Preface

About six years ago, AHLA decided to jump on the Top 10 List bandwagon. Inspired by the popularity of these tools in just about every area, we began working with members and experts to compile our own annual selection of the Top 10 Issues in Health Law. Our feature article in the AHLA Connections magazine was an instant hit. Modern Healthcare came calling and wanted to distribute our article, as did other health care related associations. Members clamored for permission to distribute the article to their clients and governance boards. We knew we were on to something!

This inaugural edition of Health Law Watch 2019 is a response to what we see as the need for a publication that precisely spells out, in detail, what health lawyers need to know right now. This book offers accessible yet sophisticated articles on each of the ten most important topics in health law this year.

There are so many reasons that everyone loves ranking lists; there is likely even a Top 10 list of the reasons why everyone loves Top 10 lists. But here are the reasons that every health lawyer and health law professional should buy this book every year and read it cover-to-cover:

1. **You need to stay current but you don’t have a lot of time.** Health Law Watch 2019 is an easy way to do that; the articles are short, authored by experts, and give you the big picture view that you need to stay competitive.

2. **Health Law Watch 2019 will make you feel like you are in control.** Top 10 Lists and Health Law Watch 2019 make information manageable by helping you to remember and organize your thoughts. Information comes in from multiple sources and at many intervals during your busy day. This book captures what you need to know in one place, to be consumed at your convenience, and is scheduled to publish annually. Plan to buy the new edition every year, and you will have a handy research archive to reference in your own writings.

3. **It’s fun to try to predict what’s on the list, or consider how the list could be different.** If you find yourself thinking about those things, you are a good candidate to help with next year’s Connections Top 10 Issues in Health Law and new edition of this book. Please volunteer!

Which brings us to the list of our highly qualified, generous, and hard-working authors who wrote the ten chapters in this book. AHLA is profoundly grateful to all of the members who contributed to make this book a valuable and comprehensive study of the 2019 Top 10 Issues in Health Law. Our thanks and appreciation go out to all of them.
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About the American Health Lawyers Association

As the nation’s largest, nonpartisan, nonprofit organization devoted to legal issues in the health care field, the American Health Lawyers Association (AHLA) leads in providing just-in-time education, establishing trusted resources, and encouraging robust dialogue among its members and the greater health law community. With nearly 14,000 members, AHLA boasts deep expertise among practitioners who represent clients across the entire health care industry spectrum. As a result, AHLA resources benefit not only attorneys, but also anyone who advises physicians, hospitals, health systems, specialty providers, payers, life sciences companies, and many other health care stakeholders. If you have an interest in health law, you have a home in AHLA. For more information about the education and resources of AHLA, please visit us at www.healthlawyers.org.
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Issue 1

The Impact of Disruptors and Disruption in the Health Marketplace

Gary Scott Davis
Kerrin B. Slattery

1.1 Introduction

In the United States, the forecast is for health care expenditures to reach twenty percent of the nation’s gross domestic product by 2025. Further, according to the Centers for Disease Control, ninety percent of the nation’s annual health care expenditures are for people with chronic and mental health conditions. These persistent “elephants in the room,” coupled with general dissatisfaction

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1 The authors would like to acknowledge the contributions of Emily Edwards and MaryKathryn Hurd.


by Americans with their health care, are pressuring many Americans to seek, and disruptors to offer, alternatives to traditional health care delivery.

In the current environment, there has been a surge of disruption and innovation. Every segment of the health care industry, including hospitals and health systems, insurers, pharmaceutical companies, medical device companies, physician practices, digital health vendors, medical educators, and employers, is seeking to reform the American health marketplace through new structures and services. Further, some previously outside the industry, including technology companies, investors, and “mega” employers, are bringing their own perspectives and innovation to the health care industry. All of these participants stand to benefit from change, but their manifestation will not always be the same. Over the next five years, traditional participants can expect major shifts in the health care landscape brought on by these other health “disruptors.” This chapter provides an overview of some of the major disruptors that are reshaping health care in America and related issues for lawyers who are advising health care industry participants through this period of rapid evolution.

1.2 Overview of Key Legal Issues

The statutory and regulatory landscape applicable to the health industry is unique in its depth and complexity and, in some instances, will need to evolve to permit and/or spur health care innovation, while at the same time continuing to protect patients and consumers. The business plans and operations of many disruptors will inevitably implicate almost every substantive area of law, including corporate practice of medicine, antitrust, provider and facility licensure, privacy and security, clinical research and compliance.

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While regulation at both federal and state levels will need to advance to address innovation in health care, notable changes facilitating market disruption have already begun. For example, the Centers for Medicare & Medicaid (CMS) formed the Center for Medicare & Medicaid Innovation (CMMI) to “promote patient-centered care and test market driven reforms that: empower beneficiaries as consumers, provide price transparency, increase choices and competition to drive quality, reduce costs, and improve outcomes.” Additionally, in 2018, CMS promoted use of remote monitoring tools (i.e., wearables and smart devices) to support care coordination and management efforts using patient-generated data. This is one of a few changes in CMS’s Merit-based Incentive Payment System (MIPS) which will allow doctors to receive credit for sending medication reminders, monitoring and reviewing patient-inputted data, and assigning patient education through non-face-to-face care.

An example of the innovative market place outpacing regulations is telemedicine, for which Medicare and Medicaid is not fully available. More than half of the states in the U.S. require private insurance companies to cover telehealth the same as an in-person visit. While telemedicine is still not fully covered under Medicare and Medicaid, many bills in the House or the Senate have been

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9 Id.
introduced addressing telehealth reimbursement signaling that changes may be coming.\textsuperscript{10}

Although the speed of innovation has overtaken the speed of changes to the health care regulatory landscape, making risk assessment and regulatory compliance challenging, health care as a large percentage of the national economy makes it a magnet for disruptors and their investors. Investors have now become more comfortable with both “health care-heavy” and “health care-light” investment opportunities that allow them to benefit from the growth in the health care space.\textsuperscript{11} Health care-heavy assets are assets with “meaningful exposure to reimbursement risk” with their success tied to the health care regulatory landscape.\textsuperscript{12} In contrast, health care-light assets are assets or businesses that are less likely to suffer adverse effects from changes in reimbursement.\textsuperscript{13} While the health care-light assets remain the most attractive for investment, investors have become more comfortable even with the reimbursement risk associated with health care-heavy assets, and investment in that area continues to grow.

1.3 The Current Environment

The health care industry has all of the attributes of an industry ripe for disruption—highly regulated, pricing opacity (value or costs


\textsuperscript{13} Souter, Trends in Private Equity, supra note 11.
or access), and consumer dissatisfaction. Start-ups may often initiate, but do not always lead, disruption. Many times, consumers are the true leaders of disruptions. When a company builds a compelling customer experience and service offering, the consumer wants to use it repeatedly. Because of consumer dissatisfaction, increasingly two cohorts within the population have become the focus of many disruptors—“Millennials” and “Baby Boomers.” There are the Baby Boomers, consisting of a large number of persons who are economically secure, technologically well informed, and active but aging. As the Baby Boomer cohort becomes fully eligible for Medicare, the program’s size and cost will nearly double, creating significant disruption opportunities. For Millennials, convenience is key and they bring with them a different attitude towards almost everything, including digital communication, work/life balance, purchasing through apps, and accessing health care on an as-needed basis only. According to the U.S. Census Bureau, in 2019, Millennials will surpass Baby Boomers as the nation’s largest population group, which could become a clarion call to the health care industry.

Disruptors commonly view the current way of doing business as “disorganized care” and seek to redefine it as more “organized

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care.” Disruptors look at the current consumer experience and seek improvement. Their differentiators: creating a sense of membership or belonging, simplification, and value creation through the adoption of technology and a greater focus on the consumer as an individual. Disruptors will likely continue to focus on the delivery of services outside of hospitals and physician offices (e.g., retail clinics, telemedicine). Availability (24/7/365) and accessibility, such as scheduling through an app and remote monitoring, will be cornerstones of the new paradigm. These market disruptions position the patient, not the provider, at the center of health care delivery. In this new paradigm, care is more convenient, easier to use, and less expensive for consumers. The competitive challenge for legacy participants, such as traditional health care providers, will be how to meet patients and consumers where, when, and how they want to receive care and services.

1.3.1 Changing Payment Models

New payment models and structures, reflecting the shift from fee-for-service payments to a value-based care model, including direct primary care, direct provider contracting, and the expanded promotion of association health plans, seek to address perceived weaknesses associated with the current system.

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19 Id.

20 Id.

21 Id.

22 Id.

23 Id.

24 Value-based Primary Care, MEDIUM (Sept. 21, 2015), https://medium.com/@healthrosetta/health-rosetta-value-based-primary-care-d739b0bf6cc.

1.3.1.1 Direct Primary Care

The direct primary care (DPC) billing model involves a physician or practice directly charging patients a fixed periodic fee for primary care services, with a patient having the option to carry a separate high-deductible insurance policy for emergencies or other services not provided by the primary care practice.\(^{26}\) DPC arrangements vary in the scope of services offered, with some covering a range of primary services including care management and diagnostic tests, and others covering just the cost of office visits.\(^{27}\) As of 2018, nearly half of the states have legislation recognizing DPC as an acceptable alternative to insurance.\(^{28}\) The Affordable Care Act also formally recognizes DPC as an acceptable payment model so long as it meets criteria established by the Secretary of Health and Human Services.\(^{29}\)

For patients, the advantage of a DPC model is simplified access to a physician for a budgeted fixed fee. Patients can contact their primary care provider more often and through new platforms such as text, phone, or video.\(^{30}\) This model allows physicians to see fewer patients in order to generate the same or greater revenue and lowers administrative costs associated with billing third parties.\(^{31}\) Additionally, providers using a DPC model may avoid restrictions associated


\(^{27}\) Id.


\(^{31}\) Id.
with Medicare or Medicaid and the costs of insurance carrier contracts.\textsuperscript{32} Although a DPC practice is relieved from the administrative costs associated with third-party payment, it must still find a way to efficiently, consistently, and successfully collect payments from patients. DPC arrangements may also exacerbate the growing shortage of primary care physicians.\textsuperscript{33}

\subsection*{1.3.1.2 Medicare Direct Provider Contracting}

The lower cost associated with subscription-based primary care models has also attracted the attention of the federal government. CMMI released a Request for Information in April 2018 asking for input on what it calls “Direct Provider Contracting.” Under Direct Provider Contracting, CMS would pay primary care and multi-specialty providers a fixed monthly fee to cover various services for Medicare and Medicaid beneficiaries. Providers would no longer need to submit claims, and those providers who meet certain performance goals would be eligible for payment incentives based upon cost of care and quality provided.\textsuperscript{34} The goals in implementing a Direct Provider Contracting model include improving access to


physician services, reducing administrative burden, and creating a revenue stream that offers providers greater flexibility in caring for patients.\textsuperscript{35}

The implementation mechanics of Direct Provider Contracting are presently unknown. The imposition of collecting and reporting metrics as well as authorization and appropriate use criteria could make participation less attractive.\textsuperscript{36} Stakeholders including the Medical Group Management Association and the American Geriatrics Society have encouraged CMS to keep Direct Provider Contracting simple and avoid overwhelming practices with paperwork and other administrative burdens that could defeat the purpose of simplifying the billing process.\textsuperscript{37} Wide spread adoption of Direct Provider Contracting could create competitive pressures on Medicare Advantage plans.\textsuperscript{38}

\subsection*{1.3.1.3 Association Health Plans}

Another new direction in government policy that is disrupting the health care industry is the Trump Administration’s expansion of access to association health plans (AHPs). AHPs are group health plans that small groups can use to offer health insurance coverage. Smaller businesses can join a group or association that is treated as the “employer” sponsor of a single group health plan, allowing the aggregate of the smaller businesses to negotiate insurance contracts akin to large-group arrangements. On June 21, 2018, the Department of Labor (DOL) published its Final Rule on Association Health Plans, expanding access to AHPs to small business owners, employees of small businesses, and family members of working owners.

\begin{footnotes}
\footnote{\textsuperscript{35} CMS, RFI \textit{DIRECT PROVIDER CONTRACTING} \textit{supra} note 34.}
\footnote{\textsuperscript{36} \textit{HEALTHLEADERS, Keep it Simple, supra} note 34.}
\footnote{\textsuperscript{37} \textit{Id.}}
\end{footnotes}
and employees.\textsuperscript{39} The Final Rule allows more groups to form AHPs based on geographic area or industry, and it permits working owners without other employees and their families to join AHPs.\textsuperscript{40}

Supporters view AHP expansion as a means for lower cost health care coverage. However, the expansion in access to AHPs may also undermine coverage for those who need more comprehensive plans than those who are healthy. Critics point out that AHPs are not subject to several of the patient protection regulations in the Affordable Care Act (ACA), including “essential health benefits” such as prescription drugs or mental health benefits.\textsuperscript{41} Beyond the ACA requirements, AHPs may also be exempt from certain state small group and individual consumer protection laws.\textsuperscript{42} Additionally, prior to the ACA’s “bona fide association” requirement, AHPs suffered from fraud and insolvency.\textsuperscript{43}

In its comments to the Final Rule, America’s Health Insurance Plans (AHIP) argued that the rule creates inconsistent regulation for the sale and operation of insurance contracts and employee protections through group coverage.\textsuperscript{44} Because the AHPs are not subject to

\textsuperscript{39} See 29 C.F.R. § 2510.3.

\textsuperscript{40} Stephen Miller, \textit{DOL’s Final Rule on Association Health Plans Expands Options}, \textsc{Soc’y for Human Res. Mgmt.} (June 20, 2018), https://www.shrm.org/resourcesandtools/hr-topics/benefits/pages/dols-final-rule-association-health-plans.aspx.


\textsuperscript{43} Id.

the same level of oversight that traditional insurers are, AHIP argued that expanding access to AHPs creates an “unlevel competitive playing field” in the insurance market.\(^{45}\) The expansion in AHPs has the potential to affect traditional health plans by diverting healthier patients conceivably triggering premiums increases.\(^{46}\) There may also be an increase in the number of uninsured Americans as healthier patients migrate out of the individual market, thereby increasing premiums.\(^{47}\) By exempting AHPs from some ACA regulations, AHPs may offer lower prices for coverage at the cost of stability and consumer protection. If an AHP becomes insolvent, as there is no state guaranty fund or other safety net to pay claims, ultimate financial responsibility could fall to the insured.\(^{48}\) The Attorneys General of New York and Massachusetts announced plans to sue over the Final Rule, arguing that it will “invite fraud, mismanagement and deception.”\(^{49}\)

1.3.2 Industry Developments and Innovations

1.3.2.1 Oscar Health

Founded in 2012, Oscar’s model is to make buying health insurance easier and more transparent, and to provide better customer service.\(^{50}\) Even after the repeal of the individual mandate

\(^{45}\) Id.

\(^{46}\) AM. HEALTH INS. PLANS, ASSOCIATION HEALTH PLANS: PROJECTING THE IMPACT OF THE PROPOSED RULE (Feb. 28, 2018) http://go.avalere.com/acton/attachment/12909/f-052f/1/-/-/-/-.-.

\(^{47}\) Id.

