

# AHLA Health Law Watch

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2019

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**AHLA**

**American Health  
Lawyers Association**

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— from a declaration of the American Bar Association

**AHLA Diversity+Inclusion Statement** In principle and in practice, the American Health Lawyers Association values and seeks to advance and promote diverse and inclusive participation within the Association regardless of gender, race, ethnicity, religion, age, sexual orientation, gender identity and expression, national origin, or disability. Guided by these values, the Association strongly encourages and embraces participation of diverse individuals as it leads health law to excellence through education, information, and dialogue.

# Preface

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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.

# *About the Authors*

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**Alexis Finkelberg Bortniker** is a partner and health care lawyer with Foley & Lardner LLP. Her practice focuses on transactional and regulatory matters with an emphasis on counseling health systems, hospitals, and other providers in managed care and physician contracting. Ms. Bortniker works with providers in negotiating, implementing, and creating compliance programs around value based payment models. Ms. Bortniker is a member of the firm's Health Care Industry Team and co-chair of the firm's Health Care Transactions work-group.

**Theresa C. Carnegie** is a member of Mintz, Levin, Cohn, Ferris, Glovsky and Popeo PC. Ms. Carnegie counsels health care clients on a variety of transactional, regulatory, and fraud and abuse matters. Ms. Carnegie focuses much of her practice on counseling health plans, pharmacy benefit managers, pharmacies, device manufacturers, and distributors on regulatory and compliance matters. Her practice extends to counseling on drug pricing and reimbursement issues, and Medicare Part D compliance. Ms. Carnegie has extensive experience drafting, negotiating, and structuring PBM agreements, retail, mail and specialty pharmacy agreements, GPO agreements, and pharmaceutical purchase, distribution, and rebate agreements. She also regularly counsels these clients on compliance with federal and state fraud and abuse laws.

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**Gary Scott Davis** is a partner at McDermott Will & Emery LLP. Mr. Davis advises clients on issues concerning managed care, including emerging health benefit plans, strategic restructurings and reorganizations, dispositions, mergers, joint ventures, and contractual matters. The Florida Bar Board of Legal Specialization and Education recognizes Mr. Davis as a Board Certified Health Law Attorney. Mr. Davis is a nationally recognized speaker on organizational and reimbursement transactions relating to managed health care, health care contracting, and joint ventures. He is also a published author of numerous writings on managed care. Mr. Davis has served as an adjunct lecturer of health care law for the Graduate School of Business Administration (MBA Programs for Executives), University of Miami and on the Advisory Board and faculty of the Nova Southeastern University Institute of Continuing Education for Health Care Professionals.

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## *About the Authors*

Mr. DeLoss represents a broad spectrum of health care clients, including physicians, behavioral health care treatment providers, health information technology (HIT) solution vendors, federally qualified health centers (FQHCs), hospitals and research organizations, as well as health care industry trade and professional associations. Mr. DeLoss has testified before the United States House of Representatives, Energy and Commerce Committee as a subject matter expert on 42 C.F.R. Part 2, the federal regulations governing the confidentiality of substance use disorder information. He has also served as an expert witness on health information privacy in court proceedings and arbitrations. Mr. DeLoss has extensive knowledge of HIPAA, HITECH, behavioral health privacy, eHealth, and telehealth requirements. He regularly represents telehealth and medical technology startups and solutions providers. Mr. DeLoss's experience includes advising health care providers on reimbursement under Medicaid, Medicare, grant funding, private insurance, and managed care. He also counsels providers on strategic acquisitions, along with preparation and negotiation of joint venture and merger agreements. In addition to his skills in representing clients in the medical, behavioral health, telehealth, and FQHC fields, Jud provides specialized representation to address discrimination and exclusion of osteopathic physicians in medical staff privileging and credentialing matters. Mr. DeLoss has written articles and presented on health law issues nationally and internationally, including on health information privacy and other compliance matters. He is an active member of the American Health Lawyers Association (AHLA) where he has served as Chair of the Health Information and Technology Practice Group, Chair of the Behavioral Health Task Force, and currently serves on the Quality Council to the AHLA Board of Directors.

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## *About the Authors*

corporate transactions and compliance programs. He has extensive experience in health care fraud and abuse and compliance issues, including the federal Anti-Kickback and Physician Self-Referral/Stark laws, false claims and overpayments, and government investigations. Mr. Maida previously served for almost a decade with the Office of Counsel to the Inspector General at the United States Department of Health and Human Services. As Deputy Chief of the Administrative and Civil Remedies Branch, Mr. Maida led a team of lawyers representing the agency on False Claims Act and Civil Monetary Penalty Law cases, including conducting investigations and negotiating settlements and corporate integrity agreements in some of the largest settlements obtained by the United States. He participated in defending the OIG in numerous exclusion appeals. Additionally, Mr. Maida was a principal author of the OIG's current Self-Disclosure Protocol and the 2009 Open Letter.

**Anna S. Ross** is an associate with Foley & Lardner LLP who focuses her practice on health care and FDA regulatory matters. Ms. Ross counsels clients in the health care and pharmaceutical and medical device industries with respect to a wide range of regulatory, compliance, and corporate matters. In the scope of her practice, Ms. Ross represents hospitals and health systems, post-acute care providers, physician practices, pharmaceutical companies, and medical device manufacturers and distributors. Ms. Ross' experience includes counseling clients with respect to Medicare and Medicaid reimbursement compliance; government and internal investigations and audits; self-disclosures; state and federal fraud and abuse issues; and state licensure issues, certificate of need requirements, and change of ownership issues. She also provides clients with support related to their compliance programs, including developing policies and procedures, creating training programs, and implementing compliance obligations in connection with a Corporate Integrity Agreement.

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# *About the American Health Lawyers Association*

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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](http://www.healthlawyers.org).



# *Table of Contents*

## **Preface**

---

## **About the Authors**

---

## **About the American Health Lawyers Association**

---

## **Issue 1                      The Impact of Disruptors and Disruption in the Health Marketplace**

---

Gary Scott Davis  
Kerrin B. Slattery

1.1	INTRODUCTION
1.2	OVERVIEW OF KEY LEGAL ISSUES
1.3	THE CURRENT ENVIRONMENT
1.3.1	Changing Payment Models
1.3.1.1	Direct Primary Care
1.3.1.2	Medicare Direct Provider Contracting
1.3.1.3	Association Health Plans
1.3.2	Industry Developments and Innovations
1.3.2.1	Oscar Health
1.3.2.2	The Shifting Paradigm
1.3.2.3	Emerging Technologies
1.3.3	Transformative Collaborations
1.3.3.1	Synergies and Merger
1.3.3.2	Synergies and Repositioning
1.3.3.3	Amazon, Berkshire Hathaway, and JPMorgan Chase

---

*Table of Contents*

1.3.3.4 New York-Presbyterian (NYP) Partnership  
with Walgreens  
1.3.4 Telemedicine  
1.4 TRENDS FOR THE NEXT YEAR  
1.5 WHAT HEALTH LAWYERS NEED TO  
KNOW NOW

**Issue 2 Structuring and Operationalizing Value Based  
Payments: Legal Developments and Practical  
Tips**

---

Alexis Finkelberg Bortniker  
Anna S. Ross  
Alexandra B. Shalom

2.1 INTRODUCTION  
2.1.1 Historical Overview  
2.1.2 Summary of Recent Events  
2.2 THE CURRENT ENVIRONMENT  
2.2.1 MACRA to Date  
2.2.2 Quality Payment Program Results  
2.2.3 Updates in Gainsharing Arrangement  
Enforcement  
2.2.4 A New Direction for the MSSP  
2.2.5 CMS Final Rule to Accelerate the Assumption  
of Downside Risk  
2.2.6 Impact of Accelerated Risk Under the MSSP  
2.2.7 Evaluating Episode-Based Payment Models  
2.3 WHAT HEALTH LAWYERS NEED TO  
KNOW NOW  
2.3.1 Managed Care Fraud and Abuse Compliance  
2.3.1.1 Anti-Kickback Statute  
2.3.1.2 Stark Law  
2.3.2 Physician Incentive Plans (PIP)  
2.4 PRACTICE TIPS AND TOOLS

---

*Table of Contents*

**Issue 3                      Artificial Intelligence and the Internet of Things in Health Care—Innovation Continues to Outpace Regulation**

---

Alaap B. Shah

3.1	INTRODUCTION
3.1.1	Rapid Innovation of AI and IoT
3.1.2	Growing Investment in and Adoption of AI and IoT
3.2	OVERVIEW OF KEY LEGAL ISSUES
3.2.1	Regulating AI and IoT Remains Difficult for Various Reasons
3.2.2	Ethical Dimensions for Managing AI and IoT Risks
3.2.3	Risks Associated with AI and IoT
3.2.3.1	Privacy and Data Security Risk
3.2.3.2	Safety Risk
3.2.3.3	Risks Related to Bias and Fairness
3.2.4	Continuing Dialogue and Emerging Consensus on Regulation
3.3	THE CURRENT ENVIRONMENT
3.3.1	Federal Regulation
3.3.1.1	HHS, Office for Civil Rights
3.3.1.2	Federal Trade Commission
3.3.1.3	Food and Drug Administration
3.3.2	European Union—General Data Protection Regulation
3.3.3	Common Law
3.4	TRENDS FOR THE NEXT YEAR
3.4.1	IoT Legislation
3.4.2	AI Legislation
3.5	PRACTICE TIPS & TOOLS

---

*Table of Contents*

**Issue 4                      Drug Pricing**

---

Theresa C. Carnegie  
Xavier G. Hardy  
Michelle L. Caton

4.1                      INTRODUCTION

4.2                      THE CURRENT ENVIRONMENT

    4.2.1                  American Patients First Blueprint

4.3                      OVERVIEW OF MAJOR DRUG PRICING  
INITIATIVES FROM 2018 THROUGH  
JANUARY 2019

    4.3.1                  Initiatives to “Improve Competition”

        4.3.1.1              FDA Action

    4.3.2                  Initiatives for “Better Negotiation”

        4.3.2.1              Immediate and Expedited Midyear  
Adjustments to Part D Formularies

        4.3.2.2              International Pricing Index Model

    4.3.3                  Initiatives to Incentivize Lower List Prices

        4.3.3.1              Proposal to Remove Safe Harbors for Part D  
Drug Rebates

        4.3.3.2              Proposal to Require Disclosure of Drug  
Prices in Television Advertisements

        4.3.3.3              Allowing Medicare Advantage Plans to  
Use Step Therapy for Part B Drugs and  
Cross-Management of Part B & D Drugs for  
Medicare Advantage Plans Offering Part D  
Coverage

        4.3.3.4              Allowing Plan Flexibility to Manage  
Protected Classes

    4.3.4                  Initiatives to Reduce Out-of-Pocket Cost

        4.3.4.1              Prohibiting Gag Clauses in Part D Plans

    4.3.5                  Drug Pricing Provisions in the Bipartisan  
Budget Act of 2018

        4.3.5.1              Changes to the Medicare Part D’s Coverage  
Gap in the Bipartisan Budget Act

---

## Table of Contents

4.3.5.2	Changes to the Medicaid Rebate Formula in the Bipartisan Budget Act
4.3.6	State Drug Pricing Initiatives
4.4	TRENDS FOR THE NEXT YEAR: PENDING AND ANTICIPATED ACTIONS IN 2019
<b>Issue 5</b>	<b>Fraud and Abuse—FCA Enforcement, New Laws and Regulatory Changes</b>

---

Tony Maida

5.1	FCA ENFORCEMENT—INTRODUCTION
5.2	FCA ENFORCEMENT—OVERVIEW OF KEY LEGAL ISSUES
5.3	FCA ENFORCEMENT—THE CURRENT ENVIRONMENT
5.3.1	Post-Escobar Litigation
5.3.2	DOJ Policy Changes
5.3.2.1	The <i>Granston</i> Memorandum
5.3.2.2	The <i>Brand</i> Memorandum
5.3.2.3	The <i>Yates</i> Memorandum 2.0
5.3.3	Expansion of FCA Targets
5.4	FCA ENFORCEMENT—TRENDS FOR THE NEXT YEAR
5.4.1	FCA Litigation
5.4.2	Continuing Interpretation of the Government’s Authority to Dismiss <i>Qui Tam</i> Matters
5.4.3	The Continuing Applicability of the <i>Brand</i> Memo
5.4.4	Continued Enforcement Against Individuals and Non-Traditional Targets
5.5	FCA ENFORCEMENT—WHAT HEALTH LAWYERS NEED TO KNOW
5.6	NEW FRAUD AND ABUSE LAW—INTRODUCTION

---

*Table of Contents*

5.7 NEW FRAUD AND ABUSE LAW—  
OVERVIEW OF KEY LEGAL ISSUES:  
    5.7.1 EKRA’s Legislative History  
    5.7.2 Statutory Prohibition and Definitions  
    5.7.3 EKRA Exceptions  
    5.7.4 EKRA Rulemaking and Preemption  
5.8 NEW FRAUD AND ABUSE LAW—TRENDS  
FOR THE NEXT YEAR  
5.9 NEW FRAUD AND ABUSE LAW—WHAT  
HEALTH LAWYERS NEED TO KNOW NOW  
5.10 REGULATORY  
CHANGES—INTRODUCTION  
5.11 REGULATORY CHANGES—OVERVIEW OF  
KEY LEGAL ISSUES  
5.12 REGULATORY CHANGES—THE CURRENT  
ENVIRONMENT  
5.13 REGULATORY CHANGES—TRENDS FOR  
THE NEXT YEAR  
5.14 REGULATORY CHANGES—WHAT  
HEALTH LAWYERS NEED TO KNOW NOW

**Issue 6 Behavioral Health—A Growing Practice Area  
for Health Lawyers**

---

Gerald (Jud) E. DeLoss

6.1 INTRODUCTION  
6.2 OVERVIEW OF KEY LEGAL ISSUES  
6.3 THE CURRENT ENVIRONMENT  
    6.3.1 IMD Exclusion  
    6.3.2 Medicaid Managed Care Regulations  
    6.3.3 42 C.F.R. Part 2  
6.4 TRENDS FOR THE NEXT YEAR  
    6.4.1 CMS Actions Relating to IMD Exclusion  
    6.4.2 Proposed Changes to Medicaid Managed Care  
Regulations  
    6.4.3 Modifications to 42 C.F.R. Part 2

---

## *Table of Contents*

6.5 WHAT HEALTH LAWYERS NEED TO  
KNOW NOW

---

### **Issue 7                    The Opioid Crisis**

---

Samantha P. Scheuler

7.1 INTRODUCTION

7.2 OVERVIEW OF KEY LEGAL ISSUES

7.3 THE CURRENT ENVIRONMENT

    7.3.1 Regulating and Monitoring Prescribing  
          Practices

        7.3.1.1 Federal Guidance

        7.3.1.2 State Regulation

        7.3.1.3 State PDMPs and Reporting Requirements

7.4 TRENDS FOR THE NEXT YEAR

    7.4.1 Continued Innovation from State Legislatures  
          as Best Practices Realized

        7.4.1.1 Changes to State PDMPs

        7.4.1.2 State and Private Prescribing Policies  
              Continue to Evolve

    7.4.2 Continued Scrutiny on Providers and  
          Dispensers

    7.4.3 New Guidance on Treatment Options and  
          Expanding Access

7.5 WHAT HEALTH LAWYERS NEED TO  
KNOW NOW

    7.5.1 Monitoring Prescribing Practices

    7.5.2 Anticipating Enforcement Actions

    7.5.3 Monitoring What’s New in Available and  
          Covered Treatments

---

*Table of Contents*

---

**Issue 8                      Private Equity Investment in Health Care**

---

Grace D. Mack  
Michael F. Schaff

8.1                      INTRODUCTION

8.1.1                  Increased Private Equity Interest in Health Care  
after Enactment of the Affordable Care Act

8.1.2                  Top Health Care Private Equity Deals in 2018

8.1.3                  The Typical Private Equity Deal and Business  
Model

8.1.3.1                Multiple of EBITDA

8.1.3.2                Rollover Equity

8.2                      OVERVIEW OF KEY LEGAL ISSUES

8.2.1                  Beware of State Law Restrictions

8.2.1.1                Corporate Practice of Medicine Restrictions

8.2.1.2                CPOM Prohibition Enforcement

8.2.2                  Taxation Issues in PE/Medical Practice  
Transactions

8.2.2.1                Stock Deal

8.2.2.2                Asset Deal

8.2.2.3                Goodwill

8.2.2.4                Carried Interest

8.2.2.5                Other Tax Considerations

8.2.3                  Fraud and Abuse Laws: Anti-Kickback/False  
Claims Act Liability/Self-Referral Laws and  
Private Equity Firms

8.2.3.1                The Federal AKS Law

8.2.3.2                State Anti-Kickback Laws

8.2.3.3                The False Claims Act

8.3.2.4                Self-Referral Laws

8.2.4                  Restrictive Covenants

8.2.5                  Fee Splitting Laws

8.2.6                  Licensure Requirements

8.2.7                  State Insurance Laws

8.2.8                  Securities Law Issues



---

## *Table of Contents*

8.2.9	Payer Related Issues
8.2.9.1	Change of Control
8.2.9.2	Network Status
8.2.9.3	Future Recoupments
8.2.9.4	Bundled Payments
8.3	THE CURRENT ENVIRONMENT
8.4	TRENDS FOR THE NEXT YEAR
8.4.1	Targeted Sectors and Specialties—Who will be Next?
8.4.2	What will be the Sectors or Specialties on Private Equity’s Radar in 2019?
8.5	WHAT HEALTH LAWYERS NEED TO KNOW NOW
8.6	PRACTICE TIPS & TOOLS
8.6.1	Representation & Warranty Insurance
8.6.2	Preemptive Due Diligence

---

## **Issue 9 Medicaid Developments**

---

Samantha P. Scheuler

9.1	INTRODUCTION
9.2	OVERVIEW OF KEY LEGAL ISSUES
9.2.1	State Medicaid Expansion and Implications for Uncompensated Care
9.2.2	Medicaid Work Requirements
9.2.3	Drug Costs and Drug Rebates
9.3	CURRENT LEGAL ENVIRONMENT
9.3.1	Medicaid Expansion and Implications of ACA Challenge
9.3.2	Implications for Supplemental DSH Payments
9.3.3	Medicaid Work Requirements Demonstration Projects: State Responses
9.3.4	Legal Challenges to Medicaid Work Requirements
9.3.5	State-Led Innovation Relating to Drug Rebates

---

*Table of Contents*

9.4 TRENDS FOR THE NEXT YEAR  
9.4.1 Medicaid Expansion and Implications for DSH Funding  
9.4.1.1 DSH Payments—Further Delay or Reform?  
9.4.1.2 Section 1115 Waiver Activity  
9.4.1.3 State Innovation Regarding Drug Rebates  
9.5 WHAT HEALTH LAWYERS NEED TO KNOW NOW  
9.5.1 Medicaid Expansion and DSH Debate  
9.5.2 State-Led Innovation: Medicaid Work Requirements and Other Waivers

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**Issue 10 The 340B Drug Discount Program**

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Justin C. Linder

10.1 INTRODUCTION  
10.2 OVERVIEW OF KEY LEGAL ISSUES  
10.2.1 Payment Reduction  
10.2.2 340B Modifiers  
10.3 THE CURRENT ENVIRONMENT  
10.3.1 Lawsuit to Enjoin Payment Reduction  
10.3.2 2019 Outpatient Prospective Payment Final Rule  
10.3.3 June 28, 2018 GAO Report on Contract Pharmacies and Compliance Audits  
10.3.4 Implementation of HRSA Ceiling Price Civil Monetary Penalty Rule  
10.4 WHAT HEALTH LAWYERS NEED TO KNOW NOW

**Index**

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# Issue 1

## The Impact of Disruptors and Disruption in the Health Marketplace

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### 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.<sup>2</sup> 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.<sup>3</sup> These persistent “elephants in the room,” coupled with general dissatisfaction

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

<sup>2</sup> Press Release, CTRS. FOR MEDICARE & MEDICAID SERVS., 2016–2025 PROJECTIONS OF NATIONAL HEALTH EXPENDITURES DATA RELEASED, (Feb. 15, 2017), *available at* <https://www.cms.gov/newsroom/press-releases/2016-2025-projections-national-health-expenditures-data-released>.

<sup>3</sup> Christine Butteroff, Teague Ruder, and Melissa Bauman, *Multiple Chronic Conditions in the United States* (2017) RAND CORP., [https://www.rand.org/content/dam/rand/pubs/tools/TL200/TL221/RAND\\_TL221.pdf](https://www.rand.org/content/dam/rand/pubs/tools/TL200/TL221/RAND_TL221.pdf); CTRS. FOR MEDICARE & MEDICAID SERVS, NATIONAL HEALTH EXPENDITURE DATA FOR 2017, *available at* <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/highlights.pdf> (last accessed Jan. 20, 2019).

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.<sup>4</sup> 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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<sup>4</sup> Kara Murphy and Nirad Jain, *Riding the Disruption Wave in Healthcare*, FORBES (May 1, 2018), <https://www.forbes.com/sites/baininsights/2018/05/01/riding-the-disruption-wave-in-healthcare/#565af4d52846> [hereinafter FORBES *Disruption Wave*].

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.”<sup>5</sup> 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.<sup>6</sup> 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.<sup>7</sup>

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.<sup>8</sup> While telemedicine is still not fully covered under Medicare and Medicaid,<sup>9</sup> many bills in the House or the Senate have been

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<sup>5</sup> CTRS. FOR MEDICARE & MEDICAID SERVS.: INNOVATION CENTER NEW DIRECTION, <https://innovation.cms.gov/initiatives/direction/> (last visited Jan. 19, 2019).

<sup>6</sup> Press Release, CTRS. FOR MEDICARE & MEDICAID SERVS., CMS Takes Action to Modernize Medicare Home Health, (Oct. 31, 2018), <https://www.cms.gov/newsroom/press-releases/cms-takes-action-modernize-medicare-home-health-0>; Eric Wicklund, *CMS to Reimburse Providers for Remote Patient Monitoring Services*, MHEALTHINTELLIGENCE (Nov. 2, 2018), <https://mhealthintelligence.com/news/cms-to-reimburse-providers-for-remote-patient-monitoring-services>.

<sup>7</sup> Eric Wicklund, *CMS, AMA Look for Common Ground on Remote Patient Monitoring*, MHEALTHINTELLIGENCE (Nov. 6, 2017), <https://mhealthintelligence.com/news/cms-ama-look-for-common-ground-on-remote-patient-monitoring>.

<sup>8</sup> *About Telemedicine*, AM. TELEMEDICINE ASS’N, <http://www.american-telemed.org/main/about/telehealth-faqs-> (last visited Jan. 19, 2019).

<sup>9</sup> *Id.*

introduced addressing telehealth reimbursement signaling that changes may be coming.<sup>10</sup>

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.<sup>11</sup> Health care-heavy assets are assets with “meaningful exposure to reimbursement risk” with their success tied to the health care regulatory landscape.<sup>12</sup> In contrast, health care-light assets are assets or businesses that are less likely to suffer adverse effects from changes in reimbursement.<sup>13</sup> 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

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<sup>10</sup> Evan Sweeny, *5 health IT predictions for 2018: Telemedicine’s final push, EHRs remain in the legal crosshairs*, FIERCEHEALTHCARE (Jan. 4, 2018), <https://www.fiercehealthcare.com/regulatory/health-it-predictions-2018-digital-health-telemedicine-cybersecurity-information>.

<sup>11</sup> Patrick Souter, *Current Trends in Private Equity Investment in Ancillary Healthcare Providers*, AM. BAR ASS’N (Sept. 27, 2018), [https://www.americanbar.org/groups/health\\_law/publications/aba\\_health\\_esource/2016-2017/december2017/ancillaryhealth/](https://www.americanbar.org/groups/health_law/publications/aba_health_esource/2016-2017/december2017/ancillaryhealth/) [hereinafter Souter, *Trends in Private Equity*].

<sup>12</sup> Mike Wright et al. *The Routledge Companion to Management Buyouts*, Chapter 11 (1st ed. 2019) [hereinafter Wright, *Routledge*].

<sup>13</sup> Souter, *Trends in Private Equity*, *supra* note 11.

or access), and consumer dissatisfaction.<sup>14</sup> 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,<sup>15</sup> 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.<sup>16</sup> According to the U.S. Census Bureau, in 2019, Millennials will surpass Baby Boomers as the nation’s largest population group,<sup>17</sup> 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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<sup>14</sup> Megan Beck and Barry Libert, *Three Signals Your Industry Is About to Be Disrupted*, MIT SLOAN (June 11, 2018), <https://sloanreview.mit.edu/article/three-signals-your-industry-is-about-to-be-disrupted/>.

<sup>15</sup> Tucker Doherfty, *Medicare’s Time Bomb, in 7 Charts*, POLITICO (Sept. 12, 2018), <https://www.politico.com/agenda/story/2018/09/12/medicare-baby-boomers-trust-fund-000694>; John Landau, *Health-care Dilemma: 10,000 Boomers Retiring Each Day*, CNBC (Oct. 3, 2017), <https://www.cnbc.com/2017/10/03/health-care-dilemma-10000-boomers-retiring-each-day.html>; Juliette Cuban-ski and Tricia Neuman, *The Fact on Medicare Spending and Financing*, KAISER FAM. FOUND. (June 22, 2018), <https://www.kff.org/medicare/issue-brief/the-facts-on-medicare-spending-and-financing/>.

<sup>16</sup> Ben Cukier, *Coming Of Age: Fintech Companies Should Move On From Millennials*, FORBES (May 8, 2018), <https://www.forbes.com/sites/benjamin-cukier/2018/05/08/coming-of-age-fintech-companies-should-move-on-from-the-millennials/#36e5414a797f>.

<sup>17</sup> Richard Fry, *Millennials projects to overtake Baby Boomers as America’s largest generation*, PEW RESEARCH CENTER (Mar. 1, 2018), <http://www.pew-research.org/fact-tank/2018/03/01/millennials-overtake-baby-boomers/>.

care.”<sup>18</sup> Disruptors look at the current consumer experience and seek improvement.<sup>19</sup> Their differentiators: creating a sense of membership or belonging, simplification, and value creation<sup>20</sup> through the adoption of technology and a greater focus on the consumer as an individual.<sup>21</sup> Disruptors will likely continue to focus on the delivery of services outside of hospitals and physician offices (e.g., retail clinics, telemedicine).<sup>22</sup> Availability (24/7/365) and accessibility, such as scheduling through an app and remote monitoring,<sup>23</sup> 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,<sup>24</sup> 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.<sup>25</sup>

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<sup>18</sup> Gary Scott Davis, *Disruptor and Disruption*, 23 AHLA CONNECTIONS 23, (2019), available at <https://www.ebglaw.com/content/uploads/2019/01/Alaap-Shah-AHLA-Connections-January-2019-Technology-Outpace-Law-p5.pdf> [hereinafter Davis, *Disruptor and Disruption*].

<sup>19</sup> *Id.*

<sup>20</sup> *Id.*

<sup>21</sup> *Id.*

<sup>22</sup> *Id.*

<sup>23</sup> *Id.*

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

<sup>25</sup> Peter Ubel, *Paying for Healthcare is So Confusing, Patients Don't Know Who to Be Angry At*, FORBES (Aug. 22), 2016, <https://www.forbes.com/>



### 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.<sup>26</sup> 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.<sup>27</sup> As of 2018, nearly half of the states have legislation recognizing DPC as an acceptable alternative to insurance.<sup>28</sup> 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.<sup>29</sup>

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.<sup>30</sup> 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.<sup>31</sup> Additionally, providers using a DPC model may avoid restrictions associated

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sites/peterubel/2016/08/22/paying-for-healthcare-is-so-confusing-patients-dont-know-who-to-be-angry-at/#254bd3a31b53.

<sup>26</sup> *FAQ on Direct Primary Care*, AM. ACAD. OF FAMILY PHYSICIANS, <https://www.aafp.org/practice-management/payment/dpc/faq.html> (last visited Jan. 19, 2019).

<sup>27</sup> *Id.*

<sup>28</sup> DCP FRONTIER, 2019 DCP “NOT INSURANCE” REGULATIONS, <https://www.dpcfrontier.com/states/> (last visited Jan. 20, 2019).

<sup>29</sup> DCP FRONTIER, AFFORDABLE CARE ACT, <https://www.dpcfrontier.com/affordable-care-act/> (last visited Jan. 20, 2019).

<sup>30</sup> *Advantages and Limitations of the Direct Primary Care Model*, MGMA, <https://www.mgma.com/data/data-stories/advantages-and-limitations-of-the-direct-primary-c> (last visited Jan. 19, 2019) [hereinafter *MGMA Direct Primary Care*].

<sup>31</sup> *Id.*

with Medicare or Medicaid and the costs of insurance carrier contracts.<sup>32</sup> 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.<sup>33</sup>

### 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.<sup>34</sup> The goals in implementing a Direct Provider Contracting model include improving access to

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<sup>32</sup> Melina Beck, *With Direct Primary Care, It's Just Doctor and Patient*, WALL ST. J. (Feb. 27, 2017), <https://www.wsj.com/articles/with-direct-primary-care-its-just-doctor-and-patient-1488164702>.

<sup>33</sup> Rob Lamberts, *Pros and Cons of Switching to A Subscription Practice*, PHYSICIAN PRACTICE (Mar. 22, 2017), <http://www.physicianspractice.com/practice-models/pros-and-cons-switching-subscription-practice>; MGMA *Direct Primary Care*, *supra* note 30; *Direct Primary Care Pros & Cons*, UMHS ENDEAVOR (Jan. 19, 2016), <https://www.umhs-sk.org/blog/direct-primary-care-pros-cons/>.

<sup>34</sup> John Commins, *Direct Provider Contracting: Keep It Simple, Stakeholders Tell CMS*, HEALTHLEADERS (May 29), 2018, <https://www.healthleadersmedia.com/strategy/direct-provider-contracting-keep-it-simple-stakeholders-tell-cms>; [hereinafter HEALTHLEADERS, *Keep it Simple*]; Meg Bryant, *CMS Mulling Direct Provider Contracting Models*, HEALTHCARE DIVE (Apr. 24, 2018), <https://www.healthcaredive.com/news/cms-mulling-direct-provider-contracting-models/522006/>; Virgil Dickson, *Medicare's Proposed Direct-Contracting Model Carries Both Rewards and Risk*, MODERN HEALTHCARE (Apr. 28, 2018), <http://www.modernhealthcare.com/article/20180428/NEWS/180429902>; CTRS. FOR MEDICARE & MEDICAID SERVS, REQUEST FOR INFORMATION ON DIRECT PROVIDER CONTRACTING MODELS, <https://innovation.cms.gov/Files/x/dpc-rfi.pdf> (last visited Jan. 20, 2019) [hereinafter CMS, RFI DIRECT PROVIDER CONTRACTING].

physician services, reducing administrative burden, and creating a revenue stream that offers providers greater flexibility in caring for patients.<sup>35</sup>

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.<sup>36</sup> 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.<sup>37</sup> Wide spread adoption of Direct Provider Contracting could create competitive pressures on Medicare Advantage plans.<sup>38</sup>

### 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

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<sup>35</sup> CMS, RFI DIRECT PROVIDER CONTRACTING *supra* note 34.

<sup>36</sup> HEALTHLEADERS, *Keep it Simple*, *supra* note 34.

<sup>37</sup> *Id.*

<sup>38</sup> ADVISORY BOARD, CMS EYES TEST THAT WOULD LET PROVIDERS CONTRACT DIRECTLY WITH PATIENTS (Apr. 26, 2018), <https://www.advisory.com/daily-briefing/2018/04/26/cms-dpc>.

and employees.<sup>39</sup> 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.<sup>40</sup>

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.<sup>41</sup> Beyond the ACA requirements, AHPs may also be exempt from certain state small group and individual consumer protection laws.<sup>42</sup> Additionally, prior to the ACA’s “bona fide association” requirement, AHPs suffered from fraud and insolvency.<sup>43</sup>

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.<sup>44</sup> Because the AHPs are not subject to

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<sup>39</sup> See 29 C.F.R. § 2510.3.

<sup>40</sup> Stephen Miller, *DOL’s Final Rule on Association Health Plans Expands Options*, 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>.

<sup>41</sup> Robert Pear, *Cheaper Health Plans Promoted by Trump Have a History of Fraud*, N.Y. TIMES (Oct. 21, 2017), <https://www.nytimes.com/2017/10/21/us/politics/trump-association-health-plans-fraud.html>.

<sup>42</sup> Sabrina Corlette, Josh Hammerquist and Pete Nakahata, *New Rules to Expand Association Health Plans*, THE ACTUARY (May 2018), <http://theactuary-magazine.org/new-rules-to-expand-association-health-plans/>; Matthew J. Smith, *Association Health Plans: Will Trump Proposal Invite Repeat Crime Wave?*, BLOOMBERG LAW (Apr. 30, 2018), <https://news.bloomberglaw.com/health-law-and-business/association-health-plans-will-trump-proposal-invite-repeat-crime-wave>.

<sup>43</sup> *Id.*

<sup>44</sup> AM. HEALTH INS. PLANS, RE: DEFINITION OF “EMPLOYER” UNDER SECTION 3(5) OF ERISA – ASSOCIATION HEALTH PLANS (RIN 1210-AB85) – AHIP COMMENTS (Mar. 5, 2018) <https://www.dol.gov/sites/default/files/ebsa/laws-and-regulations/rules-and-regulations/public-comments/1210-AB85/00406.pdf>.

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.<sup>45</sup> The expansion in AHPs has the potential to affect traditional health plans by diverting healthier patients conceivably triggering premiums increases.<sup>46</sup> There may also be an increase in the number of uninsured Americans as healthier patients migrate out of the individual market, thereby increasing premiums.<sup>47</sup> 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.<sup>48</sup> 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.”<sup>49</sup>

## 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.<sup>50</sup> Even after the repeal of the individual mandate

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<sup>45</sup> *Id.*

<sup>46</sup> 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/-/-/-/>.

<sup>47</sup> *Id.*

<sup>48</sup> Virgin Dickson, *Association Health Plan Rule Poses Financial Threat for Providers*, MODERN HEALTHCARE (Mar. 7, 2018) <http://www.modernhealthcare.com/article/20180307/NEWS/180309924>.

<sup>49</sup> Megan Mardy, Rick Stepanovic, Jacob. M. Mattinson, Judith Wethall, *All Together Now: DOL Finalizes Rule for Association Health Plans*, MCDERMOTT WILL & EMERY (June 26, 2018), <https://www.mwe.com/en/thought-leadership/publications/2018/06/dol-finalizes-rule-association-health-plans>.

<sup>50</sup> *2018 Disruptor: Oscar Health*, CNBC (May 22, 2018), <https://www.cnbc.com/2018/05/22/oscar-health-2018-disruptor-50.html> [hereinafter *CNBC Oscar Disruptor*].