PART I

Setting the Stage: An Overview of Health Policy and Law

Part I of this textbook includes five chapters aimed at preparing you for the substantive health policy and law discussions in Chapters 6–13 and the skills-based discussion of policy analysis in Chapter 14. Chapter 1 describes generally the role of policy and law in health care and public health and introduces conceptual frameworks for studying health policy and law. Chapter 2 describes the meaning of policy and the policymaking process. Chapter 3 provides an overview of the meaning and sources of law and of several important features of the legal system. Part I closes with overviews of the U.S. healthcare system (Chapter 4) and public health system (Chapter 5).

CHAPTER 1

Understanding the Role of and Conceptualizing Health Policy and Law

Learning Objectives

By the end of this chapter, you will be able to:

- Describe generally the important role played by policy and law in the health of individuals and populations
- Describe three ways to conceptualize health policy and law

INTRODUCTION

In this chapter, we introduce the role played by policy and law in the health of individuals and populations and describe various conceptual frameworks with which you can approach the study of health policy and law. In the chapters that follow, we build on this introduction to provide clarity in areas of health policy and law that are neither readily discernable—even to those who use and work in the healthcare and public health systems—nor easily reshaped by those who make, apply, and interpret policy and law.

The goals of this chapter are to describe why it is important to include policy and law in the study of health care and public health and how you might conceptualize health policy and law when undertaking your studies. To achieve these goals, we first briefly discuss the vast influence of policy and law in health care and public health. You will have a much better feel for how far policy and law reach into these areas as you proceed through this text, but we dedicate a few pages here to get you started. We then describe three ways to conceptualize health policy and law, which, as you will discover, are interwoven, with no one framework dominating the discussion.

ROLE OF POLICY AND LAW IN HEALTH CARE AND PUBLIC HEALTH

The forceful influence of policy and law on the health of individuals and populations is undeniable. Policy and law have always been fundamental in shaping the behaviors of individuals and industries, the practice of health care, the environments in which people live and work, and also to achieving both everyday and landmark public health improvements.

For example, centuries-old legal principles have, since this country's inception, provided the bedrock on which healthcare quality laws are built, and today the healthcare industry is regulated in many different ways. Indeed, federal and state policy and law shape virtually all aspects of the healthcare system, from structure and organization, to service delivery, to financing, and to administrative and judicial oversight. Whether pertaining to the accreditation and certification of individual or institutional healthcare providers, requirements to provide care under certain circumstances, the creation of public insurance programs, the regulation of private insurance systems, or any other number of issues, policy and law drive the healthcare system to a degree unknown by most people.

In fact, professional digests that survey and report on the subjects of health policy and law typically include in their pages information on topics like the advertising and marketing of health services and products, the impact of health expenditures on federal and state budgets, antitrust concerns, healthcare contracting, employment issues, patents, taxation, healthcare discrimination and disparities, consumer protection, bioterrorism, health insurance,

prescription drug regulation, physician-assisted suicide, biotechnology, human subject research, patient privacy and confidentiality, organ availability and donation, and more. Choices made by policymakers and decisions handed down through the judicial system influence how we approach, experience, analyze, and research all of these and other specific aspects of the healthcare system. Once you have read the next four preparatory chapters—one on policy and the policymaking process, one on law and the legal system, and one each covering the structure and organization of the healthcare and public health systems—and begin to digest the substantive chapters that follow them, the full force of policy and law in shaping the individual healthcare system will unfold. For now, simply keep in the back of your mind the fact that policy and law heavily influence the way in which health care is accessed, medicine is practiced, treatments are paid for, and much more.

The role of policy and law in public health is no less important than in individual health care, but their influence in the field of public health is frequently less visible and articulated. In fact, policy and law have long played a seminal role in everyday public health activities (think, for example, of food establishment inspections, occupational safety standards, policies related to health services for persons with chronic health conditions such as diabetes, and policies and laws affecting the extent to which public health agencies are able to gauge whether individuals in a community suffer from certain health conditions), as well as in many historic public health accomplishments such as water and air purification, reduction in the spread of communicable diseases through compulsory immunization laws, reduction in the number of automobile-related deaths through seatbelt and consumer safety laws, and several others.[a] Public health professionals and students quickly learn to appreciate that combating public health threats requires both vigorous policymaking and adequate legal powers. Additionally, in recent years, enhanced fears about bioterrorism and newly emerging infectious diseases have only increased the public's belief that policy and law are important tools in creating an environment in which people can achieve optimal health and safety.

Of course, policies and laws do not always cut in favor of what many people believe to be in the best interests of public health and welfare. A policy or law might, for example, favor the economic interests of a private, for-profit company over the residents of the community in which the company is located.[b] This is so because one main focus of public health policy and law is on locating the appropriate balance between public regulation of private individuals and corporations and the ability of those same parties to exercise rights that allow them to function free of overly intrusive government intervention. Achieving this balance is not easy for policymakers. Not all interested parties agree on things like the extent to which car makers should alter their operations to reduce environmentally harmful auto emissions, or the degree to which companies should be limited in advertising cigarettes, or whether gun manufacturers should be held liable in cases where injuries or killings result from the negligent use of their products.

How do policymakers and the legal system reach a (hopefully) satisfactory public health/private right balance? The competing interests at the heart of public health are mainly addressed through two types of policies and laws: those that define the functions and powers of public health agencies, and those that aim to directly protect and promote health.[c] State-level policymakers and public health officials create these types of policies and laws through what are known as their *police powers*. These powers represent the inherent authority of state and local governments to regulate individuals and private business in the name of public health promotion and protection. The importance of police powers cannot be overstated; it is fair to say that they are the most critical aspect of the sovereignty that states retained at the founding of the country, when the colonies agreed to a governmental structure consisting of a strong national government. Furthermore, the reach of police powers should not be underestimated: they give government officials the authority—in the name of public health and welfare—to coerce private parties to act (or not) in certain ways. However, states do not necessarily need to exercise their police powers in order to affect or engage in public health–related policymaking. Because the public's health is impacted by many social, economic, and environmental factors, public health agencies also conduct policy-relevant research, disseminate information aimed at helping people engage in healthy behaviors, and establish collaborative relationships with healthcare providers and purchasers and with other government policymaking agencies.

Federal policy and law also play a role in public health. Although the word *health* does not appear in the U.S. Constitution, the document confers powers on the federal government—to tax and spend, for example—that allow it to engage in public health promotion and disease prevention activities. For example, the power to tax (or establish exemptions from taxation) allows Congress to incentivize healthy behaviors, as witnessed by the heavy taxes levied on

packages of cigarettes; the power to spend enables Congress to establish executive branch public health agencies and to allocate public-health-specific funds to states and localities.

CONCEPTUALIZING HEALTH POLICY AND LAW

You have just read about the importance of taking policy and law into account when studying health care and public health. The next step is to begin thinking about how you might conceptually approach the study of health policy and law.

There are multiple ways to conceptualize the many important topics that fall under the umbrella of health policy and law. We introduce three conceptual frameworks in this section: one premised on the broad topical domains of health policy and law, one based on prevailing historical factors, and one focused on the individuals and entities impacted by a particular policy or legal determination (see **Box 1-1**).

We draw on these frameworks to various degrees in this text. For example, the topical domain approach of Framework 1 is on display in the sections about individual rights in health care and public health and healthcare quality policy and law. Framework 2's focus on historical perspectives is highlighted in the chapters on health reform and government health insurance programs. Finally, Framework 3, which approaches the study of health policy and law from the perspectives of key stakeholders, is discussed in the policy and policymaking process section and also in the chapter dedicated to the social determinants of health. We turn now to a description of each framework.

BOX 1-1 Three Conceptual Frameworks for Studying Health Policy and Law

Framework 1. Study based on the broad topical domains of:
- **a.** Health care
- **b.** Public health
- **c.** Bioethics

Framework 2. Study based on historically dominant social, political, and economic perspectives:
- **a.** Professional autonomy
- **b.** Social contract
- **c.** Free market

Framework 3. Study based on the perspectives of key stakeholders:
- **a.** Individuals
- **b.** The public
- **c.** Healthcare professionals
- **d.** Federal and state governments
- **e.** Managed care and traditional insurance companies
- **f.** Employers
- **g.** Healthcare industries (e.g., the pharmaceutical industry)
- **h.** The research community
- **i.** Interest groups
- **j.** Others

The Three Broad Topical Domains of Health Policy and Law

One way to conceptualize health policy and law is as consisting of three large topical domains. One domain is reserved for policy and law concerns in the area of *healthcare*, another for issues arising in the *public health* arena, and the last for controversies in the field of *bioethics*. As you contemplate these topical domains, bear in mind that they are not individual silos whose contents never spill over into the others. Indeed, this sort of spillage is common (and, as noted, is one reason why fixing health policy problems can be terribly complicated). We briefly touch on each domain.

Healthcare Policy and Law

In the most general sense, this domain is concerned with an individual's access to care (e.g., What policies and laws impact an individual's ability to access needed care?), the quality of the care the person received (e.g., Was it appropriate, cost-effective, and non-negligent?), and how the person's care is going to be financed (e.g., Is the person insured?). However, "access," "quality," and "financing" are themselves rather large sub-domains, with their own sets of complex policy and legal issues, and in fact it is common for students to take semester-long policy and/or law courses focused on just one of these sub-domains.

Public Health Policy and Law

The second large topical domain is that of public health policy and law. A central focus here is on why and how the government regulates private individuals and corporations in the name of protecting the health, safety, and welfare of the general public. Imagine, for example, that the federal government was considering a blanket policy decision to vaccinate individuals across the country against the deadly smallpox disease, believing that the decision was in the best interests of national security. Would this decision be desirable from a national policy perspective? Would it be legal? If the program's desirability and legality are not immediately clear, how

would you go about analyzing and assessing them? These are the kinds of questions with which public health policy and law practitioners and scholars grapple.

Bioethics

Finally, there is the *bioethics* domain to health policy and law. Strictly speaking, the term *bioethics* is used to describe ethical issues raised in the context of medical practice or biomedical research. More comprehensively, bioethics can be thought of as the point at which public policy, law, individual morals, societal values, and medicine intersect. The bioethics domain houses some of the most explosive questions in health policy, including the morality and legality of abortion, conflicting values around the meaning of death and the rights of individuals nearing the end of life, and the policy and legal consequences of mapping the human genetic code.

Social, Political, and Economic Historical Context

Dividing the substance of health policy and law into broad topical categories is only one way to conceptualize them. A second way to consider health policy and law is in historical terms, based on the social, political, and economic views that dominate a particular era.[d] Considered this way, health policy and law have been influenced over time by three perspectives, all of which are technically active at any given time, but each of which has eclipsed the others during specific periods in terms of political, policy, and legal outcomes. These perspectives are termed *professional autonomy*, *social contract*, and *free market*.[e]

Professional Autonomy Perspective

The first perspective, grounded in the notion that the medical profession should have the authority to regulate itself, held sway from approximately 1880 to 1960, making it the most dominant of the three perspectives in terms of both the length of time it held favored status and its effect in the actual shaping of health policy and law. This model is premised on the idea that physicians' scientific expertise in medical matters should translate into legal authority to oversee essentially all aspects of delivering health care to individuals—in other words, according to proponents of the physician autonomy model, legal oversight of the practice of medicine should be delegated to the medical profession itself. During the period that this perspective remained dominant, policy- and lawmakers were generally willing to allow physicians to control the terms and amount of payments for rendered healthcare services, the standards under which medical licenses would be granted, the types of patients they would treat, the type and amount of information to disclose to patients, and the determination as to whether their colleagues in the medical profession were negligent in the treatment of their patients.

Social Contract Perspective

The second perspective that informs a historical conceptualization of health policy and law is that of the "modestly egalitarian social contract."[f] This paradigm overshadowed its competitors, and thus guided policymaking, from roughly 1960 to 1980, a time notable in U.S. history for social progressiveness, civil rights, and racial inclusion. At the center of this perspective is the belief that complete physician autonomy over the delivery and financing of health care is potentially dangerous in terms of patient care and healthcare expenditures, and that public policy and law can and sometimes should enforce a "social contract" at the expense of physician control. Put differently, this perspective sees physicians as just one of several stakeholders (including but not limited to patients, employers, and society) that lay claim to important rights and interests in the operation of the healthcare system. Health policies and laws borne of the social contract era centered on enhancing access to health care (e.g., through the Examination and Treatment for Emergency Medical Conditions and Women in Labor Act), creating new health insurance programs (Medicare and Medicaid were established in 1965), and passing anti-discrimination laws (one of the specific purposes of Title VI of the federal 1964 Civil Rights Act was wiping out healthcare discrimination based on race).

Free Market Perspective

The final historical perspective—grounded in the twin notions of the freedom of the marketplace and of market competition—became dominant in the 1990s and continues with force today (though one could argue that the Affordable Care Act evidences a curbing of the free market perspective and an elevation, again, of the social contract perspective). It contends that the markets for healthcare services and for health insurance operate best in a deregulated environment, and that commercial competition and consumer empowerment will lead to the most efficient healthcare system. Regardless of the validity of this claim, this perspective argues that the physician autonomy model is falsely premised on the idea of scientific expertise, when in fact most healthcare services deemed "necessary" by physicians have never been subjected to rigorous scientific validation (think of the typical treatments for the common cold or a broken leg). It further argues that even the modest version of the social contract theory that heavily influenced health policy and law during the civil rights generation is overly regulatory. Furthermore, market competition proponents claim that both

other models are potentially inflationary, because in the first case self-interest will lead autonomous physicians to drive up the cost of their services, and in the second instance public insurance programs like Medicare would lead individuals to seek unnecessary care.

To tie a couple of these historical perspectives together and examine (albeit in somewhat oversimplified fashion) how evolving social and economic mores have influenced health policy and law, consider the example of Medicaid, the joint federal–state health insurance program for low-income individuals. In 1965, Medicaid was borne out of the prevailing societal mood that it was an important role of government to expand legal rights for the poor and needy. Its creation exemplified a social contract perspective, which in the context of health promotes the view that individuals and society as a whole are important stakeholders in the healthcare and public health systems. Medicaid entitled eligible individuals to a set of benefits that, according to courts during the era under consideration, was the type of legal entitlement that could be enforced by beneficiaries when they believed their rights under the program were infringed.

These societal expectations and legal rights and protections withstood early challenges during the 1970s, as the costs associated with providing services under Medicaid resulted in state efforts to roll back program benefits. Then, in the 1980s, Medicaid costs soared higher, as eligibility reforms nearly doubled the program's enrollment and some providers (e.g., community health centers) were given higher payments for the Medicaid services they provided. Still, the social contract perspective held firm, and the program retained its essential egalitarian features.

As noted above, however, the gravitational pull of the social contract theory weakened as the 1980s drew to a close. This, coupled with the fact that Medicaid spending continued to increase in the 1990s, led to an increase in the number of calls to terminate program members' legal entitlement to benefits.[g] Also in the 1990s, federal and state policymakers dramatically increased the role of private managed care companies in both Medicaid and Medicare, an example of the trend toward free market principles described above.

Key Stakeholders

A third way to conceptualize health policy and law issues is in terms of the stakeholders whose interests are impacted by certain policy choices or by the passage or interpretation of a law. For example, imagine that in the context of interpreting a state statute regulating physician licensing, your state's highest court ruled that it was permissible for a physician to not treat a patient who was in urgent need of care, even though the doctor had been serving as the patient's family physician. What stakeholders could be impacted by this result? Certainly the patient, as well as other patients whose treatment may be colored by the court's decision. Obviously the doctor and other doctors practicing in the same state could be impacted by the court's conclusion. What about the state legislature? Perhaps it unintentionally drafted the licensing statute in ambiguous fashion, which led the court to determine that the law conferred no legal responsibility on the physician to respond to a member of a family that was part of the doctor's patient load. Or maybe the legislature is implicated in another way—maybe it drafted the law with such clarity that no other outcome was likely to result, but the citizenry of the state was outraged because its elected officials have created public policy out of step with constituents' values. Note how this last example draws in the perspective of another key stakeholder—the broader public.

Of course, patients, healthcare providers, governments, and the public are not the only key stakeholders in important matters of health policy and law. Managed care and traditional insurance companies, employers, private healthcare industries, the research community, interest groups, and others all may have a strong interest in various policies or laws under debate.

CONCLUSION

The preceding descriptions of the role played by policy and law in the health of individuals and populations, and of the ways to conceptualize health policy and law, were cursory by design. But what we hope is apparent to you at this early stage is the fact that the study of policy and law is essential to the study of both health care and public health. Consider the short list of major problems with the U.S. health system as described in a book edited and written by a group of leading scholars: the coverage and financing of health care, healthcare quality, health disparities, and threats to population health.[h] All of the responses and fixes to these problems—and to many other healthcare- and public health–related concerns—will invariably and necessarily involve creative policymaking and rigorous legal reform (and indeed, the Affordable Care Act, about which you will read in various sections, addressed each of these topics to one degree or another). This fact is neither surprising nor undesirable: policy and law have long been used to effectuate positive social change, and neither the healthcare nor public health field is immune to it. Thus, going forward, there is little reason to expect that policy and law will not be two of the primary drivers of health-related reform.

Policy and legal considerations are not only relevant in the context of major healthcare and public health

transformations, however—they are critical to the daily functioning of the health system, and to the health and safety of individuals and communities across a range of everyday life events. Consider pregnancy and childbirth, for example. There are approximately 11,000 births each day in this country, and society views pregnancy and childbirth as more or less normal and unremarkable events. In fact, the process of becoming pregnant, accessing and receiving high-quality prenatal health care, and experiencing a successful delivery is crucial not only to the physical, mental, and emotional health and well-being of individuals and families, but to the long-term economic and social health of the nation. It also implicates a dizzying number of interesting and important policy questions. Consider the following:

- Should there be a legal right to health care in the context of pregnancy and, if so, should that right begin at the point of planning to get pregnant, at the moment of conception, at the point of labor, or at some other point?
- Regardless of legal rights to care, how should the nation finance the cost of pregnancy care? Should individuals and families be expected to save enough money to pay out-of-pocket for what is a predictable event? Should the government help subsidize the cost of prenatal care? If so, in what way? Should care be subsidized at the same rate for everyone, or should subsidy levels be based on financial need?
- Regarding the quality of care, what is known about the type of obstetrical care women should receive, and how do we know they are getting that care? Given the importance of this type of care, what policy steps are taken to ensure that the care is sound? What should the law's response be when a newborn or pregnant woman is harmed through an act of negligence? When should clinician errors be considered preventable and their commission thus tied to a public policy response? And what should the response be?
- What should the legal and social response be to prospective parents who act in ways risky to the health of a fetus? Should there be no societal response because the prospective parents' actions are purely a matter of individual right? Does it depend on what the actions are?
- Is it important to track pregnancy and birth rates through public health surveillance systems? Why or why not? If it is an important function, should the data tracking be made compulsory or voluntary?
- How well does the public health system control known risks to pregnancies, both in communities and in the workplace?
- Finally, who should answer these questions? The federal government? States? Individuals? Should courts play a role in answering some or all of them and, if so, which ones? Whose interests are implicated in each question, and how do these stakeholders affect the policymaking process?

There are scores of topics—pregnancy and childbirth among them, as you can see—that implicate a range of complex health policy questions, and these are the types of questions this text prepares you to ask and address. Before you turn your attention to the essential principles, components, and issues of health policy and law, however, you must understand something about policy and law generally, and about the organization and purposes of the healthcare and public health systems. The next two chapters provide a grounding in policy and law and supply the basic information needed to study policy and law in a health context. There, we define policy and law, discuss the political and legal systems, introduce the administrative agencies and functions at the heart of the government's role in health care and public health, and more. With this information at your disposal, you will be better equipped to think through some of the threshold questions common to many policy debates, including the following questions: Which sector—public, private, or not-for-profit (or some combination of them)—should respond to the policy problem? If government responds, at what level—federal or state—should the problem be addressed? What branch of government is best suited to address—or is more attuned to—the policy issue? When the government takes the lead in responding to a policy concern, what is the appropriate role of the private and not-for-profit sectors in also attacking the problem? What legal barriers might there be to the type of policy change being contemplated? Once you have the knowledge to be able to critically assess these types of questions, you will be able to focus more specifically on how the healthcare and public health systems operate in the United States, and on the application of policy and law to critical issues in health care and public health.

ENDNOTES

a. See, for example, Wendy E. Parmet, "Introduction: The Interdependency of Law and Public Health," in *Law in Public Health Practice*, eds. Richard A. Goodman et al. (Oxford, England: Oxford University Press, 2003), xxvii–xxxvii.
b. For a non-fictional and utterly engrossing example of the ways in which law and legal process might stand in the way of effective public

health regulation, we recommend Jonathan Harr, *A Civil Action* (New York, NY: Vintage Books, 1995).

c. See, for example, Larry O. Gostin, Jeffrey P. Koplan, and Frank P. Grad, "The Law and the Public's Health: The Foundations," in *Law in Public Health Practice*, eds. Richard A. Goodman et al. (Oxford, England: Oxford University Press, 2003), 25–44.

d. The particular historical framework described here was developed to apply to health care rather than public health. We do not mean to imply, however, that it is impossible to consider public health from a historical, or evolutionary, vantage point. In fact, it is fair to say that public health practice may have just entered its third historical phase. Throughout the 1800s and most of the 1900s, protection of the public's health occurred mainly through direct regulation of private behavior. In the latter stages of the 20th century, strict reliance on regulation gave way to an approach that combined regulation with chronic disease management and public health promotion, an approach that necessitated a more active collaboration between public health agencies and healthcare providers and purchasers. Now, it appears that public health professionals are adding to this revised practice model another strategic initiative: building collaborative relationships with policymaking agencies whose responsibilities are not directly related to public health—for example, agencies whose primary fields are transportation or agriculture.

e. The discussion of these perspectives is guided by Rand E. Rosenblatt, Sylvia A. Law, and Sara Rosenbaum, *Law and the American Health Care System* (Westbury, CT: The Foundation Press, Inc., 1997), 24–35; and Rand E. Rosenblatt, "The Four Ages of Health Law," *Health Matrix: Journal of Law-Medicine* 14 (2004): 15.

f. Rosenblatt, Law, and Rosenbaum, *Law and the American Health Care System*, 2. The authors write that the American social contract lags behind those of other developed countries, and thus use the phrase "modestly egalitarian" in describing it.

g. By 2005, proponents of weakening Medicaid-enrolled persons' entitlement to program benefits had made significant strides: Congress passed a law called the Deficit Reduction Act that, among other things, granted states the ability to redefine the benefits and services to which Medicaid beneficiaries are entitled.

h. David Mechanic, Lynn B. Rogut, David C. Colby, and James R. Knickman, eds., *Policy Challenges in Modern Health Care* (New Brunswick, NY: Rutgers University Press, 2005), 10.