Foreword

This 38th edition of the Health Law Handbook brings together 28 authors providing 16 separate articles, making it one of the heftiest editions in years. The articles can be categorized around five topic areas: (1) transactional issues; (2) payment and reimbursement; (3) data and artificial intelligence; (4) fraud and abuse; and (5) legal challenges for lawyers in the health care space.

The book opens with the transactional section and an article addressing the advent of private equity (PE) in health care. Tom Hawk and Gardner Armsby explain why healthcare is attractive to PE and the scope of its entry into this sector. They describe the three potential benefits of PE against intensifying criticisms centered around quality of care and financial instability. They move to the structure of the typical PE investment transaction and its five components and then turn to a closer examination of physician practice management company acquisitions, including structure and compensation arrangements. They describe political and regulatory scrutiny in light of these developments, with special focus on antitrust under federal and state laws. In a departure from most considerations of PE which I've read, they describe how PE exits the deal, especially important since the PE investment is typically intended to be short-lived. They conclude with some observations regarding burgeoning additional federal and state controls. This is a remarkably clear and well-organized consideration of a development that virtually every health lawyer has encountered over the last 10 years.

Many healthcare transactions include contracts with indemnifications and limitations on liabilities. Rachel Rose focuses on the distinctions between "indemnify, defend and hold harmless" versus limitations on liabilities. She offers benefits and pitfalls in general drafting of these provisions. She expounds on when and what external sources may be considered from outside the bounds of the contract itself. She examines the risks of tying these protections to insur-

ance coverage and provides practical tips in evaluating factors to take into account. She then turns to specific health care contracts, including physician employment contracts, business associate agreements (including ten specific recommendations), master services agreements with vendors, and issues in medical device agreements under the Uniform Commercial Code with particular reference to patent infringement and embedded artificial intelligence. This is a look under the hood of the real significance of these commonly drafted provisions.

In an article regarding very common but rarely analyzed provisions, Richelle Marting tackles the challenges in health plan-provider contracts of incorporated internal plan policies as part of the agreements they enter. Beginning with fundamental first year law school principles of contracting—offer, acceptance and consideration—she contends that these principles are violated in most provider contracts. She confronts electronic addition of provisions and the peculiar complexities in the plan-provider relationship. She looks at issues of notice and unconscionability. She offers examples of state legislation regarding reforms but also the barriers raised by ERISA regulated plans. She concludes with some proposals for further reform. This is an article that makes the reader rethink some of the most fundamental aspects of health plan contracting.

Healthcare facility real estate leases are everywhere in transactional health law. True real estate lawyers have different insights into these documents. Gregory Gosfield provides a sampling of core business issues in the healthcare facility lease agreement, mostly from the perspective of the tenant. His article is in three sections. The first begins with identifying the parties to the transaction, who are not merely landlord and tenant. He then moves to clauses on subordination, non-disturbance, and attornment (which I had to look up!). He takes up the tenant's right to sublet. His next section confronts business terms in commercial leases. He describes eight basic issues and sub-issues, such as physical location of the premises, commencement of the tenancy, and default and the tenant's remedies. His third section addresses the special issues in health care leases from doctor-patient privilege to confidentiality, hazardous substances,

medical waste and more. He addresses the ADA and its brethren, as well as anti-kickback and Stark, and other health law compliance concerns. He addresses permitted uses, exclusive uses, and prohibited uses. Greg assures the reader his intent is merely to shed light on some aspects of these arrangements. The depth of his know-how is self-evident, and his observations are practical.

Closing this section, restrictive covenants in physician employment relations have recently become a hotter topic than in years past. Henry Casale and Fisher Filippazzo take this on starting with arguing why such covenants should be enforceable. They review the dynamism in the FTC's actions, with their 2024 regulations invalidated by the court but their actions against providers continued nonetheless. They review the Stark law recruitment assistance restrictions and other federal laws, then move on to state common law issues. They address the process to enforce such covenants and review case law demonstrating enforceability, focusing on five distinct elements of the covenants. Next, they confront state statutes that ban in some instances and support in others the application of restrictive covenants, particularly for physicians. They survey a multiplicity of state laws but parse more closely the laws in Tennessee and Pennsylvania as examples of drafting conundra which make analysis of impact difficult. They conclude with observations about state law actions including suggestions for statute drafters. Many of us write or review restrictive covenants. This is a timely assessment of this increasingly vital and continuingly evolving aspect of doctor-employer relations.

Moving on to payment and reimbursement issues, patient assistance programs offered by health care providers are proliferating where they deliver non-clinical, and in many instances in-kind, supports to alleviate social determinants of health. Jessica Barth and Alissa Smith explain why this is happening and what these programs look like. They then address the significant compliance risks that attend these initiatives. They take into account multiple anti-kickback safe harbors (AKS), including the implications for affiliated foundations and independent charities. They consider multiple Advisory Opinions and the beneficiary inducement civil money penalty and distinguish it from the AKS restric-

tions, while also addressing exemptions from its strictures. They confront EKRA and five other potential statutory barriers or risks, including special attention to Medicaid rules. They tackle issues for tax-exempt entities offering these programs. They offer practical guidance on design of compliant programs. In incredible time-saving additions for anyone confronting the issues here, they feature a chart setting forth analysis of key Advisory Opinions that speaks to eight different issues the OIG has addressed, and a second matrix offering data with respect to the application of a range of regulations for hospital provided programs. This is virtually a handbook for lawyers advising clients on patient assistance programs.

Value-based payment arrangements are surging in the managed care space. Danielle Sloane and Alice Heywood present the advent of these transactions, enumerating the types of value-based payment arrangements. They discuss four mandatory CMMI requirements and five voluntary approaches, many with snappy acronymic names. They propose criteria to consider in choosing a model to pursue and then confront the blunt practicalities of negotiating with the plan. They offer six tips for tackling specific contract provisions and then turn to the different issues that arise when the provider's relationship with the plan is indirect through a downstream entity such as an ACO or IPA. To produce value, they argue, providers must confront social determinants of health which can create liabilities under anti-kickback as well as the civil money penalties provisions regarding beneficiary inducement. Finally, they analyze legal issues associated with engaging and motivating patients, including OIG Advisory Opinions and special problems with substance use disorder patients. An in-depth guide to these agreements, their varying perspectives as in house counsel to a value-based organization that works with plans and outside counsel representing providers is itself valuable.

Prior authorization (PA), while ubiquitous in health care, has been the bane of many providers' and physicians' lives. In my article, I review the criticisms of these initiatives, then I describe how PA has been deployed in commercial insurance through pharmacy benefit managers (PBMs) and radiology benefit managers, in Medicare Advantage and

traditional Medicare. I review the elements of major CMS reform regulations. I observe that how the health plans have managed the concerns lobbed at their programs has not been very successful. Seven years after an initial statement of commitment to change, they had to reissue a seriously watered down commitment in 2025. On a different note, the states have entered the fray by adopting a range of prior authorization constraints to improve the environment for providers, physicians, and patients. In a surprisingly detailed Congressional move, in 2026, new federal statutory provisions, which are still subject to federal regulation, were enacted dealing with significant PBM reform. Against this fairly contentious and volatile context, it was surprising to many when CMS adopted a six-year pilot program in six states to apply PA in traditional Medicare. Skeptics abound. This is an extremely dynamic area of health care policy, worthy of far greater attention than it has typically garnered among attorneys.

It has been some years since the Handbook has included a truly Medicaid-focused analysis. Here, Susannah Vance Gopalan and Matthew Bergeron present issues associated with certified community behavioral health clinics providing wide-ranging outpatient behavioral health services in Medicaid. The federal government drives how this sector operates by virtue of its financial participation in supporting these clinics. The authors present the three pathways to implement the federal payment, with particular attention to the federal support of demonstration programs in the states. Taking into account the goals and origins of these clinics as safety net providers, they describe how the demonstrations work and present the criteria the states must meet to get the money. Noting that states may choose between two methods of permitted compensation by the states to the clinics, they move on to the difficulties under the demonstration. Still, there has been Congressional support for expanding these programs. They conclude with evidence of the impact these clinics have had and offer some projections for their future. A bit of a niche topic, I found it interesting to return to the federal-state tensions I confronted years ago as a newly hatched attorney working in the War on Poverty.

The third section of the book reflects that data management and artificial intelligence challenges are burgeoning.

In their article on preparing for and managing a ransomware attack, Paul Schmeltzer and Kirk Nahra provide in-depth guidance to counsel advising in such circumstances. They offer a legal framework "map" to confront applicable laws and documents including state and federal laws as well as contracts that may be implicated in an attack. They advise that preparing effectively before an incident occurs is essential, and they deliver explicit guidance on how to do so. They consider insurance effects in light of an incident. They offer practical step-by-step guidance when an incident occurs, with special attention to maintaining and providing required notification to a range of audiences from patients to vendors to regulators. Further, they focus on issues when the client is the source of the attack to where the vendor is. This is an article that is both down to earth at its core but highly sophisticated in its manifest knowledge.

Discussion of the spread of artificial intelligence (AI) in healthcare is rampant. Daniel Shay takes up the rise of AI with particular, though not exclusive, attention to physician uses. First, he describes how AI functions, debunking some myths about how intelligent it really is. He then describes four categories of use, including clinical, documentation and administrative uses, claims-based uses, and use by payors, He moves on to legal risks such as malpractice risk including informed consent, over and under reliance on AI, false claims risks, HIPAA risk, and reimbursement risks, offering the scant case law to date in this arena. He explains risk mitigation strategies grounded in contractual provisions, compliance plans and internal audits. He concludes with the observation that state legislative and regulatory controls may be the best true hope to rein in the excesses that arise in this developing risk environment. His article is instructive on what AI actually is doing in healthcare today and provides practical observations for lawyers working with physicians.

Fraud and abuse issues comprise the fourth section. In their now-traditional contribution updating annual developments in fraud and abuse, John Eason, Travis Lloyd, and Taylor Chenery take in the sweep of activities that have occurred in the last year despite the change of administration. They begin with an OIG Special Advisory Bulletin on the re-

lationship between anti-kickback statutes (AKS) and direct-to-consumer drug sales and the OIG's industry specific compliance guidance for Medicare Advantage plans, which affects providers to those plans as well. They note the issuance of 12 Advisory Opinions and focus closely on five, including three unfavorable opinions. They take on a new Stark Advisory Opinion, of which there have only been 20 previously in the entire history of the statute. Among court decisions they include appellate opinions considering advertising versus referrals under AKS, how violations of AKS generate false claims liability, one on Stark indirect compensation, and one on the broad yet murky application of EKRA. They describe 10 noteworthy settlements and then move onto the False Claims Act, which is notoriously difficult to parse. From the constitutionality of the statute to six actual trials, including the application of the draconian financial penalties under the law, they also include a Supreme Court case on what is a "claim." Multiple opinions have confronted pleading with particularity including "who" submitted the claim, presentment of false claims, and falsity of the claims. They offer three cases on materiality post-*Escobar*; three Circuit Court opinions and one District Court on scienter; one on the public disclosure bar; and five cases focused around retaliation for bringing false claims. They conclude with data on criminal enforcement. Their collection of issues and analysis of developments is a handy guidebook to the developments of the last year.

How a False Claims Act case unfolds, and tactics to deal with the government, are elucidated by Brandon Helms and Liza Saywer. What initiates a case—whether by the government or brought by a relator—is explained, followed by a detailed description of the steps the government takes in determining whether to advance the case. How the attorneys assess the information they gather, the use of statistical sampling, interviews, and civil investigative demands (CIDs) are all explored. The authors provide a close analysis of what influences DOJ decisions as to whether to proceed or decline. They then take into account what happens if the case continues. Throughout, they offer strategic and tactical suggestions for dealing with the government's efforts. This is an illuminating presentation of what prosecutors and defense counsel contend with during the lifecycle of a False Claims

Act case.

In fraud and abuse world, potentially the worst available sanctions are criminal convictions and exclusion from the federal programs. In an insightful and practical article, Laura Laemmle-Weidenfeld and Paul Weidenfeld unravel the relationships between these penalties. First they set forth the types of alternative dispositions that are typically sought in criminal cases: e.g., pleas to lesser offenses, diversion programs, deferred prosecutions, and more. They distinguish between state and federal approaches and take into account collateral consequences of such deals. They then turn to the daunting special problems posed by the very expansive definition of "conviction" under the exclusion authorities in federal healthcare law—mandatory as well as permissive. They provide several grids which parse out the bases for exclusions as well as the parallel issues under civil money penalty laws. They take up a legal analysis of these relationships, including the constitutionality of the exclusion application in light of a criminal defense plea. They conclude with advice regarding seven specific steps counsel can take to avoid the most dire aspects of these effects. This well-thought-out consideration will be surprising to many of our readers.

The fifth section includes articles on topics lawyers must confront in their practice, in a more general sense. From time to time the Handbook has included an ethics article, and we have one this year. Stephen Lee and Felicia Sze, one a former prosecutor and the other a boutique health law practice founder, offer an article conversational in tone but soundly based on the Model Rules, presenting scenarios from real life relating to health law issues. They open with principles regarding communications with clients. Later, they take on communications with opposing parties and their employees. They consider issues around clarifying who the client is when counsel represents an organization. They pose two types of competency challenges: those pertaining to sworn statements and those which arise in government investigations. They speak to rules regarding using generative AI as applied in six categories of behavior. They conclude with when misconduct of attorneys must be reported and where the boundaries to report are softer. I always appreciate lawyers who are willing to confront these aspects of our

professional responsibilities.

When the Supreme Court overturned the 40-year precedent of the *Chevron* case in the *Loper Bright* opinion, there was significant concern about what this would mean in healthcare, given how highly controlled by regulations it is. Luckily, closing out the book, we have Dan Hettich and Marcia Foti's review of how we got here, the two seminal cases at issue, and how *Loper Bright*, decided on a very narrow regulation pertaining to fishery operations, will affect healthcare. Early cases address the impact on Medicare reimbursement litigation. They discuss at least seven cases, among which the government's interpretation in regulations did not fare so well. They also cite two Supreme Court cases where the government prevailed even in light of the new restrictions on agency interpretation of the statutes under which they operate. They note additional cases where the language in the statute could be seen to delegate interpretation in rulemaking to the Secretary but where there were disputes over the scope of the delegation. They look at other healthcare litigation in which sometimes the plaintiffs won, involving orders regarding transgender care, and then the shifting positions of the Trump, Biden, and Trump-again interpretations regarding Title X funding in light of abortion care referrals. I will let you read the article to see who won. They report other deference rules and conclude that there is plenty more interpretation to come. The good news is that all health lawyers now have this well-thought-out presentation to guide some of the approaches to challenging government regulations in the right context.

This collection of articles demonstrates the breadth and sweep of health law. It includes the most cutting edge issues as well as old wine in new bottles. The authors' contributions are a testament to their professionalism; and I am profoundly grateful for their work. I hope our readers appreciate and benefit from their expertise.

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