Healthcare Transactions and Compliance with State and Federal Laws and Regulations
Structuring Transactions, Overcoming Regulatory Challenges, Determining FMV, and Performing Due Diligence

THURSDAY, DECEMBER 20, 2012

1pm Eastern    |    12pm Central   |   11am Mountain    |    10am Pacific

Today’s faculty features:

Theresa C. Carnegie, Member, Mintz Levin Cohn Ferris Glovsky & Popeo, Washington, D.C.
Curtis H. Bernstein, CPA/ABV, ASA, CVA, MBA, Director, Altegra Health, Denver

The audio portion of the conference may be accessed via the telephone or by using your computer’s speakers. Please refer to the instructions emailed to registrants for additional information. If you have any questions, please contact Customer Service at 1-800-926-7926 ext. 10.
**Tips for Optimal Quality**

**Sound Quality**
If you are listening via your computer speakers, please note that the quality of your sound will vary depending on the speed and quality of your internet connection.

If the sound quality is not satisfactory and you are listening via your computer speakers, you may listen via the phone: dial **1-866-370-2805** and enter your PIN when prompted. Otherwise, please send us a chat or e-mail **sound@straffordpub.com** immediately so we can address the problem.

If you dialed in and have any difficulties during the call, press *0 for assistance.

**Viewing Quality**
To maximize your screen, press the F11 key on your keyboard. To exit full screen, press the F11 key again.
For CLE purposes, please let us know how many people are listening at your location by completing each of the following steps:

• In the chat box, type (1) your **company name** and (2) the **number of attendees at your location**
• Click the word balloon button to send
Healthcare Transactions and Compliance with State and Federal Laws and Regulations

Theresa C. Carnegie – Member, Mintz Levin
202.661.8710
TCCarnegie@mintz.com

Curtis Bernstein, CPA/ABV, ASA, CVA, Altegra Health
720.240.4440
curtis.bernstein@altegrahealth.com
Today's Discussion

1. Health Care Transactions Trends
2. Federal and State Regulatory Challenges
3. Effective Due Diligence
4. Valuation Considerations
5. Strategies to Minimize Regulatory Risks
6. Hypotheticals
Health Care Transactions Trends
Health Care Transactions – Trends

• Unprecedented levels of change in the health care industry.
  – Patient Protection and Affordable Care Act (ACA)
  – Care Delivery Reform
  – Payment Reform
  – Increased Enforcement

• These changes bring challenges and opportunities.
  – Some providers struggle with the intensive human and capital requirements and are motivated to sell or affiliate.
  – Other providers are more advanced and better positioned to compete and look to expand their footprint and improve scale.
Health Care Transactions – Trends

• Past few years have been very active for the health care M&A market and strategic collaborations and affiliations.
  – In 2011, 980 health care mergers and acquisitions worth $227.4 billion.
  – In first 2 quarters of 2012, 500 health care deals recorded worth $95.2 billion.

• Health Care Segment Trends
  – Hospital/Health System Consolidation
  – Physician Practice Acquisitions
  – Expansion of Health Insurance Companies into Health Care Services
  – Increase in ASC and Urgent Care Center Acquisition
Federal and State Regulatory Challenges
Navigating the Regulatory Challenges of Health Care Transactions

• Health Care is a Highly Regulated Industry
  – Businesses in the health care industry are regulated by a wide array of federal and state laws enforced by various specialized regulatory agencies.
  – Violations of these laws can subject parties to health care transactions to onerous sanctions, including criminal penalties.
Federal and State Health Care Laws

- Medicare/Medicaid Billing and Reimbursement Requirements
- State Licensing and Certification Requirements (Entities and Individuals)
- Industry Accreditation Requirements
- Federal and State Anti-Kickback Laws
- Beneficiary Inducement Prohibitions
- Stark Law and State Self-Referral Prohibitions
- Federal and State False Claims Acts
- HIPAA and State Privacy Laws
- State Corporate Practice of Medicine Prohibitions
- State Fee Splitting Laws
- Antitrust Laws
- FDA Requirements
Federal and State Fraud Abuse Laws

• Federal and State fraud and abuse laws are always a main focus of any regulatory review in health care transactions.

• Includes – Anti-Kickback Laws, Stark Laws, FCA.

• These laws can have a significant affect on deal structure.

  • Permissible Structures
  • Valuation Parameters
  • Payment Structure
Federal and State Fraud Abuse Laws

• The financial implications of non-compliance with fraud and abuse laws can be significant.

• Under ACA the reach of both the federal anti-kickback statute (AKS) and False Claims Act (FCA) has been expanded.
  
  – Lessened the government's burden on proving intent for AKS violations.
  
  – Linked AKS violations to violations of the FCA.
  
  – Provided for enhanced civil and criminal penalties for violations.
Federal and State Fraud and Abuse Laws

• This expansion is combined with an overall trend toward increased government enforcement.

• Under the HEAT Task Force health care fraud enforcement is a "cabinet-level" priority.

• OIG increasingly focused on pursuing responsible individuals for exclusion and CMPs.

• Penalty of exclusion from participation in federal health care programs can be a death sentence for a health care company.
HIPAA – Privacy and Security Laws

• Under the HITECH Amendments to HIPAA, business associates are directly subject to HIPAA privacy and security requirements.

• Business associates are subject to statutory penalties for a failure to comply with HIPAA’s Privacy, Security, or Breach Notification Rules.

• Increased OCR Enforcement
  – Massachusetts Provider Settles HIPAA Case for $1.5M (Sept. 2012)
  – Alaska DHHS Settles HIPAA Security Case for $1.7M (June 2012)
  – Phoenix Cardiac Surgery Settles Case of $100K for Lack of HIPAA Safeguards (April 2012)
  – BCBST Settles HIPAA Case for $1.5M (March 2012)
Corporate Practice of Medicine Restrictions

• **Prohibition** - Many states have strict “corporate practice of medicine” prohibitions that limit the extent to which a lay entity can control physicians and/or share medical practice revenues with physicians.

• **Exceptions** – Although restrictions and exceptions vary by state, many states have exceptions for:
  - Professional corporations
  - Not-for-Profit Hospitals
  - HMOs
  - Teaching Hospitals

• **Penalties** – If a lay entity is found to be practicing medicine through a corporate form, the corporation could be liable for the unlicensed practice of medicine and subject to criminal and civil penalties.
Corporate Practice of Medicine Restrictions

• If the state has a corporate practice of medicine prohibition alternative deal and operating structures must be considered.

• Where alternative structures involve Management Agreements, parties must consider state fee-splitting laws.
  – Some states have strict fee-splitting laws that prohibit physicians from sharing fees with non-professionals – e.g., Illinois, New York.
  – In such states, management fees may not be based on a percentage of revenues.
Effective Due Diligence
What is Due Diligence?

• It is the process of obtaining and reviewing information about a company and using that information in the context of a specific transaction.

• Due to the multi-layered regulatory environment, targeted, thorough, and thoughtful diligence is necessary in all health care transactions.
Why is Due Diligence Conducted?

- Evaluate overall transaction, value, and purchase price
- Identify risk areas
- Identify issues that must be addressed in the Purchase Agreement
- Ensure proper disclosures by Seller
- Understand Seller’s operations
- Evaluate financing and structure of transaction
- Plan for post-closing integration
Common Areas of Focus for Health Care Regulatory Due Diligence

- Contractual Arrangements
- Corporate Books and Records
- Licenses/Permits
- Compliance Program
- Government Correspondence and Investigations
- Litigation (pending/threatened)
- HIPAA Compliance
- Billing and Coding
- Marketing Materials
When reviewing these common areas, consider...

• **Contractual Arrangements**
  – Does the arrangement potentially implicate the AKS or Stark Law?
  – Is it structured to comply with a safe harbor and/or exception?
  – Are the services provided legitimate?
  – FMV payments?
  – Is the arrangement used to improperly move money from a regulated entity to an unregulated entity?
  – Are the management services and fees set up to comply with corporate practice of medicine prohibitions?
  – Does the compensation structure improperly incentivize increased services or increased coding?
When reviewing these common areas, consider...

• **Corporate Books and Records**
  – Does the structure comply with the corporate practice of medicine?
  – Is money transferred between affiliated entities in a proper way?

• **Licenses/Permits**
  – Does the seller have all of the required approvals?
  – Do employees have all required licenses?
  – What governmental filings are necessary as a result of the transaction?
When reviewing these common areas, consider…

- **Compliance Program**
  - Is the seller an entity that is required to have a Medicare compliant compliance program?
  - Does the program comply with CMS guidance and Federal Sentencing Guidelines?
  - Is it effective and updated regularly?
  - Does the seller regularly screen employees and contractors against the OIG exclusion list?
  - Is there a compliance hotline? What issues have been reported?
  - Who receives annual training?
When reviewing these common areas, consider…

• **Government Correspondence and Investigations**
  – How is the seller's relationship with the government?
  – Are there any pending investigations or audit findings?
  – Has the seller received any warning letters?

• **Litigation**
  – Health care fraud and abuse related litigation?
  – Any recent departures from the company?
  – Does the company conduct exit-interviews?
When reviewing these common areas, consider…

- **HIPAA Compliance**
  - Has the seller implemented proper safeguards and security systems along with comprehensive HIPAA policies, procedures, and training?
  - Regulators will assume lack of documentation equates to a lack of compliance.
  - Are there existing breaches or complaints that will create post-closing liability?
  - Are IT security procedures adequate?
    - Consider post-closing costs of implementing new or upgrading existing systems.
When reviewing these common areas, consider…

• **Billing and Coding**
  – May require outside consultant review.
  – Are billing and coding procedures in compliance with applicable law?

• **Marketing Materials**
  – Are the Medicare Marketing Guidelines applicable to the seller? If so, has the seller complied with them?
  – Does the seller adequately train and supervise its sales force?
  – Are the seller's materials truthful and accurate? State consumer protection laws reach much further than the federal AKS and state kickback laws – has the Seller complied with them?
Outcome of Due Diligence Review

- Based on the due diligence review, be prepared to adjust the transaction structure, documents, and price
  - Representations and Warranties
  - Indemnification/Holdback/Escrow
  - Disclosure Schedules
  - Conditions Precedent to Closing
  - Adjustments to Purchase Price
  - Legal Opinion
How do the due diligence findings affect the value of the transaction/venture?

- Has the Seller conducted business in a manner that may create risk under health laws (or other laws)?
- Will a self-disclosure need to be made? If so, how much money may need to be re-paid?
- Are the Seller's financial projections based on its past faulty billing procedures?
- Are the financial projections based on relationships and arrangements that violate the AKS or Stark Law?
- Are the Seller's facilities about to have their licenses revoked?
- Will the Seller's payor contracts be terminated as a result of the transaction?
Valuation Considerations
Importance of Fair Market Value - Legal Perspective

• That a transaction is valued appropriately and consistent with fair market value is important from both a financial and legal perspective.

• In the health care industry, an arrangement (i.e., service agreements, leases, acquisitions) that is not priced to be consistent with fair market value can raise significant red flags under fraud and abuse laws and is unable to fall within an AKS safe harbor or a Stark Law exception.

• Fair Market Value is not just an issue of the price of the transaction, it often impacts every arrangement for health related services that is reviewed in due diligence.
Importance of Fair Market Value - Legal Perspective

• Although legal counsel is generally not in a position to determine FMV, it should be on the look out for problematic compensation structures or unsubstantiated valuations.

• In Advisory Opinion 10-16, the OIG questioned the Requestor's method for establishing fair market value.

• The OIG noted that it is precluded from opining on fair market value, but stated that it must "evaluate whether the method used to determine that a fee represents fair market value appears reliable."
Fair Market Value vs. Investment Value

• Cannot account for what a specific buyer brings to the table, only what the most likely hypothetical buyers could operationally adjust.

  – Example #1: Hospital proposes to purchase a 51% interest in a physician-owned ASC. Within the hospital, physicians employed by the hospital perform 1,500 cases per year that could be performed in an ASC setting.

  – Example #2: Private equity group proposes to purchase 10 diagnostic imaging centers from radiology group. Private equity group owns 25 other centers in the regional area and has 15% higher managed care reimbursement than the radiology group.
Billing and Coding Assessments

- As part of the valuation process, valuators should perform a review of the sellers coding when applicable.
  - Volumes are compared to Medicare or other benchmarks
    - What is the distribution of patient visit codes?
    - What is the use of ancillary services as a percent of total services?
  - When reviewing MA or MA-PD Plans –
    - Has the Plan been using appropriate documentation to support its risk adjusted scores?
    - What are the RADV audit results for the Plan?
    - Will documentation practices need to change?
Adjusting Historical Financial Statements

• Removal of Non-Recurring Expenses
  – Implementation of EMR
    • Consideration of meaningful use payments

• Additional Expenses to Account for Growth
  – Space and staff needed to support growth
Projections

• When performing an income approach, most valuation practitioners will prepare a projection (generally 5 years).
  – Example: Physician practice owns a sleep lab and proposes to sell the lab to the local hospital. The sleep lab has two beds. Practice currently performs 650 sleep studies of which 200 require CPAP.

<table>
<thead>
<tr>
<th>CPT code</th>
<th>Historical</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
<th>Year 5</th>
<th>Capacity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>650</td>
<td>683</td>
<td>717</td>
<td>753</td>
<td>791</td>
<td>831</td>
<td>730</td>
</tr>
<tr>
<td>95811</td>
<td>200</td>
<td>210</td>
<td>220</td>
<td>231</td>
<td>243</td>
<td>255</td>
<td></td>
</tr>
<tr>
<td>95805</td>
<td>450</td>
<td>473</td>
<td>497</td>
<td>522</td>
<td>548</td>
<td>576</td>
<td></td>
</tr>
</tbody>
</table>
Terminal Value

• At the end of the projection period, the valuator will develop an amount projected into perpetuity (generally the point where the company matures).

  – Example #1: Hospital proposes to purchase 20 physician cardiology group. Five of the physicians are 55 or older. As part of the negotiations, physician propose to reduce compensation by 15% to drive more value to the purchase price.

  – Example #2: Rehabilitation hospital opened in March 2012 with brand new equipment and furniture. As part of the valuation, the valuator projects capital expenditure for the next five years of $25,000 per year.
Assets Purchased and Liabilities Assumed

• The valuator MUST know the terms of the transaction and tie back to the terms prior to the execution of the deal.

  – Example #1: Hospital proposes to purchase a physician practice. As part of the deal, the parties negotiate whether the hospital will assume the practice's debt. The valuator determines that assets purchased equate to $1 million. The practice has $200,000 in debt, which the hospital assumes upon execution of the transaction. Effectively, the hospital has paid $1.2 million in consideration.

  – Example #2: Hospital purchases fixed assets from practice. Practice’s debt is subject to a lien on the fixed assets.
Assets Purchased and Liabilities Assumed

• Is value transferred to the buyer upon sale?
  
  – Example #3: Hospital purchases physician practice. Hospital proposes to purchase certain tangible and intangible assets. In addition, physicians will earn higher compensation post transaction than earned when they owned the practice.
Market Approach

• Understanding the comparable transactions is critical to the application of the market approach.
  – Personal service businesses should generally not be valued based on a revenue multiple when the owners of the business remain employees
  – Application of an earnings before interest, taxes, depreciation, and amortization (EBITDA) multiple or any other “market” defined multiple is only meaningful if the factors considered by the market are considered when applying the multiple.
    • Example #1: Surgery Centers
    • Example #2: Independent Physician Associations (IPAs)
Strategies to Minimize Regulatory Risks
Transaction Structure

• **Asset versus Stock**
  - In an asset transaction, the Buyer can limit the assumed liabilities. Although certain liabilities may follow the assets even if not expressly assumed:
    - Tort Liabilities
    - Tax Liabilities
    - Environmental Liabilities
  - In stock transaction all liabilities are included (known and unknown, contingent or otherwise).
    - Accordingly, due diligence, representations and warranties, and indemnification protections are critical.
Purchase Price Allocation

• Appropriate allocation of value to assets and liabilities is critical

  – If a purchaser buys intellectual property, non-competes, etc. and does not record the value of those assets on its financial statements, the purchaser will likely have a difficult time defending against any breach for improper use of technology or competition.
Representations and Warranties

• Address Regulatory Compliance in Reps & Warranties
  – Non-compliance can impose significant successor liability and potentially large penalty assessments for fraud and abuse violations.
  – Typical Health Care Representations & Warranties
    • Licenses and Permits
    • Legal Proceedings
    • Compliance with Laws
    • Payment Programs
    • HIPAA
  – Other Considerations – Definitions, Material Contracts, Absence of Certain Events, No Undisclosed Liabilities
Holdbacks, Escrows and Earn-Outs

• Buyers can use holdbacks, escrows and earn-outs (where permitted) to address regulatory risks.

• Typically tied to performance, revenue, or compliance benchmarks.

• Holdbacks and Escrows
  – Portion of purchase price held back or placed in an escrow account for a period of time to secure indemnification obligations or to address regulatory non-compliance.
  – Mitigates risk for Buyer.
  – Recent surveys estimate that 10% is reasonable – but depends on non-compliance the escrow/holdback is intended to address.
Holdbacks, Escrows and Earn-Outs

- **Earn-Out**

  - Portion of the purchase price is contingent on the future financial performance of the target business.
  
  - Payment is contingent on a future event, such as exceeding a specified gross revenue, net income, or EBITDA.
  
  - Buyer pays the agreed earnout amount, if at all, in the years subsequent to the sale upon satisfaction of the contingency.
  
  - Must ensure that earn-out structure is permissible under applicable fraud and abuse laws.
Survival and Indemnification

• Survival Periods for Reps and Warranties
  – Create "classes" of reps and warranties.
  – "Standard" versus "Fundamental"
    • Health care representations and warranties as "Fundamental"

• Caps and Baskets
  – Limit and apply to only certain reps and warranties.
  – Exclude Fundamental reps and warranties.

• Sandbagging
  – Protection against recovery due to constructive knowledge.
Hypotheticals
Billing Practices

• Hospital is looking to acquire a chain of urgent care clinics. Hospital determines through due diligence that the Seller has been incorrectly billing federal and private payors for a specific service.

• Seller also discloses pre- and post-payment audit reviews by CMS and private payors with respect to the billing practices.

• What steps can the Hospital take to address these regulatory risks?
Corporate Practice of Medicine/Fraud and Abuse

• Private equity group is interested in acquiring large anesthesiology group in North Carolina. The anesthesiology group provides anesthesia services on an exclusive basis to several outpatient surgery/endoscopy centers owned and operated by physician-owned entities.

• The anesthesiology group pays the centers a fee for management services including pre-operative nursing assessments, space for physicians/personnel, records, etc. and assistance with transfers of billing documentation.

• What issues should the private equity group consider in connection with the potential acquisition?
Fraud and Abuse

• Outstanding MA Plan is looking to buy Standard MA Plan. During due diligence, Outstanding MA Plan learns that:
  – Standard MA Plan has engaged Codes R Us to perform coding reviews of beneficiaries medical records. Codes R Us is paid $50 per chart reviewed and $25 for each additional code found that will increase the Plan’s revenue.
  – Standard MA Plan offers senior citizens in the area free transportation, free classes, and gift cards.
  – Standard MA Plan has arrangements with physicians that are undocumented and/or provide for extremely high compensation amounts.

• Issues? What should Outstanding MA Plan do?
Questions?
Contact Information:
Theresa C. Carnegie
Direct Phone: 202-661-8710
Email: TCCarnegie@mintz.com

Curtis Bernstein
Direct Phone: 720-240-4440
Cell Phone: 561-901-5309
Email: Curtis.Bernstein@AltegraHealth.com