The 2018

Health Law Institute



Expert PerspectivesThat Will Help <u>You</u> Help
Your Clients

33 Sessions Providing
Real-World Advice and
Practice Tips

Distilled, Actionable, Forward-Looking Content

8:45 - 11:45 a.m. **MORNING PLENARY SESSIONS**



8:00 - 8:40 a.m. CHECK-IN & CONTINENTAL BREAKFAST

8:40 - 8:45 a.m. WELCOME & INTRODUCTION

8·45 - 9·45 a m

ACA Update – A Look at the Tax Repeal, the New Republican AG Lawsuit, and Congressional and Administrative Actions Taken to Unwind the ACA

Hon. Earl Pomeroy & Timothy P. Trysla

9:45 - 10:30 a.m.

Healthcare Fraud and Abuse Update 2017-18: Notable Cases, Developments and Trends

Tony Maida

BREAK 10:30 - 10:45 a.m.

10:45 - 11:45 a.m.

Human Services, Health, and Commerce: Minnesota Agency Update Snapshot

Commissioner Jessica Looman, David Orren. Commissioner Emily Johnson Piper & David M. Aafedt, moderator

11:45 a.m. - 12:15 p.m. BREAK & DISTRIBUTION OF BOXED LUNCHES Lunch provided to all attendees

12:15 - 1:00 p.m. WORKING LUNCH SESSION



Precision Medicine – What Every Health Lawyer Needs to Know

Sharon C. Zehe

1:00 - 1:15 p.m. **BREAK**

9:00 - 11:00 a.m. **MORNING PLENARY SESSIONS**









WELCOME & INTRODUCTION 8:55 - 9:00 a.m.

9:00 - 10:00 a.m.

Deadliest Enemy: Our War Against Killer Germs & the Legal Issues That Follow Michael T. Osterholm, PhD, MPH

10:00 - 11:00 a.m.

HIPAA Privacy and Security Enforcement Update

Angie Atkinson (invited)

11:00 - 11:15 a.m. **BREAK**

AUDIENCE SEGMENT KEY







Med/Pharma Payer Provider

1:15 - 2:15 p.m. **BREAKOUT SESSION A**

Legislative & Case Update

2018 Healthcare Litigation Update

Jonathan W. Dettman & William L. Roberts

Device & Drug Developments

Device & Pharma Update – Navigating the Healthcare Landscape in Washington from Congress to the FDA

Ralph F. Hall

Telemedicine

21st Century Healthcare – Telemedicine: Navigating the Legal Challenges of Licensing, Scope of Practice and Standard of Care

Meghan L. DesLauriers & Paul R. Harris

Fraud & Abuse

Utilization Management in the Crosshairs

Stephen K. Warch

Navigating the Requirements for Email and Text Messages in Healthcare

Emily E. Duke & Melissa Krasnow

Attendance for this advanced, small-group discussion is limited to 15, on a "first to arrive at the classroom" basis

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

ivacy & Data Security

HIPAA De-Identification - How to Protect **Data Privacy and Preserve Data Utility** Daniel C. Barth-Jones, MPH, PhD





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Business

Value-Based Reimbursement: Where Are We Going (and Where Are We Now)?

Jesse A. Berg

Developments

The Religious-Objection Protection for Healthcare Workers

Penelope J. Phillips

Reps & Warranties in Healthcare Industry

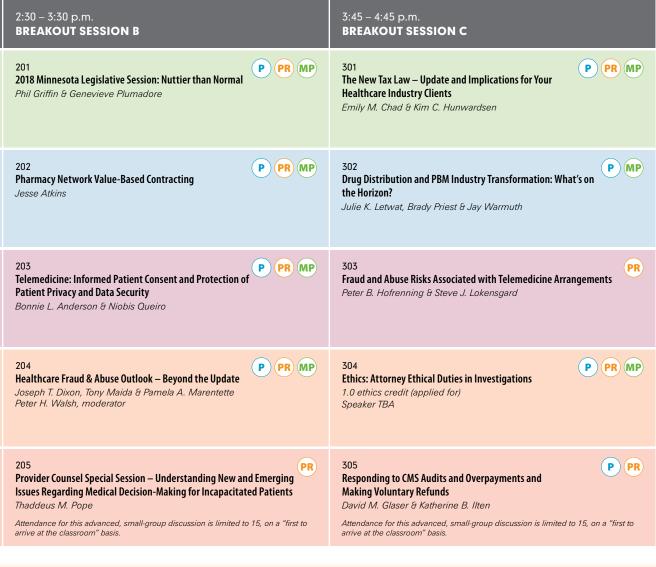


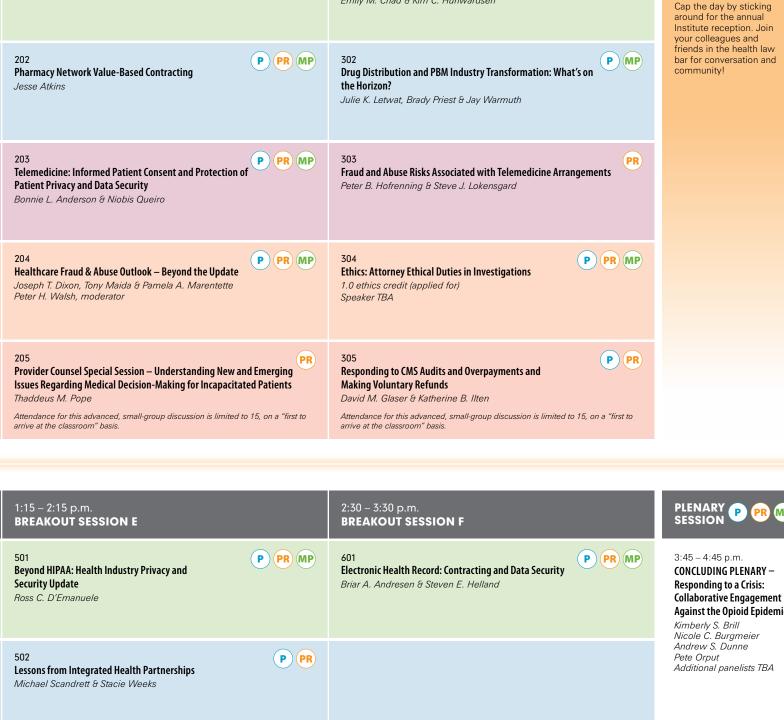




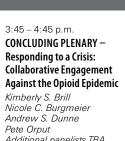
Transactions

Jason K. Engelhart & Jill R. Radloff









INSTITUTE

RECEPTION

4:45 - 6:00 p.m.

Reception

CHEERS! Institute

WEDNESDAY, JUNE 13

8:45 - 9:45 a.m.



ACA Update—A Look at the Tax Repeal, the New Republican AG Lawsuit, and Congressional and Administrative Actions Taken to Unwind the ACA

Former U.S. Representative Earl Pomeroy served as a Member of Congress for 18 years, as well as a state insurance commissioner and president of the National Association of Insurance Commissioners. Timothy Trysla served as a Senior Policy Advisor at the Centers for Medicare and Medicaid Services from October 2001 through March 2005. Now with Alston & Bird LLP in its Washington, D.C. office, they kick off the 2018 Institute with your critical ACA update.

Hon. Earl Pomeroy & Timothy P. Trysla

9:45 - 10:30 a.m.





Healthcare Fraud and Abuse Update 2017-18: **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, Department of Justice policy memos, the emerging fraud and abuse response to the opioid crisis, and new developments at the Centers for Medicare and Medicaid Services.

Tony Maida

10:30 - 10:45 a m

BRFAK

10:45 - 11:45 a.m.





Human Services, Health, and Commerce: Minnesota Agency Update Snapshot Panel

Hear priorities and updates from the leadership of Minnesota's health law regulatory agencies, followed by panel Q&A covering additional insights and analysis of the current healthcare legal landscape.

Commissioner Jessica Looman, David Orren & Commissioner Emily Johnson Piper David M. Aafedt, moderator

11:45 a.m. - 12:15 p.m. BREAK & DISTRIBUTION OF BOXED LUNCHES Lunch provided to all attendees

12·15 – 1·00 n m







WORKING LUNCH SESSION:

Precision Medicine – What Every Health Lawyer Needs to Know

Many legal barriers face providers and researchers in precision medicine initiatives: (1) how to navigate research and privacy protections to use the data gathered; (2) how to provide affordable testing for patients without running afoul of fraud and abuse laws; (3) how to use results responsibly as the data evolves; and (4) discrimination. This presentation covers the legal issues surrounding these four areas, with advice on how to avoid missteps from a provider perspective. Your presenter, Sharon Zehe, is an attorney in Mayo Clinic's Legal Department, supporting Mayo Clinic's Center for Individualized Medicine, the Department of Laboratory Medicine and Pathology, and Mayo Medical Laboratories. She also serves as the vice president of business affairs for Mayo Medical Laboratories. Sharon C. Zehe

1:00 - 1:15 p.m.

BREAK

1:15 - 2:15 p.m. **BREAKOUT SESSION A**

2018 Healthcare Litigation Update

This session will review recent caselaw developments relevant to health lawyers, including particular focus on current litigation surrounding cost-sharing reduction (CSR) subsidy payments under Section 1402 of the Affordable Care Act (ACA) and the cessation of payments under the ACA Risk Corridors program, along with practical implications for your clients

Jonathan W. Dettmann & William L. Roberts

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, recent and looming Congressional activity in the FDA space and a broad review of the overall healthcare landscape in this election year. Ralph Hall spends substantial time working with the FDA and Congress on new regulatory initiatives, has many years of experience as a healthcare law practitioner and teaches at the University of Minnesota. Among other topics, this session will discuss Congressional and FDA initiatives in cybersecurity, diagnostic testing, device safety and pre/post-market surveillance

Ralph F Hall

MP

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.

Meghan L. DesLauriers & Paul R. Harris

Utilization Management in the Crosshairs

Utilization management is an important cost and quality mechanism for health plans, but it is heavily regulated, and presents complex legal and compliance risks. This session will outline the primary risk areas for plans and other entities that conduct UM, UM practices that have recently come under regulatory scrutiny, and what we might see trending forward in terms of practical lessons and best practices. Stephen K. Warch







Navigating the Requirements for Email and Text Messages in Healthcare

Through interactive discussion and dialogue, this session will cover the requirements for email and text messages under the CAN-SPAM Act and Telephone Consumer Protection Act, respectively; how they intersect with HIPAA; issues that can arise; and approaches to addressing these requirements.

Emily E. Duke & Melissa Krasnow

Attendance for this advanced, small-group discussion is limited to 15, on a "first to arrive at the classroom" basis.

BREAK

2:15 - 2:30 p.m.

2:30 - 3:30 p.m. **BREAKOUT SESSION B**





2018 Minnesota Legislative Session: Nuttier than

An essential update for the Minnesota health lawyer, addressing developments from the 2018 Minnesota legislative session of importance to the health industry and its patient consumers.

Phil Griffin & Genevieve Plumadore

Pharmacy Network Value-Based Contracting

Jesse Atkins & Elisa Y. Muller









Patient Privacy and Data Security A practical discussion of two key compliance elements of any telemedicine offering: (1) informed patient consent; and (2) patient privacy and data security. Co-presented by HCMC's Information Security and Privacy Director and its Vice President, Revenue Cycle Management, this presentation will cover the legal and other important considerations in building an effective system that secures informed consent and

Bonnie L. Anderson & Niobis Queiro





PR MP

Healthcare Fraud and Abuse Outlook – Beyond the Update

protects privacy and security for the major types of telemedicine.

Telemedicine: Informed Patient Consent and Protection of

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, Tony Maida & Pamela A. Marentette Peter H. Walsh, moderator

205



Provider Counsel Special Session – Understanding New and Emerging Issues Regarding Medical Decision-Making for Incapacitated Patients

This is a highly interactive, small-group, advanced breakout discussion. We will address new and emerging issues regarding medical decision-making for incapacitated patients. We will place particular emphasis on two growing trends: (1) advance healthcare directives for receiving oral foods and fluids in dementia and (2) the growing population of unbefriended patients with no available surrogate decision maker. In the absence of affirmative legislative or judicial guidance on these issues, providers must develop institutional policies that balance patient rights and patient safety.

Thaddeus M. Pope

Attendance for this advanced, small-group discussion is limited to 15, on a "first to arrive at the classroom" basis

3:30 - 3:45 p.m. BRFAK

3:45 - 4:45 p.m. **BREAKOUT SESSION C**





The New Tax Law – Update and Implications for Your Healthcare **Industry Clients**

Learn about the sweeping new federal tax law and the key impacts on your healthcare industry clients - both for-profit companies and non-profit entities.

Emily M. Chad & Kim C. Hunwardsen





Drug Distribution and PBM Industry Transformation: What's on the

Two recently announced healthcare mergers and other well-publicized business ventures have the capacity to transform the drug distribution and pharmacy benefits industries. If completed, CVS/Aetna and Cigna/ESI would rapidly accelerate the vertical alignment of the drug distribution industry and result in the affiliation of effectively all major PBMs with a health plan. Other high-profile changes in this sector, such as Amazon's entry into the pharmacy arena and new business partnerships focusing on containing drug costs, add to the transformation that is occurring in the drug distribution industry today. This session will tackle some of the complexity behind these transactions and the rapidly changing drug distribution and PBM environment, as well as potential implications for health lawyers and clients across the care spectrum.

Mike Kolar, Julie K. Letwat, Brady Priest & Jay A. Warmuth



Fraud and Abuse Risks Associated with Telemedicine Arrangements

In this session we will discuss the impact of the Stark Law and Anti-Kickback Statute on various arrangements with hospitals, physician clinics, and other referral sources in the context of a telemedicine consult. We will also address unlawful patient inducement issues associated with telemedicine, and review limitations on the prescription of controlled substances stemming from a telemedicine visit.

Peter B. Hofrenning & Steve J. Lokensgard

Extensive, Practical Coverage of the Critical Issues You **Deal With Every Day!**

Ethics: Attorney Ethical Duties in Investigations



1.0 ethics credit applied for Marnie E. Fearon & Amanda M. Sicoli



Responding to CMS Audits and Overpayments and Making Voluntary Refunds

Discuss useful legal arguments for responding to overpayment allegations; how to streamline your appeal process; avoiding common mistakes in refund letters that can inadvertently increase your liability; and why you do NOT need to refund every time you find missing documentation or a missing signature.

David M. Glaser & Katherine B. Ilten

Attendance for this advanced, small-group discussion is limited to 15, on a "first to arrive at the classroom" basis.

4:45 - 6:00 p.m.

CHEERS! 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!

THURSDAY, JUNE 14

9:00 - 10:00 a.m.





Deadliest Enemy: Our War Against Killer Germs & the Legal Issues That Follow

"There has never been a time in history when the challenges to controlling and preventing the global spread of infectious disease has ever been this daunting," says infectious disease expert Michael Osterholm, discussing his new book, Deadliest Enemy: Our War Against Killer Germs. In this presentation, Dr. Osterholm will discuss the formidable public health issues that result from these challenges. He also will identify important legal issues generated by this complex landscape.

Michael T. Osterholm, PhD, MPH

10:00 - 11:00 a.m.





HIPAA Privacy and Security Enforcement Update

Angie Atkinson, the Regional Civil Rights Counsel for the U.S. Department of Health and Human Services with responsibility for HIPAA matters in the Office for Civil Rights' Midwest Region, will report on current trends in HIPAA enforcement. She will also provide insight into recurrent privacy, security and breach notification compliance issues OCR encounters, and best practices to avoid them.

Angie Atkinson (invited)

11:00 - 11:15 a.m.

BREAK

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





HIPAA De-Identification – How to Protect Data **Privacy and Preserve Data Utility**

Daniel Barth-Jones, PhD, specializes in providing HIPAA Privacy Rule compliant Expert Determinations of statistical de-identification, providing statistical disclosure analytic and control solutions for the healthcare information, healthcare management and pharmaceutical industries. His consulting clients have included Federal and State Agencies, State and National Hospital Associations, Commercial Healthcare and Healthcare Information Companies, Electronic Medical Records Technology Firms, Actuarial Firms, and Pharmaceutical/ Biotechnology Corporations. Dr. Barth-Jones will tailor this practical session to legal counsel, with a "plain English" introduction to the basics of statistical disclosure risk analysis (primarily for healthcare microdata): data intrusion scenarios, the importance of both sample and population uniqueness, record linkage methods, formulations of re-identification risks, and the appropriate use of HIPAA limited data sets. Attendees will leave able to understand and manage statistical de-identification for data sets under the HIPAA requirements while preserving analytic utility and to work more successfully with statistical de-identification data privacy professionals.

Daniel C. Barth-Jones, MPH, PhD

PR

Value-Based Reimbursement: Where Are We Going (and Where Are We Now)?

The transition from the Obama to Trump administrations has resulted in less emphasis on value (or quality-based) reimbursement. At the same time, however, the global shift in the healthcare industry away from fee-for-service payment and towards rewarding outcomes seems here to stay. These competing tensions have sewn confusion among healthcare providers and have made planning and collaboration difficult. This session will explore the current status of Medicare's value-based programs, discuss strategies for complying with the Stark Law, Anti-Kickback Statute and other key fraud and abuse principles in this unsettled area and review where CMS and HHS seem to be taking these payment models

Jesse A. Berg



The Religious-Objection Protection for Healthcare Workers

An experienced employment attorney teaches this practical session on the religious-objection protection for healthcare workers - the current legal landscape regarding this protection, scope and limits, and challenges (and best practices) for providers when they are faced with a religious objection from one of their workers who does not want to provide healthcare in certain circumstances. Among the new developments are a new HHS Division of Conscience and Religious Freedom

Penelope J. Phillips

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. Jason K. Engelhart & Jill R. Radloff

12:15 - 1:15 p.m. LUNCH (on your own)

1:15 - 2:15 p.m. **BREAKOUT SESSION E**







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 and other global privacy and security laws, state law developments, NAIC model laws, and FTC enforcement actions.

Ross C. D'Emanuele

502

Lessons from Integrated Health Partnerships



Minnesota's Integrated Health Partnership Program strives to deliver higher quality and lower cost healthcare through innovative approaches to care and payment. This session will outline the status and future directions of the program, legal issues and potential barriers, and practical considerations for all stakeholders in the healthcare system.

Michael Scandrett & Stacie Weeks

503







Sexual Harassment Compliance and the

Recent and very public instances of sexual harassment have led many organizations to look closely at existing policies and compliance initiatives. This session will evaluate and provide practical perspective on the common questions arising:

- How has the #metoo era impacted how we view sexual harassment?
- How can you ensure your compliance program is sufficient ?
- · How can compliance and attorneys work most effectively to address sexual harassment complaints?

Miaja Cassidy & Sandra L. Jezierski



Medical Office Real Estate Transactions: Tips and Traps for **Healthcare Attorneys**

A presentation focused on tips and traps relating to real estate transactions, tailored for healthcare lawyers. Focusing on purchasing and leasing of medical office properties, this session will be a good refresher for healthcare lawyers who are occasionally asked to advise on real estate transactions for their healthcare provider clients

Tyler J. Adams & Zachary J. Crain

2:15 - 2:30 p.m. **BREAK**

2:30 - 3:30 p.m. **BREAKOUT SESSION F**







Electronic Health Record: Contracting and Data

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, and tactics to manage risk in the electronic world.

Briar A. Andresen & Steven F. Helland

2018 Nursing Home and Assisted Living Update

A critical Legislative Auditor report and news stories regarding the Minnesota Department of Health's failure to investigate reports from nursing home and home care providers, as well as residents and families, have resulted in the Minnesota legislature responding with several bills. This presentation will provide an update on new laws ultimately passed, as well as analysis of current questions and issues that may remain, relating to investigations, enforcement, family oversight like "granny cams," and best practices for skilled nursing facility and assisted living facility stakeholders.

Ryan J. Burt & Mai Lee Yang





Fair Market Value in Healthcare Transactions: Advanced and **Nuanced Issues**

Healthcare transactions are subject to heightened and rigid scrutiny under the patchwork of healthcare fraud and abuse laws and tax law regulations that may apply. This session will give the legal and regulatory context for need for fair market value (FMV) and commercial reasonableness (CR) analysis and opinions; summarize the basic concepts and definitions of FMV and CR, comparing and contrasting the FMV and CR standards; review recent enforcement actions involving compliance with FMV and CR requirements; and, using real examples, provide perspectives on the roles of the attorney and valuator when evaluating FMV and CR.

Jennifer Reedstrom Bishop & Mary Heymans

3:30 - 3:45 p.m.

BRFAK

3:45 - 4:45 p.m.





Concluding Plenary Session –

Responding to a Crisis: Collaborative Engagement Against the Opioid **Epidemic**

Every day in the US:

- More than 650,000 opioid prescriptions are dispensed
- 3,900 people initiate nonmedical use of prescription opioids
- 580 people initiate heroin use
- 91 people die from opioid overdoses

These numbers represent crisis-level impacts across our systems, communities, and families. As health lawyers, it's important to understand the current legal and policy dimensions that impact your clients as stakeholders and providers of care, services, and substances within the system. This panel will evaluate the broad impacts and current efforts in abating the epidemic, with perspectives on criminal justice, medical professional licensure, health systems policies and procedures, product regulation, employment and litigation.

Kimberly S. Brill, Nicole C. Burgmeier, Andrew S. Dunne, Pete Orput & Additional panelists TBA

REGISTER TODAY!

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FACULTY & PLANNERS

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Nilan Johnson Lewis PA Minneapolis

David M. Aafedt

Winthrop and Weinstine, P.A. Minneanolis

Bonnie L. Anderson Information Security and Privacy

Director Hennepin Healthcare System Minneapolis

+ Briar A. Andresen

Fredrikson & Byron, P.A. Minneapolis

Jesse Atkins

Legal Counsel Prime Therapeutics

Angie Atkinson (invited)

Civil Rights Attorney, Midwest US HHS Office of the General

Counsel Kansas City, Missouri

Daniel C. Barth-Jones, MPH, PhD

Assistant Professor of Clinical Epidemiology Mailman School of Public Health Columbia University New York, New York

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Gray Plant Mooty Minneapolis

Jennifer Reedstrom Bishop

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Kimberly S. Brill

Group Supervisor, Diversion **Drug Enforcement Administration** Minneapolis

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Chief Compliance Officer North Memorial Health Care Minneapolis

Nicole C. Burgmeier

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Washington County Attorney Stillwater

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Felhaber Larson Minneapolis

Emily Johnson Piper

Minnesota Department of Human Saint Paul

Genevieve Plumadore

Director of State Relations University Relations University of Minnesota

Minneapolis Hon. Earl Pomeroy

Washington, D.C.

Thaddeus M. Pope

Director of the Health Law Institute Mitchell Hamline School of Law Saint Paul

Brady Priest

General Counsel Clover Health Minneapolis

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Vice President of Revenue Cycle Management Hennepin Healthcare System

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William L. Roberts

Faegre Baker Daniels LLP

Michael Scandrett

MS Strategies Minneapolis

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Stacie Weeks

Director of Public Policy and Advocacy Hennepin Healthcare

Minneapolis Mai Lee Yang

DeWitt Mackall Crounse & Moore S.C.

Minneapolis Sharon C. Zehe

Vice President – Business Affairs, Mayo Medical Laboratories Legal Counsel, Mayo Clinic

+ Planner

COURSE INFORMATION

DATE & LOCATION

Wednesday & Thursday June 13 & 14, 2018 Minnesota CLE Conference Center 600 Nicollet Mall, Suite 370 Third Floor City Center, Minneapolis

CREDITS – HEALTH LAW INSTITUTE

Minnesota CLE is applying to the Minnesota State Board of CLE for 12.5 CLE credits. This total includes 1.0 ethics credit for attendees of session #304. The maximum number of total credits attendees may claim for this course is 12.5 credits.

CANCELLATION / NO-SHOW POLICY

Paid registrants who cancel their registration at least 3 business days before the program will receive a full credit on their account; if fewer than 3 business days a \$25 administrative fee will be deducted. Paid registrants who do not cancel, yet fail to attend, will receive access to the electronic session materials. Passholders may purchase the materials at 50% of the full retail price.

ACCOMMODATION

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

COURSE MATERIALS

All Institute session materials will be available online at www.minncle.org before and after the course. At the seminar you will receive hardcopy materials for the plenary sessions and for breakout sessions you attend.

SCHOLARSHIPS AVAILABLE

Minnesota CLE maintains a scholarship program for those individuals with a financial need. Most scholarships awarded are 50% off the seminar price. To obtain a scholarship application, contact Grant at 651-254-2111 or gdavies@minncle.org.

QUESTIONS?

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View information on your mobile device or register online.



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The 2018

Health Law Institute

June 13 & 14, 2018 • Minnesota CLE Conference Center

PLE	ASE "	√" AP	PROP	RIATE	BOX:

☐ \$545 MSBA member

☐ \$545 paralegal

☐ \$645 standard

☐ NEW LAWYER DISCOUNT!

I was first admitted to the bar after June 13, 2015, and have deducted \$60 from the tuition marked above.

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Can't attend? You can still get the program materials!

The **electronic version of the session materials** will be available online for \$95 (plus tax). Please visit www.minncle.org after the seminar to purchase.

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