

PREFACE

Let's face it: Healthcare in the United States is a very highly regulated, complicated industry, comprising myriad conflicting and paradoxical forces. It is a source of healing for some and a cauldron of annoyance, agony, and expense for others. It is lifesaving, yet—because of the magnitude of error and harm—it can be life threatening. It is one of the nation's largest industries, yet it is riddled with workforce gaps. The focus of healthcare on illness care, because of what payers such as insurance companies deem reimbursable, largely ignores the upstream social influences (e.g., housing, nutrition, environment) that are the predominant determinants of health and illness. As a former president once stated, “Nobody knew that healthcare could be so complicated.”

This text aims to help readers who are neither lawyers nor regulatory experts navigate this complex, often uneven terrain. It employs a case study methodology from the perspective of the problems that regulation attempts to address. Each section provides explanatory background on specific regulatory approaches and real-world examples of their implementation. Ancillary materials include an instructor's manual that offers additional guidance to help them confidently detail scenarios, case outcomes, and—when relevant—unintended consequences and ongoing controversies. These materials also provide experiential learning exercises, including mock trials, debates, town meetings, and regulatory board hearings, that the authors have tested in the classroom. Further, the case study method will be helpful in this era of artificial intelligence applications. For example, students might work on a case in class and then compare their perspectives with a chatbot-generated answer.

The wide array of scenarios, written in an easy-to-understand format, is designed to offer insights that extend beyond the practical realities of current healthcare regulation. A journalism student, for example, might find that the cases illuminate topics frequently in the news, thus providing an exciting background for a future career. An aspiring healthcare provider might gain insight into the motivation of the regulators who will someday influence their professional work. And future lawmakers might be moved by the complexity of the regulatory process and the potential fallout of their actions.

The text is organized into six parts. Part 1 provides background on the US healthcare industry, offers an overview of healthcare regulation,

and clarifies the problems that regulation attempts to fix. Part 2 addresses regulation to contain cost, discussing cases involving certificate-of-need laws, healthcare cost growth benchmarks, insurance rate review, and price transparency to contain costs. Part 3 focuses on regulation to protect healthcare users from anticompetitive practices; it details antitrust cases involving both mergers and acquisitions and anticompetitive agreements. Protection of patient access, health, and safety is the topic of part 4, which includes cases about the regulation of healthcare professionals, the quality and safety of hospital care, and the safety and efficacy of new drugs. Part 5 describes payment- and delivery-system reform, emphasizing the regulation of hospitals' global budgets and accountable care organizations. A key feature of the text is that parts 2 to 5 can be used in any order, and each can serve as a standalone learning unit. Part 6 provides concluding thoughts about emerging policy and regulatory issues, such as artificial intelligence.

The authors—an economist (Holmes), an attorney (Lunge), and a healthcare professional and academic dean (Rambur)—have extensive experience in healthcare writ large and healthcare regulation specifically. All have served on Vermont's Green Mountain Care Board, a quasi-judicial body that oversees multiple aspects of healthcare in the state, including insurance rate regulation, certificates of need, hospital budgets, the all-payer claims database, and the transition to value-based care, to name but a few elements of this regulatory body's broad responsibility. The text deploys the authors' unique backgrounds to underscore the economic, legal, and clinical implications of healthcare regulation.

Healthcare is rapidly changing, but the legions of competing forces shaping it are not. Through active learning, we aim to deepen readers' understanding of healthcare regulation to enable them to shape these forces rather than be shaped by them. So, let's get started.

Instructor Resources

This book's Instructor Resources include PowerPoint slides, an instructor's guide, and templates for interactive exercises.

For the most up-to-date information about this book and its instructor resources, go to ache.org/HAP and search for the book's order code (2500l).

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