

# The 2011 Health Law Institute

Thursday & Friday, June 9 & 10, 2011  
Minnesota CLE Conference Center  
Seventh Street & Nicollet Mall  
Minneapolis, Minnesota



*Co-Sponsored by Minnesota CLE,  
the MSBA Health Law Section, the  
MSBA Food & Drug Law Section,  
and LifeScience Alley®*

*Extensive  
Coverage of  
NEW State  
and Federal  
Developments*

*Outstanding  
Faculty  
Including:*



**Commissioner Lucinda Jesson**  
Minnesota Department of Human Services



**Commissioner Mike Rothman**  
Minnesota Department of Commerce

# The Institute Keeps You Latest Developments, and Forecasts.

## It's Another Big Year for Health Law Changes. The Institute Provides Critical Information, Analysis and Practical Insight on those Important Developments.

The Institute is the easiest way to make sure that you know about all the new developments in major areas of health care law and litigation, whether it's new cases, new legislation or new regulations. In the plenary sessions, Minnesota DHS Commissioner Lucinda Jesson will discuss that Department's work with respect to federal and state legislation aimed at health reform. Commissioner Mike Rothman of the Minnesota Department of Commerce will update you on Minnesota's health insurance exchange planning. In the conference plenaries, you'll also get updates on the federal court cases on the constitutionality of the individual mandate in the Affordable Care Act, data privacy and security, and fraud and abuse. *And that's just for starters!*

## You Choose from 20 Breakout Session Titles to Create a Personalized Program Line-Up that Fits Your Practice.

Everyone comes with differing education needs. That's why we've created a conference that lets you choose the sessions most relevant and important to you. From start to finish, your custom-tailored Institute schedule promises to be jam-packed with topics you care about. With so many sessions to choose from, we help guide you to relevant programming by labeling tracks such as "Patient Care," "Provider," "Payor," "Med Device/Pharma" and "Ethics/Elimination of Bias." But you're the boss – feel free to select sessions from any track at the Institute. In addition, you'll receive materials from every session – both those you attend and those you do not – all in the Institute Course Manual in a searchable CD-ROM format.

## Learn from, and Compare Your Practices with, the Institute Speakers – Experienced Attorneys from Government, Private Practice and the Health Care Industry.

Check out the speaker roster and you'll see that the Institute has gathered a tremendous faculty for this year's program. They are preparing to teach you the latest legal developments and "how to" tips – all in the context of today's incredibly dynamic health care scene. Take advantage of these two days to discuss and ask questions of others who are doing the same work as you do. You'll learn better and easier ways to do things more effectively, and new strategies to employ. Don't miss this once-a-year chance to review your professional practices.

## Check Out the Ethics and Elimination of Bias Sessions Available at the Institute.

The Institute offers breakout sessions so that you can obtain ethics and elimination of bias credits. This is a good time to secure some of the special credits needed for your reporting requirements. On Thursday, your breakout session choices include a 1.0 credit (applied for) ethics session, "Responding to a 'Bet the Company' Crisis: A Compliance, Ethics and Privilege Hypothetical." And on Friday, you may select the 2.0 credit (applied for) elimination of bias session, "Mental Health and Chemical Dependency Issues in the Legal Profession."

# on Top of the Strategies

## *The Institute's Mix of Plenary and Breakout Topics Will Include the Latest on:*

### **The Time- and Research-Saving Course Materials Come on a Fully Searchable CD-ROM.**

In addition to the valuable insights you'll gain in the session presentations at the event, you also will leave with a helpful course manual covering issues, new developments and practice tips presented at the conference. You'll receive this course manual on a fully searchable CD-ROM. In addition, at each session you attend, you'll receive a set of materials in hard-copy form so that you can follow along and take notes. It's the best of both worlds – electronic and "old school."

### **This Conference Allows for Networking and Relationship Building at Its Best!**

Clients and potential clients will be there. So too colleagues and old friends to catch up with. The Institute provides a fun and relaxed conference setting in which to network. You'll have plenty of time to visit with friends, clients, potential clients and other colleagues throughout the two days – at the Institute luncheon, reception and between sessions.

- Minnesota-specific developments related to Medicaid expansion, payment reform pilots, the electronic health records incentive program, and health exchange planning
- The challenges to the constitutionality of the individual mandate
- HITECH rulemaking, state data breach laws, the *IMS v. Sorrell* case, and other recent data privacy and security developments
- Accountable Care Organizations
- Medical malpractice reform
- Health care antitrust cases, trends and enforcement policy
- Disclosure protocols regarding Stark and potential kickback violations
- Managed care litigation
- Document cleanup strategy
- Recent changes in FDA, DOJ and OIG enforcement initiatives and prosecutions related to the medical device and pharmaceutical industries
- Quality and value measurement
- Employment, reporting and patient safety issues arising from nurse misconduct
- Wellness programs
- Complying with the Physicians Payments Sunshine Act
- Legal benefits of rethinking what device companies actually sell

*And more!*

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## PLENARY SESSIONS

8:00 – 8:35 a.m.

REGISTRATION & CONTINENTAL BREAKFAST

8:35 – 8:45 a.m.

WELCOME & INTRODUCTION

8:45 – 9:30 a.m.

### Implementing Health Reform, Instituting Other Initiatives and Handling Budget Constraints

Information and insights from Commissioner Lucinda Jesson about the Minnesota Department of Health and Human Services' work with respect to federal and state legislation aimed at health reform. An overview of significant changes, Department directions and initiatives, and more. Topics will include updates on Medicaid expansion, payment reform pilots, the electronic health records incentive program, and coordinated work with the Department of Commerce on insurance exchange development.

– *Lucinda E. Jesson*

9:30 – 10:00 a.m.

### New Health Insurance Exchange Planning – An Update from the Minnesota Department of Commerce

Commissioner Mike Rothman gives you the latest information about Minnesota's health insurance exchange planning pursuant to the federal health care reform legislation.

– *Mike Rothman*

10:00 – 10:30 a.m.

### Split Decisions: A Review of the Federal Court Cases on the Constitutionality of the Individual Mandate in the Affordable Care Act

Perhaps the most contentious part of the Affordable Care Act is the individual mandate: the requirement that everybody buy a health insurance policy. So far, the federal decisions regarding the constitutionality of the mandate are split and the issue is almost certainly heading to the U.S. Supreme Court. If you're trying to keep score at home, this session will provide an overview of the various decisions and an analysis of the constitutional issues.

– *James P. Jacobson*

10:30 – 10:45 a.m.

BREAK

10:45 – 11:45 A.M.

## BREAKOUT SESSION A

### PATIENT CARE

#### 1. Why Should a Health Lawyer Care if Proposed Medical Malpractice Reform Hurts Trial Lawyers and Muzzles the Jury?

A discussion of tort reform measures, enacted and proposed, and analysis of the public policy goals that do or should guide changes to our system of justice. The faculty brings years of collective experience representing health care providers and insured patients to the table and will give you the latest on tort reform issues, quality assurance initiatives, and trends.

- *David C. Hutchinson*
- *Brandon E. Vaughn*
- *Terry L. Wade*
- *John E. Diehl, moderator*

### PROVIDERS

#### 2. Beyond the Affordable Care Act: Key Regulatory Changes and their Implications for Providers

CMS and other agencies have been hard at work over the past year implementing a vast array of regulatory changes mandated under the Affordable Care Act and other statutes. While a few of these changes have tended to grab all the headlines, a number of others are no less important in their direct implications for providers. This session will focus on those new regulations and key enforcement initiatives which go to the heart of the health law provider practice, including implementation of the meaningful use incentive payment program, Medicare and Medicaid program integrity initiatives such as enhanced oversight on enrollment and suspension of payments during fraud investigations, CMS' proposal for value-based purchasing and other quality incentives for physicians and hospitals and implications of the proposed Anti-kickback Statute, Stark Law and Civil Monetary Penalties Statute waivers for ACOs.

- *Jesse A. Berg*
- *Jennifer Reedstrom Bishop*

### PAYORS

#### 3. Managed Care Litigation: Increased Focus on Fraud, Waste and Abuse

As the government has increased its focus on fraud, waste and abuse, so have managed care organizations country-wide – from both a defensive and offensive perspective. Topics to be discussed include the False Claims Act and other relevant trends in litigation.

- *David Eldred*
- *Michael J. Vanselow*

### MED DEVICE / PHARMA

#### 4. Recent Changes in FDA, DOJ and OIG Enforcement Initiatives and Prosecutions Related to the Medical Device and Pharma Industries

A panel discusses the recent changes in the enforcement landscape and the impact on corporate compliance programs. Topics include: the new interpretation of the Responsible Corporate Officer doctrine, recent settlements and plea agreements, state laws, and more. Panelists also will share their insights – in light of this new landscape – on the elements of an ideal compliance program, how to focus and prioritize, and best use of audits.

- *Mark DuVal*
- *Ralph F. Hall*
- *Mark Gardner, moderator*

1:00 – 2:00 P.M.  
BREAKOUT SESSION B

**5. Grading Providers: The Role of Quality and Value Measurement**

A cutting-edge session on key topics in quality and value measurement. Topics will include: ratings of providers available online to consumers; what's new in Minnesota health care measurement (cost of care, specialty services, patient reported data); what new information and reporting will be needed from Accountable Care Organizations; legal and contracting implications; use of data systems – how to measure what you are measuring; and more.

- Jim Chase
- Keith J. Halleland
- Donna Zimmerman

**6. Government Investigations of Health Care Providers**

Health Care Reform has added resources to the growing number of contractors and government entities reviewing claims submitted by health care providers. Understand the enforcement initiatives being pursued by DOJ, OIG, CMS, and the Minnesota Department of Human Services, including contractors such as the FI/Carrier/MAC, RAC, MIC, and Z-PICs. Understand the status of MIC and RAC audits of Medical Assistance Claims and learn the process for appealing claim defaults determined by these contractors as well.

- Julie Beck
- Steven J. Lokensgard

**7. Exchanges, Unicorns and Rainbows – 14 Months Later: A Discussion about the Implications of Reform for Health Plans**

The Patient Protection and Affordable Care Act was enacted over a year ago, and since then regulations have been issued, lawsuits have been filed, and state exchange legislation has been, and has not been, enacted. Join our panel for a discussion of how key developments such as Medicaid expansion, payment reform and ACO rules, Minimum Loss Ratio requirements, the local and national efforts to establish exchanges, and the ongoing litigation uncertainty affect health plans.

- Geoffrey Bartsh
- Manny Munson-Regala
- Stephen K. Warch

**8. In-House Litigation Team on Document Cleanup Strategy Implementation**

If you've ever tried to get employees to comply with designated cleanup days for e-Discovery preparedness, you understand what a daunting task this is. Find out how a highly regulated global medical device company with a small law department established and executed a comprehensive company-wide cleanup strategy on a shoe string budget. Learn how they obtained senior leadership commitment; established company-wide functional teams; developed infrastructure support between Legal, IT, HR and internal business functions; conducted employee training and communications; and measured results.

- Kerry Grosz
- Spiwe Pierce
- Jordan Seethaler

2:15 – 3:15 P.M.  
BREAKOUT SESSION C

ETHICS

**9. Responding to a “Bet the Company Crisis”: A Compliance, Ethics and Privilege Hypothetical**

*1.0 ethics credit applied for*

Attendees will consider how in-house counsel of a regulated company – and those who advise them – should respond to a hypothetical “bet-your-company” crisis. Among the topics to be discussed will be: the in-house counsel's duties and obligations in a compliance environment; dealing with executives and whistleblowers; how to supervise an internal investigation; and responding to government investigators.

- Dulce J. Foster
- David L. Lillehaug

**10. Medicare's Recovery Rights – Bradley v. Sebelius and US v. Hadden**

This session will address the impact of two recent decisions on the issue of apportionments to be made for Medicare liens on settlements and on the resulting effect on the long-standing policy of encouraging settlements. It will also address Medicare's priority right of recovery from primary payers and certain other parties, reporting obligations and other issues arising under the Medicare Secondary Payer Act.

- Thomas A. Boardman
- Annamarie A. Daley

**11. Wellness Programs – Watching the Law While Promoting Health**

Employers are looking to wellness programs to help control health insurance costs. This program explores the laws and legal requirements that apply to wellness programs, including the design and taxation of incentives, laws that prohibit discrimination based on health factors, and exceptions for certain wellness plans. Employers face a number of risks, from violating GINA and ADA claims, to tax penalties for failing to properly report and withhold income and employment taxes.

- Timothy D.S. Goodman

**12. Complying with the Physicians Payments Sunshine Act: Requirements and Practical Strategies**

Understand the new federal “physician payments” reporting requirements and how the federal requirements interact with current state reporting requirements. In addition, we will discuss implementation strategies, including common obstacles, watch-outs and workable solutions, and how to integrate a physician payments tracking system into a broader compliance program.

- Ann M. Kraemer

3:30 – 4:30 P.M.  
BREAKOUT SESSION D

JOINT PROVIDER AND PAYOR SESSION

**13. Accountable Care Organizations: Provider and Payor Concerns**

We will “set-the-table with a brief look at how the Accountable Care Act came about and what it has to say about Accountable Care Organizations. Then, experienced practitioners from a provider organization and an integrated provider/payor organization will discuss legal and business issues. The legal issues will include contracting, Medicare vs. commercial products, and antitrust issues. Business issues to be discussed include risk models and payment and care re-design.

- Babette Apland
- Trudi Trysla
- John A. Breviu, moderator

**Session #13 – Accountable Care Organizations: Provider and Payor Concerns – also falls into the Payors Track.**

See session description above.

**14. Widgets or Therapy? Legal Benefits of Rethinking What Device Companies Actually Sell**

Device companies no longer sell only devices. Rather many of them have moved, at least in practice, into supporting the delivery of therapies. Revisiting and explicitly broadening the conception of a company's product may result in a more favorable analysis of common practices, under a variety of laws, including anti-kickback laws and gift ban/reporting laws. This session will explore the opportunities and limitations afforded by such an analysis.

- Sheva J. Sanders

4:30 p.m.  
INSTITUTE RECEPTION

Join your colleagues for refreshments, hors d'oeuvres, networking in a relaxed setting, and a chance to win great prizes.

**Register for a Chance to Win!**

Register for a chance to win an iPad and other fun prizes. The prize drawing will take place at the reception on Thursday, June 9, and you must be present at the reception during the prize drawing to win. Any person may receive an entry slip on Thursday, June 9, at the Institute registration desk until the reception begins at 4:30 p.m. Registration for the 2011 Health Law Institute is not required. The following individuals are not eligible to win: Institute faculty and planners; employees of Minnesota CLE and the Minnesota State Bar Association, as well as family members of those employees.

Special Thanks to **BARNES & THORNBURG LLP** – A Planner Sponsor!



## PLENARY SESSIONS

8:30 – 9:00 a.m.  
CONTINENTAL BREAKFAST

9:00 – 9:45 a.m.

### Fraud and Abuse Update

Even in an environment of mounting deficits, federal and state funding for fraud and abuse enforcement and program integrity efforts has grown. This session will cover the significant fraud and abuse enforcement trends across the industry sectors, including manufacturing (pharma and device), providers, and payors. Discussion will include DOJ, FBI, OIG, CMS Program Integrity, and State AG/MFCU efforts.

– *Howard J. Young*

9:45 – 10:45 a.m.

### New Data Privacy and Security Developments: HITECH, the Sorrell Case and More

An essential update for the health law practitioner. This session will make sure you're up to speed on the HITECH rulemaking, state law, and other recent privacy and security developments significant to your clients – including the potential implications of the *IMS v. Sorrell* case currently before the U.S. Supreme Court.

– *Brian L. Hengesbaugh*

10:45 – 11:00 a.m.

BREAK

11:00 a.m. – 12:00 p.m.

### Other Significant New Developments

The only certainty in health care is change. Come hear the “best of the rest” of new developments at the federal, state and local level that will impact health care lawyers and their clients in the coming year.

– *Gina M. Kastel*

– *Susan G. Kratz*

12:00 – 1:15 p.m.

LUNCH (on your own)

REGISTER  
TODAY!

1:15 – 2:15 P.M.

## BREAKOUT SESSION E

ELIMINATION  
OF BIAS

### 15. Elimination of Bias: Mental Health and Chemical Dependency Issues in the Legal Profession

*2-hour session*

*2.0 elimination of bias credits applied for*

This presentation covers the incidence and prevalence of these conditions in the legal profession, as well as addressing how lawyers may encounter clients who suffer from addiction or mental health conditions. Learn the signs, symptoms and implications and what resources are available, including the services of the Minnesota Lawyer Assistance Program.

– *Joan Bibelhausen*

– *John D. Culbert*

PATIENT CARE

PROVIDERS

### 16. Thinking Through Disclosures

Providers and their counsel have long struggled with how to correct and disclose Stark and potential kickback violations. Amendments to the False Claims Act, the Affordable Care Act requirement that known overpayments must be returned within sixty days, and the September 2010 OIG Self Referral make the issue of disclosure far more germane. This panel will discuss these disclosure protocols, practical advice in working through potential Stark and kickback issues and the pros and cons of each protocol.

– *Timothy A. Johnson*

– *John W. Lundquist*

– *Thomas S. Schroeder*

– *Barbara E. Trethewey, moderator*

PAYORS

### 17. Data Breach – Navigating the Technical, Strategic and Legal Issues

When health care companies lose laptops, or backup tapes, or suffer a computer intrusion on systems containing personal information regarding customers or users, they trigger notification duties under a patchwork of state statutes. This session describes how you should navigate the technical, strategic, and legal issues involved in complying with these statutes. In addition, the presentation will provide practice tips on what immediate steps to take when a data breach occurs. As part of the accompanying written materials, you'll receive a practical, comprehensive checklist that incorporates the issues a breached company should think about in dealing with a breach.

– *Paul H. Luehr*

MED DEVICE /  
PHARMA

### 18. Mergers and Acquisitions in the Medical Technology Field

As sales of core products have declined and it has become increasingly difficult to win regulatory approval for medical devices, a number of medical technology leaders are shifting to a “buy vs. make” mindset. An experienced M & A practitioner gives you his insights into a market that has been heating up and is expected to accelerate even more during 2011 as maturing companies look for new growth opportunities and the next “blockbuster” product.

– *Frank I. Harvey*

2:30 – 3:30 P.M.  
BREAKOUT SESSION F

## Elimination of Bias Session Continued

### 19. Employment, Reporting and Patient Safety Issues Arising from Nurse Misconduct

Drug diversion or other misconduct by a nurse or other licensed practitioner harms patients, employers and the licensed practitioner. Join us for this presentation to better understand licensing board reporting obligations arising out of actual or suspected misconduct. Engage in discussion of issues around law enforcement reporting, patient and family disclosures, assisting providers in seeking treatment, and disciplinary considerations. This topic will also address the special issue of when awareness of misconduct is obtained in the course of a nurse's chemical dependency treatment.

- *Rene Cronquist*
- *Bonnie Johnson*

### 20. Antitrust Checkup – Cases and Trends in Health Care Antitrust

Provider cooperatives, most favored nations, pay-for-delay, Accountable Care Organizations, and more – a review of how health care markets have been, and might be, shaped by antitrust law and enforcement policies over the past year.

- *Mark A. Jacobson*
- *Thomas F. Pursell*

### Session #20 – Antitrust Checkup – also falls into the Payors Track.

See session description above.

### Session #20 – Antitrust Checkup – also falls into the Med Device/Pharma Track.

See session description above.

JOINT PROVIDER,  
PAYOR AND MED DEVICE /  
PHARMA SESSION

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<input type="checkbox"/> #2	<input type="checkbox"/> #6	<input type="checkbox"/> #10	<input type="checkbox"/> #14	<input type="checkbox"/> #16	<input type="checkbox"/> #19
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Minnesota CLE will apply to the Minnesota State Board of Continuing Legal Education for **10.5 standard CLE credits**. The total includes **1.0 ethics credit for breakout session #9** and **2.0 elimination of bias credits for breakout session #15**. The maximum number of total credits that attendees may report for this seminar is 10.5. For example, if you attend breakout sessions #9 and #15, you would report 1.0 ethics, 2.0 elimination of bias and 7.5 standard credits.

**ACCOMMODATION**

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

**CANCELLATION / NO-SHOW POLICY**

Paid registrants who cancel their registration at least 72 hours before the program will receive a full credit on their account; if fewer than 72 hours, a \$25 administrative fee will be deducted. Paid registrants who fail to attend will receive the written materials. Passholders may purchase the materials at 50% of the full retail price.

**QUESTIONS?**

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