

## Foreword

This is the 37<sup>th</sup> edition of the HEALTH LAW HANDBOOK, all edited by me. This book brings together 25 authors writing 14 stand alone articles addressing topics which fall under the 4 following rubrics: (1) The Changing Health Care System; (2) Transactional Issues; (3) Reimbursement and Payment; and 4) Fraud and Abuse.

There are many ways in which the health care system is changing, but the arrival of digital health and artificial intelligence (AI) cannot be overstated as an issue all health lawyers will have to confront. This is the topic tackled by Vanessa Burrows and Carolyn Metnick. They distinguish the two concepts and then survey the range of regulators who have a role in this context. That range is broad, including dueling Executive Orders on point, from one Presidential administration to the next, and the FDA's concepts of what constitutes a medical device, which includes software. European Union laws have extraterritorial impact to consider as contrasted with the incipient dynamism in state laws seeking to protect consumers from a variety of applications, particularly of AI, as used in prior authorizations and determinations of medical necessity, for example. They present examples of risks under traditional principles of law and conclude with a discussion of enforcement efforts so far. This is a brisk review of what is fast becoming a mandated topic for all health lawyers to be familiar with.

Another wide ranging phenomenon is the advent of private equity (PE) in healthcare. Whether you are pro, con or agnostic regarding this development, understanding from whence it has sprung and what drives it is important to appreciate why their deals are structured as they are. Rather than presenting the documents that make for a private equity transaction, Matt Miller and Kim Harvey Looney offer a broader consideration of the context and motivations of private equity. They address how PE emerged as an investment vehicle and how PE differs from other types of investments. They have analyzed four essential factors which