

Chapter 1

The Development of Health Law

Congratulations! You are considering a career in what we believe is the best area of legal practice.

How can we make this claim? In no other field than health law will you find the immediacy of policy and law that impacts every single human being, coupled with the most complicated regulatory and industry framework that exists in the United States. The health care industry encompasses services, pharmaceuticals, supplies, and equipment totaling almost 18 percent of the gross domestic product of the United States.

The practice of health law distinguishes itself from other areas of law by several factors. First, health law is a practice area organized around an industry, not a body of law. Thus, competent health lawyers need to have a thorough understanding of the health care industry, because as the industry changes, the laws and policies that impact health law change. This requires that health law attorneys understand the *business* of health care. Without knowing how health care works—how services and products are delivered and paid for—lawyers cannot provide adequate advice. Health care attorneys are routinely involved in strategic and business counseling with their clients, necessitating a keen understanding of the industry dynamics and key players involved.

Second, because of its organization around an industry, health law is in many ways one of the last remaining fields of general practice. Typical health lawyers have a knowledge base that includes many topics, such as bioethics, corporate, insurance, administrative, Medicare/Medicaid, tax, privacy, health information, and food and drug law. In addition, a number

of specialty areas within health law have arisen, including health law criminal law, antitrust, bankruptcy, life sciences, labor and employment, medical education, and many others. For attorneys entering the field, this diversity not only creates an exciting work environment, but it means that a multiplicity of skills are needed. There is no one “mold” for a successful health lawyer, but rather room for all interests and talents.

Third, health law is constantly changing. As the industry changes, so do the issues impacting the practice of health law. No health lawyer today is doing the same thing that he or she was doing one year ago, or even six months ago. The field is exceptionally dynamic, with clients constantly bringing new issues requiring legal advice to the fore. This environment of constant change can work to the advantage of attorneys who are new to the field—because certain areas of health law are new to everyone, it is possible for you to become an expert fairly quickly.

Fourth, health law practice is challenging. The stakes are big, sometimes literally life and death. Even in a corporate transaction, the impact of legal counseling can be significant. A new health care facility may be created, needed medical providers recruited to provide services for an underserved community, or an important pharmaceutical joint venture arrangement created. The fact that at the end of the day real people will be impacted by the work of health lawyers makes the practice of health law especially important and meaningful.

Fifth, health law is exceptionally entrepreneurial. As the head of any law firm would likely attest, the most entrepreneurial attorneys in the firm are the health lawyers. Health attorneys spend a significant amount of time keeping abreast of the field and sharing their knowledge with clients and colleagues through speeches, conferences, writings, and other means. Because the law and policy are continually changing, health lawyers become expert in identifying new areas of focus and reinventing their practice to respond to client needs.

Sixth, health lawyers are an exceptionally collegial bunch. While there are always exceptions, as a rule, attorneys who practice health law truly want to be in the field and understand that the health law bar (while numbering many thousands) is indeed a “small world.” An ethos of respect and

civility, indeed kindness, pervades the health law bar. This is especially true in the welcome extended to new attorneys entering the field.

Finally, the practice of health law is just plain fun. Yes, there will always be some difficult days in the practice of law. But, generally speaking, as a health care attorney you have the privilege of working on very important matters with highly sophisticated, intelligent clients who present interesting dilemmas and who genuinely appreciate your ability to wend your way through a myriad of complicated laws and industry practices to develop an approach that satisfies their needs. For an individual practicing law, it does not get much better than this.

Because the field is so large, and the options to work within the field so many, it is important to understand some of the key aspects of the health care industry. In the sections that follow, we will first review the key actors in the health care industry and then consider the major forces impacting the provision of health care. Next, we will review some of the key trends impacting health care. We hope that as you read these sections not only will you gain a basic understanding of some of the key aspects of health care, but you will also begin to identify potential areas of interest to you in focusing your career.

Health Care Industry Background

In the United States, total health care expenditures in 2010 were \$2.6 trillion, with expenditures expected to climb to \$4.6 trillion by 2020.¹ Almost 18 percent of the U.S. gross domestic product is spent on health care.² Clearly, health care is not an industry in decline!

It can be confusing, however, to consider the health care “industry” because it is comprised of so many different types of entities, from individual

1. CTRS. FOR MEDICARE & MEDICAID SERVS., *National Health Expenditure Projections 2010-2020—Forecast Summary*, <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/downloads/proj2010.pdf> (last visited Mar. 25, 2014).

2. *Id.*

practitioners to suppliers of laundry services to multinational pharmaceutical companies. Because of this breadth and magnitude, the industry is typically segmented into four categories: providers, suppliers, payors, and pharmaceuticals. Although this segmentation is valid for purposes of understanding some of the unique issues faced by entities within the sector, it is important to understand that these sectors are continually interacting with each other and that often the lines are becoming blurred. Thus, for example, the provider side (hospitals, for example) and the payor side (insurance companies) are beginning to meld, with some hospitals purchasing insurance companies and some insurance companies purchasing hospitals and physician practices. Nevertheless, for the purpose of providing a primer to the industry, the categorization is valid.

Providers

The provider sector is just what it sounds like: those individuals or entities directly rendering health care services. On the individual side this includes doctors, nurses, therapists (respiratory, occupational, physical, audiological), psychologists, and any other individuals directly providing health care services. Providers may also be institutions, such as hospitals and nursing homes. Institutional providers may also be specialty facilities like rehabilitation hospitals, cancer care centers, cardiology hospitals, and ambulatory surgery centers. Recently, walk-in clinics, sometimes sponsored by health systems or drugstore chains, have entered the ranks of providers.

As you would expect, each type of provider has its own unique business and legal issues, requiring its health care attorney to have a concentrated body of knowledge in order to advise it. Individual providers, for example, may face licensure issues, disciplinary issues, contractual disputes, and liability concerns. Beyond these unique health law issues, however, they may also face real estate issues, tax concerns (personal or corporate), corporate law issues (shareholder issues, for instance), and the need for basic contract review services. The health lawyer brings his or her unique expertise to bear in these general matters, recognizing that health law regulations potentially impact whom a physician can rent office space from and how much rent can be paid, for example, or set limitations on how a provider may pursue collection efforts from a patient.

Institutional providers, too, offer significant legal issues to work through. State and federal governments, and sometimes local communities, heavily regulate these providers. Indeed, it is believed that health care providers are second only to the nuclear power industry in the degree of regulation that they face. Further, given their complexity, institutional providers typically face a range of sophisticated business issues, necessitating continual legal advice as they work to serve the community in their market.

Suppliers

The health care supplier side of the industry is in many ways the silent workhorse: behind the scenes but vital to the operations of health care providers. Suppliers are those entities that provide necessary items or services for health care to function, but often are not visible to health care consumers. The supplier industry is very broad, encompassing everything from laundry and food services to medical supplies and equipment to information technology and environmental services. Sometimes the subject of direct regulation, such as medical devices and equipment, suppliers are also significantly impacted by the laws directed toward providers and payors, as anything that impacts the quantity, quality, or payment of health care ultimately will affect the domain of suppliers in some way.

Payors

Although in the typical consumer transaction the “purchaser/user” and the “payor” are combined—I need a shirt so I buy one and pay for it—this is generally not the case in health care. For individuals with health insurance (still the vast majority of Americans even though we have a significant un-/underinsured population), the purchasing/using function and the payment function are separate. Indeed, there is even a debate about who the purchaser is. Is it the employer who may have purchased insurance on the employee’s behalf, is it the doctor who orders tests and treatment for the patient, or is it the patient him- or herself? Payors—private insurance companies, health maintenance organizations and other types of entities, or governmental programs such as Medicare or Medicaid—pay for the care provided. In doing so, they impose significant regulations (Medicare and Medicaid) or stringent contractual requirements that significantly impact whether and

how health care will be provided, what will be provided, where it will be provided, and when it will be provided. Understanding the payment mechanisms used by governmental and private payors, and the regulatory/contractual restraints imposed as a condition for receiving payment, is an essential body of knowledge for any health care attorney.

Pharmaceuticals

While always an important component of the health care industry, the pharmaceutical and medical device sector has bloomed in the past 15 years. Today, about 10 percent of federal health care dollars are spent on pharmaceuticals,³ and this figure is sure to grow. Further, with Medicare coverage extended to pharmaceuticals in 2006, the regulatory issues confronting pharma—always significant—have greatly expanded. Attorneys working in the pharmaceutical arena are faced with laws flowing from food and drug law, public health law, intellectual property law, Medicare and Medicaid, and many other areas beyond the bevy of traditional legal issues that arise with a large corporate client. Too, these companies often work internationally, requiring expertise in laws of other countries as well as in U.S. laws governing foreign business transactions.

Major Forces Impacting Health Care

Although familiarity with the industry structure is important as you consider your niche in health law, it is also imperative to understand the significant forces impacting the industry, because many of these forces may provide direction or a building block for a successful career in health law. While a full recitation of forces impacting every sector of the health care industry

3. AETNA, *The Facts About Rising Health Care Costs*, <http://www.aetna.com/health-reform-connection/aetnas-vision/facts-about-costs.html> (last visited Mar. 24, 2014) (stating that 10.01 percent of the health care spending budget is spent on prescription drugs). See CTRS. FOR MEDICARE & MEDICAID SERVS., *The National Health Expenditures Price Index*, <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/downloads/tables.pdf> (last visited Mar. 24, 2014).

is beyond the scope of this discussion, the following major categories are worthy of consideration.

Demographics

Life expectancy is increasing (a good thing!), and the percentage of the elderly population is rapidly growing. Indeed, one of the fastest-growing segments of the U.S. population is what is considered the “old elderly”—those over age 85. These demographics have a significant impact on the need for senior care service providers (both individual and institutional), chronic care service providers, durable medical equipment providers (walkers, wheelchairs, etc.), and medical device suppliers (artificial knees, hips, etc.), just to name a few. Pharmaceutical use is likely to continue accelerating as people live longer, with more chronic ailments, and look to medications to assist them in maintaining quality of life.

Technology

It is very obvious that technology is exploding in the health care arena. Electronic medical records are becoming the norm, medical apps are expanding, medical technology is moving from a central location to the bedside and ultimately to the home, and home monitoring is rapidly advancing.

Competition

Health care delivery and supply are becoming heavily competitive as payment mechanisms change and costs continue to decrease, but payment amounts decline. As this book is being written, federal health care reform (discussed later in this chapter) is being implemented, unleashing a massive consolidation wave among providers to drive down costs through economies of scale, integrate services to respond to quality standards, and “bulk up” to confront a rapidly changing future.

Quality

Study after study has demonstrated significant differences in how the same medical conditions are treated across the country. These disparities will no longer be allowed to continue. Further, historically, little attention has been placed on the quality of care outcome being achieved. This is undergoing

rapid change, with poor quality being financially punished and high quality of care providers being rewarded.

Integration

The boundaries between provider, supplier, payor, and to a lesser extent, pharma are receding, with entities being formed that share many of these attributes. In part, this consolidation is resulting from movements to pay providers on the basis of their ability to maintain the health of a population, as opposed to paying them for services provided when someone becomes ill or injured. How these various components of the health care industry will come together, and the contours of these relationships, will require significant thinking and work by health care attorneys.

Budgetary Pressure

As previously discussed, health care is expensive and increasingly taking an ever larger piece of federal and state budgets. We are at a point where this can no longer continue. Federal and state efforts to drive down health care expenditures, coupled with the employer trend to impose more health care costs on employees, is going to have a profound effect on how health care is delivered.

PPACA

The Patient Protection and Affordable Care Act (commonly referred to as “PPACA” or the “ACA”), the federal health reform initiative, is directly and indirectly reshaping one of the largest sectors of the U.S. economy. With a statute in excess of 2,000 pages, the breadth and depth of regulatory changes impacting all sectors within health care is unprecedented. Further, the industry’s response to the law—the indirect effects—is likewise significant. These changes will take years to filter through the system, let alone the continued retooling to further shape federal, state, and private (employer) reform efforts.

Your Career in Health Law

Given the unprecedented change impacting the industry, there simply is no better time to enter the field of health law. The industry will continue to expand and change, spawning the need for attorneys well versed in industry knowledge and adept at working with their clients to anticipate needs and respond to a rapidly evolving, challenging environment. The remaining chapters discuss specific practice areas within health law that you might pursue, various practice settings for health law, and specific strategies to begin or further your career. Regardless of which path you pursue, you will find personal and professional fulfillment in the health law field.