
Mental Distress	Wrongful interference with a person's peace of mind by insults, indignities, or outrageous conduct
	Interference with Property Rights
Trespass on property	Unauthorized entry on private land
Trespass to chattels	Direct, intentional interference (damage) to possession of another person
Conversion	Interference with a person's possession to the extent that the wrongdoer ought to pay for the chattel
Nuisance	Intentional invasion or disturbance of a person's rights in land or the conduct of an abnormally dangerous activity
	Interference with Economic Relations
Disparagement	Injurious falsehoods about a person's business or property, damaging prospective advantage

Interference with a contract	Inducing a party to a contract to breach it or interfering with its performance
Prospective advantage	Interfering with an expectancy such as employment or an opportunity to contract
Wrongful appropriation	Infringing on goodwill, patents, trademarks, copyrights, and other business interest
	Wrongful Communications
Slander	Oral defamation causing harm to a person's reputation
Libel	Written defamation causing harm to a person's reputation
Fraud	An intentional misstatement of material existing fact about an injury, also a defense to the formation of a contract
Invasion of privacy	Interfering with one's right to be let alone by the following: -Appropriating the name or picture of a person -Intruding on a person's physical solitude -Publically disclosing private facts -Using publicity that places a person in a false light in the public eye

Defenses

In a tort case, the plaintiff must prove that the defendant's actions were negligent and that the negligence caused the plaintiff's injuries. The defendant can then raise an affirmative defense to try to avoid liability. The two main affirmative

defenses in tort law are the assumption of risk and contributory/comparative negligence.

- **Contributory/comparative negligence** is a defense that applies when the plaintiff's own negligence contributed to their injuries. Awards to the plaintiff may be reduced or eliminated if the defendant can show that the plaintiff was negligent. For example, if a patient is noncompliant with treatment (medication regimes).
- **Assumption of risk** is a defense that applies when the plaintiff voluntarily and knowingly exposes themselves to the risk of harm. For example, if a person signs a waiver before participating in a dangerous activity, they may be assuming the risk of injury. For medical malpractice, the assumption of risk is more closely related to the doctrine of informed consent.

The defendant has the burden of proof for affirmative defenses. This means that the defendant is responsible for proving that the defense applies. The concept of informed **informed consent** consent is related to the assumption of risk. Informed consent means that the plaintiff voluntarily agrees to an activity after being fully informed of the risks involved. If the plaintiff does not give informed consent, they may be able to recover damages even if they assumed the risk of injury. Finally, tort claims may be dismissed if they are not filed within the time of the statute of limitations. The statute

of limitations is a law that sets a time limit on how long after an injury a person can file a lawsuit. If a lawsuit is not filed within the statute of limitations, it will be dismissed. The following must be disclosed for informed consent to be effective:

a. The diagnosis

b. What the recommended treatment is, and its purpose

c. Benefits and risks of this treatment

d. What alternatives are available, including no treatment

e. Benefits and risks of alternatives

Informed consent shields the medical personnel from liability concerning procedures described in the consent, or if an unexpected circumstance is addressed and the patient is unable to be consulted. An example is life-saving measures during surgery.

Key Takeaways

- A tort is a civil wrongdoing. When a medical provider's actions or inactions fail to meet the medical standard of care, their behavior constitutes medical negligence. If their medical negligence causes their patient to suffer an injury, it becomes medical malpractice.
- Proof of negligence requires four elements: duty, breach, causation, and damages.
- The Learned Hand Rule: B<PL (B=burden, P=probability, L=injury)
- Standards of care are defined as the actions a similar individual would do in that circumstance.
- Defenses for tort include contributory negligence, assumption of risk, informed consent, and statute of limitations.
- Correlation does not equal causation.
- Types of damages: compensatory (actual losses) and punitive (punishment wrongful for conduct)
- Strict Liability is a legal doctrine that holds someone responsible for the harm they cause, even if they did not intend to cause harm or were not negligent.

- Intentional torts are willful wrongdoings that interfere with an individual's freedom or rights.

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PART I
CONTRACT LAW

Contract disputes by Nick Youngson CC BY-SA 3.0 Pix4free

Introduction

One of the most significant areas of business law is contracts. All industry relationships are shaped by contracts, which are ubiquitous. An agreement is created whenever a business hires a worker, a company purchases a product or service, or a patient seeks a healthcare provider. Contracts are structured promises. A patient commits to pay the doctor's reasonable

price in exchange for the doctor using her best judgment in treating them. Beyond making promises, another way to see a contract is as a record of a relationship. The agreement outlines each party's obligations and rights. Contracts can typically be express (written or verbal), implied by fact (handshake), or implied by law. Both express and implied contracts are the product of an agreement between the contracting parties. This consensus of opinion is known as **mutual assent**. In an express contract, the parties formally agree to the terms of the agreement through written or verbal communication. A contract that is implied in reality is one where the actions of the parties and the environment indicate that they agree on the conditions. Voidable contracts allow one of the parties (but not the other) to escape the legal obligations of the contract. In an implied contract, the conduct of the parties and the surrounding circumstances show mutual assent to the terms. Contracts implied in law are recognized by the law on the basis of justice and equity but may not include the literal assent of both parties. These unique situations are referred to as contracts "implied in law," "quasi-contract," or "quantum meruit" (Perry & Thompson, 2017).

Learning Objectives

- Identify the requirements of a contract
- Analyze contract issues in healthcare law
- Interpret the implications related to healthcare contracts
- Analyze and develop a systematic review of case law concerning contracts

What is a contract?

Essentially, a contract is a legally enforceable promise. Typically, a contract is formed with two or more parties agreeing to something, and if one fails to uphold the agreement, that is considered a breach of contract. To be considered a legal contract, the following items must be present: mutual assent, consideration, legality, and capacity. The elements of a contract, whether written or verbal, include ***offer***, ***consideration***, and ***acceptance***. An enforceable contract is legally binding. A breach of contract occurs when one or more of the terms of the contract are violated (Perry & Thompson, 2017).

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Contracts Law [YouTube] 2016 by Lanard and Asso

Elements of a contract

For a contract to be legally enforceable when executed, several factors must be considered. The first is the competency of the parties. Certain classes of individuals (minors, prisoners, or mentally incompetent) are considered incompetent in a legal capacity to create a binding contract. Whether verbally or written, the following elements of a contract must exist: offer, consideration, and acceptance (Morgan, 2019).

A. Offers

An offer must be created with reasonable expectations where the offeror presents a commitment in exchange for one of the three following responses by the offeree:

1. does something (performs an act),
2. refrains from doing something (forbearance), or
3. promises to do something or to refrain from doing something.

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Contracts: The Offer [YouTube] 2012 by Center f

Elements of an offer:

1. Intent (intent to be bound to terms) statements lacking intent
2. Definite terms: material and essential terms
3. Communication by offeror or offeree

Duration

The duration of an offer typically refers to the period during which the terms and conditions of a particular offer or proposal are valid. The duration of an offer is important

because it sets a time limit for the recipient to accept the offer before it expires. The specific duration of an offer can vary widely depending on the context and the intent of the parties involved. In some cases, offers might be open for a short period, such as a few days or a week, while in other cases, they might have a longer duration, such as several months. The duration of an offer is often outlined in the offer itself or accompanying documentation (Morgan, 2019).

It's important to note that if an offer has a stated expiration date or time frame, the offer generally becomes invalid once that time has passed. If the recipient wishes to accept the offer after it has expired, they would need to reach out to the offeror (the party making the offer) to see if the offer can be extended or renegotiated. For legally binding contracts and important agreements, it's advisable to clearly specify the duration of the offer to avoid misunderstandings and ensure that all parties are on the same page regarding the timeframe for acceptance. The offeree has the power to accept until the offer is terminated. An offer that has been properly communicated continues in existence until it

1. lapses or expires,
2. is terminated by operation of law (illegality and incapacity),
3. is rejected by the offeree,
4. is revoked (directly or indirectly) by the offeror, or
5. receives a counteroffer (Morgan, 2019).

Methods of terminating an offer:

1. **Lapse of time**
2. **Termination by operation of law**
3. **Rejection by offereeCounteroffer**
4. **Revocation by offeror**
5. **Counteroffer**

Mutual Assent

For a contract to be formed, parties must voluntarily agree to the terms, which is **mutual assent** (Perry & Thompson, 2017). Once an offer is made by the *offeror* and accepted by the *offeree,* it is validated, provided the following exists:

1. Present intention to contract
2. Reasonably definite terms
3. Communication of offer to the proper party

Once an agreement is reached, an offeree performs tasks requested by the offeror. Tasks must be clearly communicated; otherwise, there is no mutual assent. Moreover, there is a need for clarity in defining the specific terms.

Defenses to Mutual Assent

- **Duress**

    - When someone is involuntarily forced to sign a contract under some sort of threat
- Misunderstanding
    - When parties have attached different meanings to a term but one party is unaware of the assumption
- Undue Influence
    - Unfair persuasion/abuse of trust in a Confidential or Fiduciary Relationship
- Misrepresentation or **Fraud**
    - Misrepresentation or concealment of material fact opinion/value
    - Reasonably or Justifiably Relied upon by the defrauded party
    - Causes damages to that party
    - Fraudulent assertations
- Mutual **Mistake of Fact**
    - Erroneous beliefs of the parties that induce an agreement
    - Must be made by both parties, involve basic assumptions, and materially affect the agreed-upon exchange
    - This contract is only voidable by the party that is adversely affected by the mistake.

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Contract Defenses for Lack of Mutual Assent: Mi

B. Consideration

Consideration is not a concrete concept. For consideration to exist, there must be a legal detriment (forgoing something a person is entitled to or doing something a person does not have to do) as a result of "bargained for exchanged." An example of this could be the exchange of money. Furthermore, courts do not determine if consideration is fair; however, if no money is exchanged for the promise, the courts will not enforce it because it lacks consideration. In the absence of fraud, oppression, undue influence, illegality, or statutory limitation, parties have the freedom to make any contract; moreover, the fact that it is onerous or burdensome for one or the other has been immaterial (Perry & Thompson, 2017).

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https://pressbooks.uwf.edu/healthcarelaw/?p=287#oembed-4

Contracts: What is Consideration? [YouTube] 201

C. Acceptance

Once an offer by one party (offeror) has been made, the **acceptance** by the offeree is an indication of their willingness to be bound to the terms of that offer. Once accepted in the affirmative, there is typically a written or electronically signed offer. It must be noted that the offeree is the only person that can accept the offer. In other words, the offeree cannot assign the offer to a third party. Offerees are protected by a rule making the acceptance effective at the time of dispatch, also known as the *mailbox* or *deposited acceptance rule*. However, applying the mailbox rule can be avoided if the offeror states that the offer is not effective until it is actually received (Perry & Thompson, 2017). Courts can enforce offers that prescribe an exclusive method of acceptance. A valid acceptance requires the following:

- Meeting of the minds: mutual assent
- Definite and complete: terms agreed upon are complete and understood by both parties
- Duration: offeree's time limits to accept the offer
- Complete & conforming: acceptance of all terms mirrors offer

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Contracts: Acceptance [YouTube] 2012 by Center

C. Other Requirements

For a contract to be lawful, other requirements in addition to mutual assent and consideration are needed. Both parties must have sufficient legal capability to enter the contract. This is similar to consent for treatment in healthcare. For a party to have **capacity**, the person must be conscious, have the ability to understand the contract, or has a legally appointed guardian by the court (Perry & Thompson, 2017).

Contracts must also contain **legality**. Courts will not

enforce contracts that extend over the limits of public policy. One common example is a "non-compete clause" where one party promises not to compete with the other prohibiting them from working for competing businesses. Most courts hesitate to enforce this because it reduces competition and limits labor mobility. Whether to enforce a non-compete clause is determined by whether:

(1) there is a legitimate business interest for the clause and

(2) whether the clause is tailored to protect legitimate business interests (Perry & Thompson, 2017).

Table 1. Reasonable Terms for Business Interests

Legitimate business interest	**Reasonable in terms of**
Confidential Information	Time
Good Will	Geographic Location
Special Training	Business Activity

Non-compete agreements are generally violations of public policy and are unenforceable in many states unless:

- It protects legitimate property interests or some legitimate interests of the employer
- It is reasonably tailored to the circumstances, including time, location, and business activity, within reason

It should be noted that these types of contracts must be put in writing to be enforceable. The Statute of Frauds requires certain contracts to be in writing. These contracts include contracts for real estate, contracts for goods over a certain value, suretyships, and contracts that cannot be performed within one year. To enforce a contract that falls under the Statute of Frauds, there must be a written document signed by both parties (Perry & Thompson, 2017).

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https://pressbooks.uwf.edu/healthcarelaw/?p=287#oembed-6

Statues of Frauds [YouTube] 2013 by Center for

Balancing Test

The balancing test is a complex and evolving legal concept. However, it is an important tool that allows judges to make informed decisions about the enforceability of contracts. In contract law, a balancing test is a judicial test in which the judge weighs the importance of multiple factors in a legal case (Morgan, 2019). The factors that are weighed may vary depending on the specific case, but they may include the following:

- The intent of the parties to the contract
- The fairness of the contract
- The public interest
- The economic consequences of enforcing or not enforcing the contract

The balancing test is often used in cases where there is no clear rule or precedent to apply. In these cases, the judge must weigh the competing interests of the parties and decide which interest is more important. One example of a balancing test in contract law is the unconscionability doctrine. Unconscionability is a doctrine that allows a court to invalidate a contract if it is found to be unfair or one-sided. The balancing test is a flexible tool that allows judges to take into account the specific facts of each case. However, it can also be criticized for being subjective and unpredictable (Morgan, 2019).

Here are some other examples of balancing tests used in contract law:

- The reasonable expectations test
- The good faith and fair dealing doctrine
- The economic duress doctrine
- The adhesion contract doctrine

Remedies

Remedies are an important part of the legal system. Remedies help to ensure individual rights are projected and wrongdoing should be compensated. In terms of legal remedies, it is divided into two main categories: legal remedies and equitable remedies. Legal remedies are based on the law and awarded by the court. Equitable remedies are based on fairness and justice and are awarded by a court of equity (Perry & Thompson, 2017).

Table 2. Legal and Equitable Remedies

Legal Remedies	Equitable Remedies
Damages	**Injunction**
Restitution	**Specific Performance**
Reliance	**Rescission**
Expectation	
Consequential (must be foreseeable)	
Liquidated	

Often, the calculations of damages can be uncertain. However, contracts can stipulate the level of damages in the case of breach, and this is termed **liquidated damages**. Liquidated damages act to provide assurances that both parties intend to uphold their portion of the contract. Unfortunately, courts may hesitate to enforce liquidated damages, specifically if they are seen as punitive. Enforcement of liquidated damages relies on whether or not the agreed-upon damages are reasonable estimates of damages based on the information known at the time of contracting. Consequential damages arise when the breach of one contract affects the breached-upon party's ability to perform another contract. Punitive damages are awarded to discourage particular behaviors, like fraud (Perry & Thompson, 2017).

Injunctions are court-enforced orders that require one party to do or refrain from doing something, and it can be either temporary or permanent. Damages are monetary awards

that are given to compensate someone for a loss that they have suffered. Damages are typically awarded when someone has been injured or harmed by the wrongful act of another person. Damages are a liability rule because they allow the injured party to recover money from the person who caused the harm. An injunction is a court order that requires someone to do or refrain from doing something. Injunctions are typically used to prevent someone from causing harm to another person or to protect someone's rights. Injunctions are a property rule because they allow the person who is being harmed to prevent the harm from happening in the first place. In other words, damages are a way of compensating someone for harm that has already been done, while injunctions are a way of preventing harm from happening in the first place (Perry & Thompson, 2017).

Table 3. Types of injunctions and damages

Characteristic	**Damages**	**Injunctions**
Purpose	To compensate for the harm that has already been done	To prevent harm from happening in the first place
Type of rule	Liability rule	Property rule
Who can request it?	The person who has been harmed	The person who is being harmed
What is awarded?	Money	An order to do or refrain from doing something

Equitable Doctrines

Equitable doctrines are a set of legal principles typically used to supplement the common law. Equitable doctrines are an important part of contract law. They help to ensure that contracts are fair and just and that they are enforced in a way that is consistent with the principles of equity (Morgan, 2019). Equitable doctrines can be used to intervene in contract law in a number of ways. For example, they can be used to:

- **Invalidate a contract that is unconscionable:** Unconscionability is a doctrine that allows a court to invalidate a contract if it is found to be unfair or one-sided.
- **Prevent a party from enforcing a contract that they have obtained through fraud or duress:** Fraud and duress are both grounds for invalidating a contract.
- **Order-specific performance:** Specific performance is a remedy that requires a party to a contract to perform their obligations under the contract. This remedy is typically only available when damages are not an adequate remedy.
- **Remedy a breach of contract:** If one party breaches a contract, the other party may be able to seek equitable relief, such as an injunction or specific performance.

Promissory Estoppel

Promissory estoppel is a legal doctrine that prevents a party from withdrawing a promise made to another party if the latter has reasonably relied on that promise. A promise made without consideration is generally not enforceable. Estoppels were created as rules of evidence, and some (such as estoppel by deed and judgment estoppel) remain evidential in character. It has the same binding effects as a valid contract, where a breach can result in **reliance damages** or **expected damages** (Morgan, 2019).

Quasi-Contract (Quantum Meruit)

A quasi-contract (implied contract) is a legal obligation imposed by the court to prevent one party from unjustly benefiting at the expense of another party and arises when one party provides services to another party without any agreement. Courts can award a reasonable value for services provided. Quasi-contracts can be imposed**unjust enrichment** by law to prevent unjust enrichment. In the absence of a true contract, it is either expressed or **implied in the fact**. However, because quasi-contracts are not true contracts, mutual assent is not necessary. Furthermore, when a party sues for damages under a quasi-contract, the remedy is typically either restitution or recovery under the theory of **quantum meruit** (Morgan, 2019).

Key Takeaways

- A contract is formed by two or more parties for a specific time period
- To be considered a legal contract, the following items must be present: mutual assent, consideration, legality, and capacity
- The elements of a contract, whether written or verbal, include offer, consideration, and acceptance
- A breach of contract occurs when one or more of the terms of the contract are violated
- Numerous legal and equitable remedies help ensure individual rights and deter potential wrongdoing
- Promissory estoppel is a legal doctrine that prevents a party from withdrawing a promise made to another party if the latter has reasonably relied on that promise
- A quasi-contract (implied contract) is a legal obligation imposed by the court to prevent one party from unjustly benefiting at the expense of another party and arises when one party provides services to another party without any agreement

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PART I
PRIVACY, INTELLECTUAL PROPERTY, AND CYBERLAW

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Introduction

For more than 2,500 years, patient privacy has been a fundamental principle in healthcare, as demonstrated by the Hippocratic Oath and other early Greek medical texts. This chapter provides a thorough overview of the legal aspects associated with **privacy**, confidentiality, and information management in the healthcare delivery setting. In addition, intellectual property law is critical in healthcare, as some of the most significant healthcare advancements are safeguarded by intellectual property doctrines. We will explore each principle and its role in securing healthcare business assets (Perry & Thompson, 2017).

Learning Objectives

- Distinguish the legal, ethical, and public policy considerations related to patient confidentiality and privacy of health information
- Explain patents, patent trolls, and what is patentable

- Analyze issues related to trade secrets and copyrights

Privacy and Confidentiality

The commitment to privacy has guided healthcare for centuries. The AMA Principles of Medical Ethics (2001) state, "A physician shall respect the rights of patients, colleagues, and other health professionals, and shall safeguard patient confidence and privacy within the constraints of the law." The Hippocratic Oath, attributed to the ancient Greek physician Hippocrates, required physicians to "abstain from whatever is deleterious and mischievous," seeking only the benefit of their patients. Since 1847, the AMA code has been revised extensively but has maintained the secrecy surrounding the patient-provider relationship (faqs.org, n.d.).

The principles of privacy in healthcare give rise to laws and regulations that dictate patient confidentiality, which involves protecting personal health information. Fundamentally, patients have a reasonable expectation that their health information will remain confidential, except in certain circumstances. Exceptions to confidentiality may be exceptional, as in the **Tarasoff** case, or routine, such as when processing insurance claims, conducting quality control

reviews, or fulfilling research or medical education goals. The importance of respecting patient privacy cannot be understated. Furthermore, legal and regulatory penalties against violations of confidentiality can be significant (Perry & Thompson, 2017).

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The HIPAA Privacy Rule [YouTube] 2016 by Office

Confidentiality

The obligation to uphold patient **confidentiality** arises from the fiduciary bond between a patient and their healthcare provider. The basis for this duty is the notion that respecting a patient's privacy will inspire them to seek medical care. Courts typically view confidentiality breaches unfavorably (Perry & Thompson, 2017).

Exceptions

Although it is the responsibility of healthcare providers to prioritize patient privacy and confidentiality, some exceptions exist. The intricacies of any given situation can complicate the application of legal principles, so the possibility of exceptions should always be taken into account when analyzing a case (Perry & Thompson, 2017).

There are situations where healthcare providers or organizations may have a responsibility to disclose confidential information to parties other than the patient. For example, quality control or peer review may allow for the disclosure of private information in some cases. In other cases, state or federal law, as well as common law, may require confidential information to be shared to protect a specific third party or the broader community. Statutory examples of situations where a breach of confidentiality may be justified include:

- Reporting of communicable diseases to state public health authorities;
- Wounds (from either a knife or gunshot) that appear to be non-accidental;
- Suspected child abuse;
- Suspected elder abuse; and
- Diagnosis of epilepsy among those licensed to drive or operate heavy machinery (Perry & Thompson, 2017).

Health Information Privacy

In 1972, New York designed a law to prevent drugs from being diverted into illegal channels. The law required State Health Department officials to collect personal information, including the name, address, and age of anyone who received certain Schedule II drugs with a prescription from a doctor. This information was to be transferred to computer files and kept for five years, with safeguards in place to protect patient privacy. However, a group of patients who regularly received Schedule II drugs and their prescribing physicians challenged the constitutionality of the patient identification requirements. The lower court ruled that the doctor-patient relationship is protected by the Constitution's right to privacy and that the law's patient identification provisions were too broad. In 1977, the Supreme Court made a significant ruling in Whalen v. Roe that recognized a limited constitutional right to privacy for health information. While upholding the state law, it recognized a "statutory or regulatory duty to avoid unwarranted disclosures" based on the Constitution (Perry & Thompson, 2017).

Health Insurance Portability and Accountability Act of 1996 (HIPAA)

On August 21, 1996, President Bill Clinton signed the Health Insurance Portability and Accountability Act of 1996 into law.

HIPAA established protocols for safeguarding personally identifiable information held by the healthcare and healthcare insurance sectors against fraud and theft and addressed restrictions on healthcare insurance coverage. Covered entities, such as healthcare providers and businesses, are prohibited from disclosing protected information to anyone other than the patient and their authorized representatives without consent, subject to certain exceptions. Patients are free to receive information about themselves and are not restricted from voluntarily sharing their health information (Perry & Thompson, 2017). HIPAA is made up of five titles:

- Title I safeguards health insurance coverage for workers and their families,
- Title II sets national standards for electronic health care transactions and national identifiers, and
- Titles III, IV, and V govern pre-tax medical spending accounts, group health plans, and company-owned life insurance policies, respectively.

In January 2013, the Final Omnibus Rule updated HIPAA to include the **HITECH Act** requirements. The revised regulations enhanced safeguards for patient confidentiality, granted additional privileges to individuals concerning their medical data and bolstered the government's capacity to uphold compliance with more severe penalties for HIPAA violations. However, the HIPAA Privacy Rule provides

waivers during times of natural disaster (Perry & Thompson, 2017).

It is important to note that HIPAA defines a "**Covered Entity**" and prohibits the use of personal health information (**PHI**) for any purposes other than treatment, payment, or health care operations. This excludes any information that has been de-identified. To be considered de-identified data, the information may not contain the following information:

- Name
- Address (all geographic subdivisions smaller than a state, including street address, city county, and zip code)
- All elements (except years) of dates related to an individual (including birthdate, admission date, discharge date, date of death, and exact age if over 89)
- Number of relatives in the household
- Vehicle or other device serial numbers
- Employer
- Telephone numbers
- Fax number
- Email address
- Social Security Number
- Medical record number
- Health plan beneficiary number
- Account number
- Certificate or license number
- Vehicle identifiers and serial numbers, including license

plate numbers
- Device identifiers and serial numbers
- Web URL
- Internet Protocol (IP) Address
- Finger or voice print
- Photographic image: Photographic images are not limited to images of the face.
- Any other characteristic that could uniquely identify the individual (Loyola University Chicago, 2023).

A. HIPAA Myths

HIPAA permits healthcare providers to discuss a patient's condition with others in a semi-private room or over the phone with the patient, another provider, or a family member. It also allows providers to leave messages on a patient's home answering machine and to display a patient's name next to their hospital room door or a patient care sign, such as "fall risk" or "diabetic diet," at the patient's bedside or outside their hospital room. However, HIPAA does ***NOT*** grant patients an unlimited right to their healthcare information. Requests for records may be denied if the information contains psychotherapy notes or was compiled for use in a civil, criminal, or administrative proceeding. Also, if a patient wants a copy of their medical chart, they are responsible for the cost of copying it (Perry & Thompson, 2017).

B. Enforcement

If there are accusations of noncompliance, the Department of Health and Human Services (HHS) is obligated to investigate and ascertain if the violations were due to "willful neglect." In reality, "willful neglect" does not require a high level of proof, and penalties can be substantial. In October 2009, the HHS Office of Civil Rights began publishing the names of healthcare entities with reported data breaches, thus creating the "HIPAA Wall of Shame." Details include the name of the covered entity or business associate that experienced the breach, the category of breach, the location of the breached PHI, and the number of individuals affected. Because of the intricacy of HIPAA regulations and the potential for huge fines for non-compliance, it would be wise for firms and individuals to proceed with an excess of care when using and contemplating the disclosure of PHI (HIPAA Journal, n.d.).

Health Information Technology for Economic and Clinical Health (HITECH) Amendment 2021

In 2018, the HHS issued a Request for Information to explore ways to alleviate the administrative burden of HIPAA compliance and improve healthcare coordination through better data sharing. In response, many covered entities and business associates requested a safe harbor provision in the

event of a data breach if they had adhered to the safeguards of the Security Rule. The **HITECH** Act was amended in 2021, resulting in the HIPAA Safe Harbor law, which provides the Office for Civil Rights at HHS with the flexibility to refrain from enforcing action, mitigate penalties for HIPAA violations, or shorten the duration of a Corrective Action Plan if the offending party has implemented a recognized security framework and has been operating it for twelve months prior to the breach or other security-related violation. According to Astra Security (2023), "The third quarter of 2022 saw 1 in 42 healthcare organizations targeted by ransomware attacks. The healthcare sector saw a 60% increase in attacks in 2021, with an average of 1426 attacks per week. **90%** of healthcare institutions have experienced at least one security breach in the previous few years."

Modifications of HITECH

- Creating incentives for developing the "meaningful use" of electronic health records
- Changing the liability and responsibility of business associates
- Redefining what a breach is
- Creating stricter notification standards
- Tightening enforcement
- Raising the penalties for a violation
- Creating new code and transaction sets (ICD-10)

Breaches

There were no federal requirements to notify patients of a healthcare privacy breach before HITECH. After its implementation in 2009, HITECH now mandates that all affected individuals be notified when protected health information (PHI) is breached. HITECH further defines a breach as "the unauthorized acquisition, access, use, or disclosure of PHI, which compromises the security or privacy of the information." Furthermore, a breach is anything that poses a significant risk of financial, reputational, or other harm to the individual due to the compromise of PHI (Perry & Thompson, 2017). Common breaches include:

1. Lost, missing, or stolen laptops or other portable devices;
2. Disposal of documents, computers, or other materials;
3. Hacking; and
4. third-party mistakes.

To protect its PHI, a covered entity must establish administrative, physical, and technological safeguards, as mandated by the HITECH regulations. HITECH provides a safe harbor for encrypted devices. Apart from this, the covered entity must have administrative safeguards such as policies, procedures, and documentation to ensure that the policies and procedures have been put into effect. HITECH necessitates that the covered entity conduct a risk analysis and devise a risk management plan to mitigate identified vulnerabilities.

Therefore, the covered entity should have a documented risk analysis policy and a corresponding risk management plan in place (Perry & Thompson, 2017).

Notification Requirements

Once an incident constitutes a breach, a covered entity must decide on the appropriate method of informing the impacted patients, as per HITECH regulations. HITECH requires that the covered entity should notify each individual whose unsecured PHI has been breached in writing, using first-class mail, unless the patient has previously consented to receive email communication. In cases where there is a possibility of imminent misuse of the PHI, the notification can be made via telephone. If the covered entity lacks enough information to notify 10 or more individuals, substitute notice becomes necessary. The substitute notice involves a conspicuous posting on the covered entity's website for 90 days or a notice in major print or broadcast media in areas where the affected individuals are likely to reside. If 500 or more individuals in a jurisdiction are affected, notice to prominent media outlets is required, along with immediate reporting to the Office for Civil Rights (OCR). The notification must be expedited no later than 60 days after the date of discovery of the breach (Perry & Thompson, 2017).

The notification to affected individuals must contain various details, such as a description of the incident, the breach date

(if known), the date the breach was discovered by the covered entity, the type of compromised PHI, recommendations on measures individuals can take to protect themselves from potential harm, a description of the investigation, the mitigation or protection measures implemented by the covered entity to prevent future breaches, and contact information, including a toll-free number, for addressing affected persons' questions. State laws could influence the notification's content based on the data elements involved. For example, if an electronic breach of PHI in Florida includes social security numbers and impacts patients residing in Florida, it may necessitate an analysis beyond HIPAA/HITECH requirements. The notification requirements for each state are different, and some states may have stricter regulations than HITECH. In Florida, notification to residents must occur within 45 days, with the attorney general receiving notification as well. A covered entity must look beyond just notification to patients and include attorneys general, other consumer agencies, OCR, law enforcement, the media, and credit reporting agencies when social security numbers are involved in the breach (Perry & Thompson, 2017).

Response

According to HHS.gov, the HITECH Act does not define "harm," nor does it provide direction to aid HHS in defining

the term. When a breach occurs in a covered entity, it should activate its breach incident response team, which is comprised of individuals from the C-Suite and a multidisciplinary team including legal, compliance, information technology, communications, and customer relations. In some instances, security and human resources may also be involved (Perry & Thompson, 2017).

Crisis management processes should include:

- daily status report meetings;
- daily goal setting;
- assignment of tasks for the team to accomplish;
- tracking of progress; and
- decision making.

Priorities for the crisis management team include:

- end the compromise of security or remedy the risk control deficiencies;
- restore the functioning of the affected systems;
- determine the root cause of the incident and mitigation and protection to be utilized;
- evaluate any notice obligations (federal, state, and contractual);
- outreach to key customers and business partners;
- prepare media and internal communications; and
- issue notification.

Costs

In 2022, IBM Security's "Cost of a Data Breach Report" provided evidence that healthcare data breaches cost an average of $10.1 million per incident. This was a 9.4% from the previous year and a 41.6 percent increase from 2020. Healthcare sectors suffered higher **ransomware** attack costs on average, at $4.82 million ($1 million more than the average cost for other industries) (McKeon, 2022).

In the event of security breaches involving sensitive data, healthcare establishments should consider credit monitoring and utilizing internal call centers. Also, considerations should be taken for partnering with a crisis management firm for effective communication strategies and protecting the healthcare entity's reputation. Lastly, they should engage experienced healthcare privacy and data breach attorneys for guidance on regulatory compliance and overseeing the notification process.

Post-Breach

After a healthcare data breach, organizations must address media and affected individuals' concerns, especially for breaches impacting over 500 people. These breaches can undermine community trust and attract significant media attention. Patient inquiries and effective communication by the incident response team are essential. Following the crisis, the Office for Civil Rights (OCR) investigated the entity's

HIPAA/HITECH compliance and the breach's cause, potentially resulting in fines and penalties. Compliance documentation is crucial, and organizations may face requests from other regulatory bodies or legal actions related to Protected Health Information (PHI) disclosure (Perry & Thompson, 2017).

Protection and Prevention

To ensure compliance with HIPAA/HITECH, covered entities must maintain constant vigilance and implement preventive measures against breaches and violations. These measures include adhering to administrative requirements, designating a privacy officer, conducting a risk analysis, and executing a risk management plan. Additionally, organizations should employ technical and physical safeguards, prioritize encryption, provide staff training on PHI disclosure repercussions, and incorporate IT audits. Acquiring cyber liability insurance or exploring alternative risk financing options can add extra protection against healthcare data breaches (Perry & Thompson, 2017).

Exceptions

Patients cannot access all medical records under HIPAA. Providers can withhold certain categories, like psychotherapy notes, and have the discretion to deny disclosure if it may harm the patient. Some test results follow state-specific or federal

regulations on disclosure, such as HIV tests or substance abuse cases.

Emerging Issues

As healthcare increasingly adopts electronic platforms, health law continues to evolve for better protection of individuals affected by data breaches. Electronic Health Records, health information exchanges, and patient portals introduce new vulnerabilities as organizations focus on user-friendliness. Wireless and mobile devices increase the risk of accidental losses and potential disclosures, especially when lacking robust security measures. The growing use of cloud computing and offshore data storage adds further challenges in protecting Protected Health Information. Collaboration between stakeholders, policymakers, and technology developers is crucial to establishing guidelines, standards, and regulations that ensure the responsible implementation of AI in EHR systems.

The integration of AI with EHRs presents several challenges, including data privacy and security concerns, issues of bias and fairness, interpretability and transparency of AI models, questions of liability and accountability, the need for data quality and standardization, and ethical and legal implications. These concerns must be carefully addressed to ensure effective and safe AI applications in electronic health records (Perry & Thompson, 2017).

Intellectual Property in Healthcare

The concept of intellectual property pertains to non-physical assets that embody the creations of the human intellect, as opposed to physical labor. The legal entitlements associated with intellectual property encompass those elements of intellectual property that can be safeguarded according to a country's laws. Typically, the safeguarding of intellectual property rights falls into one of the following categories: patents, trademarks, copyrights, or trade secrets (Perry & Thompson, 2017).

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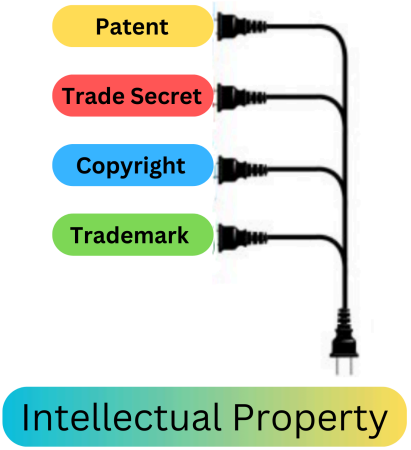
Intellectual Property [YouTube] 2016 by DurhamU

Protecting intellectual property is crucial because it prevents misappropriation, encourages creative thinking, and fosters innovation for a thriving economy. It holds significant value for businesses, with Fortune 500 companies estimating that

45-75% of their value is attributed to intellectual property. Ensuring its security maintains its value for its proprietor (Morgan, 2019).



Patent

Patents are government-granted monopolies for a limited time, with utility, design, and plant patents being the most common types. To apply for a patent, the inventor must draft claims and ensure the invention is new, useful, and nonobvious. A patent search and consideration of prior art are crucial steps to proving an invention's novelty and its nonobviousness must

be evident to someone skilled in the relevant field (Perry & Thompson, 2017).

A. What can be patented?

Patent litigation is complex and costly for healthcare businesses. Historically, patents covered processes, machines, manufacturers, or compositions of matter, while natural laws, phenomena, and abstract ideas were not patentable. However, the U.S. Supreme Court expanded patentable subject matter to include some algorithms between 1972 and 1981 (Perry & Thompson, 2017).

B. Patent Trolls

Patent trolls, or non-practicing entities, pose significant problems for healthcare businesses by filing infringement lawsuits without creating new products or ideas. They capitalize on the high costs of patent litigation, leading to increased technology development costs and potential market delays. The healthcare industry, particularly the electronic medical record (EMR) sector, is increasingly targeted by patent trolls, requiring more attention to patents as both valuable assets and potential business threats (Perry & Thompson, 2017).

C. Patent Infringement

Patent infringement involves the unauthorized making, using, selling, offering to sell, or importing of patented inventions. Encouraging such acts and supplying components of a patented invention also constitute infringement. The Supreme Court has broadened penalties and interpretations to reduce troll activity, limiting the Federal Circuit's authority to overturn infringement decisions and setting an "abuse of discretion" standard for attorney fees under 35 U.S.C. Section 285.

Trade Secrets

Companies face a choice between filing for a patent or protecting an invention as a trade secret. Trade secrets offer limited protection, only allowing the owner to sue those who improperly disclose them. Patents provide more extensive monopoly rights. Trademarks are used to identify products and services, preventing consumer confusion while not restraining legitimate competition. Trademarks are words, symbols, logos, and marks used to identify projects and services. The purpose of protection is to identify the source of the product or service and avoid consumer confusion; however, the trade-off is that the protection of a trademark should not restrain legitimate competition (Perry & Thompson, 2017).

Table 1. Patents vs. Trade Secrets

	Patent	**Trade Secrets**
Applicable Law	Federal Statute	State Law
Requirements	Invention and application to the USPTO	Information is created, kept secret, and has independent economic value due to being secret
Exclusivity	Yes	No
Reverse Engineering	Not Permitted	Complete defense if properly acquired
Official Grant from Government	Yes	No
Novelty	Required	Cannot be generally known or readily ascertainable
Obviousness	Must be nonobvious	Cannot be generally known or readily ascertainable
Duration	Generally, 20 years from application filing	No express limitation

Copyright

The copyright system encourages the creation and dissemination of new, creative works by granting authors

rights such as copying, distributing, and creating derivative works. These rights apply to various types of works, including literature, music, and architecture. However, limitations exist, such as the difference between expression and underlying idea and the "fair use" exception. Authors generally hold the copyright of their works, except in cases of work-for-hire where it belongs to the employer unless agreed otherwise (Perry & Thompson, 2017).

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Copyright Protection: What Can Be Protected and

A company website contains various copyrightable elements such as text, images, videos, and sound recordings. The company must ensure they either own the copyright, have a license, or use public domain content. Additionally, they should acquire permission from individuals in images due to "rights of publicity." This also applies to promotional materials and other documents used to support healthcare services and products (Perry & Thompson, 2017).

However, there are some gray areas regarding copyright laws. The Food and Drug Administration (FDA) allows generic manufacturers to use the same labels and user guides and requires identical labeling for generic medications.

The U.S. Copyright System has conflicting goals of encouraging creativity but also enabling distribution. It protects expression, but not ideas or facts. It protects the author under "works for hire," and no registration is required. Further, it provides protection for a very long period. It protects against copying but not independent creation. There are exceptions for "fair use" of copyrights permitted (Perry & Thompson, 2017).

A. Work for Hire

The owner of a copyright can be someone other than the creator if the situation falls under the work-for-hire doctrine. There are two categories of works that are considered "works made for hire" under U.S. copyright law. The first category includes works created by employees within the scope of their employment. In this situation, the employer is the copyright owner of the work.

The second category includes works created by independent contractors, but only if the work is specially ordered or commissioned, comes within one of nine limited categories of works, and there is a written agreement between the parties specifying that the creation is a work made for hire.

The nine limited categories of works are:

- A contribution to a collective work
- Part of a motion picture or other audiovisual work
- A translation
- Supplementary work
- A compilation
- Instructional text
- A test
- The answer material for a test
- An atlas

If a work does not fall into one of these nine categories, it cannot be considered a work made for hire unless there is a written agreement between the parties specifying that it is. In general, it is important to be aware of the work-made-for-hire doctrine if you are creating or commissioning a work that is protected by copyright. By understanding the doctrine, you can ensure that you are the rightful owner of the copyright in the work.

Here are some additional details about the work-made-for-hire doctrine:

- The work-made-for-hire doctrine is a default rule that applies if the parties do not have a written agreement specifying otherwise.
- The work-made-for-hire doctrine can be beneficial for

employers and independent contractors because it can simplify the process of transferring copyright ownership.
- However, the work-made-for-hire doctrine can also be disadvantageous for employees and independent contractors because it can prevent them from owning the copyright in their own work

B. Copyright Infringement

According to Morgan (2019), "**copyright infringement** occurs when a party copies all or a substantial amount of a copyrighted work without the owner's permission." There are two popular defenses to copyright infringement under the Copyright Act of 1976: the first sale doctrine and the fair use defense. The first sale doctrine allows the resale of copyrighted works after they have been sold by the copyright holder. The fair use defense allows the use of copyrighted works for certain purposes, such as education, literary criticism, research, and social comment (Morgan, 2019).

The *fair use defense* is a complex one, and the four factors that courts consider in deciding whether it applies are:

- The purpose and character of the use by the defendant, particularly whether it was for profit
- The nature of the copyrighted work
- The amount of work used by the defendant
- The impact of the use by the defendant on markets for

the copyrighted work

Copyright infringement can be either direct or indirect. Direct infringement occurs when a party copies all or a substantial amount of a copyrighted work without the owner's permission. Indirect infringement occurs when a party copies a copyrighted work by using a derivative work that is based on the original work. The fair use defense is a limited exception to the exclusive rights granted to copyright holders. The fair use defense is not available for all uses of copyrighted works, and the four factors that courts consider in deciding whether it applies are not always easy to apply. If you are sued for copyright infringement, you may be able to defend yourself by asserting the fair use defense. However, it is important to note that the fair use defense is not a guarantee of success.

Trademark

A trademark can be a sign, symbol, design, or expression indicating the specific source of the good or service. Businesses wanting to register a trademark must use a distinctive mark that will not cause consumer confusion with an existing mark. Therefore, organizations should fully investigate the mark and its similarity to any existing marks. **Trademark Infringement** occurs when someone other than the rightful owner of a trademark uses it without permission (Perry & Thompson, 2017).

Table 2. Symbols Associated with Trademarks

Symbol	Meaning
®	Signifies the mark is registered.
TM	Unregistered marks are used with goods.
SM	Unregistered mark used with services.

To win a trademark-infringement lawsuit, the rightful owner of the mark must show validity and priority of use, which are typically established by federal registration, and the likelihood of consumer confusion based on the following:

- Distinctiveness (strength) of the plaintiff's mark
- The similarity of the two marks
- The similarity of goods or services associated with marks
- The similarity of the facilities the two parties use in their businesses
- The similarity of advertising used by all parties
- Defendant's intent
- Proof of actual confusion

Table 3. Types of Intellectual Property

Type of Right
Patent
Trademark
Copyright
Trade Secret

Multiple types of intellectual property rights can be attached to one product or service at the same time. For example, Coca-Cola asserts trademarks for its lettering and color scheme and deems its recipe a trade secret. However, to obtain a patent for any recipe, a company must make the recipe public. Rather than disclosing this information, Coca-Cola asserts its rights under trade secret law, which does not require the disclosure of the recipe.

Trade Secrets

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Intellectual Property: Trademarks [Youtube] 201

A trade secret is valuable, non-public information used in commercial enterprises. Inconsistencies in trade secret laws led to the development of the Uniform Trade Secrets Act (UTSA) in 1979, aiming for standardization across the United States. The UTSA provides a detailed definition of trade secrets, highlighting their economic value, a wide variety of applicable information, and the requirement for reasonable secrecy measures. A national consensus on trade secret law has been achieved, with 48 states adopting relevant portions of UTSA. The UTSA (§ 1.4) provides the following definition of a trade secret as information, including a formula, pattern, compilation, program, device, method, technique, or process, that:

- derives independent economic value, actual or potential, from not being generally known to and not being readily ascertainable by *proper means* by other persons who can obtain economic value from its disclosure or use, and
- is the subject of efforts that are reasonable under the circumstances to maintain its secrecy (Legal Information

Institute, n.d.).

Proper means may include information obtained legitimately from the Internet where no expectation of privacy is present. This process is called reverse engineering and is considered a legal method of obtaining information that may be intended to be secret. As an extension of the Economic Espionage Act of 1996, Congress passed the Defend Trade Secrets Act (DTSA) in 2016 to allow owners of trade secrets the ability to sue when secrets have been **misappropriated**.

Table 4. Characteristics of the Types of Intellectual Property

	Patent	**Trademark**	**Copyright**	**Trade Secret**
Interest Protected	Inventions and methods	Indicators of the course of products and services	Expressions in a tangible form	Sensitive & valuable information
Federal or State	Federal only	Federal and State	Federal only	Primarily State
Creation Process	Registration with PTO	Use mark in commerce and get stronger protections by filing with PTO	Once in tangible form, stronger protections by filing with CO	Reasonable steps to protect the secrecy
Duration	20 years	Indefinite	Life of the author plus 70 years or 120 years from creation	Indefinite
Costs	High	High	Low	Low
Conditions for grant of protection	Novel, non-obvious, and of a specific type	Distinctiveness, based on a spectrum	Original expression	Reasonable measures to protect secrecy
Criminal Liability	No	Yes	Yes	Yes

Cyber Law

This image was created with the assistance of DALL·E 2 by Tiffany Jackman

Over the last three decades, the Internet has been the most influential means of information and communication to change our lives. The ability to instantly obtain information and communicate with one another has been instrumental on a global scale. As quickly as technology has evolved, the internet has also provided potential security concerns. The healthcare industry did not embrace emerging technology as quickly as other industries for various reasons. The main reason is the sheer cost of purchasing a product that can hold large amounts of information and protect the privacy of that information. In addition, meaningful use requires the ability of these integrated systems to talk to one another at some point in the future. With the risk of data and privacy breaches at an all-time high, the laws regulating cyber security were creeping slowly into existence. The first **cyber law** was the Computer Fraud and Abuse Act (CFAA), which was passed by the United States Congress in 1986. The CFAA prohibits unauthorized

access to computer systems and data. However, the Health Information Technology for Economic and Clinical Health Act (HITECH Act) was not passed until 2009. The HITECH Act provides financial incentives for healthcare organizations to adopt electronic health records (EHRs) and to implement security measures to protect EHR data. Cyber laws on healthcare have also been passed in other countries, such as the European Union's General Data Protection Regulation (GDPR). The GDPR applies to all organizations that process the personal data of individuals located in the European Union, regardless of where the organization is located. Cyber laws pertaining to healthcare are constantly evolving as technology changes and new threats emerge. Healthcare organizations need to stay up-to-date on the latest laws and regulations so that they can protect patient health information (Morgan, 2019).

Patent

For over four decades, it has been possible to secure a patent for a process that involves a computer program. The U.S. Supreme Court has affirmed that software can be patented because it includes a mathematical formula that puts a formula into practice within a structure or process.

A unique challenge arises when it comes to a specific category of utility patent applications, especially in the context of software and internet-based businesses. These applications

seek patents for innovative ways of conducting business, known as business method patents. Examples include Amazon.com's one-click shopping system and Priceline.com's online reverse auction. The U.S. Supreme Court supports the patenting of business methods, provided they meet the criteria of novelty and non-obviousness and fall within an acceptable subject matter category. However, a significant challenge in obtaining patent protection for business methods is demonstrating that these methods go beyond abstract ideas, as abstract ideas are not eligible for patents (Morgan, 2019).

Recognizing the potential impact of granting patents for internet-related business methods on commerce, a portion of the America Invents Act of 2011 (AIA) introduced streamlined post-issuance review procedures for certain types of business method patents. This review process is limited to patents that involve data processing or other operations related to financial products or services, excluding those covering technological innovations. In one notable case, the Patent Trial and Appeal Board (PTAB) declared in 2013 that a previously granted business method patent was invalid because it was deemed "abstract." This decision had a significant impact, as the patent holder had previously won a $345 million infringement case against a challenger. Consequently, the PTAB's decision nullified the infringement judgment (Morgan, 2019).

Trademark

Website operators, online content owners, and software developers have the freedom to use trademarks in the digital realm. A famous example is AOL's use of the trademark "You've got mail" online. This means that both trademark infringement and trademark dilution can occur in the online space. Certain practices, such as linking to other websites, deep linking, and deploying pop-up ads, can potentially violate trademark protections. For instance, there was a case where a defendant's software used a plaintiff's trademark to generate pop-up ads, but the court didn't find infringement because the ads never displayed the trademark, and they opened in new windows, reducing the likelihood of confusion. However, the legal landscape regarding trademark infringement through pop-up advertising is uncertain and will evolve over time (Morgan, 2019).

When someone registers a domain name that is identical or very similar to a trademarked domain with the intent to profit unfairly from another's trademark, it constitutes "cybersquatting" under the Anticybersquatting Consumer Protection Act (ACPA) passed in 1999 by Congress. Violating the ACPA can lead to statutory damages ranging from $1,000 to $100,000 per domain name involved in cybersquatting. Alternatively, successful plaintiffs can receive actual damages, and courts have the authority to award triple actual damages due to the "bad faith" element of this action. Typically,

cybersquatters are compelled to transfer the domain to the legitimate trademark owner, and in exceptional cases of wrongful domain name registration, attorney's fees may also be awarded (Morgan, 2019).

Copyright

Copyright law is a crucial tool for protecting intellectual property in the digital age. Most content on the internet is copyrighted, and the act of sharing this material involves making copies. Copyright safeguards the tangible expression of information but not the underlying idea. For example, while the idea behind a computer game cannot be copyrighted, the computer program running the game can be. This means that someone can create a similar game as long as they use a different program. The fair use doctrine applies to software, allowing copyrighted software to be used in educational settings without requiring permission or royalties (Morgan, 2019).

In 1980, amendments to the Copyright Act extended copyright protection to certain aspects of computer programs. A computer program is defined as a set of instructions that a computer uses to achieve a specific outcome. Courts have made it clear that literal copying, where the actual code is duplicated, constitutes copyright infringement. Even disguising the origin of a copy doesn't usually prevent copyright holders from proving this type of infringement.

However, when it comes to nonliteral elements like structure, sequence of operations, interfaces, and functions that can be copied without directly duplicating the code, courts have had mixed opinions on whether they are subject to copyright protection (Morgan, 2019).

In 1998, Congress passed the Digital Millennium Copyright Act (DMCA), which focuses on preventing the circumvention of copyright protection systems for digital content like software, music, videos, and books. The DMCA provides limited liability for Internet service providers (ISPs) and websites. They are not held liable for copyright infringement unless they are aware of a subscriber's violation. Additionally, ISPs and websites hosting infringing material must follow specific procedures, such as responding to takedown notices, to secure protection under the DMCA's safe-harbor provision (Morgan, 2019).

Trade Secret

Trade secret protection is a vital aspect for most businesses, as it applies to creative ideas at various stages of development. Trade secret law safeguards product ideas and information, often superior to trademark and copyright protection. Trademark protection primarily focuses on specific product characteristics, while copyright law only safeguards the expression of an idea. In contrast, trade secret law offers broader protection without requiring disclosure, unlike patent

registration, which demands that an invention be novel and non-obvious. For trade secrets, the main criteria are that the information is valuable and reasonable efforts have been made to keep it secret (Morgan, 2019).

However, businesses must strategically approach the protection of their trade secrets. Implementing reasonable security measures is crucial in determining whether something qualifies as a trade secret. For instance, in industries like computer and Internet-related businesses, where employee turnover is high, it's vital to take comprehensive precautions. Confidentiality agreements and non-disclosure agreements (NDAs) are commonly used to ensure the protection of trade secrets. Moreover, efforts should be made to restrict access to trade secrets only to employees who genuinely require it. For example, encryption is employed to prevent access to software codes, and decryption capabilities are granted only to those with a legitimate need (Morgan, 2019).

The implementation of provisions from the Uniform Trade Secrets Act (UTSA) throughout most of the United States has created a uniform framework to ensure consistency in defining trade secrets, determining what qualifies as reasonable measures to maintain secrecy, and specifying the remedies available in cases of misappropriation (Morgan, 2019).

Key Takeaways

- A commitment to healthcare privacy has been guided for centuries through codes of ethics and now with laws to protect the patient-provider relationship.
- There are a few exceptions to these principles including communicable diseases, wounds from acts of violence, and suspected abuse.
- HIPAA (1996) provided protocols for safeguarding personal information, and HITECH (2013) added further protection for electronic medical record data. HITECH was amended in 2021 to provide safe harbor provisions in the event of a data breach if adherence to the Security Rule is observed.
- Examples of data breaches include lost/stolen electronic devices, disposal of materials with identifiable information, hacking, and thrid-party mistakes. In the event of a data breach, several notification steps are required.
- Patents are federally-protected inventions.
- Trade secrets are state-protected valuable secrets.
- Copyrights protect original expressions but not ideas or facts.
- Trademarks protect the source of a product or

service (sign, symbol, design, or expression).

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PART I
ETHICAL CONSIDERATIONS

Introduction

The legal and financial aspects inherent in the field of medicine inevitably lead to ethical and professional questions. This chapter is dedicated to exploring these ethical and professional inquiries and lays the groundwork that will be utilized

throughout the course. Ethics pertains to the process of deciding how to behave based on a collective assessment of what is morally right and wrong. This can be represented collectively by a profession, a company, an industry, or society as a whole. The determination of what constitutes goodness or rightness is made concerning established ethical standards. While an individual's personal morals certainly factor into discussions about **ethical behavior**, it's important to note that the term "morals" typically implies something distinct from **ethics**. Morals consist of individual principles linked to one's conscience that aid in discerning what is right and wrong.

Learning Objectives

- Identify and analyze various types of ethical issues
- Compare and distinguish differing ethical and legal issues
- Interpret the dynamics that give rise to an ethical culture in a healthcare organization
- Develop a systematic, procedural approach to resolving ethical dilemmas

Ethics and Compliance

Ethics and law are important parts of healthcare. Part of the ethical decision-making process includes the consideration of alternatives. A comprehensive understanding of healthcare laws and how they govern the application of healthcare is needed to make sound ethical decisions. Ethics is often referred to as a person's personal values or beliefs; furthermore, these beliefs are influenced by an individual's religion, socioeconomic conditions, geographic location, culture, family, and friends. Healthcare workers must develop a set of beliefs that coincide with their field. For example, a surgical technologist must have a sterile conscience about the sterility of instrumentation and supplies to ensure that patients do not acquire an infection that could be fatal.

To ensure healthcare personnel are making ethical healthcare decisions, a Code of Ethics, similar to standards of care, governs professional organizations. Compliance with these standards is monitored by medical boards, credentialing, licensure, certification, and policies and procedures. Each state has the authority to set standards for credentialing; furthermore, some states offer **reciprocity** to those credentialed in other states. This recognition allows healthcare providers to practice in different locations without having to repeat the entire credentialing process. Once an individual's education, training, licensure, and certification have been verified, they are granted privileges. The term **privileging**

means that the board has made sure the provider has the appropriate training and experience to meet the minimum requirements and all authorizations to carry out requested procedures at a specific facility. Credentialing generally refers to primary source credentialing (background check), also known as primary source verification. Lastly, payer enrollment is completed, which is the process by which a medical provider gets entered into insurance plans, networks, Medicare, and Medicaid, so the provider and facility can be paid for services rendered to patients by that provider.

Once privileging is complete, each provider has a determined **scope of practice**. The scope of practice sets the boundaries determined by the **Medical Board and Practice Act**. Working outside of the professional scope of practice is not permitted and is considered a violation of the law. It is important to note that if a provider steps outside their scope, malpractice is analyzed using the standards of care they stepped into, not their own.

Healthcare institutions have a fiduciary obligation to maintain moral commitments in the face of challenges posed by economic changes in the delivery of care, which involve organizational integrity. Organizational integrity is essential to the fundamental elements of decision-making and group behavior. This applies not only to societal units in general but also to organizations in particular. What's even more challenging than the increasing number of healthcare providers engaged in patient care within modern healthcare

institutions is the intricate interplay among these individuals and the impact of the organization's contextual factors on their conduct. It's often overlooked that many ethical dilemmas in healthcare facilities are beyond the control of individual actors, given that the delivery of patient care is embedded in a complex network of organizational structures, relationships, and processes. Consequently, instead of solely attributing ethical responsibility to individual professionalism, it's crucial to recognize that the moral dimensions of patient care are significantly shaped by the dynamics of the organization.

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Healthcare organizations continuously encounter new sets of ethical issues due to the changes in the delivery and financing of care. The ethics of an organization are deeply rooted in its culture. What do we do when duty conflicts with our interests? Given the complexity and risks associated with the healthcare environment, most health systems have compliance officers who monitor ethics training, corporate policies, and violations of laws. However, ethics and compliance differ. Compliance seeks conformity through mandated rules and regulations. While compliance seeks to avoid litigation or paying fines, ethics seeks to make the right

decision for the patient's health. What do we do when the patient's welfare conflicts with the financial solvency of the institution? It should be noted that patient care outcomes are largely influenced by the organization's culture of ethics rather than by individual professionalism. An individual's behavior informs us that an organization's corporate culture, structures, and processes are important determinants in achieving organizational integrity (Perry & Thompson, 2017).

Attaining organizational integrity entails a dedicated effort to align the organization's stated mission and values with decision-making and behaviors at every level of the institution. In essence, an institution must articulate a clear vision and mission, choose a set of guiding values to support its mission, and most importantly, develop a consistent inclination to make choices and take actions that align with these chosen values. In practical terms, organizational ethics centers on the pursuit of organizational integrity.

Developing and maintaining a comprehensive compliance program entails creating and upholding internal policies and procedures designed to prevent any form of illegal, unethical, or improper conduct within the organization. These policies also include establishing standards of conduct and educational and training programs aimed at fostering an environment where individuals are encouraged to report suspected fraud, abuse, waste, or other improprieties without fear of retaliation. Achieving organizational integrity consists of two major components:

a) The culture, rooted in its fundamental values, guides decision-making.

b) The organization's framework, including its structures and processes, serves as crucial mechanisms for bolstering those core values and ensuring that decisions, actions, and outcomes are in harmony with these foundational principles.

Furthermore, the organization should have a structured approach for addressing alleged violations of rules, regulations, policies, and procedures, as well as internal standards. This involves initiating investigative procedures and overseeing a consistent system for handling any reported violations. Internal communication processes, such as a dedicated compliance or ethics hotline, should be in place to facilitate this reporting mechanism.

In addition to these measures, continuous monitoring is essential across all activities within the healthcare enterprise. This monitoring encompasses various aspects, including research data, institutional review board (IRB) processes, patient records, billing records, marketing efforts, and contractual obligations. The objective is to identify any potential issues related to referrals and payments that could trigger anti-kickback statutes or regulations prohibiting physician self-referral.

Culture

The culture within organizations varies widely, emphasizing a different set of ethical values. There isn't a universally ideal culture that suits all types of organizations. The prevailing notion is that organizations perform best when their culture aligns with the specific context and strategic goals, meaning they choose values that encourage behaviors crucial for achieving their objectives. For instance, a culture promoting quick decision-making and minimal bureaucracy can boost performance in a competitive mergers and acquisitions advisory firm but might hinder a traditional life insurance company. Similarly, a culture valuing technological excellence benefits a computer manufacturer but wouldn't suit a symphony orchestra. Finally, organizations prioritizing customer service may prefer a culture emphasizing teamwork, positive customer relations, respect, collaboration, and social responsibility.

While most topics of **organizational culture** address the values of the employees, it would be amiss not to mention the culture of the community we serve. This includes patients with different ethnicities, social groups, geographical classifications, sexual orientations, religions, etc. The term **epoche** refers to the suspended personal judgment temporarily. Moreover, a healthcare provider's personal beliefs about a patient's cultural components should not hinder their ability to provide care. Oncologist Dr. James Salwitz states,

> "Doctors must be without judgment or prejudice and must treat every person without regard to what they believe, what they have done or who they are. Murderer, mother, monster, saint, slumlord, sex offender, nurse, noble or Nazi, the physician is tasked with treating each as human and patient. This creed is not only every doctor's calling; it is the utopian vision which medicine offers the world... I have learned to see and accept without judgment the human frailties and deviation as part of the constellation of each individual. And to use those traits, even when other forums might judge, to guide and help each patient... The peril is that the shift in tolerance, diversity, and compassion of our society may penetrate so deeply that it will poison even the healers... If blame and hate grow like a disease, it may infect the whole of us... It is our calling not only to care for the sick without judgement but to teach the value of life. The altruistic voice of physicians must remind us of the beauty and potential of all persons, and we must help others see through fear to accept that while we may be different, we are more deeply the same. Any society which holds anyone as "less" by anger, bigotry or hubris has within it a spreading disease. Doctors must heal. They must guide and remind us that in the end, we are all human."

These cultural beliefs are applicable to any area of care: illness, pregnancy and childbirth, death and dying, etc. While it is our duty to respect all aspects of the patient's beliefs and wishes, there are times when healthcare must deviate from the patient's desires to effectively provide care. The most common example is the Jehovah's Witness blood doctrine. Courts will

override parental consent in cases involving life-saving measures for children. Religion also plays a critical role in treatment and healing. Things to consider are dietary restrictions, fasting holidays, medications with animal by-products, herbs/alternative medicines, communication issues, access to care, transportation issues, and gender norms for attending providers. All of these considerations affect the approach to providing care. Physicians, nurses, support staff, and administrators may need to coordinate care with a dietitian, pastoral service, translator, case manager, social worker, hospital general counsel, etc. to fully address the needs of a patient's cultural preferences. The HELP Model (Connor, 2012) is recommended when working with culturally diverse populations:

Hear what the patient perceives to be the problem.

Encourage the patient and healthcare professional to discuss the similarities and differences.

List treatment options and make recommendations.

Provide a chance to negotiate treatment.

The culture of a healthcare organization may be determined by the type of organization as well. Catholic hospitals have a mission deeply rooted in the healing ministry of Jesus Christ and the Catholic Church. As such, these organizations may omit performing procedures that deviate from the beliefs of Catholicism. They prohibit procedures that are "intrinsically immoral," including abortion (including ectopic), IVF, contraception (also in the case of rape), physician-assisted

suicide, gender reassignment surgery, and direct sterilization. These directives extend to any facilities that involve mergers with a Catholic health facility.

Systems Thinking

Systems thinking in organizational ethics shifts the focus away from individuals as the sole targets for improvement. Instead, it emphasizes understanding interconnectedness, communication, ongoing processes, and root causes of behavior. The goal is to change interactions or redesign the system itself to promote different behaviors. This approach represents a significant departure from the traditional quality assurance approach, which relies on standards and penalties to ensure ethical behavior and primarily centers on individual actions rather than addressing flawed organizational structures and processes. Within a **blameless culture**, leaders blame processes, not people. This shifts the focus on understanding why something happened, not who is responsible. By striving to identify the root cause of an issue, it creates systems that prevent errors from happening again. This process of depersonalizing mistakes can make a large impact.

While quality assurance is reactive, a systems thinking approach actively seeks to drive change and uphold workplace integrity. It bridges the gap between an organization's vision/mission and its actual performance, illustrating how the organization's structures and processes have shaped its current

state. Systems thinking also underscores the importance of continuous improvement by demanding constant attention to the structures and processes that influence ethical conduct. This application of systems theory to organizational ethics aligns with the principles of continuous quality improvement and total quality management seen in the healthcare sector, where hospitals aim to enhance the quality of healthcare outcomes.

Developing Organizational Culture

There are several steps to developing a corporate ethical culture. The first is a well-developed mission statement, vision, and guiding values. These define the core values and guiding principles of the organization and set expectations along the path toward achieving its vision. In conjunction, the support of leadership helps develop an ethical infrastructure. Leaders should personally commit to doing the right thing even when no one is watching. According to Perry & Thompson (2017), a good leader is visible and supportive, taking responsibility for making ethical decisions. Other steps include implementing the following:

1. Code of Ethics: The organization should establish a clear code of ethics. This code helps to articulate the organization's values and offers practical guidance on how to apply these values in everyday operations.

2. Ethics Forums: Create forums at various levels within the organization where ethical issues can be openly discussed. These forums should include individuals from different hierarchical levels to ensure diverse perspectives are considered.
3. Administrative Case Rounds: Develop a formal platform for discussing decisions that impact the ethical aspects of practice and patient care in the organization. This forum should involve both administrative and clinical staff to address issues that overlap their respective areas.
4. Appeals Process: Implement a mechanism for principled dissent when individuals have ethical concerns about a practice or policy. Encourage open discussion and resolution rather than punishing those who raise ethical issues.
5. Alignment of HR Systems: Ensure that the performance measurement, appraisal, and reward systems within the human resources department are aligned with the organization's ethical values. This alignment reinforces ethical behavior.
6. Ethics Training: Provide ethics training to employees at all levels of the organization. This training should increase awareness of ethical issues, clarify ethical frameworks for decision-making, and enhance ethical decision-making skills, especially in situations involving conflicting values.

7. Ethics Officer: Appoint a high-ranking ethics officer to emphasize the organization's commitment to ethics. This individual would be responsible for integrating ethics throughout the organization, signaling its importance.
8. Organizational Ethics Committee: Consider establishing an ethics committee dedicated to addressing the ethical dimensions of organizational issues. This committee would function differently from clinical ethics committees and provide a space for ethical reflection on various organizational matters (Perry & Thompson, 2017).

Monitoring and Evaluating

Monitoring and evaluating ethical performance within healthcare organizations involves various approaches, such as conducting patient and family satisfaction surveys as well as staff satisfaction surveys. Additionally, an ethics climate survey can assess whether the organization aligns with its ethical standards and values. Information systems should provide timely reports on key indicators, including morbidity and mortality statistics, infection rates, incident reports, sentinel events, and patient complaints. Evaluating service performance in terms of specific outcomes, such as pain relief for patients following hip replacements, is also essential. Furthermore, gathering insights through focus groups and interviews can

shed light on various ethical situations encountered by different members of the organization, some of which may not be brought to the attention of the clinical ethics committee (Perry & Thompson, 2017).

The increasing emphasis on organizational culture and integrity management in healthcare mirrors trends in the business world over the past few decades. The recognition of the importance of integrity in the workplace grew in response to corporate misconduct and ethical lapses in various industries. These issues were often the result of a failure to integrate integrity into an organization's culture, structures, and processes. In healthcare, administrators face challenges such as limited financial resources, reduced staffing, intense competition, and the demand for high-quality care. Understanding and addressing the organization's culture and ethics are essential for effectively managing these challenges. Recognizing the underlying forces can help administrators understand employee behavior, identify necessary organizational changes, and improve overall organizational efficiency. While many may view ethical behavior and legal compliance as common sense, the complexity of organizational relationships necessitates proactive management of the ethical climate to achieve organizational integrity (Perry & Thompson, 2017).

Ethical tendencies of a leader contribute greatly to the outcomes of morale within the organization. Leaders going beyond the typical "boss" role inspire employees and help

establish higher morale and better job attitudes and productivity. Employee morale has a direct impact on the ethical tendencies of individuals within an organization. When employees are motivated, satisfied, and have positive morale, they are more likely to exhibit ethical behavior in the workplace. High morale can contribute to a culture of ethics in the workplace. Unfortunately, while the jester of an appreciation with a pizza party may be well intended, it is condescending to support staff when other, more pressing issues need to be addressed. These attempts do little to boost employee morale. A more comprehensive approach is needed, including addressing burnout, clinician wellness councils, mental health programs, cost-of-living/hazard pay, bonuses, recharge rooms, peer support, employee recognition programs, flex work schedules, and remote work when applicable (Gooch, 2023). Organizations lose valuable resources when they focus more on staff recruitment issues than on the retention of current employees.

Mandatory Reporting

Mandatory reporting is a legal requirement that obligates individuals or entities to report certain specific information or incidents to relevant authorities or agencies. The purpose of mandatory reporting is typically to protect public safety, ensure compliance with laws and regulations, and facilitate the detection and prevention of specific issues or abuses. Vulnerable populations of often at greater risk of abuse and

deserve special attention. Laws requiring healthcare personnel to report signs of abuse are called **mandatory reporting laws** (Stanford, & Connor, 2020). Mandatory reporting can cover a wide range of areas, including:

1. **Child Abuse and Neglect:** In many jurisdictions, professionals such as teachers, healthcare workers, and social workers are mandated reporters who must report suspected cases of child abuse or neglect to child protective services.
2. **Elder Abuse:** Similar to child abuse, certain professionals may be required to report suspected elder abuse or neglect.
3. **Healthcare:** Healthcare providers often have mandatory reporting requirements for certain diseases, injuries, or adverse events to public health agencies. This can include notifiable diseases, medical errors, and adverse drug reactions.
4. **Financial Institutions:** Banks and financial institutions may have mandatory reporting requirements for suspicious financial transactions to combat money laundering and fraud.
5. **Workplace Safety:** Employers may be required to report workplace accidents or injuries to occupational safety and health authorities.
6. **Educational Institutions:** Some educational institutions have mandatory reporting requirements for

incidents like bullying, harassment, or threats of violence.

7. **Animal Cruelty:** In some places, individuals are required to report suspected animal cruelty or abuse.
8. **Ethical Violations:** In certain professions, such as law and accounting, there may be mandatory reporting of ethical violations by members of those professions to their respective regulatory bodies.
9. **Domestic Violence:** Healthcare providers and others may have mandatory reporting requirements for suspected cases of domestic violence.

Failure to comply with mandatory reporting requirements can lead to legal consequences, including fines or penalties. The specific reporting requirements and who is obligated to report can vary widely depending on the jurisdiction and the nature of the issue being reported. The aim of mandatory reporting is to ensure that potential problems or dangers are identified and addressed promptly in the interest of public welfare and safety.

Difference Between Ethics and Compliance

Ethics and compliance are related concepts in the context of organizational behavior, but they have distinct meanings and purposes. Ethics pertains to the moral principles and values that guide behavior based on what is considered right or

wrong, while compliance is about conforming to established rules and regulations to avoid legal consequences and maintain organizational integrity. While both ethics and compliance are essential in organizations, they serve slightly different purposes, with ethics encompassing broader moral considerations and compliance focusing on legal and regulatory requirements. Two prevailing approaches to regulating employee behavior within organizations are the compliance-based and integrity-based models. These two models represent distinct philosophies for managing employee behavior. The compliance-based model relies on external regulation and enforcement, while the integrity-based model focuses on internal self-governance and the promotion of shared ethical values to guide employees in their actions (Perry & Thompson, 2017).

Compliance-based model: This model relies on external regulation and the use of threats and punishments to influence employee behavior. It primarily views employee conduct through a legal and regulatory lens, emphasizing the need to deter illegal or unethical actions and incentivize behavior in line with organizational values. Essentially, it operates on the premise of "comply or face consequences."

Integrity-based model: In contrast, the integrity-based model takes a different approach to employee management. It emphasizes self-governance, the cultivation of shared values, and the recognition of employees' ethical aspirations as motivational factors for adhering to rules and standards. This

approach aims to instill a sense of employee accountability rooted in a commitment to the organization's mission. Rather than just teaching employees to follow laws and rules, it seeks to integrate ethics into their decision-making processes and inspire them to embody the company's ethical ideals.

Both compliance and integrity approaches involve elements like organizational codes of conduct, legal training, and penalties for misconduct. However, the integrity strategy has been proven to encourage responsible employee behavior and a strong ethical identity rooted in the organization's values. When employees perceive that an organization follows an integrity-based approach, it leads to benefits such as increased commitment to the organization's mission and a stronger sense of trust in the organization's support. These positive outcomes are not as prominent in organizations that primarily emphasize employee compliance with rules and regulations. Additionally, employee behavior can be influenced by their perception of the organization's cultural objectives, whether compliance-oriented or integrity-focused.

Creating an organizational climate of integrity, characterized by self-governance and shared values among employees, is particularly challenging in the complex healthcare delivery system. However, it is crucial for the success of healthcare providers. Healthcare organizations, given their responsibility for the well-being of patients, must strive to establish harmonious work environments where all healthcare personnel can thrive in serving patients. Trust is also a crucial

component of building a culture of integrity, and healthcare organizations dedicated to patient care and public health should set an example in fostering cultures of trust and integrity. Emphasizing integrity over mere compliance can lead to more responsible and ethical employee behavior, but creating such a culture in healthcare settings is complex yet essential for the success of healthcare providers and the well-being of patients.

Ethics in Medicine

The relationship between physician and patient is infused with deep trust, intimacy, and vulnerability. Often, exams require a patient to disrobe and answer personal questions. These encounters can be frequently marked by fear, discomfort, and uncertainty regarding the potential life-and-death consequences of decisions made; therefore, authoritarian figures in healthcare must be guided by ethical principles. Regardless of their socioeconomic status or level of education, patients must ultimately trust their healthcare providers with their well-being. There is said to be a gross disparity in the bargaining power of the customer in healthcare (Perry & Thompson, 2017). Financial incentives for providers can clash with patient care, tipping the scales between profit and well-being. In this sense, ethics boil down to daily choices, and in medicine, those choices carry weighty consequences.

When health policy decisions involve making choices

between conflicting values and distributing advantages and burdens, ethical reflection becomes indispensable. Furthermore, healthcare is fundamentally a compassionate endeavor, rooted in the notion of providing care rather than being solely profit-driven as seen in other businesses. Given its unique nature, individuals in the healthcare sector, particularly those directly involved in patient care but also those in administrative roles should prioritize ethics. This is essential both as a professional safeguard against the influence of competing economic interests driven by external investors, which could compromise the healthcare profession's core commitment to patient well-being and as a practical strategy for protecting healthcare providers from medical malpractice liability claims (Perry & Thompson, 2017).

Guidelines for maintaining a professional physician-patient relationship include the following:

1. Build trust
2. Provide privacy (when dressing and undressing)
3. Use appropriate language
4. Another healthcare professional should be present during an intimate examination
5. Listen to the patient without judgment
6. Do not overstep personal boundaries
7. Avoid all sexual contact, including flirting
8. Do not visit a patient outside of the healthcare setting
9. Never make promises to a patient

Resolving Ethical Dilemmas

Our ability to recognize ethical dilemmas is compromised by implicit prejudice, obedience to authority, and time pressures of decision-making. No individual is immune to elements that can compromise our ability to make ethical decisions. The elements are called an **unconscious bias**. According to UCSF (2023), individual strategies to address unconscious bias include:

- Promoting **self-awareness**: The Implicit Association Test or other instruments to assess bias are helpful tools to mitigate unconscious bias.
- Understanding the nature of bias is also essential to helping individuals approach their own biases in a more informed and open way.
- Discussions with others (especially those from socially dissimilar groups) can be helpful by promoting conversations in a safe space; furthermore, individuals must be open to alternative perspectives and viewpoints.
- Bias literacy training in the workplace reduces the impact of bias.

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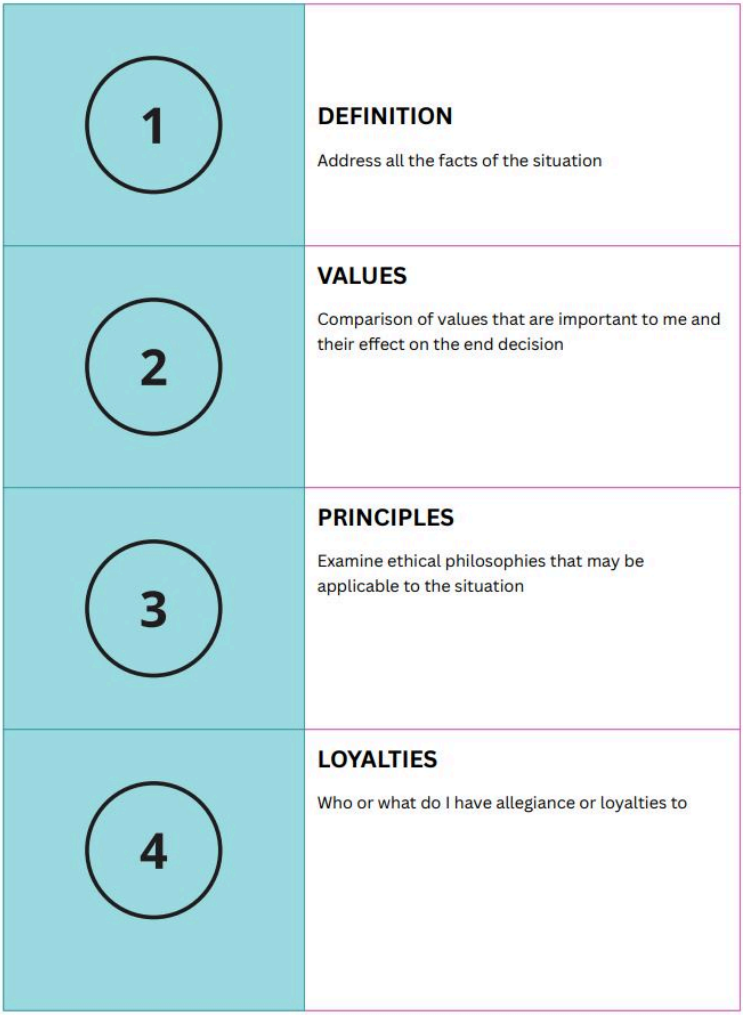
What is implicit bias? [YouTube] 2021 by Center

Healthcare providers and leadership should look beyond the issue of mere legal compliance and finance and pay attention to the dynamics of the situation. Gut instincts can manifest when moral dilemmas are met with ethical blindness. These feelings can manifest as profuse sweating, headaches, or pain in the belly, and such instinctual reactions can often provide very useful signals that moral territory where one's character is about to be tested may be compromised. When the stakes are high and reputations, stock prices, and people's livelihoods hang in the balance, emotional reactions are not as rational as once thought. Mitigation and/or resolution of these ethical dilemmas start by gathering and clarifying relevant facts. A complete process of ethical deliberation will yield a logical solution that should be monitored, and steps should be taken to avoid this type of dilemma in the future.

Ethical decision-making, as described by the Potter Box (Hagen, 2017), includes the following:



Key Takeaways

- Ethics refers to the guiding standards of conduct expected of the members of a group.
- Ethics is often used as the basis for creating legal standards where the law reflects society's view of right and wrong.
- An ethical framework will assist an individual in making an ethical decision and should include deciding legality, establishing the problem clearly, determining relevant values, exploring the views of stakeholders, considering the impact on the decision-maker, and reflecting on possible courses of action.
- A culture of ethics begins with a strong commitment from top management.
- Code of Ethics governs organizations, and compliance with these standards is monitored by medical boards, credentialing, licensure, certification, and policies and procedures.
- Healthcare institutions have a fiduciary obligation to maintain moral commitments in the face of challenges posed by economic changes in the delivery of care, which involve organizational integrity.
- Healthcare organizations continuously encounter new sets of ethical issues due to

the changes in the delivery and financing of care.

- Achieving organizational integrity consists of two major components: a) The culture, rooted in its fundamental values, guides decision-making. b) The organization's framework, including its structures and processes, serves as crucial mechanisms for bolstering those core values and ensuring that decisions, actions, and outcomes are in harmony with these foundational principles.
- Organizational culture is the shared values that have been reflected on and articulated by the members of an organization and have been accepted as the normative for culture.
- Systems thinking is a way of making sense of the complexity of the world by looking at it in terms of wholes and relationships rather than by splitting it down into its parts.
- Mandatory reporting is a legal requirement that obligates individuals or entities to report certain specific information or incidents to relevant authorities or agencies.
- The relationship between physician and

patient is infused with deep trust, intimacy, and vulnerability.

- Unconscious bias are social stereotypes about certain groups of people that individuals form outside their own conscious awareness. Everyone holds unconscious beliefs about various social and identity groups, and these biases stem from one's tendency to organize social worlds by categorizing.

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PART I
LEADING FOR SAFETY

Introduction

Most people head to work each day with the expectation of returning home in a similar state of health as when they left. Unfortunately, for a distressingly large number of workers, this expectation does not hold true. Incidents in the workplace persist, and consequences can vary from minor property

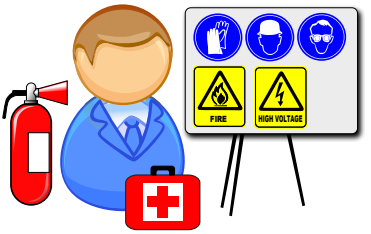
damage to tragic fatalities. In certain instances, the connection between an injury and a specific workplace factor is immediately evident, such as a roofer fracturing a leg after falling off a ladder, a data entry clerk experiencing arm strain due to repetitive motions, or a nurse sustaining a needle stick injury. However, in other scenarios, establishing a direct link between an injury or illness and the workplace is not immediately apparent. Examples include individuals working in a bar who develop noise-induced hearing loss, custodians who develop dermatitis, or firefighters who develop leukemia after retirement. In these cases, factors like the time elapsed between exposure to workplace hazards or engagement in other activities can complicate the process of linking a workplace factor to an illness (Graham & Rowley, 2017).

Learning Objectives

- Explain How to Create a Culture of Safety in the Workplace
- Identifying Potential Signs of Workplace Violence and Harassment
- Define and Identify Personal Protective Equipment

- Describe the Different Types and How to Identify Hazards in the Workplace

Occupational Safety



According to the U.S. Bureau of Labor Statistics, the United States has more than 3 million incidents of occupational injuries and illnesses reported annually (2021). An injury refers to a sudden and often traumatic wound or physical condition of the body resulting from external forces, which can include stress or strain. Typically, injuries are linked to a specific event, incident, or a sequence of events or incidents that transpire within a single workday or shift. An occupational injury, specifically, is a physical harm that stems from an accident occurring within the workplace. Additionally, occupational illness results in 25 percent of employees taking time off from work to recover or receive treatment.

The roles of occupational safety and health experts have evolved beyond their traditional functions, which included tasks like carrying out safety inspections, providing training,

probing into accidents, and pinpointing hazardous behaviors and situations. Nowadays, safety professionals have a broader scope of responsibilities that extend throughout an organization. They actively contribute to fostering innovations in occupational safety and health that can elevate the overall performance of the organization. They collaborate with individuals across all levels within the organization, as well as with government agencies, regulatory bodies, and business associations, to formulate comprehensive occupational safety and health plans and initiatives. This directly affects productivity. Even worse, it is estimated that between 4,000-5,000 people die each year from work-related injuries or illnesses (Graham & Rowley, 2017).

Culture of Safety

A workplace safety culture pertains to the shared attitudes, values, and conduct within an organization that places a paramount emphasis on the welfare and security of its employees. This culture serves as a critical foundation for upholding a secure working environment. According to the Society for Human Resource Management (SHRM) (2008), safety cultures can assume diverse forms, often categorized into four primary types:

1. Forced culture- uses bribes and threats to motivate employees

2. Protective culture- implements safety programs for employees (policies and procedures)
3. Involved culture- characterized by safety training sessions for employees and monitoring performance
4. Integral culture- characterized by safety training sessions and safety officers that have budgets and authority

Just Culture promotes reporting mistakes without punitive retaliation to efforts to address and prevent future occurrences. This concept is closely tied to patient safety and recognizing errors or near-misses. It focuses on the processes in place that led to the incident and how to improve those processes, rather than placing blame on those that reported the incident.

Leadership plays an integral role in shaping and promoting a safety-oriented culture. Leaders must lead by example, accord priority to safety, and effectively communicate its significance to the workforce. A robust safety culture is distinguished by its sustained endeavors to elevate safety standards and protocols. This entails ongoing training, the identification of potential hazards, and the establishment of feedback mechanisms. Engaging employees in safety initiatives cultivates a sense of ownership and unwavering dedication to safety concerns. Encouraging the reporting of safety issues without fear of reprisals holds paramount importance.

Safety in terms of healthcare extends not only to the patients but also to the medical professionals and support staff. Whether it be a needle stick, medication errors, or physical

assaults, the goal of workplace safety is to create a safe environment for all who enter the facility. It is important to acknowledge that any error resulting in harm or death of a patient is also devastating to the clinicians involved and has been known to lead to self-harm, depression, isolation, and even suicide. Considering the high stakes associated with the impact of enhancing workforce and patient safety, healthcare leadership should prioritize improving quality and safety through its core values.

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https://pressbooks.uwf.edu/healthcarelaw/?p=112#oembed-1

Safety Culture in Healthcare [YouTube] 2014 by

Workplace Violence and Harassment

Within the healthcare sector, workplace violence (WPV) is acknowledged as a potential danger. WPV encompasses actions or expressions of physical aggression, harassment, bullying, coercion, or any other form of menacing and

disruptive conduct that takes place in the workplace. This issue can impact various stakeholders, including employees, patients, customers, and visitors. WPV encompasses a wide spectrum of behaviors, ranging from verbal threats and abuse to physical assaults and, in the most extreme cases, even lethal acts (OSHA, 2012).

People susceptible to workplace violence include individuals engaged in tasks like handling money transactions with the public and interacting with unpredictable or emotionally unstable individuals. Those who operate in solitary or secluded settings may also be more vulnerable to potential violence. Occupations involving the provision of services, caregiving, or work in establishments where alcohol is served could heighten the likelihood of encountering violence. Moreover, variables such as the time of day and the workplace's location, such as working late at night or in areas characterized by elevated crime rates, should also be taken into account when addressing workplace violence concerns. Among the high-risk groups are employees engaged in cash transactions with the public, delivery personnel, healthcare providers, public service workers, customer service representatives, law enforcement officers, and individuals who work alone. According to the Bureau of Labor Statistics Census of Fatal Occupational Injuries (CFOI), in 2019, there were 761 cases of intentional injury by another person that led to fatalities in the U.S. Women made up 8.6 percent of all workplace fatalities

but represented 14.5 percent of intentional injuries by a person in 2021.

Preventing Workplace Violence

The best prevention is identifying and addressing potential problems early. Workers may exhibit sudden changes of typical behavior, deteriorating job performance, poor relationships with coworkers and patients, refusal to accept criticism or comply with rules, outbursts of rage, odd behavior and isolation, avoidance of eye contact, and/or others who do not want to work with them. Signs of escalating aggression could include pacing, rapid breathing, and/or aggressive posturing. They may begin to speak faster, more loudly, or use a threatening tone. According to the safety video below, de-escalating tense situations in a non-violent manner can be approached by:

1. Do not confront an angry person
2. Do not get into a power struggle
3. Do not roll your eyes, interrupt, or show frustration
4. Speak slowly and calmly
5. Ask how you can help
6. Use their name, if applicable
7. Provide options to resolve the situation
8. Use terms like "*we*" and "*us*"
9. Don't make promises that you can't keep

10. Have witnesses when comforting the angry person
11. If necessary, put space between you and the aggressor

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https://pressbooks.uwf.edu/healthcarelaw/?p=112#oembed-2

Workplace Violence Training for Healthcare Work

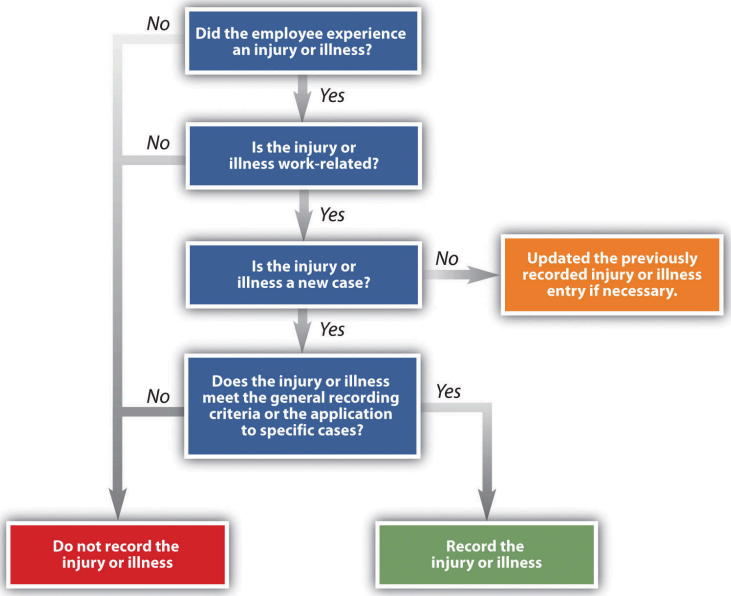
In 1996, OSHA published guidelines for preventing workplace violence for healthcare and social service workers, recommending that each facility create its own workplace violence prevention program. Additionally, the American Nurses Association's recommendations for preventing workplace incivility and bullying include the following:

1. Setting a "Zero Tolerance" policy
2. Encouraging employees to report violent incidents
3. Developing a comprehensive violence prevention program (with security measures in place)

Personal Protective Equipment

The workplace can be fraught with various risks. **Personal protective equipment** (PPE) serves as a means to safeguard against these risks. While PPE does not completely eradicate hazards, it does mitigate the impact on the wearer. Even when PPE is employed correctly, there remains a slight risk of injury, although such injuries are typically less severe than those incurred when PPE is neglected. It is vital to identify both existing and potential hazards associated with a specific task to determine the most suitable protective gear. Personal protective equipment (PPE) comprises attire and/or gear that employees wear or utilize to lower the risk of injury, illness, or disease resulting from workplace tasks or conditions. It's important to note that PPE should not be the sole reliance for protection against hazards; rather, it should complement other safety measures. OSHA regulations that address PPE for general industry are specified in OSHA 1910 Subpart I—Personal Protective Equipment. In healthcare, the most common types of PPE are hair bonnets/caps, surgical masks, N-95 masks, gowns (reinforced and isolation gowns), gloves, laser goggles or face shields, and shoe coverings.

Figure 1. The OSHA Decision Tree for Determining If an Injury or Illness Should be Recorded



OSHA.gov

Exposure Pathways

According to the Bureau of Labor Statistics Census of Fatal Occupational Injuries (CFOI), exposure to harmful substances or environments led to 798 worker fatalities in 2021, the highest figure since the series began in 2011. OSHA mandates the utilization of personal protective equipment (PPE) to decrease worker exposure to dangers in cases where engineering and administrative measures are impractical or

ineffective in reducing exposure to safe levels. Exposure pertains to coming into contact with a substance through ingestion, inhalation, absorption, or injection. Exposure can be categorized as brief (acute exposure), moderate in duration, or extended (chronic exposure). Many hazardous agents have more than one **exposure pathway**. This term refers to the methods of injury a person may contact a hazard through either absorption, inhalation, or physical contact.

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The Shocking Story of the Radium Girls: What th

1. Absorption

Toxic or hazardous materials can enter the body by permeating the skin, eyes, or mucous membranes. Absorption through the skin can happen without notice to the person being exposed, which is common with chemicals in the workplace. Once the toxic material penetrates the skin, it can enter the bloodstream.

2. Inhalation

Toxic or hazardous materials in the form of gases, fumes, and aerosols can be breathed through the nose and mouth, gaining access to the respiratory system. Inhalation hazards can exist in the air. The concentration of the substance and exposure time will determine the amount of harm. The cycle of air exchange in areas like surgical unions should also be monitored for air quality.

3. Physical Contact

Contact between two people or between a person and an object can lead to injury. Any compromised skin integrity, such as lacerations, punctures, or scrapes, can allow pathogens or hazardous materials to enter the body. Injuries by contusion, burns, or crushing are also categorized as physical contact.

4. Additional Hazards Considered

Each workplace should have current guidelines for potential hazards that a worker may encounter in the workplace and training for appropriate methods for handling these hazards. X-ray radiation, noise, chemical eye hazards, radiant energy, and biological agents should all have policies and guidelines for use and potential exposure. This includes the proper methods

of handling and disposing of laboratory chemicals, biohazardous materials, and waste.

Safety Laws

Most safety laws are a result of the Industrial Revolution and lobbying for safety regulations and safe working conditions. Factories were riddled with numerous **hazards**. Mass production during the war required women and children to work long hours exposed to these hazards. The earliest laws addressed working conditions to prevent injuries. Congress passed the Walsh-Healey Public Contracts Act in 1936, authorizing the Department of Labor to ban federal contracts for work performed under hazardous conditions. The Occupational Safety and Health Act of 1970 was the primary law established in the U.S. to ensure the safest and healthiest working conditions possible for everyone. According to this Act, employers have a legal responsibility to provide safe and healthy working conditions and to comply with occupational safety and health standards. Overseeing federal agencies includes:

The Occupational Safety and Health Review Commission- is an independent federal agency that reviews enforcement priorities, actions, and cases. The National Institute for Occupational Safety and Health (NIOSH)- is a federal agency responsible for conducting research and making recommendations for preventing work-related injury and

illness. The Occupational Safety and Health Review Commission (OSHRC)-is an independent federal agency that reviews enforcement priorities, actions, and cases. General inspections and **citations** for violations are conducted by a **compliance safety and health officer** (CSHO). **Serious violations** could result in fines between $1,500 and $7,000 depending on the severity. **Willful violations** could be fined between $250,000 and $500,000 and/or up to 6 months imprisonment. **Repeat violations** within a three-year period could be fined up to $70,000.

While there are many agencies that provide oversight for specific industries such as mining, highway safety, pipelines, nuclear energy, and much more, **The Food and Drug Administration** (FDA) established standards for food, medications, vaccines, tobacco, blood and tissue products, medical devices, cosmetics, and products emitting electromagnetic radiation. Established under Nixon in 1970, the Environmental Protection Agency **Environmental Protection Agency** (EPA) developed standards to enforce environmental regulations. Environmental regulations are created from environmental acts including the National Environmental Policy Act, the Clean Air Act, the Clean Water Act, the Resource Conservation and Recovery Act, and the Comprehensive Environmental Response, Compensation, and Liability Act.

Additional Employee Protection

Laws

The U.S. Department of Labor enforces over 180 federal labor laws (Kurt, 2022). The coverage can vary from unemployment insurance benefits, Social Security benefits, healthcare coverage, and safety laws. According to Kurt (2022), other employee protections include:

1. The Fair Labor Standards Act (FLSA) covers various labor standards, including minimum wage and workplace safety regulations.
2. Whistleblower protections protect employees from retaliation when they report unsafe conditions or illegal activities in the workplace.
3. The Civil Rights Act Title VII of 1964 made it illegal to discriminate based on "race, color, religion, sex, or national origin. In 2020, it added protections for the LGBTQ+ class of workers.
4. The Lilly Ledbetter Fair Pay Act of 2009 prohibits wage discrimination against women and minorities.
5. Family and Medical Leave Act (FMLA) signed into law in 1993 by President Clinton provides eligible employees up to 12 weeks of unpaid leave per year in the cases of childbirth, adoption, or serious personal or family member illness.
6. Thirty-six U.S. states (and the District of Columbia) recognize an *implied contract* exception to the **at-will**

employment doctrine. Employees cannot be fired except for good cause when a contract is implied. Additionally, employers may be found liable for breach of contract otherwise. However, the employee has the burden of proof (Muhl, 2001).

Workers' Compensation

Workers' compensation is a government-mandated program that provides benefits to workers who become injured or disabled while performing their job duties (Kagan, 2023). The purpose of worker's compensation is to ensure that injured employees receive the appropriate medical care and compensation for lost wages if they are injured on the job. Coverage varies from state to state and requires the employee to follow specific reporting guidelines.

It is important to note that some businesses can file for workers' compensation exemptions for the self-employed, independent contractors, and/or volunteers. Other state exclusions include those with mental health issues (not work-related), injuries from a fight or self-inflected, and injuries received away from work. When an employee is designated as 'workers' compensation exempt,' it signifies that they lack coverage under workers' compensation insurance. If such an employee sustains a work-related injury or illness, they will not be eligible for benefits aimed at aiding their recovery. Consequently, they, or their employer, will be responsible for

bearing the costs associated with medical bills, ongoing healthcare expenses, and treatment outlays. Furthermore, if an exempt employee is unable to work due to a job-related injury or illness, they will not receive compensation for lost wages.

Workplace Wellness

Workplace wellness encompasses initiatives and strategies that encourage and promote positive health behaviors among employees. This can range from conducting health screenings and organizing health education events to implementing fitness programs and offering healthcare benefits, demonstrating various ways in which organizations can cultivate a culture of well-being. This concept has been highly recognized given the global pandemic, economy, and political climate stressors over the last few years. Why is this important to healthcare leaders?

1. Healthy workers absorb less healthcare costs
2. Healthy workers have fewer absences from work and fewer road accidents
3. Healthy, happier workers are easier to retain (Aldana, 2023)

Healthy workers are beneficial to employee morale, organizational culture, and the bottom line. Organizations must commit to investing time and resources into meaningful

support endeavors. Wellness programs that focus on the detrimental consequences of smoking, maintaining a healthy weight, addressing depression, managing stress, and alleviating emotional strain due to work-related factors can address the most significant concerns and challenges faced by employees. Creating policies that support healthier living and encompass aspects of physical and mental health, as well as encouraging preventative care are good starting points.

Effective Workplace Wellness

Approaches to improve workplace wellness start with effective onboarding. Provide professional development for continued educational growth and encourage team-building. Gone are the days of 40-hour work weeks being chained to a desk. If feasible, employees prefer flexible work schedules or the ability to work from home occasionally. Some incentives, according to Forbes (2023), to boost employee wellness include:

1. Offer competitive salaries and raises
2. Create mentorship initiatives
3. Remote work
4. Flexible scheduling or reduced workdays
5. Encourage a work-life balance
6. Recognize and reward employees
7. Create a culture that employees want
8. Provide lifestyle coaching (Mediation/Yoga)

9. Teamwork
10. Addressing and preventing employee burnout
11. Wellness offerings
12. Job perks
13. Professional development
14. Allocate a healthy budget to retention, not just recruitment
15. Create a wellness team
16. Build employee engagement

Employee Engagement

Employee engagement should be sincere. Often, employees are asked for their opinions or support on an issue, but the decision has already been determined or the consensus of the employees has no impact on the final decision. This can potentially have a more detrimental impact on morale than completely excluding employees altogether from decision-making. Another warning is providing incentives that do not incentivize but rather reduce morale, such as performance or merit-based raises. Too often, employers will down-rank employees to keep these costs from rising. It can be very degrading when an individual worker is not valued for their hard work and dedication. Moreover, having those poor performance reviews affect their potential income could inadvertently cause lower motivation. Good employees who know their value will leave, and should.

Additionally, employees should have transparent knowledge of the organization's vision or current state. Communication is critical. This could include potential bonuses and raises, open positions, layoffs, furloughs, and changes in policy. Open, transparent communication builds trust. When employees are not happy, there should be avenues to address those complaints without fear of retribution. Open lines of communication should not be punitive; however, they should follow the proper chain of command or be addressed with the union representative.

Conclusion

Mental and physical workplace safety are interconnected. A safe and healthy workplace addresses both the physical and psychological well-being of employees (and patients), leading to improved safety outcomes and overall organizational success. Leadership should focus on providing safe equipment, implementing safety protocols, and maintaining a hazard-free environment to ensure that employees can perform tasks without the risk of injury or harm. They should also create an environment where employees feel supported and free from excessive stress, harassment, or discrimination. Mental safety is crucial for maintaining a healthy work atmosphere and promoting employee engagement and productivity (Breeneman, 2023).

Key Takeaways

- More than 3 million incidents of occupational injuries and illnesses are reported annually.
- Workplace safety culture pertains to the shared attitudes, values, and conduct within an organization that places a paramount emphasis on the welfare and security of its employees.
- High-risk groups are employees engaged in cash transactions with the public, delivery personnel, healthcare providers, public service workers, customer service representatives, law enforcement officers, and individuals who work alone.
- Personal protective equipment (PPE) serves as a means to safeguard against biological, virologic, chemical, and other hazardous risks.
- Exposure pathways include absorption, inhalation, or physical contact.
- Organization policies, OSHA guidelines, and safety laws were created to protect employees from hazards in the workplace.

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PART I
ORGANIZATIONAL LIABILITY

Introduction

Healthcare organizations can be held directly accountable for accidents that occur partly as a result of their own negligence.

A patient may be injured due to the inadequate care of a specific doctor, but the healthcare organization to which that doctor was connected may be responsible for putting that patient with that specific doctor. Thus, there is a need for liability insurance. The purpose of liability insurance is to distribute the costs and economic losses of risks. Premiums increase as needed to cover the costs of litigation. Due to the rising costs of malpractice premiums, physicians may limit their risks by refusing new patients or limiting the complexity of patients they will treat. Several factors affect malpractice, including uncertainty with healthcare policy, inflation, emerging technologies, and high-risk procedures (Pozgar, 2021).

Learning Objectives

- Identify the institutional liability that may result from apparent authority
- Recognize the circumstances under which institutions are subject to direct Tort liability
- Differentiate between an employee and an independent contractor in the healthcare context

- Analyze Tort liability through the application of *Respondeat Superior*

Direct Tort Liability

Direct tort liability is a legal principle where an individual or entity is legally obliged to take responsibility for causing harm or injury to another person or party due to their own actions or negligence. In this context, "tort" denotes civil wrongdoing, such as negligence, intentional harm, or a breach of duty, that results in harm or losses for someone else. With direct tort liability, the person or entity directly responsible for the wrongful action or negligence is held accountable for the resulting damages without needing to establish any intermediary or third-party liability. It involves holding the party directly at fault legally accountable for their actions or failures and pursuing compensation or legal remedies for the harm inflicted. When the negligent actions of two different parties contribute to the ultimate injury, the two parties are considered **joint tortfeasors** and will face joint liability. Plaintiffs can recover the full amount of any award from either defendant in this case. This is concerning for healthcare entities that employ negligent providers (Perry & Thompson, 2017).

A. End of Immunity

For decades between the 1940s and 1990s, charitable healthcare organizations and religious hospitals possessed immunity from legal liability under the charitable immunity doctrine. Over time, the doctrine faced criticism for allowing these organizations the ability to evade responsibility for harm caused by their negligence. Changes in the evolving healthcare system have moved away from these types of exemptions; furthermore, Britain and Canada have abandoned this doctrine entirely. While charitable immunity has been completely abolished in some states, others still maintain some version of it. Legal scholars are predicting the possible extinction of the charitable immunity doctrine in the near future (Perry & Thompson, 2017).

B. Establishing Direct Tort Liability

A healthcare organization can be held directly accountable for accidents that occur partly as a result of their own negligence; immunity is no longer applicable because the organization is showing negligence by not complying with proper supervision, monitoring, selection, and/or utilization reviews of those providers.

1. Monitor and Supervise

To safeguard patients, hospitals are required to monitor and assess the treatment patients receive. Although doctors are not required to guarantee specific outcomes, it is still expected that treatment plans are regularly assessed based on the patient's condition and do not significantly depart from established standards of care. Hospitals must also carry out these assessments to ensure that each patient receives appropriate attention from the attending physician. These principles give rise to hospitals having a general responsibility to monitor and supervise the physicians they employ (Perry & Thompson, 2017).

2. Selection

When a hospital initially brings a physician on board, it is the hospital's responsibility to ensure that the physician possesses the necessary education, training, and experience suitable for the designated role. These inquiries must be revisited when the hospital assigns a specific role to the physician, such as working in the emergency room, or when considering the physician's ongoing employment. These obligations also extend to hospitals that grant independent contractors access to their facilities. They should also be aware of any malpractice lawsuits against the physician. These duties also apply to hospitals that permit the usage of their facilities by **independent contractors** (Perry & Thompson, 2017).

3. Cost Containment and Utilization Review

One area where an insurance plan could potentially be held directly responsible for negligence is in the execution of utilization review processes. Utilization review occurs when the health plan assesses a physician's request for the approval of a specific treatment. It serves as a secondary evaluation of treatment decisions, primarily aimed at controlling expenses. Managed care organizations that prioritize cost-effective healthcare delivery may also employ some form of utilization review (Perry & Thompson, 2017).

However, these reviews must be conducted with the appropriate level of care because a denied treatment can have a significant impact on the patient. The determination of what constitutes an appropriate level of care is specific to the individual circumstances. Two cases from California, occurring within a five-year period, serve as examples. In the first case, the court ruled that the plan was not negligent, but in the second case, the court identified enough evidence of potential negligence to send the case back to the trial court for further consideration (Perry & Thompson, 2017).

4. Conclusion

Organizations can be held liable for inadequate selection of

providers, insufficient training and monitoring, as well as improper utilization reviews. Reasonable precautions should be taken by organizations to ensure the best approach for developing rules for conduct, selection, supervision, and monitoring is followed to discourage being held liable. Constant communication with staff and enforcement of policy are best practices. The ability to show a failure to follow the rules established does not automatically excuse the organization; however, inadequate rules could show direct negligence liability for the organization (Perry & Thompson, 2017). Organizations may be held liable for negligent practices such as:

1. Allowing a physician to practice outside his/her scope of practice
2. Not providing consistent time for supervision
3. Lack of emergency coverage and procedures
4. Lack of sufficient monitoring of physician's practice and/or documentation
5. Lack of consistent feedback prior to evaluation
6. Violation of professional boundaries

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Vicarious Liability for Torts of an Agent [YouT

Respondeat Superior

The primary approach for torts by agents is ***respondeat superior*** which is the legal doctrine that ascribes the responsibility to a party for the acts of others known as vicarious liability. This doctrine stipulates that employers can be held responsible for the wrongful actions of their employees. This concept stems from the nature of agency itself, where a principal delegates a task to an agent, who agrees to carry it out while operating under the principal's authority. In essence, the agent is considered an extension of the principal, acting on their behalf and under their control. Therefore, when an agent commits a tort, it can be inferred that the wrongful act was executed on behalf of and under the control of the principal. Consequently, it is reasonable to attribute vicarious liability to the principal. This extension of liability also serves the purpose of ensuring that plaintiffs have the opportunity to seek damages from additional parties who may have the financial means to adequately compensate them,

promoting fairness in the legal system (Perry & Thompson, 2017).

According to Perry and Thompson (2017), when distinguishing between an individual being classified as an employee or an independent contractor, the key factor to consider is the level of control involved. If a principal has the authority to control the way an agent carries out the services, especially regarding the physical aspects of the work, the agent is considered an employee.

When control only extends to the specific outcome of the work and not the methods used, it increases the likelihood of classifying someone as an independent contractor. Other factors to take into account include the payment method (such as salary or output-based compensation), the provision of tools and workspace, and the level of expertise required in the given occupation. Combining these elements results in a somewhat complex assessment to determine whether an individual qualifies as an employee or an independent contractor. It may be helpful to create separate lists of factors that indicate employee status and those suggesting independent contractor status, followed by an overall analysis to determine which category is more applicable. It's essential to remember that control often plays a pivotal role in this determination. Lastly, there should be a determination of whether the harm caused was within the "scope of employment" and part of the job (Perry & Thompson, 2017).

Independent Contractor vs. Employee

The scope of employment is straightforward for most healthcare providers. What is a bit more convoluted is whether or not they are actually considered hospital employees. In a traditional view, nurses and administrative staff are considered employees of the hospital. However, some nurses could be employed by a physician and contracted by the hospital. In this circumstance, the physician is the employer of the nurse in cases of respondeat superior. Alternately, physicians who are under contract with hospitals are functioning as independent contractors (Perry & Thompson, 2017).

At times, courts used legal restrictions on the corporate practice of medicine to argue that hospitals and insurance plans could not be held indirectly responsible for the mistakes of the doctors they were affiliated with. Additionally, in some cases, courts applied the "captain of the ship" doctrine, often in conjunction with the "borrowed servant" doctrine. This doctrine asserted that the attending physician had overall control over the patient's entire treatment, making it difficult to assign vicarious liability to the hospital. Courts are more likely to consider contracting physicians as employees. Once a hospital chooses to employ a provider, then that provider is no longer independent of the hospital. However, this concept becomes more complex in areas like surgical teams that consist of many different members performing various functions

(surgeon, anesthesiologist, nurse, physician's assistant, surgical technologist, etc.).

Apparent Authority

Apparent authority is a legal doctrine that deals with the authority of individuals or entities to act on behalf of another party based on the appearance or perception of authority rather than actual or express authority. In the context of contracts and agency law, it typically arises when a principal (a person or entity) leads a third party to believe that an agent (another person or entity) has the authority to act on the principal's behalf, even if that agent does not have actual authority to do so. Under this doctrine, hospitals can be liable for the torts of nurses and physicians. Through words, actions, or circumstances, the principal (a hospital) must create a reasonable belief in the third party (patient) that the agent (physician) has the authority to act on the principal's behalf. The third party must reasonably rely on the representation or appearance of authority when interacting with the agent. The third party must suffer some form of harm or detriment as a result of their reliance on the agent's apparent authority.

Apparent authority is distinct from actual authority, where the agent genuinely possesses the authority to act on behalf of the principal, either explicitly (express authority) or implicitly (implied authority). Apparent authority is based on the perception of authority created by the principal's actions or

representations. A similar theory is provided in Restatement (Second) of Torts § 429 (1966):

> "One who employs an independent contractor to perform services for another that are accepted in the reasonable belief that the services are being rendered by the employer or by his servants is subject to liability for physical harm caused by the negligence of the contractor in supplying such services, to the same extent as though the employer were supplying them himself or by his servants."

Furthermore, the conditions for applying the concept of apparent authority in tort cases involve the principal's actions or expressions that cause a reasonable belief in the third party that someone is acting as their apparent agent, followed by the third party's reasonable trust in this belief. It's important to emphasize that when seeking compensation from a healthcare institution based on apparent authority, it's a form of secondary liability. To establish such liability, evidence of the primary liability of the healthcare professional involved must be provided (Perry & Thompson, 2017).

When a patient chooses a hospital for their healthcare, the contractual relationship between the physician and hospital may not be clear. Nonetheless, patients trust that the physicians treating them have been vetted by the hospital where they practice.

Conclusion

Both *respondeat superior* and apparent authority are methods through which the legal system assigns vicarious liability to healthcare institutions for the wrongful acts of their physicians. In the case of *respondeat superior*, liability arises when the organization exercises a significant degree of control over the physician. A healthcare institution might consider reducing its liability by loosening this control. However, there are often valid reasons for maintaining some level of control over physicians. Regardless of whether physicians are legally classified as employees or independent contractors of a healthcare institution, the public perception of the institution is heavily influenced by the actions of these physicians. To establish and uphold a positive reputation, healthcare institutions may find it necessary to maintain a certain level of control over their physicians, despite the potential liability implications. Conversely, apparent authority stems from insufficient communication between the healthcare institution and patients. This issue can typically be addressed by improving communication practices (Perry & Thompson, 2017).

Key Takeaways

- Direct Tort Liability: A healthcare organization can be held directly accountable for accidents that occur partly as a result of their own negligence; immunity is no longer applicable because the organization is showing negligence by not complying with proper supervision, monitoring, selection, and/or utilization reviews of those providers.
- Respondeat Superior: A common-law doctrine that makes an employer liable for the actions of an employee when the actions take place within the scope of employment.
- Apparent Authority: When someone reasonably believes a person has the authority to act on behalf of another person or entity to engage in business transactions or enter into contracts, stemming from the person's actions leading to the belief that they have been given authority to act.
- Organizations may be held liable for negligent practices such as:

    1. Allowing a physician to practice outside his/her scope of practice
    2. Not providing consistent time for

supervision
3. Lack of emergency coverage and procedures
4. Lack of sufficient monitoring of physician's practice and/or documentation
5. Lack of consistent feedback prior to evaluation
6. Violation of professional boundaries

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PART I
ANTI FRAUD ABUSE

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Introduction

Federal legislation addressing healthcare fraud and abuse includes the False Claims Act, the Anti-Kickback Statute, and Stark Laws, or "Ethics in Patient Referrals Act." The Federal Government and society place enormous trust in physicians,

and physicians must strive to work ethically, render high-quality medical care to their patients, and submit proper claims for payment. Patients are most vulnerable and rely on the provider, placing trust at the core of the physician-patient relationship. Additionally, Medicare, Medicaid, and other federal healthcare programs rely on physicians' medical judgment to treat beneficiaries with appropriate services and to submit accurate and truthful claim information.

Dishonest healthcare providers who exploit the healthcare system for illegal personal gain have created the need for laws that combat fraud and abuse and ensure appropriate quality medical care. These federal laws guide physician relationships to help avoid potential conflicts of interest and liability.

Learning Objectives

- Explain what constitutes Medicare fraud, a False Claim, a Stark violation, and a violation of the Anti-kickback statute
- Discuss the value of an advisory opinion and the role of a legal safe harbor
- Develop a policy to reduce the likelihood of

facing liability under the False Claims, Anti-Kickback, and Stark laws.

Anti-Fraud Legislation

Established anti-fraud laws function in three ways: protecting taxpayers' funds, protecting consumers, and encouraging fair competition in the market.

Protecting Public Funds and Taxpayers:

- **Prevent financial losses:** Healthcare fraud is estimated to cost billions of dollars annually in the US alone. Antifraud laws aim to deter and punish such activities, safeguarding public funds and taxpayer dollars used to finance healthcare programs like Medicare and Medicaid.
- **Ensure program sustainability:** By curbing fraud, these laws help ensure the long-term financial viability of healthcare programs, allowing them to continue providing crucial services to eligible individuals.

Protecting Patients and Consumers:

- **Preventing unnecessary or harmful procedures:** Some fraudulent schemes involve billing for unnecessary services or even harmful procedures. Antifraud laws help protect patients from being unknowingly subjected to such practices.
- **Safeguarding access to quality care:** Fraudulent activities can distort healthcare delivery and prioritize financial gain over patient well-being. Antifraud laws help ensure patients have access to ethical and high-quality healthcare.
- **Maintaining trust in healthcare systems:** Widespread healthcare fraud can erode public trust in healthcare providers and institutions. Antifraud laws aim to uphold ethical standards and build confidence in the healthcare system.

Promoting Fair Competition and Market Integrity:

- **Leveling the playing field:** Fraudulent practices can give some providers an unfair advantage over others. Antifraud laws help create a level playing field for legitimate healthcare providers, fostering fair competition and market integrity.
- **Discouraging unethical business practices:** These laws act as a deterrent against illegal practices like kickbacks, bribery, and self-referrals, which can distort market dynamics and lead to inefficient allocation of

resources.

Table 1: Comparison of Anti-Fraud Legislation

	Anit-Kick Back Statues (AKS)	Stark Law	False Claims Act (FCA)

Prohibitions	-Prohibits offers of, solicitation of, or payment or receipt of remuneration intended to induce referrals for health care services covered by a government program. -Covers provision of anything of value to a person who refers, orders/ purchases, or recommends	-Prohibits referrals of designated health service by a physician if the physician (or an immediate family member) has a financial relationship with the entity performing the designated health service -Regulates financial relationships with physicians only (and physician's immediate family members)	-Prohibits the submission of false or fraudulent claims, false statements material to a false claim, and conspiracy to commit violation -Prohibits concealing or avoiding the obligation to repay money to the government (failure to return overpayments) -Claims that violate AKS or Stark can also be considered false claims -Common false claims: lack of medical necessity quality of care; billing/ coding issues; off-label marketing; retention of overpayments

Exceptions	-Arrangements are not required to fit within a safe harbor; however, voluntary safe harbors exist	-the arrangement must satisfy an exception, or it violates the Start Law	N/A
Penalties	-Applies to either party involved in an arrangement that violates AKS -Criminal penalties ($25K/offense, up to 5 years imprisonment)	-No criminal enforcement -CMP enforcement for knowing violations: CMP $15K/ violation + 3x claims and/or $100K/ circumvention scheme -Nonpayment of claims arising from prohibited arrangement -Recoupment of amounts received -Exclusion from federal health programs -FCA liability	-Treble damages -Per claim penalties between $10,781 & $21,562

Agency	Office of Inspector General (OIG)	Centers for Medicare & Medicaid Services (CMS)	Department of Justice (DOJ)

Context

According to the American Medical Association (2023), U.S. healthcare spending reached $4.3 trillion in 2021. The majority of these payments came from the federal government (Medicare/Medicaid) or private insurance plans. Since payers are not present for the exchange of business transactions, the opportunities for fraud and abuse are enormous. Consequently, a variety of federal laws have been created to deter and penalize fraud and abuse cases.

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What are the fraud and abuse laws? What are the

False Claims Act (31 U.S.C. §§ 3729-3733)

During the Civil War, the False Claims Act (FCA) was enacted in 1863 to combat fraud by contractors supplying the Union Army and to stop war profiteers from defrauding the government. In 1986, the law was expanded to include whistleblower projections in its scope (Perry & Thompson, 2017). The act itself states:

> (a)Any person who (1)**knowingly** presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval; (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government; (3) conspires to defraud the Government by getting a false or fraudulent claim paid or approved by the Government; . . . or (7) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government, . . . is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990, plus 3 times the amount of damages which the Government sustains because of the act of that person . . . .

The term "knowingly" means that an individual has

knowledge of the information and acts in reckless disregard of the truth or deliberate ignorance of the truth. Under FCA, no proof of specific intent to defraud is required. The whistleblower provisions allow individuals to file suit on behalf of the federal government. A whistleblower might be current or ex-business partners, hospital staff, patients, or competitors. A private citizen filing suit acts as a ***qui tam*** plaintiff on behalf of the government and is protected against retaliation by the employer.

Each civil claim can lead to an award of both five to ten thousand dollars plus **treble damages** as well as lead to criminal penalties with an individual fine of at least $250,000 and an institutional fine of at least $500,000 per false claim. This could include billing for services not provided or falsifying medical records or documentation to gain money.

Anti-Kickback (42 U.S.C. §§ 1320a-7b(b))

The Anti-Kickback Statute (AKS) was created in the Social Security Act Amendments of 1972. This statute makes paying for referrals a crime in federal healthcare programs. It applies to those who offer pay remuneration and recipients of any kickbacks, bribes, or rebates either directly or indirectly, overtly or covertly, in cash or in-kind in return for referrals. Violations are federal offenses, and penalties can include fines

of up to $25,000 and/or up to 5 years of imprisonment (Perry & Thompson, 2017).

Physicians are a great source of referrals for services from other physicians and pharmaceutical/medical supply vendors and are therefore attractive targets for kickback schemes. Physicians are in a unique position because they select what medications their patients use and who they refer the patients to for further care. There is justification for these practices, warranting a criminal statute with significant jail time and financial penalties. Courts recognize the presence of "knowingly" committing this action indicates a **scienter** requirement. The statute further guides that kickbacks in healthcare can lead to 1) overutilization 2) increased program costs 3) corruption of medical decision-making 4) patient steering 5) unfair competition. Therefore, the statute prohibits all sources of referrals where Medicare and Medicaid programs require copays for services. Waiving copays or advertisements for copay forgiveness could implicate the Anti-Kickback Statute. However, copays may be waived if the patient is unable to financial afford to pay or all collection efforts have failed. Free or discounted services can be offered to the uninsured population (Morgan, 2019).

In cases of AKS violations, the government does not need to prove patient harm or financial loss. If services were rendered medically necessary, a physician can still be found guilty of violating AKS. Any financial incentives, gifts, etc. from a vendor are unjustifiable (Morgan, 2019).

Safe Harbors

There are several safe harbors concerning AKS. Safe harbors listed below are examples of payments or arrangements that are generally considered to be fair and reasonable, and that are not likely to influence a healthcare provider's clinical judgment.

- Discounts that are disclosed and tied to the actual costs or charges incurred
- Employee compensation, but not compensation for independent contractors
- Group purchasing rebates, under certain conditions
- Certain risk-sharing mechanisms

The Department of Health & Human Services established 25 other safe harbors that include:

- fair market value leases (leases are in writing, signed by both parties and for at least one year),
- fair market value personal services contracts,
- fair market value for the sale of practices, and
- payments for referral services for patients with the **proviso** that the amount of the remuneration cannot depend on the number of referrals (Perry & Thompson, 2017).

Stark Law (42 U.S.C. §§ 1395nn)

Enacted in 1989, the Stark Law, also known as the Physician Self-Referral Law, is a federal law that prohibits physicians from referring Medicare or Medicaid patients to receive certain designated health services (DHS) payable by Medicare or Medicaid from entities in which the physician or an immediate family member has a financial relationship unless an exception applies.

The Stark Law is intended to prevent conflicts of interest and to protect patients from being referred to providers who may not be in their best interests. According to Perry and Thompson (2017), the law applies to a wide range of DHS, including:

- clinical laboratory services;
- physical therapy, occupational therapy, and outpatient speech-language pathology services;
- radiology and certain other imaging services;
- radiation therapy services and supplies;
- DME and supplies;
- parenteral and enteral nutrients, equipment, and supplies;
- prosthetics, orthotics, and prosthetic devices and supplies;
- home health services;
- outpatient prescription drugs;

- inpatient and outpatient hospital services; and
- Outpatient speech-language pathology services

Proof of specific intent to violate the law is not required since Stark law is a **strict liability** statute. Violation penalties include fines and exclusion from participating in federal healthcare programs. While both the False Claims Act and Anti-Kickback Law require a showing that the wrongdoing was done "knowingly," the Stark Law has no such requirement for intent. The Centers for Medicare & Medicaid Services (CMS) will deny payment when a Stark Law violation is determined and the entity can be fined up to $15,000 for each referral; and potentially $100,000 for an arrangement designed to circumvent the law followed by exclusion from participating in Medicare and Medicaid. Moreover, Stark violations may lead to False Claims Act violations because courts can find that an entity submitting an illegal claim under Stark is equivalent to making a false claim.

The Stark Law is complex, and there are many nuances and exceptions. Physicians and healthcare organizations need to have a good understanding of the law to avoid compliance violations. Here is a summary of the key points of the Stark Law:

    - Prohibits physicians from referring Medicare or Medicaid patients to receive DHS from entities in which the physician or an immediate family

member has a financial relationship unless an exception applies.
    - Applies to a wide range of DHS, including laboratory services, imaging services, physical therapy, and occupational therapy.
    - There are several exceptions to the law, including exceptions for in-office ancillary services, hospital-based physician services, bona fide employment arrangements, personal services arrangements, and shared savings arrangements.
    - Physicians and healthcare organizations should have a good understanding of the law to avoid compliance violations.

Exceptions

Due to the strict liability nature, once a referral is made that would violate Stark Law, an exception must apply to allow for a claim to be submitted. There are several exceptions to the Stark Law, including exceptions for:

- In-office ancillary services
- Hospital-based physician services
- Bona fide employment arrangements
- Personal services arrangements
- Shared savings arrangements

Bona Fide Employment Relationships

A Bona fide employment relationship under the Stark Law Statute includes:

(A) the employment is for identifiable services,

(B) the amount of the remuneration under the employment—

(i) is consistent with the fair market value of the services, and

(ii) is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician,

(C) the remuneration is provided pursuant to an agreement that would be commercially reasonable even if no referrals were made to the employer, and

(D) the employment meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

Subparagraph (B)(ii) shall not prohibit the payment of remuneration in the form of a productivity bonus based on services performed personally by the physician (or an immediate family member of such physician).

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Fraud and Abuse Laws I - Stark, Anti Kickback S

Limiting Risks

- Accurate coding and billing – If you do not know how to code a service, ask someone trusted.
- Maintain accurate medical records – Good documentation ensures quality patient care.
- Do not charge more than 15% above the Medicare rate.
- Exercise caution when charging extra fees.
- Admit patients to health entities that best serve their medical needs.
- Be cautious with recruitment offers. Many hospitals will incentivize local providers to gain referrals.
- Medical directors should exercise substantive responsibility.
- Be cautious with interactions with pharmaceutical and medical device companies and representatives.

- Do not sell free medication samples.
- Scrutinize promotional speaking or consulting opportunities. Ensure arrangements are legitimate.
- Review and abide by gift reporting requirements. In most cases, just say no.
- Ensure you have a compliance program in place to monitor and track activities.
- When in doubt, contact the U.S. Department of Health and Human Services' Office of Inspector General (OIG) with questions or concerns. **1-800-HHS-TIPS**

Accurate Billing and Coding

Physicians are trusted by payers to provide necessary, cost-effective, and quality care. Physicians exert significant influence over what services their patients receive and control the documentation that describes those services. This documentation is used to bill insurers. The government pays claims based solely on the information provided in these documents.

Because the government invests so much trust in physicians, it has powerful criminal, civil, and administrative enforcement tools to prosecute fraud. The government has broad capabilities to audit claims and investigate providers when it suspects unscrupulous abuse. This suspicion may be raised by irregular billing patterns or reports from others, such as staff, competitors, and patients. In other words, the government

expects physicians to be honest and ethical in their billing practices. If there is any evidence of fraud, the government will investigate and take action.

When a claim for services is submitted for a Medicare or Medicaid beneficiary, the bill is filed with the federal government and must certify that the payment requested is earned and complies with billing requirements.

The attempt to collect unearned money after submitting a false claim constitutes a violation. A common type of false claim is "upcoding," which refers to using billing codes that reflect a more severe illness than existed or a more expensive treatment than was provided. Additional examples of improper claims include:

- billing for services that you did not actually render;
- billing for services that were not medically necessary;
- billing for services that were performed by an improperly supervised or unqualified employee;
- billing for services that were performed by an employee who has been excluded from participation in the Federal health care programs;
- billing for services of such low quality that they are virtually worthless; and
- billing separately for services already included in a global fee, like billing for an evaluation and management service the day after surgery.

Upcoding

Medicare uses Evaluation and Management (E&M) codes to pay for many physician services. New patient visits generally take longer than follow-up visits for established patients, so E&M codes for new patients pay more. Upcoding is when you bill for a higher level E&M code than the services actually provided. For example, if you provide a follow-up office visit but bill for a comprehensive new patient office visit, that is upcoding which is a serious offense that can result in fines, imprisonment, and exclusion from Medicare and Medicaid programs.

Another example of upcoding includes the misuse of **Modifier 25** to claim payment for an E&M service when the patient care rendered was not significant, was not separately identifiable, and was not above and beyond the care usually associated with the procedure.

Physician Documentation

Physicians must keep accurate and complete medical records and documentation of the services they provide. They must also ensure that their claims are supported by this documentation. Medicare and Medicaid may review beneficiary medical records. Good documentation helps to ensure that patients receive the right care from all providers and that physicians can defend their bills against challenges. Physicians must document everything done for their patients,

both for the patient's benefit and to protect themselves from accusations of fraud.

Physician Investments in Healthcare Business Ventures

When physicians invest in outside businesses that provide ancillary services to their patients, they may refer disproportionately more patients to those businesses, leading to excessive and medically unnecessary referrals, which waste government and beneficiary money and can expose patients to harm. This can be a conflict of interest and may lead to patients receiving medically unnecessary and expensive services. These investment relationships have serious legal risks under the AKS and Stark Law.

Physician Recruitment

In some communities that possess multiple hospitals where the competition for patients is high, financial incentives to recruit physicians may be illegal. Meaning, that competition for loyalty to a specific hospital can cross the line into illegal arrangements for which the physician and the hospital can be liable (Perry & Thompson, 2017). Hospitals may offer financial incentives to attract physicians to underserved areas. However, competition between hospitals for patient referrals can lead to illegal inducements. As such, physicians must be

aware of the Stark Law and Anti-Kickback Statute (AKS) regulations governing recruitment arrangements. Hospitals can provide legitimate relocation assistance and practice support, but cannot offer payments, free rent, or other benefits designed to influence referrals. Patient admissions should be based on medical needs or patient preferences, not promises to be admitted to a specific hospital. Physicians offered recruitment packages should not negotiate benefits in exchange for referrals unless they are hospital employees. If pressured to admit patients to specific locations, seeking legal counsel is crucial. Legal counsel should be sought if someone enters into a relationship that requires patient admission to a specific hospital or practice group.

Considerations for Directors

Keeping in mind that a medical director of a nursing home or other facility may be held professionally responsible for their patients as well as other attending physicians' patients by State and Federal authorities, the following tips are recommended.

- Directly manage and monitor the quality of clinical care provided in the facility.
- Guide and inspire the medical staff to consistently meet and exceed the established standards of care.
- Champion ongoing learning and development opportunities for all healthcare professionals, including

physicians, nurses, and other staff members.
- Proactively identify and address any issues or concerns impacting patient care quality.

Samples

Pharmaceutical samples from industry representatives can be legally provided free of charge to a physician; however, it can be problematic. In theory, it is a good way to get low-income patients started on a medication. However, is it fair to provide samples to friends of the physician? How many samples should one patient receive? What happens if the medication gets recalled? How will those sample distributions be tracked? How will the clinic prevent theft, tampering, or reselling of samples? Billing Medicare patients for free samples has led to physician prosecution. If a clinic decides to make samples available to offer, several precautions safeguarding the above-mentioned concerns should be considered.

- A Standard Operating Procedure (SOP) and policy should be developed which clearly documents the proper process for accepting samples.
- A trusted individual should be responsible for accepting samples and logging them into an inventory log.
- Have a reliable system in place to safely store the samples and ensure that samples are not commingled with commercial stock.

- Log books for signing samples in and out should be available in the cabinet.
- Monitoring for expiration, par levels, and compliance should be performed routinely.

Vendor and Sales Rep Relationships

Sales representative and physician collaboration is critical in supporting medical advances and using new innovations in the medical field. However, these relationships must be kept at a professional level to avoid conflicts of interest. Most companies are aware of laws forbidding free lunches, subsidized trips, and gifts (bribes) to providers in exchange for loyalty to their product; however, there are some circumstances where the company may offer financial incentives for research, speaking engagements, etc. The relationship can be kept legal if the physician asks the following questions:

- Does the vendor's company really need the provider's particular expertise or input?
- Does the amount of money the company is offering seem fair, appropriate, and commercially reasonable for what the provider is being asked to do?
- Is it possible the company is paying the provider for their loyalty so that they will prescribe its drugs or use its devices?

Contributing time and effort can be legally compensated within the fair market value, and a provider can serve as a *bona fide* consultant. However, if providers are urged to prescribe a particular drug or medical device, it could likely violate fraud and abuse laws.

Transparency

The Department of Justice and OIG require "transparency" in physician-industry relationships, including the public disclosure of payments any physician receives from a vendor. The Patient Protection and Affordable Care Act of 2010 requires drug, device, and biologic companies to publicly report nearly all gifts or payments made to physicians beginning in 2013. Academic medical institutions have strict limitations on vendor interactions and policies concerning industry-sponsored research. Additionally, the pharmaceutical and medical device industry has adopted codes of ethics for provider-industry relationships.

Conflicts-of-Interest Disclosures

Healthcare providers are required to disclose their financial relationships with the pharmaceutical industry to their patients and institutions, even if legal, due to conflict-of-interest policies set by institutions, grant funders, or the FDA. Managing these conflicts involves understanding relevant

policies, openly disclosing industry funding, and following any restrictions. A conflict of interest (COI) arises when an individual's personal interests potentially influence their professional judgment or actions in a way that could harm patient care or public trust. This can happen in healthcare and pharmaceutical relationships which is a serious concern because it can lead to:

- Overuse or inappropriate use of medications
- Increased healthcare costs
- Reduced quality of care
- Loss of public trust in healthcare providers and the pharmaceutical industry

Serval measures should be in place to prevent COIs including disclosure of financial relationships; obeying laws that regulate COI, abiding by the professional code of either, and providing transparency. When unsure, consult someone.

Continuing Medical Education (CME)

Drug and device manufacturers sponsor many educational opportunities for physicians. Not all educational sessions are created equal. Watch out for industry-sponsored events, especially those promoting specific brands over broader treatment options. Even if presented by a respected doctor, their talk might be less about education and more about

marketing. Beware of off-label recommendations in medical talks, especially for drugs or devices not approved for those uses. Double-check any such claims against independent data. While doctors can prescribe off-label, manufacturers can't promote it. Remember, all drug ads must be truthful and approved-use focused. Help the FDA catch misleading ads through their Bad Ad Program. If an advertising violation occurs, it should be reported to the FDA.

Compliance and Monitoring

Maintaining a compliance program acts like a shield against fraud and guarantees accurate medical claims. Written policies and procedures outlining best practices for billing, coding, and other key areas should be clear. There should be a designated compliance officer responsible for overseeing and enforcing the program and should proactively audit and review billing and coding practices to identify errors. Lastly, swift response to violations should involve identifying compliance issues with corrective measures and disciplinary actions. The Patient Protection and Affordable Care Act of 2010 requires that physicians who treat Medicare and Medicaid beneficiaries establish a compliance program. The Office of Inspector General of the Department of Health & Human Services and the Centers for Medicare & Medicaid Services provide organizations with advice on these issues. However, the entity

must disclose relevant facts and state specifically what the opinion is for (the specific grounds and law that it addresses).

Table 2. Anti-Kickback and Stark Law Comparison

	THE ANTI-KICKBACK STATUTE (42 USC § 1320a-7b(b))	THE STARK LAW (42 USC § 1395nn)
Prohibition	Prohibits offering, paying, soliciting, or receiving anything of value to induce or reward referrals or generate Federal health care program business	• Prohibits a physician from referring Medicare patients for designated health services to an entity with which the physician (or immediate family member) has a financial relationship unless an exception applies • Prohibits the designated health services entity from submitting claims to Medicare for those services resulting from a prohibited referral
Referrals	Referrals from anyone	Referrals from a physician
Items/ Services	Any items or services	Designated health services

Intent	Intent must be proven (knowing and willful)	• No intent standard for overpayment (strict liability) • Intent required for civil monetary penalties for knowing violations
Penalties	CRIMINAL: • Fines up to $25,000 per violation • Up to a 5-year prison term per violation CIVIL/ ADMINISTRATIVE: • False Claims Act liability • Civil monetary penalties and program exclusion • Potential $50,000 CMP per violation • Civil assessment of up to three times the amount of kickback	CIVIL: • Overpayment/ refund obligation • False Claims Act liability • Civil monetary penalties and program exclusion for knowing violations • Potential $15,000 CMP for each service • Civil assessment of up to three times the amount claimed

Exceptions	Voluntary safe harbors	Mandatory exceptions
Federal Health Care Programs	All	Medicare/Medicaid

Source: Healthcare Fraud Prevention and Enforce

Key Takeaways

- Federal legislation addressing healthcare fraud and abuse includes the False Claims Act, the Anti-Kickback Statute, and Stark Laws.
- The False Claims Act (FCA) was enacted in 1863 to combat fraud by contractors supplying the Union Army and to stop war profiteers from defrauding the government.
- The Anti-Kickback Statute (AKS) was created in the Social Security Act Amendments of 1972. This statute makes paying for referrals a crime in federal healthcare programs.

- Enacted in 1989, the Stark Law, also known as the Physician Self-Referral Law, is a federal law that prohibits physicians from referring Medicare or Medicaid patients to receive certain designated health services (DHS) payable by Medicare or Medicaid from entities in which the physician or an immediate family member has a financial relationship unless an exception applies.
- There are several exceptions to the Stark Law, including exceptions for (1) In-office ancillary services, (2) Hospital-based physician services, (3) Bona fide employment arrangements, (4) Personal services arrangements, and (5) Shared savings arrangements.
- Four key elements of a bona fide employment relationship under the Stark Law Statute:

  (A) Identifiable Services: The physician must be employed to provide specific, identifiable services, not just generally to generate referrals.

  (B) Fair Market Value & No Referral-Based Compensation: The

physician's compensation must be based on the fair market value of the services they provide, and it cannot be directly or indirectly tied to the volume or value of referrals they make to the employer.

(C) Commercially Reasonable Agreement: The employment agreement itself must be commercially reasonable, meaning it would be considered fair and appropriate even if no referrals were expected.

(D) Additional Requirements: The Secretary of Health and Human Services may impose additional requirements through regulations to further protect against program or patient abuse.

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- Perry, J. E. & Thompson, D. B. (2017) Law and ethics in the business of healthcare. West Academic Publishing.
- Stark Law 1989, (42 U.S. Code § 1395nn)
- The False Claims Act (FCA) 1863, (31 U.S.C. §§ 3729-3733)
- § 1128B(b) of the Social Security Act (42 U.S.C. 1320a-7b(b)), previously codified at §§ 1877 and 1909 of the Act.

PART I
IRAC ANALYSIS & WRITING A CASE BRIEF

Legal Analysis & Case Briefing

One or more interactive elements has been excluded from this version of the text. You can view them online here:
https://pressbooks.uwf.edu/healthcarelaw/?p=321#oembed-1

Introduction to Case Reading [Youtube] 2015 by

INSTRUCTIONS FOR THE CASE BRIEF ANALYSIS

Lawyers approach legal issues with a structured, thorough analysis. To learn health law material, it is helpful to apply a similar approach. The standard approach for legal analysis is called IRAC, for:

1) **I**SSUE 2) **R**ULE 3) **A**NALYSIS 4) **C**ONCLUSION

When applying this approach, analyzing a particular case is called "briefing" the case. To complete a brief, you should do the following:

1. Identify significant legal issue(s) in the case.
2. For each issue, identify the *legal rule* that is relevant to that issue.
3. Use the legal rule to analyze the facts of the case.
    - Address each requirement of that legal rule.
    - Use a relevant fact to analyze each requirement.
    - Then, connect the facts to the rule with an appropriate explanation.

4. Finally, make a reasonable conclusion based on your analysis.

One or more interactive elements has been excluded from this version of the text. You can view them online here:
https://pressbooks.uwf.edu/healthcarelaw/?p=321#oembed-2

Legal Writing: What is IRAC? [YouTube] 2015 by

INSTRUCTIONS FOR THE CASE BRIEF ASSIGNMENT

Format the briefing case using the following sections:

1. CASE NAME: Title of paper
2. FACTS: State any relevant circumstances of the case. Remember, no opinions, please.
3. ISSUE(S): This is the legal "question" you are asking the court to resolve. Be concise. (example: Was there a legal contact? Was it breached?)
4. DECISION: What is the court's "answer" to the question on the issue?

5. REASONS: This is why the court ruled the way it did; use your legal terms from the chapter.
6. MANAGERIAL IMPLICATIONS: What is the significance? Consider that you have been hired to address the issue in this case; how will you prevent future similar litigation for the organization? Remember to tie in the content from the chapter.

When you begin, list the relevant facts and think about what seems to be the most important facets of the case. These facts can help you develop your analysis. When you get stuck on what to do next in your analysis, look back at the facts and see if one of those facts can help you get started again. The issue is the question for the court to determine, and the decision is the court's answer. Finally, when you are done with the legal analysis, you should step back and ask yourself, "What does this all mean for you as a healthcare executive or administrator? How can you prevent this type of litigation from happening again?"

GLOSSARY

negligence per se

is a doctrine in US law whereby an act is considered negligent because it violates a statute. The doctrine is effectively a form of strict liability. Negligence per se means greater liability than contributory negligence.

qui tam

is a Latin phrase that means "he who sues for the king as well as for himself." It is a legal term that refers to a type of lawsuit in which a private citizen brings a lawsuit on behalf of the government to prosecute fraud against the government.

res ipsa loquitur

a legal doctrine that doesn't require proof of breach

respondeat superior

is a Latin phrase that literally means “let the master answer.” It is also a legal doctrine applicable in many civil claims throughout the United States. Under the legal

doctrine, an employer can be held accountable for negligence or wrongdoing committed by their employee or agent.

Factual causation

refers to whether the act or omission was a necessary condition for the harm to occur. In other words, would the harm have happened anyway, even if the act or omission had not occurred?

acceptance

A statement by one party (called the offeree) that he/she is prepared to be bound to the contractual position stated in an offer, the second essential element to the meeting of the minds of the contracting parties

analogous

having a similar relationship to something else

Apparent authority

is a legal doctrine that deals with the authority of individuals or entities to act on behalf of another party based on the appearance or perception of authority, rather than actual or express authority.

Assault

an intentional act that puts another person in reasonable apprehension of imminent harmful or offensive contact. No physical contact or injury is required

at-will employment

any hiring is presumed to be 'at will'; that is, the employer is free to discharge individuals 'for good cause, or bad cause, or no cause at all,' and the employee is equally free to quit, strike, or otherwise cease work.

B<PL

Id. at 173.

battery

is the harmful touching of someone without their consent or unlawful physical restraint, which may lead to false imprisonment

blameless culture

is a workplace environment that fosters transparency, open communication, and a focus on learning from mistakes rather than assigning blame to individuals or teams.

breach

Failure to take reasonable care

capacity

denotes a person's ability to satisfy the elements required for someone to enter binding contracts. For example, capacity rules often require a person to have reached a minimum age and to be of sound mind.

causation

the relationship between an act or omission resulting in harm

citations

is a written document that informs an employer and employees of the regulations that were violated and imposes a time limit to correct the hazards.

compliance safety and health officer

is a safety and health professional employed by OSHA who enforces regulations.

confidentiality

Confidentiality refers to personal information shared

with an attorney, physician, therapist, or other individual that generally cannot be divulged to third parties without the expressed consent of the client.

Consequential

damages that are not directly caused by the defendant's actions, but are a result of those actions

consideration

Requires that each party to a contract give up something of value in exchange for something of value.

Copyright infringement

When a party copies all or a substantial amount of a copyrighted work without the owner's permission.

Counteroffer

A counteroffer not only rejects the original offer but also creates a new offer.

Covered Entity

“Covered Entity,” which includes any health insurance plan, billing company/healthcare clearinghouse, or healthcare provider that collects or transmits

electronically any "protected health information" or PHI, which is the second important category.

cream-skimming

refers to choosing patients for some characteristic(s) other than their need for care, which enhances the profitability or reputation of the provider.

cyber law

Legal matters associated with the internet, computers, and software, particularly as relating to business

Damages

a sum of money awarded by a court to a person who has been injured or harmed by the wrongful act of another person

Duress

is the use of unlawful threats or pressure to force an individual to act against their will.

Any act performed under duress is not legally binding.

duty of care

A specific legal obligation to not harm others or their property.

EMTALA

The Emergency Medical Treatment and Active Labor Act (EMTALA) is a federal law enacted by the United States Congress in 1986 as part of the Consolidated Omnibus Budget Reconciliation Act. Hospitals are required to provide this screening and treatment in a non-discriminatory manner, meaning they cannot turn away patients based on their ability to pay or any other discriminatory factor.

Environmental Protection Agency

is an agency of the federal government responsible for preventing, controlling, and abating pollution of outdoor air and water due to solid waste, pesticides, radiation, and toxic substances.

epoche

refraining from drawing conclusions or skepticism

ethical behavior

The significance of ethical behavior is the desire to be seen behaving in an ethical fashion and the recognition that members of the community owe a duty to society are important factors in shaping decisions.

ethics

Asks the question how one should act based upon a group-derived definition of right and wrong.

Expectation

is the reasonable belief that a party to a contract will perform their obligations under the contract

expected damages

Damages awarded when a party breaches a contract that are intended to put the injured party in as good of a position as if the breaching party fully performed its contractual duties.

exposure pathway

An exposure pathway is the manner in which an individual comes into contact with a hazard.

false imprisonment

unjustified restraint of a person

Foreseeability

Was the harm a reasonably foreseeable consequence of DF acts? Foreseeability at this stage is “foreseeability of

the plaintiff as a victim" as opposed to foresee-ability of the injury itself which is dealt with in remoteness

Fraud

Contract fraud occurs when at least one party in a contract knowingly misrepresents a material fact contained in the contract and intends that the other party rely on that misrepresentation.

hazards

is a condition or act that may result in personal injury, damage to equipment, or harm to the environment.

health literacy

The degree to which individuals have the capacity to obtain, process, and understand basic health information needed to make appropriate health decisions. Low health literacy is more prevalent among: Older adults.

HIPAA

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) is a federal law that required the creation of national standards to protect sensitive patient health information from being disclosed without the patient's consent or knowledge.

HITECH

The Health Information Technology for Economic and Clinical Health (HITECH) Act, enacted as part of the American Recovery and Reinvestment Act of 2009, was signed into law on February 17, 2009, to promote the adoption and meaningful use of health information technology.

HITECH Act

The HITECH Act encouraged healthcare providers to adopt electronic health records and improve privacy and security protections for healthcare data. This was achieved through financial incentives for adopting EHRs and increased penalties for violations of the HIPAA Privacy and Security Rules.

implied in the fact

Consists of obligations arising from a mutual agreement and intent to promise where the agreement and promise have not been expressed in words. Such contracts are implied from facts and circumstances showing a mutual intent to contract, and may arise by the conduct of the parties. A contract implied in fact is a true contract.

independent contractors

Is a person, business, or corporation that provides goods or services under a written contract or a verbal agreement. Unlike employees, independent contractors do not work regularly for an employer but work as required, when they may be subject to law of agency.

informed consent

is also a legal requirement, ensuring patients and research subjects the right to make informed decisions about their own bodies and health

Injunction

a court order that requires a person to do or refrain from doing something

Injunctions

are court-enforced orders that require one party to do or refrain from doing something, and it can be either temporary or permanent.

Intent

A person acts with purpose when they intend to cause a particular result.

Invasion of privacy

is a tort that occurs when someone intrudes upon another person's reasonable expectation of privacy.

joint tortfeasors

as two or more persons jointly or severally liable in tort for the same injury to person or property, whether or not judgment has been recovered against all or some of them

Just Culture

is a learning culture that is constantly improving and oriented toward patient safety.

knowingly

*The FCA defines “knowing" as not only actual knowledge but also acting in deliberate ignorance or reckless disregard of the truth or falsity of information, such as repeatedly ignoring government bulletins and transmittals regarding billing and coverage for services.

Lapse of time

As stipulated or after a reasonable time, an offer may be terminated. Lapse of time arises when one of the parties does not fulfill their promises under the contract within the expected time limit or contractual term.

legality

is an involved warranty that an agreement or contract strictly follows the law of a particular jurisdiction.

Liquidated

to make something certain or definite.

In the context of contracts, liquidated damages are a sum of money that is agreed upon by the parties to a contract in advance to be paid in the event of a breach of contract.

liquidated damages

are a sum of money that is agreed upon by the parties to a contract in advance to be paid in the event of a breach of contract

mandatory reporting laws

vary from state to state and involves reporting suspected cases of abuse

Meaningful Use

A term used to define minimum U.S. government standards for electronic health records (EHR), outlining how clinical patient data should be exchanged between

healthcare providers, between providers and insurers and between providers and patients.

Medical Board and Practice Act

defines the requirements for the practice of medicine within their borders and gives authority to a medical board to enforce the act's provisions.

medical malpractice

when a medical professional deviates from the standard of care, thereby causing injury to a patient

Mental Distress

is an invasion of a person's peace of mind by insults or other indignities or by outrageous conduct

misappropriated

Occurs if one discloses a trade secret or uses a trade secret where the trade secret was obtained improperly.

Mistake of Fact

is a mistaken belief that certain facts are true. Both parties must have made the mistake.

Modifier 25

In medical billing, this modifier is added to the E/M visit to indicate that there was a separately identifiable E/M on the same day of a procedure

mutual assent

If the offer is accepted by the offeree, and all things are legal, there is a mutual agreement. This agreement is called mutual assent, meaning two parties agreed upon the same thing and are prepared to enter into a contract.

National Quality Forum

National Quality Forum, Serious Reportable Events In Healthcare—2011 Update: A Consensus Report (2011), available at https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=69573.

negligence

when a physician does not follow customary treatment guidelines, the liability of the physician is determined by applying negligence

negligence per se

is a doctrine in US law whereby an act is considered

negligent because it violates a statute. The doctrine is effectively a form of strict liability. Negligence per se means greater liability than contributory negligence.

offer

A statement made by an offeror that he/she is prepared to be bound to a contractual position; the first essential element to the meeting of the minds of the contracting parties

organizational culture

the shared values that have been reflected on and articulated by the members of an organization and have been accepted as the normative for culture.

Personal protective equipment

Personal protective equipment (PPE) is clothing and/or equipment worn or used by an employee to reduce the possibility of injury, illness, or disease caused by work activities or the work environment.

PHI

PHI is defined as any identifying information, whether oral or recorded that is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care

clearinghouse and which relates to past, present or future physical or mental health of individual, or past, present, or future payment for health care services, that might identify the patient, including medical history, clinical findings, test results, prior procedures, insurance coverage, and demographic data.

privacy

privacy refers to the freedom from intrusion into one's personal matters, and personal information.

privileging

Making sure the provider has the appropriate training and experience to meet the minimum requirements and all authorizations to carry out requested procedures at a specific facility.

proviso

is a condition or stipulation that is attached to something, such as a contract, agreement, or law. It is a statement that must be met before the main provision of the document can take effect.

Proximate causation

refers to whether the act or omission was a foreseeable

consequence of the harm. In other words, was the harm a reasonably likely result of the act or omission?

Proximity

Were the two parties closely enough related that it would be appropriate to engage duty of care – does there exist a relationship such that there is a proximate connection?

quantum meruit

Latin for "as much as he has deserved." An equitable remedy that provides restitution for unjust enrichment. Damages awarded in an amount considered reasonable to compensate a person who has provided services in a quasi-contractual relationship. See Quasi contract (or quasi-contract).

A claim in quantum meruit is usually an action to recover the reasonable value of services rendered by one party to another.

ransomware

Ransomware is a form of malware designed to encrypt files on a device, rendering any files and the systems that rely on them unusable. Malicious actors then demand ransom in exchange for decryption.

reciprocity

in the context of healthcare credentialing refers to the process by which a healthcare professional's credentials and qualifications obtained in one state or jurisdiction are recognized and accepted in another.

Rejection by offeree

The termination of an offer's effectiveness by the offeree's statement or conduct that is inconsistent with the offer's terms

Reliance

the act of relying on the words or actions of another person

In contract law, it is used to determine whether or not a contract is enforceable

reliance damages

Damages awarded for losses suffered in reasonable reliance on a promise. Reliance damages are calculated by asking what it would take to restore the injured party to the economic position occupied before the party acted in reasonable reliance on the promise. Reliance damages may be awarded after a breach of contract or by way of promissory estoppel.

Remedies

is a legal means of enforcing a right or compensating for a wrong

Repeat violations

is a violation that breaches any standard, regulation, rule, or order where, upon reinspection, a substantially similar violation is found.

rescission

s a remedy that allows a person to cancel a contract and return the parties to their original positions

Restitution

the act of restoring something to its original state

Revocation by offeror

The termination of an offer's effectiveness by the offeror's statement that the offer is no longer available for acceptance

scienter

a mental state in which one has knowledge (deliberately)

that one's action is wrong, deceptive, or illegal; often used as a standard of guilt.

scope of practice

describes the services that a qualified health professional is deemed competent to perform, and permitted to undertake – in keeping with the terms of their professional license.

self-awareness

is your ability to perceive and understand the things that make you who you are as an individual, including your personality, actions, values, beliefs, emotions, and thoughts.

Serious violations

is a violation where there is a substantial probability that death or serious physical harm could result.

Specific Performance

is an equitable remedy that requires a party to a contract to perform their obligations under the contract

Strict liability

liability which does not depend on actual negligence or intent to harm

Systems thinking

is a way of making sense of the complexity of the world by looking at it in terms of wholes and relationships rather than by splitting it down into its parts.

Tarasoff

When a therapist determines, or pursuant to the standards of his profession, should determine, that his patient presents a serious danger of violence to another, he incurs an obligation to use reasonable care to protect the intended victim against such danger.

Termination by operation of law

Such events include the death or adjudicated insanity of either party, the destruction of the subject matter of the offer, or illegality that occurs after the offer is made.

The Food and Drug Administration

is an agency under the secretary of the Department of Health and Human Services that is responsible for food, drug, medical devices, and cosmetic safety.

tortfeasor

is a person or entity that commits a tort

Trademark Infringement

A legal cause of action occurring when someone uses the trademark of the rightful trademark owner without permission in the sale of goods and services in a manner in which there is likely to be confusion in the mind of the consumer as to the true source of the goods or service.

treble damages

is a legal term that refers to a type of monetary award in which the plaintiff is awarded three times the amount of actual damages that they suffered. Treble damages awards are typically awarded in cases of fraud or intentional wrongdoing.

unconscious bias

are social stereotypes about certain groups of people that individuals form outside their own conscious awareness. Everyone holds unconscious beliefs about various social and identity groups, and these biases stem from one's tendency to organize social worlds by categorizing.

United States v. Carrol Towing

159 F.2d 169 (2nd Cir 1947).

unjust enrichment

Unjust enrichment occurs when Party A confers a benefit upon Party B without Party A receiving the proper restitution required by law. This typically occurs in a contractual agreement when Party A fulfills his/her part of the agreement and Party B does not fulfill his/her part of the agreement.

Unjust Enrichment is distinguished from a gift, as a gift is given without the reasonable expectation of receiving something in return. As such, when Party A gives Party B a gift, Party A has no legal recourse to receive something in return.

Willful violations

is a violation that is committed intentionally and knowingly

Workers' compensation

is a government-mandated program that provides benefits to workers who become injured or disabled while performing their job duties

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