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Chapter: "Health Law and Ethics"

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Health Systems Science (Susan Skochelak, ed.; 2d edition, Elsevier 2019)

Chapter: “Health Law and Ethics”

William M. Sage, I. Glenn Cohen, and Allison K. Hoffman

Learning Objectives

1. Explain the relationship between law and ethics in the design and operation of U.S. health care.
2. List several areas of health system governance that depend heavily on law, and identify the principal health laws in each area.
3. Describe a few ways in which the transition from a dyadic approach to care based on one patient and one doctor to a systems approach based on teams, organizations, and populations presents challenges for health law and ethics.

Chapter Contents Blurb

Law and ethics are both essential attributes of a high-functioning health care system and powerful explainers of why the existing system is so difficult to improve. U.S. health law is not seamless; rather, it derives from multiple sources and is based on various theories that may be in tension with one another. There are state laws and federal laws, laws setting standards and laws providing funding, laws reinforcing professional prerogatives, laws furthering social goals, and laws promoting market competition. Complying with law is important, but health professionals also should understand that the legal and ethical constraints under which health systems operate must themselves adapt if health systems science is to advance.

Chapter Outline

- I. Introduction: Law and Ethics in Health Systems Change**
 - A. From Rationing to Justice**
 - B. Big Ethical Questions and Enforceable Legal Obligations**
 - C. Ethics of Organizations and Groups**
- II. Fiduciary Duty and Conflict of Interest**
 - A. Self-Dealing in Ethics and Law**
 - B. Ambiguities in Understanding Conflict of Interest**
 - C. Payment Reforms and Non-Financial Motivators**
 - D. Institutional Conflicts of Interest**
- III. Professional Self-regulation and Market Competition**
 - A. The Federal Antitrust Laws**
 - B. Physician-Hospital Relations**
 - C. Health Care Consolidation**
 - D. The Competitive Effects of Regulation and Self-Regulation**

- IV. **Fraud and Abuse**
 - A. **False Claims, Kickbacks, and Self-Referral**
 - B. **Structural Causes of Fraud and Abuse**
 - C. **Seeking Cultural as Well as Structural Change**

- V. **Privacy and Confidentiality**
 - A. **The Duty to Protect Information Under HIPAA**
 - B. **Other Medical Privacy and Mandatory Reporting Laws**
 - C. **Privacy and System-Based Practice**

- VI. **Health Insurance**
 - A. **Insurance Coverage in the United States**
 - B. **Accepting Patients with Different Insurance Coverage**
 - C. **Insurance Benefits and Cost-Sharing**
 - D. **Provider Network Regulations**
 - E. **The Cost of Complexity**

- VII. **Informed Consent to Treatment**
 - A. **The Ethical Consensus on Consent**
 - B. **The Weaknesses of Consent in the Law**
 - C. **Consent Involving Systems of Care**

- VIII. **Medical Malpractice and Redressing Error**
 - A. **The Unusual Salience of Medical Malpractice**
 - B. **Malpractice Litigation**
 - C. **Situating the “Malpractice System” in System-Based Care**
 - D. **Communicating and Resolving Patient Harm**

- IX. **Withholding and Withdrawing Care**
 - A. **Legal Distinctions Based on Competency**
 - B. **Revisiting End-Of-Life Practices in Health Care Systems**

- X. **Summary**

- XI. **Review questions, answers and explanations**

- XII. **Annotated Bibliography**

- XIII. **References**

I. Introduction: Law and Ethics in Health Systems Change

A systems approach to health care is replete with legal issues. State laws govern the provision of health care (such as licensing health professionals and facilities) and many aspects of health insurance. Federal laws determine how hundreds of billions of dollars flow through the health

care system each year (especially Medicare and Medicaid), and both fund biomedical innovation (the National Institutes of Health, among others) and regulate it (the Food and Drug Administration). Underlying both sets of laws is a strong commitment to professional self-regulation, which continues to entrust physicians with authority over many aspects of medical practice even as corporate control grows and expenditures rise. The pursuit of value-based health care may be impeded by existing laws, or by fear of legal liability under conditions of uncertainty. Moreover, interest groups opposed to value-improving reforms may lobby to preserve or even increase legal barriers.

The relationship between health law and medical ethics remains unsettled, although the rapid growth of the regulatory state has undoubtedly pushed law to the forefront.^{1,2} Still, ethics is intertwined with many features of the health care system, sometimes anticipating legal change, sometimes reacting to it, and sometimes filling gaps that remain in statutes, regulations, or judicial (courtroom) decisions. The ethics of personhood is a crucial aspect of health system governance, as is the related ethics of technologic change. The ethics of privacy has become particularly important as more information – including genetic information – is collected, exchanged, and analyzed electronically.

A. From Rationing to Justice

Fortunately, the ethical challenge most often associated with efforts to reduce health care expenditures – explicit or bedside rationing of life-saving services – is less of a concern in the current era of value-based health care design than in the decades that preceded it. Rationing seemed inescapable when society believed that nearly all care physicians recommended or rendered was scientifically required, precisely delivered, and fairly priced. Under those assumptions, spending more on health care meant spending less on other needs, and spending less on health care meant sacrificing quality or compromising access.^{3,4}

By contrast, the pursuit of value today is motivated by the recognition that health care delivery is grossly inefficient.⁵ Wasteful spending reduces quality rather than enhancing it, which implies that the pursuit of value can boost the health care system's accessibility and therefore its fairness without requiring tragic choices. That is why the three prongs of the Triple Aim are framed as iterative, decentralized improvements rather than as competing characteristics of a system in ethically perilous equipoise.⁶

At the same time, other ethical challenges have intensified. Many aspects of the health care system increasingly appear unjust, such as substantial barriers to receiving necessary services and demonstrable racial and ethnic disparities in both access and outcomes.^{7,8} Moreover, profound inequalities at the community level in wealth and education, endemic violence, concentrated environmental hazards, and other “social determinants” exert negative effects on health that cannot be overcome by medical care alone.⁹

B. Big Ethical Questions and Enforceable Legal Obligations

Other core issues in ethics and associated law respond to new medical technologies and changing social values. By the 1980s, the nascent field of bioethics had crystallized around a few topics:

reproductive technologies (such as in vitro fertilization) and the regulation of reproduction (abortion, contraception, sterilization, maternal-fetal conflicts); end-of-life decision-making, assisted suicide, and the definition of death; organ transplantation (procurement and allocation); and research ethics. In the late 1990s, genetics and genetic information became a central concern, along with HIV/AIDS and pandemic disease/bioterrorism. Behavioral health, drug development and pricing, population health, and global health also present persistent ethical-legal challenges.

When one teaches pure bioethics, deeply normative arguments are always on the table. Questions might include: What criteria help us determine when legal personhood should begin or when individuals are dead? How should we understand coercion or exploitation in deciding whether organs or women's eggs should be sellable? What claims can we make to health as a human right, and what do we owe one another as social solidarity?

Translating bioethics into law, by contrast, requires a kind of double vision. With very few exceptions, normative and conceptual arguments must be introduced through formal procedures and translated into enforceable obligations with associated remedies. In the *Baby K* case, for example, the morally charged question of whether it is futile to periodically administer life-saving treatment to an anencephalic infant with no possibility of higher brain function was “decided” by a federal appeals court based only on the words of a statute (EMTALA) that had been passed to assure that poor patients were not turned away from hospital emergency rooms.¹⁰

Even if bioethics seldom convinces courts, it has very likely inspired legislatures to pass statutes and administrative agencies to adopt regulations, as well as motivating various groups to support or challenge those enactments. There may also be an upside of legal analysis: the dry vernacular of the courts sometimes “takes the political charge out of contentious issues and deflects expressive contention away from [them].”¹¹ This, of course, raises an even harder “meta-question” about whether the American civic ideal of the rule of law can withstand too much engagement with comprehensive moral views.

C. Ethics of Organizations and Groups

The development of systems of care has challenged both medical ethics and health law. Historically, medical ethics focused on individual duties and rights arising from the intimate, dyadic relationship between a single physician and his or her patient. As Paul Starr documented in his Pulitzer prize-winning book, *The Social Transformation of American Medicine*, legal doctrines arose that reinforced these ethical obligations by insulating the physician-patient relationship from both governmental and corporate control.¹² A crucial task for health systems science, therefore, is to identify and rethink the ethical and legal inter-dependencies among health care professionals, health care institutions, patients, and the public.

The rapid expansion of HMO-based coverage in the early 1990s (“managed care”) precipitated a vigorous debate over two ethical issues: whether individual physicians might ethically consider group as well as individual patient interests, and whether health systems might articulate and embrace a nascent “organizational ethics.” These controversial changes, which would be reinforced by law, reflect several underlying assumptions. First, that established “fiduciary” duties (see section below) would need to be supplemented by more complex corporate

obligations, including those associated with physician employment. Second, that protecting public funds from corporate exploitation could no longer rely on certifications of necessity from individual health professionals but would need to be done more directly. Third, that substantial self-regulation would need to occur through firm-specific processes with government oversight of corporate compliance, rather than exclusively through licensed professions. And, fourth, that corporate entities should be subjected to stronger expectations of market competition than has been the case for individual professionals, raising the question of whether “professionalism” can be maintained without allowing some degree of economic protectionism (“market power”).

In the last two decades, the ethics of groups has expanded dramatically beyond HMO coverage to communities and populations more generally. In contrast to many European countries, which have a “public law” that imposes collective, constitutional obligations (“positive rights”) based on ideals of social solidarity, Anglo-American political philosophy has emphasized individual freedom from government coercion or restriction (“negative rights”). As a result, there is neither an enforceable right to health care in the United States nor a collective national commitment to providing it affordably. Both bioethics and health law are therefore entering unfamiliar territory as they confront a variety of population-based challenges: the optimal balance of individual and societal responsibility for health, emergency humanitarian interventions, health and human rights more broadly, setting priorities for health and health care investment, relating health to economic development, safeguarding vulnerable populations, environmental justice, population genetics, balancing health and civil liberties, global health equity, and social determinants of population health.

Exercise

Think of the law related to some aspect of medical care. Does the law answer all the questions of professional ethics or bioethics that occur to you in connection with that aspect of medical care? Why do you think some bioethical questions have many associated laws and regulations, while others don’t? When you need to make an ethical decision, do you expect to look up an answer, to ask a supervisor, to consult a colleague (if so, of what sort), to confide in family or friends, or to rely on your personal experiences and moral judgment? Write a paragraph about an ethical challenge you personally faced or witnessed during medical or health professions school, describing how it was resolved (or not) and whether or not its resolution depended (or should have depended) on law.

II. Fiduciary Duty and Conflict of Interest

Case Study 1: You are a noted physician-researcher who is a salaried full professor at an internationally known non-profit academic cancer center. You run a large research laboratory there that studies the biology of cancer. You do not care for patients directly; rather, your laboratory conducts research trials that make promising therapies available to physicians and their patients at the cancer center and elsewhere. Over the course of your career, you have pioneered new treatments for several deadly cancers. Some of these treatments were patented and licensed to a large pharmaceutical company, which has developed FDA-approved drugs and biologics that pay you substantial royalties. You also have a lucrative consulting contract with the pharmaceutical company. Are these payments “conflicts of interest”? Should you continue to accept them? Should you disclose them to the cancer center? To the federal government

under the ACA's "Sunshine Act" provisions? You also learned recently that the senior leadership of the cancer center and several members of its board of trustees have sizeable investments in a start-up company that has signed a contract with the cancer center to digitize its patient records and imaging results in connection with applying "big data" analytics to cancer care. Are these arrangements legally and ethically permissible?

The power long granted the US medical profession to self-regulate, rather than being subject to governmental or corporate control, has carried with it a strong presumption of ethical conduct. Whereas a physician's competence and skill in a particular case might be questioned later in court (e.g., in a malpractice suit), that physician's commitment to act for the patient's benefit has seldom been subject to direct legal oversight. This stands in contrast to the legal framework for policing the fiduciary obligations to shareholders of corporate directors and executives: bad outcomes (alleged violations of the fiduciary duty of care) are generally excused under the "business judgment rule," but acts of self-dealing or prioritizing the interests of third parties (alleged violations of the fiduciary duty of loyalty) are closely scrutinized.

In recent years, much greater attention has been paid to physicians' ethical obligations beyond clinical competence, with areas of potential compromise often labeled "conflicts of interest."¹³ Conflict of interest has entered the health policy vernacular because of a growing recognition that each physician-patient relationship is subject to institutional complexities and financial entanglements, both of which are intensified by the uncertain yet lucrative process of biomedical innovation. These pressures call into question three layers of public trust in medicine and increase the perceived need for legal regulation: trust in physicians to serve their patients, trust in researchers to serve the interests of society, and trust in professions to ensure ethical conduct by their members.

One can expect issues of loyalty and faithfulness to become even more important as care responsibilities are shared between individual professionals and health care organizations, as health care converges with health-related activities of private industry and public social service agencies, and as more data flows among (and is analyzed by) all of these actors, including using "deep learning" to anticipate and modify human behavior. Both law and ethics will need to evolve as well, going beyond the direct disclosure that has been the traditional response to conflict of interest and meeting public expectations by developing transparent processes and rules of conduct.

A. Self-Dealing in Ethics and Law

Payments to physicians by pharmaceutical companies are the clearest example of conduct that can distort care, skew research, and reveal weaknesses in professional self-governance.^{14,15} Constructing a health care system around costly services certified as necessary through individual physicians' orders, referrals, or prescriptions creates a constant risk of kickbacks or the equivalent. The pharmaceutical industry dedicates fewer resources to research and development than to marketing, and for many years spent the largest sums on face-to-face "drug detailing" by sales representatives who routinely offered gifts – ranging from trivial to lavish – to physicians likely to prescribe their products. During this period, the professional ethical response

to the tension between physicians' self-interest and their fiduciary obligations to patients was muted.

Early ethical rules either merely echoed the legal prohibitions that were being adopted by Medicare to discourage unnecessary referrals (see the section in this chapter on fraud and abuse), or drew strained distinctions between prohibited gratuities and permitted payments for services rendered such as speaking or consulting – even though the latter may sway physicians to overprescribe company products. It took a series of scandals, as well as generational change among physician leaders, to overcome this ethical complacency. In 2010, Congress passed the Physician Payments Sunshine Act as part of the ACA, requiring all medical product manufacturers to disclose payments made to physicians or teaching hospitals to CMS, which makes that information publicly available through a searchable online database.¹⁶

B. Ambiguities in Understanding Conflict of Interest

Important questions remain unsettled regarding the legal and ethical response to physicians' conflicts of interest. One question is whether the "primary interests" that take priority over "secondary interests" should be defined in terms of generally desirable attributes and broad social goals (e.g., professional altruism, scientific progress, the health of society) as opposed to specific obligations to identifiable parties (e.g., clinical decisions made to benefit patients).¹⁷ A treating physician has a specific obligation of loyalty to a patient; a biomedical researcher does not have such an obligation (and may inadvertently mislead a research participant by suggesting that such loyalty exists, which is known as the "therapeutic misconception").¹⁸ Perhaps because individual physicians have only rarely faced situations where one patient's interests directly conflict with another's, such as those of a seriously injured potential organ donor and a transplant recipient, medicine has been less focused on specific obligations than, say, the legal profession – which is scrupulous regarding whether and how to represent clients who are competitors or adversaries.

Labeling general motives and conduct as "conflicted" in the absence of specific duties can become a vehicle for professions to resist change and perpetuate bias, much as the medical profession for many years declared unethical any physician who accepted corporate employment (see the antitrust section in this chapter). It can also breed "tunnel vision" regarding available ethical or legal responses. Specific conflicts of interest between agents or fiduciaries (physicians, attorneys, etc.) and the principal parties usually present a policy choice between requiring direct disclosure and informed consent, which enables a patient or client to assess the professional's likely fidelity given the conflict, and outright prohibition, which is justified when no amount of information given to the principal party would be sufficient to assure loyalty. Larger social goals, by contrast, are likely to be better served by regulatory approaches to misconduct that take account of the broader causes and consequences of new organizational forms and financial arrangements, as well as by corresponding changes to health professions education that seek to reset professional norms.

C. Payment Reforms and Non-Financial Motivators

A second unresolved question concerns overall incentive structures for medical professionals. Ethical and legal agonizing over how physicians are paid if not on a fee-for-service basis demonstrates the limitations of the conflict-of-interest frame.¹⁹ Throughout the 1990s, attempts by managed care organizations to modify financial incentives associated with patient care to health plan enrollees (e.g., capitation, withheld fees, bonus pools) were met with accusations of conflict and demands for disclosure or prohibition.^{20,21} This faded as physician practice structures became too diverse and payments too intricate to bless or prohibit based on whether physicians were being paid to “do more” or “do less,” but was never replaced by a cohesive public policy regarding medical pricing and payment within health care organizations.

Similarly, university-based physicians have been criticized not only for receiving external payments from industry but also for failing to confront their “non-financial conflicts of interest” – such as winning government research grants, achieving institutional advancement, or gaining professional eminence.²² This is particularly challenging when those considerations are alleged to compromise character. Human motivation is complex, and attempting to distinguish selfless from selfish conduct in the absence of a specific obligation and an identifiable external threat to fulfilling it is likely to prove fruitless.

By contrast, pay arrangements for lawyers are not considered conflicts of interest but are separately governed by rules requiring written fee agreements with appropriate disclaimers while making available ethical review for reasonableness after a legal matter has concluded. The fact that a third party such as an insurance company is paying for a lawyer’s services does not substitute loyalty to that party for loyalty to the client. Lawyers’ internal motivations are not assessed under the profession’s rules of conduct unless they might compromise direct client service (e.g., family relationships, strong personal or religious beliefs).

D. Institutional Conflicts of Interest

A third unresolved question involves conflicts of interest at the institutional level, particularly within academic health care organizations that pursue mixed missions of patient care and biomedical research. Case Study 1 is based on conduct revealed in 2018 that both prompted institutional soul-searching and created potential legal liability at a renowned cancer center.²³ The ethical challenges of shifting professional services into corporate entities is not limited to medicine: defining the ethical obligations of law firms as opposed to individual lawyers is also a work in progress.

Many health care organizations require routine internal disclosure of conflicts by individual faculty and staff, which is reviewed and if necessary addressed by the organization. One real-world trend that is making this process more tractable is to emphasize each employee’s obligation to the organization rather than to general professional ideals such as scientific progress, and to monitor and address conflicts of interest within health systems on that basis. While common in the corporate world, this approach departs from the traditional treatment of academic departments and individual faculty members as autonomous professional actors. Nonetheless, it has become a practical necessity to assure compliance with each organization’s various legal responsibilities (see confidentiality section in this chapter).

When considering “institutional” conflicts, many health care organizations focus mainly on the personal conflicts of individuals in leadership positions whose outside interests could influence the direction of the overall organization. What remains to be thoroughly examined are the obligations of large health care organizations themselves given potentially conflicting commitments to patient care, funded research, and training – which may need as yet undeveloped ethical and legal solutions. This is especially true for academic organizations that, in their own operations and in their agreements with commercial partners, promote discovery for the benefit of future generations as they care for those currently afflicted. As Case Study 1 suggests, ethical conduct even by prominent organizations can no longer be taken for granted.

When it seemed in the 1990s that physician groups, hospitals anchoring organized systems of care, and health maintenance organizations would be responsible for managing cost and quality at the group level, there was a surge of interest in “organizational ethics,” which many physicians resisted as contrary to the traditional primacy of individual patient interests.²⁴ Although the value-based care models of today seem less likely than “managed care” a generation ago to raise the specter of profit-motivated rationing, more work needs to be done on the ethics of organizations such as ACOs that care for defined populations.

III. Professional Self-regulation and Market Competition

Case Study 2: You are a practicing physician appointed by the governor to serve on the state medical board. Part of the state’s Medical Practice Act provides that a physician may not prescribe medication in the absence of an established physician-patient relationship. This was enacted mainly because of concern over controlled substances. A for-profit company recently started operating in your state. The company signs contracts with large employers giving their workers telephone access to licensed physicians for medical consultations. You and the other physicians on the medical board, who have a voting majority, agree to adopt an emergency rule stating that a physician-patient relationship may not be established by telephone, and you notify the company that its physicians therefore may not prescribe medication over the phone. You adopt the rule knowing that the company’s physicians never prescribe controlled substances, and that many physicians in the state prescribe medication by telephone when “on-call” for other physicians’ patients, which the medical board regards as acceptable. How do you justify the new rule? How would you respond to a lawsuit alleging that the medical board violated the federal antitrust laws by acting anti-competitively?

Many ethical challenges for value-based health care relate to longstanding but inefficient professional practices. The medical profession’s privilege to self-regulate carries with it a significant risk of economically self-interested conduct that raises prices, reduces access to care, and discourages innovations in delivering health care or promoting health. Sometimes, such conduct violates federal and state “antitrust” laws that protect market competition in the private economy. However, self-regulation also promotes many desirable attributes of medical professionalism: expertise, diligence, loyalty, good character, altruism, charity, and collegiality. In an article describing lawyers rather than physicians, Professor Ronald Gilson asks a key question: “Is market power a precondition to professionalism?”²⁵ Economists have been divided on the answer. When health care costs began to rise in the 1960s, Milton Friedman argued that eliminating professional licensing would lower prices yet maintain ethics, while Kenneth Arrow

claimed that professional ethics helps fill information gaps between physician and patients, thereby improving efficiency.^{26,27} Each of them eventually won a Nobel Prize in economics!

A. The Federal Antitrust Laws

The Sherman Antitrust Act (passed in 1890) declares “contracts, combinations, and conspiracies in restraint of trade” to be illegal, and empowers both the government and private parties to bring suit.²⁸ Nonetheless, medical associations have routinely denied membership and the business connections and resources associated with it to physicians who deviated from professional norms regarding the economics of medical practice. In the 1940s, the United States Department of Justice brought criminal charges against the American Medical Association for organizing a physician boycott of a group health plan.²⁹ By 1980, the Supreme Court had firmly applied the antitrust laws to the “learned professions.”³⁰ Still, physicians accustomed to exercising medical authority collectively – and to having commercial actors such as hospitals and insurers defer to their collective judgment (which was routine for decades) – do not always realize that their conduct might violate antitrust law. Why shouldn’t the surgeons already practicing at the local hospital decide that their town has enough surgeons, or MD-physicians deny hospital privileges to professionals whom they regard as lower quality, such as DO-physicians or nurse practitioners? Why shouldn’t two practice groups treat each other collegially -- agreeing not to recruit each other’s staff, or not to advertise their services in the other’s neighborhood, or not to both offer the same specialized services?

B. Physician-Hospital Relations

The unusual relationship between US physicians and hospitals accounts for much of the confusion over antitrust law and medical practice. Most American hospitals are non-profit organizations with a “voluntary, self-governing” medical staff comprised mainly of economically independent, private-practice specialists from the community who admit patients and use (at no cost to them) the hospital’s resources to care for those patients. In other countries, family physicians typically have private offices but specialist physicians are hospital employees. The American approach is the product of a complex history: contributing factors include the conditions of federal funding for hospital construction after World War II, state laws that prohibit direct employment of physicians as the “corporate practice of medicine,” private (Joint Commission) accreditation standards on which Medicare payment is based that view hospitals as under professional control, and the practicalities of generating hospital revenues from physician referrals in a non-universal health care system.

Because the medical staff model of hospital operations puts independent physicians in the position of collectively monitoring one another and judging new applicants, physicians who are disciplined or excluded can allege an economic “conspiracy” against them. Antitrust lawsuits in connection with hospital privileges became frequent enough that Congress passed a special law (the Health Care Quality Improvement Act of 1986) conferring legal immunity on bona fide peer review activities – protection that physicians demanded in order to continue serving on medical staff committees.^{31,32} After Medicare changed its payment policies in the 1980s to encourage hospital cost containment, physicians accustomed to “open” medical staffs also sued hospitals and organized medical groups for excluding them from contracts to provide services in hospital-

based departments such as anesthesiology, radiology, and emergency medicine. These suits were usually unsuccessful, as courts concluded that competition *between* hospitals was more significant than competition *within* hospitals – foreshadowing a more organization-based approach to hospital care.

C. Health Care Consolidation

In recent years, the industrialization of the health care system has altered the pattern of antitrust litigation. Individual physicians are less often involved as plaintiffs or defendants, in part because many physicians are now employees of hospitals and other organizations, and employees cannot be sued as conspirators with one another or with their employers. Most legal disputes over competition today involve preventing anticompetitive mergers and acquisitions between hospitals, between health insurers (sometimes including pharmacy benefit managers), or between hospitals and large physician group practices.

These cases are usually brought by government antitrust enforcers such as the U.S. Department of Justice, the Federal Trade Commission, and state attorneys general.³³ Mergers are analyzed by defining the geographic market (e.g., Chicago) and the product market (e.g., acute care hospital services), estimating the economic effects (e.g., higher prices) of reducing the number of competitors, and determining whether any competitive benefits (e.g., reducing production costs, upgrading quality control systems) outweigh the likely harms from the challenged transaction.³⁴ Recent antitrust litigation has focused as well on contract terms imposed on other parties by dominant hospitals or health insurers that have the effect of preventing new competitors from entering the market.³⁵ Still, the hospital and health insurance sectors have become much more consolidated over the past two decades, putting into question the effectiveness of antitrust law in protecting competition in the health care sector.^{36,37} Of particular concern is that U.S. antitrust laws are not well suited to undoing (as opposed to preventing) excessive consolidation, or to keeping price and output at competitive levels in consolidated markets.

D. The Competitive Effects of Regulation and Self-Regulation

Some of the most interesting disputes under antitrust law concern the relationship between market competition in health care and other health-related laws. Litigation involving pharmaceutical companies, for example, often relates to the anti-competitive effects of using FDA rules (e.g., those created by the Hatch-Waxman Act of 1984) to delay market entry of low-cost generic drugs.³⁸ For physicians and other professionals, the Supreme Court ruled in 2015 that state licensing boards controlled by members of the regulated profession can be sued for federal antitrust violations if their regulatory actions are not supervised by actual state government.^{39,40} This decision limiting “state action immunity” has important implications for the structure and operation of self-regulatory bodies in many professions, which often control entry of potential competitors by setting rules that favor established practice styles or asserting that services are being delivered by unauthorized individuals. Echoing Case Study 2, for example, after the Texas Medical Board had acted repeatedly to discourage telemedicine, an antitrust suit led the Texas legislature to enact new rules that permit greater flexibility, promoting both competition and innovation.^{41,42} Antitrust law can even reach situations that seem mainly bioethical in nature but that have commercial implications, such as collectively agreed

limitations promulgated by a professional specialty society on the money that fertility clinics may pay to young women for egg donation.⁴³

IV. Fraud and Abuse

Imagine the following three scenarios, loosely based on the facts of actual legal cases:

- A medical device company pays a physician a small fee for every patient he refers to use the company's heart monitoring device.
- Dr. Brown is a 25% investor in an imaging facility. He sends all of his patients to this facility for imaging services, and, at the end of the year, Dr. Brown earns a share of the facility's profits.
- Mercy Hospital bills the Medicare program several thousands of dollars for a full multi-use vial of Herceptin for each breast cancer patient treated, but the hospital can—and often does—use the same vial of Herceptin for multiple patients.

Each of these situations raises legal and ethical challenges. How should the law interject to regulate or eliminate them, if at all?

Estimates suggest that ten percent or more of health care spending may be due to fraud and abuse,⁴⁴ ranging from providing unnecessary services (abuse), on one end, to upcoding for care provided or billing for care that was not provided at all (fraud), on the other. Since the inception of Medicare, laws have increasingly attempted to root out fraud and abuse, although with limited success. Increased enforcement efforts during the Obama Administration identified and prosecuted especially egregious offenders. Yet it is a problem that will only be solved with structural and cultural changes. Physicians and other individual practitioners can play an important role by resisting incentives to bill more and do more.

Prior to the ACA, CMS paid claims with minimal investigation, after which the Department of Justice (DOJ) attempted to recoup illegal payments, an approach known as “pay and chase.” The ACA introduced a more proactive strategy, using algorithms to identify fraudulent claims before payment. Although more successful, it still captures only a small percentage of cases of fraud and abuse.

A. False Claims, Kickbacks, and Self-Referral

Fraud and abuse laws aim to identify illegal practices that unnecessarily drive up the cost of health care, to recoup some of the unwarranted spending, and to target and punish wrongdoers. These laws are defined in federal and state statutes, as well as in guidance issued by the Department of Health and Human Services (DHHS) Office of the Inspector General (OIG).

The oldest federal anti-fraud law is the 1863 Civil False Claims Act (FCA), which broadly prohibits defrauding the government.⁴⁵ In health care, the FCA prohibits knowing submission of any false claim to the federal government, such as seeking payment for services not provided or provided in a way that does not meet program standards on, for example, quality and reporting.

The FCA is notable for “qui tam,” or whistleblower provisions, which allow anyone who knows of a violation to file an action on behalf of the government and to receive a percentage of recovered damages. A majority of successful FCA cases are brought in this way by employees who become frustrated with corporate practices, by competitors, or by patients. Violators face civil penalties up to \$11,000 per claim plus three times wrongfully billed amounts and, in the most severe cases, exclusion from participation in Medicare and Medicaid.

The federal anti-kickback statute (AKS) is narrower and prohibits bribes or kickbacks, whether in cash or kind, for referrals or generation of business that is payable by a federal health care program.⁴⁶ Because it is a criminal law, it includes an intent requirement—that a violation be knowing and willful—but that standard is met if one purpose of an arrangement is unlawful, even if there are also legitimate purposes.⁴⁷ For example, waiving co-payments for Medicare patients can be a violation of this law if one purpose is to induce patients to use more care, which can drive up Medicare spending. Physicians and others should be concerned about AKS because violations are punishable by up to 5 years in prison, as well as by other criminal and civil penalties. Possible sanctions include steep fines and exclusion from Medicare and Medicaid.

When the Medicare inpatient Prospective Payment System was introduced in the 1980s, capping payment for hospital stays, various services moved from hospitals to outpatient settings. Many physicians invested in these ancillary care facilities, including clinical laboratories, imaging centers, and ambulatory surgery centers. In 1989, Congress passed the Ethics in Patients Referrals Act,⁴⁸ which prohibits financial relationships that can lead to overutilization. It and its successors, called the “Stark laws” after their strongest proponent, former Rep. Pete Stark, prohibit referrals for “designated health services” to facilities in which a physician or physician’s family member has a financial interest, unless an exception applies. The Stark laws have no intent requirement, which means merely acting outside the permitted bounds triggers civil (but not criminal) penalties. The penalties are substantial, however, and may include exclusion from Medicare and Medicaid. Bills for services that violate AKS or Stark are considered false claims, and therefore are actionable under the FCA as well. Both AKC and Stark have carve-outs by statute or regulation, which explicitly make some activity permissible. For example, AKC “safe harbors” and Stark exceptions allow many arms-length transactions that do not reward patient referral, such as salaried employment and various payments at fair market value.

B. Structural Causes of Fraud and Abuse

Structural forces exacerbate fraud and abuse. The most important is how the United States pays for health care. Any payment system creates incentives and opportunities for abuse or fraud.⁴⁹ A fee-for-service system creates strong incentives for using more care, particularly when the recipient relies on professional advice regarding its necessity and the bill is mainly paid by third parties. When a physician gets paid once for an office visit, again for a lab test, and a third time for imaging—if she has an ownership interest in the laboratory and imaging facility—she has an incentive to do more, even if just to rule out a low-probability event. She also has an incentive to charge, or at least refrain from questioning, a high price.

Private insurance companies have weaker incentives to combat health care fraud than one might expect, and may even compound it. A physician told one us a story of providing a routine service

for a patient with diabetes. When he submitted a bill to the Medicare managed care plan, he got a warning reminding him that the patient had diabetes and asking if he wanted to add a modifier to the claim indicating the complexity of the service. This modifier would help the insurance company maximize its revenue because Medicare “risk-adjusts” its payment to health plans based on the health status of its covered population. The physician changed the bill, even though he believed the initial coding was correct. He said the company would stop sending him patients if he refused.

Although the evidence is mixed regarding associations between corporate form and fraud, the United States is an extreme outlier among nations in how for-profit entities permeate its health care system. Even if nonprofit organizations often behave no better than their for-profit peers, profit potential leads to abuses, a fact illustrated by the proliferation of high-profile and high-dollar fraud prosecutions. Fraud and abuse claims against pharmaceutical companies are not the most common, but are some of the biggest. The DOJ settled with GlaxoSmithKline in 2012 for \$3 billion in civil and criminal penalties and with Pfizer in 2018 for \$2.3 billion, including a \$1.3 billion criminal penalty for off-label promotions and kickbacks. DaVita Healthcare Partners paid \$350 million in 2018 to settle claims of illegal kickbacks, and soon after set aside an additional \$495 million in case ongoing fraud litigation goes badly for it. These companies engaged in systemic patterns of fraud and abuse.

Laws themselves exacerbate fraud and abuse. Compounding the piecemeal payment structure is the separation between provider and facility payments, which is a relic of state laws that attempt to protect doctors from the corrupting influence of business managers. Yet, this separation complicates billing and referral patterns, which can create opportunities for and obfuscate overuse and fraud.

C. Seeking Cultural as Well as Structural Change

Real solutions to fraud and abuse are more complex than passing and enforcing laws, even though monitoring and enforcement will always be needed. Simpler payment and delivery systems can make opportunities for abuse fewer, and can make fraud easier to detect. Physicians are increasingly being employed by hospitals and large group practices, which could reduce various parties’ incentives to pay individual physicians to boost referrals, and could make violations easier to identify by auditing contracts and imposing compliance obligations on provider organizations. Good hospital-based compliance programs might significantly reduce egregious offenses.

Changing professional culture is an indispensable part of combatting fraud and abuse, and should be integrated into physician education and training. A recent article highlighted the continued use of medical interventions after research disproves their value, focusing on stents for stable cardiac patients.⁵⁰ The article describes Grand Rounds at Barnes Jewish Hospital, where an expert first discussed his individual patient who fared well without a stent and then presented randomized clinical trials showing stents to be no more effective than less invasive treatments in stable patients. He then asked how many doctors in the room would stent the patient he first described, and half still raised their hands. Such instincts reflect a deep culture of ratcheting up care

delivery in response to the development of promising technology, but not backing off when evidence refutes the promise.

Health care will always be ripe for profitmaking. Physicians are uniquely positioned to—and have a responsibility to—resist incentives to overuse care or reap unearned profits and report those who are doing otherwise.

V. **Privacy and Confidentiality**

Case Study 3: You are a physician treating a young MSM patient. After reviewing blood tests taken as part of his annual physical, you determine he has seroconverted to being HIV+. You know he has previously attempted suicide, and you are worried about how he will take the news.

There are a number of things you would like to know to help you provide better care, but the patient has been reticent about sharing details of his personal life. Does he have a primary partner or multiple partners? Does he engage in significant drug use? Does he currently engage in sex work? Can you “Google stalk” him to uncover relevant non-health information? Read the public content of his Facebook profile? Look at police records available from public databases? Or would those kinds of searches violate his privacy rights? You also wonder about your obligations to public health authorities or his prior partners to provide information regarding his seroconversion.

The physician-patient relationship requires trust and the free flow of information within, but not outside, the health care setting. Twenty-five years ago, patients’ informational privacy was protected by a set of loosely defined professional commitments and seldom-enforced state laws generally conferring on physicians rather than patients the ownership of the paper charts in which sensitive information had been recorded. Today, protecting digital information that can be remotely appropriated, aggregated, and misused is not only an ethical requirement but also a legal one for physicians, nurses, and hospitals – an obligation primarily met through compliance with detailed federal regulations. At the same time, under certain circumstances these actors have a legal duty to report information regarding patients and others, including to law enforcement and public health authorities.

Four trends in patient and physician attitudes towards health privacy are worth highlighting. First, patients are demanding autonomy to direct their own care, and doing so requires them to have greater access to and control of their personal information. Second, new information and communication technologies such as telemedicine and AI-based predictive analytics promise greater clinical efficiency and effectiveness. Third, there is increasing interest in genetic information. More individuals are using commercial gene analysis to learn their ancestry and their medical predispositions, information that also has important ramifications for genetically related family members.

Finally, the collateral consequences of leaked health information are increasingly serious. Many purveyors of non-health care services are “data hungry,” and public disclosure of health information can be devastating. Moreover, law enforcement is making increasing use of

databases connected to genetic testing in ways that may result in police interactions or even criminal charges for patients and their family members.

A. The Duty to Protect Information Under HIPAA

The main laws that govern the privacy obligations of physicians and other care providers are the Health Insurance Portability and Accountability Act of 1996 (HIPAA)⁵¹, regulations issued under HIPAA by DHHS, and the amendments contained in the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009.⁵² Collectively, we can refer to these sources as “the HIPAA regime.” In broad strokes, the HIPAA regime requires “covered entities” to maintain the confidentiality of “protected health information” (PHI), using or disclosing PHI only in permitted ways.

The HIPAA privacy rule defines PHI as “individually identifiable health information” regardless of the medium, electronic or otherwise, in which it is held.⁵³ Individually identifiable health information is information that is a subset of health information, including demographic information collected from an individual, that:

- (1) Is created or received by a covered entity or employer; and
- (2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and
 - (i) That identifies the individual; or
 - (ii) With respect to which there is a reasonable basis to believe the information can be used to identify the individual.⁵⁴

Health care providers are covered entities, as are health plans and health care clearinghouse organizations. Covered entities are required to:

- (1) adopt internal procedures to protect the privacy of PHI;
- (2) train employees regarding privacy procedures;
- (3) designate a privacy officer;
- (4) secure patient records that contain protected information; and
- (5) establish and enforce agreements with “business associates” that are not themselves covered entities to ensure privacy protection for any PHI those organizations have access to.⁵⁵

The definition of “business associates” is expansive, and includes anyone who “creates, receives, maintains, or transmits protected health information” for claims processing or administration, or in connection with accounting, legal, management, or other services.⁵⁶

The HIPAA regime creates a default rule that no protected health information can be used or disclosed unless one of the recognized exceptions apply. One of the leading health law textbooks summarize these exceptions:⁵⁷

- PHI can be disclosed to the individual or the individual’s personal representative (with special rules if there are concerns about abuse or neglect).
- PHI can be disclosed for “treatment, payment, or health care operations” with the patient’s general consent. Disclosure for payment or health care operations must be the “minimum necessary” for the permitted use (a standard that also applies to authorized disclosures). Disclosure for treatment is not subject to that limitation, reflecting long-standing professional preferences and the perceived exigencies of medical care.
- PHI can be disclosed where the entity receives a more specific “valid authorization” from the patient, typically via a signed document that may vary depending on whether it is a general authorization or one that complies with special rules governing psychotherapy notes, marketing uses, or the sale of information.
- A subset of PHI can be disclosed without written authorization in certain situations after giving the patient an opportunity to object. For example, basic information about an individual’s identity and condition can be added to the hospital directory and made available to callers if the individual does not object, and can even be provided in emergency circumstances if doing so is consistent with any known patient preferences and is in the best interests of the patient.
- PHI can be disclosed without authorization or agreement in roughly a dozen categories of special circumstances, e.g., where the disclosure is required by law.
- A “limited data set” that excludes most identifying information can be disclosed for use in public health, research, and operations. Limited types of PHI may also be disclosed in carefully circumscribed circumstances for institutional fundraising and by health plans involved in underwriting decisions.
- Covered entities are also permitted to disclose PHI “incident to use[s] or disclosures otherwise permitted or required” so long as the covered entity has followed the standards governing the minimum necessary disclosure of information and has put in place proper administrative, physical, and technical safeguards.

Two points are worth highlighting. First, many health care providers and hospitals use the “valid authorization” pathway -- including when patients first join a medical practice – to comply with the law. Second, when it comes to *research* use of patient data, the HIPAA regime allows data to be shared by removing a set of 18 specified identifiers such as names and email addresses, in which case the data will be treated as not being PHI under the law.⁵⁸

B. Other Medical Privacy and Mandatory Reporting Laws

Beyond HIPAA, other laws protect patient privacy as to specific kinds of information. At the federal level, these include the Genetic Information Nondiscrimination Act of 2008 (GINA)⁵⁹ and the Privacy Act of 1974⁶⁰ (governing the use of information collected by federal agencies)⁶¹. Many states have their own statutes governing the confidentiality of patient data,^{62,63} which may be stricter than HIPAA. Private lawsuits are not available under the HIPAA regime, but breaches of patient confidentiality can give rise to substantial liability under state laws governing breach of contract, malpractice, general negligence, breach of fiduciary duty, and fraud/misrepresentation.^{64,65}

In some instances, the law requires physicians to *break* confidentiality and reveal information to relevant parties. Most states require physicians and others to report abuse of children or vulnerable adults. For example, Florida law requires that a physician “who knows, or has reasonable cause to suspect, that a vulnerable adult has been or is being abused, neglected, or exploited shall immediately report such knowledge or suspicion to the central abuse hotline.”⁶⁶ Under state law, physicians also typically must report knife or gunshot wounds to the police.⁶⁷ A third common category pertains to certain contagious or transmissible diseases, including sexually transmitted diseases, which statutes typically require to be reported to public health authorities. Beyond these statutory examples, judicial decisions have imposed on physicians a duty to warn others who may be at risk; these include cases involving contagious diseases⁶⁸, patients with mental illness who threaten identified persons⁶⁹, and the offspring of patients who carry a hereditary disorder⁷⁰. These legal duties to disclose vary by state and often turn on the specific facts at issue.⁷¹

C. Privacy and System-Based Practice

While this discussion has focused on individual physicians, health care institutions also have a major role to play in patient privacy. They must educate their staff about HIPAA and other privacy laws, put policies in place that ensure compliance, provide a high level of corporate data security, and respond effectively to any data breaches that may occur. It is important for health care institutions to honor HIPAA’s respect for patient rights, rather than citing it inappropriately as a “bogeyman” or “conversation ender” when, for example, patients request access to their own health records. Institutional culture is equally valuable for preventing quotidian violations of patient privacy that usually go uncorrected – for example, discussing a patient in an elevator where other patients may be in earshot⁷², or posting an x-ray or an image from a particularly challenging surgery on Facebook. As health care systems come to rely on sophisticated outsiders to augment services that were traditionally offered in-house, it is essential that the vendors selected and the flow of information among them reflect the highest standards of data security and privacy protection. These include e-prescribing practices, secure communications methods, Ransomware response plans, and policies for dealing with inadvertent disclosure.⁷³

Many academic medical centers also collect, store, and conduct research on biospecimens obtained from patients. Recent changes to the federal “Common Rule” governing research ethics in the United States (still not in effect, as of this writing) provide new methods for patient consent relating to biospecimens. In the past, a researcher could remove identifiers from the data, seek study-specific consent, or follow institutional procedures for waiver of consent.⁷⁴ The revised regulations permit “storage and maintenance of identifiable biospecimens for potential

secondary research if sources give their broad consent and the organization's Institutional Review Board (IRB) determines that such consent was properly obtained and that storage provisions to protect confidentiality are adequate." The regulations permit secondary research on properly stored biospecimens without additional consent if the IRB, again conducting only a limited review, "finds that the research is within the scope of that consent, provisions to protect confidentiality are adequate, and the study plan does not include returning individual research results."⁷⁵ It remains to be seen how many researchers make use of these new opportunities and how they play out in practice.

Going beyond the existing law, a systems-level approach presses forcefully on several questions: First, to what extent do attempts to rein in health care costs in the United States require more access to patient data? Second, should the legal system focus not just on protecting patient *health care* data, but also on the broader category of patient *health* data or even *data relevant to health*?^{76,77,78} In a world that takes seriously the social determinants of health, the physicians of tomorrow may want to use data generated from social media, fitbits, shopping habits, etc. in formulating the best treatment for their patients. At what point does the collection and sharing of such data become problematic? Do we need to move away from the current United States health privacy approach, which operates differently by sector and custodian, to a more European approach that applies uniform protection to personal data regardless of who generates or transmits it?⁷⁹ In determining when to breach confidentiality to protect other patients or the public's health, should potential stigma or possible threats to members of vulnerable minority groups (e.g., the patient in Case Study 3) outweigh the duty to disclose? What happens to trust when a physician is expected to play "double agent" with patient information? What should patients be told when forming a clinical relationship about the circumstances under which their private information might be disclosed?

VI. Health Insurance

Imagine that you are a patient arriving for scheduled surgery at a hospital that is in your insurance network. You studied your health insurance policy and understood that you would pay a \$250 deductible and 10% of the rate your insurer had negotiated for the surgery, which you estimated to be about \$1,000 in all. When the bill arrives, it is for \$5,273, including a charge for an out-of-network anesthesiologist that your insurance will not pay.

Or imagine that you are a doctor treating a patient with cancer. You would like to prescribe a treatment regimen that you know works well for this type of patient and cancer, but the patient's insurance might not pay for it. Even if the insurer confirms coverage, the patient's share of the cost might still make treatment unaffordable.

These scenarios occur and persist uniquely in the United States because of its idiosyncratic system for financing health care. A century ago, people who needed medical care simply paid for it. Medical advances and industrial growth have made services so expensive that good insurance is necessary to access good medical care.⁸⁰ For most doctors and hospitals, insurance is also the key to being paid. Laws that influence the structure of insurance are therefore important for physicians to understand, both for their patients and for themselves.

Financing health care in the United States is more complicated than in peer nations because most countries have a universal, or near universal, public system that pays for baseline medical care. This is often referred to as “single payer,” even though most countries also have a secondary system of private insurance. The United States, in contrast, relies on a patchwork of public and private financing with gaps that leave 10 percent of the population uninsured, even after the ACA’s coverage gains.

This convoluted system of financing profoundly affects the practice of medicine. A patient’s resources—financial and intellectual—can have a significant impact on access to medical care even for people with decent insurance coverage. Can the patient afford her health plan’s cost-sharing obligations? Can she navigate the complexity of her insurance benefits and find the care she needs within the health plan’s provider network? Can she take time off work for appointments, especially if a limited provider network requires her to travel farther for care?

Similarly, physicians must decide where in the system to practice and then negotiate various agreements to do so. Once practicing, they will treat patients with different types, levels, and terms of coverage. Even though most doctors – quite understandably – would rather not have to think about how their patients will pay for medically indicated care, health insurance can influence a patient’s ability to get well as much as any other factor. Physicians have no choice but to take note.

A. Insurance Coverage in the United States

Just over one-third of the U.S. population has public health insurance, mostly Medicare and Medicaid.⁸¹ For select populations, the government provides care directly through the Indian Health Services, Veterans Health Administration, and federally qualified community health centers. Medicare, a federal program, covers 57 million older Americans and some people with disabilities. Medicaid, which is funded primarily by the federal government but administered differently by each state, has become the largest insurer in the United States.⁸² It began as a program to cover poor people receiving cash welfare. Over time, it expanded to pregnant women and children whose families earned just above the welfare income thresholds.⁸³ In 1997, in turn, the Children’s Health Insurance Program (CHIP) was created for children above Medicaid’s income thresholds.

In the ACA, Congress attempted to make Medicaid a more nationally uniform program for the poor by extending eligibility to all nonelderly poor earning up to 138% of the federal poverty level (just under \$35,000 USD for a family of four in 2018). This expansion was challenged legally. In *NFIB v. Sebelius*, the Supreme Court held that it was unconstitutionally “coercive” for Congress to force states to expand their programs on pain of losing all federal Medicaid funding, rather than just the incremental funding associated with the additional beneficiaries.⁸⁴ The effect of this decision was to make expansion optional for the states. As of March 2019, 36 states and Washington, DC have embraced the Medicaid expansion, while 14 states have not yet done so.⁸⁵

Private financing includes employer-sponsored health insurance (ESI), individual health insurance, charity care, and out-of-pocket payments. Without insurance, most people cannot afford more than very basic services, and some hospitals will not admit someone for care without

proof they can pay. Annual per person medical spending in the United States is over \$10,000, while median household income before taxes is approximately \$55,000.⁸⁶ The average bill for uncomplicated childbirth in the United States is over \$10,000, while coronary artery bypass surgery costs on average over \$78,000.⁸⁷ Consequently, over half of Americans have private health insurance,⁸⁸ mostly ESI, but with individual coverage increasing because of non-discrimination rules and tax subsidies for working class enrollees under the ACA.⁸⁹ In some cases, people pay for care out-of-pocket. Charity care for the uninsured is sometimes available from free clinics, providers, hospitals' charity care programs, or drug assistance programs, but it is contingent and extremely limited in scope.

B. Accepting Patients with Different Insurance Coverage

Physicians and hospitals have significant discretion over which patients they treat, especially for non-emergency care. Private insurance generally pays (“reimburses”) health care providers the highest amount for a given service, but Medicare covers the elderly and disabled patients on whom most hospitals rely to fill beds and who represent a substantial portion of many physicians' practices. Choosing to accept patients covered by Medicare or Medicaid comes with regulatory obligations. For example, billing a federal health insurance program makes a physician subject to federal fraud and abuse laws, described elsewhere in this Chapter, and both Medicare and Medicaid impose on health facilities detailed conditions of participation, which derive from state licensure, survey, and certification as well as Joint Commission accreditation requirements.

Most hospitals and a majority of doctors accept both private and public health insurance, but some accept only private insurance and an increasing number, especially physicians in high-demand practice areas in urban centers, do not accept insurance at all or charge retainer fees to join their practice. A recent study showed that rates of provider participation are highest in ESI, followed by private ACA marketplace plans, and lowest in Medicaid.⁹⁰ The Mayo Clinic recently announced that it will prioritize privately insured patients over those with Medicare or Medicaid.⁹¹ Providers and facilities are more likely to accept Medicare than Medicaid because its reimbursement rates are higher.

Although a physician, especially one who has already built a strong reputation, can make more money by accepting only privately insured or cash-pay (“concierge”) patients, a decision to do so exacerbates problems that lower-income and elderly people have in accessing health care. In the study referenced above, physician appointments were most available for patients with ESI and lowest for Medicaid patients.⁹² Although no law requires it, many physicians consider it an ethical obligation to accept public health insurance for at least a part of their patient population.

C. Insurance Benefits and Cost-Sharing

Health plans differ in the benefits they cover and what share of the costs patients must pay. Medicaid and Medicare coverage is governed by federal law, and benefits are consistent across states and plans. Private insurance varies more because it is primarily subject to state rather than federal regulation. Employers have wide discretion over benefits design and even though ESI is usually comprehensive, few legal requirements apply to it.

The ACA imposed federal law on individual insurance, requiring all plans to cover ten categories of essential health benefits, such as outpatient care, emergency services, hospitalization, maternity and newborn care, mental health and substance use disorder services, and prescription drugs.⁹³ But the ACA gave states discretion in deciding exactly which services fall into these categories, so that even ACA marketplace plans may differ considerably from state to state.

A few of the ACAs' rules do extend to all private health plans, including ESI and individual coverage. These include coverage of certain preventive care without cost sharing, limits on annual out-of-pocket spending, and an end to annual and lifetime dollar limits on coverage (e.g., no more than \$1 million in benefits over the life of a beneficiary). Some ACA requirements have been contentious. For example, preventive care under the ACA includes all FDA approved methods of contraception. Although the ACA and related federal regulations exempted houses of worship and offered accommodations to religious nonprofits, private companies successfully challenged the contraception mandate as a violation of their religious liberty and prevailed in the Supreme Court.⁹⁴ The Trump Administration issued new regulations that are now, themselves, facing legal challenges. While these cases work their way through the courts, some patients will have plans that fully cover contraception, while others might not.

D. Provider Network Regulations

Another effect of health insurance on medical practice is through network structure. Outside of a few well-established HMOs such as the Kaiser system in California or Group Health Cooperative of Puget Sound in Washington State, for many years health insurers did not limit enrollees to certain health care providers, or even make it financially more attractive to receive care in some settings than others. This changed in the 1980s, when laws were passed to allow state Medicaid programs and then private insurers to “selectively contract” with hospitals and physicians – negotiating lower fees in exchange for channeling more patients to these “preferred” providers.

Although Medicare and most Medicaid programs accept all qualifying providers and suppliers, private insurers have significant discretion on how to compose their provider networks. In California, for example, the ACA health insurance exchange has opted not to contract with the largest, most expensive hospital systems, such as Cedars Sinai and UCLA Hospital in Los Angeles. Instead, they have contracted with smaller hospitals that are willing to offer lower prices.

For patients, the shift to network-based coverage typically resulted in more favorable financing of “in-network” than “out-of-network” providers (e.g., 90% rather than 50% coverage), creating a strong incentive for them to seek in-network care. It also occasionally exposed them to shockingly high “surprise medical bills” from non-network providers who had not agreed to specific fees by contract with their insurer but unexpectedly became involved in their care.

Initially, individual physicians applied to networks that insurers assembled and managed. Over time, physicians joined together in larger groups and associations, both for delivering care and for contracting with insurers. Today, over 40% of physicians are employees of hospitals,

compared to 25% as recently as 2012.⁹⁵ In all these circumstances, physicians should carefully examine proposed contract terms, and should consult an attorney if any seem objectionable

Some laws regulate provider networks. Several states apply legal standards for “network adequacy” to assure an appropriate geographic distribution of physician specialists. Some states prohibit or cap “surprise medical bills.” States also may restrict particular contracting practices between insurers and providers, such as “most-favored nations” (MFN) clauses. These provisions, which require a provider to give the contracting insurer the lowest rate that provider offers to any payer, have been challenged under the antitrust laws because they discourage new insurers from entering the market. Another example is the “any willing provider” law, which requires an insurer to allow any provider into its network who is willing to sign the insurer’s standard contract. As of 2014, 27 states had these laws, sometimes limited to pharmacies and pharmacists.⁹⁶ These laws make it easier for providers to remain in practice or enter new markets, but reduce insurers’ ability to bargain for lower fees in exchange for assured patient volume.

E. The Cost of Complexity

Although the details of health insurance may seem outside of the treatment relationship or secondary when time with patients is short, they likely are as important determinants of health outcomes as a good diagnosis and treatment regimen. In 2016, 50% of employer plans had a deductible of \$1,000 or more for individual coverage, five times more than a decade prior.⁹⁷ If health care costs continue to rise and more individuals join health plans with high deductibles or narrow networks, these challenges will only become more acute as fewer patients are able to afford their assigned share of treatment costs.

The multifaceted approach to paying for health care in the United States leaves significant gaps in who is covered and how meaningfully their coverage provides access to care. It also confuses patients and imposes burdens on providers. One of the greatest ironies in health policy is that physicians, fearful of the lower reimbursement rates associated with public insurance, have repeatedly blocked reforms aimed at more universal financing. However, piecemeal financing has drawn individual practitioners away from patient care and into paperwork; the resulting complexity is undoubtedly one of the greatest challenges practitioners now face.

That physicians devote so much time to complying with the administrative requirements of multiple insurers and programs has motivated many to seek hospital employment, rather than continue to practice on their own. Hospital employment may mean lower lifetime earnings for some, but perhaps higher quality of life. If the United States had created a baseline single-payer system as exists in its peer nations, this same quality of life might have been sustainable in more autonomous practice settings.

VII. Informed Consent to Treatment

Case Study 4: You are a young attending neurosurgeon at a major urban medical center with a well-regarded brain and spine institute. A 40-year-old woman with a recurrent pituitary tumor, originally treated elsewhere, consults you about additional surgery. She is having significant

symptoms and is very concerned that she will not live to raise her children to adulthood. You have only operated on a few recurrent brain tumors. You explain to her that it is a complex operation and outline the risks and benefits of being more or less aggressive in attempting to remove tumor regrowth. The institute where you work uses an interdisciplinary team approach, so you refer her for team-based pre-operative evaluation and counseling, which includes interactive, computer-based decision aids. At the end of that evaluation, the physician's assistant presents her with a surgical consent form, reviews it carefully with her, and obtains her written agreement to remove as much of the tumor as possible in the judgment of the operating surgeon. On the morning of the surgery, you speak briefly with her, and she reiterates her confidence in your ability. Unfortunately, the surgery leaves her with significant neurological deficits, which she claims were not a risk she had wanted to take. Should she be able to sue you for failure to obtain her informed consent? Should it matter that most of the information she received was provided by others on your team? Should you have been required to disclose your relative inexperience? What if part of the operation was done by a senior surgical resident under your supervision? What if you have a consulting agreement with a surgical instrument company?

Informed consent is one of the most important obligations of health professionals. Ethically, the process of engaging a patient and eliciting that person's informed consent to medical treatment has several benefits. It enables a desirable exchange of information regarding therapeutic objectives and the means available to achieve them, builds understanding and trust between the patient and the care team, aligns the expectations of both provider and patient regarding the course of care, and promotes collaboration between them that likely improves medical outcomes.

A. The Ethical Consensus on Consent

As an ethical matter, informed consent is now firmly embedded in physicians' professional expectations of themselves.⁹⁹ Broad acceptance of patient autonomy as a goal and obligation of medical practice is even carrying over to domains beyond consent-to-treatment. For example, the AMA and many other physician professional associations now recognize an ethical obligation of transparency and engagement following unexpected outcomes of care (see Medical Malpractice section of this chapter). Consent to participation in biomedical research – including threats to privacy – is also evolving as society acknowledges the therapeutic misconception often associated with biomedical research settings: that participants in research studies may incorrectly assume that the white-coated, medically trained researchers they encounter are always acting as “doctors” would toward their “patients.”

Whether informed consent truly shifts authority over treatment decisions from physician to patient, and whether that is always desirable, is a closer question. American physicians' ethical embrace of honesty with patients is relatively recent; in 1960, physicians routinely withheld a cancer diagnosis from the patient (sharing it only with family members), arguing that shielding patients from despair was medically beneficial. Such paternalism would be unthinkable in modern medical practice, although a very limited “therapeutic privilege” not to disclose risks to emotionally fragile patients remains part of the law. Still, inherent tension exists between the “patient” role and the hoped-for autonomy expressed in the idea of informed consent, and it is unrealistic to expect that merely sharing information can overcome those limitations. Particularly in cases of serious, unexpected illness that imposes both a physical and an emotional burden,

patients remain dependent on (and may strongly desire) physician guidance, which physicians are ethically obligated to provide.¹⁰⁰

B. The Weaknesses of Consent in The Law

The robust ethical grounding for informed consent is not matched in the law.¹⁰¹ American informed consent law typically applies only to surgery or other physically invasive procedures, and generally requires only the disclosure (without verifying comprehension) of risks, benefits, and treatment alternatives. Recognizing patient dependence, some countries require physicians to recommend a course of treatment. US law does not. Moreover, inadequate information only supports a lawsuit seeking damages for lack of informed consent in a narrow range of circumstances, although additional legal remedies exist where a physician blatantly disregards a patient's right to information or engages in outright deception.¹⁰²

Informed consent law is not established as a nationally uniform standard by Congress but varies from state to state, usually as the result of judges deciding cases though sometimes in the form of statutes enacted by state legislatures. Except for egregious cases of medical procedures (or worse) done to patients without either knowledge or permission – which can lead to civil claims as well as criminal charges of battery – informed consent is considered part of the law of professional negligence (see Medical Malpractice section). Informed consent law requires patients seeking redress in court to demonstrate that the failure to disclose information both breached a legal duty and caused injury.

State laws divide as to whether the sufficiency of disclosure should be set by professional custom as a “standard of care” (which seems contrary to the notion of informed consent being patient-oriented) or based on what a reasonable patient would consider material to a decision (which seems more consistent with goals of patient autonomy).¹⁰³ Texas takes a unique approach, empowering a public commission with physician leadership and attorney participation to distinguish between procedures that require specified disclosures and procedures that do not.¹⁰⁴

Even in states that apply a standard of disclosure highly favorable to patients, legal claims for lack of informed consent typically fail on the issue of causation. The undisclosed risk must be the risk that materializes and causes injury: if a patient is not told about a substantial risk of infection, but the post-surgical complication is something else, there is no legal claim for recovery. In nearly all states, moreover, the plaintiff must prove that a reasonable patient would not have undergone the treatment had sufficient disclosure been made.¹⁰⁵ This means that, even though an undisclosed risk materialized with horrific effects, a patient generally has no legal remedy if treatment was medically indicated and was performed non-negligently because a reasonable person would have elected to undergo the procedure even if fully informed. An injured patient's lawyer still may argue lack of informed consent to a jury as part of a broader malpractice suit in order to portray the physician as uncaring and potentially less attentive – and therefore more likely to have botched the procedure. In states that do not require expensive expert testimony to establish what should have been disclosed, moreover, plaintiffs' lawyers may routinely allege lack of consent to pressure a malpractice insurer to settle and avoid the expense and uncertainty of trial. Standing alone, however, lack of informed consent is a weak legal claim.

C. Consent Involving Systems of Care

The organizational role in informed consent has been mainly administrative: providing a physical venue for pre-surgical consultation and ensuring that forms are completed and signed as required. Particularly for surgery, hospitals have been regulated (and self-regulated through the Joint Commission) as staffed, equipped environments for physicians' professional work rather than as clinical service providers in their own right. Unfortunately, combining time pressure with paperwork in health facilities has set a poor example for physicians and other health professionals by making "consenting" a patient into a procedural hurdle to be overcome in a short clinical encounter rather than a deliberate process of extended information exchange and shared decision-making. Recently, some professional organizations, physician practices, and hospitals have reversed this trend and implemented systems of patient education with audiovisual, often Internet-based aids that can be used iteratively to convey information, verify comprehension, and promote informed consent.¹⁰⁶

The growth of managed care and health systems has caused courts to rethink several aspects of informed consent law, as Case Study 4 illustrates. Established law focused on disclosing characteristics of the disease and possible treatments rather than of the physician or system of care. By contrast, "physician-specific" disclosure requirements have been imposed in several situations, obligating physicians to convey information about their clinical experience and measurable outcomes, financial incentives, and direct participation in the patient's surgery (versus care by a physician in training or other assistant).^{107,108} This remains a work-in-progress, reflecting the growing pains associated with embedding physicians in a larger system and distinguishing among them, rather than assuming that all physicians are equally qualified and that treatment in different settings has the same risk-benefit profile.

There are likely to be further pressures on informed consent as health care systems implement value-based care models. Eliciting patients' goals for treatment, measuring outcomes that patients report, and incorporating a variety of organizational structures and contractual relationships that depart from the traditional one physician-one patient norm all increase potential liability. For example, attaching disclosure obligations to cross-cutting aspects of care (e.g., physicians' financial incentives, conflicts of interest, or reliance on inter-professional teams) removes the "materialized risk" constraint that has limited legal recovery to a small subset of bad outcomes. Similarly, segmenting care into a number of tactical alternatives (e.g., the choice of surgical approach, the extent of resection) among which patients select may persuade courts to find that inadequate disclosure caused harm even when some course of care was clearly necessary and the treatment administered was performed properly.

Another question raised in Case Study 4 that is being actively debated by courts and professional associations is whether the treating physician or surgeon must personally obtain a patient's informed consent. Within organized systems of care, a process that involves multiple members of the clinical team and takes advantage of institutional resources seems more likely than a single conversation with a hurried physician to educate patients effectively about their choices, offer time for reflection and questioning, and enable patients to take an active role in decision-making. Exclusive control by an authoritative physician over the site and terms of the consent conversation may build trust and reinforce a physician's sense of moral responsibility, but risks

perpetuating paternalistic attitudes and practices. Yet at least one court has ruled informed consent to be “non-delegable” by the attending surgeon, though the decision failed to distinguish between delegating the task and delegating the legal liability associated with doing the task poorly, confusion that may intensify as more physicians become hospital employees and the hospital thereby becomes legally accountable for physician negligence.¹⁰⁹

VIII. Medical Malpractice and Redressing Error

Case Study 5: You are a general surgeon in private practice. Your patient, a young man, has significant symptoms of right-side inguinal hernia and has agreed to surgery at the hospital where you typically operate. He signs a consent form for right inguinal hernia repair at his pre-op visit and again when he arrives at the hospital for surgery. However, neither form makes it into the electronic health record. He is brought into the OR and anesthetized. You and the other operating room personnel “huddle” and agree to a plan for right-sided surgery. Unfortunately, an emergency takes you out of the OR for half an hour. When you return, you quickly examine the patient and noting a likely left-sided hernia you proceed to repair that side, failing to operate on the right. When the patient wakes up in the PAR area, he is upset to find that the wrong hernia has been repaired. You immediately apologize, and arrange for him to return to the OR for additional surgery, which goes well. The following day, the hospital administrator visits the patient’s room and assures him that he will not be charged for his care. Several months later, he files a malpractice lawsuit against you and the hospital. Do you feel this is justified? The hospital settles, and reports the payment to the state medical board and to the National Practitioner Data Bank. Do you feel this is justified? The state medical board investigates and decides to sanction you and assess a fine, which will be visible for ten years on the medical board’s public website, and which you will have to disclose to hospitals where you seek privileges for the remainder of your career. Do you feel this is justified?

Physicians are trained, skilled, hard-working, and committed professionals who fervently hope never to cause harm to their patients. Yet millions of patients suffer avoidable injuries from medical care each year, and thousands die as the result.¹¹⁰ As other chapters in this book have explained, poorly designed safety systems that fail to account for predictable human behaviors are largely responsible for medical errors, particularly in hospitals. Considering this state of affairs, it is both shocking that so many adverse outcomes happen unnecessarily, and heartening that so many more are prevented by the personal dedication of physicians, nurses, and other members of health care teams.

When care does go badly, physicians can be held ethically and legally responsible for violating the “duty of care” they owe to their patients. As with the “duty of loyalty” (see section in this chapter on Conflict of Interest), the fiduciary duty of care requires physicians to act affirmatively for their patients’ benefit, faulting them as much for failure to diagnose or treat as for treatment done badly. Poor care – particularly if egregious or repeated – can subject physicians to professional discipline (including license suspension or revocation) by state medical boards. It can cause physicians to lose admitting or treatment privileges following peer review procedures undertaken by a hospital’s self-governing medical staff. In addition to these professional self-regulatory responses, poor care can lead to private litigation by patients against physicians – medical malpractice lawsuits.

A. The Unusual Salience of Medical Malpractice

Medical malpractice differs in several ways from other issues in health law and policy. It is almost entirely governed by state rather than federal law. Judges are more important than legislatures to how malpractice law develops, and no regulatory agencies play significant roles. The politics of altering malpractice law and associated procedures – called “tort reform” – involves well-funded constituencies outside of health care who exploit medical care to serve larger agendas involving the effect of private lawsuits (the “civil justice system”) on America’s economy and social fabric. In recent years, moreover, tort reform has become highly partisan, with Republicans and their corporate donors seeking to restrain litigation and Democrats and their trial lawyer donors seeking to expand it.

Medical malpractice has unique emotional resonance with physicians. Many allegations of malpractice are felt as assaults on character and reputation, and as betrayals of the intimate bond between physician and patient. Malpractice law is part of “tort law,” which provides recourse for harms that do not fall within other legal regimes governing criminal conduct or contractual agreements. The purpose of a tort claim is simple: to recover compensation for wrongful injury, typically from an insurance company (e.g., automobile, property, or malpractice coverage). Yet most physicians consider a malpractice lawsuit tantamount to a criminal accusation, describing it using terms such as “charge,” “verdict,” and “guilt” (the usual tort terms are “claim,” “judgment,” and “liability”). Moreover, although much of the patient-physician relationship is defined by contract, most aspects of malpractice liability may not be modified by agreement between a physician and her patients (except perhaps to settle claims through private arbitration rather than in court).

B. Malpractice Litigation

To prevail in a medical malpractice suit, a lawyer representing a patient as “plaintiff” must establish several elements of the case by a “preponderance of the evidence” (meaning more likely than not, which is a much easier standard to meet than in a true criminal case, which must be proved “beyond a reasonable doubt”). First, the “defendant” physician must owe a legal duty to the plaintiff in the form of a physician-patient relationship. Second, the defendant must have violated that duty by failing to meet the “standard of care” customary among physicians in the defendant’s field and circumstances, which the law terms “professional negligence.” Third, the plaintiff must have suffered injury, which can take the form of money expended (additional medical expenses) or unearned (lost wages from death or disability) and/or harm not usually measured in dollars (“pain and suffering”). Fourth, the defendant must have caused the plaintiff’s injury, both in the narrow sense of the injury not occurring but for the physician’s negligence and in the broader sense of it seeming reasonable to hold the physician (and therefore the physician’s liability insurer) financially responsible.

Because physicians collectively determine the standards of practice to which they will be held in court, malpractice liability is to a large degree just another method of professional self-regulation. The vast majority of malpractice claims are abandoned by the claimant or settled out of court (often without a formal lawsuit) with money paid by a liability insurance company. Still, physicians tend to regard a claim against them as an external and arbitrary threat. One reason is

that a binding decision can be rendered by a jury or judge with no medical training. Another reason is that both sides in a lawsuit hire physicians to serve as expert witnesses, and the plaintiff's expert will report that the defendant was negligent. A third reason is that plaintiffs' lawyers are paid a hefty percentage (around 40%) of any money they recover for their clients, which enables poor people to afford representation but which physicians see as an incentive to distort the facts. But the biggest reason may be that malpractice claims can be incredibly slow to resolve, with major claims often dragging out for five years or more. These years can be filled with stress, uncertainty, inconvenience, and even self-doubt for physicians. This can be compounded for those in traditional small practices who fear sudden, sharp increases in the cost of their malpractice insurance coverage or, as has occasionally happened, coverage becoming unavailable – putting their professional livelihoods at risk.

C. Situating the “Malpractice System” in System-Based Care

The medical malpractice system is seriously flawed as a method of either compensation or quality improvement. Several studies have established a two-sided mismatch between unsafe care and malpractice claims: many lawsuits do not reflect poor care, while the vast majority of injuries caused by medical errors are never redressed in court. The administrative costs (insurance adjusters, lawyers, expert witnesses, etc.) of compensating harm through malpractice claims consume roughly half of the available funds. Few opportunities exist in litigation to understand the causes of errors or improve safety for future patients. Fear of malpractice liability may lead physicians to make clinical decisions that do little to benefit patients but increase health care spending (“defensive medicine”). And the litigation process is convoluted, confrontational, and inhumane for nearly everyone involved. Yet most efforts to reform medical malpractice have tended to focus on only one piece of the problem – so-called frivolous suits and excessive awards – with the result being (perhaps) less of a bad system but certainly not a good system.

Medical malpractice law has adapted in decentralized, state-by-state fashion to the expansion of corporate structures and systems of care. In the early 20th century, laws in most states shielded hospitals from liability by virtue of their status as charitable organizations, while holding physicians (usually surgeons) responsible for poor care by nurses and others under the “captain of the ship” doctrine. In recent decades, however, hospitals have been held “vicariously liable” for the negligence of health professionals whom they employ or hold out to the public as their agents (e.g., an emergency physician or radiologist). Hospitals may also be directly liable for negligence in granting medical staff privileges to physicians, for inadequately supervising physicians, and for failing to maintain a safe environment for patient care. Similar theories of liability have been applied to HMOs and other health plans, particularly in the 1990s when managed care seemed to be taking a more aggressive approach to costs by denying coverage for expensive treatments or obligating patients to receive care from particular hospitals and physicians. When individuals who have health insurance through their private employers bring lawsuits, however, a federal statute governing pensions and fringe benefits called ERISA (which stands for the Employee Retirement Income Security Act of 1974) may prevent them from recovering damages under either malpractice law or state insurance law.

Malpractice insurance has also changed dramatically. Malpractice suits became more frequent and the damages awarded more generous in the 1970s, which was largely a consequence of

rising public expectations from improvements in medical technology and expertise along with expanded health insurance coverage). Commercial insurers therefore pulled back from an increasingly uncertain market, while companies owned by physicians (and hospitals) stepped in to fill the void. These companies dominated medical liability coverage for the next three decades, leveraging relationships with state and local medical societies to lobby for tort reform that had as its dominant objective keeping liability insurance available and affordable for individual physicians (and opposing system-based malpractice changes such as “enterprise liability” that would have assigned primary responsibility for errors to organizations rather than isolated professionals).

As malpractice markets stabilized in the mid-2000s and more physicians became employees of hospitals and large medical practices, however, liability insurance diversified to encompass new approaches to risk-bearing such as captive insurers, risk-retention groups, and institutional self-funding backstopped by excess coverage. There is undoubtedly some tension between physician control over medical care and corporate accountability; physicians who are employees may find it hard to speak up unless corporate culture encourages it. Moreover, corporate defendants are more likely than individual physicians to incur (and perhaps deserve) judgments against them that include substantial punitive damages. On the plus side, however, institutional coverage for medical liability is less vulnerable than individual coverage to periodic malpractice “insurance crises,” which tend to selectively burden a few “high-risk” specialties in states without tort reform. Institutional coverage also is better aligned with systems-based safety improvement strategies, and is more likely to have personnel and processes in place to support both affected professionals and injured patients. For example, physicians working in health systems can expect assistance in the event of serious error from dedicated patient safety officers, patient grievance counselors, and quality improvement support staff. These resources reflect not only greater financial capacity at the institutional level, but more detailed and demanding accreditation and regulatory requirements than apply to individual health professionals.

D. Communicating and Resolving Patient Harm

Insights from health systems science are enabling new generations of physicians to release malpractice policy from its unique professional and political history, and integrate it with other aspects of health law and professional ethics.¹¹¹ This trend is illustrated by the growth of “communication and resolution programs” (CRPs). CRPs are organized responses to medical error that prioritize transparency, immediate assistance to patients and families, timely compensation for unreasonable care, safety improvement, and caregiver support. In roughly 20 years, CRPs have moved from a few public and academic institutions such as the Veterans Administration hospital in Lexington, Kentucky and the University of Michigan into the medical mainstream, earning endorsement from the AMA, the American College of Surgeons, and other professional groups.

Although CRPs are sometimes described as a form of “alternative dispute resolution” that substitutes for malpractice litigation, an ethical commitment to good patient care, respect, and teamwork lies at the heart of the CRP approach. Over a fifty-year period, physicians’ fear of being sued, adversarial tactics by plaintiffs’ lawyers, and a “deny and defend” mentality among liability insurers normalized the concealment of errors and the refusal to engage patients and

families when care went poorly. This is finally changing, as younger physicians who fully embrace shared decision-making and who tend to practice in more organized, less financially exposed environments apply lessons from patient safety science to their own workflow. Younger professionals would never question the ethical obligation to tell patients honestly what *might* happen during medical care (see Informed Consent section in this chapter). Unlike some of their predecessors, telling patients honestly what *did* happen during medical care is equally intuitive to these emerging professional leaders. Still, as Case Study 5 implies, doing the right thing ethically will not always protect physicians from legal accountability.

IX. Withholding and Withdrawing Care

Case Study 6: Mrs. C, 84, was admitted to the hospital with signs of dementia, including periodic confusion. She was not eating adequately; eventually, the care team inserted a nasogastric tube. She was no longer ambulatory and was confined to bed, unable to move from a semi-fetal position. She suffered from arteriosclerotic heart disease, hypertension, and diabetes mellitus; her left leg was gangrenous to her knee; she had several necrotic decubitus ulcers (bed sores) on her left foot, leg, and hip; an eye problem required irrigation; she had a urinary catheter in place and could not control her bowels; she could not speak; and her ability to swallow was very limited. However, she interacted with her environment in limited ways. She could move her head, neck, hands, and arms to a minor extent; she was able to scratch herself, and had pulled at her bandages, tube, and catheter; she moaned occasionally when moved or fed through the tube, or when her bandages were changed; her eyes sometimes followed individuals in the room; her facial expressions were different when she was awake than when she was asleep; and she smiled on occasion when her hair was combed, or when she received a comforting rub. After determining she was not capable of directing her own care, the court named her nephew as her legal guardian. The nephew petitioned to discontinue her feeding tube, which would lead to her death. Mrs. C's guardian ad litem—the individual appointed by the court to protect her interests—opposed the move. How should their disagreement be resolved? What does the law permit?

Case Study 6 is similar to ones that many clinicians encounter regularly across America.¹¹² The “black-letter law”—meaning the law on the books—for these kinds of cases is relatively well-established, though it differs to some extent by state. But the law “in action” is much fuzzier. As we will see, many states adopt standard-like approaches to the legal questions, leaving open difficult fact and value judgments and problems of application. Moreover, for every case that is litigated in this area there are tens or more that are resolved without a court ever considering the matter. Hospitals, care teams, patients, and their families are all “bargaining in the shadow of law,” in the sense that they are engaged in the private resolution of disputes under assumptions about what might happen if they went to court.¹¹³ And their perceptions of the law may be very different from its actuality.

In situations involving withholding or withdrawing care, the law sometimes envisions an ideal world that is very different from what physicians see on the front lines. Advance directives often fail to capture what patients would actually want and also are sometimes disregarded by physicians.^{114,115,116} The most recent approach to these decisions in some U.S. states, termed Physician Orders for Life Sustaining Treatment (POLST), integrates patients, family members,

and physicians in end-of-life care planning, and has proven more successful at translating patients' wishes into medical actions.¹¹⁷ Even POLST, however, may rely on assumptions about available physician time and training that are not always realistic.

A. Legal Distinctions Based On Competency

At one time, both in law and in ethics, the difference between withdrawing and withholding treatment was seen as important. It was argued that "it was permissible to withhold life-sustaining treatment but not to withdraw such treatment, just as there is no obligation to come to someone's rescue, but there is an obligation not to abandon a rescue."¹¹⁸ Over time, though, both law and ethics have revisited this conclusion. Indeed, some now argue that it is worse to withhold than to withdraw because without trying a treatment, the opportunity to see if the treatment works is lost. Moreover, as Justice Brennan observed in his dissenting opinion in the *Cruzan* case, "If we did not recognize a right to have treatment withdrawn, many people might not seek care in the first place because they would be afraid of not being able to stop treatment once it was started."¹¹⁹ While many physicians may still feel more uncomfortable withdrawing than withholding treatment, the law no longer imposes a distinction.^{120,121}

Instead, the law divides its analysis of both withdrawing and withholding care according to whether the patient is "competent" or "incompetent," as those terms are used by the legal system. The law as to competent patients is today relatively straightforward. The U.S. Supreme Court's decision in *Cruzan v. Director, Missouri Dep't of Health*,¹²² is typically read as confirming the constitutional right of a competent patient to refuse medical treatment regardless of his or her medical condition.^{123,124} The case law typically grounds this right in conceptions of bodily autonomy and, according to the U.S. Supreme Court, can be seen as a "logical corollary of the doctrine of informed consent [in] that the patient generally possesses the right not to consent, that is, to refuse treatment."¹²⁵

The law as to patients not deemed competent is more complicated. As Rebecca Dresser has ably summarized, courts and legislatures in U.S. states have adopted three different approaches.¹²⁶ First, under the "subjective standard" (also called the "advance directive" approach), the treatment (or non-treatment) of the incompetent patient should reflect that patient's previously expressed wishes. When there is a clear and applicable advance directive, or a proxy directive designating someone else to make decisions should the patient become incompetent, things run relatively smoothly. That said, even well-written advance directives may fail to provide for particular situations or ambiguities. Without a detailed specification in writing, some states have accepted evidence about a patient's general or specific remarks about life-sustaining treatment to help guide decisions, but others have found such evidence too informal.¹²⁷

A second approach is the substituted judgment standard (also called the "limited-objective" standard). As the New Jersey Supreme Court described this approach in the *Conroy* case, decision-makers should permit an incompetent patient to forgo life-sustaining treatment "when there is some trustworthy evidence that the patient would have refused the treatment" and "it is clear that the burdens of the patient's continued life with the treatment outweigh the benefits of that life for him."¹²⁸ This standard allows refusal of care despite relatively weak evidence of what the patient would have wanted (the subjective element) as long as objective judgments

about the patient's quality of life with and without treatment accord with the available subjective evidence.

A final approach is the "best interests" standard (also called the "objective standard"). This standard requires "decision-makers to assess and then balance different features of the individual incompetent patient's medical situation, such as prognosis and quality of life with and without treatment. Judges and other decision-makers consider the burdens and benefits the individual patient would experience if life-sustaining interventions were provided, or conversely, forgone."¹²⁹ This determination does not turn on what a particular patient *actually* wanted, but what is judged to be in the patient's best interests from an objective point of view. The best interests standard is most often used in cases where there is no evidence of what the patient would have wanted, which usually involve profoundly disabled patients who have never been competent.

B. Revisiting End-of-Life Practices in Health Care Systems

Existing law faces several new pressures that highlight institutional and systems-based issues. First, to what extent does it make sense to resolve disputes over withholding or withdrawing care in courtroom proceedings, as opposed to relying on hospital ethics committees, or other forms of dispute resolution? The prevailing practice has changed over time.^{130,131,132} Second, choices to pursue treatment impose significant costs on patients' families and the health care system. To what extent can cost legitimately be considered in setting rules about care, or is it antithetical to medical ethics even to pose that question? Third, many physicians have strong beliefs about end-of-life care. To what extent should hospital systems make efforts to accommodate physicians whose religious or conscientious beliefs prohibit withholding or withdrawing care?¹³³

Moreover, discussions about medical care at the end of life tend to quickly become politicized, which often erases any hope of maintaining privacy for the individuals involved, while also exposing health care systems to unwelcome if arguably necessary publicity. Consider the saga of Terri Schiavo, who spent fifteen years in a persistent vegetative state while her family, the courts, and Congress very publicly fought over what should be done.¹³⁴ Or consider how a proposed provision in an early draft of the ACA to authorize Medicare reimbursement for physicians who engage patients in end-of-life care planning was distorted by partisanship into an accusation that the Obama administration was seeking to institute "death panels."¹³⁵ Finally, to what extent is dementia a challenge to the legal distinction between competence and incompetence in refusing care?^{136,137} What about a pre-dementia patient who asks for care to be withheld if dementia develops, but who after developing dementia seems to be happy and enjoying life? Are the pre-dementia individual and that individual's later, demented self the same person from a moral perspective? From a legal perspective?

In Case Study 6, Mrs. C's situation involves "withdrawing" care that has already started as opposed to "withholding" care that has not yet been initiated. Has this chapter helped you decide her case? The chapter has not discussed a third category, "physician assisted suicide" (sometimes called "medical aid in dying" by those who resist the "suicide" characterization), where the physician actively works to hasten death. It also has put aside special legal questions concerning withdrawing and withholding care for infants and other minors, where special rules and other

bodies of law (e.g., family law, child abuse and endangerment law) come into play.^{138,139,140,141,142,143,144} These are legally, medically, ethically, and socially contentious issues.

X. Summary

Law is a common feature of life, especially in important economic sectors that affect public health and safety. Unsurprisingly, law is a constant presence in the U.S. health care system. In other parts of this book, various health law issues are presented largely in terms of compliance with legal duties and obligations, as well as respect for the legal rights of others. In everyday practice, most such issues have reasonably clear answers. As long as physicians and health professionals are able to recognize the probability of legal considerations being relevant to a situation, some research and perhaps a brief consultation with a lawyer or compliance professional will generally reveal an advisable course of action.

This chapter has gone beyond pursuing that limited albeit important objective. The more deeply students explore health law, the more they realize that “it’s complicated.” Experienced lawyers often answer questions with “it depends” for good reason. In many situations, sound legal judgment requires an ability to match subtle distinctions in fact to complex legal precedents. These problems may be magnified in health law, whose sources are particularly multifarious – constitutional, statutory, regulatory, and common law along with custom and practice – and whose subjects of regulation (physicians, nurses, hospitals, insurers, patients, families, pharmaceutical companies, etc.) interact with one another in complex patterns.

For students of health system science, moreover, health law is key to understanding why the health care system operates as it does, and why it has been so challenging to improve. Legal standards, and the substantial financial subsidies that are based on them, can act as either barriers to, or facilitators of, health system change. Health law also has a profound relationship to medical ethics, a relationship derived from its grounding (for better or for worse) in the professional ethics of physicians, as well as its connection to the bioethics of adapting technological advances in biomedical science and informatics to the needs and concerns of patients and society. Considered from a broader vantage point, studying health law raises at least as many questions as it provides answers. The chapter embraces this duality across a number of legal domains from conflict of interest to end-of-life care.

XI. Questions

1. How much of a say should the medical profession have in what health laws are enacted? Should it depend on the subject matter of the law in question? Should physicians help draft or enforce laws defining or protecting the quality of care? Laws limiting who can practice medicine? Laws determining what services health insurance must cover? Laws establishing the methods of payment for those services? Laws setting fees?
2. Fair procedures are at the heart of legal governance. For adjudicating a claim or charge, these consist of notice to the defendant, a structured opportunity to gather evidence and hear from witnesses, adversarial advocacy by legal counsel for each side, an impartial decision-maker, and a public, usually reasoned decision. Legislation and administrative

regulation have similar features designed to promote transparency, public input and accountability, rationality, and even-handed enforcement. In what ways are these procedures compatible or incompatible with medical professionalism?

3. Which laws governing the system for financing health care in the United States would you change and why? Would you expand public funding for health insurance for the poor, or direct public funding for health care services instead? Would you alter the rules for how and how much physicians and hospitals are paid by Medicare and Medicaid? How would you revise health care financing to do a better job addressing health disparities and improving population health?
4. Do you agree or disagree with the following statement: “When it comes to end of life decision-making, physicians defer too much to patients’ family members”? To what extent are family members good proxies for what patients would want? Are judges and courts well suited to mediate between family members and the patient care team? Or should judicial processes be largely irrelevant to the daily operations of health care systems?

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