

#### Michael W. Chase

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November 16, 2018

WELCOME!

Thank you for joining us for the 30th 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

Providing Exceptional Legal Service Since 1873

- 7:30 8:15 a.m. | Registration and Continental Breakfast
- 8:15 8:30 a.m. Welcome

Michael W. Chase

### 8:30 – 9:15 a.m. There's An App For That – So Now What? Exploring The Latest Trends in Telehealth (and, of course, the legal implications!)

The iPhone is now 11 years old and technology has rapidly evolved. Has health care really caught up with the technology trends? Federal initiatives including Promoting Interoperability (formerly, Meaningful Use) and MACRA have helped fuel the adoption of different forms of telehealth technology. Yet, the predominant model remains acute care "hub and spoke" telemedicine, and many organizations struggle with implementing new platforms such as virtual visits and remote patient monitoring. Some of the hurdles include lack of reimbursement, liability/malpractice concerns, and provider compensation models. This session will highlight new telehealth delivery models (for example, virtual visits) and will explore legal issues including Federal, State, and commercial reimbursement; relationships with independent physicians and community organizations; and compensation issues.

Barbara E. Person Michael W. Chase

#### 9:15 – 10:00 a.m. Emerging Payment Issues – A Panel Discussion

There are a number of new and emerging payment arrangements that providers are seeing–each with their own unique set of legal issues. These include plans using reference-based pricing for their network of non-contracted providers, the direct primary care agreement practice model, and voluntary cost-sharing ministry plans. All have the potential to reduce payment to providers or result in unpaid bills from a payor. We will discuss these payment arrangements and the legal issues they present along with potential responses for providers in dealing with such arrangements.

John R. Holdenried Thomas S. Dean Steven D. Davidson

#### 10:00 – 10:15 a.m. Break

#### 10:15 – 11:15 a.m. Anatomy of a Qui Tam Case

Baird Holm is excited to host Marc Krickbaum and David Faith, as guest speakers for a panel program discussing the current climate of health care enforcement actions, specifically False Claims Act enforcement activity. Marc Krickbaum is the United States Attorney for the Southern District of Iowa, and David Faith is an Assistant U.S. Attorney in the Southern District of Iowa where he is the designated Affirmative Civil Enforcement (ACE) Attorney responsible for all the district's healthcare fraud matters. The panel will discuss an array of topics, including interactions and coordination among DOJ and other agencies with health care enforcement authority, the qui tam process, and recent enforcement activity in the Midwest.

Andrew D. Kloeckner Marc Krickbaum, U.S. Attorney, Southern District of Iowa David Faith, Assistant U.S. Attorney for the Southern District of Iowa

#### 11:15 a.m. – 12:00 p.m. CMS Initiatives to Reduce Regulatory Burden: Next Stop, the Twilight Zone?

You may remember the opening narration from The Twilight Zone series – "you are traveling through another dimension ... a journey into a wondrous land of imagination ... next stop, the Twilight Zone!" The CMS initiatives to reduce regulatory burden on providers feel like they would fit right in as an episode of The Twilight Zone. Join Kim Lammers and Zach Buxton for a review of the key initiatives for providers, including the proposed changes to E&M coding, the requests for comments and Congressional testimony from providers on what's wrong with the Stark Law and the Antikickback Statute in today's health care environment, and CMS's initiatives relating to "Patients Over Paperwork."

Zachary J. Buxton Kimberly A. Lammers

#### 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 issues, information privacy and security updates, employee benefits issues, 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. Eight Insights About Conducting Internal Investigations

Internal investigations are conducted for a wide variety of reasons, including health care and employment regulatory compliance. Whatever the reason, there are common practices that contribute to a solid investigation beginning with proper pre-investigation planning, selection of the investigator and consultants, standards for review, interim corrective action, planning for interviews and more. Julie Knutson and Scott S. Moore will provide critical insights about competent internal investigations and comment on important differences between a health care regulatory investigation and an investigation based on an employment issue.

Julie A. Knutson Scott S. Moore

#### 3:00 – 3:45 p.m. A Collection of HIPAA Hot Topics

You asked and we answered: More HIPAA! In this session, Vickie, Abby and Sean will lead you through a myriad of HIPAA privacy and security hot topics, ranging from cloud-based technology issues such as handling breaches by cloud vendors, cautionary notes for adopting hot-off-the-press technology, recent privacy and security missteps of note, and understanding that the bad guys are after you (including a brief visit to the dark web). You won't want to miss it.

Vickie B. Ahlers Abigail T. Mohs Sean T. Nakamoto





### **COMMONLY USED ACRONYMS**

ACRONYM	TERM
ACA	Patient Protection and Affordable Care Act
ACO	Accountable Care Organization
AHIA	Association of Healthcare Internal Auditors
AHLA	American Health Lawyers Association
AKS	Anti-Kickback Statute
ALJ	Administrative Law Judge
	Alternative Payment Models
	Amublatory Surgical Center
	Blood Alcohol Tests
	Critical Access Hospital
	Consolidated Data Analysis Center
	Corporate Integrity Agreement
	Centers for Medicare & Medicaid Services
	Civil Monetary Penalties
	Conditions of Participation
	Directors and Officers Liability Insurance
	Department of Health and Human Services
	Durable Medical Equipment
	Department of Justice
	Emergency Department
	Employer Information Report EEO-1
EMC	Emergency Medical Condition
	Emergency Medical Treatment and Active Labor Act
	False Claims Act
	Fee-for-Service
	Fair Labor Standards Act
	Fair Market Value
	Focused Professional Practice Evaluation
	Health Care Compliance Association
	Health Insurance Portability and Accountability Act Iowa Administrative Code
-	Immediate Care Facility
	Medicare Adminstrative Contractor
	Medicare Access and CHIP Reauthorization Act
	Medicaid Fraud Control Unit
MIPS	Merit-Based Incentive Payment System
	Medicare Shared Savings Program
	Nebraska Administrative Code
	National Labor Relations Board
	National Practitioner Data Bank
	Office of Inspector General
	Occupational Safety & Health Administration
	Protected Health Information
	Physician Quality Reporting System
	Resource Utilization Groups
	Skilled Nursing Facility
	Physician Self-referral Law
TCPA	Telephone Consumer Protection Act
	the famore Consideration in Ant

**UCA** Uniform Credentialing Act



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

## BAIRDHOLM

ATTORNEYS AT LAW

### Vickie B. Ahlers | Partner

**Tel: 402.636.8230** Fax: 402.344.0588 vahlers@bairdholm.com

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*<sup>\*</sup> in the field of Health Care Law, and was named *Best Lawyers*' Omaha Healthcare Lawyer of the Year for 2013.

#### **Selected Practice Highlights**

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

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

#### **Professional & Civic Affiliations**

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



Vickie B. Ahlers Tel: 402.636.8230 Fax: 402.344.0588 vahlers@bairdholm.com



#### 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

## BAIRDHOLM

ATTORNEYS AT LAW

### Zachary J. Buxton | Associate

**Tel: 402.636.8239** Fax: 402.344.0588 *zbuxton@bairdholm.com* 

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.

- 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)



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

## BAIRDHOLM

ATTORNEYS AT LAW

## Michael W. Chase | Partner

**Tel: 402.636.8326** Fax: 402.344.0588 mchase@bairdholm.com

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.

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



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

## BAIRDHOLM

ATTORNEYS AT LAW

## Alex M. (Kelly) Clarke | Attorney

**Tel: 402.636.8204** Fax: 402.344.0588 *aclarke@bairdholm.com* 

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

- 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

#### **Selected Recent Publications**

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



Alex M. (Kelly) Clarke Tel: 402.636.8204 Fax: 402.344.0588 aclarke@bairdholm.com



#### **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

## BAIRDHOLM

ATTORNEYS AT LAW

### Steven D. Davidson | Partner

**Tel: 402.636.8227** Fax: 402.344.0588 *sdavidson@bairdholm.com* 

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* (© 2013) and *Chambers USA, America's Leading Lawyers for Business* (© 2013).

#### 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

- 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



Steven D. Davidson Tel: 402.636.8227 Fax: 402.344.0588 sdavidson@bairdholm.com



#### Education

University of Virginia School of Law, J.D., 1994

St. John's Seminary College of Liberal Arts, B.A., Philosophy, summa cum laude, 1989

#### **Bar & Court Admissions**

Nebraska, 2017 Iowa, 2017 New Mexico, 2009 Maine, 2002 New York, 1995

## BAIRDHOLM

ATTORNEYS AT LAW

### Thomas S. Dean | Attorney

**Tel: 402.636.8267** Fax: 402.344.0588 tdean@bairdholm.com

Thomas S. Dean provides clients with a full range of health law services, including mergers and acquisitions between healthcare providers, physician recruitment and compensation design, regulatory advice including Medicaid regulations, Stark Law and Anti-Kickback Statute issues, compliance with Medicare Conditions of Participation, and HIPAA Privacy Rule Issues. He has significant experience with medical staff issues, such as bylaws re-design, merging of medical staffs, peer review, and credentialing issues. Tom also has broad experience in reimbursement and audit issues.

Prior to joining the firm, Tom spent ten years as general counsel to integrated healthcare systems. He held an additional position as Director of Patient Financial Services for several years, focusing on compliant billing and efficient management of the revenue cycle for both hospital and physician groups. Tom has also served as Chief Administrative Officer of a multi-specialty physician group that included eight clinics.

Tom has been a member of the American Health Lawyers Association since 2006, acting as the Assistant Chair of the Physician In-House Counsel Affinity Group. He has held the position of Chair of the Health Law Section of the State Bar of New Mexico. Tom received his law degree from the University of Virginia School of Law.



#### 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

## BAIRDHOLM

ATTORNEYS AT LAW

### John R. Holdenried | Partner

**Tel: 402.636.8201** Fax: 402.344.0588 *jholdenried@bairdholm.com* 

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

- 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)



John R. Holdenried Tel: 402.636.8201 Fax: 402.344.0588 jholdenried@bairdholm.com



#### 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

## BAIRDHOLM

ATTORNEYS AT LAW

### Andrew D. Kloeckner | Partner

**Tel: 402.636.8222** Fax: 402.344.0588 *akloeckner@bairdholm.com* 

Andrew D. Kloeckner represents healthcare clients with respect to a variety of issues, including regulatory, compliance, reimbursement, transactional, contracting, and taxexemption 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

- 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



#### Education

Creighton University School of Law, I.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

## **BAIRDHOLM**<sup>LLP</sup>

ATTORNEYS AT LAW

### Julie A. Knutson | Partner

Tel: 402.636.8327 Fax: 402.344.0588 jknutson@bairdholm.com

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.

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



## BAIRDHOLM

ATTORNEYS AT LAW

### Morgan L. Kreiser | Associate

**Tel: 402.636.8206** Fax: 402.344.0588 *mkreiser@bairdholm.com* 

Morgan L. Kreiser practices in the area of employee benefits, ERISA, tax law, and public employer retirement systems. She 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.

Morgan received her Juris Doctor, *cum laude*, from Creighton University School of Law, where she served on the Creighton Law Review. There, she was also inducted into the National Order of the Barristers based on her outstanding participation and performance as a student advocate, and received a CALI Excellence for the Future award in State and Local Tax. She graduated from Central College with a Bachelor of Arts in Communication Studies.

#### **Professional & Civic Affiliations**

- The National Order of Barristers, 2017
- Creighton University School of Law's Young Alumni Association
- Pension Council of the Midlands
- Omaha Bar Association
- Nebraska State Bar Association
- American Bar Association

Areas of Practice Employee Benefits & ERISA

Labor & Employment Law

Taxation

#### Education

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

Central College, B.A., 2014

#### **Bar & Court Admissions**

Nebraska, 2017

Iowa, 2018



#### 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

## BAIRDHOLM

ATTORNEYS AT LAW

### Kimberly A. Lammers | Attorney

**Tel: 402.636.8219** Fax: 402.344.0588 *klammers@bairdholm.com* 

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*.

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



#### **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

## BAIRDHOLM

ATTORNEYS AT LAW

### Abigail T. Mohs | Associate

**Tel: 402.636.8296** Fax: 402.344.0588 *amohs@bairdholm.com* 

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.

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



#### **Areas of Practice**

Immigration International Services

Labor & Employment Law

#### Education

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

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

#### **Bar & Court Admissions**

Colorado, 1993

Iowa, 2004

Nebraska, 1992

South Dakota, 2013

Utah, 2013

United States Court of Appeals, Eighth Circuit

United States District Court, District of Colorado, 1993

United States District Court, District of Nebraska, 1992

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### Scott S. Moore | Partner

**Tel: 402.636.8315** Fax: 402.344.0588 *smoore@bairdholm.com* 

Scott S. Moore regularly represents employers in various industries with respect to labor relations and employment matters, including personnel policies and decisions, labor negotiations, preventive planning, immigration, workplace investigations, workplace safety, equal opportunity, and the defense of employment-related claims. He has represented employers on labor and employment matters throughout the United States. Scott received his Juris Doctor from the University of Nebraska College of Law, with high distinction in 1992.

Scott is one of the few employment lawyers regionally who is a Fellow of The College of Labor and Employment Lawyers, the premier peer-selected organization of labor and employment lawyers in North America. Admission is by invitation only, after a rigorous screening process.

Scott has been selected by his peers for inclusion in *The Best Lawyers in America*<sup>®</sup> in the fields of Employment Law, Immigration Law, and Labor Law and was named the *Best Lawyers*' 2018 Labor Law – Management "Lawyer of the Year" for Omaha. He has been listed in the *Great Plains Super Lawyers*, has been recognized as one of Nebraska's top employment defense lawyers in *Chambers USA*, and is "AV" rated by *Martindale-Hubbell*.

Scott is the founder of the Best Places to Work in Omaha and the award for the Best Places for the Advancement of Women.

Scott is the Council Chair of the Labor Relations Committee and serves on the Board of Directors for the Nebraska State Chamber of Commerce & Industry. He is a former Special Assistant Attorney General for the State of Nebraska, the former Chair of the Labor and Employment Section of the Nebraska State Bar Association, serves on the University of Nebraska College of Law Dean's Advisory Board.

#### **Selected Practice Highlights**

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

- Establishing work-related dispute resolution systems, including pre-dispute arbitration agreements
- Successfully defending against numerous wage and hour investigations by the Department of Labor, including multiple site/organization-wide wage and hour compliance audits
- Successfully defending numerous union organizing campaigns ranging from small shops to large multi-location facilities including campaigns by the Teamsters, UFCW, AFSME and SEIU
- Effectively litigating much watched NLRB matter regarding representation units in multi-location environment

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



Scott S. Moore **Tel: 402.636.8315** Fax: 402.344.0588 *smoore@bairdholm.com* 



#### **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

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### Sean T. Nakamoto | Associate

**Tel: 402.636.8247** Fax: 402.344.0588 *snakamoto@bairdholm.com* 

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.

- 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)



#### 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

## BAIRDHOLM

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### Barbara E. Person | Partner

**Tel: 402.636.8224** Fax: 402.344.0588 bperson@bairdholm.com

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

Barbara served as law clerk to the Honorable William C. Hastings, Judge, Nebraska Supreme Court from 1985-1986. She served as a Board member (1993-1999) and as President (1997-1998) of the Nebraska Chapter of the Healthcare Financial Management Association. Since 2001, Barbara has been selected by her peers for inclusion in *The Best Lawyers in America*<sup>\*</sup> in the field of Health Care Law and was named the *Best Lawyers*' 2019 Health Care Law "Lawyer of the Year" for Omaha. She 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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## **Guest Speakers**

### Mark Krickbaum

U.S. Attorney, Southern District of Iowa Marc Krickbaum is the United States Attorney for the Southern District of Iowa. From 2009 to 2017, he served as an Assistant United States Attorney in the criminal division in Des Moines, Iowa, and Chicago, Illinois. Before that, he was Counsel to the Deputy Attorney General in the United States Department of Justice. Marc graduated from the University of Iowa and Harvard Law School.

### David Faith

Assistant U.S. Attorney for the Southern District of Iowa David Faith is an Assistant U.S. Attorney in the Southern District of Iowa where he is the designated Affirmative Civil Enforcement (ACE) Attorney responsible for, inter alia, all the district's healthcare fraud matters. Mr. Faith previously worked for five years as a litigation Associate at Dorsey & Whitney LLP in Minneapolis and for four years at the Iowa Attorney General's Office advising and representing state agencies. He also serves as a Judge Advocate in the Army National Guard.

## There's An App For That – So Now What? Exploring The Latest Trends in Telehealth (and, of course, the legal implications!)

Barbara E. Person

Michael W. Chase



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## Telemedicine Growth65% of U.S. hospitals connect with patients

- and consulting practitioners through the use of video and other technology
- Almost every state Medicaid program has some form of coverage for telehealth services
- Private payers are embracing telehealth

Source: https://www.aha.org/factsheet/2018-04-12-fact-sheet-telehealth

Factors Contributing to Growth
Lack of clinicians
Aging population with increasing health care needs

- Lack of access to services for patients in rural areas and other underserved areas
- Desire of clinicians to practice in urban areas
- Improvements in technology

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#### How is Medicare Responding to Technology?

- Medicare telehealth payments
  - 2001: \$63,302
  - 2015: \$17,600,000
- Includes professional fee (distant site) and originating site fee (where beneficiary received services)

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#### Telehealth and Medicare Coverage

- 1. Patient must be in a qualifying <u>**rural**</u> area:
  - A county outside a MSA or
  - A rural Health Professional Shortage Area (HPSA)
  - Geographic areas (see map)
    - Automatic facility HPSAs: Rural Health Clinics (RHCs); Federally Qualified Health Centers (FQHCs); FQHC look-alikes; Indian Health Facilities; IHS and Tribal Hospitals; and Dual-funded community health centers/tribal clinics



















#### Telehealth and Medicare Coverage

- 2. At one of eight qualifying facilities ("originating sites") -Doctor's office -Hospital
  - -Hospi -CAH
  - -CAH -RHC
  - -Federally Qualified Health Center (FQHC)
  - -Hospital- or CAH-based dialysis facility
  - -Skilled Nursing Facility (SNF)
  - -Community Mental Health Center

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#### Telehealth and Medicare Coverage

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- 3. Service provided by one of ten eligible professionals ("distant site practitioner")
  - -Physician -Clinical Nurse Specialist
  - -NP -CRNA
    - -Clinical Psychologist or Social Worker

-Dietitian or Nutritionist

-Nurse-Midwife

-PA

- 4. Technology is interactive two-way telecommunication system with real-time audio-video
- 5. Service is listed by CPT/HCPCS code as Medicarecovered



#### So ... Is Medicare Keeping Up with Technology?

"We [at CMS] have come to believe that section 1834(m) of the [Social Security] Act does not apply to all kinds of physicians' services whereby a medical professional interacts with a patient via remote communication technology. Instead, we believe that [it] applies to a discrete set of physicians' services that ordinarily involve, and are defined, coded, and paid for as if they were furnished during an in-person encounter between a patient and a health care professional"

2019 Proposed Physician Fee Schedule, 83 Fed. Reg. 35723

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#### MedPac 2018 Report

 Congress "should take a measured approach to further incorporating telehealth into Medicare by evaluating individual telehealth services to assess their capacity to address ... cost reduction, access expansion, and quality improvement"

MedPac Report to the Congress: Medicare Payment Policy, Ch. 16, http://www.medpac.gov/docs/default-source/reports/mar18\_medpac\_ch16\_sec.pdf?sfvrsn=0

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### Bipartisan Budget Act of 2018

- Dialysis/ESRD-related services
  - Includes dialysis facilities and <u>homes</u> as telehealth originating sites
  - <u>Only</u> for the purposes of the monthly ESRDrelated clinical assessments
  - No originating site facility fee is paid if the patient's home is the originating site

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#### Bipartisan Budget Act of 2018

- Acute Stroke-Related Services
  - Telehealth services for the "diagnosis, evaluation, or treatment of acute stroke"
  - Removes restrictions on geographic locations and types of originating sites
  - Can be furnished in any hospital, CAH, <u>mobile</u> <u>stroke unit</u>, or any other site determined appropriate by the Secretary

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#### CY 2019 Physician Fee Schedule Pre-Recorded Information

- CMS will make separate payments for physician use of recorded video and/or images captured by a patient to evaluate a patient's condition
- Not meant to replace an in-person service
- Not a Medicare "telehealth service"

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#### CY 2019 Physician Fee Schedule Pre-Recorded Information

- HCPCS Code G2010
  - Remote evaluation of recorded video and/or images submitted by the patient (e.g., store and forward), including interpretation with verbal follow-up with the patient within 24 business hours, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment
  - "Verbal follow-up" could take place via phone call, a/v communication, secure text, e-mail, or patient portal



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#### CY 2019 Physician Fee Schedule Pre-Recorded Information

- CMS views this as a stand-alone service
- Could be separately billed to the extent there is no resulting E/M visit (and no related E/M visit within the previous 7 days)
- CMS sought comments:
  - Limited to established patients only?
  - Appropriate for new patients (e.g., dermatology)?
  - Final rule: established patients only (existing clinicianpatient relationship)

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Pre-Recorded Information Legal Issues
<ul> <li>HIPAA privacy and security         <ul> <li>Transmission and storage of images to/from the health professional             <li>Communications between health professional and patient</li> </li></ul> </li> </ul>
<ul> <li>What if the provider doesn't have enough information to assess whether an office visit is warranted?</li> </ul>
<ul> <li>Follow-up to obtain better/sufficient images?</li> <li>Medical record documentation</li> <li>Must obtain patient's verbal or written consent</li> </ul>

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#### CY 2019 Physician Fee Schedule Virtual Check-In

What is it?

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- Brief communication technology-based service - To evaluate if an office visit (or other service is needed)
  - If the virtual visit results in an office visit, the remote check-in would be bundled w/visit
  - If no office visit after the virtual check-in, CMS proposes to pay for the virtual check-in (lower rate than E/M services)

  - Audio-only real-time telephone
    Two-way audio interactions enhanced with video

CY 2019 Physician Fee Schedule Virtual Check-In
<ul> <li>HCPCS Code G2012         <ul> <li>Brief communication technology-based service by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion</li> <li>Requires direct interaction between the patient and the billing practitioner</li> </ul> </li> </ul>
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#### CY 2019 Physician Fee Schedule Virtual Check-In

- If the communication originates from a related E/M visit within the previous 7 days, the virtual check-in is bundled in the previous E/M visit
- If the communication relates to a subsequent E/M visit within 24 hours or first available appointment, it is also bundled
- · Limited to established patients

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#### Virtual Check-In Legal Issues • What types of technology are needed?

- Audio-only? Telephone?
- Can a health care organization provide free technology to patients? (e.g., iPad, cell phone?)
   What about free or discounted equipment donated by an urban hospital to a rural facility re: specialty services?
- Use as part of Chronic Care Management Services? - Documentation of verbal consent in the medical record? - There is a check sheet of items to be covered for consent. •
- How to document medical necessity of the virtual check-in?

#### CY 2019 Physician Fee Schedule Peer-to-Peer Internet Consult

 Separately payable codes when a professional "requests the opinion and/or treatment advice of a consulting physician or qualified health care professional with specialty expertise to assist with the diagnosis and/or management of the patient's problem without the need for the patient's face-to-face contact with the consulting physician"

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#### CY 2019 Physician Fee Schedule Peer-to-Peer Internet Consult

- These types of consults were historically bundled into a separate patient visit with the consulting physician
- CMS notes "specialist input is often sought through scheduling a separate visit ... when a phone or internet-based interaction between the practitioner and the consulting provider would have been sufficient"

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## CY 2019 Physician Fee Schedule Peer-to-Peer Internet Consult • CPT Codes 99451, 99452, 99446, 99447, 99448, 99449

 Assessment and management services conducted through telephone, internet, or electronic health record consultations furnished when a patient's treating physician or other qualified healthcare professional requests the opinion and/or treatment advice of a consulting physician or qualified healthcare professional with specific specialty expertise to assist with the diagnosis and/or management of the patient's problem without the need for the patient's face-to-face contact with the consulting physician or qualified healthcare professional

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# The RUSH Act Reducing Unnecessary Senior Hospitalizations

Act of 2018
Seeks to avoid hospitalizations through financial incentives for providing certain nonsuraical

incentives for providing certain nonsurgical services furnished by EDs at SNFs that are qualified to provide such services

• Act specifically states that some services could be provided through the use of telehealth

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# Legal Issues (of Course!) Privacy/security State licensure Credentialing and privileging Commercial insurance laws

#### Legal Issues (of course!)

- Medicare enrollment
  - Each place where a telehealth physician is located must be enrolled as a practice location of the Group
  - Group completes Form CMS 855B
  - Indicates "Telemedicine Location" in Section 4A of Form CMS 855B.
  - Program Integrity Manual Ch. 15, sec 15.5.20.1

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# Questions?

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# 30TH ANNUAL BAIRD HOLM LLP HEALTH LAW FORUM

# Emerging Payment Issues A Panel Discussion

John R. Holdenried

Thomas S. Dean

Steven D. Davidson



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#### Emerging Payment Issues: Referenced-Based Reimbursement

Self-funded benefit plans are increasingly turning to reference-based reimbursement models ("RBR") to address rising employee health expense. Larger employers, labor unions, municipalities, and TPA's searching for a cheaper benefit solution to market to their clients, among others, are using RBR plans to gain a competitive advantage over PPO and standard insurance options.

RBR begins with the adoption of a health benefit plan that limits payment for some or all health services to a plan-determined, capped amount tied to an external pricing reference, typically Medicare. Used most frequently for services that carry a wide pricing variance among providers, but with normally uniform results (like knee or hip replacement), RBR plan provisions will limit the plan's payment obligation to a defined sum, often between 120% and 170% of Medicare reimbursement. Then, when the provider approaches the payer about the insufficient payment, the plan or its RBR consultant will oppose the provider's inquiry with a tenacious letter-writing campaign, resulting in a significant burden on provider financial services representatives. The patient is advised not to pay any balance billing, and the plan engages counsel to actively defend the patient from the provider's collection efforts, arguing that the billed charge is excessive and unreasonable. To avoid those burdens, providers will often agree to resolve the balance for a negotiated sum that is higher than the plan's initial payment, but often materially lower than the provider's negotiated rates with contracted payers. The RBR plan's cost-saving goals are then successfully realized.

RBR plans encourage covered participants to be purposefully involved in managing their own health care planning, by exploring provider options in advance to find a provider that will agree to accept the plan's defined payment for the procedure. Or, where there is a particularly important local provider that actively serves many of the plan's participants, the plan may approach that provider about a direct contract. However, in many cases those advance efforts are either not undertaken or are not successful, and providers unexpectedly see payments made by RBR plans at a significant reduction from billed charges. The RBR strategy is sometimes used even when the benefit plan has contracted with a PPO network, essentially ignoring the PPO's contracted rates when high dollar claims are at issue. RBR consultants then take as their compensation a percentage of the "savings" they achieve for the plan, building in an extra incentive to aggressively discount the payments they recommend.

Providers have multiple options for managing RBR payment disputes, and all require significant effort and attention. First, providers can, on behalf of the patient, appeal the plan's determination to the plan or its consultant. Notably, the appeal option is sometimes coupled with plan terms stating that if an appeal is pursued or if benefits are assigned to the provider, the provider waives its right to balance bill the patient. Those disclaimers are sometimes found in less than conspicuous places, like the back of an ID card or in small print at the bottom of an explanation of benefits form. If an appeal is taken, the plan will retain discretion to interpret and apply its terms, and the result of the appeal is a typically unfavorable denial of further benefits. While a lawsuit challenging the plan's determination on appeal is available, it will usually be governed by ERISA, which gives benefit plans many significant procedural advantages. The record before the court will be limited to the information already provided to the plan, which is often minimal, and the plan's decision can be reversed only for an abuse of discretion, a very difficult burden of proof.

Second, providers can file direct actions raising their own legal claims against the benefit plan and its consultants. While legal theories on this subject are still developing, providers can argue that implied contracts for reasonably reimbursement have been breached, that the plan and its consultants have improperly interfered with the relationship between provider and patient by, for example, advising the patient not to pay a valid balance bill, or that the plan and its consultant have been unjustly enriched. Through these and other legal theories, providers can impose upon RBR plans the same kinds of administrative burdens and legal risks that the RBR plans seek to impose on providers, hopefully changing the dynamics of the settlement conversation.

Finally, in those cases where a PPO network is not involved, providers can pursue collection of account balances from individual patients. While the RBR plan will typically provide a defense to those claims, patients do not like being the subject of a lawsuit, and will often complain loudly to their employer. That dynamic can create important leverage for the provider to successfully engage the benefit plan in negotiations to fairly resolve the outstanding invoice.

All of these options require time, effort, and potentially significant expense. The RBR business model counts on providers not having the willingness to incur those burdens, and either simply giving up and accepting the reduced payment, or accepting a settlement that still fulfills the goals of the RBR model. Providers need to be strategic about these issues, investing resources in those claims where the most productive outcomes can be achieved.

#### Health Care Sharing Ministries

As health insurance premiums rise, about a million Americans have become members of "health care sharing ministries." These ministries are intended to allow members to contribute to and receive contributions for medical expenses, providing some protection against unforeseen health care bills. While the ministries do not provide insurance, guarantee payment of a member's medical expenses, or assume the risk for a member's debt, they make some effort to assist members in need. And they offer membership at a cost far below insurance premiums.

The ministries' membership began to grow, from 160,000 individuals in 2014, because the Affordable Care Act permits persons to avoid the "individual mandate" to buy health insurance if they are members of a qualified ministry that satisfies the following requirements:

- The ministry is a tax-exempt public charity;
- Its members share a common set of ethical or religious beliefs, and share medical expenses among members in accordance with those beliefs and without regard to the State in which a member resides or works;
- Members retain membership even after they develop a medical condition;
- The entity or a predecessor has been in existence at all times since December 31, 1999, and its members have shared medical expenses without interruption since that date; and
- The ministry conducts an annual audit by an independent certified public accounting firm, and makes the audit results available to the public.

Thirty states, including Nebraska and Iowa, have passed legislation recognizing health care sharing ministries as exempt from State insurance laws.

Nebraska law provides for a health care sharing ministry to "[I]imit its participants to those who are of a similar faith." Each ministry must circulate "a written monthly statement to all participants that lists the total dollar amount of qualified needs submitted to the . . . ministry, as well as the amount actually published or assigned to participants for their contribution." All application and guideline materials are required to include a disclaimer that the ministry does not offer insurance, and that members are considered uninsured and are "always personally responsible for the payment of [their] own medical bills."

lowa's statute does not use the term "health care sharing ministry," but rather provides for certain "religious organizations" to be exempt from insurance regulation. Like Nebraska, Iowa limits participation to "subscribers who are members of the same denomination or religion." An exempt entity "through its publications to subscribers, solicits funds for the payment of medical expenses of other subscribers." It must register with the United States postal service and act as an "organizational clearinghouse for information between subscribers who have financial, physical or medical needs, and subscribers who choose to assist with those needs." Iowa does not require a specific disclaimer to members that the organization does not provide insurance.

The main advantage to membership in a ministry over purchasing insurance is that the cost may be as little as \$30 per member per month. This is considerably less than either the premiums for ACA-qualifying health insurance, or the penalty for violating the individual mandate. While the ministries are not obligated to pay for medical bills, the news reports about them generally report the benefits to members, including the payment of large medical bills.

The ministries apparently take aggressive positions when settling members' debts. For example, one article recounts a ministry that took charge of negotiating a member's payment for a large surgery. The initial bill was for more than \$100,000, and the ministry settled it at \$40,000, with no obligation from the member. We did not find news accounts of a ministry abandoning a member in need. These positive aspects of the ministries likely account for their sevenfold growth since 2014.

Ministries, however, have some unique requirements. Most ministries require church membership and regular attendance. Some require the application for membership to be co-signed by the applicant's pastor. Smoking and alcohol use are often banned. And because they are not insurers, ministries are not obligated to accept members with pre-existing conditions.

Almost all ministries are faith-based organizations, and the overwhelming majority identify as Christian. Gospel Light Mennonite Church Medical Aid Plan accepts Jewish and Muslim members. Trinity Healthcare requires only a non-sectarian statement of belief in God.

The promotional literature for plans tends to appeal to the members' shared faith, and play up the plan's religious affiliation. Slogans include "Healthcare savings you can believe in," and "The original biblical solution to healthcare costs." Despite Nebraska's requirement to include disclaimers on applications and guideline materials, we did not find advertisements that clearly state the plans have no legal obligation to pay for members' care.

A study by the Commonwealth Fund, a private foundation that promotes "a high-performing health care system," acknowledged that the ministries have benefited some members. It expressed concern, however, that some consumers can be confused by the ministries' marketing tactics, and may believe that they have bought insurance. It also pointed out that by screening out members with pre-existing conditions, ministries might negatively impact the efficiency of the marketplace for individual health insurance.

Health care providers can help prevent patient confusion about health care sharing ministries. Registration staff are in a position to identify ministry members and inform them that they are uninsured. Nebraska hospitals might also consider providing ministry members with the statutory language that should be included on all membership applications, setting out the members' personal obligations. In any case, a health care provider is within its rights to refuse to discount care based on ministry membership and to hold members personally responsible for the entire cost of care.

DOCS/2159826.1

#### **Direct Primary Care Arrangements**

Direct primary care arrangements (DPCAs) are generally membershipbased arrangements between physicians and patients covering a defined set of primary care and preventive health care services. There's typically a monthly fee for membership that provides a specified array of services from the provider to the patient.

There were concerns in some states that DPCAs constituted insurance and were thus subject to regulation by the state's department of insurance. Legislation was passed in Nebraska in 2016 (LB 817) to specifically authorize DPCAs and exempt them from insurance regulation. Iowa passed similar legislation in 2018 (HR 2356). Both laws provide a general framework for DPCAs but stop far short of a full regulatory scheme. Rather they provide the broad framework for such arrangements—certain provisions that the agreement must contain including the services covered and fees, provisions for termination, anti-discrimination, and required notice period for changes. They declare that a DPCA is not insurance and that it is not a plan that provides health coverage for purposes of federal mandates. DPCAs are specifically not subject to regulation by the Department of Insurance.

There are some differences between the laws of the two states. Nebraska limits Direct Providers to physicians and nurse practitioners who specialize or are board-certified in general practice, family medicine, internal medicine, or pediatrics. Iowa is broader and allows Direct Providers to include any individual health care professionals who are authorized to provide primary health care services.

Both states limit the scope of DPCAs to direct services. Nebraska specifically provides that a direct provider cannot pay for health care services rendered to patients by providers other than those in the same direct primary care practice or their employees. Iowa's language is less direct but refers to primary care services provided by the health care professional alone or with other health care professionals professionally associated with the health care professional. The direct charge or retainer fee is limited to primary health care services provided by the Direct Provider to the Direct Patient. Thus, a DPCA charge cannot cover services provided by other professionals or entities and cannot cover services that are not primary care health services regardless of who provides them. However, the definition of primary care health services is quite broad.

Both states require that the DPCA contain statutory language recommending that patients obtain health insurance to cover health care

services not covered under the DPCA and that they are personally responsible for payment of additional health care expenses they may incur.

Currently, DPCAs can vary widely and are marketed in varied ways. These include:

• Some are marketed to employers as an additional benefit to provide to employees on top of a high deductible health plan, on the premise that a DPCA will result in lower total costs.

• Some are marketed to employers as an alternative to health insurance, leaving employees with no coverage for costs not covered by the DPCA.

• Some are marketed to individuals as a concierge-type medical plan to supplement existing health care coverage.

• Some are marketed to individuals as alternatives to other health insurance, promoting that most services can be performed by a primary care physician and that the provider will help negotiate fee arrangements for services outside the DPCA.

There are some significant barriers to the success of DPCAs:

- One is their status with respect to HSA rules. Currently, the IRS position is that a person with a high deductible health plan cannot make HSA contributions if the person has a "second health plan" that covers the same services. The IRS maintains that a DPCA constitutes a second health plan and thus a person cannot make a tax-deductible contribution in a month in which he or she is covered under both a high deductible plan and a DPCA. A bill is currently pending before Congress (HR365/S1358) to change this and specifically DPCA fees to be paid from HSA funds.
- A second is their integration with health coverage. Direct primary care
  practices can continue to see Medicare beneficiaries only so long as the
  practice's retainer fee does not cover services already covered under
  Medicare. This is a very difficult process to maneuver. However, CMS
  recently issued an RFI seeking input on numerous issues related to "direct
  provider contracting", which it defined to include both primary care and
  multi-specialty practices, perhaps foretelling a DPCA opportunity in the
  future for Medicare beneficiaries.
- Providers who participate in managed care networks can face similar issues when they charge DPCA fees to patients when their contracts otherwise obligate them not to charge patients anything other than deductibles and co-pays for covered services.
- There are also significant questions concerning the financial viability of the model since the risk or providing all a patient's primary care needs falls on a single physician or group, without larger risk pools over which to share that risk.

While some physicians venture into DPCAs on their own, there are also national franchise operations that provide physicians with models and resources in exchange for a portion of the monthly fee.

DOCS/2160014.1



# Anatomy of a Qui Tam Case

Andrew D. Kloeckner

Marc Krickbaum, U.S. Attorney, Southern District of Iowa

> David Faith, Assistant U.S. Attorney, Southern District of Iowa



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## Common Types of FCA Cases

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- Statutory investigations (e.g. violations of Stark/AKS)
- · Coding investigations (e.g. upcoding)
- Improver services (e.g. unnecessary procedures/lack of documentation)

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# The "Brand" Memo Prohibits DOJ from using agency guidance as binding legal obligations Cannot create binding requirements that do not exist by statute or regulation May not use noncompliance with documents as basis for proving violations of applicable law. Failure to comply with guidance does not mean the party violated the underlying legal requirements. DOJ may continue to rely on agency documents for "proper" purposes (i.e., to explain or paraphrase existing statutes and regulations)



- CMS and MACs have a HUGE body of subregulatory guidance (does not go through the formal rule-making process)
- Different standards applied by different MACs

#### The "Granston" Memo

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- Under FCA, when a private individual (whistleblower) files suit, gov't can intervene (or decline)
- FCA allows gov't to dismiss the action notwithstanding the objections of the qui tam relator
  - Sparingly used; cases traditionally proceeded
  - Providers spend considerable resources defending claim
- Potential shift in how DOJ treats meritless FCA cases

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Yates Memo
<ul> <li>Guidance to be used by DOJ in any investigation of corporate misconduct <ul> <li>Hold <u>individuals</u> accountable for the illegal corporate conduct</li> <li>Individual could include administrators and Board members</li> <li>Settlement <u>does not release</u> any directors or officers</li> <li>Requires hospital to continue to cooperate in identifying and providing information about responsible individuals</li> </ul> </li> </ul>
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# Questions?

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# 30TH ANNUAL BAIRD HOLM LLP HEALTH LAW FORUM

# CMS Initiatives to Reduce Regulatory Burden: Next Stop, the Twilight Zone?

Zachary J. Buxton

Kimberly A. Lammers



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Regulatory Burden: Next Stop, the Twilight Zone?

> Zachary J. Buxton Kimberly A. Lammers



In this episode, you unlock this door with the key of imagination. Beyond it is another dimension—a dimension where CMS & OIG request your feedback on fraud and abuse laws to make your lives easier. Ladies and gentlemen, submitted for your approval:

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## General Industry Comments

- In mid-2017, CMS and OIG requested comments/information from industry stakeholders on general regulatory burden
- Received 3000+ responses on wide range of real (and perceived) barriers
- Opportunity to address barriers in transition to innovative health care delivery models based on value and quality; specifically, with fraud and abuse laws

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# Regulatory Sprint to Coordinated Care

- Eric Hargan, HHS Deputy Secretary
- Four priorities for HHS under HHS Secretary Alex Azar
  - Individual health insurance market
  - Prescription drugs
  - Opioid crisis
  - Value and outcomes over procedures and spending
- Testimony before House Ways & Means Committee, Subcommittee on Health (July 17, 2018)

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## Regulatory Sprint to Coordinated Care

"Our country's **thicket of health care regulations** has gotten in the way of each of these [four] goals in complicated ways, and HHS has committed itself to solving this problem."



Eric Hargan (R) Deputy Secretary, HHS

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#### Regulatory Sprint to Coordinated Care Stark Law based on fee-forservice model Stakeholders: Fraud and abuse

- Stakeholders: Fraud and abuse laws (i.e., Stark, AKS, CMP law) among most significant obstructions to new models of health care delivery
- Prevents physicians from participating in APMs or integrated delivery models



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#### Quick Refresher: Fraud and Abuse Laws

- False Claims Act (31 USC § 3729)
- Anti-Kickback Statute (42 USC § 1320a-7b(b))
- Stark Law (42 USC § 1395nn)
- Civil Monetary Penalties Law (42 USC § 1320a-7a)
- State law

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CMS/OIG Requests for Information (RFI)	
<ul> <li>CMS &amp; OIG release RFIs in June and August, 2018, respectively         <ul> <li>CMS: Stark Law (83 FR 29524)</li> <li>OIG: Anti-Kickback Statute (AKS) (83 FR 43607)</li> </ul> </li> </ul>	
<ul> <li>Essentially: What changes can we make to Stark &amp; AKS in order to realize goal of the triple aim (i.e., improved patient experience, improved health of populations, and lower costs)?</li> </ul>	
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#### Those Submitting Comments...

- American Hospital Association
- State hospital associations (Arizona, California, Iowa, Missouri, New Hampshire, New York, Ohio, South Carolina, West Virginia, Wisconsin) •
- Health systems (Northwestern Memorial HealthCare, Trinity Health, Vanderbilt University Medical Center, Cedar Sinai Health System, Henry Ford Health System)
- Several industry groups (ACOG, American College of Radiology, Association of American Medical • Colleges)

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Some individuals

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#### Comments on Stark

- New regulatory exceptions
  - Value-based initiatives
  - Data analytics software to achieve care coordination
  - Add protections for coordination among care team Reward for outcomes primarily facilitated from other members of the care team (i.e., social workers, dieticians,
- APNs) • Burden of compliance
  - AHA estimates ~\$20,000 per contract (includes FMV opinion)
  - Midwest health system estimates annual compliance costs at approximately \$4 million
     HSSR: Greater complexity, increased compliance costs

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#### Comments on Stark, cont. APMs or novel financial arrangements often abandoned due to Stark concerns Define common terms

- Commercial reasonableness, FMV, referral, signed by the parties, compensation arrangement
- Takeaway: Stark created for FFS world and requires updating for new innovative payment models

#### Comments on AKS & CMP

• Adopt new safe harbors

- Value-based arrangements

- Permit activities that address "social determinants of health"
- Rural health care
- Permit any item or service transferred for below FMV if based on financial need •
- Care coordination for all provider types - Hospital systems v. solo hospitals

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#### Comments on AKS & CMP, cont.

- · Increase "nominal value" annually for CMP - Currently: \$15/\$75
  - Texas Health Resources: Uber rides exceed \$15
- Cybersecurity
  - Interconnected providers share information & liability for security threats
  - Larger institutions connecting to smaller
- Safe harbor incorporating all Stark exceptions

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## Takeaways: Stark & AKS/CMP RFIs RFIs outside of formal rulemaking process; CMS/OIG do not have to act on comments

- Don't expect changes anytime soon - However, step in right direction
- Stark & AKS address fee-for-service fraud and . abuse issues
- Laws are real & perceived barriers to incentivizing value-based care models · Significant costs to compliance
- Fraud and abuse waivers good start, need to • expand





In this episode, you discover there is a fifth dimension beyond that which is known to mankind. It is the middle ground between light and shadow, between science and superstition.

In this dimension you are able to spend more time caring for patients and less time on paperwork.

Ladies and gentlemen, submitted for your approval . . .

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## **CMS** Regulations

 On average over the last 5 years, CMS has published 58 rules per year equating to 11,000 published pages



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#### CMS Administrator Selma Verma



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- Simplify our requirements
- Make them easier to understand
- Get rid of requirements we no longer need
- Seek input from stakeholders (focus groups)
- Challenge the way we have always done things

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#### Work Groups and Open Door Forums

- Various workgroups established and open forums being held
- Feedback being sought on how to simplify or reduce requirements
- One work group is the Provider Compliance Focus Group
  - Various provider types represented
  - Has met four times in 2018

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#### Provider Compliance Focus Group – January 2018

- Provider Documentation Manual
- Use of ESDI (Electronic Medical Documentation Interoperability)



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#### Provider Compliance Focus Group – April 2018

- Comparative Billing Reports; CBR201801 Opioids
- Prior Authorization Requirements



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#### Provider Compliance Focus Group – July 2018

- Medical Review
   Correspondence
- Targeted Probe and Educate Audits



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Provider Documentation Manual



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- One source for coverage/payment rules
- No looking among different manuals, bulletins, etc.
- Checklists for providers for self-audit
- Email to: providerdocumentationmanual@cms.hhs.gov

# Provider Documentation Manual

• First chapter released May 2018 on home use of oxygen

https://www.cms.gov/Resear ch-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Downloads/PDM-Home-Oxygen-Therapy-Manual-DRAFT.pdf



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- CPAP
- Non-emergency ambulance transport











#### **Payer Partners**



- BCBS Companies (Anthem, Cambia, HCSC, etc.)
- Other potential partners: Humana and Cigna

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#### Comparative Bill Reports



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- Educational tool that provides data on Medicare billing practices compared to peers and nationally
- Claims data from 7/1/16 through 6/30/17
- Providers who prescribed for 30 or more beneficiaries (excluding cancer and hospice) = 23,826 CBR recipients

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#### **Metrics**

- Prescribers significantly higher than peers in at • least 2 of the following metrics:
- Percent of beneficiaries prescribed opioids above 90 morphine equivalent dose for 3 months
- Average number of days prescribed per beneficiary
- Average charges per beneficiary
- Percentage of beneficiaries prescribed opioids by 4 or more prescribers

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require prior authorizations Model and demonstration programs

**Prior Authorizations** 

- Power mobility devices
- Non-emergent hyperbaric oxygen therapy
- Repetitive scheduled nonemergent ambulance transports

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 Addresses come from PECOS system



- Suggestion to allow "audit" address to be specified in PECOS for all audits and medical reviews
  - Also consider adding "attention to" line

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• Transition period until



- Can use either HCINs or MBIs

- Beginning 1/1/20, must use MBIs
  - With some limited exceptions (i.e., appeals)

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12/31/19



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# Next Steps?



- Ideas regarding changes?
- Ask your clinicians, case managers, HIM departments, and business office areas
- Think about survey deficiencies
- Consider things that don't add value
- Email to: ReducingProviderBurden@cms.hhs.gov BAIRDHOU

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# The Latest Word

Panel of Baird Holm Attorneys



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# Two Updates from the TCJA

John R. Holdenried

#### Tax Cut and Jobs Act Moving Expenses

- Moving expenses are now included in income of the recipient and no longer deductible by the employer
- Implications for physician/staff recruiting contracts

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# Tax Cut and Jobs Act Qualified Parking –UBIT?

- IRC 512(a)(7)—Qualified parking is now either:
   Taxable to the employee
  - Includable in UBIT of exempt employers
- So, there's a tax not on income but on an expense—How can that be?
- Lots of questions/uncertainties
- Watch for IRS regulations/notices

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### Bond Refinance Opportunities

- IRS guidance published October 26, 2018 broadens the scope of permissible advance refunding of tax-exempt bonds
- Except for certain federally subsidized bonds, bonds may be refinanced before maturity with new tax-advantaged debt





#### **Employee Benefits Update: Wellness Plans**

- Voluntariness
- Reasonable alternative standards
- FLSA requirements
- Income taxation of wellness program incentives
- ACA compliance

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### Employee Benefits Update: Misc.

• Eased restrictions on hardship withdrawals

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- Disability claims procedures
- Association health plans
- Proposal to increase employer and worker health insurance options

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#### Wounds of Violence Reporting • Nebraska • Amended Neb. Rev. Stat. 28-902 (effective July 19, 2018) • Expands definition of mandatory reporters to nclude midlevel providers and nurses • Sexual assault-specific reporting nuances • Sexual assault-specific reporting nuances • Demail • No change • Ar more expansive list of mandatory reporters

#### Nebraska Examination and Reporting Considerations

• Scope of practice

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- "We don't do that here"
- Counseling patients on reporting options
- Additional information requested by law enforcement

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# Labor, Employment and Immigration

- Arbitration/dispute resolution
- NLRB decisions/employee behavior
- Data privacy/biometrics
- Skilled worker visas

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• Workplace immigration enforcement

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# TTORNEYS AT LAW Posting Standard Hospital Charges Online

Zachary J. Buxton

### Background

- Affordable Care Act (ACA § 2718; codified at 42 • USC § 300gg-18)
- Rough outline (statutory language):
  - Applies to "[e]ach hospital operating within the U.S." Must make public a list of hospital's "standard charges" in accordance with guidelines established by Secretary of DHS
  - Applies to "items and services" provided by the hospital
- 2015 Guidance: Either make available to the public (1) list of standard charges, or (2) policies permitting access to standard charges BAIRDHOL

# Posting Standard Charges New requirements: Effective January 1, 2019 "Standard charges" is undefined Hospital's choice of how it will interpret Does not mean chargemaster Available on the internet in "machine readable" format (XML, CSV) Does not include PDFs Applies to all items and services Nebraska, Iowa, and South Dakota state Iaw Additional questions? CMS published helpful FAQs Google: CMS standard charges FAQ; should be the first link

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#### **OIG Audit Raises Concerns**

- OIG audit report was issued in September 2018 (OEI-09-16-00410)
- Audit was conducted due to "potential incentive" for plans to deny services and payment for services
- OIG noted "concerns" with MA plan denials and appeals

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### **OIG** Findings

- During 2014 2016, beneficiaries and providers appealed <u>only 1%</u> of plan denials
- During the same period, for appeals that were filed, plans overturned **75%** of their **own denials** (216,000 denials)
- In earlier audit in 2015, CMS cited **56%** of plans it audited for making inappropriate denials

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Updated National Practitioner Data Bank Guidebook

# Updated NPDB Guidebook

- Issued without prior notice or opportunity for input
- Guidance on interpretation of "investigation"
  - Agreement not to exercise privileges
  - Leave of absence
  - Reappointment review
  - Quality improvement plans
  - Requirement to operate with a qualified first assistant

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# Updated NPDB Guidebook

- Other notable items:
  - "Length of Restriction" section
  - Reporting a court-ordered change to a prior report
  - Private agreements between state agencies and providers
  - Impaired practitioners
  - Malpractice payment from sole shareholder P.C.







	Questions?	
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# Eight Insights About Conducting Internal Investigations

Julie A. Knutson

Scott S. Moore



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# It's Not Always How it Seems

- Avoid pre-conceived ideas about the nature of the issue, bad actors, scope of the problem
- Avoid stating interim conclusions about scope, fault, causation-stick to the facts
- Verify each aspect of fact and law

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#### Don't Make a Move Without a Plan

- Be willing to adjust and revise the plan
- When, how and how often to inform the Board
- Threshold decision: repayment or selfdisclosure? Critical deadlines

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#### Identify and Correct Immediate Issues

- Patient care quality issues
- Continuing adverse impact on employees
- People who may need to be suspended or other
- Protection of records; <u>all</u> records
- Suspension of billing

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#### Careful Selection of Investigator and Team

- Who should be the investigator?
- Legal counsel as investigator
- Structuring the team
- The challenges with complex investigations
- Interviews are not the first step; preparation is key-document review, legal research, initial audits

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#### Avoid Creating Additional Legal Issues

- Background checks
- Polygraphs
- Poorly thought out retrospective audits
- Prematurely contacting regulatory authorities

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# Unbridled Consultants

• Engage under privilege?

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• Define scope and standard of review; agree upon applicable legal authorities

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Necessity of Preparing a Good Record of the Investigation
Standard single record of interviews
Documents supporting facts
Experts' reports



- Minimize risk of retaliation
- Don't reward bad actors
- Make necessary reports required by law
- Care in reporting outcomes and corrective actions

# Questions?

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# A Collection of HIPAA Hot Topics

Vickie B. Ahlers

Abigail T. Mohs

Sean T. Nakamoto



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# ALJ Decision—Encryption

- "There's no requirement to encrypt" Encryption is an "Addressable" standard...Addressable does not equal optional
- While the regulations provide flexibility to covered entities on how to protect their ePHI, "the bottom • line is that whatever mechanisms an entity adopts must be effective"
  - MD Anderson identified the risk of the loss of PHI as early as 2006
  - It chose encryption as a security mechanism as early as 2008

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- Yet, it had not encrypted all of its devices in 2013



#### ALJ Decision—Unlawful Disclosure · Losing ePHI is an Unauthorized Disclosure

- "If Respondent had its way, if and other covered entities could literally cast ePHI to the winds and be immune from penalty so long as OCR fails to prove that someone else received and viewed that information" Research is not an excuse
- OCR can blame the victim
  - The manner of the disclosure (i.e. workforce members acting outside of Hospital policy and a thief stealing a laptop) does not matter
  - A covered entity is liable for its workforce member actions when acting within their scope of their duties
- "This case is about [MD Anderson's] failure to protect ePHI from disclosure BAIRDHOLM

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<ul> <li>Civil Monetary Penalty</li> <li>Upheld the proposed \$4,348,000 penalty</li> <li>Rebuked MD Anderson's arguments against the amount</li> <li>Penalty is a "fraction" of what could have been imposed when calculating each violation per person impacted</li> <li>"The reality is that the penalties imposed in this case are quite modest given the gravity of [MD Anderson's] noncompliance" (and their revenues – yes, the ALJ went there too)</li> </ul>
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#### Wearables

- Based on Fast Healthcare Interoperability Resources (FHIR): a standard for transferring and sharing electronic medical records
- · PHI is encrypted in motion and at rest
- PHI is not stored on Apple servers, only locally on the user's Apple device
- Beta version: Johns Hopkins Medicine, Cedars-Sinai, Cerner Health eClinic, and OhioHealth
- Near future: Apple will allow third-party developers to import PHI into their Apps

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#### Wearables

- Concerns
  - If HIPAA is triggered, Apple or third-party developers
  - If in Arks inggered, Apple of intra-pully developers become business associates?
     70% of Providers and 66% of Payers support providing wearables to patients at no cost or at a subsidized price as a part of their wellness and preventative medicine programs
  - How to discern the source of PHI (EHR, independent third-party, user)?
  - How do providers negotiate with these large technology companies that have no previous experience in the health care industry?
  - PHI = sensitive personal data = \$\$\$ on the Dark Web





# NIST Report

- "Considerations for Managing IoT Cybersecurity and Privacy Risks"
- Identified top 3 risks compared to conventional IT:
  - Unconventional interaction with the physical world
  - IoT access, management, and monitoring
  - Availability, efficiency, and effectiveness of privacy and cybersecurity controls

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# FDA Draft Guidance

- "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices" . .
- If finalized, the following will help providers with HIPAA compliance:
  - Cybersecurity Bill of Materials (CBOM): a list of software and hardware components that are or could be susceptible to cyber vulnerabilities
  - "Trustworthy device framework" based on NIST Cybersecurity Framework
  - Devices should be designed with the following in mind: detection and logging of security compromises: routine security and antivirus scanning; enables forensic capture through the creation and storage of security log files;
  - notify users upon detection of a security incident; and
     anticipate, validate, and deploy patches and updates through the product lifecycle.









# Media-Related Settlements 2016—New York Presbyterian Hospital

- paid \$2.2 Million
  2018—Three Boston Hospitals to pay
- 2018—Three Boston Hospitals to pay (collectively) \$999,000

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#### <u>Boston Globe</u> Article – January 12, 2015 The story continues...

The dean of one of America's top medical schools was stunned.

Jeffrey Flier, who presides over Harvard Medical School, had just finished reading a story about the televised death of a man in a New York emergency room, a death aired without the family's permission.

"How could this be allowed to happen?" the incredulous dean recently tweeted from @jflier.

Four minutes later came a reply tweet from Dr. Gerard Doherty, chief of surgery at Boston Medical Center. "The same group is filming a trauma series at your place (MGH) and ours (BMC) right now. On balance — good public education."

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### The Takeaways

- It doesn't matter if no one complained OCR is watching and reading
- Confidentiality Agreements and training do not fix an otherwise impermissible disclosure
- Authorizations must be obtained by the covered entity before access provided to the media

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 Is that ever feasible in this type of scenario? OCR clearly thinks – NO!

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# ...to help facilitate other HHS initiatives...

- Patients Over Paperwork—reducing the regulatory burden
- Care coordination and VBP
- Breach enforcement
- The Support for Patients and Communities Act

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#### Dark Web is based in anonymity

- Political Dissent
- Whistleblowing
- Espionage
- Journalism
- The Silk Road of Contraband

   Weapons
  - Drugs
  - Fraud
- Illicit ServicesHacking as a
- Service
- Child Pornography

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# Guided Tour of the Dark Web

- These screenshots were taken in August of 2018
- Please do not try and access the Dark Web if you do not know what you are doing
- Simply accessing the Dark Web submits your computer and data to risk
- Never purchase anything from the Dark Web...unless you want to be the newest cast member of Orange is the New Black







Item	Price (2017-2018)
SSN	\$.5 to \$1
Insurance ID	\$1
"Fullz" (Complete record: medical history, prescriptions, preferred pharmacy etc.)	\$60 to \$1000
Complete EHR database	\$500,000















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