



7:30 – 8:15 a.m. Registration/Breakfast

8:15 – 8:30 a.m. Welcome/Introduction

**8:30 – 9:15 a.m. Real World Issues with Financial Assistance**

The Affordable Care Act and related proposed regulations have caused an uproar in the industry due to a never seen before level of complexity in what should be a simple mission: financial assistance. Even those providers who are not subject to the additional scrutiny brought about by §501(r) find the provision of financial assistance to be complex and burdensome. Some providers have yet to adopt, develop or revise their financial assistance policies to comply with the statute or the proposed regulations. Some providers have assumed that their current financial assistance policies are enough. In this session, the presenters will discuss real world issues providers of all types face in providing financial assistance.

*Andrew D. Kloeckner*  
*Shelly Cassidy, Director | Patient Business Services, Mary Lanning HealthCare*

**9:15 – 10:00 a.m. Thinking on Your Feet... or How to Communicate with Regulators About Practically Anything**

In today's environment of increased enforcement and myriad audits, it's more important than ever to communicate effectively with regulators—and increasingly, with private payors—in a variety of situations, ranging from the unannounced survey or investigation to the seemingly benign medical record request. When is it appropriate to volunteer information, refrain from asking questions, or challenge an outside investigator or auditor? Julie Knutson and Whitney West will share lessons learned from managing these complex interactions, whether they arise in the course of a ZPIC audit, state licensure survey, or investigation by the OIG or a U.S. Attorney. This session will discuss best practices for responding to auditors on-site, communicating with agencies during voluntary repayments and self-disclosures, and effectively appealing adverse findings or disciplinary action.

*Julie A. Knutson*  
*Whitney C. West*

10:00 – 10:15 a.m. Break

**10:15 – 10:45 a.m. Halifax Health: Where Did They Go Wrong?**

Halifax Health recently settled Stark claims for \$85 million, an amount that threatened the future viability of this publicly-owned safety net hospital in Daytona Beach, Florida. Where did they go wrong? What led to all this? What lessons can be learned both from the payments and the way in which the matter was handled? This session focuses on these important issues for all health care providers.

*John R. Holdenried*  
*Zachary Buxton*

**10:45 a.m. – 12:00 p.m. Health Information Privacy and Security: The Perfect Storm of Risk**

Every organization will face a data breach at some point – it's no longer a matter of if, but when. Enforcement of privacy and security breaches is at an all-time high and the Office for Civil Rights is no longer the only player in town ready to take your money and put you on a corrective action plan. This session will focus on the increasing challenges and heightened scrutiny faced by health care providers and other covered entities over the protection of one of the organization's biggest assets – its patient or enrollee data. The penalties are real and the costs are significant. Vickie Ahlers and Kelly Clarke will discuss actual breaches faced by organizations and the legal and financial fall-out from those breaches. Along with Vickie and Kelly, guest speaker Cameron Burt, Vice President of Holmes Murphy, a risk management and insurance brokerage firm will offer additional insight into the steps you can take now to insure the organization from such risks, and will cover important questions such as how much insurance is enough and what does it really cover?

*Vickie B. Ahlers*  
*Alex M. "Kelly" Clarke*  
*Cameron Burt, Vice President, Holmes Murphy*

12:00 – 1:00 p.m.	Lunch
1:00 – 2:00 p.m.	<p><b>The Latest Word</b></p> <p>This session includes the always popular, fast paced discussion of a variety of issues affecting health care organizations. This year's panel of Baird Holm attorneys will cover topics including HR compliance, immigration updates, intellectual property, and several other health care compliance updates.</p> <p><i>Panel of Baird Holm Attorneys</i></p>
2:00 – 2:45 p.m.	<p><b>Disruptive Physicians: Tolerance No Longer</b></p> <p>Licensing authorities and managed care panels are no longer turning a blind eye to disruptive behaviors by physicians. Finally there is support for hospitals seeking to address the negative impact of disruptive physicians on quality of care. We will discuss the options commonly available to physician employers and hospitals with regard to their medical staff members. Information will be provided concerning available assessment and treatment programs specializing in disruptive physicians, and employers' and hospitals' ability to pay for such assessments and treatment for key physician personnel.</p> <p><i>Barbara E. Person</i></p>
2:45 – 3:00 p.m.	Break
3:00 – 3:45 p.m.	<p><b>C-Suite – Pay Attention (or Pay Up!): Getting and Keeping Your Meaningful Use Dollars</b></p> <p>Meaningful Use incentive payments are real money – and can mean millions of dollars for health care organizations. Implementing and monitoring Meaningful Use must include participation from senior leadership. Your organization's strategic initiatives and budget may depend on receipt of these incentive payments. Can you afford to lose these funds? To date, CMS has paid out over \$20 billion in Meaningful Use Incentives. With these high dollars involved, it is no surprise that the CMS Meaningful Use audit program is underway. For most organizations it is only a question of when the audit request will reach your inbox. This session will focus on the need for strategic approaches to Meaningful Use, including a discussion of myths about key requirements of the program, budgeting for IT infrastructure, and real life lessons learned in responding to actual audits.</p> <p><i>Michael W. Chase</i></p>
3:45 p.m.	<p><b>Cocktail Reception</b></p> <p><i>Please join us for cocktails and appetizers immediately following the program in the lobby reception area at the Omaha Marriott Regency Hotel.</i></p>



# BAIRD HOLM<sup>LLP</sup>

ATTORNEYS AT LAW

## Vickie B. Ahlers | Partner

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### Areas of Practice

Health Care

Privacy & Data Protection

### Education

Southern Illinois University School of Law, J.D., 1998

University of Nebraska at Kearney, B.A., English, 1994

### Bar & Court Admissions

Iowa, 2005

Nebraska, 1998

Vickie B. Ahlers represents health care clients with respect to a variety of issues including regulatory, transactional and contracting issues, HIPAA, medical staff and allied health professionals issues, organizational compliance, and compliance with FDA medical device regulations. Vickie also focuses her practice on privacy and data protection issues for businesses across all industry sectors. She has handled more than 300 breach analyses and response efforts, ranging from preparation and evaluation of privacy & data protection processes, incident evaluation & response, and regulatory enforcement defense.

Prior to joining the firm, Vickie served as a clerk for the Honorable James L. Foreman, District Judge for the United States District Court for the Southern District of Illinois. In 1997, she also served as a clerk for the United States Attorney's Office.

Vickie leads the firm's Privacy & Data Protection group. She has spoken to numerous industry groups such as the American Hospital Association and the Health Care Compliance Association on the topic of privacy and security for healthcare providers, insurers and employers. She has been listed in *Chambers USA*, *America's Leading Lawyers for Business* (© 2013). Since 2007, Vickie has been selected by her peers for inclusion in *The Best Lawyers in America*® in the field of Health Care Law, and was named *Best Lawyers' Omaha Healthcare Lawyer of the Year* for 2013.

### Selected Practice Highlights

- Successfully providing assistance to a client through a HIPAA Performance Audit that was in the pilot phase of audits conducted by KPMG on behalf of the Office for Civil Rights (OCR)
- Representing numerous clients in HIPAA complaints filed with OCR and data breach investigations by OCR, including mandatory investigation following a breach of over 500 records requiring media and government notice
- Developing compliant policies and processes for privacy and security and training and consultation for workforce and Medical Staff on HIPAA compliance
- Handling more than 300 data breach responses for clients
- Assisting large national employers through multi-state breach notification under various state laws
- Representing clients in developing medical staff bylaws, rules and regulations and policies
- Successfully obtaining FDA 510(k) clearance on behalf of client for three medical devices
- Advising clients with respect to physician recruitment and employment and other hospital-physician relationship issues

- Acting as co-author of four compliance publications for health care providers and health plans on compliance with HIPAA and HITECH

## **Professional & Civic Affiliations**

- Nebraska Organ and Tissue Donor Coalition Board of Directors, Chairperson
- American Health Lawyers Association, Health Information Technology Practice Group Leadership Committee
- Nebraska Chapter of Healthcare Financial Management Association, Past President
- Iowa Society of Healthcare Attorneys, President-Elect
- Prior Activities include: Latino Center of the Midlands Board of Directors, Nebraska Aids Project Board of Directors, Friends of Planned Parenthood Board and Leadership Omaha (Class 26), Wellness Council of the Midlands Board of Directors, Past President

## **Recent Speaking Engagements**

- “The Need for CAH-tion for Critical Access Hospitals and Rural Health Clinics” (with Barbara E. Person), Nebraska Hospital Association Mid-Year Meeting, May 22, 2014
- “Legal Implications of a Breach in the Cloud” (with James E. O’Connor), Infotec 2014, April 14, 2014
- “The Next Decade of HIPAA: Understanding and Implementing the Omnibus Final Rule,” NAHAM Spring Conference, April 3, 2014
- “Supervision of Outpatient Therapeutic Services,” Nebraska Hospital Association Webinar, February 13, 2014
- “HIPAA Beginning Steps & Common Misperceptions” (with Michael W. Chase), LeadingAge Webinar Compliance Series, February 12, 2014
- “Scary situations: Protecting Your Hospital From Violent Patients, Employees or Visitors” (with Heidi Gutttau-Fox), Iowa Hospital Association Annual Meeting, October 9, 2013
- “HIPAA Performance Audits: Inside Perspective,” The Healthcare Roundtable for General Counsel, September 9, 2013
- “Using Hospital Data in the Next Decade of HIPAA,” MidAmerican Information Summit, Iowa Hospital Association, September 5, 2013
- “Scary Situations Protecting Your Hospital from Violent Patients, Employees, or Visitors,” (with Heidi Gutttau-Fox), Nebraska Hospital Association Mid-Year Meeting, May 23, 2013
- “The Next Decade of HIPAA: Understanding and Implementing the Omnibus Final Rule,” Nebraska HIMSS Spring Meeting, May 21, 2013
- “The Next Decade of HIPAA: Understanding and Implementing the Omnibus Final Rule,” ISHA Spring Conference, May 14, 2013
- “The Next Decade of HIPAA: Omnibus Final Rule and Enforcement”, IMGMA Spring Conference, May 9, 2013
- “Managing the Data Breach,” Creighton University School of Law, May 4, 2013
- “iNeed my Device - Issues and Challenges Facing Health Care Providers in Today’s Mobile World,” co-presented with James E. O’Connor, Baird Holm Health Law Forum, November 16, 2012
- “Data Risk and Crisis Management: Are You Prepared?” co-presented with James E. O’Connor, Baird Holm CLE Program, September 19, 2012

- “Data Risk and Crisis Management: Are You Prepared?” co-presented with James E. O’Connor, Baird Holm ACC Presentation, February 8, 2012
- “Medicare and Medicaid Recovery Audit Contractor (RAC) Program,” Nebraska Rural Health Association Rural Health Clinic Billing & Coding Workshop, September 21, 2011
- “Breach Notification from the Inside – Lessons Learned,” Iowa Society of Healthcare Attorneys Health Law Conference, May 17, 2011
- “HITECH Impact on Business Associate Relationships,” Iowa Medical Group Management Spring Conference, May 13, 2011
- “Breach Notification From The Inside – Lessons Learned,” The Healthcare Roundtable for General Counsel, March 15, 2011
- “Alphabet Soup: Deciphering RACs, MICs and ZPICs,” Iowa Hospital Association, October 7, 2010



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### Areas of Practice

Health Care

### Education

Saint Louis University School of Law, J.D., 2014

Saint Louis University College for Public Health & Social Justice, Master of Health Administration, *with distinction*, 2014

University of Northern Iowa, B.A., English and Sports Psychology, *cum laude*, 2009

### Bar & Court Admissions

Iowa, 2014

Zachary J. Buxton concentrates his practice on health care law. He represents hospitals, health care facilities, physician practices and other health care providers in regulatory, transactional and reimbursement matters.

Zach earned a Juris Doctor from Saint Louis University School of Law in 2014 with a certificate in health law. While there, he served as a staff editor (2012-2013) and a lead editor (2013-2014) of the Saint Louis University Journal of Health Law & Policy. His comment on the ACA's changes to Community Benefit was published in the Spring 2014 issue of the journal. He was also a member of the Saint Louis University Health Law Association and earned two Academic Excellence awards in HIPAA Privacy Law and Theories of Health Law Seminar.

Also in 2014, Zach earned a Master of Health Administration, *with distinction*, from the Saint Louis University College for Public Health & Social Justice. He graduated from the University of Northern Iowa with a Bachelor of Arts in English and Sports Psychology, *cum laude*, in 2009.

### Professional & Civic Affiliations

- American Health Lawyers Association
- American College of Healthcare Executives
- AHLA (American Health Lawyers Association)
- Iowa Society of Health Care Attorneys



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ATTORNEYS AT LAW

## Michael W. Chase | Associate

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### Areas of Practice

Health Care

Privacy & Data Protection

### Education

Saint Louis University School of Law, J.D., 2009

Saint Louis University College for Public Health & Social Justice, Master of Health Administration, *with distinction*, 2009

Creighton University, B.S.B.A., Accounting and Finance, *summa cum laude*, 2004

### Bar & Court Admissions

Iowa, 2009

Nebraska, 2009

Michael W. Chase assists clients with issues including compliance with Federal health care program fraud and abuse laws, reimbursement, clinical research and institutional review board compliance, and governance. His practice also focuses on electronic health records (EHR) technology and issues under HIPAA, HITECH, Meaningful Use and other Federal and State laws regarding privacy of data.

Michael received his law degree from Saint Louis University School of Law, with certificates in Health Law Studies and International and Comparative Law. During law school, he served as a lead editor for the Saint Louis University Journal of Health Law and Policy. In addition, he received a Masters in Health Administration, with distinction, from Saint Louis University School of Public Health.

Michael graduated from Creighton University, *summa cum laude*, with a Bachelor of Science in Business Administration in Accounting and Finance. Prior to joining the firm, he worked at the Institute for Latin American Concern in Santiago, Dominican Republic and at the Mayo Clinic in Rochester, Minnesota.

### Professional & Civic Affiliations

- American Health Lawyers Association
- ICAN, Defining Leadership Class 14
- Iowa Chapter of the Healthcare Financial Management Association, Program Committee
- Iowa Society of Healthcare Attorneys
- Down Syndrome Alliance of the Midlands, Board Member
- Nebraska Court Appointed Special Advocates, Board Member
- Health Care Compliance Association
- Omaha Bar Association



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### Areas of Practice

Health Care

Privacy & Data Protection

### Education

University of Colorado, J.D., 1970

University of Virginia, B.A., 1966

### Bar & Court Admissions

Iowa, 1992

Nebraska, 1970

Kelly Clarke's practice concentrates on regulatory and transactional work, corporate compliance issues (reimbursement, fraud and abuse, Stark, tax exemption, HIPAA, etc.), physician contracts, governance and medical staff issues.

Kelly is a former member of the Board of Directors (1985-1993) and Past President (1991-1992) of the American Academy of Healthcare Attorneys, which is now the American Health Lawyers Association. He also served on the Governing Committee of the American Bar Association's Health Law Forum (1985-1990), and on the Legal Services Committee of Catholic Health Association (1984-1987). He is a member of the Iowa Society of Healthcare Attorneys and a member and fellow in the American Health Lawyers Association. Since 1991, Kelly has been selected by his peers for inclusion in *The Best Lawyers in America*<sup>®</sup> in the field of Health Care Law and he is top-ranked in *Chambers USA, America's Leading Lawyers for Business* (© 2013). Additionally, he is "AV" rated by Martindale-Hubbell.

Kelly is a frequent lecturer on health care issues to industry and professional groups. He is active with the Nebraska and Iowa chapters of the Healthcare Financial Management Association and has spoken before many national and regional groups including the American Health Lawyers Association, the American Hospital Association, the American Bar Association, and numerous state hospital associations and regional groups.

### Selected Practice Highlights

- Assisting hospitals and medical staff leaders with practitioner health, performance and peer review issues
- Advising on hospital and health system affiliation and integration strategies
- Developing, in cooperation with partners, HIPAA resources for institutional and professional providers and group health plans and assisting with investigations and breach notifications
- Representing clients on regulatory analysis and investigations, self-disclosure and voluntary repayments
- Assisting with physician recruitment and contracting
- Developing and advising several health information exchanges

### Professional & Civic Affiliations

- Nebraska Bar Association
- Iowa Bar Association



- Omaha Bar Association
- American Bar Association
- Iowa Society of Healthcare Attorneys
- American Health Lawyers Association
- Past President and Board Member of Big Brothers, Big Sisters of the Midlands; Santa Monica, Inc.; and ICAN

### **Selected Recent Publications**

- “The Choice to Refuse or Withhold Medical Treatment: The Emerging Medical-Ethical Consensus,” 13 Creighton Law Review, 795 (Spring 1980).



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ATTORNEYS AT LAW

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### Areas of Practice

Health Care

Privacy & Data Protection

Public Finance

### Education

University of Iowa College of Law,  
J.D., *with distinction*, 2013

University of Iowa, Masters of  
Public Health, 2013

American University, BA, *magna  
cum laude*, 2008

### Bar & Court Admissions

Iowa, 2013

Nebraska, 2014

Laura A. Feldman concentrates her practice in the areas of public finance and health care law. Her work as bond counsel focuses on municipal law and economic development, and involves the preparation of election proceedings, bond resolutions, and closing certifications for public finance transactions. Laura advises health care clients on regulatory, transactional and contracting issues, HIPAA and organizational compliance. She also assists businesses in various industries with privacy and data protection matters, including breach analysis and response efforts.

Laura earned a Juris Doctor, *with distinction*, from the University of Iowa College of Law in 2013, where she was a member of the Iowa Law Review. She also earned a Master of Public Health from the University of Iowa, where her research focused on strategies to address homelessness in the local community. She received a Bachelor of Arts, *magna cum laude*, from the School of Public Affairs at American University in 2008.

### Professional & Civic Affiliations

- Iowa State Bar Association
- Nebraska State Bar Association
- Iowa Society of Healthcare Attorneys
- American Health Lawyers Association
- Healthcare Financial Management Association – Iowa Chapter



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ATTORNEYS AT LAW

## John R. Holdenried | Partner

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### Areas of Practice

Health Care

### Education

University of Michigan Law School,  
J.D., *cum laude*, 1975

Creighton University, B.S., Business  
Administration, *magna cum laude*,  
1972

### Bar & Court Admissions

Nebraska, 1975

Iowa, 1992

United States District Court of  
Nebraska, 1975

John R. Holdenried provides a full range of health law services to healthcare providers, with a concentration on regulatory, transactional, and contracting issues; managed care contracting and network formation; tax exemption; and corporate compliance issues, including reimbursement, tax, Stark, and fraud and abuse.

John is the Chair of the Firm's Health Care section, and was the Managing Partner of the firm from 2001-2009. From 1975 to 1977, he served as law clerk to the Honorable Warren K. Urbom, United States District Court for the District of Nebraska.

John is very active in local, regional and national health care associations, including the American Health Lawyers Association for which he serves on the Board of Directors. He was the Program Chair of the annual AHLA Tax Issues for Healthcare Organizations Program for several years and is an emeritus member of the IRS Council for Tax Exempt and Governmental Entities-Great Lakes Region.

He is a frequent presenter at programs of the American Health Lawyers Association. He has also spoken at regional and local programs sponsored by state hospital associations, state hospital attorney societies, and chapters of the Healthcare Financial Management Association and the Health Care Compliance Association. Topics on which he has spoken include duties of hospital directors, physician recruitment, physician practice acquisition, managed care, accountable care organizations, corporate compliance programs, tax exemption issues, Stark, fraud and abuse, fair market value, and rural hospital issues. Since 1991, John has been selected by his peers for inclusion in *The Best Lawyers in America*<sup>®</sup> in the field of Health Care Law. John has also been named in *Chambers USA* (© 2013) and *Great Plains Super Lawyers* since 2007 for his work in Health Care Law. He has passed the Iowa Uniform Certified Public Accounting Examination.

### Selected Practice Highlights

- Establishing and advising PHOs, PPOs, and other managed care entities
- Assisting clients in negotiating and reviewing managed care and shared risk contracts
- Drafting physician employment compensation plans and contracts
- Drafting and negotiating physician co-management arrangements
- Counseling tax-exempt clients on compliance issues
- Counseling hospital boards on fiduciary and compliance duties
- Counseling physician groups on structure, contracts and operational issues
- Representing clients in transactions for purchase, sale, and affiliations of healthcare providers

- Counseling on corporate organization and structure issues of tax-exempt organizations
- Drafting and counseling on hospital-physician joint ventures

### **Professional & Civic Affiliations**

- American Health Lawyers Association, Board of Directors, Program Chair of Tax Program, former Vice Chair of Tax and Finance Practice Group
- Iowa Society of Hospital Attorneys, former President
- Nebraska Chapter of Healthcare Financial Management Association
- IRS Council for Tax Exempt and Governmental Entities- Great Lakes Region
- New Cassel, Inc., Board of Directors
- Member of Finance Committee, St. Margaret Mary Parish (Previously President and Board member of St. Margaret Mary Board of Education and Parish Council)
- Prior community activities include board membership of Alzheimer's Association of the Midlands Chapter (President), One World Community Health Center, Inc. (President), South Omaha Affordable Housing (Board Secretary), Family Housing Advisory Services (President), Big Brothers-Big Sisters of the Midlands (President), Leadership Omaha participant (1983-1984), and Instructor for Legal Research and Writing, Creighton University School of Law (1981-1987)

### **Selected Recent Publications**

- Fair Market Value Issues. Avoiding Trouble; *Health Law Handbook*, 2014 Edition, Thomson Reuters
- "ACOs—IRS Notice Leaves Many Questions," AHLA Connections, August 2011
- "Tax and Tax Exemption in Transactions," *Health Law Practice Guide*, American Health Lawyers Association.
- "Hospital Compensation of Employed Physician—Hospitals Struggle with Compliance and Economics," *Insights*, Willamette Management Associates, 2005



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### Areas of Practice

Health Care

### Education

Creighton University School of Law,  
J.D., *magna cum laude*, 2006

Creighton University, B.S.B.A.,  
*summa cum laude*, 2003

### Bar & Court Admissions

Iowa, 2006

Nebraska, 2007

Andrew D. Kloeckner represents healthcare clients with respect to a variety of issues, including regulatory, compliance, reimbursement, transactional, contracting, and tax-exemption matters. He received his Juris Doctor from Creighton University School of Law, *magna cum laude*, where he graduated with a concentration in Business, Taxation and Commercial Transactions. Andy also holds a Bachelor of Science in Business Administration, with an emphasis in accounting, *summa cum laude*, from Creighton University.

### Selected Practice Highlights

- Advising clients on the impact of Stark, anti-kickback, and tax-exempt principles on contractual and other arrangements
- Representing hospitals in physician practice acquisitions
- Representing hospitals in mergers & divestitures, and acquisitions of ambulatory surgical centers
- Assisting in the preparation and submission of Stark self-disclosures under the Self-Referral Disclosure Protocol
- Structuring and advising clients on the creation of Accountable Care Organizations
- Preparing and negotiating a wide variety of other health care contractual arrangements

### Professional & Civic Affiliations

- OneWorld Community Health Centers, Inc., Board Member & Past President
- Nebraska Chapter of the Healthcare Financial Management Association, Treasurer & Board Member
- Down Syndrome Alliance of the Midlands, Board Member (2010-2011)
- American Health Lawyers Association
- Iowa Society of Healthcare Attorneys

### Recent Speaking Engagements

- “Board Meetings – Open Meetings, Compliance & Effectiveness,” Nebraska Leading Age, January 23, 2014
- “ACO Update & Impact of ACA Insurance Reforms on Providers,” Health Law Forum, November 22, 2013

- “501(r) Update & Private Use,” Compliance Network, August 12, 2013
- “Physician Relationships – Stark, Anti-Kickback & Other Compliance Risks,” Nebraska HFMA – Annual Meeting, March 27, 2013
- “501(r) Update – Community Health Needs Assessments and Charity Care,” Iowa HFMA Annual Institute, October 24, 2012
- “Top Ten Mistakes Hospitals Make When Recruiting Physicians,” Nebraska Hospital Association, Mid-Year Meeting, May 24, 2012
- “A Compliant Community Health Needs Assessment,” Nebraska HFMA - Annual Meeting, March 28, 2012
- “Physician Relationships – Are You in Compliance?,” January 18, 2012



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ATTORNEYS AT LAW

## Julie A. Knutson | Partner

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### Areas of Practice

Health Care

### Education

Creighton University School of Law,  
J.D., 1993

University of Nebraska at Omaha,  
M.S.W., 1980

Creighton University, B.A., 1974

### Bar & Court Admissions

Nebraska, 1993

Iowa, 1995

### Publications

Editor, *Health Law Advisory*,  
Baird Holm LLP

Julie Knutson's practice primarily focuses on providing health care facility and physician/provider practice clients with advice and representation concerning a wide variety of regulatory compliance, reimbursement, contracting, medical staff, licensure and behavioral health issues. Prior to joining the firm, she spent 18 years working in the health care industry as a manager, internal consultant and trainer.

Julie is active in legal associations related to her field in both Nebraska and Iowa. She is also a member of the American Health Lawyers Association and the Health Care Compliance Association. Since 2001, Julie has been selected by her peers for inclusion in *The Best Lawyers in America*® in the field of Health Care Law and has been ranked by *Chambers & Partners USA* (© 2013). Additionally, she is "AV" rated by *Martindale-Hubbell*.

Ms. Knutson is a frequent speaker and resource on health care topics including many aspects of regulatory compliance and investigations; complex capacity, consent and substitute decision-making issues, medical staff, physician contracting, behavioral health law, credentialing and human subject research and IRB issues.

### Selected Practice Highlights

- Training and consultation for boards, senior management and compliance committees regarding compliance matters including conflict of interest policies and reimbursement and billing matters
- Advises clients regarding a wide variety of health care compliance and operational issues
- Development and negotiation of physician contracts
- Representation of clients in regulatory investigations, self-disclosures, voluntary repayments and implementation of corporate integrity agreements.
- Assists hospitals in developing medical staff bylaws, rules and regulations and policies
- Consultation and advice regarding human subject and IRBs.

### Professional & Civic Affiliations

- American Health Lawyers Association
- Health Care Compliance Association, Member
- Iowa Society of Health Care Attorneys, Past President
- Latino Center of the Midlands, Executive Committee and Board Member
- Past President of the Board of Directors of Community Alliance, Inc.
- Leadership Omaha, Class 6 (1984) and Past President, Leadership Omaha Alumni Association
- Intercultural Senior Center, Board of Directors



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ATTORNEYS AT LAW

## Scott S. Moore | Partner

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### Areas of Practice

Immigration

International Services

Labor & Employment Law

### Education

University of Nebraska College of Law, J.D., *with high distinction*, Order of the Coif, 1992

University of Nebraska at Lincoln, B.A., *magna cum laude*, 1989

### Bar & Court Admissions

Colorado, 1993

Iowa, 2004

Nebraska, 1992

South Dakota, 2013

Utah, 2013

United States Court of Appeals, Eighth Circuit

United States District Court, District of Colorado, 1993

United States District Court, District of Nebraska, 1992

Scott S. Moore regularly represents employers in various industries with respect to labor relations and employment matters, including personnel policies and decisions, labor negotiations, preventive planning, immigration, workplace investigations, workplace safety, equal opportunity, and the defense of employment-related claims. He has represented employers on labor and employment matters throughout the United States and was previously Vice President of Human Resources for a New York Stock Exchange organization. Scott is a partner and member of the firm's executive committee.

Scott received his Juris Doctor from the University of Nebraska College of Law, *with high distinction* in 1992. Since 2006, Scott has been selected by his peers for inclusion in *The Best Lawyers in America*® in the fields of Employment Law, Immigration Law, and Labor Law. He has been listed in the *Great Plains Super Lawyers*, has been recognized as one of Nebraska's top employment defense lawyers in *Chambers USA*, and is "AV" rated by Martindale-Hubbell. Scott is a Special Assistant Attorney General for the State of Nebraska. He is the former Chair of the Labor and Employment Section of the Nebraska State Bar Association.

### Selected Practice Highlights

- Investigator and Counsel for Workplace Fraud and Compliance Investigations
- Implementation of successful labor negotiations and labor strategies for private and public employers
- Development of corporate wide-incentive programs
- Creation of executive recruitment strategies, agreements and incentive plans
- Integrating foreign businesses into the United States Labor Market
- Coordinating and providing direction for multi-national downsizings
- Advising and representing numerous employers on EEO matters against numerous state and federal equal employment opportunity agencies
- Advising corporate boards on CEO and executive selection processes
- Routinely advising and pursuing work-related authorization for employers on behalf of key immigrant employees, especially J-1 Waivers, H-1B and Green Cards for physicians
- Establishing work-related dispute resolution systems, including pre-dispute arbitration agreements
- Successfully defending against numerous wage and hour investigations by the Department of Labor, including multiple site/organization-wide wage and hour compliance audits



- Successfully defending numerous union organizing campaigns ranging from small shops to large multi-location facilities including campaigns by the Teamsters, UFCW, AFSME and SEIU
- Effectively litigating much watched NLRB matter regarding representation units in multi-location environment

### **Professional & Civic Affiliations**

- Founder, Best Places to Work in Omaha, sponsored by the Omaha Chamber of Commerce
- Chairman, NSBA Labor and Employment Section, 2005-2007
- Chairman, Nebraska Lung Association Leadership Council, 2007-2008
- Board of Directors, Central States American Lung Association, 2006-2008
- Board of Directors, Conestoga Public Schools
- SHRM Nebraska State Council member, 2007-2010
- Legislative Director, SHRM Nebraska, 2007-2010
- Legal Counsel Human Resources Association of the Midlands
- Former Committee Chair and Board Member for the Human Resources Association of the Midlands
- Legal Counsel, Central Human Resources Management Association
- Labor Committee, Nebraska State Chamber of Commerce
- Corporate Chairman, 2007 Asthma Walk
- Corporate Chairman, 2007 Corporate Cup
- Executive Committee and Board member, Heartland Chapter of the American Red Cross, 2000-2006
- Former Board member for Omaha Theater Company for Young People
- ICAN Focus Leadership Graduate 1999
- American Bar Associations' Sections on Labor and Employment
- American Immigration Lawyers Association

### **Selected Recent Publications**

- Scott is formerly the Chapter Chairman and Editor for BNA's employment discrimination law treatise, Employment Discrimination Law, and a Contributing Editor for BNA's leading labor law treatise, The Developing Labor Law. He has written several law review articles addressing the equal opportunity laws, the Americans with Disabilities Act and the drafting of pre-dispute arbitration agreements. He has been cited by the Wall Street Journal, Bloomberg, and the Associate Press on employment law issues.



# BAIRD HOLM<sup>LLP</sup>

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## Y. Kamaal Patterson | Associate

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### Areas of Practice

Copyright & Trademark

Intellectual Property

Patents

Privacy & Data Protection

Technology & E-Commerce

### Education

Creighton University School of Law,  
J.D., *magna cum laude*, 2013

Duke University, B.S.E., Electrical  
Engineering, B.S., Economics, 2008

### Bar & Court Admissions

Nebraska, 2013

Colorado, 2014

U.S. Patent and  
Trademark Office, 2013

U.S. District Court,  
District of Nebraska, 2013

Kamaal Patterson assists start-ups and established businesses with patent prosecution for new inventions, and negotiates contracts for the licensing or sale of software, hardware and technology services. As a registered patent attorney, Kamaal uses his background in engineering to translate complex technical innovations into protected business assets. As a transactional attorney, Kamaal guides clients through contract negotiations large and small, all of which are critical to the continued success of their operations. To complement these focuses, Kamaal also practices in other areas of intellectual property law and business entity management.

Kamaal is a 2013 graduate of the Creighton University School of Law, *magna cum laude*, where he completed the school's concentration in Business Law. There, he earned five CALI Excellence for the future awards. He also served as Editor-in-Chief of the Creighton Law Review. Prior to joining the firm, he worked as a patent examiner at the U.S. Patent and Trademark Office. Kamaal is a native of Durham, North Carolina but grew up in Omaha, Nebraska.

### Professional & Civic Affiliations

- Nebraska State Bar Association
- Omaha Bar Association
- American Intellectual Property Law Association
- Creighton Law Young Alumni Council



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## Barbara E. Person | Partner

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### Areas of Practice

Health Care

### Education

University of Nebraska College of Law, J.D., 1985

University of Nebraska at Lincoln, B.A., 1981

### Bar & Court Admissions

Iowa, 1996

Nebraska, 1985

Barbara E. Person primarily represents health care clients, concentrating on corporate compliance, Medicare and Medicaid reimbursement, Medicare fraud and abuse, EMTALA, physician practice and other health business acquisition, medical staff issues, tax exemption, practitioner licensure and sanctions, physician contracts, pharmacy and nonprofit corporations.

Barbara served as law clerk to the Honorable William C. Hastings, Judge, Nebraska Supreme Court from 1985-1986. She served as a Board member (1993-1999) and as President (1997-1998) of the Nebraska Chapter of the Healthcare Financial Management Association. Since 2001, Barbara has been selected by her peers for inclusion in *The Best Lawyers in America*<sup>®</sup> in the field of Health Care Law and is included on the *Chambers USA* (© 2013) list.

Barbara is a frequent lecturer to many organizations, including the American Academy of Healthcare Attorneys, the Nebraska Hospital Association, the Iowa Hospital Association, the Healthcare Financial Management Association (Nebraska and Iowa Chapters), the Nebraska Mental Health Association, the Nebraska Association of Medical Staff Services and Nebraska Continuing Legal Education, Inc., on such topics as corporate compliance, EMTALA, privacy of protected health information, credentialing, and fraud and abuse.

### Selected Practice Highlights

- Assisting hospitals in reorganizations, affiliations with regional health systems, hospital asset transfers, hospital management agreements, and medical practice asset acquisitions.
- Assisting in all aspects of EMTALA compliance, including medical and nursing staff education and policy development, and defending EMTALA investigations and civil monetary penalties
- Advising on medical staff bylaws and governance, and representing hospitals in medical staff focused review and discipline cases
- Educating and advising on Medicare and Medicaid compliance
- Representing institutional providers and practitioners in Medicare and Medicaid recoupment actions, repayments and self-disclosures
- Defending false claims investigations by US Attorneys' offices and the Office of Inspector General

### Professional & Civic Affiliations

- Nebraska State Bar Association
- Iowa State Bar Association

- American Bar Association
- Omaha Bar Association
- American Health Lawyers Association
- Chair, Conference for Mercy Higher Education
- Past President, Nebraska Chapter of the Healthcare Financial Management Association
- Past Secretary, Women's Fund of Greater Omaha
- Past Chair, Board of Directors of College of Saint Mary
- Past Chair, Board of Directors of Covenant Ministries of Benevolence, an affiliate of the Evangelical Covenant Churches of America
- Past President, Board of Directors of Santa Monica, Inc.
- ICAN, Influence, Class XI



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### Areas of Practice

Health Care

### Education

University of Iowa College of Law,  
J.D., 2011

New York University, B.A., 2007

### Bar & Court Admissions

Iowa, 2011

Nebraska, 2012

Whitney West represents health care providers on a wide range of regulatory, governance, and reimbursement issues. She regularly advises clients on all aspects of compliance programs, from developing policies and conducting training to assisting with voluntary self-disclosures and responding to governmental audits and investigations. Her practice also focuses on health care transactional matters, including business formation, mergers and acquisitions, and contracting.

Whitney graduated from New York University with a B.A. in Politics and received her law degree from the University of Iowa College of Law, where she served as Articles Editor for the *Iowa Law Review*.

Whitney is active in both local and national legal and health care associations and frequently speaks on topics such as fraud and abuse, corporate compliance, and pharmacy and medical device regulations.

### Selected Practice Highlights

- Representing providers in state licensure proceedings and federal administrative appeals
- Counseling clients with respect to certification, licensure, and accreditation standards, including preparing for and responding to facility surveys
- Assisting hospitals on developing medical staff bylaws, credentialing, peer review, and medical staff disciplinary matters
- Advising clients on HIPAA privacy and security standards and data breach notification requirements

### Professional & Civic Affiliations

- American Health Lawyers Association
- Healthcare Financial Management Association—Nebraska Chapter
- Iowa Society of Healthcare Attorneys
- Nebraska AIDS Project Board of Directors
- Nebraska Bar Association
- Iowa Bar Association

# 26<sup>th</sup> annual HEALTH LAW FORUM

## Real World Issues with Financial Assistance

*Andrew D. Kloeckner*

*Shelly Cassidy, Director*

*Patient Business Services, Mary Lanning HealthCare*

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## Real World Issues with Financial Assistance

Andrew D. Kloeckner  
Shelly Cassidy  
Director, Patient Business Services, Mary Lanning HealthCare

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## Objectives

- Overview of § 501(r)
- Financial assistance and billing and collection issues

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## Overview of IRC § 501(r)

- Requirements of § 501(r)
  - Written financial assistance policy (FAP)
  - Limitations on charges
  - Prohibition on certain collection efforts
  - CHNA

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## Overview of IRC § 501(r)

- Effective Dates
  - Apply for taxable years beginning after March 23, 2010 (date of PPACA enactment)
  - Statutory requirements apply now

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## Overview of IRC § 501(r)

- Range of compliance
  - Minimum – Statutory
    - “Good faith” interpretation of statute
  - Maximum – Proposed Regulations
    - Notice 2014-2 – Hospitals can rely on proposed regulations for compliance

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## Statutory Provisions

- § 501(r)(4) - Written FAP that includes:
  - Eligibility criteria and basis for calculating amounts charged to patients
  - Method for applying
  - Actions hospital may take in the event of non-payment
  - Measures to widely publicize FAP within community served

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## Statutory Provisions

- § 501(r)(5) – Limitations on Charges
  - Limit charges for emergency and other medically necessary care provided to FAP eligible individuals to amounts generally billed to insured individuals (AGB)
  - Prohibits “gross charges”

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## Statutory Provisions

- § 501(r)(6) – Billing and Collection Requirements
  - Requires “reasonable efforts” to determine eligibility under FAP before engaging in Extraordinary Collection Actions (ECAs)

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## High Deductible Plans

- Coinsurance and deductibles
  - Are deductibles and/or co-pays eligible for financial assistance?
    - “Uninsured”/“Underinsured” – definitions
  - Managed care contracts – Violation?

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## High Deductible Plans

Patient insured with high deductible plan (\$5K)

- Gross Charges – \$10,000
- Contractual discount – 10%
- Amount owed – \$9,000
- AGB – 60%
- Patient qualifies for 50% discount under FAP
- Insurance pays \$4,000
- Outstanding balance – \$5,000
- Apply 50% discount – Patient pays \$2,500
- Total hospital receipts – \$6,500
- $\$10,000 * 60\% = \$6,000$
- $\$6,500 > \$6,000$

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## Medical Indigence

- Eligibility criteria must be defined in detail
- If medically indigent eligible for assistance, limitations on charges rules apply

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## Medical Indigence

- Limitations on Charges (Example)
  - Medically indigent: medical bills in excess of 20% of net assets
  - Net assets – \$100,000
  - Gross charges – \$25,000
  - Expected payment – \$20,000
  - AGB – 60%
  - Maximum Charge – \$15,000

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## Prohibition on Gross Charges

- FAP-eligible individual will not be charged more than AGB *for emergency or other medically necessary care* **BUT**
- Prohibition on gross charges applies to all types of care
- What is non-medically necessary care?
  - Elective?
  - Cosmetic?

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## Calculating AGB

- Prop. Reg 1.501(r)-5 requires use one of two methods
  - Prospective Medicare Method
  - Look-Back Method

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## Calculating AGB

- Lookback Method
  - Multiply gross charges for a service by AGB percentage
  - AGB percentage calculated by dividing all claims for emergency and other medically necessary care paid in full by associated gross charges for those claims
    - "Paid in full" – Includes deductibles and co-pays

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## Calculating AGB

- Claims based on prior 12 month period
  - Must be computed at least annually
  - Must begin applying by the 45th day after the end of the 12 month period
  - Must continue to use chosen method
- Both methods include Medicare FFS

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## "Reasonable Efforts"

- Hospitals may not take ECAs until "reasonable efforts" have been made to determine whether FAP eligible
- Proposed Reg. 1.501(r)-6 defines "reasonable efforts"
  - Tied to actions taken during notification and application periods

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## "Reasonable Efforts"

- Notification period
  - 120 days after first bill
- Application period
  - 240 days after first bill

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## "Reasonable Efforts"

- Notification
  - Provide plain language summary of FAP and offer a FAP application prior to discharge;
  - Provide plain language summary with all (and at least three) bills and all other written communication;
  - Discuss the FAP in any oral communications about the charges; and
  - Give at least one written notice of types of ECAs that may be taken, and the deadline after which they may begin (not earlier than 30 days)

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## "Reasonable Efforts"

- When is "first bill for care" provided?
  - Multiple episodes of care
    - Does 120/240 day clock begin running when first bill for first episode of care is sent?
- All and at least three billing statements
  - Insurance pending statements – do they count?

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## "Reasonable Efforts"

- Documentation standard
  - Documentation of informing patients of FAP in every interaction with patient about the bill
    - Systems?
    - Training?
- Bank loan programs – are they ECAs?

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## “Reasonable Efforts”

- Final notices
  - At least 30 days’ notice
  - Can’t have action date earlier than end of notification period
- Presumptive eligibility disallowed
- Patients may not waive notice or opportunity to apply

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## Collection Vendors

- Referral to debt collection agency is not an ECA **BUT**
- Hospitals potentially liable for actions of vendors:
  - Contractually require billing collection vendors to follow hospital’s policies
  - Provide policies and educate vendors
  - Prohibit ECAs until after notification period
  - Require that vendor suspend ECAs if FAP application received during the application period
  - If FAP application is approved, require return of account and reversal of ECAs

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## Thank You

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# 26<sup>th</sup> annual HEALTH LAW FORUM

## Thinking on Your Feet... or How to Communicate with Regulators About Practically Anything

*Julie A. Knutson*

*Whitney C. West*

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Thinking on Your Feet . . .  
or How to Communicate with  
Regulators About Practically  
Anything

Julie A. Knutson  
Whitney C. West

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Who are the Players and  
What's at Stake?

- State surveyors
- Federal agents (e.g., OIG)
- Government contractors (e.g., RACs, ZPICs)
- Law enforcement (e.g., FBI, AGs, US attorneys)
- Private payers

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Tips for Managing  
Interactions with Regulators

1. Consider your approach
  - Avoid adopting a "litigation" mindset
  - Kill them with kindness – it's difficult to get the benefit of the doubt going forward if you get off on the wrong foot
  - Tailor your approach to the situation (responding to a record request vs. responding to surveyors on-site)

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## Tips for Managing Interactions with Regulators

2. Don't be afraid to ask questions
  - Communicate at the outset to determine regulators' area of concern or focus
  - Ask:
    - Is your organization or someone within your organization a target?
    - "What can you tell me about...?"
    - What prompted the inquiry, survey, or audit?

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## Tips for Managing Interactions with Regulators

3. Tell your side of the story
  - Giving reviewers the context/big picture is important at the beginning and throughout a review or investigation
  - It's best to clarify the underlying facts as early as possible to avoid the possibility that a regulator interprets a misunderstanding or possibly suspect activity as a legal violation or compliance problem
  - Surveyors do not always represent the facts accurately or completely in a Statement of Deficiencies

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## Tips for Managing Interactions with Regulators

4. Concede or avoid further discussion about errors and deficiencies where they exist
  - Concentrate on the strongest parts of your case which may be providing context and background as well as improvements and corrective action
  - Emphasize your ongoing compliance program. But what if you don't have one?

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## Tips for Managing Interactions with Regulators

4. Concede or avoid further discussion about errors and deficiencies where they exist (continued)
  - Important to concurrently undertake internal reviews and make corrections - don't wait for regulators to tell you what the problem is
  - "Immediate jeopardy" survey findings - try to avoid or abate before the end of the survey by sharing information to rebut the finding/concern

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## Tips for Managing Interactions with Regulators

5. Manage the internal process
  - Your goal should be to actively manage the survey/review/investigation as it develops as much as possible
  - Keep a complete record of all that transpires, e.g., interviews, documents provided
  - Establish coordinated internal communications both before and throughout the review process
  - Consult with counsel where necessary

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## Tips for Managing Interactions with Regulators

6. Respond strategically
  - Develop a strategy - based on the type of review, potential adverse consequences, type of regulator involved - *prior* to responding
  - It's important to do so quickly in light of the typically tight response deadlines
  - Don't give written responses short shift!

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## Tips for Managing Interactions with Regulators

7. Maintain focus on quality
  - When billing or reimbursement issues are investigated, it's important not only to respond to the immediate allegation, but also to focus on potential quality-of-care issues

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## Tips for Managing Interactions with Regulators

8. Adopt your reviewer's mindset
  - E.g., audit contractors think in terms of individual claims and a successful appeal requires a claim-by-claim response
  - Don't assume the reviewer is familiar with conditions of payment/coverage

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## Tips for Managing Interactions with Regulators

9. Reach out to regulators' regulators if necessary
  - Contractor reviews are frequently inadequate, overly general, poorly explained, and repetitious
  - CMS may be willing to go to bat for providers where its contractors have made mistakes
  - Also useful when contractors fail to respond, which frequently occurs

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## Self-Disclosures

- If you need to make a disclosure...
  - Problems beyond mere error
  - You may make an initial disclosure that is not complete
  - Ultimately disclosures will need to be made to all affected payors and beneficiaries who made copayments
  - Check timing – e.g., Nebraska’s Medicaid False Claims Act has a 30-day reporting window

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## Dealing with Regulators in Formal Adjudications

- Considerations when you reach an adjudication stage (e.g., state licensure hearing, PRRB appeal, ALJ hearing) include:
  - Often a limited ability to introduce new evidence
  - Posture of appeal has changed – the provider no longer enjoys benefit of the doubt
  - Delays mean even if you’re successful, it may be years before you recoup funds/are repaid

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## Final Thoughts

Communications need to be . . .

1. **Relevant** to the regulators & what they think of the case;
2. **Strategic** in terms of the type of case and who you’re interacting with;
3. **Coordinated** (having many different people interact with regulators is at best confusing and at worst detrimental);
4. **Timely**, with respect to hard deadlines as well as enhancing trust/transparency with reviewer; and
5. **Reasonable** and **respectful**.

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# Thank you

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# 26<sup>th</sup> annual HEALTH LAW FORUM

## Halifax Health: Where Did They Go Wrong?

*John R. Holdenried  
Zachary Buxton*

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## Halifax Health: Where Did They Go Wrong?

John R. Holdenried  
Zachary J. Buxton

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## Halifax Health – The Headlines

Florida Hospital to Settle Stark Law Case for \$85 Million: Tentative settlement between Halifax Hospital Medical Center and United States will end much-watched case alleging violations of False Claims Act

Health Care Alert  
3/5/2014

### Halifax Health settles fraud case

2nd trial to go forward in July

March 5, 2014 | By Mari Jemison, Orlando Sentinel

Halifax Health defends whistleblower settlement  
By *Skyler Swisher*  
[skyler.swisher@news-jmi.com](mailto:skyler.swisher@news-jmi.com)

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## Halifax Health – Baklid-Kunz



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## *Baklid-Kunz v. Halifax Hospital*

- *Background*

- Daytona Beach Halifax Hospital – 678 bed public hospital
- *Qui tam* suit, US intervened
- Many claims involve physician comp under Stark, others involve medical necessity

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## *Baklid-Kunz v. Halifax Hospital*

- Alleged 74,000 false claims, seeking damages and penalties between \$725 million and \$1.14 billion
- If successful, Baklid-Kunz would be eligible for 15 % to 25 %

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## Halifax – Allegations

- *Psychiatrists* – paid bonus of 100% of collections above base comp, free rent, free billing employee
- *Neurosurgeons* – paid bonus of 100% of collections after covering base comp and cost of medical secretary, includes PA services, exceeds FMV (all 3 over \$1 million, one at \$1.9 million)

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## Halifax – Allegations

- *Oncologists* – offered six employed oncologists' bonuses based on 15% of the hospital oncology department's operating margin
- *Directorships* – paid at hourly rate to non-employees well above 90<sup>th</sup> percentile, no real services performed

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## Baklid-Kunz – Who is She?

- Native of Norway, came to United States to learn English in 1986 after graduating high school
- MBA, CPC, CCS
- Halifax compliance officer until 2008, suit filed in 2009

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## Baklid-Kunz – Who is She?

- Said she tried to resolve questions she had about Halifax physician contracts and other issues internally
- The Halifax Director of Physician Services during the lawsuit
- Resigned July 31, 2014, to teach and serve as consultant to compliance industry; received one year severance as part of resignation

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## Key Ruling – November 2013

- Court rules:
  - Payments to medical oncologists violated Stark, based on Hospital revenues
  - Payments to neurosurgeons did not violate AKS since they were employees
  - Set for trial on damages and other issues

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## Settlement – March 3, 2014

- Settlement limited to physician comp claims – oncologists
- \$85 million, 24.5% of that to Baklid-Kunz
- Paid \$10 million for Baklid-Kunz legal fees

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## Settlement – March 3, 2014

- Also a five-year, Corporate Integrity agreement
  - Substantial internal compliance reforms
  - Includes independent review and compliance experts
- Medical necessity claims to be tried later (settled for \$1 million)

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## Settlement – March 3, 2014

- Public records request disclosed \$22.8 million spent on Halifax legal fees and another \$1.5 million on other legal-related costs
- Where did \$85 million come from? Appears to be \$27-\$35 million of hospital claims paid in violation of Stark (that's before treble damages and civil penalties)

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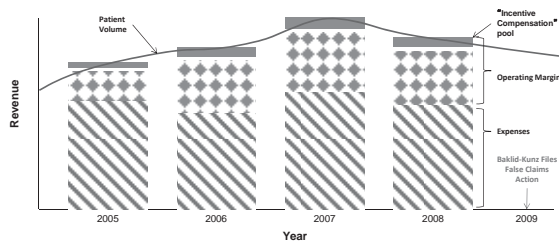
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## The Ultimate Error

- Funding of bonus pool for Employed Oncologists from Hospital's margin from medical oncology services



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## Hospital Position

- Hospital continues to contend
  - This was “technical” violation
  - Had community's best interest in mind
  - Settled to minimize legal expenses
  - Structured agreements to keep vital physicians in the community

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## Hospital Position

- Says Stark is 10 pages long but open to 900 interpretations
- But will now view contracts from standpoint of how they will be viewed by Government and outsiders

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## Error #1 – Thinking that Public, Safety-Net Hospitals are Immune

- Baklid-Kunz: "I was always told that Halifax was not liable under (the False Claims Act) because we were a tax-supported hospital."
- No broad governmental immunity
  - No different treatment
  - Four factors:
    - State law characterization, state control, source of funding & fiscal autonomy, and responsibility for judgments

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## Error #2 – Misunderstanding A/C Privilege and How to Protect It

- Failing to create, segregate, and protect attorney/client privileged documents
  - Initial disclosure without claiming privilege
  - Dealings with in-house counsel on legal and non-legal issues
  - Communications to counsel to keep in the loop
  - Compliance advice is not inherently privileged
  - Crime/fraud exception still there
  - Mixing business/legal advice communications – no attorney in "to" or "from" lines, and no legal advice sought in emails

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### Error #3 – Dealing with Whistleblowers' Concerns

- Baklid-Kunz: "I filed the case because I was afraid hospital officials and I would face criminal charges. I honestly felt that I didn't have a choice."



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### Error #3 – Dealing with Whistleblowers' Concerns

- OIG speech at HCCA:
  - These are issues that can be best avoided by ensuring that your compliance officials are listened to
  - The compliance officer was really pleading with management to note what she viewed as serious Stark violations with respect to these contracts



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### Error #4 – Overreacting to Physician Departures/Competitive Pressures

- Hospital PR piece:
  - Four employed oncologists had left for more lucrative private practice
  - In an effort to achieve FMV for the remaining cancer specialists and fulfill its safety net role, Halifax amended bonus structure to encourage cost containment in the highly variable and expensive treatment of cancer



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**Error #5** – Relying on Second Opinion that Bonuses “Arguably” Comply with Stark

- In-house lawyer’s opinion said it was illegal, recommended self-disclosure
- Second opinion sought from McDermott Will – reasonable argument that contracts could be defended in court but no assurances a judge or Gov’t would agree
- Justice Department: Review by McDermott Will found only “a reasonable argument” that the contract was legal

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**Error #6** – Destruction of Records Requested in Litigation

- Litigation hold notice December 28, 2009
- Relevant patient records created in 2002, 2003, and 2004 destroyed between January and September 2012
- Magistrate Judge recommended awarding attorneys’ fees as sanctions

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**Error #7** – Misunderstanding the Burden of Proof

- Clear now that Government need only prove financial relationship and referral
- Relatively easy hurdle for Government
- Hospital must then prove exception

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# Thank you

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# 26<sup>th</sup> annual HEALTH LAW FORUM

## Health Information Privacy and Security: The Perfect Storm of Risk

*Vickie B. Ahlers*

*Alex M. "Kelly" Clarke*

*Cameron Burt, Vice President*

*Holmes Murphy*



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## Health Information Privacy and Security: The Perfect Storm of Risk

Vickie B. Ahlers  
Alex M. (Kelly) Clarke  
Cameron Burt  
Vice President, Holmes Murphy

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### "JP Morgan reveals data breach affected 76 million households"

*USA TODAY October 3, 2014*

SAN FRANCISCO — The cyber attack on JPMorgan Chase & Co., first announced in July, compromised information from 76 million households and 7 million small businesses, the company revealed Thursday in a filing with the Securities and Exchange Commission.

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### The Home Depot Message



- »Sept. 18: 56 million credit cards compromised
- »Nov. 6: Oh, *and* 53 million emails compromised
- »Nov. 7: We expect our sales to increase 5% this year

**Are consumers numb to data breaches?**

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## "Your medical record is worth 10x more to hackers than your credit card"

(Reuters) – Last month, the FBI warned health care providers to guard against cyber attacks after one of the largest U.S. hospital operators, Community Health Systems Inc., said Chinese hackers had broken into its computer network and stolen the personal information of 4.5 million patients....

The data for sale includes names, birth dates, policy numbers, diagnosis codes and billing information. Fraudsters use this data to create fake IDs to buy medical equipment or drugs that can be resold, or they combine a patient number with a false provider number and file made-up claims with insurers...

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## "Medical Records Inappropriately Accessed by Team Member"

"Newport News, VA - Riverside Health System is offering free credit monitoring to several hundred patients affected by a privacy breach.

The breach was discovered during a random company audit on Nov. 1. After an investigation, Riverside's Compliance department determined that an employee had inappropriately accessed 919 medical records, spanning September 2009 through October 2013." -Hospital press release

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## The Perfect Storm of Risk:

- Threats from cybercriminals
  - At all time high
  - Health care industry targeted
- The insider threat:
  - Misconduct/poor judgment of employees continues to be widespread, despite training
  - Can and may be held against you
    - Large liability for health care organizations

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## The Perfect Storm of Risk

- HIPAA Permanent Audit Program
- Breach notification requires you to self-report most violations
- OCR investigations
- State AGs and FTC taking their shots
- New theories allowing private lawsuits to proceed

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## HIPAA Audits

- First phase of Audits completed in 2012
- Permanent Audit Program announced
  - February 2014 – OCR announcement that second round of audits authorized (i.e., funded)
  - Pre-survey by OCR conducted initially of up to 1200 covered entities
    - Assess size, complexity and fitness of an organization for an audit
    - Request number of patient visits, use of EHR, revenue and business locations, in addition to other data

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## Phase 2 Audit Distribution Projections\*

Entity Type	Privacy	Breach	Security
<b>Covered Entities</b>	100	100	150
• Health Plans	33	31	45
• Providers	67	65	100
• Clearinghouses	-	4	5
<b>Business Associates</b>	0	0	50
• IT Related	-	-	35
• Non-IT Related (e.g., TPAs, claims)	-	-	15
<b>Total Audits by Protocol</b>	100	100	200

\*Presentation by Linda Sanchez, OCR Senior Advisor, March 31, 2014

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## Phase 2 Timing\*

Period	Activity
Spring 2014	CE address verification
Summer 2014	Pre-audit surveys link sent to covered entity pool
Fall 2014	Notification and data request letters to selected entities
Two weeks	Period for entity response
October 2014 – June 2015	CE Audit Reviews
2015	Business Associates

\*Presentation by Linda Sanchez, OCR Senior Advisor, March 31, 2014

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## Phase 2 Audit Focus\*

- **2014 – Covered Entities**
  - Security – risk analysis and risk management
  - Breach – content and timeliness of notifications
  - Privacy – notice, access and **workforce training**
- **2015**
  - *Round 1 Business Associates*
    - Security – risk analysis and risk management
    - Breach – breach reporting to CE

\*Presentation by Linda Sanchez, OCR Senior Advisor, March 31, 2014

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## Phase 2 Audit Focus\*

- *Round 2 Covered Entities (Projected)*
  - Security – device and media controls, transmission security
  - Privacy – safeguards, training to policies and procedures
- **2016 (Projected)**
  - Security – encryption and decryption, facility access control (physical); other areas of high risk as identified by 2014 audits, breach reports and complaints

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## Desk Audit Expectations\*

Data request will specify content & file organizations, file names, and any other document submission requirements

Only requested data submitted **on time** will be assessed

All documentation must be **current as of the date of the request**

Auditors will **not** have opportunity to contact the entity for clarifications or to ask for additional information, so it is critical that the documents accurately reflect the program

Submitting extraneous information may **increase difficulty** for auditor to find and access the required items

Failure to submit response to requests may lead to referral for regional compliance review

\*Presentation by Linda Sanchez, OCR Senior Advisor, March 31, 2014

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## From Audit to Investigation

- If audit raises concerns, will be referred for full compliance investigation
- So.....how are those turning out?

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## OCR HIPAA Enforcement

- Unprecedented settlement amounts
- Large and small entities
- Governmental and private
- Privacy and security
- Multiple entities at same time

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## Skagit County, Washington

- Skagit County Public Health Department
- ePHI of **seven individuals** accessed after the ePHI had been inadvertently moved to a publicly accessible server
- Breach report to OCR on the seven individuals
- OCR investigated, found exposure of 1,581 individuals
- Uncovered “widespread non-compliance”
- **Settlement: \$215,000**

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## QCA Health Plan, Inc. of Arkansas

- Unencrypted laptop computer containing ePHI of **148 individuals** stolen from workforce member's car
- Breach report to OCR (year end)
- OCR found they failed to comply with numerous requirements of Security Rule dating back to 2005 – 2012
- **Settlement: \$250,000**

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## Concentra Health Services

- Unencrypted laptop stolen from facility in Springfield, Missouri
- Concentra previously documented in multiple risk analyses that lack of encryption on its devices containing ePHI was a critical risk
- Steps taken to begin encryption but efforts incomplete and inconsistent
- **Settlement: \$1.725 Million**

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**New York  
Presbyterian/Columbia U**

- Joint breach report involving 6,800 patients
- Faculty members of Columbia University serve as attending physicians at NYP
- Shared data network
- CU physician who also developed applications for NYP and CU attempted to de-activate a personally-owned computer server on the network – resulted in ePHI being accessible on internet search engines

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**New York  
Presbyterian/Columbia U**

- OCR found neither entity made efforts to assure the server was secure or contained appropriate software protections
- Neither had conducted accurate or thorough risk assessment
- Lack of security policies on authorizing access and access management
- **Settlement: NYP - \$3.3 Million**
- **Settlement: CU - \$1.5 Million**

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**Parkview Health System**

- Parkview Health System took custody of 5,000 – 8,000 patient records of physician
- Evaluating purchase of physician's practice
- Dispute with physician
- Left 71 cardboard boxes of records in physician's driveway
- **Settlement: \$800,000**

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## State Attorney General Enforcement

- Cal. v. Kaiser Found. Health Plan (Jan 2014)
  - External hard drive w/PHI donated, later purchased at public thrift shop
  - \$150K settlement due to 3-month delay in notifying 20,000 employees
- Triple-S Management Corp. (Feb 2014)
  - \$6.8M fine for including patients Medicare claim numbers on mailing labels

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## FTC Enforcement

- Section 5 of FTC Act
  - Prohibits “unfair” or “deceptive” trade practices
  - Any promises you make to customer that are not upheld, FTC believes it can enforce (Notice of Privacy Practices)

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## FTC Enforcement

- Notable FTC health information enforcement cases
  - CVS (improper disposal)
  - Rite Aid (improper disposal)
  - Accretive Health (unencrypted laptop)
  - GMR Transcription (overseas vendor issues)
- In all the above cases, FTC imposed ***20 years of monitoring!***

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## FTC Enforcement

- Legal Challenges to FTC Authority Were Watching
  - LabMD (P2P file sharing)
    - LabMD: FTC no authority over HIPAA-regulated entity
    - Eleventh Circuit will hear case soon
  - Wyndham Worldwide (hackers)
    - Wyndham: FTC lacks authority to regulate data security practices
    - On appeal to Third Circuit

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## What's Happening in the Courts

- Defendants largely successful in private suits
  - Plaintiffs struggle to allege cognizable injuries
  - *Clapper v. Amnesty International*, 133 S. Ct. 1138 (2013)
    - Supreme Court raises bar for standing
    - Threatened future identity theft does not satisfy Article III standing
    - Possible future injury – may be enough, but must be “certainly impending,” and not speculative
  - Plaintiffs have difficulty in proving with certainty that identity theft was a result of *that* breach

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## \$4 Billion+ Lawsuit Dismissed

### Court halts \$4 billion privacy suit against Sutter Health

By Associated Press  
Published: Monday, Jul 21, 2014 - 9:12 pm

A state appellate court Monday ordered the dismissal of a lawsuit that could have cost Sutter Health more than \$4 billion when it ruled that millions of the health care giant's patients had no right to sue over the theft of a computer with their personal, medical and insurance records on its hard drive.

The court decided it has not been shown — and the patients have not alleged — that any unauthorized persons have actually viewed the contents of the hard drive, a fact that deprives the patients of grounds to seek civil damages.

Soon after Sutter's announcement in November 2011 that a desktop computer had been stolen from a South Sacramento office, patients began filing individual lawsuits alleging violations of California's Confidentiality of Medical Information Act. Those suits were eventually consolidated and a master complaint, proposed as a class action, was filed in Sacramento Superior Court.

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## What's Happening in the Courts

- Then Came AvMed...
  - Theft of two laptop computers containing 1.2 million customers' personal information
  - Lawsuit alleging AvMed failed to implement adequate safeguards to properly protect their electronically stored information
  - Claims: Negligence, Negligence *per se*, Breach of Contract, Breach of Fiduciary Duty, and Restitution/Unjust Enrichment

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## What's Happening in the Courts

- Eleventh Circuit Appellate Court Rules:
  - Plaintiffs sufficiently alleged causes of action for negligence, breach of contract, breach of implied contract and breach of fiduciary duty and unjust enrichment
  - Because AvMed did not properly secure its customers' data, it "cannot equitably retain their monthly premiums – part of which were intended to pay for the administrative costs of data security."
  - March 14, 2014: AvMed settles for \$3.0 Million

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## Other Notable Cases

- *In re LinkedIn User Privacy Litigation (Mar. 28, 2014)*
  - Plaintiff purchased premium membership; information compromised; now claims she did not receive the benefit of her bargain because LinkedIn promised to secure her personal information and failed to do so.
  - Court: Sufficient to secure Article III standing
  - \$1.25 million settlement pending

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## Other Notable Cases

- *In re Adobe Systems, Inc. Privacy Litigation* (N.D. Cal. Sept. 4, 2014)
  - 38 million customers data compromised
  - Court: Risk that Plaintiff's personal data will be misused by the hackers is immediate and very real. Allowed case to proceed.

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## Wait and See Game...

- Illinois state court dismisses class action suit against Advocate Health (four unencrypted laptops with records of four million patients stolen)
- Court: Plaintiffs have not alleged that the information contained on the stolen laptops has been accessed or disseminated by unknown third parties or that they have been victims of identity theft
- Several more cases pending against Advocate; Plaintiffs counsel states they plan to raise the *AvMED theory* in remaining cases

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## When (not if) your organization faces a data breach:

- Breaches of medical information cost the industry \$5.6 billion each year
- Criminal attacks on provider data increased 100% over last year

Source: Fourth Annual Benchmark Study on Patient Privacy and Data Security (3/12/14)

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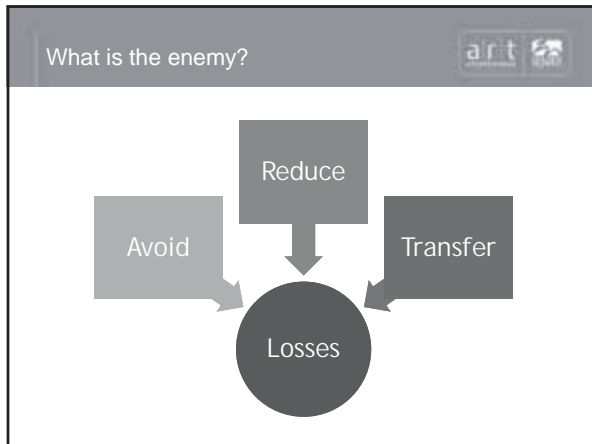
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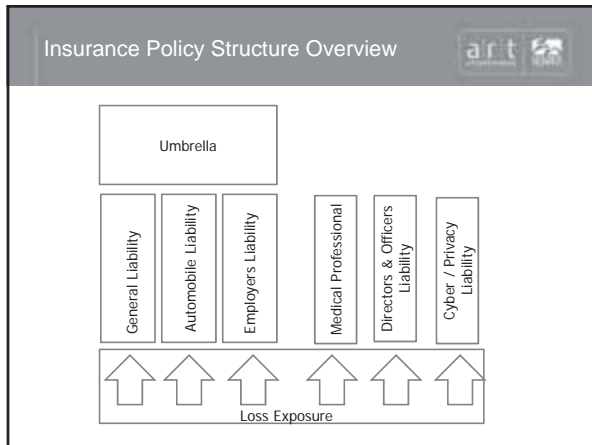
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Why Cyber/Privacy Liability? 

- **General Liability** – (may provide limited coverage) for "publication of material that invades a person's right to privacy"
- **Commercial Property** – electronic data extension only covers replacement of destroyed or corrupted data. Indirect or consequential loss excluded
- **Commercial Crime / Computer Crime** – generally excludes loss from theft of confidential information & excludes indirect or consequential loss
- **D&O Policy** – D&Os unlikely to be named. Some policies have invasion of privacy excluded in BI/PD or Personal Injury Exclusion. No 1<sup>st</sup> party expense coverage
- **Med Prof. Policy** – generally respond only to loss from a defined professional service and typically no "first party" coverage for breach-related expenses

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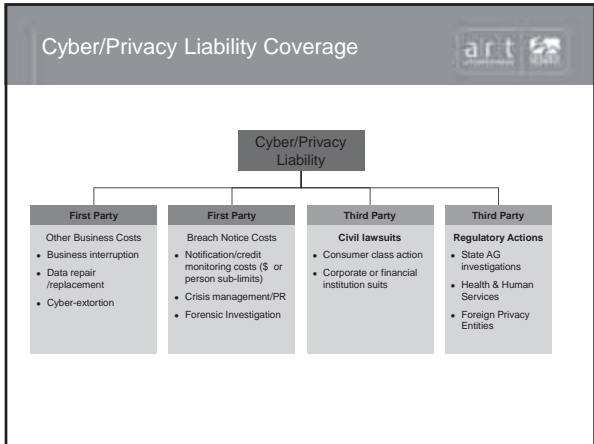
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- Choosing an Insurance Carrier
- Financial stability
  - Coverage terms and conditions
  - Appetite for clients in your industry
  - Appetite for the size of your client's business
  - Commitment to the product
  - Claims paying reputation and infrastructure
  - Industry expertise
  - Relationships with expertise – attorneys, security firms, forensic specialists

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## Insurance Carrier Underwriting



- Data/Confidential Info – Types/How much?/location
- Encryption (Safe harbor) – At rest, in motion, backup, mobile devices
- Systems & Software – Patches/updates/controls
- Use of cloud vendors – who/what services (payroll, payments, services, etc.)
- Vendor Controls – Due Diligence/ Contracts/Data shared/Access control
- Network Access – How and who accesses your network remotely?
- Subsidiary acquisitions – Due diligence, conversion process
- Compensating controls – What else are you doing?

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## How much does a breach cost?



### Breaches: By the numbers.... Cost of a breach record




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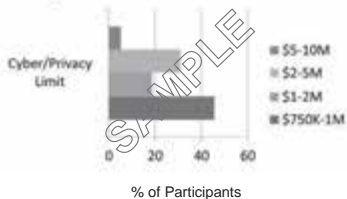
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## How much limit should we buy?



- History** - How much have other companies had to pay in defense expenses, settlements, and fines?
- Exposure** - Amounts and types of data stored - Exposure for data loss is tied to the number of individuals you have information on
- Peer Benchmark** - How much do my peers buy?
- Industry Benchmark** - How much do others in my industry/size buy?




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Case Study #1 : Cascade Medical Center



On May 3, 2013, news appeared that cybercriminals recently stole more than \$1 million from a county hospital that's part of Cascade Medical Center. The complex scheme is suspected to have involved hacking into the medical center's accounting system, says Chelan County Treasurer David Griffiths. Griffiths suspects that the cyber fraud is likely to have started through spear-phishing e-mails to Cascade employees who unknowingly turned over the keystrokes needed to access the medical center's accounting system. The theft, from county funds held with Bank of America, was initiated on April 19 but not discovered until April 22, a Monday. Griffiths' office noted three unauthorized transaction files that shipped a total of \$1.03 million to 96 separate accounts across the country. On June 3, 2013, Griffiths said Cascade Medical Center has definitely lost at least \$478,886 of the total theft. The stolen money was probably gone to Russia. About \$414,800 has been recouped through coordination with outside banks where the money was fraudulently transferred. Much of the lost money was likely funneled out through wire transfers and cash withdrawals. Brian Krebs, a cyber security journalist, attributed the crime to hacker organizations operated from Russia and Ukraine, which hired or subcontracted freelance "mules" through a wide-ranging set of work-from-home frauds.

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Case Study #2 : Stanford Hospital & Clinic



On September 28, 2011, Shana Springer commenced a lawsuit in the Superior Court of the State of California, County of Angeles, Central District against Stanford Hospitals & Clinics and Multi Specialty Collection Services in violation of the California Confidentiality of Medical Information. The class action lawsuit claimed that Stanford and Multi-Specialty Collection Services violated the California Confidentiality of Medical Information Act, which prohibits medical providers from disclosing patients' medical information without their written consent. The Stanford data breach lawsuit initially sought damages in the amount of \$1,000 per affected patient. Corcino & Associates one of affiliated vendor of SHC was later added as one of the defendant of the case. On March 19, 2014, the Court preliminarily approved the settlement. Multi-Specialty Collection Services, LLC and Corcino & Associates agreed to pay \$3.3 million to the plaintiffs. Consequently, SHC will pay \$500,000 for vendor education fund; \$250,000 for administrative cost; and the remaining \$75,000.

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Questions?



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Self Assessment Survey:  
[www.holmesmurphy.com/infosecurity](http://www.holmesmurphy.com/infosecurity)

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## Thank you

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## TALK THE TALK CYBER, INFORMATION SECURITY, & PRIVACY TERMINOLOGY

As cyber crime emerges as a major risk for businesses, the volume of information on the subject coming at you from various media can be dizzying. Yet, having knowledge of the risk is an important step in effectively managing it for your company. To help you talk the talk of cyber crime and better understand the issue, we've compiled key terms and ideas to know.

**Cyber** - A general term used to refer to computer and information technology.

**Cyber Liability** - Insurance coverage purchased to address privacy and security risks. It is typically broken down into two silos:

- **1st Party Expense Reimbursement:** Typical coverages include crisis management event expenses, security breach remediation and notification, computer program and electronic data restoration expenses, computer fraud, funds transfer fraud, e-commerce extortion, and business interruption.
- **3rd Party Liability:** This coverage typically includes network security liability, data privacy liability, communication and media liability, and regulatory defense coverage.

**Cyber Extortion** - A crime in which an individual demands payment to prevent the threat of or stop an attack on an organization's computer network or website.

**Electronic Theft** - Theft of data or other information that is monetarily valuable.

**Encryption** - The method of protecting text, data, or other communications from those who should not have access to it. Those who do not have the password or key needed will not be able to make sense of an encrypted file, and the file will appear as gibberish.

**Firewall** - A protective barrier between the outside world and your computer or network that blocks all unnecessary traffic and increases security.

**Flash drive** - A portable data storage device that uses flash memory and has a built in USB connection. Also called a jump drive, thumb drive, or USB drive.

**Malware** - Also known as malicious code. A general term used to refer to any kind of software that causes damages to a computer or network, including viruses, worms, etc.

**Media/Personal Injury coverage** - Coverage for libel, slander, disparagement of individuals and/or businesses, false arrest.

**Network** - Two or more computers connected to each other to enable sharing of files and information between them.

**Notification Costs** - Those costs associated with notifying individuals whose privacy has been breached. Governed by state law. Also called privacy notification costs.

**PCI Compliance** - PCI stands for Payment Card Industry, whose set of requirements, officially called the Payment Card Industry Data Security Standard, ensure that all companies that process, store, or transmit credit card information maintain a secure environment.

**Personal Identification Information (PII)** - Any name or number that may be used, alone or in conjunction with any other information, to identify a specific individual.

**Phishing** - An attack aimed at getting your personal or confidential information. It typically involves spam emails that are designed to bring a user to a web site, which may be a spoof to look like a bank or a retail site, where you enter in your personal information.

**Protected Health Information (PHI)** - Any health information created, received, transmitted, or maintained by a covered entity that links an identifiable person with their health condition.

**Regulatory Proceedings** - Proceedings brought by federal or state agencies against an Insured. The most likely entities to be bringing these proceedings would be the Federal Trade Commission or an individual State Attorney General.

**Security Breach** - A general term used to indicate when a computer system has been infiltrated by an individual without access (or beyond approved access). This security breach may result in disclosure of private or confidential information, but it also may not.

Sources: CRC Insurance Services, Inc., Travelers



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holmesmurphy.com

# 26<sup>th</sup> annual HEALTH LAW FORUM

## The Latest Word

*Panel of Baird Holm Attorneys*

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## Latest Word

Panel of Baird Holm Attorneys

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## Duties and Authority of Public Health Officials

Alex M. ("Kelly") Clarke

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## AUTHORITY

- Issue – federal, state or local authority to impose restraints on individuals?
- Authority –
  - State authority under 10<sup>th</sup> Amendment
  - Limitation: *Jacobson v. Commonwealth of Massachusetts*
  - Scope of federal authority

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## Nebraska Authority

- Local health department (LHD) primarily responsible unless –
  - State-wide risk or exposure
  - Local officials fail or refuse to act
  - No local authority established
- LHD to adopt and enforce rules, conduct investigations
- DHHS retains overall authority

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## Directed Health Measures

- General findings to support directed health measures
  - There has been an exposure
  - DHMs can prevent, limit or slow the threat
  - Findings of risk
- If Director makes findings and also finds delay will increase risks, Director may impose the DHMs

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## Orders

- Directed Health Measures take the form of an "Order" with required content
  - Orders first approved by State Public Health Department
- Violations are a Class III Misdemeanor
- Individual or mass notice required

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## Directed Health Measures

- Quarantine –
  - Of individuals
  - Of populations
  - Of premises
  - Of animals
- Isolation –
  - At home or at a health care facility
  - At another designated area

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## Directed Health Measures

- Decontamination
- “Such other protocols or measures as may be identified as effective ... by the American Public Health Association or [CDC].”
- Temporary seizure of real or personal property

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## Federal Quarantine Authority

- Authority is “at the border” or where the risk of spread is across state lines
  - Includes quarantine and detention
  - Includes closing the borders to populations or individuals
- If state efforts insufficient to prevent interstate spread, Director of CDC may “take measures”

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## State of Emergency

- Governor can declare a state of emergency
  - Authorizes application of additional state resources to the local effort
  - Lets the Governor request that the President to declare a state of emergency, which opens possibility of federal resources
  - State takes the lead following Declaration

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## Conclusions

- Public health authority is well developed and understood
- Extraordinary powers available to deal with a health emergency
- Individual restraints require a nexus to risk and remediation

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Thank you

Alex M. ("Kelly") Clarke

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## Trade Name Registrations The What, Why and How

Kamaal Patterson

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### What is a Trade Name?

- A **trade name** is the official name under which a company does business
  - “Doing business as” name
  - Assumed name
  - Fictitious name

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### What is a Trade Name?

- Difference between
  - Trade name and legal name
  - Trade name and a trademark

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## Why is it Important to Register?

- Allows public to associate the business with the legal entity
- Grants protection within the state
- Allows you the right to bring a civil action for misuse of trade name
- Be careful not to infringe!

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## How to Register

- Nebraska – Secretary of State
  - \$100 filing fee
  - Publication requirement
  - Valid for 10 years
- Iowa
  - Fictitious Name vs. Trade Name
  - County Recorder vs. Secretary of State

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Thank you

Kamaal Patterson

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## New Competitor Use of Stark / Anti-kickback Claims

John R. Holdenried

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## New Competitor Use of Stark / Anti-kickback Claims

- Ameritox sues urine screening competitor Millennium Labs claiming unfair competition and tortious interference
- Alleges violation of Stark and anti-kickback laws as basis for claims

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## New Competitor Use of Stark / Anti-kickback Claims

- At issue:
  - Providing free point-of-care test cups to physicians in order to secure their business
- Evidence:
  - Cups only provided to physicians who sent them urine specimens and agreed to have Millennium conduct a minimum number of tests on each specimen

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## New Competitor Use of Stark / Anti-kickback Claims

- Jury found this violated Stark and Federal anti-kickback statute when physicians billed for chemical analysis of the same specimen
- Awarded Ameritox \$14.775 million in damages (\$2.755 in actual damages, \$12 million punitive) (Subsequently reduced to \$8.5 million punitive)
- Court denied permanent injunction

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## Important Points

- Note:
  - Not a qui tam case
  - Government not involved
  - Claim is based on state unfair competition laws
  - Still no private right of action under Stark/anti-kickback laws
  - Potential new remedy for businesses that think competitors are violating laws

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Thank you

John R. Holdenried

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## Proposed Anti-Kickback Safe Harbors & ACA CMP Exception

Zachary J. Buxton

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## Changes to Existing AKS Safe Harbors

- Referral services (42 CFR § 1001.952(f))
- Cost-sharing waivers (42 CFR § 1001.952(k))
  - Medicare Part D Cost-Sharing Waivers by Pharmacies
  - Cost-Sharing Waivers for Emergency Ambulance Services

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## Proposed AKS Safe Harbors

- FQHCs and Medicare Advantage Organizations (42 CFR § 1001.952(z))
  - Medicare Modernization Act amendment
- Medicare Coverage Gap Discount Program (42 CFR § 1001.952(aa))
  - Patient Protection and Affordable Care Act amendment

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## Proposed AKS Safe Harbors

- Local Transportation (42 CFR § 1001.952(bb))
  - Limited to established patients
  - Excludes DME suppliers and pharmaceutical companies
  - Equal access based on provider
  - Eligibility not based on treatment
  - May protect other services “related” to health care (i.e., social services or benefits application)

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## Proposed AKS Safe Harbors

- Local Transportation (42 CFR § 1001.952(bb)) (cont.)
  - No planes, luxury vehicles, or ambulances
  - No marketing or advertising
    - Hospital name on vehicle okay
  - Driver and other transportation employee compensation not based on per-beneficiary transported
  - Friends, family, or others permitted in transport
  - Varying distance criteria
  - No costs transferred to Federal health care programs

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## ACA Civil Monetary Penalty Exception

- ACA added exception to “remuneration” for CMP
  - Protects remuneration “which promotes access to care and poses low risk of harm to patients and Federal health care programs [...]”

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## ACA Civil Monetary Penalty Exception

- Promotes access to care
  - Improves a particular beneficiary's ability to obtain medically necessary health care items and services
- Low risk of harm to Medicare and Medicaid programs and beneficiaries
  - (1) Unlikely to interfere with, or skew, clinical decision-making;
  - (2) Unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization; and
  - (3) Does not raise patient-safety or quality-of-care concerns

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## Proposed Rules, Not Finalized by OIG

Federal Register:

<http://www.gpo.gov/fdsys/pkg/FR-2014-10-03/pdf/2014-23182.pdf>

Comments due December 2, 2014:

<http://www.regulations.gov/#!submitComment:D=HH SIG-2014-0005-0002>

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Thank you

Zachary J. Buxton

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## Labor and Employment Update

Scott S. Moore

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## Labor and Employment

- Pregnancy leave and light duty
- Immigration reform?
- Labor election processes
- Wage and Hour Exemption Overhaul

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## Thank you

Scott S. Moore

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## Medicare Appeals Backlog

Julie A. Knutson

#1331779.1

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## Medicare Appeals Backlog

- November 5, 2014 Federal Register (79 Fed. Reg. 65,660)
- Request for comments by the DHHS Office of Medicare Hearings and Appeals (OMHA)

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## Medicare Appeals Backlog

- Comments due December 5, 2014
  - Comments on previously announced initiatives, plus
  - Suggestions for additional actions

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## Medicare Appeals Backlog

- ALJ appeals are seriously backlogged
  - approximately 500,000 claims; MAC, RAC and ZPIC audits
  - 2013 – 506% increase in RAC appeals
- July 13, 2013 – ALJ hearings were suspended for two years to allow time to catch up

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## Medicare Appeals Backlog

- Center for Medicare Advocacy filed a lawsuit in August 2014 seeking to force the Secretary of DHHS to comply with a statutory requirement that an ALJ rules on an appeal within 90 days of filing
- Several other lawsuits are pending

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## Medicare Appeals Backlog

- ALJ hearing is crucial for providers and suppliers
  - Most claims are denied in initial steps conducted by CMS

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## Medicare Appeals Backlog

- With a total of 65 ALJs, it seems doubtful that the backlog of claims will be cleared
- Processing time has increased from 94.9 days in 2009 to 329.8 days in 2014

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## Medicare Appeals Backlog

- Chief Administrative Law Judge Nancy Griswold has recommended:
  - Issuing an adjudication manual to improve consistency and efficiency in decisions
  - Use of statistical sampling to resolve large groups of appeals

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## Medicare Appeals Backlog

- Using mediation
- Improving case management efficiency, e.g., electronic filing

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## Medicare Appeals Backlog

- How Realistic Are Reforms?
  - Procedural improvements are clearly inadequate to address backlog
  - Fundamental improvements are needed re: low reversal rates in early appeal stages; redetermination and reconsideration

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## Medicare Appeals Backlog

- Industry groups have called for a moratorium on interest charges on overpayments as well

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Thank you

Julie A. Knutson

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# 26<sup>th</sup> annual HEALTH LAW FORUM

## Disruptive Physicians: Tolerance No Longer

*Barbara E. Person*

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## Disruptive Physicians: Tolerance No Longer

Barbara E. Person

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### Drivers of Disruptive Behavior

- Substance abuse, psychological issues
- Narcissism, perfectionism, selfishness
- Spillover of chronic/acute family/home problems
- Poorly controlled anger; especially under stress
  - Poor clinical/administrative systems support
  - Poor practice management skills
  - Providers' constant criticism creates poor practice environments
- Bad behavior gets results and is rewarded!
- Clinical administrative inertia
  - No one does anything about it and the behavior is considered the individual's norm

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### Risks of Disruptive Behavior

- Risk to patient safety
  - Reluctance to interact with disruptive physician
    - Clarification of orders
    - Call for instructions
    - Call to provide updated info
    - Reluctance to question inappropriate orders
    - Reluctance to bring errors to physician's attention

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## Risks of Disruptive Behavior

- Risk to patient safety
  - 40% of clinicians remain quiet rather than confront known intimidator
  - 75% asked colleagues to help interpret an order to avoid interacting with an intimidating prescriber
  - 39% felt hospital dealt effectively with intimidating behavior

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## Risks of Disruptive Behavior

- Risk to employee morale
  - Loss of confidence in leadership
    - Feeling no one cares
    - Feeling abused
    - Loss of respect for organization
  - Resulting in:
    - High employee turnover
    - Disgruntled employees (whistleblowers)
    - Poor job performance
    - Stop reporting incidents
- Risk of employment-related claims (e.g., sexual harassment)

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## Disruption and Sexual Harassment

- *Kopp v. Samaritan Health System, Inc.*
  - Hospital and cardiologist defendants
  - Cardiologist threw stethoscope at plaintiff
  - Referred to plaintiff as "that stupid bitch"
  - Cardiologist grabbed plaintiff's bra straps and skin
  - Cardiologist shook plaintiff for approximately 30 seconds
  - Hospital's response: required cardiologist to send apology letter and take two week vacation (during which he attended a seminar for which he had previously registered)
  - Cardiologist responsible for \$4 million in hospital admissions in previous year

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## Disruption and Sexual Harassment

- 29 C.F.R. § 1604.11
- "(e) An employer may also be responsible for the acts of non-employees, with respect to sexual harassment of employees in the workplace, where the employer (or its agents or supervisory employees) knows or should have known of the conduct and fails to take immediate and appropriate corrective action."

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## Elements of Sexual Harassment Claim

- Belong to protected group
- Subject to unwelcome sexual harassment
- The harassment was based on sex
- The harassment affects a term, condition, or privilege of employment
- Employer knew or should have known of the harassment and failed to take proper remedial action

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## Federal District Court Holding

- "Once an employer becomes aware of sexual harassment, it must promptly take remedial action which is reasonably calculated to end the harassment."
- Evidence of physician's abuse of employees included administration's discussion of cultural bias based on Iraqi background. (Noted as inappropriate ethnic stereotype.)

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## Federal District Court Holding

- Physician was more abusive of female employees than of male employees.
  - Ten examples were provided of abuse of females, and many involved physical abuse.
  - Four examples of verbal abuse of men.

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## Risks of Disruptive Behavior

- Risks to Hospital Reputation
  - Inappropriate conduct in front of patients and families
  - Hospital's reputation plummets with health care providers, both employed and contracted, as well as medical staff members
  - Erodes community confidence in the hospital's ability to provide quality patient care

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## Publications

- American Medical Association
  - Model Code of Conduct
  - Educational Programs and Materials
- The Joint Commission
  - Sentinel Event Alert Issue 40, July 9, 2008
  - Joint Commission Standards LD.03.01.01; EP5 – Process for managing disruptive practitioners

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## Risk of Not Addressing Disruptive Behavior

- Nieto v. Kapoor, 268 F.3d 1208 (10<sup>th</sup> Cir 2001):
- "Dr. Kapoor's behavior -- which led at least six people to leave the Eastern New Mexico Medical Center, some to leave the state, and some the profession of nursing altogether -- affected not only the patients, plaintiffs and other employees of the ENMMC, it arguably impacted the overall public health."
- Compensatory Damages - \$1,875,000
- Punitive Damages - \$1,875,000

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## Dealing with Disruptive Behavior

- Infrastructure
  - Policies and Procedures re Disruptive Practitioners
    - Code of Conduct
    - Policy of Zero Tolerance
  - Medical Staff Bylaws with Fair Hearing Procedures
    - Absolute and Unconditional Revocation
    - Disruptive Conduct Defined as Threat to Patient Safety
  - Institutionalized Peer Pressure
    - Build expectations by pursuing disruptive behavior

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## Choose Between Employer and Medical Staff Approach

- Employer approach (termination):
  - No due process hearing
  - Resolution not as public
  - May be easier to resolve by settlement
- Medical Staff Approach (revocation):
  - Can be time consuming
  - Hearing panel wants to be assured that physician was given chance to correct behavior
  - Due process hearing is expensive
  - Adverse action leads to formal reporting

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## Evaluation of Disruptive Physician

- Due to risk to patient safety, Hospital can probably pay for evaluation demanded pursuant to MS Bylaws, as well as an eval demanded for continued employment
- Employers may be able to pay for counseling of employed disruptive physicians following evaluation
- However, counseling required by Medical Staff of an independent physician should be at the expense of the physician to avoid private inurement and private benefit

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## National Programs for Evaluation/ Counseling of Disruptive Physicians

- Program for Distressed Physicians (Vanderbilt University)
- Anger Management for Health Care Professionals (UCSD)
- Anderson & Anderson Executive Coaching/Anger Management Program (LA, CA)
- Inner Solutions for Success (Chula Vista, CA)

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## National Programs for Evaluation/ Counseling of Disruptive Physicians

- Pinegrove Professional Enhancement Program (Hattiesburg, MS)
- Elmhurst Memorial Healthcare (Elmhurst, IL)
- Professional Renewal Center (Lawrence, KS)
- Physicians Development Program, (Miami, FL)

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## References after Termination of Relationship w/Disruptive Physician

- Requests for references come in two forms:
  - Employment references
  - Credentialing inquiries
- Employment references may be affected by severance agreements
- Credentialing inquiries must carry immunity from civil liability – signed form enclosed with inquiry
  - Waiver by disruptive physician applying to another facility

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## Nebraska Medical Regulations: Unprofessional Conduct

14. Disruptive physician behavior as manifested by a physician's aberrant behavior which interferes with patient care or could reasonably be expected to interfere with patient care, including, but not limited to, the following:

- a) Outbursts of rage or violent behavior;
- b) Repeated failure to respond to calls;
- c) Throwing instruments, charts, or objects;
- d) Insulting comments to a patient, patient's family, physicians, or healthcare staff;
- e) Striking or assaulting a patient, patient's family, physicians, or healthcare staff; and
- f) Poor hygiene

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## Nebraska Licensure Discipline

- S.O., M.D.; Settlement 7/14/14
- Allegation: Unprofessional conduct  
(disruptive behavior, whether verbal or physical which interferes with consumer care or could reasonably be expected to interfere with such care)
- Facts: Co-workers expressed concerns regarding behavior at work which caused an uncomfortable work environment and staff retention issues:
  - Yelling; verbal abuse of nurses
  - Demeaning or condescending comments to nurses
  - Nurses afraid to call; he would hang up on them

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## Nebraska Licensure Discipline

- S.O., M.D.
- Settlement: 6 months probation
  - Enroll in Physician Universal Leadership Skills Education Training (PULSE) at physician's expense
  - Provide notice of discipline to all employers and licensing agencies
  - Provide Department with proof of completion and final evaluation/recommendations
  - Employer provide quarterly reports to Department

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## Nebraska Licensure Discipline

- K.S., M.D.; Settlement 1/28/11
- Allegation: Unprofessional conduct
- Facts:
  - Placed inappropriate comments in charts relating to NF residents' medical condition or treatment
  - Incorrectly charted the date and time at which he examined residents and issued orders or prescriptions
  - Wrote "whatever" in chart with no further explanation
  - Used profanity toward staff and within patient hearing

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## Nebraska Licensure Discipline

- K.S., M.D.
- Settlement:
  - Complete an evaluation at physician's expense at the Center for Personalized Education for Physicians
  - Attend and complete a disruptive physician course pre-approved by the Board at his own expense, within 6 months
  - Provide the Board with proof of completion

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## Nebraska Licensure Discipline

- E.R., M.D.; Settlement 3/28/13
- Allegation: Unprofessional conduct
- Facts:
  - Precautionary suspension of privileges at a hospital due to failure to maintain a collegial atmosphere with hospital employees and another medical staff member
  - Requested and was granted 30-day leave of absence
  - Attended PULSE program in Florida
  - Privileges were reinstated upon compliance with PULSE

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## Nebraska Licensure Discipline

- E.R., M.D.
- Settlement:
  - Consented to entry of a final disciplinary order finding that the allegations of the Petition are true and grounds exist to impose the sanction of censure and a civil money penalty in the amount of \$2,000

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## Nebraska Licensure Discipline

- S.S., D.O.; Settlement 4/28/14
- Allegations:
  - Abuse of, dependence on or active addition to alcohol
  - Failure to comply with treatment program;
  - Practice of profession while impaired
- Facts:
  - Reported by employer in emergency medicine group for working impaired
  - Entered Nebraska Licensee Assistance Program
  - Relapsed; worked while impaired; failed to report relapse

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## Nebraska Licensure Discipline

- S.S., D.O.
- Settlement: Licensure probation -5 yrs
  - Abstain from alcohol and controlled substances
  - Subject to random body fluid or chemical testing at his expense as directed by Department
  - Provide a monthly listing of medications
  - Provide notice of discipline to all employers
  - Provide notice within seven days of any change in employment, residence or phone number
  - Pay all costs of ensuring compliance with order

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## Iowa Medical Regulations: Unprofessional Conduct

IAC 653 section 13.7(5) Disruptive behavior.

A physician shall not engage in disruptive behavior. Disruptive behavior is defined as a pattern of contentious, threatening, or intractable behavior that interferes with, or has the potential to interfere with, patient care or the effective functioning of health care staff.

13.7(6) Sexual harassment.

A physician shall not engage in sexual harassment. Sexual harassment is defined as verbal or physical conduct of a sexual nature which interferes with another health care worker's performance or creates an intimidating, hostile or offensive work environment.

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## Iowa Licensure Discipline

- Adel S. Al-Jurf, M.D.
- Iowa Board of Medicine, 1/13/2011:  
Public Reprimand and 3 yrs probation
- Allegation: Engaging in a pattern of unprofessional conduct
- Based on I. C.A secs. 147.55(3), 272C.10(3)
- Regulations interpreting "unprofessional conduct" not yet promulgated

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## Iowa Licensure Discipline

- Adel S. Al-Jurf, M.D., cont.
- Facts:
  - 6/13/2003: Provost complained that Dr. Al-Jurf subjected colleagues to personal vilification and verbal abuse in a manner that creates an unacceptable work environment
  - Employment termination by UIHC for violating its standards on ethics and academic responsibility

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## Iowa Licensure Discipline

- Adel S. Al-Jurf, M.D., cont.
- Appeal to Iowa Court of Appeals, arguing the BOME had no authority to prosecute him for unethical conduct; alleged abuse of discretion in publishing press release with penalties
- Court (7/30/13): BOME penalties upheld. BOME interpretation of "unethical conduct" was not illogical or wholly unjustified

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## Iowa Licensure Discipline

- Amjad Butt, M.D.
- Charges (2009): Engaging in a pattern of unprofessional conduct and/or sexual harassment in the practice of medicine
- BOME Factual allegations dated 8/25/2011:
  - Asked subordinate to enter into romantic relationship;
  - Made unwanted phone calls to this nurse;
  - Threatened serious bodily harm to her;
  - Asked another physician to call her to resolve their dispute;
  - Made offensive and threatening statements to another nurse;
  - Made unprofessional comments to a third employee

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## Iowa Licensure Discipline

- Amjad Butt, M.D., cont.
- BOME Findings: Dr. Butt
  - Engaged in unethical and/or unprofessional conduct
  - Acted unprofessionally when he made repeated unwanted phone calls to nurse
  - Asked another physician to call the nurse
  - Made offensive and threatening statements to second nurse
  - Made unprofessional comments to a third employee

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## Iowa Licensure Discipline

- Amjad Butt, M.D., cont.
- BOME was unable to conclude that Dr. Butt:
  - Threatened to kill the nurse;
  - Asked the nurse to have a personal relationship or to have his baby;
  - Told nurse he had driven past her house during the night;
  - Offered to pay off nurse's car if she withdrew complaint;
  - Made inappropriate sexual comments to patients

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## Iowa Licensure Discipline

- Amjad Butt, M.D., cont.
- BOME Order:
  - \$5,000 civil penalty
  - 5 years probation
  - Completion of a professional boundaries program
- BOME reported to National Practitioner Data Bank
- Court of Appeals:
  - Dr. Butt was not denied a fair hearing;
  - BOME has authority to discipline for unprofessional conduct;
  - There was substantial evidence to support misconduct toward only one nurse, not the other;
  - BOME was ordered to determine propriety of discipline imposed, in light of Court's conclusions

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## Iowa Licensure Discipline

- Malik E. Juweid, M.D.
- Inactive License: 9/1/2013 due to nonrenewal
- BOME Confidential Evaluation Order (11/18/2011):
  - Complete a physical, neuropsychological, mental health, unprofessional conduct and/or disruptive behavior evaluation
  - Based on concerns he had engaged in a pattern of unprofessional conduct and/or disruptive behavior
- Physician objected to evaluation
- Stipulated Order (9/11/2012)
  - Physician had moved out of country
  - Did not intend to practice under Iowa license at that time
  - Stayed enforcement of evaluation order

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## Iowa Licensure Discipline

- Malik E. Juweid, M.D., cont.
- Physician later requested a hearing on his objection to the evaluation order
- BOME Hearing 6/13/2013:
  - Physician ordered to complete evaluation within 90 days of 8/13/2013 Findings of Fact
  - No such evaluation was completed
  - No post-hearing settlement appears in public record

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## Response by Commercial Insurers to Licensure Discipline

- Termination of panel membership based on Order by Nebraska Chief Medical Officer
  - No apparent distinction based on type of penalty (probation or fines)
- Rationale: Panel should include physicians who support quality of care
- Based on licensure discipline, whether:
  - Disruptive behavior
  - Inappropriate prescription practices
  - Physician chemical dependency

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## PPOs Initiate Discipline re Panel Participation

- Process depends on PPO rules; may differ
- BCBS
  - Physician has opportunity to defend
  - Hearing before panel of physicians
  - Appeal available
  - May be allowed to continue participation pending hearing and/or appeal

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## Defending Physician Investigated for Licensure Discipline

- Possible PPO termination must be considered as part of any proposal to settle a licensure discipline matter
- This is in addition to severe penalties (suspension, revocation, etc.) that lead to permissive exclusion of the physician from Medicare and Medicaid programs
- There is good reason to approach licensure settlements with extreme caution

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## Mandatory Reporting - Iowa

- Reporting Other Physicians
  - A physician must file a report with the BOME when he/she has knowledge that another physician may have engaged in wrongful acts or omissions that are grounds for license revocation or suspension or that otherwise constitute negligence, careless acts or omissions that demonstrate a physician's inability to practice medicine competently, safely or within the bounds of medical ethics.
  - 30-day deadline

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## Mandatory Reporting - Iowa

- Self-Report
  - Physician shall file a written report with the BOME describing any disciplinary action taken by a hospital for reasons relating to his/her competence or conduct which results in a limitation, restriction, suspension, revocation, relinquishment or nonrenewal of the licensee's hospital privileges to avoid an investigation or other hospital disciplinary action
  - No report of suspension . . . for less than 10 days
  - 30-day reporting deadline
- Hospital Chief of Staff: must file a full/confidential report within 10 days of any final hospital disciplinary action approved by a hospital board relating to a physician's competence or conduct that results in limitation, suspension, revocation of privileges

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## Mandatory Report-Nebraska

- Self-Report
  - Lost privileges in a hospital or other health care facility due to alleged:
    - Incompetence
    - Negligence
    - Unethical or unprofessional conduct
    - Physical, mental or chemical impairment
  - Voluntarily limited privileged or resigned while under formal or informal investigation for
    - Clinical incompetence
    - Unprofessional conduct or
    - Physical, mental, or chemical impairment

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## Mandatory Report-Nebraska

- Self-Report, cont.
  - Lost employment due to alleged:
    - Negligence
    - Unethical or unprofessional conduct
    - Incompetence
    - Physical, mental or chemical impairment

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## Mandatory Report-Nebraska

- Reporting within Same Profession:
  - Every health care professional must report when he/she has firsthand knowledge of facts giving him/her reason to believe that any person in the same profession has committed acts indicative of:
    - Gross incompetence
    - A pattern of negligent conduct
    - Unprofessional conduct
    - Practice while that person's ability to practice is impaired by alcohol, controlled substances, narcotic drugs, or physical, mental or emotional disability
    - Other violations of laws or regulations governing the practice

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## Mandatory Report-Nebraska

- Reporting a Different Profession:
  - Every health care professional must report when he/she has firsthand knowledge of facts giving him/her reason to believe that any person in a different profession:
    - Has committed acts indicative of gross incompetence; or
    - May be practicing while his/her ability to practice is impaired by alcohol, controlled substances, narcotic drugs, or physical, mental or emotional disability

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## Mandatory Report-Nebraska

- Reporting by Health Care Facilities:
  - Upon making a payment due to adverse judgment settlement or award of professional liability claim arising out of acts or omissions of the licensee
  - Upon taking action adversely affecting privileges or membership of a health care professional due to alleged:
    - Incompetence
    - Professional negligence
    - Unprofessional conduct; or
    - Physical, mental or chemical impairment

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Thank you

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# 26<sup>th</sup> annual HEALTH LAW FORUM

## C-Suite – Pay Attention (or Pay Up!): Getting and Keeping Your Meaningful Use Dollars

*Michael W. Chase*

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## C-Suite - Pay Attention (or Pay Up!)

Getting and Keeping  
Your Meaningful Use Dollars

Michael W. Chase

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## Agenda

- Fast facts / statistics
- Breaking news / important program updates
- Common problems with MU planning and implementation
- Strategies and best practices

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## Fast Facts

- \$20+ *BILLION* in incentive payments
- 500,000+ registered Eligible Professionals, Eligible Hospitals, and Critical Access Hospitals
- 90+% of hospitals have adopted EHRs

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## Fast Facts

- 90% of hospital executives: MU is a priority
  - Of these, 67% say MU is the top priority

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## Fast Facts

- CMS MU Audit Program
  - 613 Hospitals (~5% failure rate)
  - 8,000 Eligible Professionals (~22% failure rate)
- Pre and post-payment audits
- Medicaid audits underway

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## Important Program Updates

- CMS Final Rule (August 29, 2014)
  - Flexibility options for 2014 reporting period
  - Extended Stage 2 through 2016
  - Stage 3 now begins 2017
  - Did not change the 2014 EHR reporting period

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## Important Program Updates

- Flexibility options – *only* if:
  - Delay in 2014 CEHRT availability
  - Inability to fully implement 2014 CEHRT
- Analyze carefully
- Document (in case of audit)

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## Important Program Updates

<b>2011 CEHRT</b> If you are scheduled to report Stage 1 or Stage 2: <ul style="list-style-type: none"><li>• 2013 Stage 1 objectives and 2013 CQMs</li></ul>
<b>Combination of 2011 &amp; 2014 CEHRT</b> If you are scheduled to report Stage 1: <ul style="list-style-type: none"><li>• 2013 Stage 1 objectives and 2013 CQMs; <b>or</b></li><li>• 2014 Stage 1 objectives and 2014 CQMs</li></ul> If you are schedule to report Stage 2: <ul style="list-style-type: none"><li>• 2013 Stage 1 objectives and 2013 CQMs; <b>or</b></li><li>• 2014 Stage 1 objectives and 2014 CQMs; <b>or</b></li><li>• Stage 2 objectives and 2014 CQMs</li></ul>
<b>2014 CEHRT</b> If you are scheduled to report Stage 1: <ul style="list-style-type: none"><li>• 2014 Stage 1 objectives and 2014 CQMs</li></ul> If you are schedules to report Stage 2: <ul style="list-style-type: none"><li>• Stage 2 objectives and 2014 CQMs; <b>or</b></li><li>• 2014 Stage 1 objectives and 2014 CQMs</li></ul>

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## Important Program Updates

- Payment penalties begin in 2015
- Hardship exception application process re-opened until Nov. 30, 2014
  - Unable to fully implement 2014 CEHRT due to delay; AND
  - Unable to attest under flexibility rule (July 1 for EH; October 1 for EP)

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## Common Problem

- Insufficient planning and lack of resources
  - Panic immediately before attestation
  - Delay in rollout/functionalities
  - Failed to perform or review a Security Risk Assessment

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## Strategy / Best Practice

- Devote financial and human resources
  - MU implementation *must* involve more than the IT department
  - Budget (do not underestimate) for MU
  - Perform/review Security Risk Assessment each reporting period; *document* correct deficiencies
  - Start planning early

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## Common Problem

- Lack of understanding (or misunderstanding) of MU objectives and measures
  - What is included in the numerator/denominator?
  - Is the software correctly capturing data?
  - What functionalities and/or software updates are required?

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## Strategy / Best Practice

- Educate your organization before (and throughout) the MU process
  - CMS sub-regulatory guidance (comments, tipsheets, listserves, FAQs)
  - Involve those who enter information
  - Involve those who analyze the information and/or attest to MU

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## Common Problem

- Late in the reporting period – you realize you're not meeting a measure
  - Have excluded too many patients from the numerator (i.e., patient portal)
  - Have not engaged in testing or submission of certain data (i.e., public health)
  - CEHRT functionalities not turned on

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## Strategy / Best Practice

- Monitor MU thresholds continually
  - Establish a dashboard
  - Monitor MU thresholds
  - Double-check the numerator/denominator requirements
  - Confirm system setup/functionality

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## Common Problem

- Relying on what another facility/provider does to achieve MU
  - Counting (or not counting) certain patients in numerator/denominator
  - Workflows or processes to achieve MU

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## Strategy / Best Practice

- Analyze your organization's structure and corresponding requirements
  - Each organization is unique
  - Different organizations in different stages
  - Various state laws (i.e., consent; minors)
  - No one-size-fits-all EHR

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## Common Problem

- Relationship with CEHRT software vendor
  - Delays in getting upgrades/fixes
  - Slow to respond to questions on functionality and processes
  - Confusing guidance on capturing data, thresholds and processes

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## Strategy / Best Practice

- Be cautious when relying on vendors
  - Each hospital/professional is responsible for achieving/attesting to MU
  - Vendor must follow ONC requirements
  - Certified software does not mean automatic achievement of MU
  - Vendor is not the one attesting!

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## Common Problem

- Fading memory of what happened throughout the reporting period
  - Where did the numbers come from?
  - What was our process to achieve the objective/measure?
  - Did someone leave the organization or the department?

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## Strategy / Best Practice

- Document everything
  - Decisions made in the reporting period
  - Attestation process
- Assume you will be audited!
  - Previous estimate: 5-10% of hospitals
  - May receive multiple audit requests (for both hospitals and professionals)

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## Common Problem

- Insufficient response (or no response) to a MU audit request
  - Audit request went to an old or expired e-mail address
  - After submitting an initial response you receive more follow-up requests
  - “We don’t know what they’re asking for”

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## Strategy / Best Practice

- Treat MU audit request like other compliance audits/investigations
  - Consider a MU e-mail address/group
  - Notify Compliance Officer; engage legal counsel
  - Have a response team ready to go
  - Respond completely and accurately
  - Don’t miss a deadline

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## Takeaways

- Continue to plan for MU
- Pay attention to new CMS rules and guidance for Stage 2 (and Stage 3)
- Devote time, attention, and resources upfront
- Ask questions/seek guidance early on

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Thank you

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