Join your clients, colleagues and friends for a fun event that delivers the health law content you need –

- Practical Annual Updates
- Privacy and Security Takeaways
- Fraud and Abuse Enforcement Trends
- Government Program Insights
- Healthcare Industry Transaction Tips
- Digital Health How-To’s
- On-Point Ethics and Elimination-of-Bias Sessions
- And More!

June 19 & 20, 2019    |    Minnesota CLE Conference Center    |    Minneapolis
Expert Insights on Key Developments and Real-World Scenarios!

How New Developments Impact Your Clients

The 2019 Health Law Institute brings you comprehensive updates, expert insights, practical advice – and the opportunity to tailor your own personalized agenda through numerous breakout session options in addition to the plenary sessions. Conference topics include:

- **2019 Healthcare Litigation Update** – The ACA and More
- **New Healthcare Fraud and Abuse Developments**
- **2019 Privacy and Data Security Update**
- **New and Emerging Benefit Models** – How to Get to Implementation Beyond the Regulatory Chaos
- **Device and Pharma Update** – Key Issues and Initiatives at FDA and Congress
- **Minnesota Legislative, Agency and Enforcement Updates**
- **Beyond the Basics – How to Handle Tough Breach Questions**
- **Responding to Government Audits**
- **Medicare Advantage and Part D Update**
- **Hot Topics for Medical Staff Leaders and Counsel Who Advise Them**
- **Electronic Health Records** – Including Newly Proposed Interoperability Rules
- **And More!**

Expert Perspectives

A team of conference faculty and planners spends hundreds of hours distilling information – new cases and rules, business trends, frequently asked client questions, and more – so you don’t have to. At the conference, you’ll hear **experts from private practice, in-house legal, compliance and government** – all there to share real-world advice and practice tips for tackling complex legal, technical and business issues.

**NIST-Facilitated Discussions on New Privacy Framework**

Ellen Nadeau – Deputy Manager, Privacy Framework, National Institute of Standards and Technology (NIST) – will brief Institute attendees on NIST’s development of a voluntary privacy framework as an enterprise risk management tool. Then, you can elect one or two of the designated breakout sessions to join active discussions facilitated by Ms. Nadeau, to advance the development of the framework.

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Sr. Director, Privacy Officer
Integrity and Compliance
HealthPartners
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MAI LEE YANG
DeWitt LLP
Minneapolis
8:15 – 8:50 a.m.
CHECK-IN & CONTINENTAL BREAKFAST

8:50 – 9:00 a.m.
WELCOME & INTRODUCTION

9:00 – 9:30 a.m.
2018-2019 ACA Litigation Review: Straining the Acronym Soup
The past year has been busy with Affordable Care Act (ACA) related litigation, with ongoing cases over the validity of the individual mandate, cost-sharing reductions, the risk adjustment program, association health plans, short-term plans, and more. This session will outline the key issues and status of the most important cases, helping practitioners distill down to the most critical potential impacts for clients and the system overall.
– Caitlyn Francois

9:30 – 10:30 a.m.
Healthcare Fraud and Abuse Update 2018-19: Notable Cases, Developments and Trends
This plenary session will highlight significant developments during the past 12 months, including trends in recent False Claims Act litigation and settlements, proposed changes to key fraud and abuse authorities, and enforcement priorities within the Department of Health and Human Services.
– Thomas Beimers

10:30 – 10:45 a.m.
BREAK

10:45 – 11:45 a.m.
Minnesota Agency Updates
Hear priorities and updates from Minnesota’s health law regulatory agencies, followed by panel Q&A covering additional insights and analysis of the current healthcare legal landscape.
– Attorney General Keith Ellison, Steve Kelley, Jan Malcolm & Stacie Weeks
– David M. Aafedt (moderator)

11:45 a.m. – 12:15 p.m.
DISTRIBUTION OF LUNCHES

12:15 – 1:00 p.m.
LUNCH PRESENTATION
Doctor Says…What Lawyers Can Learn in Conversation with Physician and Hospital Leaders
In this session, Paul Harris, Vice President & General Counsel of CentraCare, will facilitate an informative discussion among physicians and hospital leaders, designed to give useful, practical insight to how health lawyers can be more clear, efficient, and effective in their communication with clients and organizational leaders.
– Dr. Joseph M. Blonski, Dr. Cindy Firkins Smith & Dr. Thomas G. Schrup
– Paul R. Harris (moderator)

1:15 – 2:15 p.m.
BREAKOUT SESSION A

101 Provider Privacy Hotspots: Social Media, Proactive Monitoring, and Genetic Information
Expert insights on key privacy and data security issues being encountered – and on the horizon – for provider entities in the healthcare space. Topics will include social media breaches, medical device IoT security, genetic information privacy, and more. The panelists will share practical updates and tips for proactive, programmatic approaches for effective preparation and compliance.
– April Carlson

102 2019 Healthcare Litigation Update
This session will review recent caselaw developments relevant to health lawyers (including but not limited to litigation related to the Affordable Care Act), along with practical implications for your clients.
– Caitlyn Francois & Archana Nath

103 Responding to Government Audits: Specific Tips That Will Produce Better Outcomes for Your Client
There’s more than one right way to respond to specific issues that arise in government audits – and there’s more than one way to set up the roles that compliance and legal may play in determining those responses. That said, there are more effective ways than others to plan and execute an entity’s response to a government audit. This discussion will highlight concrete ways to improve how you work with a client – as between legal and compliance professionals – to respond to government audits, leaving you with practical take-aways and lessons learned. We will look at strategies for responding to real-life scenarios including determining whether and how to challenge the scope of the government’s data request; data collection protocols; documentation of the audit process; divvying up responsibilities between audit and legal functions; and more.
– Ann Beimdiek Kinsella & George Lyford

104 Ethical Considerations in Contract Drafting and Negotiation
1.0 ethics credit applied for
A real-world look at contract drafting and negotiation scenarios that generate legal ethics issues…and how to anticipate and handle them effectively and ethically.
– Susan M. Humiston, John Liethen & Mai Lee Yang

2:15 – 2:30 p.m.
BREAK

AUDIENCE SEGMENT KEY

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### 2:30 – 3:30 p.m.
**BREAKOUT SESSION B**

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| 201     | **Beyond the Basics: How to Handle Tough Breach Questions** | This session assumes a working knowledge of breach-response protocol. By way of real-world types of examples, this session will tackle specific, tough questions that privacy/security lawyers encounter including: does the notification clock start ticking when an incident is suspected but not confirmed; what to do if the incident plan isn’t working; and are there situations when proactively providing notice is a good idea (even if it is not required).  
- Mitchell W. Granberg & Anna Shimanek |
| 202     | **Healthcare Fraud and Abuse Outlook: Beyond the Update** | Expanding upon the morning plenary update session, this panel discussion will bring together diverse private practice and government perspectives to highlight the most important recent developments and trends related to fraud and abuse enforcement activity, leaving you with practical take-aways and lessons learned.  
- Joseph T. Dixon & Pamela A. Marentette  
- Thomas Beimers (moderator) |
| 203     | **Medicare Advantage and Part D Update** | An update on recent CMS changes to Medicare Advantage and Part D Plans and how those changes impact payer, provider, and pharma clients.  
- David O. Ault & Erin E. Weber |
| 204     | **Business Process Outsourcing Concepts for the Health Lawyer** | The session will provide an overview of key considerations in structuring and negotiating healthcare business process outsourcing agreements, including delegation of regulated activities, risk allocation, vendor oversight, audit rights, regulatory compliance, and more.  
- Frederik W. Struve |

### 3:45 – 4:45 p.m.
**BREAKOUT SESSION C**

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| 301     | **Beyond HIPAA: Health Industry Privacy and Security Update** | This essential update for the health law attorney covers new privacy and security developments beyond HIPAA enforcement. Topics will include GDPR, the California Consumer Privacy Act, and state law developments.  
- Ross C. D’Emanuele |
| 302     | **Device & Pharma Update: Navigating the Healthcare Landscape in Washington from Congress to the FDA** | Please join us for a session that will review key issues and initiatives relating to FDA’s regulation of therapeutic products, as well as recent and looming Congressional activity in the FDA space. Among other topics, this session will discuss Congressional and FDA initiatives in affordability, access, innovation, cybersecurity, diagnostic testing, safety, and pre/post-market surveillance.  
- Ralph F. Hall & Brent G. Elefson |
| 303     | **Smooth Sailing on Choppy Waters: Provider Integration in an Uncertain Environment** | There is no one “right way” to integrate and what works for one provider might not be the right fit for another. Physicians, hospitals and other providers bring a range of sometimes competing business needs and financial priorities to transactions and different perspectives on fair market value, all while operating in a complex regulatory and reimbursement environment. As the population ages and payment systems shift towards rewarding bundles of care, providers and their counsel sometimes struggle to understand available options. From management agreements, true joint ventures, coverage arrangements to full-fledged mergers, this session will walk through a range of integration models and discuss the pros and cons of various approaches.  
- Jennifer Reedstrom Bishop |

### 3:30 – 3:45 p.m.
**BREAK**

### 4:45 – 5:45 p.m.
**INSTITUTE RECEPTION**

Cap the day by sticking around for the annual Institute reception. Join your colleagues and friends in the health law bar for conversation and community!
8:50 – 11:00 a.m. PLENARY SESSIONS

8:15 – 8:50 a.m.
CONTINENTAL BREAKFAST

8:50 – 9:00 a.m.
WELCOME & INTRODUCTION

9:00 – 9:30 a.m.
2019 Minnesota Legislative Session
An essential update for the Minnesota health lawyer, addressing developments from the 2019 Minnesota legislative session of importance to the health industry and its patient consumers.
– Phil Griffin

9:30 – 10:30 a.m.
2019 HIPAA Privacy and Security Enforcement Update
Steve Mitchell, the Acting Midwest Regional Manager for the HHS Office for Civil Rights, will report on major HIPAA enforcement cases that HHS OCR has concluded and made public over the past 12 months. In addition, he will provide an update on other privacy and security developments out of HHS.
– Steven M. Mitchell

10:30 – 11:00 a.m.
Brief on New NIST Privacy Framework Development
Ellen Nadeau – Deputy Manager, Privacy Framework, National Institute of Standards and Technology (NIST) – will brief Institute attendees on NIST’s development of a voluntary privacy framework as an enterprise risk management tool. Learn what to expect from the new Privacy Framework – targeted for release later in 2019 – and how it could benefit your organization and clients.
– Ellen Nadeau

11:00 – 11:15 a.m.
BREAK

11:15 a.m. – 12:15 p.m. BREAKOUT SESSION D

401
NIST-Facilitated Discussion to Get Your Input on the New Privacy Framework – Topic #1
Ellen Nadeau – Deputy Manager, Privacy Framework, National Institute of Standards and Technology (NIST) – will be this session’s discussion group leader. Institute attendees are invited to actively engage in facilitated discussion to advance the development of the new Privacy Framework. NIST will use the breakout session’s input to validate or adjust the discussion draft of the Privacy Framework, to support the next stage of development of the framework. Additional information about the particular breakout session topic for this session will be shared closer to the event.
– Ellen Nadeau

402
Tracking the Elusive Unicorn: How to find the Win-Win-Win in Value-Based Contracting
Value and outcomes based reimbursement is here to stay, even though providers and payors sometimes struggle to operationalize programs in a way that can achieve the goals of the Triple Aim. This session will provide a comprehensive exploration of important considerations for successful value-based contracting: the drivers of value-based contracts from both governmental and policy perspectives; an overview of key CMS and CMMI reimbursement programs; legal considerations within the four-corners of the deal documents; strategies for addressing Stark Law and other regulatory matters that arise in value-based arrangements; practical tips on negotiations with private plan and public programs; and more.
– Jesse A. Berg & Santo Cruz

403
Electronic Health Record: Contracting Data Security
The world of medical records is mostly an electronic one, and along with those records systems come complicated contracts and data security worries. Briar and Steve will discuss some of the most important contracting issues, ways that you and your clients can protect from some of the most common problems, tactics to manage risk in the electronic world – and what to keep your eye on with respect to newly proposed interoperability rules from HHS.
– Briar A. Andresen & Steven E. Helland

404
21st Century Healthcare – Telemedicine: Navigating the Legal Challenges of Licensing, Scope of Practice and Standard of Care
With over 70% of providers now utilizing some form of telemedicine in their practice, and 75% of patients willing to attend a doctor’s appointment by video, there is no question that telemedicine is here to stay. Like any other developing area, however, there are legal risks and traps for the unwary. This presentation will cover the major types of telemedicine and their potential legal pitfalls with respect to licensing, scope of practice and standard of care – and how to best anticipate and handle those evolving legal issues.
– Paul R. Harris & Katherine B. Ilten

12:15 – 1:15 p.m.
LUNCH (on your own)
BREAKOUT SESSION E

501 NIST-Facilitated Discussion to Get Your Input on the New Privacy Framework – Topic #2
This is not a repeat of the facilitated discussion from the previous session, #401. In this session, Institute attendees are invited to actively engage in a NIST-facilitated discussion about a different topic related to the new Privacy Framework. The specific topic for this session will be shared closer to the event. NIST will use the breakout sessions’ input to validate or adjust the discussion draft of the Privacy Framework, to support the next stage of development of the framework.
– Ellen Nadeau

502 New and Emerging Benefit Models: How to Get to Implementation Beyond the Regulatory Chaos
What benefits must or may healthcare plans provide now and in the future? It sounds like a straightforward question to answer, but the near-day developments regarding the Affordable Care Act (ACA) over the past two-plus years have left uncertainty on many fronts. This session will detail new and innovative efforts from health insurers, employers, and associations, in response to legal and regulatory changes in the ACA and other laws. How can coverage be offered through an Association Health Plan? In what ways can short-term coverage be structured to comply with the ACA and state laws? Which other ACA-related uncertainties most challenge and inspire the creation, negotiation, and implementation of new benefit models? And how are industry players successfully tackling these uncertainties to craft truly workable and effective models?
– Jason K. Englehart & Paul A. Sand

503 Hot Topics for Medical Staff Leaders and Counsel Who Advise Them
The medical staff plays a critical and evolving role in a hospital’s efficient delivery of quality care. This session will discuss incorporating recently issued state and federal opioid prescribing guidelines into medical staff quality standards, applying opioid addiction treatment best practices to impaired practitioners, issues and strategies in incorporating advanced practice professionals as part of and alongside the medical staff, and the latest updates to the NPDB Guidebook.
– Mary Foarde & Laura J. Nelson

See Session #501.

BREAKOUT SESSION F

601 Drug Price Policy and Other Key Developments Affecting Drug Costs
This session will highlight some of the more impactful current federal and state drug price policy actions (and proposed actions) and explore how these changes could reshape the prescription drug distribution industry: Will drug costs go down if rebates are eliminated entirely? Who would benefit (or not) from government ‘negotiation’ for drug prices or from drug price controls? Will drug price or cost transparency result in lower prices (and for whom)? We will discuss these questions and other possible implications from the rapidly changing drug price policy landscape.
– Tricia A. Beckmann & Jay A. Warmuth

602 Reps & Warranties in Healthcare Industry Transactions
Healthcare transactions can subject the parties to regulatory risks that are fundamentally different from those the parties have seen before. Well-drafted representations and warranties are a key method of managing these risks. This session explores how such representations and warranties (regarding government programs, privacy and security, medical device regulation, and other areas) can protect your clients.
– Kari Bomash & Jill R. Radloff

603 The Future Is Now: Emerging Issues with Digital Therapeutics
Evidence-based digital therapeutics offer potential to improve health care quality, outcomes, and value through the use of advanced technology and data-driven interventions. This session will provide an overview of the technology and associated legal/regulatory issues, including the interfaces with FDA, FTC, privacy and security, fraud and abuse, reimbursement aspects, and more.
– Ryan S. Johnson

CONCLUDING PLENARY

1.0 elimination of bias credit applied for
James C. Burroughs II is Chief Equity and Inclusion Officer at Children’s Minnesota. In that role, he is responsible for developing, implementing, and advocating for a comprehensive health equity, inclusion and diversity strategy. Mr. Burroughs has more than 25 years of experience in the areas of non-profit management, diversity and inclusion, and employment law. He has helped both for- and non-profit organizations develop workplace diversity and inclusion training, policies and procedures that promote hiring and retention of employees of color, and partnerships with communities of color and other diverse communities. This session will offer his key values and learnings in approaching this work – applicable to healthcare, the roles lawyers play in the healthcare system, and the legal profession.
– James C. Burroughs

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The 2019 HEALTH LAW INSTITUTE

Wednesday & Thursday, June 19 & 20, 2019
Minnesota CLE Conference Center, Minneapolis

DATE & LOCATION

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If you have a disability and need an accommodation in order to attend this seminar, please contact us as soon as possible. Contact Minnesota CLE at 2550 University Avenue West, Suite 160-S, Saint Paul, MN 55114 or call us at 651-227-8266 or 800-759-8840.

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