CHAPTER

1

USING THE LAW TO PROMOTE OUR POLICY GOALS AND ETHICAL PRINCIPLES

The study of law is more than simply memorizing a list of activities that are illegal, such as Medicare fraud or price-fixing. It is more than memorizing the penalties for particular violations, such as the number of years in prison one can receive for a class B felony or the fine for driving 50 miles per hour in a 35-mile-per-hour zone. It is more than trying to remember the names of court cases or the citations to statutes and regulations. Instead, law is a policy discipline and a social science.

Moreover, the law is not cast in stone but is subject to change. For hundreds or perhaps thousands of years, people have reconsidered and changed the rules that govern their activities. In a democratic society, we have the power to make further changes in the laws by which we live. Therefore, as students and teachers of law, we not only study the current state of the law, but also what we think the law should be. In particular, we consider how we can use the law to accomplish our goals of public policy.

We begin this type of analysis by identifying a practical problem. For example, we may want to focus on discrimination, environmental pollution, or inadequate access to healthcare services. Then we try to figure out how to use the law and the legal system to solve that particular problem, by creating a new law or by changing an existing law.

"There Ought to Be a Law!"

When we talk about reforming the healthcare system, we are really saying we should change the laws that regulate that system. For example, if we think health insurance companies should be required to provide coverage for everyone without regard to health status, we are really arguing for a particular type of law that governs the operation of insurance companies. If we think insurance companies and health maintenance organizations should be required to authorize potentially lifesaving care for patients dying of cancer or should be held liable in damages for the harm caused by their refusal to authorize care, we are really arguing in favor of laws that would make those changes to the existing rules of law. Thus, when we say we want to reform the healthcare system to achieve our policy goals, what we really are saying is, "There ought to be a law."

Coming to this conclusion is the relatively easy part. The harder—and more interesting—part is figuring out what kind of law to create and what that law should provide. Several alternatives will arise, and each will have its own advantages and disadvantages. The task is to choose the alternative that will be most effective and most efficient in achieving the particular policy goal.

The first set of alternatives to consider is whether the problem can best be handled by a single federal law or a series of separate state laws. As discussed in Chapter 2, one of the underlying themes of healthcare law and policy is determining the appropriate roles for the federal government and state governments in regulating healthcare providers and third-party payers. Each level of government has its own legal powers and its own practical advantages. The federal government has the power to create laws that establish uniform standards throughout the country and has greater resources than the states to finance and enforce its laws. The states, however, may be more aware of and responsive to local needs and may be able to experiment with new approaches for which a national consensus has not yet developed. Of course, regulation by one level of government does not necessarily preclude regulation by the other, and many activities are subject to overlapping regulation by federal, state, and even local authorities.

In addition to choosing local, state, or federal law, the next step is to select an approach or combination of approaches to using the law as a way to solve a particular problem. For example, several different approaches to using the law as a means of promoting quality of patient care and reducing medical errors are available. Under a regulatory approach, a governmental body would prohibit certain activities or require that those activities only be performed under governmental supervision. One example of this regulatory approach is licensure of healthcare professionals, in which state governments prohibit unqualified persons from practicing a specific healthcare profession and provide governmental supervision over those persons who are permitted to practice. A different approach would be to allow or create a private right of action in civil court for monetary damages by an injured patient against the healthcare provider who allegedly caused the injury. In a combination of these different approaches, our legal system attempts to promote quality of care by requiring a physician to obtain a license to practice medicine from a state licensing board, but also permits an injured patient to sue the licensed physician for medical malpractice in a civil action for monetary damages. A third approach would be to use the government's power as a large-scale buyer of healthcare services to impose legal requirements on those healthcare facilities and professionals who elect to serve the beneficiaries of government payment programs.

Once we decide on the best approach or combination of approaches, the next step is to decide where to draw the line between lawful and unlawful

conduct. It may be obvious that certain bad conduct should be against the law and that certain good conduct should be lawful. However, most activities in the real world fall somewhere in the middle. In creating a law, we have to draw a line and say that everything on one side of the line is lawful and everything on the other side is unlawful. As a matter of fundamental fairness, that line must be clear and understandable, so that people will have fair notice of what is prohibited and will be able to conform their behavior to the requirements of the law.

In deciding where to draw the line, we want to choose the point at which the law will be most effective in stopping the bad conduct without inhibiting socially useful activities. If the rules of law are too weak, they will not be effective in achieving the policy goal. If the rules are too restrictive, however, they will be impractical to follow, difficult to enforce, and prohibitively expensive for society as a whole. We also need to avoid, or at least minimize, the unintended consequences that are almost certain to occur when we create a new law or revise an existing law. Thus, the challenge is to create or revise a law that will accomplish our policy goals effectively with minimal adverse consequences.

Ethics in the Healthcare Field

When people talk about ethics in healthcare, they may be speaking about a variety of topics, including bioethics, professional ethics, and business or organizational ethics. Depending on the context, this book will address each of these different aspects.

Sometimes the term *ethics* is used to refer to the moral quandaries of bioethics, such as defining the extent of a patient's right to refuse treatment or the right to a natural death. We might conclude, for example, that a competent adult patient should have the right to refuse a lifesaving blood transfusion on the ground of religious belief. Under those circumstances, an individual's right to religious freedom may outweigh society's interest in keeping its members alive. However, if the patient's death would leave the patient's child as a ward of the state, we might conclude that the interests of society should take precedence over the rights of the individual in those circumstances. In either case, our view of the appropriate ethical solution is *not* a question of what is required or allowed by the laws of the state. Rather, our view of what is right and wrong is an expression of our moral philosophy and our beliefs about the proper relationship between the individual and society.

In other situations, the concept of ethics in healthcare refers to the professional standards of medical practitioners, such as the Principles of Medical Ethics adopted by the American Medical Association (AMA). These

principles do not have the force of law and do not purport to dictate how society as a whole should resolve difficult questions of morality. Rather, the AMA's Principles of Medical Ethics only set forth the standards of ethical conduct for physicians.

For example, the ongoing debate over physician-assisted suicide involves several aspects of healthcare ethics. Apart from the legal issue of criminal prosecution for causing the death of a human being, an ethical issue arises as to whether it is morally right to cause the death of another person. In addition, a separate issue of professional ethics exists about whether a member of the medical profession should participate in the suicide of a patient. In that regard, the AMA Council on Ethical and Judicial Affairs has indicated that physicians should *not* assist terminally ill patients in committing suicide, whether or not suicide is justifiable in a moral sense or permissible under the laws of the state.[1] This example shows the importance of distinguishing among the legal, moral, and professional issues in this type of debate, as well as the importance of clarifying how the term *ethics* is being used.

Aside from the moral issues of bioethics and the professional standards of medical ethics, the term may refer to business or organizational ethics in the context of the healthcare industry. As one author has explained, "[b]usiness ethics is the study of how personal moral norms apply to the activities and goals of commercial enterprise."[2] As in any other enterprise, each organization in the healthcare industry must determine what it considers to be appropriate conduct for its officers and employees. The Joint Commission (formerly the Joint Commission on Accreditation of Healthcare Organizations), for example, has required accredited healthcare facilities to operate in accordance with a "code of ethical business and professional behavior."[3] Moreover, because of the unique importance of healthcare services for individuals and society, organizations in the healthcare industry and the people who work in those organizations have additional ethical duties to the people and communities they serve.

The Relationship Between Law and Ethics

Contrary to popular notions, the law is not totally separate from ethics. In fact, the rules of law are based on ethical beliefs that are commonly held in our society. These basic ethical principles include respect for individual autonomy, beneficence (helping others), nonmaleficence (not harming others), and justice or fairness.[4] Regardless of whether these ethical duties are derived from religious faith, natural law, or a social contract, these principles form the basis for the legal rules of our society. For example, the legal prohibitions against violence and theft are expressions of the ethical principle of nonmaleficence.

In some cases, however, these ethical duties require us to do more than what is currently required by law. As discussed in Chapter 11, U.S. law generally imposes no duty to help a stranger in distress, even though most people believe an ethical obligation exists to do so. Therefore, it is reasonable to ask at this point why the law does not always go as far as ethics in requiring particular conduct.

Creating rules of law to implement the principle of nonmaleficence, such as prohibiting one person from attacking another or stealing the property of another, is relatively easy. Members of our society generally agree that attacking other people in any way or stealing any amount of their money or property is morally wrong. In contrast, creating rules of law that would require us to help others, in accordance with the ethical principle of beneficence, is more difficult.

No consensus can be reached on precisely how far each of us should be required to go in giving our time and money to help other people or how much sacrifice and risk we should be required to incur in doing so. In addition, developing clear rules in advance that would put people on notice of how much help they are required to provide to others to avoid violating the law is difficult. If we cannot reach a consensus or draw clear lines between lawful and unlawful conduct, we cannot hold people legally liable for failing to act as we would have preferred.

The disparity between ethical principles and legal obligations can be particularly acute with regard to providing healthcare services to people in need. According to the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, society has a moral obligation to provide access to an adequate level of healthcare for all of its members, even though there is no comprehensive legal right to healthcare at the present time.[5] Under these circumstances, the ethical duty of beneficence requires us to do more than is currently required by law. In the meantime, we can also work to change the law in ways that would provide greater access to care.

This dynamic interaction between healthcare law and ethics can be seen in the tragic case of a 15-year-old boy who died outside the door of Ravenswood Hospital in Chicago. On May 16, 1998, Christopher Sercye was playing basketball when he was shot twice in the stomach. His friends helped him get to the bottom of the entrance ramp of the private hospital's emergency department, but Christopher collapsed outside the door. Although his friends and police officers pleaded with hospital employees to help him, the emergency department employees refused to leave the building because of hospital policy. Eventually, a police officer took Christopher in a wheelchair to the emergency department, where he died. Later, the director of the Illinois Department of Public Health spoke to the *Washington Post* about this tragic case:

> "It's important for people in healthcare to be first and foremost care-givers and not lawyers," complained John Lumpkin, director of the Illinois Department of Public Health, whose office mailed letters to that effect to all hospitals licensed by his regulatory agency. "First and foremost, you do what's right for the patient. There is no legal obligation for them to provide care outside their doors but morally we would expect them to do the right thing."[6]

In fact, if Christopher was on the hospital's property, the hospital was legally obligated to provide the necessary emergency care. In 1986, Congress enacted the Emergency Medical Treatment and Active Labor Act (EMTALA), which is also known as the Consolidated Omnibus Budget Reconciliation Act (COBRA) antidumping law.[7] That law requires all hospitals that have an emergency department and participate in the Medicare program to provide certain emergency services, regardless of a patient's ability to pay. The law applies to any individual who "comes to the emergency department."[8] Under regulations that had been issued by the U.S. Department of Health and Human Services (HHS), a person was considered to have come to the emergency department if he was "on the hospital property."[9] Therefore, if Christopher was on the property of the hospital, the hospital was legally required to provide emergency services.

As a result of this incident, Ravenswood Hospital changed its policy. In addition, without admitting that it did anything wrong, the hospital paid $40,000 in a settlement with the HHS Office of Inspector General (OIG).[10] Morality may have required more than the law in that case, but it does appear that some legal obligations were already in effect at that time.

These events also caused HHS to clarify or change the law on a prospective basis. In its amended regulations, HHS explicitly provided that the hospital property includes "the entire main hospital campus . . . including the parking lot, sidewalk, and driveway."[11] In addition, HHS defined the term "campus" to include areas within 250 yards of the main hospital buildings.[12] These amendments remind us that we have the ability to change the law over time to become more consistent with our ethical principles.

Moreover, the OIG, which reached the settlement with Ravenswood Hospital, has encouraged all healthcare organizations to adopt effective compliance programs. According to the OIG, those compliance programs should not be limited to ensuring compliance with the law; they should also be designed to encourage ethical business behavior.[13] Each healthcare organization should strive for a standard of ethical behavior that exceeds the current requirements of law. In addition, each organization should encourage its officers, employees, and trustees to consider the ethical implications of their decisions, and should develop policies and systems that encourage people to act in the best interest of the patient and of society in general.

In figuring out how to do "the right thing," you should *not* begin your analysis by asking what the law requires you to do. That would be like the tail wagging the dog. Instead, determine what act or decision would be the most ethical. Then, find a way to do that in a manner that complies with the law and minimizes the risk of liability. In addition, you may decide that advocating for a change in the law is necessary to encourage or require people to act in an ethical manner.

The Goals of This Book

One of the goals of this book is to help you to stay out of jail and reduce the risk of civil and criminal liability. In fact, you *can* be sent to prison for breaking some of the laws in the healthcare industry, such as those against price-fixing and Medicare fraud. In addition, healthcare providers can be held liable for millions of dollars in damages, and can be excluded from participation in government payment programs. From a positive perspective, knowing what the laws permit you to do—not merely what the laws prohibit—is important.

However, memorizing every one of the potentially applicable laws or creating a complete list of legal "dos and don'ts" is impossible. Even if that could be done, it would not be particularly helpful, because laws change every day with the issuance of new statutes, regulations, and court decisions.

Moreover, legal consequences depend on the unique facts of each particular case, and every case is different. For example, we may know that factors A, B, and C would make an arrangement between a hospital and a physician lawful, but that factors X, Y, and Z would make it unlawful as a violation of the federal Medicare Anti-Kickback Statute.[14] The problem is that your situation will never be exactly like A, B, and C or exactly like X, Y, and Z but rather will be somewhere in the middle. Under these circumstances, the lawyer's job is to analyze the particular set of facts, apply the rules of law to those facts, and form a professional opinion or prediction as to whether a court or government agency is likely to find your facts more similar to A, B, and C or to X, Y, and Z. In fact, that is precisely what lawyers are trained to do.

In contrast, managers and healthcare professionals need to learn how to identify situations that raise potential legal issues. In that way, they will begin to develop a good intuitive sense for avoiding legal problems and for knowing when to consult their lawyers. Therefore, another goal of this book is to help managers and healthcare professionals learn how to identify potential legal problems that they are likely to encounter in the healthcare industry.

Another important objective is to understand how legal rules have changed over time and how they continue to change to promote the

underlying goals of an evolving public policy. As discussed earlier, the laws regulating the U.S. healthcare system are the result of the collective desire of society to change the previous laws for reasons of policy and ethics. By studying the underlying policy goals and ethical principles, you can gain a better understanding of the existing laws that regulate the healthcare system. Moreover, by understanding the policies on which the laws are based, recognizing a situation that raises a potential legal issue will be easier. In other words, you will be able to recognize when something *should* be against the law.

Understanding what the law currently requires of participants in the healthcare field is important, but that alone is not sufficient. You should also understand how to change the law. In that way, you will be able to achieve your policy objectives, promote your ethical standards, and make progress toward the common goal of healthcare reform.

In many ways, the study of health reform is the study of law, particularly healthcare law. The Patient Protection and Affordable Care Act (ACA)[15] is a law that was enacted by Congress in 2010 in two parts, as Public Law No. 111-148 and Public Law No. 111-152. The ACA creates some new federal laws and makes significant changes to some existing federal laws on subjects such as Medicare, fraud and abuse, and the obligations of tax-exempt hospitals. In addition, the ACA requires federal agencies to issue many new federal regulations, which also are a type of law. Finally, the U.S. Supreme Court, which is a court of law, rendered a decision on the extent to which the ACA meets the requirements of the U.S. Constitution, which is our highest law.[16] Under these circumstances, studying and understanding healthcare law is necessary to understanding health reform.

Notes

1. Council on Ethical and Judicial Affairs, American Medical Association, "2.211," in *Code of Medical Ethics: Current Opinions with Annotations* (1996–1997).
2. L. L. Nash (1990). *Good Intentions Aside: A Manager's Guide to Resolving Ethical Problems*. Boston: Harvard Business Review Press: 5.
3. Joint Commission on Accreditation of Healthcare Organizations (1997). "New Standards Seek to Protect Integrity of Clinical Decision Making." *Joint Commission Perspectives*, Jan./Feb.: 18–19.
4. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (1979). www.hhs.gov/ohrp/humansubjects/guidance/belmont.html.

5. President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (1998). *Securing Access to Health Care: A Report on the Ethical Implications of Differences in the Availability of Health Services*, no. 5, vols. 1–3.
6. J. Jeter (1998). "Chicago Cringes at Teen's Death; Hospital Wouldn't Treat Gunshot Victim 35 Feet from Its Door," *Washington Post*, May 20, A2.
7. Emergency Medical Treatment and Active Labor Act of 1986 (EMTALA), 42 U.S.C. § 1395dd (2005).
8. *Id.* § 1395dd(a).
9. 42 C.F.R. § 489.24 (2001).
10. L. Meckler (1999). "Ravenswood Hospital Is Fined $40,000 in Boy's Death," *Chicago Sun-Times*, March 13, 4.
11. Office of Inspector General; Medicare Program; Prospective Payment System for Hospital Outpatient Services, 65 Fed. Reg. at 18434, 18548 (April 7, 2000).
12. *Id.* at 18538 (adding a new 42 C.F.R. § 413.65).
13. See Publication of the Office of Inspector General Compliance Program for Hospitals, 63 Fed. Reg. at 8987, 8988 (Feb. 23, 1998).
14. 42 U.S.C. § 1320a–7b (2000).
15. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010), amended by Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 (2010).
16. *National Federation of Independent Business v. Sebelius*, 132 S. Ct. 2566 (2012).