WELCOME

- Introduction of Panelists
- Highlights From American Health Lawyers Annual Meeting
- Timing
- Topics
TOPICS:

- Year In Review (Myra)
- Developments in Health Care Transactions (Kevin)
- Trends in Health Care Fraud and Abuse (Bob and Taryn)
- False Claims Act Developments (Bob)
- Dealing with Disruptive Physicians (Bob)
- New Managed Care Strategies for Health Care Providers (Kevin)
- Health Care IT and mHealth (Taryn)
- Other Miscellaneous Issues (All)
  - Post-Acute Providers Update (Taryn)
Year in Review

Source: AHLA Presentation by Elizabeth Carder-Thompson and Jack S. Schroder Jr.
Health Care Rule Creating Surprise Bills

Hospitals Are Between A Rock And A Hard Place
Alternative Dispute Resolution (ADR) Year-In-Review

- Increasing use of ADR to resolve disputes in health care setting
- Why transactional, in-house, and litigation lawyers should have an awareness of arbitration laws
- Claims subject to arbitration
- New AHLA ADR services
Health Information and HIPAA

Growing number of serious PHI data breaches although a perhaps slight reduction in total number of breaches.

Breaches in the News:

Do you still swipe at Target?.....over 39 million credit and debit card holders later…

The medical record (EHR) is considered on the black market to be more valuable than credit or debit cards because of the nature and type of patient information it contains. The going price of up to $50.00 per record coupled with EHR systems that are vulnerable to hacking and thefts (Medscape Medical News, 4/28/2014)

Advocate Medical Group (Chicago, August 2013)

Four million patient charts on stolen computers, password-protected, not encrypted

Boston Medical Center

Patient charts posted on vendor’s website

Affinity Health: Digital copiers (August, 2013)

Adult & Pediatric Dermatology PC (Mass., December, 2013)

HIPAA & CLIA Regulations: Provide direct access to laboratory test reports (76 Fed. Reg. 7289)
Liability

- Duty to provide Interpreter (foreign language, sign language)
- Talk Show Host = Physician for purposes of treatment?
  - Dr. Oz recommended a “heated rice footsie” for sleeplessness
  - Neuropathy prevented plaintiff from noticing overheated rice
  - Feet seared: claimed Dr. Oz had a duty to warn
  - This Court found no physician-patient relationship
  - 2013 WL 5511365 (N.Y. Sup. Ct. 10/10/13)
- Jane Does v. Johns Hopkins Hospital #24-C-13-001041 (Md. Cir. Ct., Baltimore)
Fraud and Abuse

Department of Justice and Health and Human Services announce another successful year in the fight against fraud with records along all important measures:

- Significant increase in *qui tam*/whistle-blower lawsuits
- CMS urged to improve oversight of ZPICs
- CMS: RACs are on hold
False Claims/\textit{Qui Tam}

\textbf{U.S. v. Quest Diagnostics}

CEO, CFO and GC got together and formed an entity in order to bring \textit{qui tam} action alleging kickbacks consisting of swapping discounted capitated rates to MCOs/IPAs for commercial patients in return for Medicare/Medicaid.

-The General Counsel gets nabbed by the state ethics requirements for attorneys which found that in order to have made the disclosures in the lawsuit, the attorney relied on confidential information obtained while in the attorney-client relationship with Quest.

\textbf{United States ex. rel. Nathan v. Takeda}

Question of what must be alleged in a fraud count under Rule 9(b) requirements of pleading with “particularity” a count of fraud or mistake.

Split in the federal circuits, in this case the 4\textsuperscript{th} Circuit affirmed the dismissal of relator’s complaint for failure to satisfy particularity requirements. This case was appealed/cert was sought.

Importantly, the Solicitor General asked the U.S. Supreme Court not to hear the case.

# SGR/Medicare Program Deficit Reduction Options

1. Eligibility Age
2. Deductibles/Copayments
3. Medigap
4. Premiums
5. SGR
6. Site Neutrality
7. Bad Debt
8. CAHs
9. Value-based Purchasing
10. Clinical Lab Services
11. Post Acute Providers
12. IPAB
13. DME
14. Part D

Developments in Health Care Transactions
Developments in Health Care Transactions

Information from Various Presentations

- The New Frontier: Physician Integration From The Trenches
  Katrina English, Robert A. Gerberry, Kim Harvey Looney

- Hospital Affiliations and Mergers – Preserving What Matters For The Community Hospital
  John R. Holdenried and Joseph R. Lupica

- Joint Operating Agreements: Everything Old Is New Again
  Ethan E. Rii and Marcia B. Smith

- Antitrust Year In Review
  John J. Miles and Christine L. White
Degree of Integration Continuum

LOW

Affiliation *

Management Services Agreement

Joint Operating Agreement

JV Sale of Minority Interest

JV Sale of Controlling Interest

Change of Controlling Member

Sale/Acquisition

Merger

HIGH

*Affiliation can include a wide spectrum of structures, including shared services organizations, branding agreements, ACOs, clinical integration arrangements, etc.
Historical Trend: For Many Community Hospitals, Trend Has Been Toward Acquisition or Merger

- Key Drivers: Capital needs, cost control and access to key payer agreements
- Trade independence for benefits of consolidation
- “Rescue” for underperformers
- Independence and local control sacrificed for to be part of a larger system

Source: Hospital Affiliations and Mergers – Preserving What Matters For The Community Hospital
“New Trend”: Complete Acquisition or Merger

Not Necessarily a Given

- New Drivers: Need new delivery models based on physician alignment
- Seek interdependence to support shift from FFS to FFV
- Some “rescue” features but also “quest for excellence”
- Local control is structured to promote collaboration
- Goals to achieve network incentives govern behavior

Source: Hospital Affiliations and Mergers – Preserving What Matters For The Community Hospital
Marketplace is evolving with various models reflecting a willingness on both sides to share equity and control.

Source of Examples: *The New Frontier: Physician Integration From The Trenches*
Non-Profits and For-Profits Form Joint Ventures to Acquire Other Entities

<table>
<thead>
<tr>
<th>Non-Profit</th>
<th>For-Profit</th>
<th>Acquisition Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marquette General Health System</td>
<td>Duke University Health System</td>
<td>Founded</td>
</tr>
<tr>
<td>Pearson Memorial Hospital Nova</td>
<td>Parham Medical Center</td>
<td>Acquired</td>
</tr>
<tr>
<td>Twin County Regional Healthcare</td>
<td>Wilson Medical Center</td>
<td>Acquired 20%</td>
</tr>
</tbody>
</table>

Source: Kaufmann Hall

Increasing Integration Between Hospitals, Physicians, Insurers and Other Providers

<table>
<thead>
<tr>
<th>Hospital</th>
<th>Acquisition Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tufts Medical Center</td>
<td>Founded</td>
</tr>
<tr>
<td>Highmark</td>
<td>Acquired</td>
</tr>
</tbody>
</table>

Source: Kaufmann Hall
Increasing Integration Between Hospitals, Physicians, Insurers and Other Providers

Source: Kaufmann Hall
As we all know, there are various legal issues which impact transactions in the health care marketplace, including Stark and Anti-kickback issues, licensure and reimbursement concerns, tax issues and antitrust.

The FTC under the Obama Administration has been much more active in the antitrust area than was the Bush Administration.

String of Successful FTC Challenges
Recent Successes for FTC

- Unprecedented string of FTC successes
  - Inova/Prince William (2008) (abandoned)
  - Reading Health System (2012) (abandoned)
  - Universal Health (15 divestitures ordered)
  - Phoebe Putney (2013) (no state-action exemption)
  - Capella/Mercy Hot Springs (2013) (abandoned)
Recent Successes for FTC

- Community Health/HMA (2014) (two divestitures ordered)
- HCA/Ascension (2014) (abandoned)
- ProMedica Health Sys. (2014) (4 opinions; merger unlawful; divestiture ordered)
Antitrust Theme

FTC Chairwoman:

- Belief that provider consolidation is increasing health care costs.
- With string of successes, any future potential consolidation involving significant market share is at risk of challenge.
Trends in Fraud and Abuse
Health Care Fraud & Abuse Update

Focus on individual accountability

- Criminal Cases
- Affirmative CMPs and Exclusion Cases
- CIA provisions that require management and boards to be involved in decision making
Trends in Fraud & Abuse

- Transparency
  - Open Payments (Sunshine Act)
  - Disclosure of Physician and Hospital Data
- Disclosure of Overpayments
- Audits
  - Shift in Congressional viewpoint on RACs
  - Re-examination of benefit/burden
Trends in Fraud & Abuse

- ACA/Exchanges
  - False Claims Act
  - OIG Reports on Marketplaces
  - Congressional Oversight
  - Premium Tax Credit Program
  - Anti-kickback Statute
Misbranding

**Conduct**
- Injecting patients with a drug that is not approved by the FDA
- Substituting cheaper, imported drugs that have not been approved for use in the United States
- Selling drugs with false, incomplete or misleading labels
- Promoting drugs for unapproved uses

**Targets**
- Physicians and Pharmacists
- Distributors and Internet Pharmacies
Physician Compensation

Issues

- Paying for work that isn’t being done or paying to stifle or eliminate competition (Tuomey)
- Paying physicians part of the hospital’s revenue, not the revenue the physician generates (Halifax)
- What about physicians who lose money? Is this commercially reasonable? (All Children’s/Villafane)
Kickbacks

- Looking at the individuals who receive the kickback

- Patient Assistance Programs
  - Supplemental Special Advisory Bulletin

Data mining is getting more sophisticated and resulting in more enforcement actions.
Rules to Watch

- Proposed revisions to OIG’s CMP authority
- Proposed revisions to OIG’s exclusion authority
- Two-midnight rule
False Claims Act Update
False Claims Act

- Record number of actions in 2013 – 753 (101 more than 2012/nearly double 2008)
- $3.8 billion in recoveries - $2.9 billion in *qui tam* recoveries in FY 2013
- $2.6 billion in healthcare fraud recoveries in FY 2013
- 80% of cases from whistleblowers
- Government declination is no longer a death sentence for *qui tam* actions. *Qui tam* relators appear to be proceeding in more declined cases.
Expanded FCA Liability

- Materiality
- Overpayments – *United States v. Continuum Health Partners, Inc.*
Recently Targeted Conduct

- Focus on clinical research activities
- Off-label marketing
- Manufacture and distribution of adulterated drugs
- Home health
Dealing With Disruptive Physicians

Changing relationship with hospitals – shift away from the independent contractor model toward a physician-employee model

- Need to consider the impact of Federal and State employment laws
- Interplay between MEC and HR

Disruptive Behavior

- Have a written policy
- Hospital must be able to explain how the physician’s disruptive behavior negatively and objectively impacted patient care
- Hospital should maintain a consistent approach when dealing with incidents of disruptive behavior
"New" Managed Care Strategies For Health Care Providers

Source: AHLA Presentation from Almeta E. Cooper and Lisa G. Han
Trends:

- Line separating payers and providers has become blurred as more are increasingly venturing in each other’s market

- Examples of Payor Activity
  - Cigna and Weill Cornell Physician Organization (850 Member Multispecialty Group Practice in NYC) “Collaborative Accountable Care Initiative”
  - Cigna has pursued similar initiatives in at least 15 States
  - Wellpoint: Acquisition of Care More Health Group, a Medicare Advantage Plan, and Special Needs Plan (CA, NV and AZ)
  - Highmark’s transaction with West Penn Allegheny Health System
  - United Health Care’s acquisition of management arm of Monarch Healthcare
  - Humana’s acquisition of Concentra, Inc. and Senior Bridge (Home Health)
Provider Sponsored Plans:

- “Back to the Future”
- Why?
  - Alignment strategy
  - Alternative revenue stream
  - More ability to influence quality and efficiency
  - Better able to utilize data
  - Impact of ACA, including enhanced coverage, Exchanges and ACOs
  - Enhance population health management expertise
  - Alternative to large payors
Provider Direct Contracting:

- Cleveland Clinic – direct contracts with Boeing, Lowe’s and Wal-Mart
- NAIC: Unless the provider contracts through a licensed insurer, provider may be considered to be engaging in the insurance business
- Real issue which needs to be analyzed in each State
  - Indiana: I.C. §27-13-1-19
  “Health Maintenance Organization” means a person that undertakes to provide or arrange for the delivery of health care services to enrollees on a prepaid basis, except for enrollee responsibility for co-payments or deductibles
Health Care IT and mHealth
FDA Mobile Medical App Guidance

- Apps that are not medical devices
- Apps subject to "enforcement discretion"
- Mobile medical apps
Clinical Decision Support (CDS) Tools

- Provide health care providers and patients with person-specific information, intelligently filtered and presented, to enhance health and inform and influence health care decisions

- Doesn't replace clinical decision-making, rather assists clinicians in informed, higher-quality decisions

- FDA will be issuing future guidance about how CDS products are categorized
April 2014 FDASIA Health IT Report

- Administrative Health IT
- Health Management IT
- Medical Device Health IT
Other Privacy/Security Considerations

- Cyber liability insurance
- More audits likely
- FTC
  - Also regulates privacy and security
  - Interpreted “unfair or deceptive acts or practices in or affecting commerce” to require appropriate information privacy and security safeguards
    - NPP lists ways in which use or disclose PHI, then any impermissible use or disclosure could be deemed “unfair”
    - Unsafe security protection could be deemed “unfair” practice
  - Issued guidance on photocopier hard drives and P2P software or workstations
FTC Actions

- 5 Health Care Vendors
  - CVS (Dumpster; 20 year monitoring)
  - Riteaid (Dumpster; 20 year monitoring)
  - LabMD (P2P file sharing; appealing)
  - Accretive (Unencrypted laptop; 20 year monitoring)
  - GM Transcription Services (Overseas vendor; 20 year monitoring)
Other Miscellaneous Issues
Post-Acute Care Explosion

According to Kaiser Health News:

- 1 out of every 6 Medicare dollars went to rehab facilities, nursing homes, long-term care hospitals and home health agencies
- More than 25% of 2011 Medicare spending in LA, TX, MS, OK and MA
- Uneven post-acute care around the country accounts for 73% of the variation in Medicare spending
- For example, McAllen, TX has 2nd highest Medicare spending in nation
- Not because of hospital costs (which are average), but because of post-acute costs (which are 2½ times the national average)
Post-Acute Providers Update

Post-acute providers are no longer in competition to take patients away from acute care providers, but rather are working with acute care organizations to meet the goal of higher quality care in the most cost-effective manner.

- ACOs

- Preferred Providers

- Bundled Payments – expect to see bundled payment programs where hospitals and post-acute providers work together to treat patients for a fixed sum
Post-Acute Providers Update

Keys to Success/Attractive Partners (SNFs):
- Medicare 5-star rating
- Document improved outcomes
- Drive reduced lengths of stay without elevated risks of re-hospitalization
- High patient satisfaction
Questions ??