

ENTREPRENEURIAL MEDICINE: OPPORTUNITIES TO ENHANCE YOUR PRACTICE AND BOTTOM LINE

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PRESENTERS



Jayme R. Matchinski concentrates her practice on health care and corporate law. She handles regulatory compliance, reimbursement, licensure and certification issues affecting health care providers, health care transactions, and the purchase, sale and formation of health care entities. She has also successfully represented health care providers in reimbursement claims against insurance carriers and the Centers for Medicare and Medicaid Services.



Serene K. Zeni represents health professionals, hospitals, insurance companies, and other health care organizations in licensing, regulatory actions, applications, appeals, and corporate matters. Her work ranges from establishing and maintaining quality, risk management and compliance programs to assisting entrepreneurs in developing and expanding innovative businesses. She is also a member of Clark Hill's Cybersecurity Group aiding technology innovators in compliance with HIPAA and HITECH.

WHAT IS THE MEDICAL ENTREPRENEUR?

- The physician, health professional, or health investor who recognizes new opportunities in medicine and is prepared to meet the challenges, complexity and sophistication of upholding the values of medical care while advancing his/her business interest in compliance with the law.

CURRENT MEDICAL PRACTICE ENVIRONMENT

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CURRENT PRESSURES FOR PHYSICIANS

- Complex Regulatory Environment
- Continual Proposed Cuts to the Medicare Part B Physician Fee Schedule
- Increasing Costs for Overhead, Staff, Technology, and Professional Liability Insurance Correlated with Increasing Regulatory Demand
- Shortages of Health Care Providers in Certain Geographic Areas

CURRENT PRESSURES FOR PHYSICIANS (CONTINUED)

- Health Care Reform and Its Impact on Providers, Patients and Reimbursement (SGR legislation is a temporary fix)
- Changing Reimbursement Levels by Third Party Payers Under Managed Care Contracts
- Education of Patients, Other Providers, and the Public
- Emergence of the Assertive Patient

CHALLENGE: MANAGING A PRACTICE & PROVIDING CARE

- Achieving Compliance with Federal and State Regulations
- Increasing Operational Efficiencies and Effectiveness
- Improving Patient Relations and Managing Risk
- Engaging in Continued Professional and Organizational Development
- Maximizing Current and Future Revenues

THE REGULATORY CHALLENGE

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REGULATORY ISSUES AFFECTING PAY & PATIENT CARE

- Stark Law
- Anti-Kickback Statute
- HIPAA
- Anti-Markup Rule
- 2014 Physician Fee Schedule (PFS)
- Key Compliance Issues
- Medicare Coverage and Payment
- Billing and Reimbursement
- National Coverage Determination (NCD)
- Local Coverage Determination (LCD)
- OIG Work Plan for FY 2016
- Expanded Enforcement Activities

** Government is Expanding Fraud and Abuse Enforcement Efforts

STARK LAW

- The federal Stark Law prohibits a physician (or an immediate family member of such physician) from making a referral for a designated health service to an entity in which the physician has a financial relationship, including a compensation arrangement, if the service is reimbursed by a governmental program. (42 U.S.C. § 1395nn(a)(1))

ANTI-KICKBACK LAW

- It is unlawful for anyone to knowingly and willfully solicit or receive any payment in return for referring an individual to another person or entity for the furnishing, or arranging for the furnishing, of any item or service that may be paid in whole or in part by any federally-funded health care program. (42 U.S.C. § 1320a-7b(b)(1))

HEALTH CARE REFORM'S IMPACT ON HEALTH CARE PROVIDERS – LEGAL ISSUES

- Overpayments
 - Now health care providers must report and return any overpayment within 60 days of:
 - The date the overpayment is identified, or
 - The date a correspondent cost report is due, whichever is later
 - Retaining an overpayment creates potential False Claims Act liability

HEALTH CARE REFORM'S IMPACT ON HEALTH CARE PROVIDERS – LEGAL ISSUES (CONTINUED)

- Enforcement
 - The government has allocated \$100 million for fiscal years 2011 through 2020 to cover administrative and operational costs for health care fraud and abuse control programs

GENERAL STRATEGIES TO SURVIVE

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MAXIMIZING REIMBURSEMENT

- Don't Leave Money on the Table
- Joint Ventures
- Join a Health System and Other Providers
- Addition of Ancillary Services
- Exclusive Provider Agreements
- Medical Directorships
- Participation in Clinical Trials and Research

CURRENT CONSIDERATIONS TO ENSURE COMPENSATION

- How Do You Provide Incentives to Staff and Physicians?
- Incentives to Maintain or Reduce Expenses
- Effectively Managing the Care and Treatment of Patients from Start to Finish
- Diversification of Pay or Mix
- Maintaining and Retaining Good Documentation

GENERAL GUIDANCE FOR THE ENTREPRENEUR

1. Don't stick out of the crowd or become "low hanging fruit"
 - Avoid too many recruitments, medical directorships, joint ventures etc.
2. Cease and desist all personal favors to referral sources or closely related business partners
 - Key message from TAP case and pharmaceutical guidance
 - No free vacations, computers, tickets
 - No unrestricted educational grants, etc.

GENERAL GUIDANCE FOR THE ENTREPRENEUR (CONTINUED)

3. Make compliance a priority and a part of everyone's job description
 - Educate and train all staff about regulatory compliance and the associated risk areas
 - Monitor compliance on an ongoing basis
 - Frequently check documentation to ensure compliance, confidentiality, and proper implementation

GENERAL GUIDANCE FOR THE ENTREPRENEUR (CONTINUED)

4. Use Fair Market Value as a benchmark for all deals
 - Overall protection if FMV is established:
 - For necessary services, expenditures and investments
 - By independent and reliable source
 - Using recognized and legitimate methodology

Ask: Does the deal/transaction/contract pass the “smell test?”

GENERAL GUIDANCE FOR THE ENTREPRENEUR (CONTINUED)

5. Run a tight ship

- Do not facilitate any alteration of documentation, e.g., shredding, backdating or altering
- Do not withhold information from the government or produce incomplete information (half truth)
- Do not ask for numeric “odds” on being detected or being prosecuted when communicating with government agencies or officials

GENERAL GUIDANCE FOR THE ENTREPRENEUR (CONTINUED)

6. Create and maintain good documents

- Document FMV, business purposes, and services to be provided and time spent providing such services
- Good documentation is evidence of good faith and may block an investigation and/or audit
- Documentation can be a pitfall if records are inaccurate or incomplete

GENERAL GUIDANCE FOR THE ENTREPRENEUR (CONTINUED)

7. Do not create or raise any “red flags”
 - E-mail can and will be used as evidence of wrongdoing and bad intentions
 - Any communication (verbal and written) regarding referrals, money and physicians will be scrutinized
 - Carefully review business planning documents regarding statements or guarantees about anticipated referrals

GENERAL GUIDANCE FOR THE ENTREPRENEUR (CONTINUED)

8. Do not be greedy

- Investigators will target any investment or any compensation arrangement that appears excessive

THE RISE OF THE ENTREPRENEUR

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ACCOUNTABLE CARE ORGANIZATIONS

- A network of doctors and hospitals sharing in financial and medical responsibility for providing coordinate care to patients in hopes of limiting unnecessary spending
- 2015, HHS goal for next 3 years:
 - Tie 30% (2016) □ 90% (2018) of traditional or Fee-For-Service to quality/value through models like ACO's
- Compliance Program must be available to CMS

AMBULATORY SURGICAL CENTERS

- Aging population is a major force in the significant growth in demand for surgical services. Solution and Entrepreneurial Opportunity: Ambulatory Surgical Center (ASC)
- Issues: Safety and Quality; Acquiring Certificate of Need; Types of Surgeries Allowed; Specific Federal Requirements; AKS and Meeting Safe Harbor

URGENT CARE CENTERS

- Since 2008, investors have invested \$2.3 billion into Urgent Care Centers as of July 2014
- Model: treat as many patients as quickly as possible; provide alternative to ER
- Low Margin Profit balanced against High Volume
- Advantage over hospitals: no obligation to accept Medicaid
- Race to build powerful national brands
- Issues: Accurate billing; Compliance; Quality

TELEMEDICINE AND REMOTE CARE

- Technology enabling medical care through visual communication and information exchange at a distance
- Models ranges from complete practice to option in care, sometimes integrated with concierge offerings
- Top targeted medical conditions through telemedicine: 1) congestive heart failure; 2) diabetes; 3) chronic obstructive pulmonary disease; 4) hypertension; and 5) mental health
- Increases number of patients under single doctor's care; increases access to physicians; increases quality and frequency of patient contact

TELEMEDICINE AND REMOTE CARE (CONTINUED)

- Types: Broad range from in-home heart pressure monitoring to live video consultations; includes televisits, web-based group meetings; and pre-recorded video presentations
- ICD-10 offers limited telemedicine codes (ex. non-facility fee for chronic conditions; annual wellness; psychotherapy; prolong services)
- Global expansion of telemedicine projected to soar past \$30 billion
- Issues: Licensure; Compliance; HIPAA; Reimbursement; Malpractice

MEDICAL TOURISM – DOMESTIC AND INTERNATIONAL

- Attracting patients from outside the limits of one's typical radius
- Models: Packaging multiple services at one cash fee; traveling to another country for a short period to provide medical care; participating with a third party intermediary who packages your services with the services of others

MEDICAL TOURISM – DOMESTIC AND INTERNATIONAL (CONTINUED)

- International Medical Tourism allows patients to travel overseas to obtain better rates for medical care. Typically thought of as patients leaving the US to obtain care overseas, but there are centers attracting medical care to the US as well
- Domestic Medical Tourism allows patients to travel domestically from one part of the country to another to obtain care at a lower cost than what might be available locally
- Issues: Compliance; Pre and Post Care; Limited to Certain Services

CONCIERGE MEDICINE

- Providing premium medical care at a fixed rate
- Models: Complete Practice and Supplemental or Hybrid Concierge
- Complete Practice Model Advantages: Charge fixed periodic fee for comprehensive care and increased availability; Minimize number of patients, ensure reimbursement, high quality care
 - Issues: Ability to find patients willing to pay fixed rate; concern over the fact that Concierge Medicine is perceived as medicine for the wealthy

CONCIERGE MEDICINE (CONTINUED)

- Supplemental or Hybrid Concierge: Offer premium add-on services to current patients
- Issues: Necessary to very carefully design such services and the structure of such services to ensure compliance with federal health care programs and third-party payer contracts

JOINT VENTURE ARRANGEMENTS

- Entering into joint ventures with either other physicians, other health professionals, or health investors
- Models: Too numerous to list, but include ASC's, In-Office and Third Party Laboratory Agreements; Physician Owned Distributorships; ACO's, etc.
- Added revenue for the physician entrepreneur
- Ease of access for patients
- Control quality
- Issues: COMPLIANCE!!!

HEALTH CARE TECHNOLOGY

- Can be everything from an app on your phone to a massive machine at the hospital
- Model: Numerous technologies from battery-powered, ultrasonic energy to enable minimally invasive surgical procedures to connected health technologies allowing for e-health
- Increases frequency of patient monitoring to improve patient compliance, results in higher quality outcomes, increases efficiency, measures quality, etc.

HEALTH CARE TECHNOLOGY (CONTINUED)

- No barriers to innovation
- Issues: Intellectual property; HIPAA in development and use; access to funding; corporate structuring; proliferation of product; liability exposure

LOOKING TO THE FUTURE: PAY FOR PERFORMANCE

- The least you can do for your practice is understand and implement initiatives aimed at improving and measuring quality, efficiency, and overall value of the care you deliver to your patients
- Elements: 1) Process; 2) Outcome; 3) Patient Experience; and 4) Structure
- SGR legislation increases reimbursement through 2019, stabilizes reimbursement through 2025, then links reimbursement to your ability to perform starting in 2026
- Issues: Starting the implementation process

QUESTIONS?



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THANK YOU

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