SECTION

I

INTRODUCTION: PROBLEMS ADDRESSED THROUGH HEALTHCARE REGULATION

Learning Objectives:

After completing this introduction, the student will be able to

- identify the key problems in healthcare that regulation attempts to address and
- understand the organization of this book and how the chapters fit together in each section.

Overview of This Book

In 2007, the Institute for Healthcare Improvement (IHI) in Cambridge, Massachusetts, developed the IHI Triple Aim framework. Focusing on three primary problems in the United States' healthcare systems that merit improvement, IHI based the framework on the concept that successful healthcare systems will "simultaneously deliver excellent quality of care, at optimized costs, while improving the health of their population" (IHI 2023). The Triple Aim's goals still inform many state and federal regulatory systems that focus on cost containment, quality, and patient safety. Although the healthcare problem that policymakers and regulators have considered most urgent has varied across time and place, cost has consistently been a primary concern. Regulatory goals also may shift depending on the industry's responses to the processes in place.

Governments in the United States typically regulate industries as an attempt to remedy a problem. As discussed further in chapter 1, information

asymmetries, uncertainty, and market power often create inefficiencies in healthcare markets. The free market, left to its own, does not allocate resources efficiently, often prompting government intervention. Given the high stakes and the share of healthcare spending in federal, state, and household budgets, protecting consumers from poor-quality care and high prices justifies regulatory oversight. However, significant debate continues over when, where, and how the government should intervene. The result is considerable variation in government regulation of healthcare markets among states, among federal and state agencies, and over time.

To best present the challenges facing policymakers, regulators, and industry participants, the book is organized as follows. Section 1 provides background on the US healthcare system (chapter 1) and offers the reader a brief overview of US healthcare regulation (chapter 2). Subsequent sections and chapters are organized by the problems that healthcare regulations are designed to solve, using case studies to highlight the complexities of the regulatory process. Section 2 focuses on regulations to contain healthcare costs, Section 3 reviews regulatory oversight of anticompetitive practices, Section 4 examines regulations that ensure patient access to safe and quality care, and Section 5 discusses regulatory attempts to better achieve the Triple Aim through payment and delivery reform. Section 6 concludes the book by discussing emerging issues in healthcare regulation. We detail each section next.

Section 2: Regulation to Contain Costs

The United States spends more on healthcare per capita than all other developed countries and about twice the average of comparable countries (OECD Data 2021). US healthcare costs also have risen faster and absorb a larger share of gross domestic product than in other high-income countries (OECD Data 2021; Peterson–KFF Health System Tracker 2023). Not surprisingly, cost containment has become a major focus of legislators and regulators, particularly at the state level.

In chapters 3–6, we look at several state regulatory efforts to contain costs:

- Chapter 3, Health Planning and Certificates of Need: containing costs by limiting capital costs and capacity expansion
- Chapter 4, Benchmarking to Control Costs: containing costs by setting a state goal for healthcare cost growth
- Chapter 5, Insurance Premium Rate Review: containing costs by regulating insurance premiums
- Chapter 6, Price Transparency and Regulation: containing costs by arming patients with price comparison data

Section 3: Regulation to Protect Consumers from Anticompetitive Practices

Participants in markets that lack competition cannot rely on the forces of demand and supply to achieve efficient outcomes. Highly concentrated markets (e.g., few sellers of a product or service) are often characterized by high prices, restricted consumer choice, reduced quality, and stifled innovation. US antitrust laws aim to protect market participants from the harms associated with market concentration and anticompetitive behavior. Recent greater consolidation in the healthcare sector and rising prices have led federal and state governments to exert greater antitrust scrutiny.

In chapters 7 and 8, we look at federal antitrust regulation and efforts to combat industry consolidation and anticompetitive business practices:

- Chapter 7, Antitrust and Consolidation: regulating mergers and acquisitions to ensure competition
- Chapter 8, Antitrust and Anticompetitive Agreements: regulating to ensure competition by protecting against collusive and exclusionary behavior

Section 4. Regulation to Protect Patient Access to Health, Safety, and Quality Care

People seeking care from a healthcare provider can reasonably assume the care delivered will be necessary, high quality, and safe. However, limited information makes it difficult for patients and their loved ones to discern between high- and low-quality care. In addition, most payment mechanisms also reward volume rather than value, which can lead to the provision of unnecessary and potentially harmful care. To mitigate the imbalance and protect consumers, federal and state governments, as well as private organizations, play a crucial role in regulating the quality and safety of healthcare.

In chapters 9–11, we look at the current state of regulation related to patient health and safety:

- Chapter 9, Regulation of Healthcare Professionals and Professional Licensure: defining licensing and scope of practice to protect patients
- Chapter 10, Regulation of Hospital Access, Quality, and Safety: ensuring access to safe, quality care
- Chapter 11, Regulation of Drug Safety and Efficacy: protecting patient safety through regulation of drugs

Section 5. Regulation to Reform the Payment and Delivery System

Policymakers and researchers have recognized for some time that many of healthcare's most vexing challenges stem from the dominant fee-for-service

(FFS) reimbursement system. Citing the World Health Organization's overview of healthcare financing systems, Ikegami (2015) describes FFS as a well-recognized "evil practice leading to overprovision, inefficiency and uncontrollable health expenditures." FFS payment models have this reputation because they reimburse healthcare providers for each item, procedure, or service, creating a financial incentive for providers to "unbundle" services and offer treatments even if they are marginally effective or even harmful.

Shrank and colleagues (2021) confirmed that "significant potential remains for payment models to accelerate value-based care delivery, but several barriers must be addressed. First, most alternative payment models remain anchored in a fee-for-service architecture." A 2022 *Health Affairs* research brief, citing Berwick and Hackbarth (2012) and Shrank, Rogstad, and Parekh (2019), estimates that 20 to 30 percent of all healthcare spending is wasteful.

In chapters 12 and 13, we look at emerging regulation designed to move away from FFS payment to reimbursement models intended to reduce costs, eliminate waste, and improve the quality of care:

- Chapter 12, Hospital Global Budgets: changing how hospitals are paid to promote cost containment and quality improvement through global budgets
- Chapter 13, Accountable Care Organizations: regulation of provider-based organizations that take responsibility for managing cost and quality

Conclusion

First, however, we begin with section 1, which presents brief overviews of healthcare in the United States and of healthcare regulation and regulators. We describe central principles of economic theory along with taxation parameters and other foundational content. Together, these topics form the bedrock that undergirds every other chapter and are essential to understanding the contemporary US healthcare system.

References

Berwick, D., and A. Hackbarth. 2012. "Eliminating Waste in U.S. Health Care." *Journal of the American Medical Association* 307 (14): 1513–16.

Health Affairs. 2022. "The Role of Clinical Waste in Excess US Health Spending." Research Brief. Published June 9. https://healthaffairs.org/do/10.1377/hpb20220506.432025/full/.

Ikegami, N. 2015. "Fee-for-Service Payment—An Evil Practice That Must Be Stamped Out?" *International Journal of Health Policy Management* 4 (2): 57–59.

Institute for Healthcare Improvement. 2023. "Overview." Accessed January 24. http://ihi.org/Topics/TripleAim/Pages/Overview.aspx.

OECD Data. 2021. "Health Spending." https://data.oecd.org/healthres/health-spending.htm.

Peterson–KFF Health System Tracker. 2023. "Total Health Spending." Accessed January 24. https://healthsystemtracker.org/indicator/spending/per-capita-spending/.

Shrank, W., N. DeParle, S. Gottlieb, S. Jain, P. Orszag, B. Powers, and G. Wilensky. 2021. "Challenges and Strategies for a New Administration." *Health Affairs* 40 (2): 235–42.

Shrank, W., T. Rogstad, and N. Parekh. 2019. "Waste in the U.S. Health Care System: Estimated Costs and Potential for Savings." *Journal of the American Medical Association* 322 (15): 1501–9.