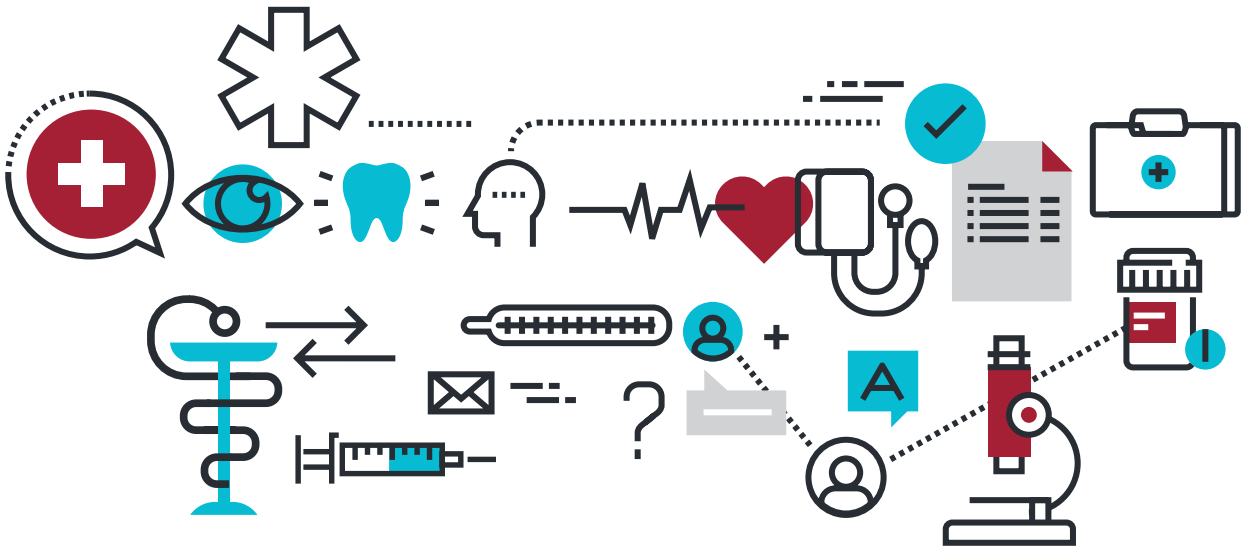


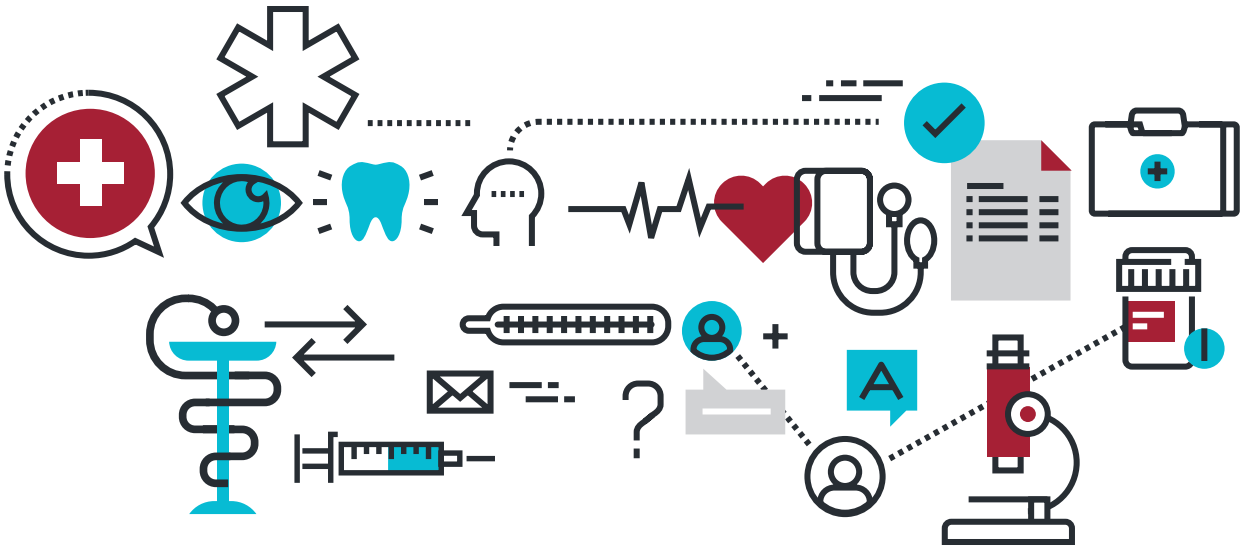
2018 Health Care

Regulatory and Compliance Seminar

February 13, 2018 – Los Angeles, CA

Davis Wright Tremaine LLP

DEFINING SUCCESS TOGETHER



2018 Health Care

Regulatory and Compliance Seminar

Agenda

8:00 – 8:30 AM	REGISTRATION & CONTINENTAL BREAKFAST
8:30 – 8:45 AM	**Welcome & Introduction** Presented by Dennis S. Diaz *Bunker Hill Room*
8:45 – 9:30 AM	**What's New in HIPAA-Land?** Presented by Becky Williams *Bunker Hill Room*
	"Protecting the C Suite: Individual Liability in Health Care Enforcement" Presented by Jeffrey B. Coopersmith and Renee Howard *Museum Room*
	Licenses, COPs, Drugs, Oh My! Presented by Dayna Nicholson and Andrew Patterson *Watercourt Room*
9:30 – 9:40 AM	BREAK
9:40 – 10:25 AM	**Stark, Anti-Kickback, and the False Claims Act: Recent Developments and Hot Topics** Presented by Darby Allen, Dennis S. Diaz and Caitlin Forsyth *Bunker Hill Room*
	Hospital Litigation Update Presented by Anna R. Buono, Loring Rose and John R. Tate *Museum Room*
	Update on Medicare Provider-Based & Site-Neutral Payment Rules Presented by Jordan Keville *Watercourt Room*
10:25 – 10:35 AM	BREAK
10:35 – 11:20 AM	**Regulatory Challenges of Value-Based Physician Compensation** Presented by Bob Homchick *Bunker Hill Room*
	Hospital Board Authority vs. Medical Staff Self-Governance Presented by Terri D. Keville *Museum Room*
	Current Issues in Health IT Presented by Jane Eckels *Watercourt Room*
11:20 – 11:30 AM	BREAK
11:30 AM – 12:30 PM	**Compliance Officers Roundtable** Participants: Christopher Finch, Sarah Finnegan and Karen S. Kim Moderator: Dennis S. Diaz *Bunker Hill Room*

Table of Contents

“Protecting the C Suite: Individual Liability in Health Care Enforcement”

PRESENTED BY

Jeffrey B. Coopersmith | Partner
Renee Howard | Partner

Protecting the C-Suite:

Individual Liability in Healthcare Enforcement

Jeff Coopersmith and Renee Howard

February 13, 2018

Davis Wright Tremaine LLP

Roadmap

- **Overview of Health Care Fraud Enforcement Priorities**
  - What to expect in 2018
  - Individual accountability and the "Yates Memo"
- Recent Prosecutions of Individuals
  - Executives, physicians, sales agents, and others
- Practical and Ethical Implications of Advising Organizations
- Possible Clarifications to Yates Memo and DOJ Policy

Federal Priorities: Misconduct Involving Opioids

- Economic Impact of the Opioid Epidemic
  - $55 billion in health and social costs related to opioid abuse each year.
  - $20 billion in emergency department and inpatient care for opioid poisonings.
- Part D Drug Spending (2015)
  - From 2006 to 2015, total spending for Part D drugs increased by 167%, growing from $51.3 billion to $137 billion.
  - Nearly one in three beneficiaries received a commonly abused opioid.
  - Part D spending for opioids was highest for OxyContin, hydrocodone-acetaminophen(Vicodin), oxycodone acetaminophen (Percocet), and fentanyl.
  - Part D spending for commonly abused opioids reached $4.1 billion in 2015.

Source: HHS OIG Data Brief, June 2016, OEI-02-00290, "High Part D Spending on Opioids and Substantial Growth in Compounded Drugs Raise Concerns."

Federal Priorities: Misconduct Involving Opioids

- Multi-Prong Strategy
  - Fraud cases against corporate entities
  - Fraud cases against providers
  - DEA pharmacy cases
  - State medical board cases

- Recent Developments
  - Aug 2017: AG Sessions forms Opioid Fraud & Abuse Detection Unit—a pilot program relying on big data to identify outlier prescribers
  - Also assigned 12 experienced prosecutors to focus solely on investigating and prosecuting opioid-related fraud cases in 12 locations (incl. E.D. of CA)

Other Health Care Fraud Priorities

- Pharmacies and Prescription Drug Compounding
- Medicare Part D Billing
- Home Health-Related Services
- Diagnosis Coding under Medicare Advantage
- Billing for Substandard Care (Particularly in SNFs)
- Hospital/Physician Relationships
  - Above-market compensation arrangements that violate Stark / AKS

Focus on Individual Accountability

> ***The rules have just changed.*** *Effective today, if a company wants any consideration for its cooperation, it must give up the individuals, no matter where they sit within the company. And we're not going to let corporations plead ignorance. If they don't know who is responsible, they will need to find out. If they want any cooperation credit, they will need to investigate and identify the responsible parties, then provide all non-privileged evidence implicating those individuals."*
>
> Deputy Attorney General Sally Yates
>
> September 10, 2015

DOJ Yates Memo

- Sept. 2015 - "Individual Accountability for Corporate Wrongdoing"
  - Mandates full company cooperation in disclosing information about individuals allegedly involved in fraud if organization expects to receive cooperation credit for resolving investigations.
- New DOJ website on individual accountability: *https://www.justice.gov/dag/individual-accountability*
- Possible revisions/clarification to Yates Memo forthcoming (discussed later on)

Yates Memo – 6 Principles

1	All-or-Nothing Approach to Cooperation Credit
2	Increased Focus on the Culpability of Individual Actors
3	Broadening Pursuit of Remedies With Increased Civil/Criminal Communication
4	No Protection for Individuals in Corporate Resolutions
5	Requirement of Clear Plan for Individual Resolutions
6	Focus on Deterrence and Retribution

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Recent Prosecutions of Individuals

- Early Results
  - May 2016 Speech by Yates:

    "[C]ompanies are not only continuing to cooperate, they are making real and tangible efforts to adhere to our requirement that they identify facts about individual conduct, right down to providing what I'm told are called '**Yates Binders**' . . . that contain relevant emails of individuals being interviewed by the government."

  - Nov 2016 Speech by Yates:

    "**We're getting exactly what we wanted**—companies showing up to their first meeting with the government with information about who did what."

  - In 2017, DOJ recovered more than **$60M** in actions against individuals that did not involve joint and several liability with the corporate entity.

Recent Prosecutions of **Executives**

Former Tuomey Health CEO Jay Cox paid $1M and agreed to a four year exclusion to settle allegations related to his role in hospital's FCA/Stark issues (9/16)

Tenet CEO indicted for alleged role in $400M scheme to defraud; faces 50 years in prison (2/17)

North American Health Care Inc. – Chairman and SVP paid $1.5M to settle FCA allegations related to medically unnecessary rehab therapy services provided to SNF residents (9/16)

Oklahoma Hospital, former hospital administrator, and six physicians pay $1.6M to settle FCA allegations related to supervision of radiological practitioner assistants (4/17)

COO of Freedom Health, managed care provider, for risk adjustment fraud: $750K (5/17)

Recent Prosecutions of **Executives**

Two principals of mental health nonprofit Complementary Support Services paid $4.52M to resolve FCA allegations related to batch-signing of progress notes and billing for time spent completing paperwork (6/17)

Family Med Ctrs of SC – Owner/CEO, along with lab director, paid $443K to settle FCA/Stark allegations based on company's incentive compensation plan and submitting claims for medically unnecessary lab services (9/17)

Rehab and hospice providers and their two executives paid $19.5M to resolve FCA/AKS allegations based on the submission of claims for medically unnecessary services (7/17)

Seven high-ranking officials of Insys Therapeutics, Inc., including its founder, its former CEO, a former VP sales, former national sales director (10/17)

BestCare Laboratory Services – Lab owner held personally liable for $10.6M in fraudulent travel expenses billed to Medicare for specimen collections (12/17)

Recent Prosecutions of **Executives**

Owner of Texas home health agency sentenced to 80 years in prison for submitting false claims, paying kickbacks to Medicare beneficiaries in return for allowing the agency to bill for services that were not medically necessary or not provided, and filing false tax returns. (12/17)

Three owners of major Brooklyn diagnostic labs accused of paying kickbacks to providers and beneficiaries and submitting over $44M in false claims. (unsealed 12/17)

- Latest in a series of prosecutions of multimillion-dollar Medicare-Medicaid billing mills in the borough of Brooklyn, commonly run by former nationals of Soviet Union republics.

Recent Prosecutions of **Physicians**

Galena Biopharma paid $7.55M and cooperated in the prosecution of two physicians to whom the company provided remuneration.

- Company accused of paying kickbacks (free meals, speak fees) to induce physicians to prescribe fentanyl-based drug Abstral.
- Government also alleged that Galena paid $92,000 to a physician-owned pharmacy under a performance-based rebate agreement to induce owners to prescribe Abstral.

As a result of Galena's cooperation, two physicians convicted and sentenced to 240+ months and ordered to pay $14M in restitution.

- Charged with conspiracy to commit wire fraud, mail fraud, health care fraud, Anti-Kickback Statute violations, and prescribing of controlled substances without a legitimate medical purpose.

Recent Prosecutions of **Physicians**

Physicians' Pain Specialists of Alabama - two physicians were sentenced to 20 and 21 years respectively for health care fraud associated with prescribing narcotics (including fentanyl spray Subsys) and upcoding patient visits. (5/17)

Florida parathyroid surgeon paid $4M related to false billing of pre-op exams. (6/17)

Miami physician pled guilty to writing prescriptions for medically unnecessary drugs and referring Medicare patients to pharmacies in exchange for kickbacks. (7/17)

Houston physician convicted for role in scheme to admit unqualified patients for home health services billed to Medicare and to pay kickbacks. (7/17)

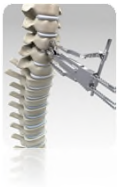
Recent Prosecutions of **Sales Agents**

Warner Chilcott managers sentenced based on HIPAA and fraud violations (directed sales reps to access patient health information and fill out prior authorizations for physicians). (11/16)

Three founders of eClinical Works found jointly liable with company for $155M; program developer paid $50K and project managers paid $15M to settle FCA allegations for causing false claims to be submitted for EHR incentive payments. (5/17)

Insys sales rep indictments (including forging speaker program sign-in sheets and fabricating prior authorization information to get Subsys claims paid by Medicare Part D plans).

Ripped from the Headlines – Operation Spinal Cap



- $600M in fraudulent billings over eight years tied to scheme that exploited former CA spinal "pass through" law for L&I claims
  - Law allowed hospitals to pass on to workers' comp insurers the full cost of devices implanted in spinal surgery patients
  - Law also permitted hospitals to receive separate DRG-type payment for the surgery tied to the Medicare fee schedule
- Former owner of Pacific Hospital (Long Beach) used numerous mechanisms to allegedly pay kickbacks and inflate the costs of devices
  - Concealed payments through bogus contracts with referral sources
  - Used shell companies to artificially increase hardware invoices
- Investigation also resulted in charges against several others, including hospital's former CFO, two surgeons, and a chiropractor

Prosecution Aid: **CMS Open Payments Data**

Prosecution Aid: **CMS Open Payments Data**

National Health Care Fraud Takedown

- Announced July 13, 2017
- Largest health care fraud enforcement action in DOJ history
- Led by Medicare Fraud Strike Force
- 412 defendants across 41 federal districts
  - 115 doctors, nurses, and other health care professionals
  - $1.3B in alleged false billings
  - 120 defendants charged for role in prescribing/distributing opioids and other narcotics
  - HHS initiated suspension of 295 providers

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Practical and Ethical Implications of Advising Healthcare Organizations

Prosecutors now have less discretion

- Not prosecuting an individual requires a declination memo approved by the U.S. Attorney or his designee

Defending large corporation in a government investigation will be even more challenging

- Identifying potentially culpable individuals in large companies with many decision makers can be daunting
- Yates Memo changes stakes for companies deciding whether to cooperate in a government investigation
- "Absent extraordinary circumstances, no corporate resolution will provide protection from criminal or civil liability for any individuals."

Practical and Ethical Implications of Advising Healthcare Organizations

More investigations/prosecutions of senior executives

- Execs may be less willing to cooperate with internal investigations
- Obligation to recommend separate counsel (next slide)
- Investigations will take more time and consume more resources

More cooperation deals with rank and file

- Workforce members may feel pressure to provide prosecutors with something of evidentiary/investigative value against higher-ups
- Increased importance of providing (enhanced) Upjohn warnings and documenting their use
- These employees may also be less willing to cooperate with internal investigations

Practical and Ethical Implications of Advising Healthcare Organizations

Issues of fairness to employees

- Whether *Upjohn* warnings must be given even where the employee is merely collecting information or turning over records.
- The extent to which the company should disclose the investigation to its employees.

Individual counsel for executives/ implicated employees may be needed if:

- The government has communicated that an employees is a subject/target of an investigation.
- The investigation concerns a specific individual's actions or decisions.
- The interests of the CEO or other implicated individual diverge from the interests of the company.

Practical and Ethical Implications of Advising Healthcare Organizations

How well do you know your organization's coverage and indemnification policies?

- D&O Insurance Policy (breadth and limits)
- Corporate policies and employment agreements

Practical and Ethical Implications of Advising Healthcare Organizations

Increases importance of evaluating the effectiveness of your corporate compliance program

New evaluation tools include:

- Jan 2017: OIG, in collaboration with HCCA, released, "Measuring Compliance Effectiveness: A Resource Guide," listing over 400 individual compliance program metrics.
- Feb 2017: DOJ releases guidance document, "Evaluation of Corporate Compliance Programs," with common questions the Fraud Section may ask in evaluating a compliance program in a criminal investigation.
- Does your organization have a plan for applying these tools?

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Clarifications Provided to Date

- May 2016 Speech by Yates:
  - "[C]ounsel for the company is not required to serve up someone to take the fall in order for the corporation to get cooperation credit – a hypothetical person sometimes referred to as the 'vice president in charge of going to jail.'"
  - "[W]e don't expect a company to make a legal conclusion about whether an employee is culpable, civilly or criminally. We just want the facts."
  - "The policy specifically requires only that companies turn over all relevant non-privileged information." Companies are not required "to waive attorney-client privilege."

Clarifications Provided to Date

- DOJ's FAQs re Yates Memo – What corporations are not required to do:
  - Receiving cooperation credit not contingent on waiving attorney-client or the work product privilege.
  - Companies are expected carry out investigations that are thorough but tailored to the scope of the wrongdoing.
  - A company also is not required to deliver a prosecutable case in order to obtain credit for cooperation.
  - Corporate counsel is not required to present its legal conclusions or theories to the government.
  - Company is not required to take specific actions against employees as part of its efforts to obtain cooperation credit.

Reading DOJ's Tea Leaves

- July 2017: AG Sessions stripped DOJ's Health Care Corporate Fraud Strike Force of key personnel
  - HCCF Strike Force, established by former AG Holder in 2015, focuses on complex corporate health care fraud
  - Significant victories include the October 2016 settlement with Tenet for $516M
- But AG Sessions has repeatedly expressed that health care fraud continues to be a priority for DOJ
  - Might the change at the HCCF Strike Force indicate a shift in focus/resources to the opioid epidemic?
- 2018 Federal Budget may include $70M increase for OIG/DOJ Health Care Fraud & Abuse Program

Possible Clarifications to Yates Memo and DOJ Policy

- Changes may be on the horizon . . .
  - Heritage Foundation Q&A Session (Sept '17): Deputy AG Rod Rosenstein indicated, "there may be some change in policy on corporate prosecutions."
  - NYU Program on Corporate Compliance & Enforcement (Oct '17): In keynote address, Rosenstein announces DOJ is reviewing Yates Memo, as well as many other corporate enforcement policies.
  - DOJ may move away from issuing guidance through informal instruments (memos, speeches, FAQs), and instead consolidate policies in official sources (e.g., US Attorney's Manual)
  - The timeline for completing the review is unclear

Possible Clarifications to Yates Memo and DOJ Policy

- DOJ appears to remain committed to holding individuals accountable for corporate wrongdoing
- Rosenstein: Any modifications to the Yates Memo will reflect certain "common themes":
  - Any modifications "will reflect [DOJ's] resolve to hold individuals accountable for corporate wrongdoing."
  - "[T]he government should not use criminal authority unfairly to extract civil payments."
  - "[A]ny changes will make the policy more clear and more concise."
  - Modifications will "reflect input from stakeholders inside and outside the DOJ."

Thank You!

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Licenses, COPs, Drugs, Oh My!

PRESENTED BY

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Licenses, COPs, Drugs, Oh My!

2018 Regulatory Update for Healthcare Providers

Dayna Nicholson and Andrew Patterson

February 13, 2018

Davis Wright Tremaine LLP

Agenda

- Provider Licensing & Operations
- Medicare Participation
- Enforcement
- Joint Commission 2018 National Patient Safety Goals

Provider Licensing & Operations

- **Nonprofit health facilities: Sale of assets** (AB 651)
  - Nonprofit health facilities with a suspended license must obtain attorney general approval befor selling to a for-profit corporation. Overturns *Gardens Regional Hospital and Medical Center, Inc.*, a May, 2017, bankruptcy court decision, which held that a closed hospital is not a "health facility" under California law and thus not required to obtain such approval.
  - Nonprofit health facilities must inform the attorney general of the primary languages spoken at the facility before selling to a for-profit corporation. Attorney general may require health facilities to translate specified notices into any of those languages and must consider whether the transaction may create a "significant effect on the availability and accessibility of cultural interests provided by the facility in the affected community." Corp. Code §§ 5914, 5915, 5916, 5917, 5920, 5921, 5922, 5923, 5926.
- **Whistleblower protections** (AB 1102)
  - As originally drafted, would have prohibited hospitals from disciplining an employee for refusing an assignment (or change in assignment) on the grounds that the assignment would violate the nurse ratio staffing law. A lack of appropriate coverage for meal and rest periods was given as the reason for this bill. Due to opposition bill was amended to instead increase the civil penalty for willful whistleblower violations to $75,000. Health & Safety Code § 1278.5

Provider Licensing & Operations

- **Workplace safety prevention** (8 CCR § 3342)
  - Addresses violence: (1) committed by a person with no legitimate business at the work site; (2) directed at employees by customers, clients, patients, inmates, visitors or other individuals accompanying a patient; (3) between two employees or ex-employees; and (4) committed by an individual with no relationship to the workplace other than a relationship with one of the employees.
  - Hospitals must:
    - Report violent incidents to the Division of Occupational Safety and Health of the Department of Industrial Relations;
    - Maintain a violent incident log;
    - Develop a violence prevention plan; and
    - Provide employee training.

- **Procedures of emergency medical services providers** (SB 432)
  - Updates the process for hospitals to notify emergency medical services (EMS) personnel (e.g., paramedics, firefighters and private ambulance employees) that they were exposed to specified communicable diseases. Hospitals and EMS employers must provide employee training and post the title and telephone number of their infection control officer on their website. HSC § 1797.188

Provider Licensing & Operations

- **Hospital satellite compounding pharmacy** (SB 351)
  - Provides additional options for hospitals to license pharmaceutical services in a satellite or approved service area that is located separate from the hospital's physical plant and that is not under the hospital's consolidated license. Authorizes the Board of Pharmacy to issue a license to a hospital satellite compounding pharmacy. Bus. & Prof. Code §§ 4029, 4127.15, 4400

Provider Licensing & Operations

- **Remote Dispensing Site Pharmacy/Telepharmacy** (AB 401)
  - A remote dispensing site pharmacy is a licensed pharmacy located in California that is exclusively overseen and operated by a supervising pharmacy and staffed by one or more qualified registered pharmacy technicians who work at the remote dispensing site pharmacy and perform order entry, packaging, manipulative, repetitive, and other nondiscretionary tasks.
  - Supervising pharmacist is located at supervising pharmacy. Uses "telepharmacy" technology to monitor prescription drug dispensing, with drug regimen review and patient counseling by an electronic method such as audio, visual, still image capture or store and forward technology.
  - Must be in a medically underserved area, 150 miles or closer to the supervising pharmacy, and under common ownership of the supervising pharmacy. A supervising pharmacy may supervise only one remote dispensing site pharmacy.
  - Remote pharmacy technicians may not perform tasks such as taking oral prescription orders or compounding drug preparations and must be videotaped receiving any controlled substances. Bus. Prof. Code §§ 4044.3, 4044.6, 4044.7, 4130, et seq.

Provider Licensing & Operations

- **Cleaning Product Right to Know Act** (SB 258)
  - Provides consumers and workers with ingredient information about designated products to encourage informed purchasing as well as to reduce public health impacts from exposure to potentially harmful chemicals. The bill requires product manufacturers to provide a specific list of chemicals used in their products on their website and product labels, and requires specified employers to provide that information to their employees. Employers that are required to make MSDS accessible to employees to also make accessible, in the same manner, the information included in the new online disclosures. Health & Safety Code § 108950, et seq., Labor Code § 6398.5
- **Diesel back-up generators** (AB 1014)
  - Establishes testing and maintenance standards for emergency back-up generators in health care facilities that align with the edition of the National Fire Protection Association 110: Standard for Emergency and Standby Power systems adopted by the Life Safety Code and the CMS. Health & Safety Code § 41514.1

Provider Licensing & Operations

- **Health Care Districts** (AB 1728)
  - Board of directors of a health care district must adopt an annual budget during a public meeting on or before September 1 of each year.
  - Health care districts must have a website with district contact information.
  - Health care districts that award grants must adopt annual policies for financial assistance or grant funding provided by the district. HSC § 32139.
- **Clinics in Shared Space** (AB 401)
  - Primary care clinics and specialty clinics licensed under Health & Safety Code § 1204 may operate in shared clinic space with government clinics (exempt from licensure under HSC 1206(b)). Licensed clinic is responsible for any statutory or regulatory violations occurring on the premises.
  - Requirements include:
    - Signage that clearly identifies which clinic is operating during the hours of operation.
    - Separate medical records and drug storage.
    - Both clinics are licensed by the State Board of Pharmacy (Bus. & Prof. Code section 4180.5 added to permit clinics in shared space to obtain license for wholesale purchase and dispensing of drugs).
    - CDPH entitled to access and inspect records of the exempt clinic. Health & Safety Code § 1211.

Provider Licensing & Operations

- **Confidentiality of Mental Health Records** (AB 1119)
  - Under Lanterman-Petris-Short Act, explicitly permits communication of patient information during the provision of emergency services between a physician, psychologist, social worker with a master's degree in social work, marriage and family therapist, professional clinical counselor, nurse, emergency medical personnel at the scene of an emergency or in an emergency medical transport vehicle, or other professional person or emergency medical personnel at a health facility. Welf. & Inst. Code § 5328
- **Patient Access to Medical Records**
  - SB 241. Aligns state law with federal regulations. Limits amount patients may be charged for copies of their medical record. Explicitly permits certain mental health care providers to disclose patient information to business associates with a HIPAA-compliant business associate agreement and to use and disclose patient information for health care operations purposes. Health & Safety Code §§ 123105 and 123110; Welf. & Inst. Code § 5328
  - SB 575. Requires hospitals, physicians and other health care providers to give a free copy of the relevant portion of the medical record to a patient if needed to support a claim or appeal regarding eligibility for a public benefit program (e.g., Medi-Cal, Social Security disability insurance benefits, Supplemental Security Income). Health & Safety Code § 123110

Provider Licensing & Operations

- **Involuntary treatment for mental health** (AB 191)
  - Authorizes a marriage and family therapist or professional clinical counselor to sign a notice of certification to extend an involuntary hold beyond 72 hours for a patient's mental health assessment and treatment. The therapist or counselor must have participated in evaluating the patient, and may only provide the second signature (the first must be provided by a physician or psychologist). Welf. & Inst. Code §§ 5251, 5261, 5270.20
- **Involuntary commitment** (SB 565)
  - Currently, mental health facilities must hold a certification review hearing to extend an involuntary hold by 30 days for intensive mental health treatment services. Now, such facilities must make "reasonable attempts" to notify family members or other persons designated by the patient of the time and place of the certification hearing at least 36 hours before the hearing, unless the patient requests this information not be provided. Welf. & Inst. Code §§ 5260, 5270.15

Provider Licensing & Operations

- **Stem cell therapy** (SB 512)
  - Requires health care practitioners administering stem cell therapies without FDA approval for an investigational new drug to disclose to patients that the therapies have not yet been approved by the FDA. Bus. & Prof. Code § 684
- **Opioid addiction**
  - SB 554. Authorizes nurse practitioners and physician's assistants with specified training to order or furnish, as applicable, buprenorphine (an opioid used to treat opioid addiction) in accordance with the federal Comprehensive Addiction and Recovery Act of 2016. Bus. & Prof. Code §§ 2836.4, 3502.1.5
  - California Prescription Drug Monitoring Program, AB 40. Authorizes prescribers and pharmacists to query the Controlled Substance Utilization Review and Evaluation System (CURES) database through an online portal or through a health information technology system. Will permit the California DOJ to integrate the electronic history of controlled substance dispensing into the patient information system used by emergency department physicians, thus giving emergency physicians efficient access to information needed to help fight prescription drug abuse. Health & Safety Code § 11165.1
  - Pain management, AB 1048.
    - Permits a pharmacist to dispense a Schedule II controlled substance (Health & Safety Code § 11055) as a partial fill if requested by the patient or the prescriber. Beginning January 1, 2019, a health care service plan will be required to prorate an enrollee's cost sharing for a partial fill of a prescription.
    - Changes requirement that health facilities assess pain each time a patient's vital signs are obtained; permits such assessment in a manner appropriate for the patient. Bus. & Prof. Code § 4052.10, Health & Safety Code § 1254.7, 1367.43, 1371.1, Ins. Code §§ 10123.145, 10123.203

Provider Licensing & Operations

- **Skilled Nursing and Long-Term Care Facilities**
  - Requirements for changes (AB 275)
    - Extends, from 30 to 60 days, the timeline and notice periods that long-term care (LTC) facilities are required to give residents, their families, and various agencies before they close. Clarifies and strengthens requirements to medically and socially assess residents in order to prevent and reduce transfer trauma. Requires LTC facilities, as part of their relocation plans, to provide specific information regarding the number of residents who do not have the capacity to make decisions for themselves, the availability of alternative LTC beds in the community, and the reason for the proposed closure, among other things. Health & Safety Code §§ 1336, 1336.1, 1336.2, and 1336.3
  - Notice of transfer or discharge (AB 940)
    - Requires a skilled nursing facility to send to the local long-term care ombudsman copies of written notices to residents of a facility-initiated transfer or discharge. Noncompliance is a class B violation. Health & Safety Code § 1439.6

  - Rights of residents (SB 219)
    - Protects the rights of lesbian, gay, bisexual, and transgender (LGBT) seniors in skilled nursing and assisted living facilities, to prevent those facilities from discriminating against them. Creates the LGBT Long-Term Care Facility Resident's Bill of Rights, making it unlawful for any long-term care facility to take specified actions based on a person's actual or perceived sexual orientation, gender identity, gender expression or HIV status. Health & Safety Code §§ 1569.318, 1338.4

Provider Licensing & Operations

- **Hospice Licensure Act** (SB 294)
  - A hospice may provide any service described in the Hospice Licensure Act, including palliative care, to a patient with a serious illness (as determined by the physician caring for the patient), including a patient who continues to receive curative treatment from other licensed health care professionals.
  - A hospice that elects to provide palliative care under this bill must provide CDPH with specified information, including the date of commencement of palliative care, the types and numbers of patients receiving palliative care, and staff qualifications. HSC § 1747.3
- **Clincal Laboratory fees** (AB 658)
  - The Bureau of State Audits determined that CDPH has inappropriately raised licensing fees assessed to cover the cost of inspecting and licensing clinical laboratories and amassed a surplus in excess of $22 million. Annual renewal fee for clinical laboratory licenses suspended for calendar years 2018 and 2019. BPC § 1300.1

Provider Licensing & Operations

- **Medical Board of California** (SB 798)
  - Midwives
    - Adds licensed midwives and midwifery societies to peer review provisions. Bus. & Prof. Code § 805(a)
    - Authorizes licensed marriage and family therapists to be shareholders, officers, and directors, and employees of professional corporations. Corp. Code § 13401.5.
  - Lists adverse events that must now be reported to MBC by an outpatient setting accredited pursuant to Health & Safety Code Section 1248.1 (surgery centers) within five days from detection of adverse event or, if that event is an ongoing urgent or emergent threat to the welfare, health, or safety of patients, personnel, or visitors, not later than 24 hours after the adverse event has been detected. Bus. & Prof. Code § 2216.3
  - Imposes a $50,000-$100,000 fine for a failure to file a required report with MBC. Bus. & Prof. Code § 805
- Occupational Therapy – Standards of Practice for Telehealth (16 CCR 4172)
  - Clarifies that once the patient is informed and consents to receive occupational therapy services via telehealth, an occupational therapist does not need to affirmatively obtain the patient's consent each time the OT delivers services.

Medicare – Conditions of Participation

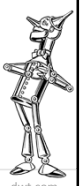
Modernization of Home Health Agency (HHA) Conditions of Participation (CoPs)
(42 CFR 409, 410, 418, 440, 484, 485, 488). 82 FR 4504

- Effective January 13, 2018 (originally July 13, 2017).
- CMS' stated goals include:
  - Reflect current HHA practices by focusing on the care provided to patients and the impact of that care on patient outcomes.
  - Assure the protection and promotion of patient rights; enhance the process for care planning, delivery, and coordination of services; and build a foundation for ongoing, data-driven, agency-wide quality improvement.
  - Improve the quality of care furnished through the Medicare and Medicaid programs, while streamlining requirements for providers. HHA (CoP) Final Rule (CMS-3819-F) at Federal Register.

Medicare – Conditions of Participation

Modernization of Home Health Agency (HHA) Conditions of Participation (CoPs)
(42 CFR 409, 410, 418, 440, 484, 485, 488). 82 FR 4504

- *Historically, we have adopted a quality assurance approach that has been directed toward identifying health care providers that furnish poor quality care or fail to meet minimum Federal standards. Facilities not meeting requirements would either correct the inappropriate practice(s) or would be terminated from participation in the Medicare or Medicaid programs.* ***We have found that this problem-focused approach has inherent limits****. Ensuring quality through the enforcement of prescriptive health and safety standards, rather than improving the quality of care for all patients, has resulted in expending much of our resources on dealing with marginal providers rather than on stimulating broad-based improvements in the quality of care delivered to all patients.*



Medicare – Conditions of Participation

Proposed **Revision to Requirements for Long-Term Care Facilities' Arbitration Agreements**
(42 CFR 483) 82 FR 26649

- Reform of Requirements for Long-Term Care Facilities Final Rule (published 10/04/16) listed requirements for obtaining residents' agreement to binding arbitration and prohibited pre-dispute agreements for binding arbitration. The American Health Care Association and a group of nursing homes obtained a preliminary injunction of CMS's enforcement of that requirement on November 7, 2016. CMS subsequently reviewed and reconsidered the arbitration requirements.
- Proposed revision published June 6, 2017. Comments deadline August 17, 2017.
- CMS' stated goals:
  - Strengthen transparency in the arbitration process
  - Reduce unnecessary provider burden
  - Support residents' rights to make informed decisions about important aspects of their health care

Medicare – Conditions of Participation

Proposed **Revision to Requirements for Long-Term Care Facilities' Arbitration Agreements**
(42 CFR 483) 82 FR 26649

- Includes the following proposals:
  - Remove prohibition on pre-dispute binding arbitration agreements.
  - All agreements for binding arbitration must be in plain language; if agreement is a condition of admission, language must be in plain writing and in the admissions contract.
  - Agreement must be explained to the resident and any representative in a form and manner (including a language) they understand.
  - The resident must acknowledge understanding of the agreement.
  - The agreement must not have language prohibiting or discouraging a resident or other person from communicating with governmental officials.
  - If arbitration occurs, facility must keep a copy of the signed arbitration agreement and the arbitration decision for inspection by CMS or its designee.
  - Facility must post a notice regarding its use of binding arbitration in an area that is visible to both residents and visitors.

CDPH – Immediate Jeopardy Penalties

- Immediate Jeopardy (IJ): noncompliance with licensing requirements causing or likely to cause serious injury or death.
- IJ Penalties in 2017

Date	# Penalties	# Hospitals	Total Fines
Jan 5	15	14	$913,550
Apr 20	17	14	$1,135,980
Aug 31	10	10	$618,002
Dec 28	10	9	$549,555
		Total	$3,217,087

Medicare – Systems Improvement Agreements

- Time-limited contractual arrangement between a Medicare-accredited healthcare organization and CMS. More time to correct deficiencies than might be available after a validation or for-cause survey.
- Historically used for home health agencies, nursing homes, and transplant centers, etc. More recently, hospitals too.
- Western State Hospital.
  - SIA #1, June 2016
  - Survey + 60-day Extension, June 2017
  - 30-day Extension, September 2017
  - SIA #2, November 2017

Joint Commission: National Patient Safety Goals 2018

- Established 2002
- Patient Safety Advisory Group
- Current Goals
  - 1. Improve the accuracy of patient identification.
  - 2. Improve the effectiveness of communication among caregivers.
  - 3. Improve the safety of using medications.
  - 6. Reduce the harm associated with clinical alarm systems.
  - 7. Reduce the risk of health care-associated infections.
  - 9. Reduce the risk of patient harm resulting from falls.
  - 14. Prevent health care-associated pressure ulcers (decubitus ulcers).
  - 15. The hospital identifies safety risks inherent in its patient population.
  - Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery

Joint Commission: National Patient Safety Goals 2018

- Changes effective for 2018
- 7. Reduce the risk of health care-associated infections.
  - NPSG.07.03.01 — multidrug-resistant organisms (MDROs):
    - Previously applicable to hospitals and critical access hospitals; now applicable to nursing care centers.
    - Carbapenem-resistent enterobacteriaceae (CRE) added to the list of organisms covered by the goal.
    - Organizations may determine the appropriate time frame for education.
  - NPSG.07.04.01 — central line-associated bloodstream infections (CLABSIs):
    - Reordered elements of performance (EPs) for hospitals and critical access hospitals.
    - Revision to allow organizations to determine the appropriate time frame for educating staff and licensed independent practitioners.
    - Similar modifications for nursing care centers.
    - Added requirement for education of residents and patients.

Questions?

What's New in HIPAA-Land?

PRESENTED BY

Becky Williams | Partner

What's New in HIPAA-Land

Rebecca L. Williams, RN, JD, Partner
Co-Chair, Health Information Practice
Davis Wright Tremaine, LLP

Davis Wright Tremaine LLP

Agenda

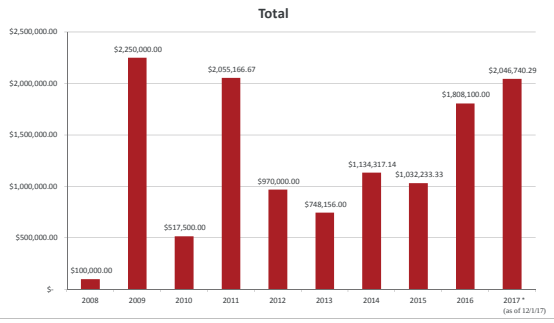
- Enforcement Trends
- Breach Trends
- Audits
- Recent Developments
- On the Horizon

OCR ENFORCEMENT TRENDS

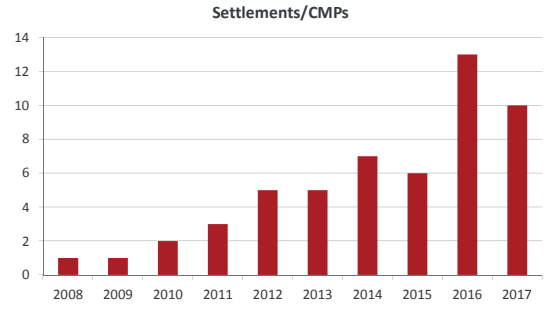
OCR Enforcement Statistics

- 53 OCR financial settlements or fines
- $1.5 million – Average settlement/fine
- 26 settlements/fines that alleged lack of or inadequate risk analysis
- 2017
  - Began the year with 9 settlements
  - Only 1 since May
  - Consistent with change of Administrations
  - Uncertain enforcement policy

Average Settlement/Fine Per Year



Number of Settlements/CMPs Per Year



Future Enforcement

"At most I will say the big, juicy case is going to be my priority and the methods for us finding it - stay tuned."

- Director Roger Severino, OCR, NIST/OCR Conference (Sept. 5, 2017)

Other Enforcement

- State Attorneys General
- Class Actions
- Department of Justice
- Federal Trade Commission

Lessons Learned

- Be alert to temptations:
  - Disgruntled employees
  - Ex-factors
  - Family ties
  - The Rich and Famous
- Social media
- Don't get pulled into a public fight – even if the patient starts it
- Stay out of the press

Lessons Learned

- Risk analysis / Risk management – Do It and Keep Doing It
- Pay particular attention to mobile devices
- Audit controls – know who is looking at PHI
- Don't leave portable media containing PHI unattended
- Keep track of business associates and make sure paperwork is done
- Finalize policies and procedures
- Size of breach does not always correlate to amount of settlement

Data Breach Trends

Breach Statistics

- ~2200 Breaches affecting 500 or more individuals
  - 46% Theft and Loss
  - 19% Hacking/IT
  - 25% Laptops and portable storage devices
  - 21% Paper
- 300,000+ "smaller breaches"

Recurring Issues

- Lack of encryption
- Lack of control over portable media
- No incident response or contingency planning
- Failure to patch software
- Improper disposal of PHI
- **Failure to learn from previous mistakes**

HIPAA AUDITS

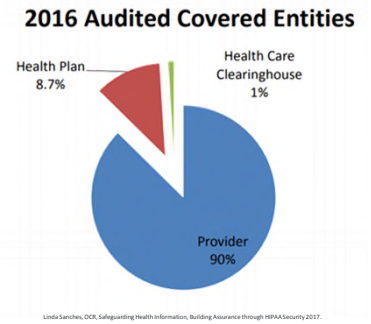
Where We've Been

2011-2012	Pilot audits
2013	OCR evaluation of results
2016-2017	Phase 2

Phase II Audit Program: Status

- Completed focused desk audits for:
  - 166 Covered Entities
  - 41 Business Associates
- Security: Risk analysis and risk management
- Privacy: Notice of privacy practices and access
- Breach notification: Content and timeliness
- Uncertainty for on-site audits
- Report on Phase II expected 2018
- No likely enforcement expected except for entities that did not respond

What Covered Entities Were Audited

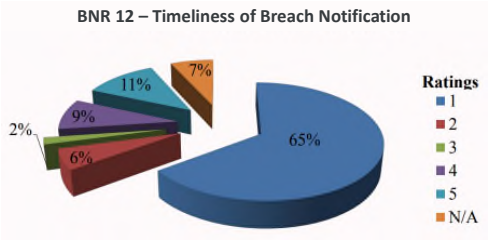


Linda Sanches, OCR, Safeguarding Health Information, Building Assurance through HIPAA Security 2017.

Compliance Effort Ratings—Legend	
Rating	Description
1	The audit results indicate the entity is in compliance with both goals and objectives of the selected standards and implementation specifications.
2	The audit results indicate that the entity substantially meets criteria; it maintains appropriate policies and procedures, and documentation and other evidence of implementation meet requirements.
3	Audit results indicate entity efforts minimally address audited requirements; analysis indicates that entity has made attempts to comply, but implementation is inadequate, or some efforts indicate misunderstanding of requirements.
4	Audit results indicate the entity made negligible efforts to comply with the audited requirements - e.g. policies and procedures submitted for review are copied directly from an association template; evidence of training is poorly documented and generic.
5	The entity did not provide OCR with evidence of serious attempt to comply with the Rules and enable individual rights with regard to PHI.

Linda Sanches, OCR, Safeguarding Health Information, Building Assurance through HIPAA Security 2017.

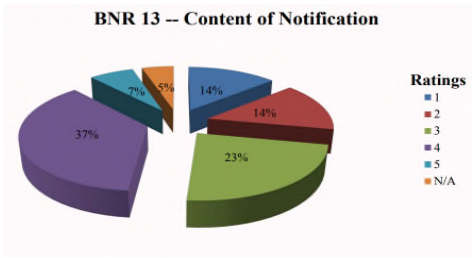
Audit Results: Breach Notification



TIPS:
Concerns about "no" breaches

Linda Sanches, OCR, Safeguarding Health Information, Building Assurance through HIPAA Security 2017.

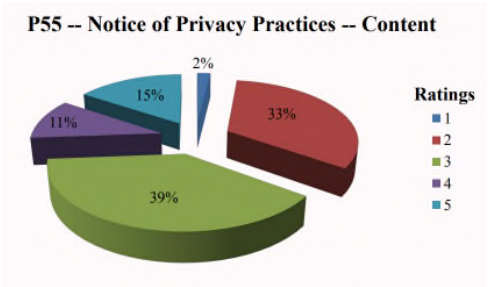
Audit Results: Breach Notification



TIPS:
Problems with dates and types of information

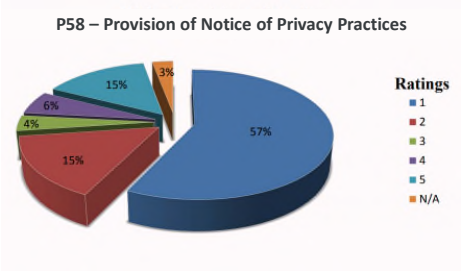
Linda Sanches, OCR, Safeguarding Health Information, Building Assurance through HIPAA Security 2017.

Audit Results: Privacy



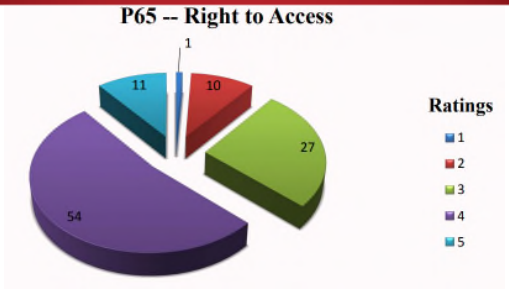
Linda Sanches, OCR, Safeguarding Health Information, Building Assurance through HIPAA Security 2017.

Audit Results: Privacy



Linda Sanches, OCR, Safeguarding Health Information, Building Assurance through HIPAA Security 2017.

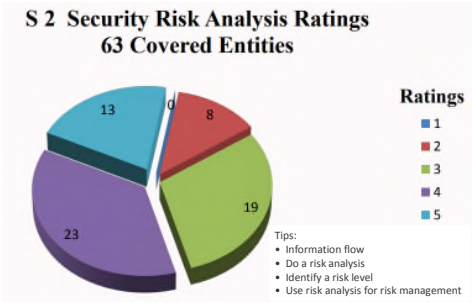
Audit Results: Privacy



TIPS:
- Revisit the access process
- Area of concern for OCR

Linda Sanches, OCR, Safeguarding Health Information, Building Assurance through HIPAA Security 2017.

Audit Results: Security



Tips:
- Information flow
- Do a risk analysis
- Identify a risk level
- Use risk analysis for risk management

Linda Sanches, OCR, Safeguarding Health Information, Building Assurance through HIPAA Security 2017.

Audit Results: Security

Linda Sanches, OCR, Safeguarding Health Information, Building Assurance through HIPAA Security 2017.

Phase II Audit Program: Lessons Learned

- Not many "A"s
- OCR wants extremely detailed policies and procedures – not merely recitation of regulations
- OCR has particular expectations for risk analysis and risk management plan
- OCR has expressed concerns about the right to access

WHAT'S NEW:
Recent Development

Recent Guidance

- Communication of Mental Health and Substance Use Disorder:
  Response to Opioid Abuse Crisis
- Health Developer Portal:
  Implications for apps, wearables, Artificial Intelligence
- Cloud Computing Guidance
- Cyber Security Newsletters
- Rights of Access:
  "Old news" (2016) but still a concern
- Ransomware

Laws and Regulations: Substance Use Disorder Information

- 2017: SAMHSA published a final rule amending 42 CFR Part 2
  - First significant revision in 30 years
  - Some good; some not so much
- 2018: Revised (effective 2/2/18)
- Goal to align with health information exchange

Laws and Regulations: 21st Century Cures Act

- Prohibits "Information Blocking"
  - Practices that restrict authorized access, exchange, or use of information for treatment and other permitted purposes
  - Implementing HIT in non-standard ways that are likely to substantially increase the complexity or burden of accessing, exchanging, or using electronic health information
  - Implementing HIT in ways likely to–
    - Restrict exchange and use of electronic health information in transitioning or exporting
    - Leads to fraud, waste, or abuse

Other Developments: Affordable Care Act's Nondiscrimination Provision

- Affects notice of privacy practices and data breach notifications
- Nondiscrimination Notice
- Taglines in top 15 languages spoken by individuals with limited English proficiency within the state
- HHS providing:
  - Model notice and tagline language
  - Chart of top 15 languages spoken in each state

ON THE HORIZON

HITECH Act: Old News and New News

- HITECH Regulations
- Not pleasant to explain to a new director that regulations due in 2014 still haven't been published
  - Distribution of Penalties
  - Accounting of Disclosures

21st Century Cures Act

- HHS to issue regulations on reasonable activities that do not constitute information blocking
- Other implementing regulations possible
- Uncertainty about current enforcement

Re-Opening HIPAA

- Re-opening HIPAA??????
- Goal: To make HIPAA less burdensome

Questions

Thank you

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Hospital Litigation Update

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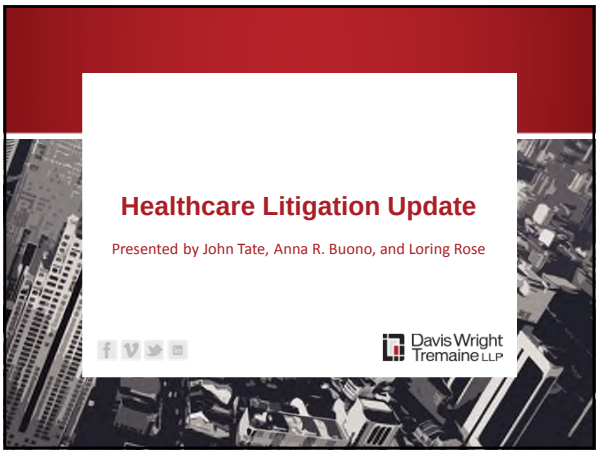

Overview

- National Litigation trends and developments
- California Litigation highlights
- Takeaways and cases to watch

National Trends and Developments

National Trends and Developments

- False Claims Act
- DOJ recovered over **$3.7 billion** from FCA cases in FY2017.
  - About **$2.4 billion** from healthcare-related cases.
  - Most FCA cases are "whistleblower" actions, 64% brought by former employees.
  - "Relators" get a cut of any recovery, up to 30%.
  - In 2017, California had the most "unsealed" *qui tam* cases (Central District of California).

False Claims Act

- False Claims Act basics
- False Claims Act imposes liability on:
  - Whoever "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A).
  - Whoever "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." *Id*. § 3729(a)(1)(B).
  - Claims can be *factually* false or *legally* false.
  - Legally-false certifications can be *express* or *implied.*

False Claims Act - *Escobar*

- Key case: ***Universal Health Services v. United States ex rel. Escobar***, 136 S. Ct. 1989 (2016).
- Case involved claims for mental health counseling services that Universal Health submitted to the Massachusetts Medicaid program.
- Alleged that Universal Health"submitted reimbursement claims that made representations about the specific services provided by specific types of professionals, but that failed to disclose serious violations of regulations pertaining to staff qualifications and licensing requirements for these services."
- *Implied certification* theory of liability.

Flase Claims Act - *Escobar*

- Dismissed at the District Court level, but that dismissal reversed on appeal to the First Circuit Court of Appeals.
- First Circuit held that that *every* submission of a claim *implicitly represents compliance with all relevant regulations*, and that *any undisclosed violation of a precondition of payment* (whether or not expressly identified as such) renders a claim "false or fraudulent."
- Circuit court differences with regard to import of implied certifcation theory (a "circuit split") led the Supreme Court to review the case.

False Claims Act - *Escobar*

- Supreme Court held that "the implied false certification theory can, at least in some circumstances, provide a basis for liability."
- "[*A*]*t least* where two conditions are satisfied:"
  - The claim "does not merely request payment, but also *makes specific representations* about the goods or services provided"; *and*
  - Defendant's failure to disclose its noncompliance "with *material* statutory, regulatory, or contractual requirements makes those representations misleading half-truths."
- The misrepresentation about compliance must be "*material* to the Government's payment decision" to be actionable.
- This "materiality" standard is "rigorous" and "demanding".

False Claims Act – *Stephens Institute*

- Key case: *U.S. ex rel. Rose et al. v. Stephens Institute* (N.D. Cal.).
- Plaintiffs alleged that defendant fraudulently obtained funds from the U.S. Department of Education by falsely alleging compliance with Title IV of the Higher Education Act.
- Is *Escobar*'s two-part implied certification test *mandatory*?
  - Judge says "no," both parts of test not necessary for liability.
  - "At least" language = *permissive*
- Appeal argued before the Ninth Circuit in December 2017.
- *U.S. ex rel. Badr v. Triple Canopy, Inc.*, 857 F.3d 174 (4th Cir. 2017), sets up potential circuit split.

False Claims Act

- False Claims Act: Statistical Sampling
- Analysis of a representative sample of a provider's claims.
- Sample used to draw inferences about the totality of those claims.
- Frequently used to prove *damages*, in cases where liability is established (or not contested) and a claim-by-claim review is not practical.
- Can statistical sampling be used to prove *liability*?
  - Due process violation?

False Claims Act - *Berntsen*

- Key case: *United States ex rel. Berntsen v. Prime Healthcare Services* (C.D. Cal.).
- Alleged falsity of potentially tens of thousands of Medicare claims.
  - Government served subpoenas for documents on *some* of the claims
- Motion to exclude statistical sampling evidence to prove *liability.*
- *Government has the* ***burden*** *to* ***prove*** *liability.*
- Motion denied without prejudice, case is proceeding.
- *Tyson Foods, Inc. v. Bouaphakeo*, 136 S. Ct. 1036 (2016)?

False Claims Act - *AseraCare*

- False Claims Act: Medical Necessity
- Key case: *United States ex rel. Paradies v. AseraCare, Inc*. (N.D. Ala.).
- $200 million False Claims Act suit targeting Medicare billing by hospice chain AseraCare.
- Alleged that AseraCare billed Medicare for hospice services for patients that were ineligible for end-of-life care, notwithstanding that patients were certified as eligible by physicians.
- DOJ's medical expert disagreed with physicians' conclusions.

False Claims Act - *AseraCare*

- Trial court granted summary judgment to AseraCare.
- "When hospice certifying physicians and medical experts look at the very same medical records and disagree about whether the medical records support hospice eligibility, the opinion of one medical expert alone cannot prove falsity without *further evidence of an objective falsehood*."
- Case was appealed to Eleventh Circuit, oral argument held in March 2017, still no decision.
- *U.S. ex rel. Dooley v. Metic Transplantation Lab*, 2017 WL 4323142 (C.D. Cal. June 27, 2017).

Other Cases of Interest

- Medicare secondary payor
  - When there is more than one potential payor on a claim, coordination rules apply.
  - Medicare does not pay for items or services to the extent that payment has been, or may reasonably be expected to be, made through someone else, but may make a "conditional" payment, which it will later recover.
  - *Morales v. Providence Health and Services, Inc.*, 702 Fed. Appx 550 (9th Cir. 2017).
    - Dismissal upheld by Ninth Circuit for failure to exhause administrative remedies.
    - Case "arose under" Medicare Act, even though Medicare not a party.

California Litigation Highlights

California Litigation Highlights

- Consumer Class Actions
- Retaliation/Peer Review Updates
- Enforceability of Arbitration Clauses
- Patient Personal Rights Claims
- Health Care Worker Meal-Period Waivers

California Litigation Highlights

Consumer Class Actions

Chargemaster Rates for Self-Pay Patients

- 2 major cases in which self-pay patients challenged the rates charged for emergency medical services.
- Both were asserted as class actions in an attempt to raise the stakes.
- Both courts denied class certification.

Kendall v. Scripps Health, 16 Cal. App. 5th 553 (Oct. 18, 2017):

- Uninsured patient challenging Scripps's billing and collection practices for emergency services to self-pay patients.
- Signed an agreement stating he was responsible for paying all billed charges as listed in the hospital's Charge Description Master.
- Charge Master rates were billed for the services provided.
- The patient sued under theories of unfair business practices, asserting a class action.
- The trial court denied class certification: the proposed class was not ascertainable and common issues did not predominate.

Kendall v. Scripps

- The Court of Appeal affirmed the order denying class certification.
- Common issues did not predominate. "[I]ndividualized inquiries would be necessary to calculate liability and damages, by generating a hypothetical reasonable rate for emergency services, and determining what portion of it each patient should be held liable to pay, after treatment was completed."
- The proposed class was not ascertainable: "[Plaintiff] did not show the existence of a reasonable method for Scripps 'to ascertain who has claims and who does not without an individualized analysis of each patient's payment record.' "
- Declaratory relief could not be certified as a class action: "Certifying a class to issue declaratory relief . . . could not properly be granted in a theoretical vacuum that disregards not only the related substantive statutory claims, but also the existence of specialized regulations of emergency services billing that allow the use of the Charge Master format."

Hefczyc v. Rady Children's Hospital – San Diego, 17 Cal. App. 518 (Nov. 17, 2017):

- Guarantor of uninsured minor patient challenging Hospital's billing practices for emergency services to self-pay patients.
- Sought a declaration that the form contract allowed the Hospital to charge only for the reasonable value of its services, not Charge Master rates.
- Trial court denied class certification: the class was not ascertainable, common issues did not predominate, and class action litigation was not a superior means of proceeding.

Hefczyc v. Rady Children's Hospital – San Diego

- The Court of Appeal affirmed the order denying certification.
- As in *Kendall*, the plaintiff argued for declaratory relief using a federal class certification rule (an attempt to avoid having to satisfy state-law ascertainability, predominance, and superiority requirements.)
- Also as in *Kendall*, state court precedent applies, and in state court, litigants seeking class certification must demonstrate ascertainability, predominance, and superiority regardless of whether the claim is for damages or declaratory relief.

Hefczyc v. Rady Children's Hospital – San Diego

- Denial of class certification was not an abuse of discretion:
  - Required individualized factual inquiries as to whether Chargemaster rates were reasonable as to each potential class member
  - Proceeding on a classwide basis would have been an inferior method of adjudication.
  - The class was not ascertainable because members of the public could not be expected to know whether they had been billed Chargemaster rates.

Consumer Class Actions

- Take away:
  - Courts are reinforcing that the reasonable value of medical services is a complicated issue requiring individual determination on a case-by-case basis, rather than presenting a common question suitable for class determination.
  - Courts are showing their reluctance to be the mechanism for addressing the serious problem of health care affordability, at least on a class-wide basis.
  - Class treatment would raise the stakes and invite far broader scrutiny into billing practices and how providers maintain data. Instead, the courts are embracing the view that rising health care affordability is a problem that requires a legislative rather than judicial solution.

California Litigation Highlights

Retaliation/Peer Review Updates

Brenner v. Universal Health Services of Rancho Springs, Inc., 12 Cal. App. 5th 589 (June 7, 2017):

- The wife and son of a deceased patient sued the patient's hospital and doctor for negligence, retaliation in violation of Health and Safety Code section 1278.5, and elder abuse.
- Plaintiffs' complaint alleged that the defendants retaliated against the patient as a result of the wife's complaints to the hospital's nursing staff about the patient's care.
- The trial court granted the defendants' motion for summary judgment, and plaintiffs appealed.

Brenner v. Universal Health Services of Rancho Springs, Inc.

- The Court of Appeal affirmed the summary judgment because plaintiffs lacked standing to sue for retaliation under section 1278.5, both individually and as representatives of the patient's estate.
  - First, retaliation claims are not authorized against individual doctors, as explained in *Armin v. Riverside Community Hospital,* 5 Cal.App.5th 810 (2016).
  - Second, plaintiffs lacked standing to sue the hospital because section 1278.5, subdivision (b), does not apply to complaints made by a patient's family. The court interpreted subdivision (c) to allow only certain non-family members—an employee, a member of the medical staff, or another health care worker—to submit a grievance on the patient's behalf creating the predicate for a retaliation claim.

Anti-SLAPP Overview

- Strategic Lawsuit Against Public Participation (C.C.P. § 425.16)
- Forbids lawsuits aimed at chilling speech or intimidating defendants in retaliation for exercising their First Amendment Rights.
- Anti-SLAPP motions are brought as special motions to strike, under a two-prong test:
  - Does the complaint arise from protected activity?
  - If yes, burden shifts to plaintiff to show a probability of prevailing using admissible evidence
- Fee-shifting provision mandates payment of attorneys fees to defendants who successfully bring an anti-SLAPP motion. Plaintiff can get fees if motion is defeated, but only if motion is "frivolous or solely intended to cause unnecessary delay."
- An anti-SLAPP motion stays discovery, and has a right to an immediate appeal.

Bonni v. St. Joseph Health System, 13 Cal. App. 5th 851 (July 26, 2017), review granted 11/1/17:

- Surgeon reported suspected unsafe and substandard conditions and services at the hospital, including in the robotics surgery facilities.
- The Hospital MEC summarily suspended and ultimately denied his medical staff privileges after hearing.
- Surgeon sued alleging retaliation for his whistleblower complaints. The trial court granted the Hospital's anti-SLAPP Motion. Surgeon appealed.

Bonni v. St. Joseph Health System

- Following *Park v. Board of Trustees of California State University* (2017) 2 Cal.5th 1057 and *Nam v. Regents of University of California* (2016) 1 Cal.App.5th 1176, this decision holds that a whistleblower suit under H&S Code 1278.5 could not be stricken under the Anti-SLAPP statute.
- The alleged wrongful purpose or *motive* was not protected activity, so the defendant could not satisfy the first prong of an Anti-SLAPP motion to strike.

Melamed II (Melamed v. Cedars Sinai, unpublished (Oct. 26, 2017))

- *Melamed I*, 8 Cal. App. 5th 1271 (Feb. 27, 2017) affirmed the trial court's grant of the hospital's special motion to strike.
- The Supreme Court transferred it back to the Court of Appeal for reconsideration in light of *Park*.
- Reversing its initial rule affirming the trial court, the Court held that "[i]n this case, as in *Bonni* [citation], the hospitals alleged retaliatory motive in suspending Melamed and subjecting him to a lengthy and allegedly abusive peer review proceeding is the basis on which liability is asserted. The alleged liability does not arise merely from the initiation and pursuit of the proceedings or from statements made during those proceedings."
- "Accordingly, the hospital cannot make a prima facie case that Melamed's causes of action arose from their protected activity… Consequently, we cannot proceed to the second step to determine whether Melamed has shown a probability of prevailing on his claims."

Central Valley Hospitalists v. Dignity Health, 2018 Cal. App. LEXIS 18 (Jan. 9, 2018):

- A group of doctors providing hospitalist services to the hospital alleged unfair business practices and interference claims based on the hospital harassing group physicians, inducing them to leave the group, discouraging others from working with the group, and referring their patients to other providers.
- The complaint expressly stated that it was not alleging any wrongs arising from peer review activities.
- Defendant hospital filed a demurrer on the basis that the complaint did not state sufficient facts to state a claim.
- Defendant also filed an anti-SLAPP motion arguing that the claims arose from protected peer review.

Central Valley Hospitalists

- Trial court sustained the demurrer. Since the complaint did not allege sufficient facts to state a claim on demurrer, the court then determined on the motion to strike that "[i]f there are no acts alleged, there can be no showing that alleged acts arise from protected activity."
- Thus, any first prong determination must necessarily be deferred until plaintiffs allege acts committed by the hospital.
- The trial court did not exclude a possible anti-SLAPP motion directed to an amended complaint. Despite the apparent prematurity of the motion, the hospital appealed.

Central Valley Hospitalists

- The Court of Appeal affirmed in an opinion strongly disapproving of the defendant's argument and decision to press the issue on appeal.
- The anti-SLAPP motion was properly denied because the complaint contained no allegations of protected activity.
- The Court, ***sua sponte***, considered imposing sanctions on the hospital and/or its counsel for taking a frivolous appeal.

Central Valley Hospitalists

- In response, the hospital's counsel tried to dismiss the appeal. The court did not file the dismissal. Instead, it affirmed the trial court.
- Further, the court was not persuaded by counsel's explanations of why the appeal was not frivolous.
- For unknown reasons, however, the plaintiffs did not express interest in sanctions being issued, and so the court left it there rather than issuing sanctions that would require reporting of counsel to the State Bar.

Retaliation/Peer Review

- Take aways:
  - The areas in which an anti-SLAPP motion to strike can apply to quickly resolve a lawsuit appear to be narrowing. Properly plead discrimination and retaliation claims may no longer be subject to motions to strike because those claims attack wrongful motives, not the official proceedings in which the wrongful motives bring about adverse employment actions.
  - These types of claims are premised on the plaintiff having made a complaint, enhancing the benefits for employers to institute systems to track complaints, procedures for investigating them, and keeping in mind that Health & Safety Code Section 1278.5 includes a rebuttable presumption of retaliation if the act occurs within 180 days of a complaint.
  - Employers should carefully consider the basis of the claims being asserted when filing an anti-SLAPP motion. Making a meritless motion (and appeal) could result in owing a plaintiff money or being issued sanctions.

California Litigation Highlights

Enforceability of Arbitration Clauses

Hutcheson v. Eskaton FountainWood Lodge, 17 Cal. App. 5th 937 (Nov. 28, 2017):

- Decedent appointed both her sister and her niece as attorneys-in-fact for personal care matters under the Power of Attorney Law (Prob. Code, § 4000 et seq.), but also appointed only her niece as attorney-in-fact to make health care decisions under the Health Care Decision Law (Prob. Code, § 4600 et seq.).
- The sister later admitted decedent to a licensed residential care facility for the elderly under the California Residential Care Facilities for the Elderly Act (Health & Saf. Code, § 1569 et seq.), executing an admissions agreement that contained an arbitration provision.
- Decedent later passed away at a hospital after she choked on food at the facility, which caused her to develop severe dysphagia and aspiration pneumonia. Sister and niece then sued the facility for elder abuse, fraud, and negligent infliction of emotional distress, but the facility moved to compel arbitration.
- The trial court denied motion, ruling that the admission agreement was invalid as *beyond the scope* of the sister's authority as a personal care attorney-in-fact. FountainWood appealed.

Hutcheson v. Eskaton FountainWood Lodge

- The Court of Appeal affirmed, holding that the sister lacked authority to execute the admissions agreement for a dementia care facility.
- FountainWood had received the health care power of attorney naming the niece as attorney-in-fact, and therefore knew that only the niece had authority to make health care decisions for the decedent.

Baker v. Italian Maple Holdings, LLC, 13 Cal. App. 5th 1152 (July 31, 2017):

- The decedent signed two agreements shortly after being admitted to a skilled nursing facility, each of which contained arbitration provisions including the language required by Code of Civil Procedure 1295.
- She passed away 10 days after signing the agreements. The heirs sued, and the facility petitioned to compel arbitration.
- The trial court denied the petition under *Rodriguez v. Superior Court,* 176 Cal.App.4th 1461, 1469-1470 (2009), which held that arbitration agreements in medical services contracts cannot be enforced if the patient dies before section 1295's 30-day rescission period expires. The facility appealed.

Baker v. Italian Maple Holdings, LLC

- The Court of Appeal reversed, disagreeing with *Rodriguez*.
- The plain language of section 1295 requires arbitration agreements to govern the signing parties' relationship *upon execution* "until or unless" either party rescinds within the 30-day rescission period.
- Thus, the woman's death before the expiration of the statutory period did not render the agreements unenforceable.

Enforceability of Arbitration Clauses

- Take Away:
  - The scope of authority under a power of attorney is critical, particularly where a patient has designated more than one.
  - Arbitration agreements *might be* otherwise binding upon execution.

California Litigation Highlights

Patient Personal Rights Claims

Julian v. Mission Community Hospital, 11 Cal. App. 5th 360 (May 2, 2017):

- Middle school teacher was removed from her school by police on a 5150. She sued the school, the police, the hospital, and the physician who examined her, alleging violations of the Lanterman-Petris-Short Act (Welf. & Inst. Code, §§ 5000 *et seq*.) and her civil rights under the federal and state constitutions.
- Trial court ruled that plaintiff had no private right of action under the provisions of the Act she invoked and the medical defendants were protected by the Act's immunity provision (*id*., § 5278). She also failed to demonstrate that the medical defendants were state actors for purposes of her civil rights claims.

Julian v. Mission Community Hospital

- The Court of Appeal affirmed, deciding as an issue of first impression that the provisions of the Act invoked by plaintiff conferred no private rights of action.
- The medical defendants were not state actors under 42 U.S.C. § 1983 and therefore could not be liable for violating plaintiff's rights under the federal and California Constitutions.
- Mere "'extensive government regulation of a private business is insufficient to make that business a state actor'" if the challenged conduct was not compelled by the state.

Stewart v. Superior Court, 16 Cal. App. 5th 87 (Oct. 12, 2017):

- Elderly patient died after admission to hospital. His designee sued, alleging that the hospital denied and withheld the patient's right to refuse an unnecessary surgery, the right to be involved in secret hospital meetings to invalidate his designated consent, and the right to a second opinion prior to proceeding with an unwarranted surgery that resulted in his death.
- Trial court granted the hospital's summary adjudication on the causes of action for elder abuse, medical battery, and fraudulent concealment, allowing other claims including medical negligence to proceed to trial. Plaintiff sought a peremptory writ of mandate.

Stewart v. Superior Court

- The Court of Appeal issued the peremptory writ directing the court to vacate the summary adjudication and substitute an order denying the motion.
- "[W]e find it important to emphasize that elders have the right to autonomy in the medical decisionmaking process." Substantial impairment of this right can constitute actionable "neglect" of an elder within the meaning of Welfare and Inst. Code §15610.57(a)(1) and §15610.57(a)(2).
- "[L]abeling this case one for no more than professional negligence seriously undervalues the interest Carter had in consenting or objecting to the surgery that, in the opinion of Stewart's experts, contributed to his death."
- The designee showed triable issues regarding custodial neglect when the hospital authorized the patient's pacemaker surgery over the designee's repeated objections.
- Triable issues also existed as to whether the hospital's actions qualified as reckless.

Patient Personal Rights Claims

- Take Aways:
  - No private right of action under the Lanterman-Petris-Short Act.
  - Hospitals are not state actors simply based on extensive regulation.
  - Ignoring or impairing a personal right of autonomy can be found to constitute neglect.

California Litigation Highlights

Health Care Worker Meal-Period Waivers

Gerard v. Orange Coast Memorial Medical Center, 9 Cal. App. 5th 1204 (Mar. 1 2017) (*Gerard II*); review granted by: 219 Cal. Rptr. 3d 908 (July 12, 2017):

- Three health care workers sued their hospital employer for illegally allowing them to waive their second meal periods on shifts exceeding 12 hours.
- Labor Code section 512, subdivision (a), requires employees to take two meal periods for shifts exceeding 12 hours, but Industrial Wage Commission Wage Order No. 5-2001, section 11(D), has authorized health care workers to waive one required meal period on shifts exceeding 8 hours.
- The trial court granted summary judgment to the hospital. The Court of Appeal affirmed, holding that the Wage Order was valid.
- "As a result, the second meal period waivers signed by plaintiffs in this case, 'were valid and enforceable on and after October 1, 2000, and continue to be valid and enforceable.'"

Gerard v. Orange Coast Memorial Medical Center

- The California Supreme Court granted review and will address the following questions:
  - (1) Did Senate Bill 327 constitute a change in the law or a clarification in the law?
  - (2) Is Wage Order No. 5, section 11(D), partially invalid to the extent it authorizes healthcare workers to waive their second meal periods on shifts exceeding 12 hours?
  - (3) To what extent, if any, does the language of section 516 regarding the "health and welfare of those workers" affect the analysis?

Issues and Cases to Watch:

- *Bonni* and *Melamed II* are both on appeal, so expect clarification regarding the role of motive in an anti-SLAPP context.
- *Baker* is not on appeal, but raises a court split that should result in further clarification regarding C.C.P. § 1295.
- *Gerard II* is on appeal, so expect further guidance with regard to meal waivers.

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Stark, Anti-Kickback, and the False Claims Act: Recent Developments and Hot Topics

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Stark, Anti-Kickback, and the False Claims Act: Recent Developments and Hot Topics

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Overview

- Stark Law Developments
- Recent Anti-Kickback Cases
- Gainsharing Advisory Opinion
- Post-*Escobar* "Materiality" Standard in False Claims Act Cases
- The 60-Day Overpayment Rule: Stories from the Trenches

Recent Stark Case – Mercy Hospital (MO)

- Mercy Hospital and Mercy Clinic entered into a $34 million settlement and CIA to resolve allegations that the compensation formula for employed oncologists violated the Stark Law by improperly accounting for referrals of patients to the hospital infusion center.
  - Outpatient infusion clinic was converted to hospital department
  - Oncologists had been sharing in profits and were told they would be "made whole" by a wRVU credit for drug administration
  - wRVU credit was a proxy to keep the compensation at the same level
  - Complaint also alleged compensation was above FMV and not commercially reasonable

Stark Law - Applying the New Writing Requirement Guidance

U.S. ex rel. Tullio Emanuele v. Medicor Associates Inc. et al. No. CV 10-245, W.D. Pa. (Mar. 15, 2017)

- Medicor – a private physician practice group - was the exclusive outside cardiology provider at Hamot Medical Center.
- Hamot had several medical directorship arrangements with Medicor physicians. Only six were documented in written contracts.
  - Contracts signed by the parties with termination on December 31, 2006, if not formally extended
  - Parties did not formally extend contracts but Medicor continued to provide services and Hamot continued to pay for services
  - In November 2007, the parties executed written addenda, retroactive to January 1, 2007. However, under the addenda, contracts were set to terminate on December 31, 2007, unless formally extended. Once again, there was no formal extension and Medicor continued to provide services and Hamot continued to pay.

Stark Law - Applying the New Writing Requirement Guidance

- In 2008, Hamot created a new medical directorship position.
  - Emails, memoranda, and a draft written contract document this arrangement, but there was no signed, written agreement
  - Medicor physician Dr. Kelly Hayes performed the role of medical director from sometime in 2008 until March 31, 2010, and Hamot paid her for those services
- Also in 2008, Dr. Robert Farraro assumed the administrative duties as the head of Hamot's Department of Cardiovascular Medicine and Surgery.
  - The parties never executed a written contract but Dr. Farraro provided services and was paid for this position until March 31, 2010
- In 2010, a former physician member of Medicor filed a *qui tam* action alleging that the medical directorship arrangements between the parties violated the Stark Law.

Stark Law - Applying the New Writing Requirement Guidance

- The Court had to decide whether the arrangements met the personal services arrangements or fair market value exceptions, both of which require a signed writing.
- For the medical director agreements that took effect in 2006 and lapsed, the court looked for written evidence of the agreement's term, services, and compensation:
  - Medicor and Hamot pointed to invoices, checks, and the lapsed written contracts in arguing that the compensation terms were consistently followed and argued the description of services, timeframe, and signature requirements were satisfied through original agreements and later addenda
  - The court agreed - "[w]hen viewed in conjunction with the original written agreements and the subsequent addenda, each of which are formalized documents that meet the statutory standards, a reasonable jury could conclude that the defendants presented the necessary collection of documents."

Stark Law - Applying the New Writing Requirement Guidance

- The court disagreed with defendants about the later medical director arrangements
  - For the Dr. Hayes arrangement, defendants pointed to emails, memoranda, and an unsigned draft of a written agreement
    - The court found that while this collection of documents provided some indication of the services, there was still lack of written evidence as to the compensation and timeframe of the arrangement
  - For the Dr. Farraro arrangement, the defendants pointed to Hamot's bylaws, organizational manual, meeting minutes, invoices, general ledger, and emails
    - The court concluded that there were only uncertain references to the arrangement's timeframe or compensation; the court also noted the lack of signatures by either party
- The court concluded that no reasonable jury could find that either of these arrangements met the Stark Law's writing requirement

Stark Law – CMS Advisory Opinion No. 2017-01

- Laboratory proposed to provide pop-up notifications on the laboratory's portal used by physicians to order and receive laboratory test results
- The pop-ups would alert physicians of various potential issues relating to the particular test result being reported
- The alerts would be available free of charge to physicians who used the portal to order testing services from the laboratory
- CMS concluded that the arrangement would not create a compensation arrangement because the alerts will be used solely in connection with ordering or communicating test results

Stark Law – CMS Advisory Opinion No. 2017-01

> "An essential consideration in our analysis is that Laboratory Alerts assist physicians in the deliberative process of determining which additional tests, if any, to order from Requestor. In this context, we believe that **safeguards are necessary to ensure that the Laboratory Alerts are used solely to communicate and order tests, as opposed to being used also to encourage overutilization or medically unnecessary or duplicative testing**. Requestor certified that the Portal, as equipped with Laboratory Alerts, includes such safeguards. First, the **recommendations for additional testing** provided in Laboratory Alerts **will be based on industry standard, peer-reviewed guidelines**. Second, Laboratory **Alerts are not overly intrusive**, and they do not override the physician's independent judgment. Where multiple additional tests are recommended, **there is no "select all" button**. Likewise, physicians have the **ability to turn off Laboratory Alerts for a particular disease condition**. Third, the **information provided** in Laboratory Alerts is **available free of charge from other sources**. Thus, Laboratory Alerts do not incent a physician to order additional tests in order to gain access to information for which he or she would otherwise have to pay."

Proposed Legislation to Reform the Stark Law

Stark Administrative Simplification Act of 2017 (HR 3726)

- Revises penalties for technical violations
  - Violations must be **inadvertent** and **self-disclosed**
- Technical violations include
  - Absent signatures
  - Lapsed term (holdover arrangements)
  - Failure to meet writing requirement

- Alternative protocol for technical noncompliance
- CMPs pursuant to the alternative protocol
  - $5,000 – where disclosure of technical noncompliance made no more than one year after the initial date of technical noncompliance
  - $10,000 - where disclosure of technical noncompliance made between one to three years from the initial date of technical noncompliance

Recent Cases – Houston-area HCA Hospitals

- Four Houston area HCA hospitals entered into an $8.6 million settlement to resolve allegations that they received kickbacks from various ambulance companies in exchange for the hospitals' referrals for Medicare and Medicaid transports
- Lawsuit alleged the hospitals accepted kickbacks in the form of deeply-discounted rates for their facility-responsible transports and free or deeply discounted wheelchair van service in exchange for agreeing to an exclusive contract with the ambulance companies for all transports that were separately payable by the federal health care programs

- Ambulance companies were also named as defendants in the lawsuit
- Trend of the government pursuing enforcement against the facilities and the ambulance companies

*Bayshore Medical Center, Clear Lake Regional Medical Center, West Houston Medical Center and East Houston Regional Medical Center

Recent Cases – Pacific Medical Center

- Pacific Alliance Medical Center entered into a $42 million settlement and a CIA to resolve allegations that it paid above-market rent to physicians and engaged in inappropriate marketing agreements with referring physicians.
  - Relator alleged the hospital violated the Stark Law and Anti-Kickback Statute in its arrangements with physicians for community outreach
  - Conduct included paying above market rent for using physicians' office space to hold community meetings; rental rate also depended on the physicians' referrals to the hospital
  - The hospital engaged in a "shared marketing program" that advertised the physicians' services
  - Participation in these programs was conditioned on achieving admissions targets

Recent Cases – IU Health and HealthNet

- IU Health allegedly paid kickbacks to HealthNet, an FQHC, in the form of an interest-free line of credit to induce HealthNet practitioners to refer OB/GYN patients to IU Health's hospital.
- HealthNet was alleged to have drawn down $10 million in excess of the line of credit permitted under the affiliation agreement with no expectation to repay the balance.
- IU Health and HealthNet paid a combined $18 million to settle the FCA case brought by a physician who worked at both the hospital and the FQHC.
  - Each defendant paid $3.9 million to Indiana Medicaid

Gainsharing: OIG Advisory Opinion 17-09

- Analyzed gainsharing arrangement between a medical center and neurosurgeons based on cost savings for spinal fusion products over a three-year period.
- Strong infrastructure includes medical center subsidiary to administer the arrangement, a program administrator, and an oversight committee .
- Patients are notified of the arrangement and that the group will be compensated based on cost savings to the medical center.
- The group would share in 50% of the cost savings (less certain administrative costs) and distribute payments to the neurosurgeons on a per capita basis.

Gainsharing: OIG Advisory Opinion 17-09

- First gainsharing opinion after the CMP law was revised to apply only to payments that induce a physician to reduce or limit medically necessary services.
- OIG found the following factors reduced the risk of violating the gainsharing CMP:
  - Method used to develop the cost-saving recommendations
  - Monitoring and documentation safeguards
  - Method for calculating the savings

Gainsharing: OIG Advisory Opinion 17-09

- Factors evidencing low risk of fraud and abuse under the AKS:
  - Per capita distribution of savings, capped savings based on number of spinal fusions in base year, capped cost savings based on projections at the start of the term, and monitoring of patient selection reduce incentive to increase referrals.
  - Annual rebasing method prevents duplicate payments for realized savings.
  - Neurosurgeons provided compensable services in developing the program.
  - All 34 cost-saving recommendations are described specifically and incentives are tied to verifiable cost savings.
  - Neurosurgeons still have access to all products they formerly used.
  - Program is limited to neurosurgeons in existing group.
- Open Question: how does the Stark Law apply?

The *Escobar* "Materiality" Standard

- *Universal Health Services Inc. v. U.S. ex rel. Escobar et al.*, 136 S. Ct 1989 (June 2016)
  - Complaint asserted violations of the FCA - UHS "submitted reimbursement claims that made representations about the specific services provided by specific types of professionals, but that failed to disclose serious violations of regulations pertaining to staff qualifications and licensing requirements for those services."

The *Escobar* "Materiality" Standard (cont.)

- The Supreme Court held that implied false certification can be a basis for liability:
  - The claim must not merely request payment, but also make specific representations about the goods or services provided.
  - The defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements must "make[ ] those representations misleading half-truths."
  - The violation need not be of a contractual, statutory, or regulatory provision that the Government expressly designated as a condition of payment.
  - The misrepresentation must be "material to the Government's payment decision."

Escobar "Materiality" Standard – 9th Circuit

United States ex rel. Campie v. Gilead Scis., 862 F.3d 890 (9th Cir., July 2017)

- Relators alleged drug company imported HIV drugs from China that failed to comply with FDA regulations. Gilead represented to the FDA and others that it would source materials only from Canada, Germany, the US and South Korea.
- Government alleged that by submitting claims for "FDA approved drugs," Gilead impliedly certified that its drugs were made pursuant to FDA requirements (*i.e.*, with sources from approved countries).
- Court held that the relator adequately pled an FCA violation notwithstanding the fact that Medicare continued to pay Gilead for the drugs, even after it became aware of the FDA violations.

Escobar "Materiality" Standard – 9th Circuit

"Here, Gilead insists that because the government continued to pay for the medications after it knew of the FDA violations, those violations were not material to its payment decision. Relators outline a variety of facts that speak to the government's knowledge, such as a September 2010 warning letter regarding impurities in the form of black specks and spots, a June/July 2012 inspection and noncompliance letter regarding product from Synthetics China, December 2012 and July 2013 inspections of a specific facility, and two recalls that took place in 2014. **Gilead's argument is premised on the continued FDA approval of the drugs even after the agency became aware of certain noncompliance**. Relators and the United States persuasively argue, however, that **to read too much into the FDA's continued approval—and its effect on the government's payment decision—would be a mistake**. First, to do so would allow Gilead to use the allegedly fraudulently obtained FDA approval as a shield against liability for fraud. Second, as argued by Gilead itself, **there are many reasons the FDA may choose not to withdraw a drug approval, unrelated to the concern that the government paid out billions of dollars for nonconforming and adulterated drugs**. Third, … **Gilead ultimately stopped using FTC from Synthetics China**. **Once the unapproved and contaminated drugs were no longer being used, the government's decision to keep paying for compliant drugs does not have the same significance** as if the government continued to pay despite continued noncompliance…"

Escobar "Materiality" Standard – *Genentech* Case

U.S. ex rel. Petratos v. Genentech Inc., 855 F.3d 481, 490 (3d Cir., May 1, 2017)

- Relator alleged that Genentech concealed information about cancer drug's risks and that the reporting of such information would have required Genentech to file adverse-event reports with the FDA, which could have resulted in changes to the drug's FDA label.
- Relator alleged that this concealment caused physicians to submit Medicare claims that were not reasonable and necessary.
- However, relator made no allegation that the government would have denied payment if it knew of alleged violations.
- The court concluded that the alleged data suppression was minor and insubstantial noncompliance.
- Moreover, there were subsequent government actions and inaction that counseled against a finding of materiality: (1) FDA approved expanded use of the cancer drug after relator's allegations were disclosed to FDA; (2) FDA never initiated enforcement; and (3) DOJ declined to intervene.

Escobar "Materiality" Standard – *Prather* Case

United States ex rel. Prather v. Brookdale Senior Living Cmtys., Inc., Case No. 12-cv-764 (M.D. Tenn., June 2017)

- Relator, a nurse employed by Brookdale to perform utilization review, alleged that Brookdale violated the FCA by (1) billing Medicare for home health services, despite knowing that it had not obtained face-to-face documentation or physician signatures on certifications at the time that the physician established the patient's plan of care "or as soon thereafter as possible," as required by Medicare rules; and (2) retaining such payments after reimbursement by Medicare, despite knowing that Medicare would not have paid the claims if it had known about Brookdale's failure to comply with the "as soon as possible" requirement.
- Realtor couldn't point to a single instance in which Medicare denied a claim because the physician signature was obtained after Brookdale submitted a claim.
- The court held that failing to obtain the required physician signature to certify a need for home health care before submitting a bill to Medicare doesn't make the claim fraudulent.

Escobar "Materiality" Standard – *Ruckh* Case

United States ex rel. Ruckh v. Salus Rehabilitation, LLC, 2018 WL 375720, M.D. Fla., Jan. 11, 2018

- Relator worked at two SNFs owned or operated by defendants. Relator claimed that defendants falsified the minimum data set assessments submitted to CMS, making the resulting claims based on those MDS assessments false. Allegations included:
  - That residents' medical needs and the amount of care provided to them were overstated
  - That defendants did not complete residents' care plans but nonetheless reported on MDS Assessments that they had completed care plans
  - That employees who were not RNs falsely certified the completeness of MDS assessments using the electronic signature of an RN who had not reviewed or certified the proper completion of the MDS assessment

Escobar "Materiality" Standard – *Ruckh* Case (cont.)

United States ex rel. Ruckh v. Salus Rehabilitation, LLC, 2018 WL 375720, M.D. Fla., Jan. 11, 2018

- District Court judge overturned a ~$350 million False Claims Act verdict against the nursing home operator defendant:
  - The relator's witnesses were unable to testify on the controlling question of whether the government would refuse to pay claims due to a deficiency by "a health care provider engaged actively in providing qualified and essential health care to thousands of aged, infirm, and dependent patients at scores of residential facilities throughout the third largest state in the United States."
    - "My guess is that under these circumstances no government answerable to the people would refuse to pay, especially in Florida and especially in the pertinent patient population, unless every administrative and other remedy was exhausted and until an alternative provider was identified and prepared to capably serve the same patients without interruption."

Escobar "Materiality" Standard – *Ruckh* Case (cont.)

United States ex rel. Ruckh v. Salus Rehabilitation, LLC, 2018 WL 375720, M.D. Fla., Jan. 11, 2018

- "[T]he controlling question is … whether on a large scale, on the scale of a major statewide provider of a scarce health care resource in a large and potent state, the federal government or the state government would refuse to pay the provider because of a dispute about the method or accuracy of payment after the government has permitted a practice to remain in place for years without complaint or inquiry."
- Court ruled the relator "offered no meaningful and competent proof that the practices were "material to each government's decision to pay the defendants…"
- "In fact, both governments were — and are — aware of the defendants' disputed practices, aware of this action, aware of the allegations, aware of the evidence, and aware of the judgments for the relator — but neither government has ceased to pay or even threatened to stop paying the defendants for the services . . . [f]or these and for each of the other reasons argued by the defendants, the judgments cannot stand."

The 60-Day Overpayment Rule

October 2017 Settlement

- First Coast Cardiovascular Institute, P.A. agreed to pay nearly $450,000 to resolve FCA allegations that it knowingly delayed repayment of more than $175,000 owed to federal health programs.
- *Qui tam* filed by former executive director, who noticed that financial records did not reflect a credit balance for overpayments. His follow-up inquiries to CFO and CEO were ignored and deflected for over a year.
- Overpayments were reported as cash or assets in revenue reports.

The 60-Day Overpayment Rule: Mount Sinai Audit

April 2017 OIG Audit Report for Mount Sinai

- OIG found nearly $42M in overpayments for the audit period 2012-2013
  - Most claims were outside the four-year Medicare claims reopening window because audit report was published in 2017.
  - Nonetheless, OIG states that under the 60-day repayment rule, Mt. Sinai should "exercise reasonable diligence" to identify and return overpayments that are outside the four-year reopening period but within the six-year lookback period of the 60-day repayment rule.
  - OIG also recommended that Mt. Sinai "exercise reasonable diligence to identify and return any additional similar overpayments outside of our audit period, in accordance with the 60-day rule."

The 60-Day Overpayment Rule: Mount Sinai Audit

- "Providers must exercise reasonable diligence to determine whether overpayments of a similar type existed during a 6-year lookback period. Providers are obligated to quantify the entire amount of overpayment for this period and may do so by using a statistically value extrapolation methodology."
- OIG was not persuaded by the fact that the hospital had challenged many of the OIG's audit findings.
  - Some findings were not disputed
  - The disputed findings were subjected to additional review and OIG continued to stand behind most of them
  - OIG noted that federal courts have upheld its extrapolation methodology as a valid method to determine Medicare overpayments

The 60-Day Overpayment Rule: Stories from the Trenches

- Does the 60-Day Overpayment Rule apply to violations of Conditions of Participation?
  - Parts A and B final rule indicates overpayments result from violations of "payment rules"
  - Remains to be seen whether "reverse false claims" cases will apply an *Escobar*-like materiality standard
- Be prepared to respond to potential overpayments:
  - Put in place a reasonable overpayment investigation policy
  - If billing systems change, make sure there is an efficient way to run reports for the previous 6 years
  - Ask questions to make sure you understand how data is reported for your issue. For example, does a report for a duplicate billing issue include only the duplicates or the payable items as well?

Thank You!

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Update on Medicare Provider-Based & Site-Neutral Payment Rules

PRESENTED BY

Jordan Keville | Partner

Agenda

- Review of Provider-Based Rules - requirements and reimbursement significance
- Review of Site-Neutral Payment Policies - general policies and exceptions
- Intersection Between Provider-Based and Site-Neutrality Rules - what's still provider based, what is not, and is there a way to expand existing provider-based sites?
- Discussion - hypotheticals

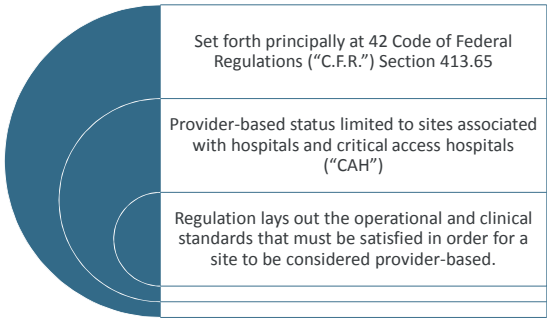
What is Provider-Based Status?

A Medicare concept that allows services rendered outside of the main location of a hospital provider to be treated as hospital services for billing, payment and certain other purposes.

Why is Provider-Based Status Important (at Least, Historically)?

- Allows a provider-based site to appear on a hospital's Medicare cost report and receive an allocation of the hospital's overhead.
- Makes provider-based sites eligible for higher rates of payment as compared to non-hospital settings, like physician clinics and ambulatory surgery centers — subject to new site-neutral payment policies.
- Certain services, such as partial hospitalization services, must be furnished in certain settings in order to be covered by Medicare.

Requirements for Obtaining Provider-Based Status



Requirements for Obtaining Provider-Based Status (Cont.)

- UNIVERSAL REQUIREMENTS
  - Common Licensure - as determined under state law.
  - Financial Integration - must be treated like any other hospital department on Medicare cost report.
  - Clinical Integration - same clinical oversight as any other hospital department, included in unified medical record system, medical staff of hospital have privileges at site/location.
  - Public Awareness - general public must be aware when entering site that it is part of the hospital and they will be treated as hospital patients.
  - Under Arrangements - not all patient care services at the facility/location may be provided under arrangement.

Requirements for Obtaining Provider-Based Status (Cont.)

- SPECIAL REQUIREMENTS FOR OFF-CAMPUS LOCATIONS
  - Common Ownership - same legal entity and governing body.
  - Administration and Supervision - supervised in the same way as any other hospital department; HR, billing, payroll, benefits, etc., done by same department/employees that service other parts of hospital.
  - Location - within 35 miles of main provider or meet certain other requirements.
  - NOTE: No joint ventures permitted for off-campus sites.

Obligations of Provider-Based Departments

- Once provider-based status is conferred, the location is subject to certain compliance obligations :

  - Provider Agreement/Conditions of Participation: All the terms of a hospital's Medicare provider agreement apply equally to a provider-based department, which means deficiencies/ non-compliance at any site have implications for the hospital's Medicare participation status.
  - EMTALA: if on-campus, EMTALA applies to the provider-based unit as part of the hospital; if off-campus, EMTALA requirements apply only if the location qualifies as a "dedicated emergency department."
  - Patient Status: Must treat all patients as hospital outpatients for billing purposes, etc.
  - Notices to Patients: Off-campus provider-based locations must advise beneficiaries that they are subject to coinsurance obligations associated with both the professional and facility component of services.

Payment Implications of Provider-Based Status

- Differential Payment Rates: Medicare generally pays a higher aggregate payment for diagnostic and therapeutic services furnished in a hospital-based department as compared to the same services being furnished in another setting like a physician clinic.
- Rate differential intended to account for higher costs of furnishing services in a facility setting.
- Billing Requirements: Facility services rendered in provider-based outpatient departments are billed to MACs using billing form UB-04, while physician services are billed on the CMS 1500 claim form. Services performed in a freestanding physician clinic result in only one bill on the 1500 claim form.

Additional Implications of Provider-Based Status

- Federal 340B drug discount program: An off-site department must be recognized by Medicare as provider-based in order to dispense drugs acquired at 340B prices to hospital patients.
- Medical Education Program Payments: For hospitals that operate medical resident training programs and receive additional reimbursement from Medicare accordingly, residents rotating in provider-based locations count for purposes of calculating IME/GME reimbursement.
- Provider-Based Rural Health Clinics, Skilled Nursing Facilities and Home Health Agencies: Traditionally received greater rates of reimbursement than entities not affiliated with hospitals.

Recent Developments – Scaling Back the Benefits of Provider-Based Status

- Starting sometime after 2010, various regulatory agencies and organizations, including the Centers for Medicare Services and the HHS Office of the Inspector General and Medicare Payment Advisory Commission ("MedPAC") started to express concern that the higher, differential payment rates generally enjoyed by provider-based units was not justified.
- These organizations questioned whether the services being rendered in provider-based departments added anything beyond the same care furnished in other settings, so as to justify the higher payments. They began pushing for a legislative or regulatory change to potentially eliminate the payment differential.

Legislative and Regulatory Changes – The Move to Site-Neutral Payments

- BIPARTISAN BUDGET ACT OF 2015
  - Section 603 of the Bipartisan Budget Act: Establishes that provider-based departments established after the date of the statute's enactment many not be paid under the Medicare Outpatient Prospective Payment System ("OPPS") for services rendered on or after January 1, 2017.
  - Several Exceptions to General Elimination of OPPS Treatment of "New" provider-based locations:
    - *Dedicated emergency departments;
    - *On-campus provider-based units (within 250 years of the main campus)
    - Off-campus provider based department that already was billing under OPPS as of November 2, 2015 ("grandfathered" provider-based units).

Legislative and Regulatory Changes – The Move to Site-Neutral Payments (Cont.)

NOVEMBER 14, 2016, FINAL RULE	Published by the Centers for Medicare and Medicaid Services on November 1, 2016, after an active comment process with significant input provided by the hospital industry.
	Promulgates formal regulations to expanding and clarifying the basic requirements set forth in the BBA of 215 regarding site-neutral payments.

Legislative and Regulatory Changes – The Move to Site-Neutral Payments (Cont.)

NOVEMBER 14, 2016, FINAL RULE (Cont.)	Establishes what payment methodology applies to facility services rendered at provider-based units that cannot bill under OPPS (the "applicable payment system");
	For CYs 2017 and 2018, professional services rendered in provider-based units paid under the physician fee schedule; facility services paid at a reduced OPPS rate (50% of normal OPPS payment for 2017, 40% of normal OPPS payment for 2018).
	Clarifies Scope of Exceptions to Elimination of OPPS Treatment: Among other things, CMS clarifies that provider-based facilities will lose grandfathering status for payment purposes if relocated.
	Addresses status of provider-based units that were in "mid-build" at the time the BBA of 215 was enacted.

Legislative and Regulatory Changes – The Move to Site Neutral Payments (Cont.)

NOVEMBER 14, 2016, FINAL RULE (Cont.) – the "Grand-fathering" Exception	Off-Campus provider-based units that were furnishing services and billing OPPS as of November 2, 2015, can continuing billing OPPS for facility services.
	An off-campus provider-based unit that was in operation and billing under OPPS as of November 2, 2015, will lose grandfathered status if it relocates.
	For purposes of relocation limitation, location of provider-based unit is determined by CMS using information in provider's enrollment profile as of November 2015.
	Only exception to relocation bar is for "circumstances outside of a hospital's control" like natural disasters, significant seismic building code changes and significant public health/safety issues.
	Bar on relocation does not necessarily preclude a provider-based unit from expanding the scope of services furnished, as long as the physical location does not change.

Legislative and Regulatory Changes – The Move to Site-Neutral Payments (Cont.)

NOVEMBER 14, 2016, FINAL RULE – Expansion of services and changes in ownership	Bar on relocation for grandfathered off-campus provider-based units does not necessarily preclude an entity from expanding the scope of services furnished within them, as long as the physical location does not change.
	A grandfathered provider-based unit will retain the ability to bill OPPS after a change in ownership only if the entire hospital facility, including the provider-based unit, is acquired by a new owner and the new owner accepts assignment of the previous owner's Medicare provider agreement.

Legislative and Regulatory Changes – The Move to Site-Neutral Payments (Cont.)

- 21st CENTURY CURES ACT
  - Enacted in 2017.
  - Expands/clarifies grandfathering exception to general elimination of OPPS billing for provider-based units .
  - Under the statute, providers will be deemed to have been billing under OPPS as of November 2, 2015, if that provider submitted to CMS a provider-attestation as of that date. That means as long as the attestation was filed, the provider-based unit will get grandfathering treatment even if it was not actually providing services and billing under OPPS as of November 2, 2015.

Where Are We Now? Does Provider-Based Status Still Matter?

PREFERENTIAL PAYMENT TREATMENT

Provider-based status is not nearly as financially advantageous as it used to be.

- Many locations that would have been able to qualify as new off-campus provider-based departments in the past and, consequently, receive both a facility and professional payment for services, no longer qualify for that payment treatment.
- Even for facilities that meet the exceptions to the site-neutral payment policies, the overall differential in payments has been reduced.
- Still some positive impact on payment rates for provider-based units that meet exceptions to site-neutral payments.

Where Are We Now? Does Provider-Based Status Still Matter? (Cont.)

OTHER CONSIDERATIONS

Provider-based status still matters for reasons other than payment differential

- 340B – Off-site hospital locations still must meet provider-based requirements in order to dispense 340B discounted drugs to hospital patients.
- IME/GME – provider-based status still relevant to what resident rotations factor into IME/GME reimbursement calculations.

Where Are We Now? Does Provider-Based Status Still Matter? (Cont.)

- STRATEGIC CONSIDERATIONS
  - Is it still beneficial to the hospital to operate off-campus units as provider-based?
  - Expansion and relocation of existing units
    - For hospitals that have provider-based units that are exempt from site-neutral payments, decisions about expanding or relocating provider-based units are now more complicated.
    - Will the relocation of the provider-based unit cause the location to lose grandfathered preferential payment status?
    - If the provider-based unit will lose grandfathering because of a relocation, do the other practical/business, etc., advantages to relocation offset the loss of additional reimbursement under IPPS?

Where Are We Now? Does Provider-Based Status Still Matter? (Cont.)

- STRATEGIC CONSIDERATIONS
  - Beneficial for entities to develop a process for evaluating potential changes that can put site-neutral exempt status at risk.
  - Facilities should be aware of how all provider-based units are reflected in the Medicare enrollment records – what does CMS consider to be the location of the provider-based unit?
  - Facilities should be able to prove through documentation to demonstrate that certain provider-based units were in operation prior to November 2, 2015, and are therefore eligible for grandfathering exemption to site-neutral payments.

Where Are We Now? Does Provider-Based Status Still Matter? (Cont.)

- STRATEGIC CONSIDERATIONS
  - Not always entirely clear how a proposed change in services will impact a grandfathered provider-based location
    - Example 1: Provider-based unit is located in an off-campus medical office building. The unit is contemplating an expansion of services by taking over additional space in the same building that is currently empty. The unit will not change addresses, just add space at the same site. Is this a change in location for site-neutral payment purposes?
    - Example 2: An off-campus provider-based unit that meets grandfathering requirements is considering adding additional lines of service at the location, including occupational and physical therapy. Would expanding the services of this nature put the unit's grandfathered status at risk?

Current Issues in Health IT

PRESENTED BY

Jane Eckels | Partner

Agenda

- Cloud Services: Building Out Your IT Operations in the Cloud
- Changing Roles Through HIT Innovation: When a Provider Becomes an Innovator
- Meaningful Use: Update on EHR Incentive Programs and Advancing Care Information (MIPS)

Cloud Services On the Rise

- The rise of Cloud Computing
  - Speed of broadband networking
  - Enabling access to most current technologies as they are updated
  - Data explosion, mobility explosion
- Organizations are increasingly extending their infrastructure into the cloud
  - Not just about cost-cutting
  - Increased IT performance
  - Business agility
- Transforming IT operations
  - May have multiple deployment models, including on-premise and cloud based, public and private

The Cloud Paradigm

- The Promise
  - Computing as a commodity
  - Elastic, scalable, on-demand
  - Economies of scale = cost savings
- But it comes with challenges
  - Compliance, privacy and security - #1 customer issue
  - Infrastructure complexity
  - Standard solutions rarely fit 100%

Types of Cloud Services

- It's not just for EHRs
- Software as a Service (SaaS) (end user layer)
  - Big systems, such HRIS and ERP
  - Smaller applications, such as scheduling, email, social media
- Platform as a Service (PaaS) (application layer)
  - Web servers, databases, development tools
- Infrastructure as a Service (IaaS) (base layer)
  - Storage, virtual machines, data center servers

Public vs. Private Cloud Services?

- Private
  - Hosted at a service provider site
  - Supports one customer / client
  - Does not share infrastructure
- Public
  - Hosted at a service provider site
  - Shared infrastructure
  - Multiple clients
  - Lower price point

New or Amplified Risks

- Agreements with limited or no negotiability (shifted risk)
- Data breach / loss
- Business interruption (outages)
  - Ability to reclaim data
  - Replace services
- Government action
- Private actions and class action lawsuits
- Mitigation costs (notice and credit/identity monitoring)
- Loss of control (discovery, auditability, exit (lock-in))

Key Contract Terms

- **Privacy, Data Security**
- Service level commitments
- Changes in services
- Warranties
- Indemnification
- Limitation of liability
- Return of Data
- Insurance

Privacy and Security Concerns

- How is my data being used and for what?
- What security practices are in place and can my own policies be followed?
- Data transfer issues
- Data location issues
- Movement and storage of data
- Use of subcontractors
- Data breach protocol
- Data destruction issues
- Ability to impose privacy and security requirements
- Compelled disclosure to the government

Building Out in the Cloud – Security Issues

- Cloud Services come with a framework of security practices
  - These describe various controls used by a service provider to deliver services
  - Operations may be ISO 27002 or other standards
  - For large scale operations, cannot customize for particular customers
- Security Controls Scope
  - Physical, logical controls
  - Encryption
  - Account control
  - Incident response
  - Certifications, Audits
  - Use of subcontractors
- Auditing Controls
  - Auditing standards attest to adequacy of controls and safeguards
  - Statement on Standards for Attestation Engagement (SSAE 16)
  - SOC 1, 2 and 3
  - SAS 70 (Statement on Auditing Standards No. 70) is outdated

Security Incidents

- Breach-related provisions are more negotiated
  - Compliance with laws
- Defining “breach” or “security incident”
- Time frame for notification of breach upon discovery
  - Your receipt of notice may start your own clock for notice
- Who controls notice process (affected individuals, government reporting, etc.)?
- Who bears costs of: investigation, notification, mitigation, remediation
- Corrective action plan

Risk Allocation - Warranties

- Warranties are typically very limited
  - Performance: Substantial or material compliance with documentation for period of time, e.g., 90 days
  - Non-Infringement, Rarely: Warranties of non-infringement are not common
  - Non-degradation of services: Functionality of services will not be materially decreased
  - Exclusive remedy: Correction or reasonable efforts to correct
- Negotiation tips:
  - Determine if issues can be resolved through contractual commitments rather than warranties.
  - Consider appropriately crafted indemnities

Risk Allocation – Indemnities

- Indemnities almost always tied to third party claims
- Non-infringement – normally provided by vendors, may include qualifiers
- May also get coverage for compliance with laws
- Potential Traps:
  - Who has the legal compliance obligation? You or the vendor?
  - May only cover data breach if arising from breach of security obligations
  - Data breach only gives you protection if an affected person sues; does not cover other costs and liabilities, e.g., notification
  - Does it cover allegations and claims? There are still costs of defending even meritless claims.

Risk Allocation – Limitations of liability

- Current standard:
  - Disclaim all consequential damages
  - Cap on damages, usually a 12 month lookback or other cap related to customer spend
- Exclusions: Don't focus only on the liability number. The exclusions to the cap may be more significant.
  - Confidentiality/privacy/indemnity are the #1 negotiated items
  - Special (higher) caps are common, e.g., higher liability for privacy/security
  - Due to nature of damages, cap should include consequential damages
  - Increased liability for privacy/security tied to breach of security obligations, not strict liability
- Reminder: Limitation of liability addresses the available damages you *may* be able to recover. It is not an affirmative right to recover.
- Negotiation Tip: In addition to indemnity for data/security breach, consider affirmative obligation to reimburse costs of notification and remediation.

Adventures in HIT Innovation

- Traditional role of providers as procurers of HIT
- Seeing hospitals taking on development projects
- Many different ways to do this
  - In-house development
  - Hiring third party to provide WFH services
  - Customization of existing third party materials
  - Collaborating with third parties
    - May incorporate third party materials
  - Any combination of these

Who's involved in the innovation effort?

- Engaging with external developers
  - Development services
  - Starting with existing third party code
- Internal team members
  - IT staff
  - Medical staff
  - Non technical employees
  - Other non-employees workers:
    - Management staff
    - Residents and interns, volunteers
- Collaborative projects
- Role of investors and financial partners

How will the innovation be used?

- Limited to internal use only
- External use cases (end users)
  - By patients
  - Other providers – local or in other areas
- Various ways to enable external use, including:
  - Direct licensing
  - Using a reseller or other third party
  - Proprietary licensing
  - Open source, creative commons and other licenses

Ownership Issues

- Different types of IP involved
  - Copyright, patent, trade secrets, trademark
  - Related assets:
    - Data
    - URLs and electronic / digital assets
    - Documentation
- Default rules – differ depending on type of IP
- Manage expectations and reduce risk of disputes and claims
    - Get it in writing …. from all contributors

Practical Considerations for IP Ownership

- Friction point: Getting hung up on "owning it all"
  - What do you need?
    - Do you have the rights for the planned use case?
    - Expansion and new applications
    - Consider 3, 5, 10 years down the line
  - What do you want?
    - To be able to do
    - To prevent others from doing

Ownership and External Use

- Additional Considerations
  - Compatibility / support of mission
  - Core competencies
  - Client relationships
  - Tax treatment of income
- Use of related entity

Alternatives to IP Ownership

- Other structures to protect your investment
  - Licensing
  - Exclusivity
    - By geography
    - By use
    - For limited time period
  - Financial compensation
    - Recoupment of costs
    - Sharing in the upside

Licensing to Others

- Key considerations for external use
  - Scope of permitted use
    - Licensing parameters (quantities) tied to payment structure
  - Financials
  - Risk allocation: warranties, indemnities and limitation of liability
  - Data and security
  - Termination rights
  - Related services
    - Implementation
    - Support

Compliance issues

- Don't forget about compliance issues
- But, they may apply to you differently in this context
- HIPAA – Are you now a Business Associate?
  - Don't automatically reuse your standard BAA
- Stark and AKS compliance
  - Beware compensation arrangements that may create a financial incentive for referrals

Meaningful Use - Regulatory Backdrop

- "Meaningful Use" established by Medicare and Medicaid EHR Incentive Programs under HITECH Act in 2009
- Various implementing regulations issued by CMS and ONC
- Applicable to Eligible Professionals and Eligible Hospitals
- Sets specific objectives that eligible professionals (EPs) and Eligible Hospitals must achieve to qualify for incentives and avoid penalties
  - Adopt Certified EHR Technology
  - Use Certified EHR Technology to achieve certain objectives over a specified period of time
  - Must successfully attest to demonstrating meaningful use

MACRA and Changes to Meaningful Use

- Fall of 2016 = MU changes
- Regulations implementing Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) issued creating Quality Payment Program
  - Quality Payment Program has two tracks for participation for eligible clinicians: Merit Based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (APMs).
  - Transition from fee-for-service payments to payments for quality and value
- New regulations introduced changes to EHR Incentive Programs for 2017 focused on streamlining and greater flexibility
- Alignment of meaningful use under QPP and EHR Incentive Programs
  - Same definition of Certified EHR Technology
  - Same structure of objectives and thresholds
  - Scoring and financials different

Updates to Medicaid and Medicare EHR Incentive Programs

- **2017** changes: removed clinical decision support and CPOE objectives and measures, reduced certain thresholds for remaining objectives and measures, new naming conventions
- **Changes for 2018** under 2018 IPPS Final Rule issued in August 2017
  - Flexibility in Certified EHR technology for CY 2018
    - May use 2014 Edition CEHRT, 2015 Edition CEHRT or combination
  - EHR reporting periods for 2018 Medicaid and Medicare Programs a minimum of continuous 90 day period
    - Applies to all participants

EHR Incentive Programs – What's New for 2018

- Medicare hospitals may report on Modified Stage 2 or Stage 3 requirements in 2018
  - Delays requirement for hospitals to meet meaningful use stage 3 measures and objectives until 2019
- 21st Century Cures Act Provisions:
  - A new exception from the Medicare payment adjustments for decertification of formerly Certified EHR Technology
  - An exception to the 2017 and 2018 Medicare payment adjustments for ambulatory surgical center (ASC) - based EP
- Beginning on January 2, 2018, eligible hospitals and critical access hospitals (CAHs) attesting to CMS will submit their 2017 meaningful use attestations to the QualityNet Secure Portal (Qnet).
- CMS' eCQM annual update for CY 2018 reporting. Updated measure specifications for CQM reporting are available at https://ecqi.healthit.gov/

Use of Certified EHR Technology under QPP

- Implementation of Quality Payment Plan began in 2017 as transition year
- Both payment tracks (MIPS and APMs) include several provisions that related directly to the use of certified EHR technology
- Meaningful Use folded into MIPS – Advancing Care Information category
  - Beginning in 2017, Medicare eligible clinicians now report under Advancing Care Information requirements of MIPS

ACI is the New MU

- Within MIPS, "Advancing Care Information" category replaces the Medicare EHR Incentive Program for eligible professionals
- Uses parallel objectives and measures
  - Examples: Send a Summary of Care, Request/Accept Summary of Care, Patient Specific Education, View, Download or Transmit (VDT)
- Advancing Care Information scoring
  - **Moves away from "all or nothing" approach**
  - Individual measures can score up to 10%
    - Can earn lesser points if not making the maximum
  - Scoring components: Required Base score + Performance score + Bonus score
    - Available % scores for combined components can exceed >100%, but capped at 100%

ACI in CY 2018

- CY 2018 Updates to the QPP issued Nov. 2, 2017 and is effective Jan. 1, 2018 implements policies for "Quality Payment Program Year 2"
  - 2018 will be a further transition year
  - 2018 performance period is the full calendar year; will be the basis for 2020 MIPS payment year
  - For CY 2018 performance period, Advancing Care Information will continue to be weighted at 25% of MIPS composite score
  - In 2018, MIPS eligible clinicians may continue to use 2014 Edition Certified EHR Technology
    - Option to use combination for 2014 Edition and 2015 Edition CEHRT
    - May earn a bonus for using only 2015 Certified EHR Technology

ACI is the New MU…BUT only for Medicare EPs

- MIPS Advancing Care Information category replaces only the Medicare EHR Incentive Program for eligible professionals
- Medicare EHR Incentive Program stays in place for eligible hospitals and critical access hospitals
- Medicaid EHR Incentive Program stays in place
  - Eligible professionals
  - Acute care and children's hospitals
- *Organizations with both Medicare and Medicaid payments will need successfully to manage both programs simultaneously to maximize reimbursement*

Questions?

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Hospital Board Authority vs. Medical Staff Self-Governance

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Medical Staff Self-Governance vs. Hospital Board Corporate Responsibility: Who's In Charge—and What Are the Potential Regulatory Consequences of Getting it Wrong?

Davis Wright Tremaine
Health Care Regulatory Compliance Update
February 13, 2018
Omni Hotel—Los Angeles, California

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Medical Staff Self-Governance

Medicare Conditions of Participation

- The medical staff is responsible—and accountable to the governing body—for the quality of medical care provided to patients by the hospital. (42 CFR § 482.22)

Medical Staff Self-Governance (cont'd)

The Joint Commission Medical Staff Standards

- "The organized medical staff oversees the quality of patient care, treatment, and services provided by practitioners privileged through the medical staff process." (MS.03.01.01)

Medical Staff Self-Governance (cont'd)

California Business and Professions Code Section 2282.5

- (a) The medical staff's right of self-governance shall include, but not be limited to, all of the following:
  - (1) Establishing, in medical staff bylaws, rules, or regulations, criteria and standards, consistent with Article 11 (commencing with Section 800) of Chapter 1 of Division 2, for medical staff membership and privileges, and enforcing those criteria and standards.
  - (2) Establishing, in medical staff bylaws, rules, or regulations, clinical criteria and standards to oversee and manage quality assurance, utilization review, and other medical staff activities including, but not limited to, periodic meetings of the medical staff and its committees and departments and review and analysis of patient medical records.

Medical Staff Self-Governance (cont'd)

California Business and Professions Code Section 2282.5 (cont'd)

- (3) Selecting and removing medical staff officers.
- (4) Assessing medical staff dues and utilizing the medical staff dues as appropriate for the purposes of the medical staff.
- (5) The ability to retain and be represented by independent legal counsel at the expense of the medical staff.
- (6) Initiating, developing, and adopting medical staff bylaws, rules, and regulations, and amendments thereto, subject to the approval of the hospital governing board, which approval shall not be unreasonably withheld.

Medical Staff Self-Governance (cont'd)

California Business and Professions Code Section 2282.5 (cont'd)

- (b) The medical staff bylaws shall not interfere with the independent rights of the medical staff to do any of the following, but shall set forth the procedures for:
  - (1) Selecting and removing medical staff officers.
  - (2) Assessing medical staff dues and utilizing the medical staff dues as appropriate for the purposes of the medical staff.
  - (3) The ability to retain and be represented by independent legal counsel at the expense of the medical staff.

Medical Staff Self-Governance (cont'd)

California Business and Professions Code Section 2282.5 (cont'd)

- (c) With respect to any dispute arising under this section, the medical staff and the hospital governing board shall meet and confer in good faith to resolve the dispute. Whenever any person or entity has engaged in or is about to engage in any acts or practices that hinder, restrict, or otherwise obstruct the ability of the medical staff to exercise its rights, obligations, or responsibilities under this section, the superior court of any county, on application of the medical staff, and after determining that reasonable efforts, including reasonable administrative remedies provided in the medical staff bylaws, rules, or regulations, have failed to resolve the dispute, may issue an injunction, writ of mandate, or other appropriate order. Proceedings under this section shall be governed by Chapter 3 (commencing with Section 525) of Title 7 of Part 2 of the Code of Civil Procedure.

Medical Staff Self-Governance (cont'd)

California Code of Regulations, Title 22, Section 70703

- (a) Each hospital shall have an organized medical staff responsible to the governing body for the adequacy and quality of the care rendered to patients. . . .
- (d) The medical staff by-laws, rules, and regulations shall include, but shall not be limited to, provision for the performance of the following functions: executive review, credentialing, medical records, tissue review, utilization review, infection control, pharmacy and therapeutics, and assisting the medical staff members impaired by chemical dependency and/or mental illness to obtain necessary rehabilitation services. These functions may be performed by individual committees, or when appropriate, all functions or more than one function may be performed by a single committee. Reports of activities and recommendations relating to these functions shall be made to the executive committee and the governing body as frequently as necessary and at least quarterly....

Medical Staff Self-Governance (cont'd)

Title 22, Section 70703 (cont'd)

- (g) The medical staff shall participate in a continuing program of professional education. The results of retrospective medical care evaluation shall be used to determine the continuing education needs. Evidence of participation in such programs shall be available.
- (h) The medical staff shall develop criteria under which consultation will be required. These criteria shall not preclude the requirement for consultations on any patient when the director of the service, chairman of a department or the chief of staff determines a patient will benefit from such consultation.

Hospital Board's Responsibility for Facility Operations

- California Corporations Code Section 5210 requires the Board of a nonprofit public benefit corporation to control its operations, even if some management activities are delegated:

"The board may delegate the management of the activities of the corporation to any person or persons, management company, or committee however composed, ***provided that the activities and affairs of the corporation shall be managed*** and all corporate powers shall be exercised ***under the ultimate direction of the board.***" (Emphasis added).

Hospital Board's Responsibility for Facility Operations (cont'd)

Corporations Code Section 5231 provides that while directors may act based upon information provided by other directors or appropriate experts, the directors must perform their duties by acting, in good faith, based upon "reasonable inquiry":

- (a) A director shall perform the duties of a director, including duties as a member of any committee of the board upon which the director may serve, in good faith, in a manner that director believes to be in the best interests of the corporation and with such care, including reasonable inquiry, as an ordinarily prudent person in a like position would use under similar circumstances.

Hospital Board's Responsibility for Facility Operations (cont'd)

- (b) In performing the duties of a director, a director shall be entitled to rely on information, opinions, reports or statements, including financial statements and other financial data, in each case prepared or presented by:
  - (1) One or more officers or employees of the corporation whom the director believes to be reliable and competent in the matters presented;
  - (2) Counsel, independent accountants or other persons as to matters which the director believes to be within that person's professional or expert competence; or

Hospital Board's Responsibility for Facility Operations (cont'd)

- (3) A committee upon which the director does not serve that is composed exclusively of any or any combination of directors, persons described in paragraph (1), or persons described in paragraph (2), as to matters within the committee's designated authority, which committee the director believes to merit confidence, **so long as, in any case, the director acts in good faith, after reasonable inquiry when the need therefor is indicated by the circumstances and without knowledge that would cause that reliance to be unwarranted.** (Emphasis added.)

- (c) Except as provided in Section 5233, a person who performs the duties of a director in accordance with subdivisions (a) and (b) shall have no liability based upon any alleged failure to discharge the person's obligations as a director, including, without limiting the generality of the foregoing, any actions or omissions which exceed or defeat a public or charitable purpose to which a corporation, or assets held by it, are dedicated.

Hospital Board's Responsibility for Facility Operations (cont'd)

- Thus, directors can act based on information provided by a committee of experts, but the law requires the directors to act and to ask questions if the information furnished by the experts raises any issues that should be explored before action is taken.

- In the credentialing context, that means directors can rely on information provided by a medical staff committee, but the Board needs to make the final decisions—and the directors need to ask questions if the information received from the medical staff raises doubt about the propriety of approving a particular practitioner to practice in the hospital.

Hospital Board's Responsibility for Facility Operations (cont'd)

Medicare Conditions of Participation

- Governing Body (42 Code of Federal Regulations (CFR) § 482.12)
  - The governing body must be effective and responsible for the conduct of the hospital.
  - The governing body must "[e]nsure that the medical staff is accountable to the governing body for the quality of care provided to patients."

Hospital Board's Responsibility for Facility Operations (cont'd)

Leadership Standards of The Joint Commission

- The governing body must work with the medical staff, but final decisions "are always the responsibility of the governing body," and the medical staff is accountable to the governing body. (*Comprehensive Accreditation Manual for Hospitals* (CAMH), Introduction to Leadership Structure, Standards LD.01.01.01 through LD.01.07.01; LD.01.05.01, Element of Performance 6)

Hospital Board's Responsibility for Facility Operations (cont'd)

Leadership Standards of The Joint Commission

- The governing body must establish processes:
  - for making decisions when a leadership group, e.g., the Medical Executive Committee, "fails to fulfill its responsibilities and/or accountabilities" (LD.01.02.01, EP 2);
  - for addressing conflicts of interest that could affect safety and/or quality of care (LD.01.03.01, EP 7; LD.02.01.01, LD.02.04.01, LD.04.02.01);

Hospital Board's Responsibility for Facility Operations (cont'd)

Leadership Standards of The Joint Commission

- The governing body must establish processes:
  - for evaluating patient safety and implementing effective improvement measures based on available data (LD.03.01.01 through LD.03.06.01);
  - for ensuring compliance with applicable laws and regulations (LD.04.01.01); and
  - ensuring that services provided through contracts are provided safely and effectively (LD.04.03.09).

Hospital Board's Responsibility for Facility Operations (cont'd)

Medical Staff Standards of The Joint Commission

- "The hospital's governing body has the ultimate authority and responsibility for the oversight and delivery of health care rendered by licensed independent practitioners…." (CAMH, Overview to Medical Staff chapter)

Hospital Board's Responsibility for Facility Operations (cont'd)

- Title 22, Section 70701 of the California Code of Regulations (CCR) requires the governing body of a general acute care hospital to "[a]dopt written bylaws in accordance with legal requirements and its community responsibility" that provide for "[f]ormal organization of the medical staff with appropriate officers and bylaws." Section 70703 mandates that "[e]ach hospital shall have an organized medical staff **responsible to the governing body** for the adequacy and quality of the care rendered to patients." (Emphasis added.) Consistent with the Medicare CoPs, 22 CCR Section 70703 requires the medical staff to adopt its own written bylaws **"with the approval of the governing body."** (Emphasis added.)

Health Facility Corporate Negligence in California: The Tort of "Negligent Credentialing"

- Based on the fundamental principles of corporate governance described above, the tort doctrine of health facility corporate negligence for "negligent credentialing" developed in the hospital context.
- In 1982, California joined other states whose courts had held that a hospital's governing board may be held liable under the doctrine of corporate negligence* for failing to oversee its doctors and to review their qualifications and the quality of care rendered to patients.

* This trend began with the Illinois Supreme Court in 1965. *Darling v. Charleston Community Memorial Hospital*, 33 Ill. 2d 326 (1965), and the majority of states (28) now recognize the tort of negligent credentialing.

Health Facility Corporate Negligence in CA: The Tort of "Negligent Credentialing" (cont'd)

- In *Elam v. College Park Hospital*, 132 Cal. App. 3d 332 (1982), the California Court of Appeal held the defendant hospital accountable as a corporation for "negligently screening the competency of its medical staff to insure the adequacy of medical care rendered to patients at its facility." *Elam*, 132 Cal. App. 3d at 347.
- The theory of corporate negligence has been applied to "impose a direct and independent responsibility to [the organization's] patients of insuring the competency of its medical staff and the quality of medical care provided through the prudent selection, review and continuing evaluation of the physicians granted staff privileges." *Id*. at 345-346.

Hospital Board's Responsibility for Facility Operations (cont'd)

- In *Hongsathavij v. Queen of Angels/Hollywood Presbyterian Medical Center*, 62 Cal. App. 4th 1123 (1998), the California Court of Appeal confirmed the doctrine of hospital corporate liability and specifically held that, "[u]ltimate responsibility is not with the medical staff, but with the governing body of the hospital." *Hongsathavij*, 62 Cal. App. 4th at 1143.

Hospital Board's Responsibility for Facility Operations (cont'd)

- The court in *Hongsathavij* relied on several California Corporations Code provisions to support its determination that hospital governing body members have "fiduciary duties as directors ***and under certain circumstances have exposure to personal liability***. (See Corp. Code, §§ 309 [corporations, generally], 5231 [nonprofit benefit corporations]…)," which require a director to "perform the duties of a director…in good faith, in a manner such director believes to be in the best interests of the corporation.

Hospital Board's Responsibility for Facility Operations (cont'd)

- The *Hongsathavij* court cited Elam in noting hospital corporate liability for negligently failing to ensure medical staff competence and quality of care and expressly held that the "hospital's ***governing body must*** remain empowered to ***render a final medical practice decision***.... A hospital's governing body must be permitted to align its authority with its responsibility and to ***render the final decision*** in the hospital administrative context." *Id.*

Other Hospital Board Authority Case Law

- In *Ellison v. Sequoia Health Services*, 183 Cal. App. 4th 1486 (2010), the court upheld the decision of the hospital's governing body to terminate a physician in accordance with the recommendation of the Medical Executive Committee, even though the members of the Judicial Review Committee thought termination was too drastic a remedy based upon the facts as the JRC found them. The court held that the board's decision was consistent with the JRC's findings, the hospital's Medical Staff Bylaws, and California law.

Other Hospital Board Authority Case Law (cont'd)

- In *El-Attar v. Hollywood Presbyterian Medical Center*, 56 Cal. 4th 976 (2013), the California Supreme Court reversed the Court of Appeal and held that the physician was not denied a fair hearing solely because the governing board appointed the Hearing Officer and the Judicial Review Committee. Although a governing body conceivably might abuse its authority in that situation, there is no basis to presume that such abuse is inevitable—so the procedure was not inherently invalid.

Other Hospital Board Authority Case Law (cont'd)

- In *Fahlen v. Sutter Central Valley Hospitals*, 58 Cal. 4th 655 (2014), the California Supreme Court held that the hospital could not require the physician to exhaust judicial mandamus remedies before filing a whistleblower lawsuit under California Health and Safety Code Section 1278.5 to challenge the hospital's allegedly retaliatory termination of his medical staff membership and privileges. (So, hospital boards don't always win.)

Some Areas of Controversy

- Who can conduct peer review?
- Who has legitimate access to peer review records?
- Can a physician be terminated (or not reappointed) by administrative/board action or inaction? If so, under what circumstances?
- Can administrative members of medical staff committees vote?
- Can a medical executive committee hold executive sessions from which ex officio non-physician members such as the hospital CEO are excluded?

Cautionary Tales:

TJC and State Regulators Hate Battles Between Hospital Leadership Groups

- Community Medical Center of Ventura
- This protracted dispute caused The Joint Commission to require all TJC-accredited hospitals to amend their Medical Staff Bylaws substantially with respect to Organized Medical Staff and Governing Body functions.
- Tulare Regional Medical Center
- The governing body's action to replace uncooperative medical staff leaders with a new MEC led to a lawsuit and adverse regulatory action. The hospital is currently in bankruptcy and closed.

Questions

Thank You!

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Los Angeles Times | ARTICLE COLLECTIONS

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Doctors Groups Underwrite Ventura Suit

The state and national medical associations send $100,000 to local physicians battling with Community Memorial Hospital.

July 30, 2003 | Daryl Kelley | Times Staff Writer

State and national physicians groups have donated more than $100,000 to Ventura doctors to underwrite a lawsuit against Community Memorial Hospital that they see as key in a nationwide effort to reaffirm the role of doctors as patient advocates in medical centers.

"We're going to spend whatever it takes until the integrity of the medical staff has been reestablished," said Jack Lewin, chief executive of the California Medical Assn. "A medical staff operates under a distinct set of defining principles, and every one has been violated in Ventura."

Community Memorial has been embroiled in an internal fight for more than a year, as the 242-bed hospital has tightened controls over its medical staff and physicians have bristled at what they consider an erosion of their rights. After attempts at mediation, a group of doctors led by a majority of the medical staff executive committee filed suit in April.

Now, as both sides prepare for a pivotal court hearing today, physician leaders announced that the California and American medical associations have each contributed more than $50,000 to press the Ventura case.

"I think this raises a question," said Lowell Brown, a Los Angeles lawyer specializing in health-care issues who is representing Community Memorial. "Here we have a single community hospital in a small city in California, and it has attracted the attention of the largest medical association in the world. Why?"

Brown said the medical associations are interested not because the traditional role of doctors in hospitals is being challenged, but because it's in their interest to stoke controversy.

"Only 35% of the doctors in California are members of the [California Medical Assn.] and frankly, they make quite a name for themselves when they stir up strife, which they're doing in spades," he said. "I've never seen them more involved in a case."

The state medical association's Lewin said the doctors groups are supporting the Ventura doctors so strongly because Community Memorial has taken a radical position in refusing to recognize the medical staff as a self-governing part of the hospital or to respect its role as watchdog on behalf of patients.

"If this were to become some sort of legal precedent, it could cause a cataclysmic interruption of what are typically healthy and constructive relationships between physicians and hospitals," Lewin said. "Occasionally, we have a flare-up, but this is really an extreme case in Ventura."

The state medical association is, in fact, working to ease tensions and improve relations, he said, by talking with California's 500-member hospital association to iron out a set of principles that both sides can embrace to avoid the kind of rancor that has occurred in Ventura. Yet, attorneys for the hospital group, the California Healthcare Assn., filed a legal brief Monday supporting Community Memorial. "The case is one of vital importance to the operation of hospitals throughout the state of California," the brief states.

"This particular circumstance has gotten completely out of control," Lewin said. "We have to wage a legal battle to protect the doctors, but which seems extremely counterproductive to everybody."

In the Ventura case, doctors specifically claim that administrators tried to rig a staff election, adopted an 18-page code of conduct to stifle dissent, implemented a conflict-of-interest policy to disqualify selected physicians from leadership positions, and illegally allowed physicians to practice at the hospital without the staff's review.

Hospital attorneys maintain that Community Memorial's medical staff has no legal standing or authority beyond that granted by the facility's board of trustees.

The medical staff functions as an advisory group only, they have argued.

"This is one of the biggest issues yet to be decided in California," said Brown, the hospital's lawyer. "But if you look at all of the case law, I think it's clear how the court should come down.... The board of trustees is supreme. The medical staff is subject to the board in every way."

Indeed, the hospital maintains that the dispute is purely financial and is being pressed by doctors with conflicts of interest -- such as competing in-office surgery units -- that take business away from the hospital.

Under Community Memorial's new policy, such doctors could not be elected leaders of the medical staff or vote in staff elections.

The physicians, however, have said that any conflicts are minor and that the key issue is their autonomy, which is well-established in law, industry regulation and practice.

The hospital is to argue its case for dismissing the lawsuit without trial before county Superior Court Judge Henry Walsh this morning.

California Healthline Daily Edition (https://californiahealthline.org/morning-briefing/tuesday-january-16-2018/)

Summaries of health policy coverage from major news organizations

THURSDAY, AUG 19 2004

Community Memorial Hospital, Medical Staff Settle Lawsuit Over Staff Rights

Community Memorial Hospital (http://216.103.143.181/) in Ventura and its medical staff have reached a settlement in a lawsuit brought by doctors against the hospital for "allegedly undercutting their rights as a self-governing branch of the medical center," the *Los Angeles Times* (http://www.latimes.com/news/local/la-me-settle18aug18,1,7749368.story) reports (Kelley, *Los Angeles Times*, 8/18).

Physicians at the hospital filed a lawsuit in April 2003 over allegations that hospital administrators tried to influence a staff election in November 2002, adopted an 18-page code of conduct intended to silence opposition, implemented a conflict-of-interest policy to disqualify certain physicians from leadership positions and illegally allowed physicians to practice at the hospital without a review by the staff.

In September 2003, the board of Community Memorial voted to change some of the more controversial elements of the code of conduct and conflict of interest policy, but the lawsuit continued. In October 2003, CEO Michael Bakst resigned from his position at the request of the hospital board in an effort to begin resolving issues between the hospital and its physicians (*California Healthline* (/index.cfm?Action=dspItem&itemID=95645), 10/3/03).

On Tuesday, the hospital and the medical staff announced the settlement, which was approved last week by hospital trustees and the executive committee of the medical staff. Medical staff members are expected to ratify the settlement next month (*Los Angeles Times*, 8/18). The settlement will become final when the medical staff changes its bylaws to include new policies governing physician conduct and conflicts of interest (Wilson, *Ventura County Star* (http://www.venturacountystar.com/vcs/ve/article/0,1375,VCS_251_3119063,00.html), 8/18).

In the announcement, the hospital and medical staff stated, "The medical staff has full confidence in the board's leadership, and the board recognizes the medical staff's indispensable role in fulfilling CMH's mission" (*Los Angeles Times*, 8/18). Hospital officials said they must now work to regain patient volume lost when doctors began withdrawing admissions last year. New hospital administrator Gary Wilde said CMH revenue decreased by $720,000 in the last year because of lower admissions (*Ventura County Star*, 8/18).

Settlement Details

In the settlement, trustees agreed that medical staff bylaws could not be changed unilaterally by hospital administrators and promised to "comply with staff bylaws," according to the *Times*. The hospital also agreed to increase funding for the medical staff; return $250,000 in medical staff dues, allowing the funds to be used to hire a lawyer, even to sue the hospital; and not to "unreasonably withhold" approval of new medical staff bylaws. The medical staff agreed not to pursue incorporation as a separate entity for at least two years (*Los Angeles Times*, 8/18). In addition, the medical staff will draft a new conflict-of-interest policy that will be overseen by the staff and not the hospital board. The staff will regain control of its bank account and will be allowed to select its own leaders. The settlement establishes a system for resolving future conflicts through methods such as mediation and judicial review (*Ventura County Star*, 8/18).

Reaction

"We're very happy with what we've achieved," John Hill, president of the medical staff, said, adding, "This settlement allows the medical staff to continue to be the prime entity to determine medical policies. And (trustees) have agreed to not unreasonably withhold their blessing." Hill also said two key elements for resolving the dispute were a Superior Court judge's ruling last year that the medical staff represented a legal entity with the ability to file suit against the hospital and the trustees' decision to replace Bakst (*Los Angeles Times*, 8/18).

Wilde said the settlement is a "win-win" for doctors, hospital trustees and the hospital administration. He added, "It gets back to how a typical, well-run hospital works together. Everything in the document I can live with and support" (*Ventura County Star*, 8/18).

Jack Lewin, CEO of the California Medical Association (http://www.cmanet.org/), said, "It took professionalism and courage to stand for the rights of physicians against the raw power of a wrong-headed hospital administration. This is a significant victory for quality of care and patients."

Larger Impact

According to the *Times*, the lawsuit resulted in a bill that would define a self-governin with hospital administrators and permit medical staff members to sue to block hospit sponsored by Sen. Sheila Kuehl (D-Santa Monica), has passed both chambers of th a joint committee before going to the governor (*Los Angeles Times*, 8/18).

PRACTICE MANAGEMENT

Lawsuit fights "existential threat" to medical staff independence

SEP 12, 2017

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While "L.A. Law" and other TV courtroom dramas often focused on the rich and glamorous, a lawsuit originating in a rural dairy community in California's Central Valley has captured the attention of the state's legal and medical professionals and—given the state's outsized influence—the case's impact could be felt far and wide.

"Every once in a while, you get a really important case that's a flashpoint," said Long Do, California Medical Association (CMA) legal counsel and director of litigation. "This case serves as an existential threat to independent hospital medical staffs."

The suits stems from actions taken Jan. 26, 2016, when the Tulare Regional Medical Center (TRMC) board of directors voted to terminate the hospital's medical staff organization and effectively remove the hospital's elected medical staff officers, install a slate of appointed officers, and approve new medical staff bylaws and rules drafted without staff input.

Except for the newly appointed officers, the rest of the staff was then terminated, stripped of their rights as active members and then granted "provisional" status as part of the new medical staff which they had not applied or consented to membership with, according to a post-trial brief filed by the TRMC Medical Staff.

The replacement bylaws also contained a provision, since amended, that physicians could achieve and maintain "active" status by proving their economic value to the hospital, according to the brief—which described that provision as "basically, an illegal kickback scheme."

Frightening prospect: Cooperate, or else

"If you could imagine hospital medical staff bylaws written by hospital lawyers, this is what they would look like," Do said. "Doctors shouldn't be making decisions on patient care based on hospital profitability."

The case went to trial in April and post-trial briefs are being filed. Closing arguments are scheduled for Oct. 2 and Do said the judge is expected to issue a ruling 45 to 60 days after that.

"We're hoping to get resolution by the end of the year," he said.

The CMA filed pre- and post-trial amicus briefs. It has also provided financial support—as has the Litigation Center of the American Medical Association and State Medical Societies—and has organized fundraising for the case.

Do, the CMA's litigation director, said the medical staff's legal team presented strong arguments during the trial, but the potential impact of a negative outcome leaves him concerned.

"If the hospital is allowed to do what they did, it basically ends medical staff independence in the state of California," he said. "Our biggest concern is that some sort of legal precedent would be set if they were allowed to get away with it. Another hospital could say to its staff, 'If you don't cooperate, that's what we're going to do to you.'"

The CMA brief argues that the TRMC board's actions were direct violations of legislation passed in 2004 establishing the self-governing rights of all medical staffs at the state's hospitals. These rights include the right to determine and enforce medical staff bylaws and select staff leaders.

"Nothing in the law permits a hospital to simply dissolve an entire medical staff," the amicus brief states. "Nor does the law condone a select group of individuals undemocratically stealing power from elected medical staff leaders and imposing their will on all the members of the medical staff."

Related Coverage

Get help with your medical staff bylaws with AMA guide

Interestingly, both sides in the suit sought to bolster their arguments by citing a 2013 California Supreme Court case, *El-Attar v. Hollywood Presbyterian Medical Center*. In that case, a physician supported by the CMA and the Litigation Center did not prevail, but the court's ruling upheld many of the principles of medical staff governance that organized medicine was fighting for.

"Their argument, which they haven't changed since day one, is that hospitals have the ultimate authority to do whatever they must in defense of hospital operations and patient care," Do said. "What we've proven is that that defense is both factually and legally incorrect."

In the *El-Attar* case, the court ruled that if the medical staff is failing to fulfill a specific duty, the hospital has the authority to step in and fulfill that specific duty, Do said. TRMC has argued its actions were necessary because of a negative survey of the hospital conducted by the Centers for Medicare and Medicaid Services (CMS).

The medical staff's post-trial brief states that the CMS audit blamed the hospital's governing body for problems with quality control, infection control, and lack of fire and safety control. CMS found the medical staff deficient in credentialing and peer review, according to the brief, but the defendants had not

presented any evidence that the governing board had any complaints regarding staff performance in these two functions.

Reinstatement of bylaws, officers sought

Actions the medical staff is seeking include: reinstatement of original medical staff with prior privileges and status, reinstatement of original bylaws, and reinstatement of all department and committee chairs or other leadership posts previously held by medical staff unless they voluntarily resign.

While typically cases such as these can drag on through a long cycle of appeals, Do said that this may not happen with this suit.

Though TRMC is now managed by a private entity and a defendant in the lawsuit—Healthcare Conglomerate Associates—the 108-bed hospital is owned by the taxpayer-funded Tulare Local Healthcare District, which is governed by a publicly elected five-person board.

Publicity surrounding the lawsuit has spurred citizen activism that resulted in two incumbent board members being defeated last year and a recall election defeat of another incumbent in July, Do said. A fourth incumbent resigned Aug. 23, so the chances of reaching a settlement have increased, he added.

"If there is a settlement, it would have to be structured in a way that sets a precedent," Do said. "We don't want other hospitals to get any ideas about trying something like this."

The opening paragraph of medical staff plaintiffs' post-trial brief can be seen as a legal clarion call to hospitals contemplating similar action.

"In this case," the brief begins, "defendants are asking this court to bless an act that not only defies statutory law, public policy, and their own bylaws, but is also unprecedented in the history of the state, and this country, and which no expert in this case—despite more than 150 years of combined industry experience—has ever seen or even heard of before."

Staff self-governance webinar set

The CMA is hosting a Sept. 13 webinar, 12:15–1:15 PDT, on medical staff rights and self-governance under federal and California statutes. The CMA's Do will be the lead presenter and, while the Tulare case will be cited prominently in the program, it will not be its sole focus, he said. The webinar is free for CMA members and $99 for nonmembers.

More on this

- Medical staff autonomy upheld in state supreme court ruling
- Medical liability reform at risk in state supreme court case
- Ruling protects doctors who stand up for patient safety

Litigation News Physician Advocacy

California hospital suspends all services, notifies 524 employees of possible layoffs

Written by Ayla Ellison (Twitter | Google+) | October 27, 2017 | Print | Email

Tulare (Calif.) Regional Medical Center shut down Oct. 29, as the local healthcare district is voluntarily suspending its license with the state to operate the 112-bed hospital, as well as clinics and other outpatient facilities, according to the *Fresno Bee*.

Although the hospital officially shut down Sunday, the facility stopped admitting new patients earlier in the week. At a board meeting Wednesday night, Kevin Northcraft, president of the Tulare Local Healthcare District, said the hospital's 23 patients were being transferred to other medical facilities, according to the report.

Tulare Regional Medical Center filed for Chapter 9 bankruptcy in late September. At that time, the hospital had zero cash in its bank accounts, and the board said the facility faced closure. In a Worker Adjustment and Retraining Notification Act notice sent to hospital workers Wednesday, the hospital's management company, Tulare-based HealthCare Conglomerate Associates, said the "sudden and unexpected" bankruptcy filing is what prompted the company to suspend operations at Tulare Regional Medical Center.

Tensions have flared between HCCA and the healthcare district for months, and the district recently filed a motion in bankruptcy court seeking to oust HCCA. On Wednesday, the bankruptcy court granted the district's request to sever its contract with HCCA and find a new management company.

Although the transition is not slated to take place until Nov. 27, HCCA said it had to suspend operations at the hospital on Oct. 29 because of financial pressure.

"Due to the district's declaration of bankruptcy, failure to meet its funding obligations under the [management services agreement] and the bankruptcy court's rejection of the MSA, HCCA is faced with faltering financial conditions and is forced to temporarily suspend all its operations at TRMC until additional funding or other arrangements can be secured," states the WARN notice.

HCCA said it would permanently cease operations at Tulare Regional Medical Center and terminate all 524 employees if the district fails to meet its funding obligations under the MSA by Nov. 27 or if the district appoints an interim operator of the hospital.

The district board voted to temporarily suspend the hospital's license to prevent the state from shutting down the facility if HCCA exited without a clear handover plan in place, according to the *Valley Voice*.

The district has approached Fresno, Calif.-based Community Medical Centers about taking over management of Tulare Regional Medical Center, but no application to transfer management has been submitted to the state.

More articles on healthcare finance:

Los Angeles hospital to close, lay off 638 employees
Shareholders push for changes at Tenet and CHS: 6 things to know
Florida hospital to suspend all services as it seeks capital

Regulatory Challenges of Value-Based Physician Compensation

PRESENTED BY

Bob Homchick | Partner

Regulatory Challenges of Value-Based Physician Compensation

Robert G. Homchick

Davis Wright Tremaine LLP

Agenda

- Overview of value-based payment models
- Regulatory landscape and fraud and abuse waivers
- Analysis of value-based compensation metrics

From Volume to Value . . .

FEE-FOR-SERVICE (FFS) PAYMENTS	ADJUSTED FFS PAYMENTS	APMs INCORPORATING FFS PAYMENTS	POPULATION-BASED APMs
A Traditional FFS	A Pay for Reporting	A Total Cost of Care Shared Savings	A Condition-Specific Population-Based Payments
B Infrastructure Incentives	B Pay for Performance	B Total Cost of Care Shared Risk	B Primary Care Population-Based Payments
C Care Management Payments	C Pay/Penalty for Performance	C Retrospective Bundled Payment	C Comprehensive Population-Based Payments
		D Prospective Bundled Payment	

CMS Value-Based Reimbursement Goals

By December 31, 2016:

85% of Medicare fee-for-service payments tied to scores on quality and efficiency measures.

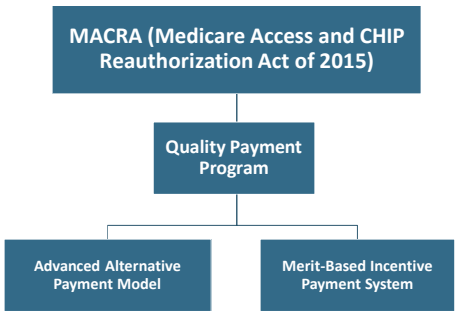
30% of traditional Medicare payments through APMs

03/03/2016 - Mission Accomplished

By December 31, 2018:

90% of Medicare fee-for-service payments tied to scores on quality and efficiency measures.

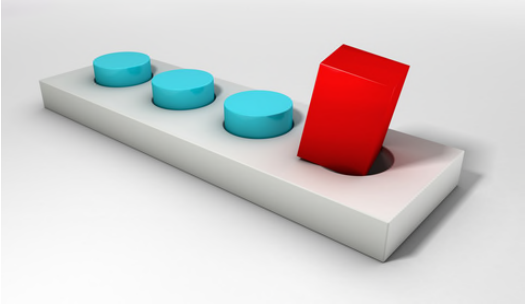
50% of traditional Medicare payments through APMs



Advanced APMs (Traditional Medicare)

- Medicare Shared Savings Program (Tracks 2 and 3 Only)
- Next Generation ACO Model
- Comprehensive ESRD Care (LDO arrangement and Two-Sided Risk)
- Comprehensive Primary Care Plus (re-open applications)
- Oncology Care Model (Two Sided Risk)

Fraud and Abuse in a Value-Based World



Regulatory Overview

- The federal Physician Self-Referral Prohibition
  42 U.S.C. §1395nn
- Anti-Kickback Statute - *42 U.S.C. §1320a-7b(b)*
- Civil Money Penalty Gainsharing Prohibition
- Internal Revenue Code prohibition on Private Benefit/Private Inurement

Snapshot Analysis: Value-Based Payments

- The Stark Law
  - Threshold issue in analysis of physician compensation
  - Generally speaking, if comp passes muster under Stark the AKS risks should be relatively modest
- Civil Money Penalty Gainsharing Prohibition
  - MACRA: CMP only prohibits payments to limit medically necessary care
- IRS prohibition on Private Benefit/Private Inurement
  - Applies only to tax-exempt organizations
  - Stark compliance relevant to tax issues but not the end of the analysis
    - Note, IRS has its own definition of FMV
  - IRS analysis is more principled and more logical than Stark
    - Relationship of payments to Exempt Organization's Mission is important

The Stark Law: Trigger

- An entity directly or indirectly provides remuneration to a physician who refers Medicare patients to the entity for designated health services
- Key terms:
  - Entity
  - Remuneration
  - Referral
  - DHS

Value-Based Payments almost always trigger for Stark Analysis

Fraud and Abuse Waivers

- Several Alternative Payment Models include fraud and abuse waivers
  - MSSP
  - BCPI
  - CJR
- Waivers address Stark, AKS and CMP
- Waivers do not address: laws governing tax-exempt organizations, antitrust laws, state laws
- Each program has different waivers with different requirements

MSSP Waivers

- Five fraud and abuse waivers
  - ACA sec. 3022 authority
  - Pay attention to the safeguards
  - Key concepts include:
    - Governance/accountability
    - Reasonably related to MSSP purposes
      - Governing Body finding
    - Transparency
      - Website disclosure
  - MSSP Waivers very broad, user friendly

Other Program Waivers

- The Bundled Payments for Care Improvement (BPCI) initiative
  - Voluntary Program – 4 Models
  - Each model has its own F&A Waiver
    - Not user friendly
- Comprehensive Joint Replacement Program (CJR)
  - Mandatory bundled payment program for hospitals located in selected zip codes
    - 2018: scope of mandatory program narrowed; now optional for many
  - Three waivers set forth in Separate Notice from OIG and CMS
  - Each waiver protects only those arrangements that meet the applicable regulatory requirements
    - Original Waivers Not User Friendly
    - Changes made — improved from participant perspective

Value-Based Compensation Paid Under Waiver

- If a hospital makes a valued-based payment to a physician that fits within a F&A waiver, that payment does not have to comply with a Stark exception and is immune from AKS prosecution even if is not within a AKS safe harbor.
- Thus, value-based payments made pursuant to a waiver are not subject to Stark/AKS FMV or Commercial Reasonableness tests because no need for an exception/safe harbor.
- But if a physician receives other payments that implicate Stark, his/her financial relationship with the payor entity must fit within an exception.
  - Are value-based payments protected by a waiver considered when analyzing overall compensation the physician receives under either a hospital employment agreement or services contract?
  - Should waiver-protected payments be taken into account in a "stacking" analysis?

FMV and CR (cont.)

- Strong argument can be made that waiver-protected payments should not be considered when assessing FMV or CR for purposes of Stark/AKS.
  - If CMS intended to apply some type of FMV and CR assessment, it would have included that in the requirements of the waiver.
- Some argue waiver-protected payments can be considered but that the final result is the same because achievement of the value-based metric increases FMV and provides foundation for CR.
- CAUTION: Waivers are the exception, not the rule.
  - Value-based reimbursement that is not protected by a F&A waiver must be considered in FMV and CR assessment of physician compensation.
    - MIPS payments, commercial gainsharing, etc., would be included when evaluating overall compensation paid to an employed or contracted physician.

Tax-Exempt Organizations: FMV and CR

- Tax-Exempt Organization: Private Inurement Analysis
  - IRS guidance on MSSP
    - Notice 2011-20 summarizes how the IRS expects federal tax law to apply to tax-exempt hospitals and health systems participating in the Medicare Shared Savings Program (https://www.irs.gov/pub/irs-drop/n-11-20.pdf)
    - Generally positive, but notice indicates arrangements between ACO and ACO participants should be FMV

- Other value-based reimbursement payments appear to be subject to private inurement prohibition
  - Whether the payments are FMV and CR is relevant to the analysis

Stark Exceptions: Value-Based Payments

- Risk-Sharing Exception
- Indirect Compensation Arrangement Exception
- Group Practice/In Office Ancillary Services Exception
- Personal Services Arrangement/FMV Exceptions
- Employment Exception

Risk-Sharing Exception

Compensation pursuant to a risk-sharing arrangement (including but not limited to withholds, bonuses, and risk pools) between a managed care organization or an independent physicians' association and a physician (either directly or indirectly through a subcontractor) for services provided to enrollees of a health plan, provided that the arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission. For purposes of this paragraph (n), "health plan" and "enrollees" have the meanings ascribed to those terms in §1001.952(l) of this title.

42 CFR 411.357(n)

Potential Coverage Is Broad

- Enrollee definition: 42 CFR 1001.952(l)(2)
- Health Plan definition: 42 CFR 1001.952(l)(2)
- CMS Guidance:
  - Comment: *A commenter welcomed the new exception for risk-sharing arrangements but requested a definition of the term "managed care organization"* as used in the exception or clarification in preamble language that the new exception is meant to cover all risk-sharing compensation paid to physicians by an entity downstream of any type of health plan, insurance company, or health maintenance organization (HMO). *A commenter sought clarification that the downstream entity could itself be an entity that furnishes DHS, such as a hospital.*
  - Response: *The new exception is meant to cover all risk-sharing compensation paid to physicians by an entity downstream of any type of health plan, insurance company, HMO, or Independent Practice Association (IPA), provided the arrangement relates to enrollees and meets the conditions set forth in the exception. All downstream entities are included.* We purposefully declined to define the term "managed care organization" so as to create a broad exception with maximum flexibility.
    - *69 Fed Reg at 16114*

Stark Analysis: Risk-Sharing Exception

- Exception applies if Hospital or ACO is
  - At risk for fixed payment from plan (or otherwise at risk)
  - Downstream of plan (downstream contractor)
  - Managing care (Hospital or ACO is acting as the "Managed Care Organization")
  - As MCO it is sharing risk with physicians for cost of care furnished to plan enrollees

- If the above criteria are satisfied, the payment to the physician would qualify as a covered bonus under the Risk-Sharing Exception

Risk-Sharing Exception

Pros

- NO FMV requirement
- NO Commercial Reasonableness requirement
- NO limitation on payments based on v/v

Cons

- Only available when Hospital or ACO/CIN acting as MCO downstream of Health Plan
- Not available in Medicare FFS Context
- Unclear how compensation paid pursuant to this exception should be treated in evaluation of overall compensation if Physician is an employee
- IRS private inurement/private benefit issues must still be addressed

The Stark Compensation Exceptions

- Employment
- Personal Services or Fair Market Value Arrangements
- Group Practice/In Office Ancillary Services
- Indirect Compensation

Stark Analysis– Compensation Exceptions

Generally Three Tests

FMV	Commercial Reasonableness	Volume or Value
• Is the compensation within the range of fair market value?	• Is the compensation commercially reasonable?	• Is the compensation based on the volume or value of the physician's DHS referrals?

Group Practice Compensation

- Groups have more flexibility in determining how to compensate their physician members
  - NO FMV requirement (assuming group is not a TEO)
  - NO Commercial Reasonableness requirement
- However, Compensation cannot vary directly with the v/v of physician's DHS referrals
- When Value-Based Reimbursement received by Group
  - Often group has flexibility in determining how to distribute among its members
  - Some limitations imposed by specific programs
    - CJR does not permit groups to share payments received from a hospital with physicians not involved in providing care to CJR beneficiaries

Indirect Compensation Arrangements

Indirect Compensation Arrangement:

- "Unbroken Chain" of any number of entities between physician and DHS entity
- Compensation to physician from closest link in chain varies with, *OR OTHERWISE REFLECTS*, volume or value of referrals to entity providing DHS
- Entity providing DHS has actual knowledge or acts in reckless disregard of existence of such relationship
- *42 CFR 411.354(2)*

Indirect Compensation Exception:

- Compensation received by MD from closest entity in the chain is FMV for services and not determined based on v/v of referrals or other business generated by MD for the DHS entity
- Set out in writing, signed, etc., except if employment, where must be for identifiable services and commercially reasonable even if no referrals to employer
- Does not violate the AKS
- *42 CFR 411.357(p)*

Value-Based Payments: Analytical Framework

First, identify who is paying the physician

- Hospital – a DHS entity
- CIN or ACO – an intervening entity triggering the indirect analysis under Stark
- Group Practice

Second, what type of financial arrangement governs payment

- Employment
- Services Agreement

Value-Based Compensation Metrics

- Most hospitals/systems/groups still perceive need for a significant portion of physician compensation to be tied to volume but want to embrace value based incentives
- Industry experimenting with a broad range of performance metrics
  - Both pooled and individual
  - Efficiency/Cost
  - Quality
- Comp systems increasingly complex

Analysis of Value-Based Compensation Metrics

- When reviewing performance metrics:
  - Understand how performance is measured and payment calculated for each goal
  - Undertake a legal analysis of each goal
  - Address FMV and commercial reasonableness
  - Address application of "management" goals to physician administrators
  - Ensure implementation and payment are consistent with description of goal
    - System for tracking performance and matching to compensation plans
  - How to address the inevitable mistakes?

Group Metrics/Pooling

- Performance can be measured either individually or at a group level
- Measuring aggregate performance or paying out of a pool created by the contributions of multiple physicians can raise regulatory issues
- Stark employment exception clearly permits productivity payments based on personally performed services
  - What if productivity bonus is based on performance of a group?
    - Some take position that it not permissible under the employment exception
    - Better analysis is that measurement/payment based on group performance is permissible if there are no revenues from DHS referrals included
  - In any event, pooling arrangements must satisfy FMV and commercial reasonableness standards.

Quality Metrics

- Payments for improved quality –
  - Phase III Commentary: "compensation related to patient satisfactions goals or other quality measures unrelated to the volume or value of business generated by the referring physician and unrelated to reducing or limiting services would be permitted under the personal services arrangement exception . . . (for example, compensation to reward physicians for providing appropriate preventative care services . . .)." 72 Fed Reg at 51046.
- Are quality payments FMV/commercially reasonable?
  - Are payments being made to right party?
    - Is the physician really responsible for the quality outcomes on which the payments are based?
  - How is FMV determined?

Cost Metrics

- Payments to Reduce Costs
  - Lowering device/drug costs, average cost per case, readmissions
  - Special rule on compensation per service payments deemed not to be based on volume or value: Product substitution? Other utilization targets?
- Q: Isn't Stark about controlling costs and reducing referrals?
  - A: Not exactly . . .
    - When asked if a hospital could pay an employed physician for meeting hospital or drug utilization targets, CMS responded that there "is no exception that would permit payments to physicians based on their utilization of DHS, except as specifically permitted by the risk sharing arrangements, prepaid plans and personal services arrangements exceptions. None of those exceptions permit those payment other than in the context of services provided to enrollees of certain health plans." *Phase II Commentary*, 69 Fed. Reg. at 16088.
    - When asked for guidance on the payment of incentives to physicians to reduce or limit services, CMS indicated that such payments would run afoul of the general restriction on compensation that takes into account the volume or value of referrals unless they are qualifying physician incentive plan payments made in connection with enrollees of managed care plans. *Phase III Commentary*, 72 Fed. Reg. at 51046.
  - Has the government's thinking evolved? Reimbursement policy suggests it has.

Readmissions

- Payment for reducing readmissions
- Are such payments based on volume or value of referrals or other business between the parties?
  - Maybe – Maybe not
  - Is the physician receiving payment involved in readmission decision?
  - Can you make a per-patient payment for specific – using the special rules on compensation?
  - Have an ACO/CIN make the payments – indirect analysis applies
    - Enables parties to take advantage of more liberal indirect compensation arrangement exception
  - Still must address: FMV and commercial reasonableness

HACs

- Payments for decreasing HACs
- Are payments based on volume or value of referrals?
  - Perhaps – need details
  - Structure as a per-patient or per-service payment – use special rules on compensation
  - FMV and Commercial Reasonableness

Questions?

Thank You!

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Darby Allen focuses her practice on the health care industry, advising hospital systems, physician groups, and ancillary providers on a wide spectrum of health care regulatory matters. Darby has extensive experience with the Stark Law and federal and state anti-kickback laws, including structuring compliant physician arrangements and representing clients in civil and administrative enforcement matters. Darby also has defended clients in False Claims Act cases and state Medicaid investigations, and regularly assists clients with internal investigations, self-disclosures, and Medicare and Medicaid audit responses

Additional Qualifications

- Associate, 2010-2017; Summer Associate, 2009 – Baker & Hostetler LLP, Houston
- Claims and Litigation Intern, Houston Methodist, Houston, 2008

Professional and Community Activities

- American Health Lawyers Association, 2010-present
- Washington State Society of Healthcare Attorneys, 2017-present
- Texas Bar Association, Health Law Section, 2010 -present

Education

J.D., University of Houston Law Center, 2010, magna cum laude

- Business Development Editor, Houston Journal of Health Law and Policy

B.S., Biology, University of Texas at Austin, 2006

- Alpha Chi Omega Sorority

Related Practices

Health Care
Health Care Litigation
Health Care Mergers & Acquisitions
Health Care Operations
Health Care Reform
Health Care Regulation & Compliance
Health Care Reimbursement & Payment
Hospitals
Physician Groups
Medical Staff

Admitted to Practice

Texas, 2010

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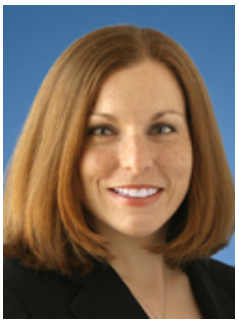

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Anna Buono is a commercial trial lawyer who practices extensively in the health care and financial services industries, as well as handling intellectual property litigation and privacy and security issues across various industries. She represents clients on a wide range of claims, including breach of contract and business torts, antitrust and unfair competition, trademark, copyright, and patent infringement, data breach and security enforcement, as well as employment and franchising disputes.

Representative Experience

Employment defense for Providence Health System, City of Hope and others
Defending single-plaintiff claims involving discrimination, harassment, wrongful termination, failure to accommodate, retaliation, and wage and hour violations for companies in health care and financial industries. (Ongoing)

Defense of health care company developer in business accounting action
Representing health care company developer/manager against claims of breach and accounting arising from disputed implied partner relationship. (Ongoing)

Defense of California physician interindemnity arrangement and its trustees against former trustee
Represented interindemnity arrangement trustees in writ action by former trustee seeking reinstatement, and representing interindemnity arrangement against claims of retaliation by same former trustee. (Ongoing)

Natkin v. American Osteopathic Association et al.
Representing hospital and doctor in breach of contract and defamation claims stemming from termination of resident from residency program. (Ongoing)

Digital Archives, Inc. v. Providence Health System - Southern California
Represented a healthcare provider in breach of contract action relating to records storage and management. (2016)

Education

J.D., Loyola Law School, Los Angeles, 2004, cum laude

B.S., Hospitality Administration, Boston University, 1997, summa cum laude

Related Practices

Appellate Litigation
Employment Litigation
Food, Beverage, Restaurants & Hotels
Franchising
Intellectual Property Litigation
Theft of Ideas
Health Care Litigation
Litigation
Media & First Amendment
Privacy & Security
Antitrust
White Collar, Investigations, and Government Controversies

Admitted to Practice

California, 2004
U.S. Court of Appeals 9th Circuit, 2011
U.S. District Court Central District of California, 2004
U.S. District Court Eastern District of California, 2005
U.S. District Court Southern District of California, 2011

Providence Health System – Southern California v. GRM Information Management Systems, Inc.
Represented healthcare provider in declaratory relief and breach of contract action relating to records storage and management. (2016)

Medi Entity v. Health Investment Corp. & VCFB Management v. Anaheim General Hospital LP
Defended hospital-related entities in breach of contract and related claims arising from two failed attempts by plaintiffs to acquire hospital. (Cal. Super. Ct. 2012)

Additional Qualifications

- Associate, Arnold & Porter LLP, Los Angeles, 2008-2010
- Associate, Heller Ehrman LLP, Los Angeles, 2004-2008
- Research Assistant, Professor Laurie L. Levenson, Loyola Law School, Los Angeles, 2002

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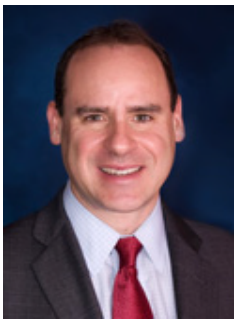

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Jeffrey B. Coopersmith is a veteran trial lawyer with an extensive practice focusing on civil and criminal matters, internal investigations for private and public entities, and complex commercial litigation. A former federal prosecutor, Jeff has substantial experience as lead counsel representing companies and individuals, both in the U.S. and abroad, in connection with investigations and criminal and civil enforcement proceedings in the areas of health care, securities, FCPA, antitrust, tax, banking, legal ethics, and others. Jeff's internal investigation work has involved representation of Board committees, companies, municipalities, and corporate officers, and he has deep experience with the difficult issues that come up in these matters. Jeff also teaches and writes extensively on these and other topics relating to government controversies and investigations. Jeff currently serves as a member of the firm’s Quality Assurance Committee.

Additional Qualifications

- Faculty, Kessler-Eidson Program for Trial Techniques, Emory University Law School, 2010-present
- Partner, DLA Piper, Seattle, 2005-2012
- Assistant United States Attorney, U.S. Attorney’s Office, Western District of Washington, Seattle, 1997-2005
- Covington & Burling, Washington, D.C., 1991-1997
- Law Clerk, The Honorable R. Lanier Anderson III, United States Court of Appeals for the Eleventh Circuit, 1990-1991

Professional and Community Activities

- Past Member, Board of Ethics, Port of Seattle Commission, 2013-2014
- Washington State Bar Association
- National Association of Criminal Defense Lawyers
- Washington Association of Criminal Defense Lawyers

Education

J.D., Emory University, 1990, first in class

- Order of the Coif

A.B., Economics, Duke University, 1986

Related Practices

White Collar, Investigations, and Government Controversies
Arbitration
Appellate Litigation
Government Relations & Litigation
Government Investigations and Crisis Management
Antitrust
Litigation
Health Care Litigation
Health Care Regulation & Compliance
Tax: Federal, State & Local
Securities Litigation
Consumer Financial Services: Supervision, Enforcement & Litigation

Admitted to Practice

California, 2007
District of Columbia, 1991
Washington, 2001
U.S. Supreme Court, 1995
U.S. District Court Eastern District of Washington, 1995

Professional Recognition

- Named as one of the "Best Lawyers in America" by Best Lawyers, 2011-present
- Selected to "Washington Super Lawyers" by Thomson Reuters, 2010-2017; Selected to "Top 100 Washington Super Lawyers," 2012-2013, 2016-2017
- Thomas C. Wales Performance Award

Admitted to Practice (cont.)

U.S. District Court Western District of Washington, 1997
U.S. District Court District of Columbia, 1991
U.S. Court of Appeals D.C. Circuit, 1991
U.S. District Court Northern District of California, 2007
U.S. Court of Appeals 4th Circuit, 1994
U.S. Court of Appeals 9th Circuit, 1997
U.S. Court of Appeals 10th Circuit, 1995
U.S. Court of Appeals 11th Circuit, 1990

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Dennis Diaz is a health care regulatory and transactional lawyer. For more than 25 years, he has represented a wide range of health care providers, including multi-hospital systems, community hospitals, physician-hospital organizations, accountable care organizations, ambulatory surgery centers, and medical groups, in California and nationally. Dennis focuses his practice on regulatory and compliance matters, fraud and abuse, provider transactions including hospital-physician alignment and joint ventures, provider operations, and billing and payment issues. He regularly advises and defends providers against government enforcement actions and leads large-scale internal investigations for providers. He also has served as lead counsel in structuring hospital-physician integrated delivery organizations, including accountable care organizations, medical foundations, and ambulatory surgery centers. Dennis also acts as outside general counsel to hospitals and medical groups.

Practice Highlights

- Defending actions brought by the Department of Health and Human Services (DHHS), the Office of Inspector General (OIG), the Centers for Medicare and Medicaid Services (CMS), the California Department of Health Care Services (DHCS), the California Department of Public Health (CDPH), and local governmental authorities
- Internal health care regulatory and compliance matters, including audits and investigations, corrective actions, refunds, and disclosures to the government
- Structuring and negotiating hospital-physician contracts and joint ventures, including strategies for integrated care organizations and hospital-physician alignment
- Federal and state physician self-referral (Stark and PORA), anti-kickback, and fraud and abuse issues in connection with physician contracts and provider operations
- Billing and reimbursement disputes with governmental and commercial payors, including the Medicare and Medicaid programs
- Conducting due diligence of health care regulatory and compliance affairs on behalf of buyers, investors, lenders and sellers in acquisitions and financing transactions
- General counsel to community hospitals and medical groups

Education

J.D., University of California, Los Angeles, School of Law

B.A., University of California, Santa Barbara, with honors

Related Practices

Health Care Litigation
Administrative Law Disputes
White Collar, Investigations, and Government Controversies
Health Care Regulation & Compliance
Health Care Mergers & Acquisitions
Health Care Operations
Health Care Finance
Health Care Reimbursement & Payment
Litigation
Hospitals
Physician Groups
Health Care
Health Care Reform

Admitted to Practice

California, 1980

Additional Qualifications

- Adjunct Professor of Law, Health Law, University of Southern California Gould School of Law
- Adjunct Professor of Law, Health Law, Loyola University School of Law
- Lecturer, Health Care Law for Managers and Entrepreneurs, University of California, Irvine - Executive MBA Program
- Partner, Sonnenschein Nath & Rosenthal LLP
- Staff Counsel, Office of General Counsel, U.S. Department of Health and Human Services, Washington, D.C.

Professional and Community Activities

- American Health Lawyers Association

Professional Recognition

- Named one of "America's Leading Lawyers for Business" in Health Care (California) by Chambers USA, 2010-2017
- Named one of the country's 12 "Outstanding Hospital Lawyers" by Nightingale's Healthcare News, 2007
- Selected by Best Lawyers as Los Angeles' "Lawyer of the Year" in Administrative/Regulatory Law, 2017
- Named one of the "Best Lawyers in America" in Health Care Law by Best Lawyers, 2010-present
- Selected to, "Top Rated Lawyers Guide to Health Care Law," Corporate Counsel
- Highest rating (AV) by peers – Martindale-Hubbell Legal Rating Service

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Jane Eckels practices in the areas of information technology and intellectual property, with a focus on health information and technology transactions. Jane represents hospitals, practice groups, trade associations, nonprofit organizations, healthcare technology vendors and others in a full range of health information and technology matters. She supports clients in procurement and implementation of traditional and cloud-based systems, innovation and launch of new technologies, information exchange and sharing arrangements for technology and data, licensing and distribution of health technology products and services, as well as mobile and digital health initiatives. With over two decades of experience, she has extensive experience structuring and negotiating complex licenses, commercial agreements and other projects involving software, hardware, data, content, Internet technologies, and services.

Professional and Community Activities

- Health Information Technology Group, American Health Lawyers Association
- Legal Aspects of the Enterprise Task Force, Health Information Management Systems Society
- Adjunct Faculty, Seattle University Arts Legal Clinic, 1999-2006
- Volunteer Attorney, Washington Lawyers for the Arts, 1999-2006
- President, Earshot Jazz Society Board, 2001-2006
- Volunteer Attorney, Northwest Immigrants' Rights Project, 1997-2003

Professional Recognition

- Named one of the "Best Lawyers in America" Technology Law by Best Lawyers, 2017-present
- Selected to “Washington Rising Stars,” Thomson Reuters, 2002-2008

Education

J.D., University of Michigan Law School, 1997, cum laude

- Note Editor, Michigan Law Review

A.B., French, Dartmouth College, 1994, cum laude

Related Practices

Corporate and Business Transactions
Intellectual Property
Health Information
Health Information Technology
Startups & Emerging Companies
Tax-Exempt Organizations
Technology Services for Financial Institutions
Technology
Internet & E-Commerce
Communications, Media, IP & Technology
Digital Media
Telecommunications
Health Care
Physician Groups
Cloud Services
Telemedicine
Digital Health

Admitted to Practice

Washington, 1997
Alaska, 2007

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Caitlin Forsyth focuses her practice on the health care industry, regularly providing guidance to health care providers on a wide spectrum of regulatory matters, including changes of ownership; federal and state licensure requirements; state health information privacy laws; Medicare and Medicaid coverage, reimbursement, and compliance; telemedicine; and other regulatory matters.

Caitlin also serves as general regulatory counsel for several clinical, molecular, and toxicology laboratories. She provides advice on an array of issues including: regulatory laws (e.g., CLIA, HIPAA, Stark, Anti-kickback, False Claims Act), billing and reimbursement, state law distinctions, government guidance (OIG Fraud Alerts and Advisory Opinions), documentation requests (particularly Medicare Comprehensive Error Rate Testing (CERT) audits), and phlebotomy/specimen collection.

Additional Qualifications

- Legal Intern, Children's Hospital, Seattle, 2013-2014
- Research Assistant, Professor Sallie Sanford, University of Washington School of Law, Seattle, 2013-2014
- Legal Intern, MultiCare Health System, Tacoma, Wash., 2013
- Law Clerk, U.S. Attorney's Office, Western District of Washington, Seattle, 2013
- Legal Intern, Washington State House of Representatives, Office of Program Research, Olympia, Wash., 2013 and 2012
- Research Assistant, Professor Anne Mastroianni, University of Washington School of Law, Seattle, 2012-2013
- Research Assistant, Seattle Institute for Biomedical and Clinical Research, Seattle, 2010-2011

Professional and Community Activities

- American Bar Association
- American Health Lawyers Association
- Washington State Society for Healthcare Attorneys
- King County Bar Association

Education

J.D., University of Washington School of Law, 2014, with honors

B.A., Biology, University of San Diego, 2010, magna cum laude

Related Practices

Health Care
Telemedicine

Admitted to Practice

Washington, 2014

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Bob Homchick is a health care regulatory lawyer, he counsels clients in areas such as physician self-referral (i.e., the federal Stark Law and its state law counterparts), regulatory compliance, and fraud and abuse. Bob also regularly represents hospitals, physicians, ancillary services providers, and others in a wide variety of transactional matters including mergers, acquisitions and affiliations, and the formation and operation of joint ventures. His extensive experience includes the development and implementation of compliance programs, defending providers in government audits, investigations, administrative proceedings and litigation, including qui tam False Claims Act lawsuits.

Bob regularly speaks and writes on a variety of health law regulatory topics.

Practice Highlights

- Works with hospitals, physician groups, and academic medical centers to resolve Stark Law and anti-kickback issues arising out of physician relationships, organizational structures, and joint ventures
- Advises clients in the formation or acquisition of new entities, the restructuring of existing entities, and creation of alliances or other integration initiatives
- Advocates directly with state and federal regulatory agencies on behalf of providers and other clients
- Directs internal investigations of compliance issues and advises clients regarding corrective action and the voluntary disclosure processes
- Represents both physician groups and hospitals in practice and service line acquisitions, co-management agreements, and other integration strategies
- Works with providers, managers, and private equity funds in connection with the formation of specialized joint ventures (i.e., stereotactic radiosurgery, intraoperative monitoring, nuclear medicine, wound care and various types of imaging)
- Assists providers, investors and creditors in assessing the regulatory risks of mergers, acquisitions, affiliations or investments
- Serves as an expert witness on health care regulatory and compliance issues

Education

J.D., University of Notre Dame Law School, 1982, summa cum laude

B.A., University of Puget Sound, 1979, summa cum laude

Related Practices

Health Care
Health Care Regulation & Compliance
Health Care Mergers & Acquisitions
Health Care Operations
Health Care Reimbursement & Payment
Health Care Litigation
White Collar, Investigations, and Government Controversies
Litigation
Hospitals
Physician Groups
Health Care Reform

Admitted to Practice

District of Columbia, 2013
Washington, 1983

Professional and Community Activities

- Chair, Program Committee American Health Lawyers Association Fraud and Compliance Forum
- Past Member, Board of Directors, American Health Lawyers Association
- Past Chair, Practice Group on Fraud and Abuse, Self-Referrals and False Claims, American Health Lawyers Association
- Past Chair, Health Law Section, Washington State Bar Association
- Past President, Western District of Washington, Federal Bar Association

Professional Recognition

- Received the "John M. Davis Award for Outstanding Legal Expertise," Davis Wright Tremaine, 2017
- Named Fellow of the American Health Lawyers Association, 2016
- Named the "Seattle Best Lawyers Health Care Lawyer of the Year" for 2012 by Woodward/White
- Named one of the "Best Lawyers in America" in Health Care Law by Best Lawyers, 2001-present
- Selected to "Washington Super Lawyers," Thomson Reuters, 2004-2017
- Named as one of "155 Top Lawyers" by Seattle Magazine and Seattle Business Monthly, 2007
- Recipient of the "Patricia Meador Leadership Award," Practice Group on Fraud and Abuse, Self-Referrals and False Claims, American Health Lawyers Association, 2009

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Renee Howard is a seasoned health care attorney with nearly two decades of experience in regulatory and litigation matters. She counsels a wide range of health care providers and suppliers, including hospitals, health systems, physicians, imaging centers, laboratories, medical device manufacturers and distributors, and behavioral health agencies. Renee represents clients in federal False Claims Act, Anti-Kickback, and Stark law matters, FDA issues, Medicare and Medicaid reimbursement litigation, and professional licensing investigations and complaints. She also advises on internal investigations pertaining to fraud and abuse and routinely counsels on compliance-related policies and procedures.

Additional Qualifications

- Partner, Perkins Coie, Seattle, 2012-2016
- Shareholder, Bennett Bigelow & Leedom, P.S., Seattle, 2006-2012
- Associate, Jones Day, Washington, D.C., 2000-2005
- Associate, Honigman, Miller, Schwartz & Cohn, Detroit, 1999-2000

Professional and Community Activities

- Health Law Section, American Bar Association
- Editorial Board Member, ABA Stark and Anti-Kickback Toolkit

Professional Recognition

- Named the "Seattle Best Lawyers Health Care Lawyer of the Year" for 2015
- Named one of the "Best Lawyers in America" in Health Care Law by Best Lawyers, 2013-present

Education

J.D., University of Notre Dame Law School, 1999, magna cum laude

- Executive Articles Editor, Notre Dame Law Review

B.A., Government/Philosophy, University of Notre Dame, 1996, magna cum laude

Related Practices

Health Care
Health Care Litigation
Health Care Regulation & Compliance
Health Care Reimbursement & Payment
Health Care Operations
Health Information
Physician Groups
Medical Staff

Admitted to Practice

Washington, 2006
U.S. Court of Appeals 9th Circuit
U.S. District Court Western District of Washington

Jordan Keville // PARTNER // LOS ANGELES

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Jordan B. Keville has a practice that focuses on reimbursement and regulatory issues for a number of health care provider categories that include hospitals, physicians, Federally Qualified Health Centers (“FQHCs”), pharmacies, and physical therapists. He has also regularly advised transplant centers and organ procurement organizations on reimbursement and compliance issues. As a part of his work with these types of clients, Mr. Keville offers general advice and litigates at both the court and administrative level.
Mr. Keville also advises clients on various regulatory matters. His areas of focus include the federal “340B” drug discount program, with respect to which he assists clients with, among other things, negotiating and executing third-party pharmacy contracts and responding to 340B-related audits by the Health Resources and Services Administration and pharmaceutical manufacturers. Mr. Keville also regularly works with clients on issues relating to medical education, particular special Medicare payments available for direct graduate medical education (“GME”), and indirect graduate medical education (“IME”).

Additional Qualifications

- Partner, Hooper, Lundy & Bookman, PC, Los Angeles, California, August 2001-October 2016

Professional Recognition

- Named as one of the "Best Lawyers in America" in Health Care Law by Best Lawyers, 2018-present
- Recognized as a Southern California Rising Star by Super Lawyers, 2009
- Recognized as an Outstanding Young Healthcare Lawyer by Nightingale Healthcare News, 2008

Education

J.D., Loyola Law School, Los Angeles, 2001

- Order of the Coif
- St. Thomas More Honors Society

B.A., English and Anthropology, University of California, Santa Barbara, 1998

- Highest Honors
- Phi Beta Kappa

Related Practices

Administrative Law Disputes
Appellate Litigation
Litigation

Admitted to Practice

California, 2001

Davis Wright Tremaine LLP
DEFINING SUCCESS TOGETHER

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Terri Keville advises health care clients on credentialing, peer review and other medical staff issues, consent (including end-of-life issues), confidentiality (HIPAA and CMIA), emergency care requirements (EMTALA), clinical research, and other operational matters. Terri concentrates on helping clients avoid and minimize problems and disputes. When litigation cannot be avoided, her litigation practice emphasizes case-dispositive motions and appeals involving hospitals, physician groups, and other health care clients. Terri has made new favorable law for California health care organizations in cases involving physician peer review, Medicare and ERISA preemption, and California's Unfair Competition Law.

Practice Highlights

- Advises numerous hospital clients such as Dignity Health and Huntington Hospital on complex peer review and patient-care issues, including dealing with impaired and disruptive practitioners, sexual harassment allegations against medical staff members, clashing medical groups and medical staff factions, and difficult end-of-life decision-making
- Reviews and revises medical staff bylaws, rules and regulations, and policies to keep them in compliance with evolving legal and accreditation standards for multiple health care providers
- Advises medical staffs on issues relating to credentialing for appointment, reappointment and new privileges for multiple health care providers
- Assists medical staffs in addressing clinical and behavioral deficiencies of their members, including by serving as an advocate or hearing officer in peer review hearing proceedings for multiple health care providers
- Defends hospitals, medical staffs, and physician groups against claims by individual physicians for wrongful exclusion that involve complex issues of alleged disability discrimination, substance abuse, peer review duties and procedural rights, and the interplay of those elements with physician employment or partnership agreements

Education

J.D., University of Southern California Law School, 1992

- Order of the Coif

Graduate Studies, Philosophy, California State University, Northridge, 1974

B.A., Philosophy, University of Pennsylvania, 1972

Related Practices

Medical Staff
Health Care Regulation & Compliance
Health Information Privacy, Security & Breach Response
Health Information
Health Care Operations
Health Care Litigation
Appellate Litigation
Health Care
Health Care Reform
Telemedicine

Admitted to Practice

California
U.S. Supreme Court
U.S. Court of Appeals 9th Circuit
U.S. Court of Appeals 1st Circuit
U.S. District Court Central District of California
U.S. District Court Northern District of California

Professional and Community Activities

- Vice Chair, Substance Use Disorders and Mental Health Interest Group (previously Task Force), 2014 – Health Law Section, American Bar Association
- Member; President, 2004-2005 – California Society for Healthcare Attorneys
- President, 2008-2012; Board of Directors, 2005-present – Friends of the Los Angeles County Law Library
- Co-chair, Joint Committee on Biomedical Ethics, Los Angeles County Medical Association and Los Angeles County Bar Association
- Executive Committee, Appellate Courts Section; Past Member and Co-chair, Bioethics Committee, 2000-2002; Member, Healthcare Law Section – Los Angeles County Bar Association
- American Health Lawyers Association
- Vice Chair, Oct. 2014-Sept. 2015; Member, Oct. 2011-Sept. 2015 – California State Bar Health Law Committee

Professional Recognition

- Selected by Best Lawyers as Los Angeles' "Lawyer of the Year" in Health Care, 2014
- Named one of the "Best Lawyers in America," in Health Law by Best Lawyers, 2007-present
- Named one of "America’s Leading Lawyers for Business" in Health Care (California) by Chambers USA, 2007-2017
- Selected to "Southern California Super Lawyers" by Thomson Reuters in Health Care, 2004-2017; in Appellate, 2004-2017; in Business Litigation, 2004-2017
- Named in Who's Who in America, 2006-present
- Named in Who's Who in American Law, 2005-2011
- Named in Who's Who of American Women, 2007, 2010

Dayna Nicholson // COUNSEL // LOS ANGELES

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Dayna C. Nicholson focuses her practice on health care-related matters, such as licensing and other regulatory compliance, peer review and credentialing, and corporate and medical staff governance. Her clients include hospitals, medical staffs, managed care organizations, medical groups, medical device retailers, and other health care providers. Dayna also has experience in patient information privacy issues, appeals of state-issued administrative penalties, Medicare and Medi-Cal certification, emergency care requirements, and litigation arising out of peer review matters.

Dayna has significant experience counseling health care organizations regarding operational issues and regulatory and litigation matters. She has reviewed or drafted numerous policies, rules and regulations, bylaws, and other procedural documents, and regularly assists clients in interpreting and following such guidance. In the area of credentialing and peer-review, she is well-versed in state, federal and accreditation requirements, as well as the roles, responsibilities, and concerns of an organization's leadership, including medical directors and chief medical officers, credentialing and peer review committees, individual reviewers, and support staff. In such matters, Dayna makes every effort to communicate a clear, accurate assessment of the legal landscape, and to provide realistic, effective resolutions.

Practice Highlights

- Counsels clients regarding credentialing best practices, including structuring information flow, decision-making criteria, communication activities, etc.
- Develops/ revises multiple credentialing policies and procedures.
- Creates and presents training materials to credentialing/peer review committees and administrative staff.
- Attends credentialing and peer review meetings.
- Counsels clients in corrective action, including suspension and termination, and handles all aspects of peer review hearings.

Education

J.D., Georgetown University Law Center, 2003, cum laude

M.P.H., Johns Hopkins University, Bloomberg School of Public Health, 2003

B.S., Business Administration, Pepperdine University, 1993

Related Practices

Corporate Finance & Securities
Health Care
Health Care Mergers & Acquisitions
Health Information Privacy, Security & Breach Response
Privacy & Security

Admitted to Practice

California, 2003

Additional Qualifications

- Associate, Pepper Hamilton, LLP, Los Angeles, 2013-2016
- Associate, Norton Rose Fulbright, Los Angeles, 2003-2013
- Summer Associate, Norton Rose Fulbright, Los Angeles, 2002
- Summer Associate/Law Clerk, Duane Morris, LLP, Washington, D.C., 2001-2002

Professional and Community Activities

- Board Member and Past President, Women in Health Administration of Southern California
- Chair, Executive Committee, Health Law Section of the Los Angeles County Bar Association, Los Angeles County Bar Association
- American Health Lawyers Association
- Health Law Section, American Bar Association
- California State Bar
- California Society for Health Care Attorneys
- Executive Committee Member, The Johns Hopkins University's Los Angeles Alumni Chapter

Professional Recognition

- Pro Bono Champion, American Health Lawyers Association, 2014
- Selected to “Southern California Rising Stars,” Thomson Reuters, 2007, 2009, and 2013

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DEFINING SUCCESS TOGETHER

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Drew Patterson represents companies at every stage of their life cycle, from startups and emerging companies to mature public and private companies. He represents banks, financial institutions, and companies in many different industries, health care, real estate, entertainment, hospitality, and information technology.

His experience in corporate and transactional matters include venture capital financing, mergers and acquisitions, data privacy and security, debt and equity financings, commercial real estate issues, corporate governance, securities law issues, environmental compliance, corporate dissolutions, and loan workouts for bank lenders and borrowers.

He also has experience in a variety of litigation matters, including intellectual property, fraudulent transfer, antitrust, real estate, commercial, and bankruptcy-related disputes. In the courtroom, Drew has successfully litigated and negotiated millions of dollars of bankruptcy claims on behalf of debtors, trade creditors, lenders, investors, and corporate officers. He also has represented purchasers and rights-holders in bankruptcy-related asset sales and intellectual property licensing transactions.

Additional Qualifications

- Associate, Bankruptcy and Corporate Restructuring, Arnold & Porter LLP, Los Angeles
- Law Clerk, United States Department of Defense Office of General Counsel, International Affairs Division, Washington, D.C.

Education

J.D., University of California, Los Angeles, 2009

- Order of the Coif
- Bulletins Editor, UCLA Journal of Law and Technology

B.A., International Relations, Claremont McKenna College, 2006, cum laude

- Phi Beta Kappa
- Donald A. Henriksen Fellowship in Economic Diplomacy

Related Practices

Corporate and Business Transactions
Mergers & Acquisitions
Energy Regulation & Litigation
Environmental & Natural Resources
Commercial Lending
Distressed Real Estate, Bankruptcy & Workouts
Bankruptcy & Creditors' Rights
NextGen Tech
Health Care

Admitted to Practice

California
U.S. District Court Central District of California
U.S. District Court Southern District of California

Loring Rose // ASSOCIATE // LOS ANGELES

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Loring Rose has handled all aspects of general civil litigation. His practice includes entertainment, real estate, and environmental matters, as well as title insurance defense and contract and partnership disputes. Loring has extensive experience with electronic document review and production, and has worked on a full range of legal research and documentation, including settlement agreements and appellate briefs. Prior to his legal career, Loring spent nearly a decade in information technology, working with banks, Internet startups, and software and insurance companies.

Representative Experience

Zhang v. China Free Press
Currently defending U.S.-based nonprofit organization, which provides free Web hosting services to websites operated by Chinese dissidents, in libel lawsuit brought by movie actress concerning articles about her on one of the hosted sites. (C.D. Cal. Ongoing)

Additional Qualifications

- Associate, Litigation, Glaser, Weil, Fink, Jacobs, Howard & Shapiro, LLP, Los Angeles, 2007-2010
- Summer Associate, Litigation, Law and Motion, Murchison & Cumming, LLP, Los Angeles, 2006
- Volunteer Advocate, Workers’ Rights Self-Help Center, Neighborhood Legal Services of Los Angeles County, Los Angeles, 2005-2007

Education

J.D., Loyola Law School, Los Angeles, 2007, cum laude

- Order of the Coif
- Scott Moot Court Honors Board
- Staff Member, Loyola Law Review
- Dean's Honor List
- St. Thomas More Law Honor Society
- First Honors: Introduction to Appellate Advocacy, Trial Advocacy, Supreme Court Seminar

M.F.A., Acting, DePaul University, 1995

B.A., Communications, English, North Carolina State University, 1991

Related Practices

Litigation

Admitted to Practice

California, 2007
U.S. District Court Central District of California, 2007
U.S. Court of Appeals 9th Circuit, 2009

John R. Tate // PARTNER // LOS ANGELES

Co-chair, Health Care Litigation Group

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John Tate is a commercial trial lawyer who practices extensively in the health care and financial services industries, as well as real estate and insolvency-related litigation. He represents clients on a wide range of claims, including commercial torts, unfair competition, breach of fiduciary duties and creditor's rights, as well as issues specific to the health care and real estate finance industries.

Health Care Litigation

U.S. ex rel. ProTransport-1 LLC v. Kaiser Foundation Health Plan
Obtained early dismissal of False Claims Act and retaliation claims asserted by an ambulance service relator. (N.D. Cal. 2013)

Enki Health and Research Systems, Inc. v. County of Los Angeles, State of California, et al. and 18 related actions
Chief trial counsel representing 18 mental health providers seeking payment of claims in excess of $18 million for mental health services provided to Short-Doyle/Medi-Cal beneficiaries that were not paid due to defects in the claims processing systems of the state and county. (L.A. Cnty. (Cal.) Super. Ct. Ongoing)

Bernard v. City of Oakland; Martinez v. City of Union City
Prevailed in defense of the California Public Employees' Retirement System in an action by retired firefighters seeking to alter the premium contribution obligations of contracting public agencies under the Public Employees' Medical and Hospital Care Act (California Government Code sections 22751, et seq.). 202 Cal.App. 4th 1563 (2012)

Erin Brockovich v. Sisters of Charity of Leavenworth Health System, Inc.
Defense of two hospital systems in qui tam actions purporting to enforce Medicare's Secondary Payor provisions (42 U.S.C. Â§ 1395y(b)(3)). Plaintiff sought recovery of all Medicare funds paid to treat alleged but unspecified hospital malpractice injuries. The cases were dismissed while on appeal to the 9th Circuit Court of Appeals. (C.D. Cal.)

Education

J.D., Vanderbilt University Law School, 1976

A.B., Government, Dartmouth College, 1973, cum laude

Related Practices

Health Care Litigation
Consumer Lending
Bankruptcy & Creditors' Rights
Real Estate Finance
Arbitration
Financial Services
Health Care
Communications, Media, IP & Technology
Hospitals
Telecommunications
Appellate Litigation

Admitted to Practice

U.S. Supreme Court, 1983
California, 1977
U.S. Court of Appeals 9th Circuit
U.S. District Court Northern District of California
U.S. District Court Central District of California
U.S. District Court Southern District of California

Fraud actions against former employee of large regional hospital
Represented large regional hospital in multiple actions arising from theft and kickbacks perpetrated by a former employee and his associates. Obtained judgment and/or settlement against multiple defendants, recovering substantial portion of funds taken. Cooperated with criminal prosecution resulting in conviction of principal participants. (2012)

Defense of national pharmacy chain against pharmacy seller
Represented acquirer of three pharmacies against seller's claims for breach of sale agreement arising from disputed reimbursement claims. (2010)

Defense of hospital chain arising from failed hospital sale
Defended regional hospital system in litigation disputing responsibility for failure to close the sale of a hospital. Plaintiff voluntarily dismissed case. (2012)

Defense of indemnity claims by former corporate officers
Represented regional hospital system against claims for former officers for reimbursement involving California Labor Code Â§2802 and California Corporations Code Â§317 for expenses incurred in legal defense of criminal investigations. (2012)

Promise Hospital of East Los Angeles v. Providence Health System
Defense of hospital in dispute over responsibility for charges incurred by patients transferred under letter of agreement. (2012)

Defense of civil enforcement action alleging wrongful transportation, treatment and billing of indigent patients
Represented regional hospital system charged with violating California Business and Professions Code Â§17200 by the Los Angeles city attorney arising from allegations of improper patient referrals. (2012)

CHA Hollywood Medical Center v. Kravitz
Represented hospital and skilled nursing facility in successful eviction of patient refusing discharge. (2010)

Additional Qualifications

- Partner, Litigation Department, Arter & Hadden LLP, 1994-2003
- Partner, Head of Litigation Department, McDermott & Trayner, 1987-1994
- Partner, Gendel, Raskoff, Shapiro & Quittner, 1983-1987

Rebecca L. Williams // PARTNER // SEATTLE

Chair, Health Information Technology & HIPAA Practice

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Becky Williams, a registered nurse with hands-on health care experience, is the chair of the Health Information Technology/HIPAA Practice Group.

A nationally recognized authority on HIPAA and the HITECH Act, Becky focuses much of her practice on privacy, security, and health care regulatory issues. She counsels clients on health care privacy and security compliance (e.g., HIPAA, the HITECH Act and their state counterparts). She regularly works on structuring and developing processes and documentation for the electronic sharing of health information, health information exchange and electronic health record "provisioning donation." Becky is a health care regulatory attorney who advises clients on anti-kickback, physician self-referral (e.g., the Stark Law), tax exemption, patient care, health care quality, governance and other health law issues. She also works on contracts and transactional matters.

Becky has written numerous publications, articles, briefings, chapters and other publications. She also is a contributing author to the Employee Benefits Institute of America's HIPAA Portability, Privacy and Security Manual. Becky is a frequent national speaker and regularly quoted in national health law publications.

Practice Highlights

- Develops effective HIPAA compliance strategies and counsels health care provider and health plan clients, as well as health care vendors and TPAs, on addressing ongoing HIPAA issues
- Structures arrangements – and develops implementing documents such as contracts, terms of use, bylaws, policies and procedures – for electronically sharing health information
- Assists clients in responding to data breaches, including providing notification of such breaches and addressing mitigation efforts
- Represents hospitals and health systems in EHR provisioning, including providing physicians and hospitals with subsidized technology – often called EHR donations – to promote electronic data sharing in compliance with Anti-Kickback Statute, Stark Law and tax-exemption requirements

Education

J.D., Loyola University Chicago School of Law, 1986

B.S.N., Nursing, Duke University, 1981, magna cum laude

Related Practices

Privacy & Security
Privacy & Security: Counseling & Compliance
Health Information
Health Information Technology
Health Information Privacy, Security & Breach Response
Health Care Operations
Health Care Regulation & Compliance
Health Care
Hospitals
Physician Groups
Health Care Reform
Internet & E-Commerce
Communications, Media, IP & Technology
Technology
Digital Health
Incident Response & Breach Counseling
Telemedicine
Artificial Intelligence

Admitted to Practice

Washington, 1998
Illinois, 1986

- Performs covered entity and business associate analyses and develops structures for complying with HIPAA
- Provides guidance with respect to risk analyses and risk management
- Develops privacy, security and breach notification policies and procedures and related documents, including notices of privacy practices and authorizations
- Drafts and negotiates business associate contracts from both a covered entity and business associate perspective
- Advises a variety of clients in addressing compliance issues, conducting internal investigations, and developing corrective action plans
- Creates innovative methods for alternative uses of health information, including quality reporting and promotion of research and public health
- Develops effective approaches in establishing and sharing information through personal health records and shared care plans
- Advises hospitals, health systems and others in the health care industry in resolving Stark Law and Anti-Kickback Statute issues including those arising out of organizational structures, physician relationships and vendor agreements
- Represents hospitals, health systems and other health care providers in procuring software and technology to support their electronic health records
- Counsels numerous health care clients in general regulatory, transactional and contract matters

Professional and Community Activities

- Co-Chair, Sub-workgroup on Enforcement – Workgroup for Electronic Data Interchange (WEDI), Strategic National Implementation Project (SNIP)
- Chair, Sub-workgroup on Preemption, WEDI-SNIP
- Vice Chair, Health Information and Technology Practice Group, American Health Lawyers Association, 2004-2010
- Legal Aspects of Health Information Exchange Task Force, Health Information and Management Systems Society
- Secretary, Trustee; Executive Committee Member – Villa Academy
- Trustee, 2001-2009; Executive Committee Member, 2006 – American Lung Association of the Northwest
- Washington State Society of Healthcare Attorneys
- American Bar Association

Professional Recognition

- Named as one of the "Best Lawyers in America" in Health Care Law by Best Lawyers, 2005-present
- Named a "Best Lawyer in Seattle" by Seattle Metropolitan magazine
- Listed in "Who’s Who in America," "Who’s Who Among Women" and "Who’s Who in Law"

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San Francisco | Seattle | Shanghai | Washington, D.C.