HFMA Massachusetts Chapter Managed Care Committee

EHR-PHR – A Legal Perspective on Challenges and Opportunities

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I. Why A Legal Perspective – It's All Good!

- The Cost Challenge – Who Will Bear The Cost?
  - Estimates abound, but EHR is not cheap-
    - Solo/small group practices:
      - $44K/FTE – start up
      - $8500/FTE/yr – ongoing
    - Ongoing savings:
      - $13K/yr/provider (reduction in office personnel)

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I. Why A Legal Perspective – It's All Good!

- What is the legal exposure?
  - Key issues –
    - Negligence/malpractice liability from use/misuse of information
    - Third party cost shifting arrangements
      - Fraud & abuse liability (Stark/kickback concerns)
      - Tax liability (for-profit/non-profit arrangements)
      - Antitrust exposure (exclusive networks/price fixing)

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II. Negligence/Malpractice Liability

- Accuracy of data
- Use of data
- Real challenges in the PHR arena
  - Accuracy
  - Completeness
  - Usefulness
  - privacy

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III. Cost Shifting Challenges

- **Fraud & abuse** – The AKS prohibits any person from "knowingly and willfully" paying, offering, soliciting or receiving any remuneration, directly or indirectly, in cash or in kind, in exchange for or to induce the referral of any item or services covered by a federal health care program, or in exchange for arranging for or recommending purchasing, leasing or ordering any good, facility, service or item covered by a federal health care program..."

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III. Cost Shifting Challenges

- **Stark** – The federal Stark law prohibits a physician from making referrals for certain designated health services (DHS) to an entity in which the physician has a compensation arrangement or ownership interest, unless an exception applies. Entities are prohibited from billing services provided pursuant to a prohibited referral.

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III. Cost Shifting Challenges

- **Tax exempt rules –** Entities that are exempt from federal income tax are prohibited from entering into arrangements involving inurements of their earnings, or the provision of undue private benefit. Revenues generated unrelated to tax exempt purpose subject to UBIT. If non-tax exempt activities are significant, tax exempt entity could risk losing tax exemption.

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IV. Cost Shifting Solutions

- Stark (exceptions) and AKS (safe harbors) relief
  - Electronic prescribing and EHR capabilities
  - Effective October 10, 2006

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IV. Cost Shifting Solutions

- Electronic Prescribing
  - Permits donation of items and services including
    - Hardware
    - Software
    - Internet connectivity
    - Training & support services
  - Non-monetary
  - Necessary and used solely to transmit and receive electronic prescription information.

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IV. Cost Shifting Solutions

- Limitations on donors and recipients
- No restrictions on use of compatibility with other systems
- No consideration of value or volume of referrals or other business
- Written arrangements
- No restrictions with respect to payor status
- Other restrictions as well

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IV. Cost Shifting Solutions

- Electronic Health Records
  - Donations of EHR software or IT and training services
  - Necessary and used predominantly to create, maintain, transmit, or receive EHR

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IV. Cost Shifting Solutions

- Requirements include –
  - Donations must be by individuals or entities providing covered services and submit claims to federal health care program or health plan and must be provided to recipients engaged in the delivery of health care
  - Donated software must be deemed interoperable (e.g. as determined through certification)
  - Meets Part D standards

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IV. Cost Shifting Solutions

- Requirements include –
  - Donor may not limit or restrict use or compatibility with other systems
  - Recipient Must pay 15% of donor's cost before receipt and financing not allowed
  - No limits on patients without regard to payor status
  - No consideration of value or volume of business generated
  - Not a condition of doing business

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IV. Cost Shifting Solutions

- Requirements include –
  - May not include staffing
  - Costs may not be shifted to any Federal health care program by the donor
  - Transfer must occur on or before December 31, 2013

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IV. Cost Shifting Solutions

- The Questions –
  - What is "interoperability"?
    - Communication and exchange with different IT systems, software applications and networks, in various settings
    - Is the software as interoperable as feasible given the prevailing state of technology at the time provided to the recipient

  But –
    - Final rules do not preclude requiring appropriate disclaimers, indemnities and limitations of liability from each user of software and systems

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IV. Cost Shifting Solutions

- The Questions –
  - What technology is covered?
    - Includes items and services in the form of software or IT and training services
      - Interface and translation software, rights licensures and IP
      - Clinical support and information services related to patient care, maintenance services, secure messaging help desk, similar support
    - Does not apply to hardware, staff or monetary remunerations
    - EHR predominant, not sole use (What is "predominant use"?)
    - May include functionality related to care and treatment of patients

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IV. Cost Shifting Solutions

- The Questions –
  - What restrictions may be placed on technology?
    - No restrictions on interoperability
    - But –
      - Standard confidentiality protections
      - Warranty disclaimers
      - Indemnities
      - Limitations of liability

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IV. Cost Shifting Solutions

- The Questions –
  - Must the technology be given to anyone who requests it?
    - No – but...
      - Cannot select based on value or volume of referrals
    - Can use –
      - Number of prescriptions – total number written
      - Size of practice
      - Use of technology
      - Medical staff membership
      - Level of uncompensated care
      - Any reasonable manner

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IV. Cost Shifting Solutions

- Potential Selection Criteria
  - Which physicians are practicing in Hospital's service area?
  - Which physicians are most likely to actually use the donated technology? This could potentially be determined through a questionnaire or test designed to gauge a physician's familiarity with technology.
  - What are the physicians' specialties?

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IV. Cost Shifting Solutions

- Potential Selection Criteria
  - Which physicians are good "community citizens"? For example, Hospitals should consider:
    - Participation in hospital quality improvement activities;
    - Willingness to serve as a trainer for other physicians;
    - Medical staff meeting attendance;
    - Prompt completion of patient charts;
    - Involvement in Hospital committees;
    - Consistent use of Hospital-based information technology systems; Continuing medical educational seminar attendance; and
    - Participation in local professional associations.

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IV. Cost Shifting Solutions

- Potential Selection Criteria
  - Which physicians have compliance programs?
  - Which physicians are on the Hospital's medical staff? Active vs. courtesy? (Watch for referrals claims)
  - Which physicians participate on hospital call panels?
  - With which managed care plans do the physicians contract?
  - Do the physicians participate in the Medicaid and Medicare programs?
  - Where did the physicians go to school? Where did they do their residencies?

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IV. Cost Shifting Solutions

- The Questions –
  - How must a physician pay?
    - 15% of cost
      - Provided to the recipient (not total cost)
      - Consistent enforcement required to avoid inducement argument
      - Initial and "ongoing" costs
        - A periodic payment approach recommended

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IV. Cost Shifting Solutions

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IV. Cost Shifting Solutions

- The Questions –
  - How do I evaluate the tax exposure?
    - May 11, 2007 – IRS Memorandum
      - Benefits by hospitals to other medical staff physicians
        - For the provision of "Health IT Items and Services" at a discount
    - Must comply with HHS EHR Regulations
      - Arrangements provide, to the extent permitted by law
        - Hospital may access all electronic medical records created by a physician using the Health IT items and services subsidized by the hospital
        - Same level of subsidy to <u>all</u> (!) medical staff physicians

        Or
        - Varies level of subsidy by applying criteria related to meeting the healthcare needs of the community

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IV. Cost Shifting Solutions

- The Questions –
  - Did You Say Antitrust?
    - Use of shared IT resources con not be allowed to "spill over" to facilitate
      - Price fixing
      - Group boycotts

    →Keep price sensitive information out of the process

    →Exclusionary or selection criteria should be rational, reasonable and not referral based

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V. EHR And The Provider-Payer Relationship

A. Medical Necessity
B. Quality Disparities and Transparency
C. Contracting and Reimbursement

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Medical Necessity: The Debate

- What is "medical necessity" and why does it matter?
- Provider definitions: Prudent physicians and generally accepted standards
- Payer definitions: Evidence-based Medicine

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Medical Necessity: Barriers to Developing an Evidence Base

- What constitutes a valid scientific basis
- Randomized Controlled Trials – The "gold standard"
- The barriers of cost, complexity & bias
- RCTs may work for drugs and devices with the promise of monopoly profits, but what about everything else?

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Medical Necessity: EHRs as a Solution to the Dearth of Evidence

- EHR Treatment & Outcome Databases
  - Tens of millions of *real-world* encounters and results
  - Can be stratified against multiple subpopulations (e.g. race, age, co-morbidity)
  - Prompt results, updating and reporting
- Integration of evidence with decision-support tools
- Evidence-compliance monitoring
- Cost-effectiveness analyses

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The Impact of EHRs on Medical Necessity Processes

- The evidence-base will grow & grow, encompassing more office and surgical care
- Plan medical policy will expand in scope, to define a far greater number of covered and non-covered diagnostic and treatment procedures
- Individual medical necessity determinations will more and more be measured against evidence
- Physicians, through EHR tools, will have the evidence available in real-time. No excuses.

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Medical Necessity & EHR: The End Result

- Should be higher quality, evidence-based care
- Should be lower cost care
- But what's the impact on physician satisfaction?
- And, during the transition to this brave new world, what happens to volume and nature of physician/member disputes with payers?

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Quality/Transparency

- Payers are increasingly relying upon quality metrics to create:
  - Scorecards
  - Tiered networks
  - Consumer directed products
- All rely upon available measures of quality
- All rely upon the ability to view provider performance against those measures

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Quality/Transparency: The EHR Solution

- Broadened evidence-base will increase the available quality standards many-fold.
- EHR aggregation and analytic tools will enable payers to measure providers against those standards more readily, and immediately
- Result is "better" quality metrics and scorecards, further transparency, and more available (and better designed?) tiered network and consumer directed products

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Quality/Transparency/EHR: Landscape for Lawyers

- Among providers, there will be winners & losers. Some will look great against the broadened standards, and some will not
- Those who do not, may seek legal remedies:
  - Trade disparagement/defamation
  - Breach of contract in use of data for quality scorecards & disclosure to patients
  - Trademark violations
  - Antitrust theories where data is shared
  - The next round of contract negotiations

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Who Benefits: EHR-Induced Quality Savings (1)

- Quality is the key perceived benefit of EHR.
- The data on quality enhancement to date is quite mixed
  - Kaiser Permanente start-up issues
  - Children's Hospital Pittsburgh data
- None of the negative reports factor in expansion of the evidence-base or start-up barriers of disruptive processes
- At the end of the day, EHR hold out tremendous promise for quality improvement

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Who Benefits: EHR-Induced Quality Savings (2)

- Quality is about better health and lower costs
  - Patients benefit through both
  - Employers benefit through both (premium or med. cost savings and productivity gains)
  - Payers benefit through reduced med. Costs
  - And providers who install EHRs benefit through better reputations and more business
- Seemingly, all stakeholders have an interest in subsidizing improved quality

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Who Benefits: Practice Pattern Changes (2)

- Payers gain through reduced utilization.
  - Telephone care often replaces urgent or emergent encounters, not just office visits
- Do providers lose through reduced billable encounter time?
- Will the dynamic lead to increased acceptance of billing for telephone care?
  - Codes already exist, but not uniformly accepted
  - Could be a win-win

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Who Benefits: Billing Patterns & Office Efficiencies

- EHRs analytic tools can "scan" the medical record and insure full capture of charges and full, appropriate billing intensity
- EHRs, once fully operational, should reduce office personnel.
  - One study shows savings = $13,000 per year per provider
- Essentially, these are bonus payments to providers who adopt EHRs

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Who Benefits: EHRs & Fraud Detection

- Massive amounts of aggregated data will be a great resource for EHR analytic tools.
  - Increased ability to identify outliers, as more data to measure against
  - Will be able to automatically link claims with corresponding medical record and electronically compare.
  - Will be able to automatically link claims with information about the same patient in other EHRs to determine whether they correspond, using advanced analytics
- Jan. 2007 RTI proposed model anti-fraud standards for EHRs . Standards will be submitted to Cert. Commission for HIT as potential certification standards.
- Fraud prevention will $ save for payers, and will enhance quality

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Who Benefits: Summation

- At the end of the day, it appears that there are benefits for all stakeholders, including payers, employers, patients and providers
- The question is: If payers are willing to subsidize in part, what are the mechanisms?

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Pay for EHR Performance

- P4P Basics: Providers receive additional compensation, or avoid a financial penalty, based upon meeting certain performance standards
  - Tied to quality/performance metrics or utilization levels
  - Goal is to align provider incentives with payer's
- EHR adoption can itself be a performance measure
  - Means of incentivizing, and paying for, quality enhancement and efficiency gains from EHRs that benefit payers
  - Specifics of the measures become the negotiation rub (CPOE adoption; decision support; all-inclusive EHRs; etc)
- EHR-induced expansion of the evidence base will expand the universe of other P4P quality measures

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EHRs & New Payment Models: PROMETHEUS

- PROMETHEUS PAYMENT: Prospective payment tied to resources required to provide care for specific conditions in accordance with clinical guidelines.
  - Payment based upon "evidence-informed case rates (ECRs)."*
- Also, portion of the payment is withheld and ultimately distributed based upon "measures of clinical process, . . ."*
- Need the evidence; need the guidelines. That's where EHRs come in. The expanded evidence-base, again

*F. de Brantes, et al, "Evidence-Informed Case Rates: A New Health Care Payment Model," at www.prometheuspayment.org/assets/documents/prometheus_white_paper.pdf

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EHR Grants

- Through this point, discussion on payer subsidization of EHR is tied to reimbursement process: telephone care reimbursement; P4P; PROMETHEUS Payment.
- Straight contributions may be a more direct avenue, particularly for non-profit payers seeking to incorporate EHR support within community benefit programs.
  - May be viable to fund non-profit provider-adopters of EHR, but inurement/private benefit standards will limit the approach with for-profit provider organizations

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Summing it Up

- EHRs will change context for payer-provider relations
- Evidence-base will grow:
  - Impacting medical necessity policy and determinations
  - Increasing quality metrics, transparency and disparities data
  - Perhaps changing the role of the physician
- Allocation of EHR Costs will be the subject of much negotiation
  - Will be tied to what stakeholders benefit and how much
  - Will integrate with reimbursement models such as P4P and new models such as PROMETHEUS Payment

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