

31ST ANNUAL BAIRD HOLM LLP **HEALTH LAW FORUM**

FRIDAY, NOVEMBER 22, 2019

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November 22, 2019

WELCOME!

Thank you for joining us for the 31st Annual Baird Holm LLP Health Law Forum. We are excited to host you for a day of learning and in-depth discussion of current information in the world of health care. We hope you find the topics and presentations covered today interesting, informative and beneficial to you and your organization.

As you are aware, the areas of law addressed in the Forum are changing rapidly. We caution that the materials in this binder, as well as today's presentations, are intended to serve as general information only, and should not be considered legal advice to any particular matter.

We strive to provide practical, cost-effective and innovative solutions to the legal issues which arise in today's complex health care environment each and every day. If you have questions about today's presentations or any other legal matter, please do not hesitate to contact us.

Very truly yours,



Michael W. Chase
Partner
FOR THE FIRM

7:30 – 8:15 a.m. Registration and Continental Breakfast

8:15 - 8:30 a.m. Welcome and Introduction

Michael W. Chase

8:30 – 9:15 a.m. Betting the Odds and Covering the Spread: Updates on the Regulatory Sprint to Coordinated Care

We've all heard about the U.S. Department of Health and Human Services' "Regulatory Sprint to Coordinated Care." HHS has published a number of new regulations, requests for information, and proposed other changes in its efforts to cross the finish line (think Stark law, information blocking, etc.). In this session, Baird Holm's "sharps," Andy Kloeckner and Abby Mohs, will look at past performance (regulatory changes over the past few years) to handicap the current race and prognosticate where the "smart money" is going in the future. How will the sprint end? Who will win? Who will lose? We can only speculate on the odds.

Andrew D. Kloeckner
Abigail T. Mohs

9:15 – 10:15 a.m. Double Duty: Serving as a Director of a Non-Profit Health Care Board

Directors of non-profit governing boards are subject to a number of legal obligations and duties to ensure effective oversight of the organization. In a health care organization, the responsibilities become significantly more demanding. Given the heightened scrutiny of non-profit boards and the myriad of Federal and State laws governing health care organizations, directors play a critical (and challenging) role in achieving the organization's overall mission and strategy. Meghan Stoppel of the Nebraska Attorney General's Office will discuss the role of state attorneys general in the oversight of non-profit entities, and Julie Knutson and Michael Chase will lead a discussion of best practices and specific guidance for health care organizations.

Julie A. Knutson
Michael W. Chase
Meghan Stoppel, Bureau Chief, Assistant Attorney General, Consumer Protection Bureau, Nebraska Attorney General's Office

10:15 – 10:30 a.m. Break

10:30 – 11:00 a.m. The Kinetic Theory of EMTALA: Definitions in Motion

The Emergency Medical Treatment and Active Labor Act has been around since 1986, so it's surprising that CMS' interpretation of and enforcement of definitions under the Act might still be developing. CMS has published a Survey and Certification Letter contrasting the clinical definition of "stability" with the definition of "stability" under EMTALA. This has implications for the extent of diagnosis and treatment a transferring hospital must perform prior to transferring its patient to another hospital. It also challenges the propriety of lateral transfers, where the transferring hospital has the capability to perform the medically necessary surgery. Enforcement has frustrated surgeons and hospitals alike. This session will cover recent hospital citations in Iowa and Nebraska that demonstrate the importance of these EMTALA developments.

Barbara E. Person

11:00 a.m. – 12:00 p.m. Managing Medical Staff Matters in Today's Health Care Environment

While the need to handle Medical Staff matters appropriately has not changed, the health care environment and certain rules have certainly changed. Decisions made when first learning of an alleged incident can impact any later investigation, hearing, and reporting requirements. Our panel will use a practical scenario-based approach to discuss three important developments in Medical Staff matters, including the impacts of the #MeToo era, the increase in employed physicians versus independent Medical Staff members, and the revised National Practitioner Data Bank reporting guidelines relating to investigations.

Vickie B. Ahlers
Kimberly A. Lammers
Steven D. Davidson, Partner, Baird Holm Litigation Section

12:00 – 1:00 p.m. Lunch**1:00 – 2:00 p.m. The Latest Word**

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 recent topics including compliance and governance issues, information privacy and security updates, employee benefits issues, immigration, and several other health care law topics.

Panel of Baird Holm Attorneys

2:00 - 2:15 p.m. Break**2:15 – 3:00 p.m. It's No Longer Business as Usual in the Business Office**

There are a lot of changes in the works for the business offices of health care providers. This session will include a potpourri of hot topics, including surprise medical bills legislation, transparency pricing, the latest on reference-based pricing, Senate Finance Committee hearings on hospital billing practices, and other similar late-breaking topics.

John R. Holdenried
Zachary J. Buxton

3:00 – 3:45 p.m. Artificial Intelligence in Health Care: Observations from a Regulatory Perspective

Advances in technology have sparked a wave of artificial intelligence (A.I.) hype, especially in the health care industry. A.I. is designed to analyze data and make predictions or decisions with minimal human intervention. While we might be years away from robots operating on patients without a surgeon in the room, A.I.'s role in health care is rapidly evolving due to a treasure trove of valuable data. Technology companies are already starting to analyze such data to promote advancement and efficiencies including new diagnosis and treatment techniques, improved business operations, reduced lengths of stay, and increased patient satisfaction. Michael Chase and Sean Nakamoto will provide background on A.I., discuss the current regulatory environment (e.g., HIPAA), identify risk areas, and provide best practices and practical considerations when implementing and using A.I.

Michael W. Chase
Sean T. Nakamoto

3:45 p.m. Adjourn and Reception

COMMONLY USED ACRONYMS

AAMC	Association of American Medical Colleges
ACA	Affordable Care Act
ACO	Accountable Care Organization
AG	Attorney General
AHA	American Hospital Association
AHIA	Association of Healthcare Internal Auditors
AHIP	America's Health Insurance Plans
AHLA	American Health Lawyers Association
AI	Artificial Intelligence
AKS	Anti-Kickback Statute
ALJ	Administrative Law Judge
AMA	American Medical Association
APM	Alternative Payment Models
ASC	Amublatory Surgical Center
BAT	Blood Alcohol Tests
CAH	Critical Access Hospital
CAP	Corrective Action Plan
CBO	Congressional Budget Office
CDAC	Consolidated Data Analysis Center
CIA	Corporate Integrity Agreement
CLIA	Clinical Laboratory Improvement Amendments
CMS	Centers for Medicare & Medicaid Services
COI	Conflict of Interest
COP	Conditions of Participation
D & O INSURANCE	Directors and Officers Liability Insurance
DHHS	Department of Health and Human Services
DHS	Designated Health Services
DME	Durable Medical Equipment
DOJ	Department of Justice
ECA	Extraordinary Collection Action
ED	Emergency Department
EEO-1 REPORT	Employer Information Report EEO-1
EHR	Electronic Health Record
EMC	Emergency Medical Condition
EMTALA	Emergency Medical Treatment and Active Labor Act
FAP	Financial Assistance Policy
FCA	False Claims Act
FDA	Food and Drug Administration

COMMONLY USED ACRONYMS

FFS	<i>Fee-for-Service</i>
FLSA	<i>Fair Labor Standards Act</i>
FMV	<i>Fair Market Value</i>
FPPE	<i>Focused Professional Practice Evaluation</i>
HCCA	<i>Health Care Compliance Association</i>
HCQIA	<i>Health Care Quality Improvement Act</i>
HIPAA	<i>Health Insurance Portability and Accountability Act</i>
HRA	<i>Health Reimbursement Arrangement</i>
IAC	<i>Iowa Administrative Code</i>
ICF	<i>Immediate Care Facility</i>
IDR	<i>Independent-Dispute Resolution</i>
IRS	<i>Internal Revenue Service</i>
MACRA	<i>Medicare Access and CHIP Reauthorization Act</i>
MEC	<i>Medical Executive Committee</i>
MFCU	<i>Medicaid Fraud Control Unit</i>
MIPS	<i>Merit-Based Incentive Payment System</i>
MSSP	<i>Medicare Shared Savings Program</i>
NAC	<i>Nebraska Administrative Code</i>
NFP	<i>Not-For-Profit</i>
NLRB	<i>National Labor Relations Board</i>
NPDB	<i>National Practitioner Data Bank</i>
NPP	<i>Notice of Privacy Practices</i>
NPRM	<i>Notice of Proposed Rulemaking</i>
OIG	<i>Office of Inspector General</i>
OSHA	<i>Occupational Safety & Health Administration</i>
PART 2	<i>42 CFR Part 2; Confidentiality of Substance Use Disorder Patient Records</i>
PHI	<i>Protected Health Information</i>
PII	<i>Personally Identifiable Information</i>
PQRS	<i>Physician Quality Reporting System</i>
RFI	<i>Request for Information</i>
RUG	<i>Resource Utilization Groups</i>
SNF	<i>Skilled Nursing Facility</i>
STARK	<i>Physician Self-referral Law</i>
TCPA	<i>Telephone Consumer Protection Act</i>
TPO	<i>Treatment, Payment, and Healthcare Operations</i>
UCA	<i>Uniform Credentialing Act</i>
USC	<i>United States Code</i>
VBP	<i>Value Based Purchasing</i>



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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

Wisconsin, 2019

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 is the Chair of the Firm's Health Care section and 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 and 2020.

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



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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

Nebraska, 2015

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

- Community Bike Project (2016-present)
- American Health Lawyers Association (2014-present)
- Healthcare Financial Management Association (2014-present)
- Iowa Society of Health Care Attorneys (2014-present)
- Health Care Compliance Association (2014-present)



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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

- One World Community Health Centers, Board Member
- Susan G. Komen Great Plains, Board Member
- Chronic Care International, Board Member
- Nebraska Court Appointed Special Advocates, Board Member
- Iowa Chapter of the Healthcare Financial Management Association, Board Member
- American Health Lawyers Association
- Health Care Compliance Association
- Iowa Society of Healthcare Attorneys
- Omaha Bar Association
- FBI Citizens Academy
- ICAN, Defining Leadership Class 14
- Down Syndrome Alliance of the Midlands, Past Board Member



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Areas of Practice

Employee Benefits & ERISA

Labor & Employment Law

Education

Creighton University School of Law,
J.D., 2011

Creighton University College of
Business, MBA, 2012

University of South Carolina, B.S.
Finance and Real Estate, 2008

Bar & Court Admissions

Iowa, 2011

Nebraska, 2012

Jeremy T. Christensen practices in the area of employee benefits, ERISA, tax laws and public employer retirement systems. He represents clients with respect to all aspects of ERISA compliance and employee benefit programs, including retirement and 401(k) plans, deferred compensation, and health and welfare benefits.

In 2011, Jeremy received his Juris Doctor from Creighton University School of Law, where he worked on the Creighton Law Review. He received his Masters of Business Administration from the Creighton University College of Business in 2012. In 2008, he graduated from the University of South Carolina, *magna cum laude*, with a Bachelors Degree in Finance and Real Estate. Jeremy has been recognized by *Super Lawyers* who has named him a "Rising Star" in 2019.

Prior to joining the firm, Jeremy worked in the Retirement Planning and Compliance industries where he gained valuable experience working with legal matters as they pertain to insurance, ERISA, and tax law.



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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*® 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
- 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



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Areas of Practice

Energy & Renewable Energy

Employee Benefits & ERISA

Litigation

Real Estate

Transportation

Education

University of Nebraska College of Law, J.D., *with high distinction*, 1986

University of Nebraska at Lincoln, B.A., *with distinction*, 1983

Bar & Court Admissions

Nebraska, 1987

Missouri, 1986

United States Court of Appeals for the Eighth Circuit, 1986

United States Supreme Court, 1988

Steven D. Davidson is a commercial litigator with 30 years of experience across a wide range of federal, state and administrative proceedings, including insurance, health care, real estate, energy, transportation, and personal injury matters. He has tried more than 30 cases to verdict before juries, judges and arbitrators, and has obtained successful, efficient pretrial resolution of hundreds of disputes for clients across the country. Steve is the Chair of the firm's Litigation section.

In 1986, Mr. Davidson was conferred a Juris Doctor, *with high distinction*, from the University of Nebraska College of Law. While in law school, he was selected as a member of the *Nebraska Law Review* and was inducted into the Order of the Coif. In 1983, he received a Bachelor of Arts degree, with distinction, from the University of Nebraska-Lincoln, where he was selected as a member of Phi Beta Kappa. Prior to joining the firm, Mr. Davidson served as law clerk to the Honorable C. Arlen Beam of the United States Court of Appeals for the Eighth Circuit in 1987, and as law clerk to Judge Beam in the United States District Court for the District of Nebraska in 1986. Since 2008, Steve has been selected by his peers for inclusion in *The Best Lawyers in America*® in the fields of Commercial Litigation and was named the *Best Lawyers*' 2016 Insurance Law "Lawyer of the Year" for Omaha. He is also included in *Benchmark, America's Leading Litigation Firms and Attorneys*, *Super Lawyers* and *Chambers USA, America's Leading Lawyers for Business*.

Selected Practice Highlights

- Representing leading health, life and disability insurance carriers in coverage defense and bad faith matters
- Defending national transportation companies and health care clients in serious personal injury matters
- Successfully defending a Fortune 100 company in complex toxic tort actions
- Obtaining reformation of a commercial lease, preserving rent obligation for property owner of more than \$30 million
- Obtaining more than a combined \$50 million in property tax valuation reductions for commercial office and shopping center owners
- Obtaining a \$4.7 million jury verdict against a publicly-held defense contractor for the unpaid value of sophisticated storage and security services

Representative Reported Cases

- *Heritage Disposal & Storage, LLC v. VSE Corp.*, 2017 WL 361547 (E.D. Va. 2017)

- Northeast Nebraska Public Power District v. Nebraska Public Power District, 24 Neb. App. 837 (2017)
- Synergy4 Enterprises, Inc. v. Pinnacle Bank, 290 Neb. 241, 859 N.W.2d 552 (2015)
- Kuehl v. Jefferson Pilot Financial, 2012 U.S. Dist. LEXIS 160430 (D. Neb. 2012) (motion for remand)
- Boles v. Unum Life Ins. Co., 847 F.Supp.2d 1161 (D. Neb. 2012)(motion to dismiss)
- Kabasinkas v. Haskin, 2011 U.S. Dist. LEXIS 150038 (D. Neb. 2011)(summary judgment and Daubert motions)
- Hyke v. Ohio National Life Ins. Co., 2011 U.S. Dist. LEXIS 145025 (D. Neb. 2011) (summary judgment)
- IVESCO Holdings, LLC v. Professional Veterinary Products, Ltd., 2010 U.S. Dist. LEXIS (N.D. Ia. 2010) (summary judgment)
- Reilly v. Northwestern Mutual Life Ins. Co., 2007 U.S. Dist. LEXIS 39594 (S.D. Ia. 2007) (summary judgment)
- Marmo v. Tyson Fresh Meats, Inc., 457 F.3d 748 (2006)

Professional & Civic Affiliations

- Fellow, Nebraska State Bar Foundation
- Senior Fellow, Litigation Counsel of America
- International Association of Defense Counsel
- Nebraska Association of Trial Attorneys
- Past President, Board of Directors, Catholic Charities of Omaha
- Past President, Board of Directors, Family Housing Advisory Services, Inc.
- Past President, Board of Directors, Omaha Theater Company for Young People



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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 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*® 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, former Program Chair of Tax Program, and Vice Chair of Tax and Finance Practice Group
- Iowa Society of Healthcare 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
- 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), St. Margaret Mary Parish (Board of Education, Parish Council, and Finance Committee), 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)



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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, President-Elect & Board Member
- Down Syndrome Alliance of the Midlands, Board Member (2010-2011)
- American Health Lawyers Association
- Iowa Society of Healthcare Attorneys



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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

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



BAIRD HOLM^{LLP}

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Areas of Practice

Health Care

Education

Creighton University School of Law,
J.D., *summa cum laude*, 1997

University of South Dakota, B.A.,
Political Science and Classics,
*magna cum laude with University
honors*, 1994

Bar & Court Admissions

Nebraska, 1997

Iowa, 2005

Wisconsin, 2019

Kimberly A. Lammers assists clients with advice and representation for issues relating to Federal health care program fraud and abuse laws, regulatory compliance, Medicare and Medicaid reimbursement, clinical denials and appeals including RAC audits, contracting, medical staff, licensure, credentialing, conflict of interest, and human subject research and IRB issues. Prior to joining the firm, she spent 13 years working for a large health system in the areas of compliance and revenue cycle, and most recently served as that health system's Vice President of Compliance.

Kim is also a Certified Professional Coder through the American Academy of Professional Coders, and has completed ICD-10 proficiency testing through the AAPC.

Kim is licensed in both Iowa and Nebraska, and is active as a member of various legal associations, including the American Health Lawyers Association and the Health Care Compliance Association.

Kim received her law degree from Creighton University School of Law, *summa cum laude*, and received her undergraduate degree from the University of South Dakota, *magna cum laude, with University honors*.

Professional & Civic Affiliations

- American Health Lawyers Association, Member
- Health Care Compliance Association, Member
- American Academy of Professional Coders, Certified Professional Coder



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Areas of Practice

Fair Housing & Public
Accommodation Law

Labor & Employment Law

Litigation

Education

University of Nebraska College of
Law, J.D., *with distinction*, 2014

University of Nebraska-Lincoln,
Bachelor of Journalism,
News-Editorial and Broadcasting,
with highest distinction, 2010

Bar & Court Admissions

Nebraska, 2014

United States District Court for the
District of Nebraska, 2014

Sara A. McCue's practice focuses on employment, ADA, and fair housing law. She represents and counsels housing providers, property management companies, educational institutions, and the affordable housing industry.

Sara received her Juris Doctor, *with distinction*, from the University of Nebraska College of Law in 2014, where she was the Editor in Chief of the Nebraska Law Review and President of the Multicultural Legal Society and Black Law Students Association. She graduated from the University of Nebraska-Lincoln with a Bachelor of Journalism in News-Editorial and Broadcasting, *with highest distinction*, in 2010.



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Areas of Practice

Health Care

Privacy & Data Protection

Education

Hamline University School of Law,
J.D., 2010

Creighton University, B.A., History,
magna cum laude, 2007

Bar & Court Admissions

Minnesota, 2010

Missouri, 2011

Nebraska, 2015

Abigail T. Mohs' practice focuses on regulatory, transactional, and reimbursement matters for health care providers with a special emphasis on electronic health records, and issues under HIPAA and other Federal and State laws regarding privacy of data.

Prior to joining the firm, she worked in insurance compliance and health IT compliance where she gained valuable experience navigating the changing landscape of legal and regulatory matters.

Abby received her undergraduate degree from Creighton University in 2007 and her law degree from Hamline University School of Law in 2010. She served as staff editor of the Hamline Journal of Public Law and Policy. Additionally, she participated in the William E. McGee National Civil Rights Moot Court competition.

Professional & Civic Affiliations

- American Health Lawyers Association
- Healthcare Financial Management Association
- Mutual First Federal Credit Union, Board of Directors



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Areas of Practice

Health Care

Intellectual Property, Copyright & Trademark

Technology & E-Commerce

Privacy & Data Protection

Education

Creighton University School of Law,
J.D., *magna cum laude*, 2017

University of Washington, B.S.,
2013

Bar & Court Admissions

Nebraska, 2017

Iowa, 2019

Sean T. Nakamoto practices in the area of health care and information technology. He represents clients with regard to health care compliance matters, data privacy and security compliance (e.g., HIPAA, FERPA, and GDPR), and transactional issues. Sean also represents clients with regard to information technology matters including licensing agreements, technology acquisitions and related contracts, emerging technologies (e.g., IoT, Blockchain, and Wearables), and general information security.

Sean graduated from the Creighton University School of Law, *magna cum laude*, in 2017. While in law school, he earned the CALI Excellence for the Future Awards in Health Care Insurance Law, Alternative Dispute Resolution, Health Law Survey, Legal Issues in E-Commerce, and Taxation of Business Enterprises. He was also the Research Editor of the Creighton Law Review, and a student tutor for Legal Writing and Civil Procedure I & II. Sean graduated from the University of Washington with a Bachelor of Science in Biology in 2013.

Professional & Civic Affiliations

- Creighton Law Young Alumni Council, Board Member, (2017-present)
- Nebraska State Bar Association, Member, (2017-present)
- Omaha Bar Association: Young Lawyers Division, Social Chair, (2018-present)
- American Health Lawyers Association: Tax and Finance Practice Group, Social Media Coordinator, (2018-present)
- Nebraska Infragard (an association of businesses, academic institutions, state and local law enforcement agencies, and the FBI created to help protect the critical national infrastructure)



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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® in the field of Health Care Law and was named the Best Lawyers' 2019 Health Care Law "Lawyer of the Year" for Omaha. She is also rated AV Preeminent® by Martindale-Hubbell, and has been named a 2019 Woman Leader in Law by the Corporate Counsel & The American Lawyer magazines. Barbara 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

Immigration

Labor & Employment Law

Education

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

Creighton University, B.A. English
and Spanish, *magna cum laude*,
2009

Bar & Court Admissions

Iowa, 2013

Nebraska, 2014

United States District Court for the
District of Nebraska, 2016

Kara Stockdale assists employers in various industries with respect to labor and employment matters, including workplace safety, personnel policies and decisions, equal opportunity, discrimination claims, and employment-based immigration. Her immigration work focuses on assisting employers seeking to sponsor foreign nationals for work authorization in the United States. In addition, she advises clients in the healthcare sector seeking assistance with J-1 waivers for foreign medical graduates who complete residency training in the United States. Prior to joining the firm, Kara worked in human resources in the healthcare industry and as a community organizer. During law school, she clerked at a Fortune 200 company, assisting in-house counsel with labor and employment issues involving state and federal regulations and emerging laws including the Railway Labor Act and the Federal Railway Safety Act.

In 2013, Kara graduated from the Creighton University School of Law, *magna cum laude*. While in law school, she earned six CALI Excellence for the Future Awards and the 2012 Nebraska State Bar Association's Silver Quill Award. She was also named to the Order of Barristers – a national honorary organization that recognizes graduating law students who excel as student advocates in written and oral advocacy. Kara was a co-founding member of the Employment & Labor Law Society and a member of the *Creighton Law Review*.

Professional & Civic Affiliations

- Nebraska State Bar Association
- Omaha Bar Association
- Iowa State Bar Association
- American Immigration Lawyers Association
- Creighton Law Young Alumni Council

Guest Speaker

Meghan E. Stoppel

*Assistant Attorney
General & Chief,
Consumer Protection
Division, Nebraska
Attorney General's Office*

Meghan E. Stoppel is an Assistant Attorney General and Chief of the Consumer Protection Division in the Nebraska Attorney General's Office. Prior to that, she was an Assistant Attorney General in the Kansas Attorney General's Office from 2008 to 2016. She holds a B.A. in History and Communications from Texas Christian University and a J.D. from the University of Colorado. In the Consumer Protection Division, Meghan oversees a team of attorneys and investigators working cases related to consumer protection, nonprofit organizations, charitable trusts, tobacco enforcement, and antitrust matters. She also supports Attorney General Peterson in his role as co-chair of both the NAAG Consumer Protection Committee and the NAAG Charities Committee.

Meghan is licensed to practice in Kansas and Nebraska and holds a Certified Information Privacy Professional/US certification from the International Association of Privacy Professionals. She lives in Lincoln, Nebraska with her husband and children.

BETTING THE ODDS AND COVERING THE SPREAD: UPDATES ON THE REGULATORY SPRINT TO COORDINATED CARE

Andrew D. Kloeckner

Abigail T. Mohs

Betting the Odds and Covering the Spread: Updates on the Regulatory Sprint to Coordinated Care

Andrew D. Kloeckner
Abigail T. Mohs

HHS Regulatory Sprint: The Contenders

- HIPAA
- Part 2
- The Stark Law
- The Anti-Kickback Statute



HIPAA Request for Information

- 4 Goals
 - Promote information sharing
 - Encourage providers to share emergency-related treatment information to loved ones
 - Implement TPO accounting
 - Changing the NPP written acknowledgement requirement

HIPAA Request for Information

- RFI published December 2018
- Comments due February 2019
- When can we expect a Proposed Rule?

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Part 2 Proposed Rule

- Third update in last few years
- Purpose is to further align Part 2 with HIPAA
- Statutory limitations

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Part 2 Proposed Rule

- Clarify Part 2 Program definition
- Expands Part 2 consent options
- Additional consent-related clarifications
- Other guidance related to Part 2 requirements

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Part 2 Proposed Rule

- Proposed Rule published August 2019
- Comments due October 2019

- When can we expect a Final Rule?

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Stark Law/AKS Proposed Rules

- Three "Themes"
 - Interpretations and clarifications of current regulatory provisions
 - New exceptions to reduce technical non-compliance
 - New exceptions related to value-based care

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New/Revised Definitions

- Commercially Reasonable

- Volume or Value/Other Business Generated Standard(s)

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New/Revised Definitions

- Fair Market Value & General Market Value
- Designated Health Service

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Helpful Revised Exceptions

- Remuneration Unrelated to DHS
 - No writing or set in advance standard
 - Can't be "related to patient care services"
 - Supply, device, equipment, space, technology used in the diagnosis or treatment of patients
 - Could the service be provided by a non-licensed individual?

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Helpful Revised Exceptions

- Payments by a Physician
 - Compensation for items or services
 - Not office space (but could be storage space)
 - Must be FMV
 - But, no writing requirement
 - Exclusion only limited by statutory exceptions
 - Even if FMV exception would apply, can utilize the payments by a physician exception

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Helpful New Exceptions

- Limited Remuneration to a Physician
 - Does not exceed \$3,500 per calendar year (in aggregate)
 - FMV, commercially reasonable, no volume or value
 - No set in advance/no writing requirement

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Technology Updates

- EHR Exception
 - Sunset removed
- Cyber-technology Exception
 - Nonmonetary (technology and services; not reimbursement)
 - No hardware
 - Predominantly used to implement, maintain or reestablish "cybersecurity"
 - "Cybersecurity" is a newly defined term
- Corollary AKS safe harbors

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Helpful Revised AKS Safe Harbors

- Personal Services/Management Contracts
 - *Aggregate* compensation no longer must be set in advance
 - Compensation methodology must be set in advance, FMV and not directly take into account volume or value of referrals
 - No requirement for a schedule or exact charge for part-time work

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Helpful Revised AKS Safe Harbors

- Warranties
 - Includes bundled items and related services
 - Product support
 - Educational services
- Transportation
 - Expand mileage limits for patients in rural areas
 - 50 to 75 miles
 - Eliminates distance limits for discharged patients

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Other Helpful Nuggets

- Mistaken Payments
 - Not a violation if:
 - Corrected promptly once identified
 - Payment made in error was still consistent with FMV
 - Corrected while the arrangement is ongoing
- Directed referrals = must satisfy "set in advance" standard

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Other Helpful Nuggets

- Inclusion of "writing" requirement in the 90-day temporary non-compliance window
 - Previously only available for signatures
 - Needed "collection of documents;" can still use the collection of documents requirement to satisfy the writing requirement
 - "Set in advance" must still be satisfied

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Other Helpful Nuggets

- "Set in advance" standard can be met outside of "writing"
 - That "set in advance" required it be reduced to writing was only a "deeming" provision
- Confirm that parties can look to multiple exceptions to protect various components of problematic arrangements
- Physicians and entities acting as a pass-through is not in and of itself a financial relationship
- Decoupling from the anti-kickback statute

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One Not So Helpful Nugget

- Isolated Transaction Definition and Exception
 - Revised definition and commentary prohibit use of exception to protect one-time payments for services
 - Exception was sometimes used to fix undocumented arrangements
 - CMS does not view "services" as within the purview of the exception
 - Could call into question ability to utilize exception to negotiate settlements of contested issues

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Value-Based Care-Related Definitions

- Target patient population
- Value-based activity
- Value-based arrangement
- Value-based enterprise
- Value-based purpose
- VBE participant
- ...and many more!

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Financial Risk

- Stark Exceptions and AKS Safe Harbors
 - Full Financial Risk
 - Partial Risk
 - Stark: Meaningful Downside Financial Risk to Physician
 - AKS: VBP with Substantial Financial Risk
- Value-Based/Care Coordination Arrangements
- Definitions are key!

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Additional AKS Safe Harbors

- Arrangements for Patient Engagement
 - Would exclude from the definition of remuneration certain tools and support to patients in a target patient population
- CMS-Sponsored Model Arrangements
 - Would exclude from the definition of remuneration the exchange of anything of value between parties in a CMS-sponsored model arrangements...for which CMS determines this Safe Harbor is available

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Stark and Kickback NPRM

- Proposed Rules published October 2019
- Comments due December 31, 2019—Happy New Year!
- Final Rules expected...?

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Questions?

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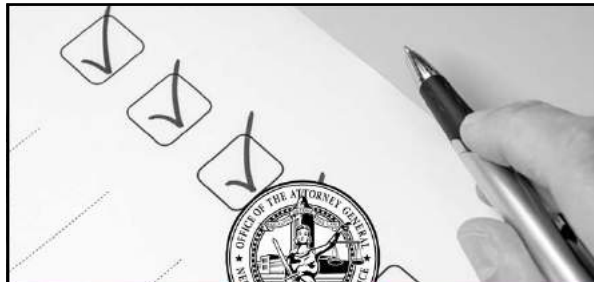


DOUBLE DUTY: SERVING AS A DIRECTOR OF A NON-PROFIT HEALTH CARE BOARD

Julie A. Knutson


Michael W. Chase

*Meghan Stoppel,
Bureau Chief, Assistant Attorney General,
Consumer Protection Bureau,
Nebraska Attorney General's Office*




Double Duty: Serving as a Director of a Non-Profit Health Care Board

Julie A. Knutson & Michael W. Chase, Partners, Baird Holm LLP
Meghan E. Stoppel, Chief, Consumer Protection Division, Nebraska Attorney General's Office



- The information provided in this presentation is for educational purposes only and is not intended to be complete and comprehensive.
- We highly recommend that you seek legal, tax, and financial advice from professionals.
- The Nebraska Attorney General's Office cannot provide legal, tax, or financial advice regarding new or existing nonprofit entities.



The privileges provided by law to public benefit corporations, and other charitable institutions, carry a corresponding obligation to be accountable to the public for the actions such institutions undertake.

Gilbert M. & Martha H. Hitchcock Found. v. Kountze, 272 Neb. 251, 259, 720 N.W.2d 31, 37(2006).

The Attorney General's Mission & The Public's Interest



...statutory authority has been given to the AG to act in the public good in enforcing the requirements applicable to nonprofit corporations, particularly public benefit corporations. In other words, the AG has standing to protect the public interest...

Gilbert M. & Martha H. Hitchcock Found. v. Kountze, 272 Neb. 251, 259, 720 N.W.2d 31, 37(2006).

Attorney General's Mission



- Nebraska nonprofit corporations do an incredible job
- A successful nonprofit sector is absolutely essential to Nebraska's well-being
- The Attorney General's work supports that goal

Goodwill Investigation



AGO Files Consent Judgment and Issues Report at Conclusion of Goodwill Omaha Investigation

June 16, 2018

On June 15, 2018, Attorney General Thomas was joined by AGC Douglas Wagner, who leads the Consumer Protection Division in the Office of the Attorney General, to announce the issuance of a consent judgment and issues report at the conclusion of the Goodwill Omaha investigation. The consent judgment resolves the matter and the issues report provides a detailed analysis of the findings of the investigation.

The AGC Douglas Wagner, who leads the Consumer Protection Division in the Office of the Attorney General, to announce the issuance of a consent judgment and issues report at the conclusion of the Goodwill Omaha investigation. The consent judgment resolves the matter and the issues report provides a detailed analysis of the findings of the investigation.

The AGC Douglas Wagner, who leads the Consumer Protection Division in the Office of the Attorney General, to announce the issuance of a consent judgment and issues report at the conclusion of the Goodwill Omaha investigation. The consent judgment resolves the matter and the issues report provides a detailed analysis of the findings of the investigation.


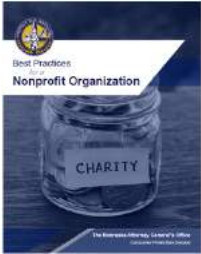


Nebraska Department of Justice
Attorney General Douglas F. Thomas

Report on Investigation of Goodwill Industries, Inc.
Goodwill Industries, Inc.

June 16, 2018

Best Practices


<https://protectthegoodlife.nebraska.gov/nonprofit-corporations>

Pitfalls in the Non-Profit, Healthcare Sector




- 1.Failure to Follow Mission
- 2.Conflicts of Interest
- 3.Failing to Operate with Needed Transparency
- 4.Directors and Senior Leadership Failing to be Sufficiently Active
- 5.Paying Excess Compensation

#1 Failure to Follow Mission
"Asleep at the Wheel"



- Identify
 - Nonprofits and their Boards have a duty to actively work toward fulfilling their mission.
 - Business planning must be grounded in mission
- Communicate
 - Review indicators of mission, focus, and accomplishments
 - Strategic plans, reports, minutes, etc.
- Evaluate
 - The organization should have tangible, critical assessments of efficiency and program successes.



#2 Conflicts of Interest



- A nonprofit corporation should be above reproach.
 - If any transaction gives even the appearance of a conflict of interest, think hard about avoiding it.
- IRS, donors, media, and the general public all have different views of conflicts.
 - None are good.

Bad excuse: "Technically, it's legal."
(What will your donors and constituents think?)

Director's Conflict of Interest

Neb. Rev. Stat. § 21-1987



- A conflict of interest transaction is a transaction with the corporation in which a director of the corporation has a direct or indirect interest.
- A conflict of interest transaction is not voidable or the basis for imposing liability on a director if the transaction was fair at the time it was entered into or approved by certain parties.

Director's Conflict of Interest

Neb. Rev. Stat. § 21-1987



- A conflict matter may be approved either before or after the transaction if it is approved by the Attorney General or the district court.
- A conflict matter may be approved before the transaction by the board of directors or a committee of the board under certain circumstances.

#3 Failing to Operate with Needed Transparency



- Top complaint generator
 - Easy for Attorney General to follow up
- *Neb. Rev. Stat. § 21-19,165 et seq.*
 - Nebraska statutes list required corporate records and inspection rights for members
 - Directors get access to everything
- Goal: Seek to operate with glass pockets

Bad excuse: "Only our Treasurer gets to see the financial records."

#4 Directors & Senior Leadership Failing to be Sufficiently Active



- Directors have a fiduciary duty to seek and obtain sufficient information to make informed decisions.
- Directors must understand the organization's financial health.
- There must be regular reporting to the Board.
 - Directors must be familiar with the nonprofit's activities.
 - Directors must actively seek the information they need.
 - The Executive Director works for the Board.
- Beware of consent agendas.

Bad excuse: "We're a volunteer board and don't have the time to _____."

#5 Paying Excess Compensation



- All of your assets must go to your charitable purposes, and you must pay reasonable compensation.
- Everything should be reasonable and justified.
- Avoid paying substantially more than similar organizations and lavish expense accounts.
 - Remember IRS excess compensation rules
 - Expense accounts matter

Bad excuse: "We didn't think it was necessary to perform a compensation analysis."

Questions?

Authorities & References

- NE Attorney General's Office, *Best Practices for a Nonprofit Organization*
 - <https://protectthegoodlife.nebraska.gov/nonprofit-corporations>
- U.S. Department of Health and Human Services, Office of Inspector General, *Practical Guidance for Healthcare Governing Boards* (April 20, 2015)
 - <https://oig.hhs.gov/compliance/compliance-guidance/docs/Practical-Guidance-for-Health-Care-Boards-on-Compliance-Oversight.pdf>

Authorities & References

- IRS Guidance
 - <https://www.irs.gov/charities-non-profits/charitable-hospitals-general-requirements-for-tax-exemption-under-section-501c3>
- HCCA-OIG, *Measuring Compliance Program Effectiveness: A Resource Guide* (March 27, 2017)
 - <https://oig.hhs.gov/compliance/101/files/HCCA-OIG-Resource-Guide.pdf>

Authorities & References



- U.S. Department of Justice, *Evaluation of Corporate Compliance Programs* (February 8, 2017)
 - <https://www.justice.gov/criminal-fraud/page/file/937501/download>

Contact Information



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- **Michael W. Chase, Partner**
 - Baird Holm LLP, 402-636-8326, mchase@bairdholm.com

THE KINETIC THEORY OF EMTALA: DEFINITIONS IN MOTION

Barbara E. Person

The Kinetic Theory of EMTALA: Definitions in Motion

Barbara E. Person

Stabilization: Why Do We Care?

- An unstable emergency medical condition (EMC) is the basis for application of EMTALA:
 - Patient's right to:
 - Stabilizing Treatment or
 - "Appropriate Transfer"
 - Establishes obligation of receiving facility to accept transfer
- Once patient is stabilized, EMTALA no longer applies

42 CFR Section 489.24(d)

(d) Necessary stabilizing treatment for emergency medical conditions -

(1) General. Subject to [an exception for inpatient admission], if any individual . . . comes to a hospital and the hospital determines that the individual has an emergency medical condition, the hospital must provide **either** -

(i) Within the capabilities of the staff and facilities available at the hospital, for further medical examination and treatment as required to stabilize the medical condition. **[OR]**

(ii) For transfer of the individual to another medical facility in accordance with [regulation defining "appropriate transfer"].

Four Requirements for an “Appropriate Transfer”

- Provide medical treatment within transferring hospital's capacity to minimize risks of transfer (attempt to stabilize)
- Obtain receiving facility's acceptance
- Send all medical records and name and address of any on-call physician who failed or refused to come to attend the patient
- Use appropriate equipment and personnel to effect transfer

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Stabilization: Why Do We Care?

- Regulators distinguish clinical stability (vitals) from "stabilization" as defined by EMTALA
- That's why peer reviewers quibble over transfer form stating the patient is "stable"
- There's no negative in saying the patient was "unstable" at time of transfer, under the EMTALA definition.
 - That just means that EMTALA applies.

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EMTALA Regulatory Definitions

- Emergency Medical Condition:
 - Acute symptoms of sufficient severity (including severe pain, psychiatric disturbances and/or symptoms of substance abuse) that without immediate medical attention could reasonably be expected to result in:
 - placing health in serious jeopardy
 - serious impairment to bodily function
 - serious dysfunction of any bodily organ or part
 - Pregnant woman who is having contractions
 - inadequate time to effect safe transfer
 - transfer poses a threat to health of woman or child

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EMTALA Regulatory Definitions

- **Stabilized**

- Non-pregnant patient: no material deterioration of the condition is likely, within reasonable medical probability to result from or occur during the transfer
- Pregnant patient: woman has delivered child and placenta

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CMS Survey & Certification Letter December 13, 2013

- Definition of "stabilized" ≠ clinically stable.
- Similarity of these terms causes confusion.
- Clinical stability= normalization of vital signs.
- But EMTALA continues to apply unless patient's EMC is "stabilized" consistent with the statutory definition.
- E.g., patient with appendicitis, requiring surgery, is not stabilized until surgery is performed.

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CMS Survey & Certification Letter December 13, 2013

- Patient's ability to withstand risk of transfer does not necessarily establish stability, as defined.
- "Stable for transfer" is not EMTALA terminology; it's misleading.

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CMS Survey & Certification Letter December 13, 2013

- CMS: "Appropriate Transfer" assumes that:
 - Individual has an EMC that has not been stabilized
 - Hospital lacks capability or capacity to provide stabilizing treatment; AND
 - Benefits from appropriate treatment at another medical facility outweigh increased risks from transfer.
- An individual with an unstabilized EMC remains protected under EMTALA *before, during and after* the transfer.

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Capacity of Transferring Hospital

- Hospital's full capacity must be used to TRY to "stabilize" the patient prior to transfer
- "Minimize the risks of transfer"
- "Stabilization" is not required prior to transfer
- But Hospital's capabilities must be exhausted before transfer
 - Unless efforts would be time-consuming and improperly delay transfer and undermine patient safety

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Nebraska 2019 Citation CMS Regional Office in KC, MO

- Five days after discharge from acute hospital, a male insulin-dependent diabetic presented to CAH ED with nausea and vomiting.
- Blood sugar was high; white blood cell count critically elevated; normal EKG and chest x-ray; Respirations 18; pulse 111; temp 96.8; BP 106/53; lactate level 3; sepsis screen score of 2; x-ray showed mild ileus.
- NP started IV with normal saline.
- NP called on-call, back-up physician, who recommended a CT scan of chest, abdomen and pelvis, and transfer to acute hospital.

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Nebraska 2019 Citation CMS Regional Office in KC, MO

- NP called the acute hospital and was connected with the physician who treated this patient during his recent admission at the acute hospital. NP mentioned that back-up physician had recommended CTs.
- Physician at receiving hospital asked for report from CTs.
- NP thought this was to be done prior to transfer, and that transfer was otherwise accepted.
- Physician at acute hospital wanted CT results and a call back from the NP **prior to** accepting transfer.
- The physician at the acute hospital wanted to know if surgery was needed.

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Nebraska 2019 Citation CMS Regional Office in KC, MO

- NP did not review the CT scan, but proceeded with transfer.
- NP thought the patient was in an unstable emergency medical condition the entire time he was at the CAH.
- Stated reason for transfer: "Hypotension, Elevated WBC; nausea/vomiting; sepsis."
- NP did not review worsening vitals prior to transfer.

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Nebraska Citation 2019 CMS Regional Office in KC, MO

- Transfer of 2 ½ hours to acute hospital.
- ACLS ambulance squad documented worsening BP.
- Called receiving hospital for orders.
- Physician ordered increased infusion rate of IV Normal Saline, first to 300 ml/hr, then later to 500 ml/hr upon 2nd call from EMS squad.

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Nebraska 2019 Citation CMS Regional Office in KC, MO

- CAH was cited for failure to stabilize the patient.
 - CMS found CAH was capable of providing the needed stabilizing treatment, so transfer wasn't necessary.
 - 2 ½ hours in ambulance only delayed stabilizing treatment.
- Other problems:
 - No acceptance of transfer by receiving physician
 - Failure to use CAH's capabilities to [stabilize] prior to transfer
 - Failure of NP to review pre-transfer vitals
 - No physician signature on transfer form (until 13 days later).

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CMS Survey & Certification Letter December 13, 2013

- CMS: "Appropriate Transfer" assumes:
 - ☐ Individual has an EMC that has not been stabilized
 - ☐ Hospital lacks capability or capacity to provide stabilizing treatment; AND
 - ☐ Benefits from appropriate treatment at another medical facility outweigh increased risks from transfer.

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Lateral Transfers: Background

- Definition: Transfer between facilities of comparable resources and capabilities
 - Transfer occurs even though the first facility has the capability to perform the service needed by the transferred patient
- Historically viewed benevolently by CMS
 - CMS: "a receiving facility does not have to accept a lateral transfer," implying it was permissible if transfer was accepted
- New CMS Enforcement Stance:
 - CMS cites for unnecessary transfers for surgery
 - Reviews surgeons' privileges at transferring hospital to determine if any need for transfer

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Nebraska 2017 Citation CMS Regional Office in KC, MO

- Hospital had post-op patient in ED, with a bowel obstruction that seemed to be related to GYN surgery performed weeks earlier at a hospital 60 miles away
- EDP called his on-call general surgeon
- On-call general surgeon: "Am. College of Surgeons says the operating surgeon has an ethical responsibility to handle complications within a month of surgery."

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Nebraska 2017 Citation CMS Regional Office in KC, MO

- EDP calls the GYN surgeon
 - She says she would not work on a bowel obstruction at her community hospital
 - On-call gen. surgeon would do it
- EDP calls that on-call general surgeon
- Receiving gen. surgeon accepts transfer if the transferring hospital's gen. surgeon will not
 - Interpreted by CMS as less than acceptance.

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Nebraska 2017 Citation CMS Regional Office in KC, MO

- CMS cited transferring hospital for failure to stabilize patient prior to transfer
 - Faulted an unnecessary transfer of 60 miles
- As authority, CMS cites responsibility to use full capabilities to stabilize
 - This includes surgery if an on-call specialist at transferring hospital has necessary privileges

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What About Higher Expertise?

- Must the orthopedic surgeon who has done only one digital amputation in the past 5 years perform the surgery if his privileges say he can?
 - CMS would probably say yes.
- But wouldn't each of us want the most experienced physician to do our surgery?
- Shouldn't there be an understanding that the patient could be transferred to a hand surgeon?

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Transfer Requirements

- For patient in EMC, transfer is generally restricted until patient is stabilized
- For transfer of unstable patient:
 - Patient must request transfer **or**
 - Physician must certify that benefits of transfer outweigh the risks, **and**
 - Transfer must be "appropriate"

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Iowa 2018 Citation CMS Regional Office in KC, MO

- An orthopedic group with offices in 2 communities (with 2 different hospitals) have an agreement with each of the hospitals to provide on-call coverage. The two hospitals are 21 miles apart.
- These on-call physicians sometimes cover both hospitals from one community or the other.
- On some occasions, the on-call physician has requested that the ED patient at one hospital be transferred to the other (where the on-call physician is) rather than the on-call physician going to the first hospital to stabilize the patient there.

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Iowa 2018 Citation CMS Regional Office in KC, MO

- On complaint survey, CMS reviewed all orthopedic transfers from the ED at one of the 2 contracting hospitals.
- ED physician diagnosed a patient as having an abscess in a finger on the right hand.
 - On-call orthopedic surgeon indicated he was at the other hospital.
 - Patient was transferred by private vehicle so that the surgeon could continue providing on-call coverage at the other hospital.

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Iowa 2018 Citation CMS Regional Office in KC, MO

- Another patient complained of pain in the left wrist after a fall the previous evening.
 - X-ray showed splintering of bone in forearm near the wrist.
 - On-call orthopedic surgeon indicated he was near the other hospital, and requested the patient's transfer to that hospital.
 - Transfer was by private vehicle.
- Similar facts regarding a patient with fractures in lower leg, presenting on same day as when the patient fell and injured it.

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Iowa 2018 Citation CMS Regional Office in KC, MO

- The hospital was cited for having on-call physicians who did not respond to an ED request to come and serve an ED patient.
- Failure to come to the ED placed all patients with an unstabilized EMC at risk for delay in treatment and further deterioration of their condition up to and including death.
- Different citation, but same failure to perform surgery at first hospital where patient presented.

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Can Hospitals Share On-Call Physicians?

- Hospitals are not required to have on-call physicians in all specialties 24/7.
- Call schedules could have coordinated coverage at one hospital or the other.
 - One hospital would have on-call coverage
 - The other would not; but could transfer to the covered hospital as its back-up plan for whenever orthopedic coverage was not available
- Or both hospitals could authorize "simultaneous coverage" of two hospitals in their call coverage policies
 - If on-call physician was busy at one hospital, he would be considered unavailable to the other, supporting transfer to the hospital he was at.

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Takeaways

- For CAHs, the answer to a complicated case is not necessarily transfer.
- For smaller acute hospitals, transfer for surgery is not a given.
- Review privileges and delete those not used or not desired to be used.
- Otherwise, review with patient any recommendation for transfer to access a more experienced surgeon.
 - Turn this into a patient request for transfer

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MANAGING MEDICAL STAFF MATTERS IN TODAY'S HEALTH CARE ENVIRONMENT

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Managing Medical Staff Matters in Today's Health Care Environment

Vickie B. Ahlers

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Becker's Hospital Review



Sexual misconduct claims against physicians jumped 62% in California after #MeToo

Emily Rapaport (Twitter) - Monday, August 12th, 2019 Print | Email

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An analysis conducted by the Los Angeles Times reveals sexual misconduct allegations against physicians have increased 62 percent since the fall of 2017, when the #MeToo movement began.

A similar upsurge in allegations for sexual misconduct has been observed in other states around the country, the Federation of State Medical Boards confirmed to the LA Times.

The analysis, which was based on data from the California medical board, found complaints of sexual misconduct against physicians have increased to 279 and 280 in the past two fiscal years, respectively. Prior to that, in the 2016-17 fiscal year, the state medical board received 173 complaints against physicians for sexual misconduct, according to the report.

However, the increase in complaints has not translated to an increase in actions against physicians. The LA Times found disciplinary action for sexual misconduct has actually decreased in the last fiscal year.

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Employed Physicians Outnumber Self-Employed



PRESS RELEASE – AMA MAY 6, 2019

CHICAGO — For the first time in the United States, employed physicians outnumber self-employed physicians, according to a newly updated study on physician practice arrangements by the American Medical Association



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A Surgeon So Bad It Was Criminal



- Christopher Duntsch's surgical outcomes were so outlandishly poor that Texas prosecuted him for harming patients
- Why did it take so long for the systems that are supposed to police problem doctors to stop him from operating?
 - By Laura Beil, special to ProPublica Oct. 2, 2018, 5 a.m. EDT

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Handling Difficult Medical Staff Matters

- Now that many more physicians are employed, creates option for handling difficult personnel issues either as employment matters or Medical Staff matters
 - Pros/cons
 - Which approach is the better approach?
 - Policy violations?
 - Harassment/misconduct?
 - Retaliation?
 - Disruptive behavior in the hospital?
 - Quality issues?



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Employment v. Medical Staff Discipline



- What are the key differences in these processes?
 - Timeline
 - Cost/disruption
 - Confidentiality
 - Rights of impacted physician
 - Likelihood of litigation
 - NPDB and licensure reporting requirements
 - Liability exposure once problem physician lands elsewhere
 - References

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Dr. Brady the Terrible



Dr. Brady, a surgeon at Shady Lane Hospital, was having a bad day. In fact, Dr. Brady, much like Alexander in the classic children's story, was having "a terrible, horrible, no good, very bad day." At around 4:00 p.m., she was told that her use of the operating room was going to be delayed (for 20 minutes as it turned out). Apparently, that was the final straw for her. She pitched a fit.

*Judith Viorst, *Alexander and the Terrible, Horrible, No Good, Very Bad Day* (1972), as cited by Judge Carnes in *Jorge J. Leal, M.D. v. Secretary, U.S. Department of Health and Human Services*, 620 F.3d 1280 (2010).

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Dr. Brady the Terrible

Dr. Brady became so enraged that she broke a telephone, shattered the glass on a copy machine, shoved a metal cart into the doors of the operating suite, flung a medical chart to the ground when a nurse asked her for written authorization to proceed with surgery, and verbally abused a male nurse manager by stating that he'd probably do his job better if he was getting more action, and that "she could fix that problem for him if he wanted in the supply closet." Dr. Brady is known for her excessive flirting with male colleagues in between outbursts.

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Dr. Brady is an Employed Provider



- HR investigation, Medical Staff investigation or both?
- **PRO:** Strictly employment investigation is not "investigation" for NPDB purposes (maximum flexibility)
- **CON:** If outcome is termination of employment, haven't dealt with medical staff privileges; no peer review privilege

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Employed Providers



- Employee handbooks should strictly prohibit disruptive behavior (including harassment)
 - Include examples of what constitutes harassment
- Medical Staff Bylaws or policy should also prohibit disruptive conduct
- Employment Agreement should tie back to compliance with policies and Medical Staff Bylaws

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Hospital-Based Exclusive Providers



- Often same options as for employed physicians
 - Can address through contract with group or
 - Can institute Medical Staff action
- Contract may also permit hospital to disapprove of any individual physician as long as not for discriminatory reasons

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Economy v. Sutter East Bay Hospital, 31 Cal. App. 5th 1147 (2019)

- Anesthesiologist was employed by group that was exclusive provider of anesthesia services
- Quality issue with anesthesiologist resulted in "immediate jeopardy" finding in hospital survey
- Anesthesiologist was placed on leave of absence

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Economy v. Sutter East Bay Hospital

- Anesthesiologist completed education course and returned to work
- Quality issue resurfaced
- Hospital informed group it could not approve schedules with this anesthesiologist included
- He refused to resign
- Group terminated him



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Economy v. Sutter East Bay Hospital

- Anesthesiologist sued Hospital
- Argued failure to give him notice or hearing violated California law
- Trial court found Hospital's request to remove him from scheduling was effectively summary suspension that entitled him to due process from Hospital
- Court awarded anesthesiologist \$3,867,122



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Economy v. Sutter East Bay Hospital

- Hospital appealed, arguing anesthesiologist was terminated by his group, and not by Hospital
- Appellate court determined Hospital was indirectly responsible for anesthesiologist's termination
- If Hospital could not terminate anesthesiologist's privileges without providing notice and hearing, then cannot do so indirectly through group



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Lessons from Economy



- This was in California
- Empathy for physicians in these cases may cause rationale to be adopted by other courts
- Need to think through whether having group terminate physician at Hospital's request is best option

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Quality Concerns? – Dr. Frank



- Dr. Frank is a non-employed OB/GYN specialist on the Medical Staff
- The Hospital has a policy prohibiting the induction of deliveries < 39 weeks absent clinical justification
- Dr. Frank has had 9 inductions < 39 weeks so far this year, which is two times the rate of any other OB/GYN on staff

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Quality Concerns? – Dr. Frank

- Dr. Frank has provided clinical justifications, including fetal growth restriction, pre-eclampsia, and post-term pregnancy
- 6 of the 9 patients ultimately required C-sections
- The Peer Review Committee regularly reviews inductions < 39 weeks, but believes a targeted review of Dr. Frank's inductions and supporting justification is needed

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Medical Staff Investigation

- Separate from HR Investigation
- Governed by
 - Federal laws
 - State laws
 - Medical Staff Bylaws
 - Medical Staff Policies
 - Sexual Harassment Policy
 - Disruptive Practitioner Policy
 - Behavior Policy



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Medical Staff Investigation

- Follow Medical Staff Bylaws and policies:
 - Who reviews initial complaint?
 - Who investigates?
 - If Ad Hoc committee, who appoints?
 - Timeline for investigation, findings and recommendations to meet any deadlines
 - Remember to obtain physician's side of story

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Medical Staff Investigation

- General stages of Peer Review investigation
 - Receive complaint
 - Interview complainant and witnesses
 - Collect documents, text messages, etc.
 - Notify Provider of complaint
 - Interview Provider
 - Complete investigation
 - Make findings
 - Communicate results
 - Ad Hoc committee report to MEC
 - MEC report to Board



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Medical Staff Hearings: A Litigator's Perspective



- Remember your audience (i.e., the Hearing Panel)
- Peers of disciplined physicians
 - Looking for fair treatment
 - Put off by perceived abuse of authority
- Sophisticated in subject matter
 - Will test the medicine
 - Will want details and supporting information
- Volunteers
 - Desire to reach the right result
 - Protective of the institution



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Problem Areas



- Failure to follow bylaws
- Timing
- Procedure/disclosure
- People involved
- Failure to obtain and consider both sides of story
- Lazy investigation
- Lazy documentation of good investigation
- Reluctant decision makers
- Absence of external opinions
- Informal assurances ("hallway conversations")
- Inconsistent prior outcomes
- Breaches of confidentiality

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Advantages – Legal and Procedural

- Don't lose the built-in advantages!
 - Standard of review
 - Hearing officer control and advice
 - Peer review privilege
 - Statutory liability protection



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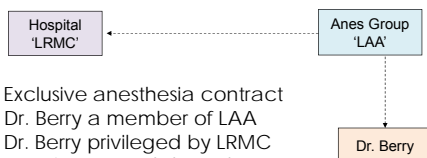
References

- If a problem employed physician was terminated, what can be shared with prospective employers?
 - What effect does a "without cause" termination of employment have on what an employer can say?
- Should a prospective employer/Medical Staff credentialing office ask **why** there was a without cause termination or whether there were any issues?
- What about comments like "they just weren't a good fit?"
- What if employer only verifies dates of employment and eligibility for rehire?

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Kadlec Medical Center v. Lakeview Anesthesia Associates, 527 F.3d 412 (2008)



- Exclusive anesthesia contract
- Dr. Berry a member of LAA
- Dr. Berry privileged by LRMC
- Impairment and drug abuse
- Terminated by LAA
- Could no longer practice at LRMC

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Kadlec Medical Center v. Lakeview Anesthesia Associates



- Lower court found that if a hospital chooses to respond, public policy should encourage disclosure
- What were the possible misrepresentations?
 - For LRMC:
 - Saying they routinely do not answer "due to the large volume of inquiries received in this office"
 - 13 other credentialing requests were answered fully on the same day
 - For LAA:
 - Neutral or favorable recommendations

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Kadlec Medical Center v. Lakeview Anesthesia Associates

- 5th Circuit Court of Appeals reversed the lower court's finding that LRMC had a duty to disclose Dr. Berry's drug problem
- Letter from LRMC to Kadlec not misleading
 - LRMC had no affirmative duty to disclose
 - Could not make misrepresentations
- LAA reference letters were



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Lessons from Kadlec



- Better to share no information than to share misleading information
- Responses should be:
 - Carefully thought through
 - Not misrepresent information
 - Be truthful

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National Practitioner Data Bank

National Practitioner Data Bank
NPDB



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National Practitioner Data Bank

- Issued revised guidebook without prior notice or opportunity for comment
 - October 2018



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Redefining Investigation



- HRSA concerned about unreported activity
- Revised definition of investigation to interpret it "expansively"
- Investigations alone are not reportable, but actions taken during investigation are
- Not bound by definitions and processes in Medical Staff Bylaws

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What Is An Investigation?



- Investigation? **No**
 - Routine, formal peer review process under which practitioner is evaluated against defined measures and where process applicable to all practitioners
- Investigation? **Yes**
 - Targeted process used when issues related to specific practitioner's professional competence or conduct are identified

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When Does an Investigation End?

- Investigation concludes when Medical Staff/Board takes:

- Final action or
- Formally closes investigation



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NPDB Reporting

- Voluntary and involuntary actions are reportable, including:
 - Resignation of clinical privileges
 - Failure to renew clinical privileges
 - Leave of absence



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Miller v. Huron Regional Medical Center, No. 18-1522 (8th Cir. 2019)

- Dr. Miller began working at HRMC as surgeon in 2004 and entered into three-year contract in 2009
- Dr. Miller settled several malpractice lawsuits
- HRMC Board asked MEC to conduct review of her medical records
- MEC conducted three-month review; found no issues
- Board asked MEC to conduct another review
- While second review was under way, Dr. Miller had two bad patient outcomes

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Miller v. Huron Regional Medical Center



- Dr. Miller testified that Medical Staff representative (Dr. Blessinger) told her MEC was recommending voluntary reduction in her surgical privileges to appease Board and avoid her termination
- She alleged Dr. Blessinger expressed his opinion that a voluntary reduction would not trigger NPDB report
- Dr. Miller submitted revised privilege checklist that same day omitting abdominal surgeries

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Miller v. Huron Regional Medical Center



- HRMC's CEO consulted with legal counsel and determined if Board accepted Dr. Miller's request for reduction in privileges, would trigger NPDB report
- CEO showed Dr. Miller copy of draft report; she did not withdraw her request to reduce privileges
- NPDB report stated:
 - Dr. Miller voluntarily surrendered a portion of her surgical privileges while the MEC was investigating her quality of care
- Board voted to terminate Dr. Miller's contract anyway under a without cause termination

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Miller v. Huron Regional Medical Center



- Dr. Miller remained unemployed for six months before accepting a position in Florida as a wound care provider
- She stated she had applied for a surgical position but was told she would not be able to get credentialed due to NPDB report
- Dr. Miller sued HRMC for breach of contract and defamation
 - Alleged MEC was not "investigating her quality of care" at time she surrendered privileges

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Miller v. Huron Regional Medical Center

- At trial, Dr. Miller presented evidence HRMC failed to comply with Medical Staff Bylaws because she received no hearing before request made for reduction in her privileges
 - Also alleged the review of her cases was not "investigation" under Bylaws
- One expert testified that NPDB report was "absolutely devastating" to her career
 - Another called it the "kiss of death"



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Miller v. Huron Regional Medical Center



- Jury found in favor of Dr. Miller on contract claim and in favor of HRMC on defamation claim
- Awarded \$1,180,000 for lost wages, lost future earning capacity and mental anguish
 - Mental anguish award of \$250,000 later struck by trial court

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Miller v. Huron Regional Medical Center

- HRMC appealed to 8th Circuit
- Argued Dr. Miller's contract was terminated without cause and therefore was no breach
- 8th Circuit noted in HRMC's motion for summary judgment, lower court determined breach of contract related to Bylaws which were independently enforceable contract under South Dakota law



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Miller v. Huron Regional Medical Center



- HRMC argued it had immunity under HCQIA
- Argued damages awarded by jury were not for termination but for NPDB report
- 8th Circuit determined HRMC made this argument too late
 - Jury instructions and verdict form both indicated jury was free to award damages if it found in Dr. Miller's favor on either claim

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Lessons from Miller



- Another case where there was sympathy for physician?
 - she did what Medical Staff asked and was still terminated
- Important to rely from the start on protections hospitals and Medical Staffs have under HCQIA

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31ST ANNUAL BAIRD HOLM LLP
HEALTH LAW FORUM

**THE
LATEST
WORD**

Panel of Baird Holm Attorneys

[illegible]

CMS Changes to Provider Enrollment

- Goal: End "pay and chase" and stop fraud and abuse *before* it starts (like Tom)
 - "Program Integrity Enhancements to the Provider Enrollment Process"
- Implements Section 6401 of the ACA
 - Subtitle E "Medicare, Medicaid, and CHIP Program Integrity Provisions"
- Timeline to date
 - Proposed rule: March 1, 2016
 - Final Rule: September 5, 2019

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What to Know

- Competing views on utility of changes
 - CMS: Antifraud and will help us protect the Medicare trust fund
 - Industry: Overly burdensome and operationally challenging to implement
- Key concepts:
 - Affiliations disclosure requirement
 - Applies to current and former enrollees
 - CMS authority to revoke or deny Medicare enrollment
 - Increased bars to reenrollment and reapplication
- Effective November 4, 2019 but CMS adopting "phased-in" approach in response to concerns about burden on providers & suppliers
- Several unanswered questions

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Labor & Employment Updates

Sara A. McCue

It's Raining Cats, Dogs, and Emotional Therapy Monkeys

- Americans with Disabilities Act
 - Title I (employment)
 - Title II (state and local government agencies)
 - Title III (places of public accommodation)
- Service Animals
 - Title II and Title III
 - Definition
- What can we ask?

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It's Raining Cats, Dogs, and Emotional Therapy Monkeys

- What about Title I of the ADA?
 - Reasonable accommodation requests
- What about the Fair Housing Act?
 - Does it apply to the health care industry?

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Peer Review Data

- Background on risks
- *Williams v. Baptist Health*

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OCR Resolution Agreements & Civil Monetary Penalties

Abigail T. Mohs

2019 Settlements

- Notified of breach by OCR and FBI
- Breach caused by hacker
- Right to Access settlement
- Social Media breach
- (another) Civil Monetary Penalty
- Others?

Employee Benefits Update

Jeremy T. Christensen

Employee Benefits Update

- Individual Coverage HRAs
- Association Health Plans
- Proposed rules on electronic disclosures

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What's New with Direct Primary Care?

Sean T. Nakamoto

Background

- DPC vs. Concierge Medicine
- Growth of DPC Offerings
 - Lots of growth in 2017-18 (model DPC legislation introduced in many states)
 - 2019 – Future?

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Nebraska

- Direct Primary Care Agreement Act (Neb. Rev. Stat. §§ 71-9501-9511)
- Key Elements
 - Not health insurance
 - Detailed scope of services
 - Clear explanation of fees

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Federal

- Use of Health Savings Accounts or Flex Accounts to pay for DPC Fees and Costs?
- CMS Direct Contracting Payment Models

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DOJ Compliance Program Guidance Update

Kimberly A. Lammers



Evaluation of Corporate Compliance Programs

- Original guidance released in February 2017
- Heavily focused on compliance program design
 - Existence of compliance policies and procedures
 - Autonomy and resources available for compliance
 - Organization's conduct in analyzing and remediating misconduct
- Updated guidance released April 2019 with expanded focus

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New Focus on Implementation and Effectiveness

- New guidance contains increased focus on implementation and effectiveness of organization's compliance program
- DOJ does state it does not use "rigid formula"



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Topics Regarding Whether Compliance Program Works in Practice

- Continuous improvement, periodic testing and review
- Investigation of misconduct
- Analysis and remediation of misconduct



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Investigation of Misconduct

- Failure to prevent or detect misconduct does not mean program is not effective
- DOJ recognizes no compliance program can ever prevent all misconduct
- If compliance program did effectively identify misconduct, and misconduct was timely remediated and self-reported, this is "strong indicator" compliance program was working effectively

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Handling of Misconduct

- When issues are identified, is there timely action and self-reporting?
- Does the organization conduct a root cause analysis and make changes to prevent similar misconduct from occurring in future?
 - Which controls failed?
 - How was misconduct funded and what processes could have detected improper access to or use of funds?
 - Were prior indications of misconduct missed?
 - Were changes to policies and procedures made to prevent similar issues of misconduct?
 - Were managers held accountable for misconduct that occurred under their supervision?



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Nursing Home Compliance Program Mandate

Kimberly A. Lammers

Compliance Program Requirement – 42 C.F.R. § 483.85

- Deadline is **November 28, 2019**
- Skilled nursing facilities and nursing homes must adopt and implement compliance program as condition of participation
- State survey agencies will review whether effective compliance programs have been implemented



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Update on CLIA Surveys and Corrective Action Plans (Nebraska)

Kimberly A. Lammers

What Is Required?



- Must be:
 - Made by representative of laboratory with history of having maintained commitment to compliance and taking corrective action when required
 - Realistic in terms of possibility of corrective action being accomplished between date of survey and date of allegation
 - Indicates resolution of problems identified

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Corrective Action

- Documentation showing what corrective actions have been taken for affected patients
- How laboratory has identified other patients potentially affected and what corrective actions have been taken
- What measures or systemic changes have been put in place to ensure deficiencies do not recur
- How corrective actions are being monitored to ensure deficient practice does not recur

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What Happens When Corrective Action Plan Is Not Accepted?



- Revocation of CLIA Certificate
- Civil Money Penalties (assessed per day)
 - Laboratory was found to be out of compliance with condition-level requirements
 - Laboratory has failed to correct deficiencies after being provided opportunity to do so
 - Laboratory has expressed no rational reason for its failure to achieve compliance with all applicable condition-level CLIA requirements
- Directed Portion of Plan of Correction
- Cancellation of Approval to Receive Medicare and Medicaid Payments

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Immigration Updates

Kara E. Stockdale

Immigration Updates

- Premium Processing Fee
- H-1B Lottery Changes
- H-4 EAD – Proposed Regulation
- Philippines Hiring
- Form I-9

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501(r) Developments

Andrew D. Kloeckner

501(r) Developments

- February 19, 2019 –Sen. Grassley letter to Commissioner inquiring as to current IRS 501(r) enforcement efforts
 - Reports of hospitals cutting charity care
 - Reports of collection actions

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501(r) Developments

- Information requested:
 - Data related to the number of IRS reviews
 - Results of those reviews
 - Particular findings related to hospital debt collection practices and "reasonable efforts"

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501(r) Developments

- April 11, 2019 - Commissioner response
 - from February 24, 2018 through February 22, 2019:
 - 832 reviews of tax-exempt hospitals
 - 625 closed without further action
 - 129 referred for a compliance check
 - 78 referred for examination (audit)
 - 57 audits remained open

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Questions?

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IT'S NO LONGER BUSINESS AS USUAL IN THE BUSINESS OFFICE

John R. Holdenried

Zachary J. Buxton



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It's No Longer Business as Usual in the Business Office

John R. Holdenried
Zachary J. Buxton

Outline

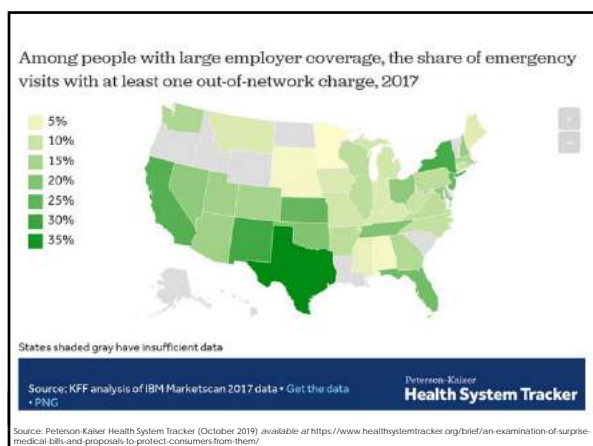
- Surprise medical bills & proposed legislation
- Suing patients for unpaid bills
- Price transparency & the tale of the 100,000 row Excel spreadsheet
- Reference-based pricing

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Out-of-network visits, out-of-network providers, emergency room visits, and Congress' attempts to fix it

SURPRISE MEDICAL BILLS

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Proposed Federal Legislation



COMMUNITY HEALTH INVESTMENT MODERNIZATION AND EXCELLENCE ACT OF 2019 (H.R. 2328)
Rep. Tom O'Halleran (D-AZ)
District 1



PROTECTING PEOPLE FROM SURPRISE MEDICAL BILLS ACT (H.R. 3502)
Rep. Raul Ruiz (D-CA)
District 36

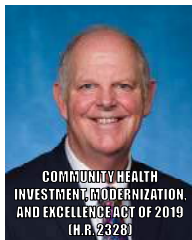


LOWER HEALTH CARE COSTS ACT (S. 1895)
Sen. Lamar Alexander (R-TN)

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Proposed Federal Legislation



Rep. Tom O'Halleran (D-AZ)
District 1

- Emergency services; post-emergency inpatient stabilization*; out-of-network practitioner services at in-network hospitals/facilities
- Caps on out-of-network charges for facilities and practitioners
- Default payment amount*
- Independent dispute resolution



So, What Happened?

- Reported lobbying efforts from special interests
 - Doctors Patient Unity funded by TeamHealth and Envision Healthcare
 - Air ambulance providers
- Although bipartisan support, several issues with proposed legislation
 - IDR process is costly
 - CBO estimates "double digit billion" in costs for H.R. 3502
 - Disagreement on starting point for benchmark
- Some Democrats reluctant to give Republicans legislative victory on health care while attacks on ACA continue
- Don't expect any movement as we enter election cycle



Provider Strategies to Reduce Surprise Medical Bills

- Contract provisions with hospital-based providers requiring them to participate in payor contracts specified by hospital
 - Radiology, anesthesiology, emergency room, Locum tenens
- Contract provisions with hospital-based providers that charges be limited to specified levels



Provider Strategies to Reduce Surprise Medical Bills

- For non-emergency services, encourage patients to check with insurer
 - Increasingly important as "narrow networks" increase
- Note: Nebraska, Iowa, and South Dakota have some of the lowest rates of surprise medical bills
 - Less than 10% of inpatient and emergency visits resulted in surprise medical bills
 - Nebraska and South Dakota: 2% and 4% of inpatient and emergency visits, respectively

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Senator Chuck Grassley's (R-IA) continued interest in tax-exempt hospitals & charity care

SUING PATIENTS FOR UNPAID BILLS

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501(c)(3) Hospitals: 501(r)(6)

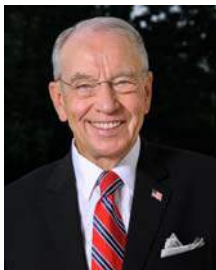
- Restricts "extraordinary collection actions" (including suits for services)
- Requires
 - 30 day notice to patients
 - Plain language FAP
 - Reasonable effort for oral notice
- Must suspend ECA upon receipt of FAP application

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Grassley—Letter to Mosaic Health

- Letter to CEO, 1-16-15
 - Appear to be suing patients even when eligible for financial assistance
 - Uses in-house agency to sue
 - 11,000 lawsuits over 4 years, 6,000 garnishments
 - More than any other Missouri hospital
 - Most were uninsured
 - Asked several questions



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Response of Mosaic Health

- We comply
- We engage in many charitable activities
- We only sue less than 2,000 patients per year
- Most are insured and suits are for co-pays
- We believe we have obligation to pursue collection



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Source: NPR, Senator "Astounded" That Nonprofit Hospitals Sue Poorest Patients (January 2015) Photo Credit: Steve Hebert for ProPublica available at: <https://www.npr.org/2015/01/22/37888447/senator-astounded-that-nonprofit-hospitals-sue-poorest-patients>

Grassley Investigation of Mosaic

- Grassley report on investigation, 5-24-16, results of 18 month investigation
- "Let me be clear, non-profit hospitals should not be in the business of aggressively suing their patients."
- Mosaic took the following actions:
 - 3 month debt forgiveness period
 - Forgave debt of 5,070 patients—\$16.9 million
 - Hired staff to help patients with financial assistance
 - Will no longer charge interest
 - Expanded eligibility for financial assistance

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Grassley/Hatch Letter to IRS —2-15-18

- Requests data on hospital compliance with 501(r) and status of exams

Grassley Letter to IRS—2-19-19

- Asks for further information about reviews in last 12 months
- Specific questions about reviews as to debt-collection practices and ECAs
- IRS Response, 4-11-19
 - None of the closed hospital exams resulted in a violation of ECA rules

JAMA Report, June 2019

- 36% of Virginia hospitals sued and garnished wages in 2017
- Over 20,000 suits, 9,000 garnishments
- 5 (4 were NFP) had over ½ of suits
- NFPs sued more often than FPs
- Mary Washington sued the most
- Reported in WSJ and NPR

Wage Garnishments

	Garnished	Did Not Garnish
NFP	34	46
FP	13	26
Government	1	15
Urban	46	79
Rural	12	8
Number	3 to 1,756	
Amount	\$24.80 to \$25,000	

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JAMA Report Observations

- Hospitals with greater financial need (NFP, lower annual gross revenue) may be pursuing debt collection to the final stage of garnishment

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Response of Mary Washington

- We only sue as last resort
- We're only #1 because we don't sell our debt to collection agencies
- Suspended practice of suing patients and will re-evaluate its entire payment process
- Will work to eliminate current garnishments

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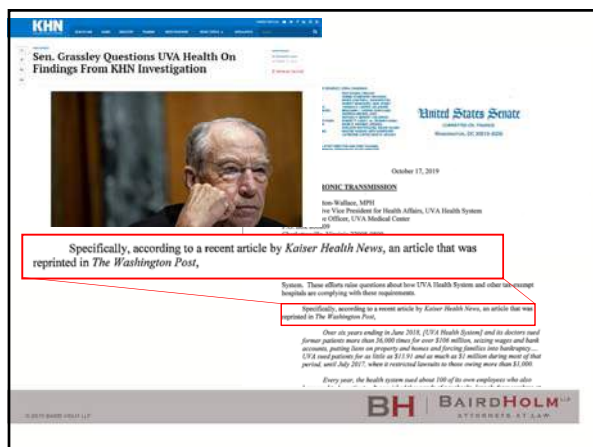
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Report on U of Virginia Health, September 2019

- 36,000 suits over 6 years
- Included garnishments, liens, forced bankruptcy
- After July 2017, restricted suits to over \$1,000
- Also sued over 100 employees each year
- Also seized \$22 million in state tax refunds
- Added 15% for legal cost plus 6% interest
- Restrictive FAP eligibility

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Grassley Letter to VA Health System, 10-17-19

- 19 detailed questions with many subparts about process
- Includes 501(r) compliance questions
- Questions eligibility standards
- Questions about cost of care and self-insured discounts
- Questions pricing
- "Unfortunately, I have seen a variety of news reports lately discussing what appear to be relentless debt-collection efforts by tax-exempt hospitals, including UVA Health System. I am also concerned about how patients' hospital bills get so high in the first place."

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UVA Response

- Will review the letter and look forward to working with Senator Grassley to respond to his questions and share with him the policy changes we have announced and started implementing over the past month to better serve our patients

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So Where Does that Leave Us

- Important to comply with 501(r)(6)
- But that may not be enough
- Oversight of lawsuit/garnishment process by senior management
- Consider how it will look in newspaper
- Using collection agencies doesn't solve the problem
- Be prepared to defend reasonableness of bills, particularly to the uninsured

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What's the price of your Tisagenlecleucel Intravenous Suspension-all?

PRICE TRANSPARENCY IN HEALTH CARE

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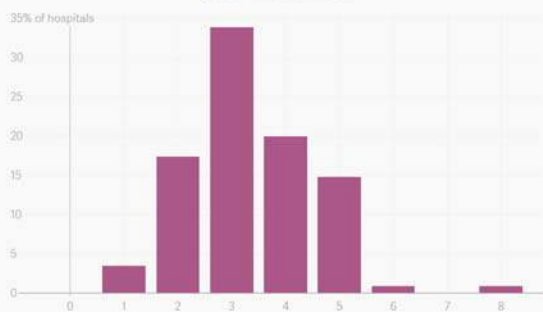
A Walk Down Memory Lane

- Provision in ACA added to Public Health Services Act requiring hospitals to post list of "standard charges"
 - Bringing Down the Cost of Health Care Coverage (§ 2718 of PHS Act)
- Obama Administration: List publicly available upon request
- Trump Administration: Publish your chargemasters online!
- Executive Order (June 2019)
- Another proposed rule July 2019

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Number of clicks to get from hospital home page to price-list data



Yale New Haven Hospital

Item C#	Item Description	Item Price	Effective Date
63000002	TISAGENLEUCEL INTRAVENOUS SUSPENSION-ALL	\$ 2,375,000.00	1-Sep-19
63000002	AKICARTAGENE CILIOFUCEL (YESCARTA) - DIBCL INFUSION	\$ 1,865,000.00	1-Sep-19
63000002	TISAGENLEUCEL INTRAVENOUS SUSPENSION-DIBCL	\$ 1,865,000.00	1-Sep-19
25000005	ROTHUSOLAM HEMINE GLOBULIN (BARRING) (50 MG/ML) IV (NEONBORN/PEDIATRIC)	\$ 275,800.00	1-Sep-19
27800003	HEARTMATE LVAD IMPLANT KIT	\$ 256,856.55	1-Sep-19
27800003	HEARTMATE LVAD IMPLANT KIT	\$ 256,856.55	1-Sep-19
27800003	HEARTMATE LVAD IMPLANT KIT	\$ 256,856.55	1-Sep-19
27800003	HEARTMATE LVAD IMPLANT KIT	\$ 256,856.55	1-Sep-19
27800003	HEARTMATE LVAD IMPLANT KIT	\$ 256,856.55	1-Sep-19
27800003	DEVICE HEARTMATE LVAD	\$ 231,875.00	1-Sep-19
27800003	DEVICE HEARTMATE LVAD	\$ 231,875.00	1-Sep-19
27800003	DEVICE HEARTMATE LVAD	\$ 231,875.00	1-Sep-19
27800003	HEARTMATE VENT PUMP CONTROL SM	\$ 231,875.00	1-Sep-19
27800003	HEARTMATE VENT PUMP CONTROL SM	\$ 231,875.00	1-Sep-19
27800003	HEARTMATE VENT PUMP CONTROL SM	\$ 231,875.00	1-Sep-19
27800003	HEARTMATE PUMP/POCKET CONTROL	\$ 200,737.50	1-Sep-19
27800003	HEARTMATE PUMP/POCKET CONTROL	\$ 200,737.50	1-Sep-19
27800003	HEARTMATE PUMP/POCKET CONTROL	\$ 200,737.50	1-Sep-19

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Mount Sinai

	A	B
1	As of January 2019	
2	MULTIVISCERAL ORGAN TRANSPLAN	\$266,363.00
3	SYNCRDIA HEART IMPLANT	\$244,939.00
4	HEARTWARE HVAD IMPLANT KIT	\$226,029.00
5	IMPLANT KIT HEARTMATE II VAD	\$223,769.00
6	LVAS HEARTMATEIII G140113	\$201,998.00
7	CORD BLOOD ACQUISITION CHARGE	\$168,000.00
8	ALLOGENIC BMT ACQUISITION-803	\$166,000.00
9	SMALL BOWEL	\$101,891.00
10	LIVER ACQUISITION CADAVER	\$89,592.00
11	LIVER ACQISTN LIVING DONOR	\$89,592.00
12	OPERATING ROOM - 24 HOURS	\$88,600.00
13	IPG NEURO 1.34CM PROCLAIM DRG	\$87,630.00
14	HEART ACQUISITION	\$86,592.00
15	CAD BENTON/CAD BENTON 1.00L 60ML	\$75,430.00

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Barnes-Jewish Hospital

Barnes-Jewish Hospital

Code	Description	Charge Amount
101717	SUPPLS	\$55,907.00
101718	SUPPLS	\$55,907.00
101719	SUPPLS	\$55,907.00
101720	SUPPLS	\$55,907.00
101721	SUPPLS	\$55,907.00
101722	SUPPLS	\$55,907.00
101723	SUPPLS	\$55,907.00
101724	SUPPLS	\$55,907.00
101725	SUPPLS	\$55,907.00
101726	SUPPLS	\$55,907.00
101727	SUPPLS	\$55,907.00
101728	SUPPLS	\$55,907.00
101729	SUPPLS	\$55,907.00
101730	SUPPLS	\$55,907.00
101731	SUPPLS	\$55,907.00
101732	SUPPLS	\$55,907.00
101733	SUPPLS	\$55,907.00
101734	SUPPLS	\$55,907.00
101735	SUPPLS	\$55,907.00
101736	SUPPLS	\$55,907.00
101737	SUPPLS	\$55,907.00
101738	SUPPLS	\$55,907.00
101739	SUPPLS	\$55,907.00
101740	SUPPLS	\$55,907.00

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Executive Order

- Section 3 titled "Informing Patients About Actual Prices"
- Directive to DHHS to draft new regulation for hospitals to post prices in a patient-friendly format
- Standard charges and negotiated rates



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Source: <https://www.npr.org/sections/health-shots/2019/06/24/735432387/trump-administration-pushes-to-make-health-care-pricing-more-transparent/#targetText=President%20Trump%20signed%20an%20executive%20order%20to%20div%20down%20cost,Photo%20Credit%20to%20Carolyn%20Kistner/AP>

CMS Proposed Rule

- By January 1, 2020, all hospitals post standard charges and negotiated rates with insurers
- Negotiated rates for 300 "shoppable" services
 - 70 selected by CMS; 230 selected by provider
- Consumer-friendly format
- Publicly available website & updated annually
- Civil Monetary Penalties for noncompliance & appeals process

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Industry Response

- Nearly 4,000 industry comments
- AHA, AAMC, AHIP
- AHA's 66-page letter is roadmap of its likely litigation strategy
 - Law uses the term "standard charges"
 - Negotiated rates are trade secrets
 - CMS lacks authority to penalize hospitals
 - Constitutional issues
- File size & whether all information can be "user-friendly" format

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Final Rule

- Released November 15, 2019
- Delayed implementation until January 1, 2021
- Applies to all hospitals
- Defines "standard charges" as:
 - Gross charge (chargemaster)
 - Payer-specific negotiated charge
 - De-identified minimum negotiated charge
 - De-identified maximum negotiated charge
 - Discounted cash price (if none, can be gross charges)

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Final Rule

- Machine readable format
- 300 “shoppable services” in consumer-friendly format
 - 70 picked by CMS/230 selected by hospital
- Penalties for noncompliance
 - Written warning
 - Corrective action plan
 - Civil penalty of up to \$300 per day

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TABLE 2—SAMPLE OF DISPLAY OF SHOPPABLE SERVICES

Hospital XYZ Medical Center			
Prices Posted and Effective [month/day/year]			
Notes: [insert any clarifying notes or disclaimers]			
Shoppable Service	Primary Service and Ancillary Services	CPT/ HCPCS Code	[Standard Charge for Plan X]
Colonoscopy	primary diagnostic procedure	45378	\$750
	anesthesia (medication only)	[code(s)]	\$122
	physician services	Not provided by hospital (may be billed separately)	
	pathology/interpretation of results	Not provided by hospital (may be billed separately)	
	facility fee	[code(s)]	\$500
Office Visit	New patient outpatient visit, 30 min	99203	\$54
Vaginal Delivery	primary procedure	59400	[\$]
	hospital services	[code(s)]	[\$]
	physician services	Not provided by hospital (may be billed separately)	
	general anesthesia	Not provided by hospital (may be billed separately)	
	pain control	Not provided by hospital (may be billed separately)	
	two day hospital stay	[code(s)]	[\$]
	monitoring after delivery	[code(s)]	[\$]

TABLE 3—SAMPLE OF DISPLAY OF SHOPPABLE SERVICES

Evaluation & Management Services	2020 CPT/HCPCS Primary Code
Psychotherapy, 30 min	90832
Psychotherapy, 45 min	90834
Psychotherapy, 60 min	90837
Family psychotherapy, not including patient, 50 min	90846
Family psychotherapy, including patient, 50 min	90847
Group psychotherapy	90853
New patient office or other outpatient visit, typically 30 min	99203
New patient office or other outpatient visit, typically 45 min	99204
New patient office or other outpatient visit, typically 60 min	99205
Patient office consultation, typically 40 min	99243
Patient office consultation, typically 60 min	99244
Initial new patient preventive medicine evaluation (18-39 years)	99385
Initial new patient preventive medicine evaluation (40-64 years)	99386

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Laboratory & Pathology Services	2020 CPT/HCPCS Primary Code
Basic metabolic panel	80048
Blood test, comprehensive group of blood chemicals	80053
Obstetric blood test panel	80055
Blood test, lipids (cholesterol and triglycerides)	80061
Kidney function panel test	80069
Liver function blood test panel	80076
Manual urinalysis test with examination using microscope	81000 or 81001
Automated urinalysis test	81002 or 81003
PSA (prostate specific antigen)	84153-84154
Blood test, thyroid stimulating hormone (TSH)	84443
Complete blood cell count, with differential white blood cells, automated	85025
Complete blood count, automated	85027
Blood test, clotting time	85610

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Anticipated Outcomes

- Lawsuit will be filed once rule goes into effect on January 1, 2021
- Several commenters focused on term "standard charges" in law (42 USC 300gg-18)
 - Standard charges ≠ negotiated rates
- CMS proposal is operationally challenging
 - Negotiated rates with each payor * number of plans offered by payor * all items and services = large spreadsheet

Is Price Transparency a Good Idea?

- Consumer interest is (comically) low
 - *Castlight* (California); *HealthCost* (New Hampshire); *Wear the Cost* (Maryland)
- Antitrust issues with revealing negotiated prices
- Upward or downward pressure on health care prices? Conflicting arguments
- Figures vary, but 30-40% of health care services are not "shoppable"

"Hello, we'd like to offer you a great new rate for your service."

REFERENCE-BASED PRICING

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Referenced-Based Pricing An Update

- A health care cost containment model that limits what a group plan pays for certain services based on an external reference (e.g., multiple of Medicare)
- Proactive model—patient or plan identifies providers who will accept the spending limit as full payment, and patients seek care at such facilities; no formal contract with hospital

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Reference-Based Pricing An Update

- Passive Model—Patient shows up with ID card, receives services, hospital paid a fraction of its bill; plan tells patient not to pay the balance
- Some apply a *quantum meruit* approach rather than a multiplier
- Bottom line: Plan dictates what is fair pricing for healthcare services, without any negotiation with providers

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Pitch to Plans

- Pitch:
 - Employers save money
 - Employees don't have narrow networks
 - If they take us to court, we'll defend based on what's fair and reasonable payment

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Hospital Responses

- Recognize when self-funded plan and RBP is involved
- Watch for small print on ID cards and EOB's
- Explain and confirm patients obligation to pay difference
- Require deposits or other advance arrangements
- Balance bill
- Refuse access to further services
- Litigation
- Challenge fiduciary duties of plan to members

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ARTIFICIAL INTELLIGENCE IN HEALTH CARE: OBSERVATIONS FROM A REGULATORY PERSPECTIVE

Michael W. Chase

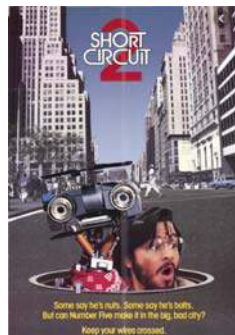
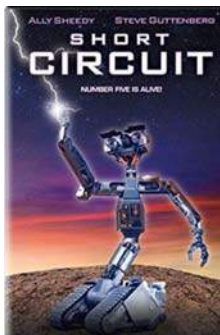
Sean T. Nakamoto


Artificial Intelligence in Health Care: Observations from a Regulatory Perspective

Michael W. Chase
Sean T. Nakamoto

When You Think of A.I.
What Comes to Mind?








Man falls in love with A.I.

Man marries hologram virtual assistant Hatsune Miku



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Artificial Intelligence & Health Care

<https://www.youtube.com/watch?v=H0etieBDxeY>



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Topics for Discussion

- What is Artificial Intelligence?
- What is A.I. used for? What are the benefits?
- Legal and regulatory issues
- Practical considerations

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artificial intelligence

noun

Definition of *artificial intelligence*

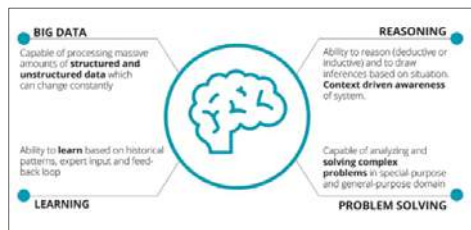
- 1 : a branch of computer science dealing with the simulation of intelligent behavior in computers
- 2 : the capability of a machine to imitate intelligent human behavior

<https://www.merriam-webster.com/dictionary/dictionary>

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What is Artificial Intelligence?

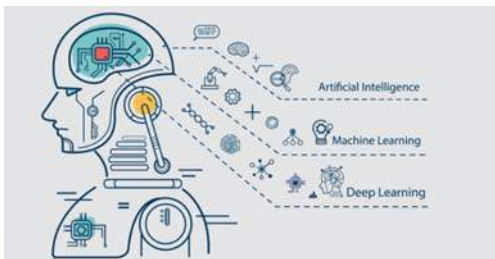


<https://www2.deloitte.com/se/sv/pages/technology/articles/part1-artificial-intelligence-defined.html>

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To Put It Another Way...



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American Medical Association House of Delegates

- "Augmented" Intelligence
 - A conceptualization of artificial intelligence that focuses on A.I.'s assistive role, emphasizing that its design enhances human intelligence rather than replaces it.

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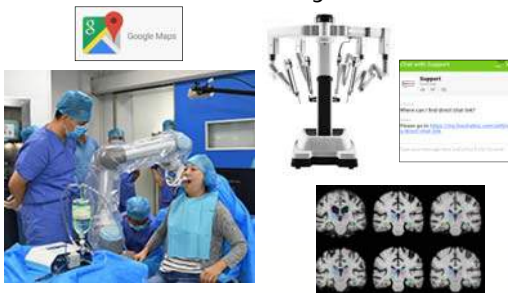
No Really – What Is It?

- A.I. uses data – a *LOT* of data – to drive predictive analytics, clinical and non-clinical functions, and precision medicine, among other things
- And we know health care has DATA galore

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A.I. – It's Already Here



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A.I. in Health Care

- Recent survey: 75% of health care organizations are actively implementing or planning for A.I.
- 43% say the first area of focus will be business processes

<https://www.hfma.org/topics/hfrn/2019/september/4-strategies-for-ai-driven-approach-to-improve-revenue-cycle.html>

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Imagine the Possibilities (or realities)

- Clinical decision making
- Diagnoses and reduced errors
- Finance/revenue cycle management
- Detecting high risk patients
- Identifying and filling workforce gaps
- Cybersecurity
- Education/workforce development

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Imagine the Possibilities (or realities)

- Population and public health
- Personalized treatment plans
- Point of care learning
- Patient engagement/improved experience
- Research (drug development)
- Quality reporting
- Enhanced clinical documentation

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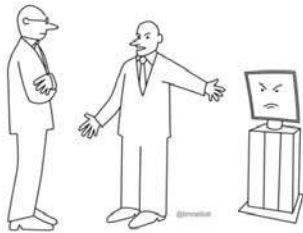
CMS A.I. Health Outcomes Challenge

- Objectives
 - Use A.I./deep learning methods to predict unplanned hospital and SNF admissions and adverse events within 30 days based on a set of Medicare administrative claims data
- \$1M prize
- 25 Participants Announced on Oct. 30 2019 including:
 - IBM
 - Mayo Clinic
 - Deloitte Consulting LLP

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So What's the Benefit?



*His decisions aren't any better than yours
— but they're WAY faster...*

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So What's the Benefit?

- AMA Quadruple Aim:
 - (1) Enhance the patient experience of care and outcomes
 - (2) Improve population health
 - (3) Reduce overall costs for the health care system while increasing value
 - (4) Support the professional satisfaction of physicians and the health care team

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Legal Issues

- Patient Rights, Informed Consent, and Transparency
 - Right to be informed of treatment
 - Right to care consistent with sound medical and nursing practices (competent care)
 - Right to privacy and confidentiality
 - Right not to be discriminated against (but what about the bias that is implicit in A.I.?)

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Legal Issues

- Data Privacy and Security
 - A.I. involves a massive amount of data
 - Does not reconcile with longstanding data protection principles
 - Collection limitation
 - Purpose specification
 - Use limitation
 - Fairness principle

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Legal Issues


- Data Privacy and Security
 - A.I. systems have no concept of data privacy or limitations unless that concepts are implemented in advance
 - Who owns the data generated?
 - Does the developer have rights to use and process the data collected?
 - Will the developer create derivative works using the data, and re-disclose it?

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Legal Issues



- HIPAA Compliance
 - Who has access to the data/PHI? For what reason? How is the PHI flowing?
 - Analyze the covered entity/business associate relationship
 - What will A.I. do with the data/PHI?
 - De-identification by the Covered Entity?
 - De-identification by the developer?
 - Then what? Will it be used to develop more A.I.?



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Legal Issues










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Legal Issues



- Cloud-based infrastructure
 - Co-mingling of data?
 - Accounting for use of data in an A.I. cloud
 - Amending and Right to be Forgotten?
 - Controls?
 - Privacy, security, use, disclosure, etc.



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Legal Issues



- Liability
 - Who is responsible for what happens with the data?
 - Data breach
 - Incorrect application of the data (botched robotic surgery; incorrect diagnosis)
 - Do you try to allocate liability?
 - Indemnification
 - Limitations of liability
 - Insurance requirements

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Legal Issues




- State Boards and Licensing Bodies
 - Few inroads into A.I.
 - How can physicians and practitioners use A.I. and what are the limitations based on their licensure?
 - Illinois example: IL Medical Practice Act prohibits "making a false or misleading statement regarding skill or *the efficacy or value of the medicine, treatment, or remedy prescribed*...at their direction in the treatment of any disease or other condition of the body or mind."


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Legal Issues



- FDA and regulatory approval
 - Seek (and maybe obtain) approval for an algorithm that will help a patient
 - That algorithm learns from more data
 - Is updated approval needed?
 - The current regulatory approval cycle probably is not set up to address the A.I. environment
 - FDA is considering a new framework

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Practical Considerations

- A.I. is a constantly moving target
- Think through the arrangement on the front-end
 - To whom is the A.I. vendor providing services?
 - Is the A.I. ingesting PHI/PII?
 - What activities and services are being performed?

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Practical Considerations

- In the clinical context, providers using A.I. should be:
 - Informed and understand the role and risks
 - Competent to use A.I.
 - Able to communicate clearly and effectively about the role of A.I., the role of the provider, and the risks/benefits

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Practical Considerations

- Clear and transparent documentation and informed consent in patient care settings
- Contracting with A.I. vendors
- Updating medical staff policies and rules and regulations for use of A.I.
- Ethical considerations

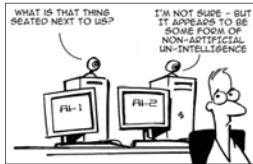
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