Financing electronic health record (EHR/EMR) systems

Should your practice accept a donation?

Presenters

Heidi Echols
Partner, McDermott Will & Emery LLP
hechols@mwp.com

Jay Want, MD
President and CEO, Physician Health Partners
jwant@phpmcs.com

Jeff Archambeau
Project Development Manager, Physician Health Partners
jarchambeau@phpmcs.com

Disclosure

The content of this presentation does not relate to any product of a commercial interest; therefore, there are no relevant financial relationships to disclose.
Objectives
Following the Web conference, participants will be able to:

- Determine whether they should accept subsidized electronic health record and/or electronic prescribing technology
- Comply with regulations governing subsidized (donated) electronic health record and/or electronic prescribing technology
- Recognize regular components of donation agreements and general information technology contracts
- Prepare more effectively for any HIT selection

Introduction

- President Bush’s promotion of interoperable electronic health records (“EHR”)
  - Creation of Office of National Coordinator of Health Information Technology (“ONCHIT” or “ONC”)
  - All Americans will have “interoperable EHR” within ten years
- Use still lags
  - 15-20% of physicians’ offices have EHR systems
  - 20-25% of hospitals have EHR systems

- Many EHR systems are cost-prohibitive for physicians
  - Physician Costs:
    - Cumulative costs to reach 90% adoption rate by physicians is $17.2 billion (split between one-time costs and ongoing maintenance costs)
    - Average yearly cost is $1.1 billion
    - Potential annual average efficiency and safety benefits: $11 billion
    - Estimates range from $15,000 - $50,000 per physician
  - Hospital Costs:
    - Cumulative cost for 90% of hospitals to adopt an EMR system is $98 billion (assuming 20% already have a system)
    - Average yearly cost is $6.5 billion
    - Source: David Drummond and John F. Halamka, Information Technology Comes to Medicine, New England Journal of Medicine 356;24 (June 14, 2007).
Pre-implementation costs of EHR systems

- TIME!
  - Select vendor
    - Issue RFPs
    - Evaluate responses
    - Check references
    - Site visits
  - Contract process
    - Time to contract
    - Legal costs
    - Resources allocated to contracting process
  - Development of EHR policies and procedures, particularly in context of Health Information Exchanges ("HIE")

Costs of EHR systems

- Costs of EHR system to third party vendors
  - License costs
  - Implementation costs
  - Hardware costs
  - Ongoing maintenance and support costs
  - Training costs
- Other hidden costs: Cost of using EHR systems
  - Implementation time and resources dedicated to implementation
  - Training and education time to physicians and staff
  - Temporary loss of efficiency during learning curve
  - Patient education, particularly in context of HIEs

Potential benefits of EHR systems

- Benefits to health care organization
  - Reductions in drug expenditures
  - Improved utilization of radiology tests
  - Improvement in charge capture
  - Decreased billing errors
- Financial benefits to payer
  - Donations and subsidies by payers
- Non-financial benefits
  - Improved quality of care
  - Reduced medical errors
  - Better access to information

Potential solution to defray costs

- Subsidization of EHR costs by a donor
  - Hospital to physicians (and other participants)
  - Regional Health Information Organization ("RHIO") to physicians
  - Physician organizations to physicians
- Problem: Hospital subsidization to a physician requires use of Stark exception and (perhaps) Anti-Kickback Safe Harbor
- Problem: Subsidization by a not-for-profit entity presents tax considerations for not-for-profit entity
- Problem: Subsidization to physician presents tax considerations in form of income

Regulatory “solution”

- Two Exceptions and Two Safe Harbors (Effective October 10, 2006, Published August 1, 2006)
  - EHR and E-prescribing Stark Exceptions
  - EHR and E-prescribing Anti-Kickback Safe Harbor
- To promote use of EHR systems
  - "Electronic Health Record" means a repository of consumer health status information in computer processable form used for clinical diagnosis and treatment for a broad array of clinical conditions.

Stark exception

- What is Stark?
  - Unless a Stark exception applies, a physician cannot refer a Medicare or Medicaid patient to an entity for a designated health service ("DHS") if there is a financial relationship between the referring physician and the entity to which the patient has been referred.
  - Every direct and indirect compensation arrangement between a DHS provider and a physician must be structured to satisfy a Stark exception or the physician cannot refer Medicare or Medicaid patients to the DHS provider.
  - Therefore, donations of Health Information Technology must satisfy a Stark exception
Anti-Kickback safe harbor

What is the Anti-Kickback Statute (AKS)?

- The Anti-Kickback Statute prohibits the offer or receipt of certain remuneration in return for referrals for or recommending purchase of supplies and services reimbursable under government health care programs.

- These relationships are subject to scrutiny under a facts and circumstances test, unless the conduct is "safe harbored."

Key points for EHR donations

- Stark Exception
  - Permissible Donors: Any entity eligible for Medicare payment for DHS (could include hospitals, health systems, laboratories, and others)
  - Permissible Recipients: Any physician

- Anti-Kickback Safe Harbor
  - Permissible Donors: (i) any individual or entity that provides and submits claims for covered services paid for by a federal health care program and (ii) health plans.
  - Permissible Recipients: Any individual or entity engaged in the delivery of health care is an eligible recipient.
  - Donor cannot directly take into account volume or value of referrals or other business generated between the parties.

Any reasonable and verifiable manner that does not directly take into account volume or value of referrals or other business generated between the parties

- Number of prescriptions written (but not the volume or value of prescriptions dispensed or paid by the donor or billed to the program)
- Size of medical practice
- Total number of hours that the physician practices medicine
- Overall use of automated technology in his or her medical practice ("tech-savvy")
- Whether the physician is a member of the donor’s medical staff, if the donor has a medical staff
- Level of uncompensated care provided by the physician
Key points for EHR donations

- May subsidize software or information technology and training services necessary and used predominantly to create, maintain, transmit or receive electronic health records
- Permissible donations
  - EHR software
  - Other software so long as EHR Functionality predominates
  - Practice Management Software
  - ASP models
  - Support
  - Implementation

Key points for EHR donations

- Excluded items and services
  - Hardware
  - Maintenance for hardware
  - Operating system software
  - Staffing (such as to scan items)
  - Items used primarily to conduct personal business or business unrelated to clinical practice or operations
- “Necessary” and “Used Predominantly”
  - Cannot be duplicative, unless for standardization
  - Perhaps means that technology with a high probability for duplicative or non-EHR uses will not be donated (e.g., Word or web browsers)

Key points for EHR donations

- EHR software MUST be interoperable
  - HHS Definition: Ability to “communicate and exchange data accurately, effectively, securely and consistently with different information technology systems, software applications, and networks, in various settings and exchange data such that the clinical or operational purposes and meaning of the data are preserved and unaltered.”
  - May be “deemed interoperable” by being certified by the Certification Commission on Health Information Technology (“CCHIT”) within twelve months of being provided to the recipient
  - New interoperability standards
  - Cannot limit or restrict interoperability with other systems
  - EHR software MUST contain e-prescribing functionality that meets Medicare Part D standards
Key points for EHR donations

- Donor may donate up to 85% of the donor’s actual cost (not FMV)
  - Incremental costs such as license fees, implementation costs, support costs
  - Sunk costs such as previously purchased hardware
  - Cost does not mean fair market value

- Cannot provide cash
  - Money must go to the technology vendor
  - Impacts contractual structure
    - Sublicense arrangement
    - Direct agreement between vendor and end user, plus a vendor – donor agreement

- Donor may not finance or loan funds to the recipient

Key points for EHR donations

- Requires payment by physician prior to receipt of items and services
  - Implementation costs
  - License costs
  - Subscription costs
  - Support costs

- May require termination of agreement or other remedy if payment is late
  - Consider quarterly or annual costs instead of monthly to avoid late payment scenarios
  - Downside is more expensive

Key points for EHR donations

- Documentation required by EHR regulations
  - Signed, written agreement between donor and recipient
  - Specifies the items and services being provided
  - Specifies the donor’s cost
  - Specifies the recipient’s contribution
  - Covers all of the EHR items and services to be provided by the donor

- Other documentation
  - Detailed business plans to document their objectives
  - Document nuances such as selection criteria or ways donations further tax-exempt purposes.
Key points for EHR donations

- Recipient cannot make the receipt of the items or services, or the amount or nature of the items or services, a condition of doing business with the donor
- Donor may not limit the recipient’s right or ability to use the items of services for any patient
- Donor cannot shift the costs to any Federal health care program
- Sunsets on December 31, 2013.

Tax “solution” (at least partially…)

- IRS issued a directive on May 11, 2007 (the “Directive”): Will not treat the benefits a hospital provides to its medical staff physicians as an impermissible private benefit or private inurement if:
  - Hospital and the physicians comply with the requirements of the EHR Regulations on a continuing basis.
  - To the extent permitted by law, the hospital may access all of the electronic medical records created by a physician using the donated items or services.
  - The hospital ensures that the donated items and services are available to all of its medical staff physicians.
  - The hospital provides the same level of subsidy to all of its medical staff physicians or varies the level of subsidy by applying criteria related to meeting the healthcare needs of the community.

Tax “solution” (at least partially…)

- Limitations
  - Exempt hospitals providing technology to members of medical staff
  - Does not address RHIOs
  - Does not address Practice Management Software
  - Does not address whether donations result in taxable income to physicians
  - Facts and circumstances test for non-hospitals and those hospitals that do not meet all of the requirements of the Directive
Key points to IRS directive

- All physicians on medical staff
- Difficult with phased approach to a rollout
- Use criteria that promote the community’s healthcare needs (high percentage of indigent patients or fill a “hard-to-fill” specialty)
- Same level of subsidy
- Could be financially inappropriate
- Use criteria that promote the community’s healthcare needs (high percentage of indigent patients or fill a “hard-to-fill” specialty)
- IRS has clarified in FAQs posted on its web site that it is permissible to provide access to various groups of physicians at different times, so long as the criteria meet the health care needs of the community

Key points to IRS directive

- Access to EHRs by hospital
- Subject to applicable law
- May be politically unpopular for fear of potential for other uses of data
- FAQs clarified that physician may deny a hospital access to the medical records if it would violate the physician’s contractual obligations to patients
- Physician and hospital can agree upon reasonable conditions to access
- Need for community stakeholder involvement
- Develop and implement policies and procedures
- Allocate appropriate access, use, and disclosure of patient information
- Complies with law
- Furthers interoperability and the community benefit

Other tax issues

- Value of donations likely to be income and donors will likely issue 1099s to physicians
- IRS has not yet addressed this issue
EHR challenges and solutions

• Implementation
  • Resources are stretched
  • Results are not as expected
  • Loss of productivity: 10-20% slowdown for period of months
    • Source: David Blumenthal and John P. Glaser, Information Technology Comes to Medicine, New England Journal of Medicine 356:24 (June 14, 2007).

• Education and training are critical
  • Don’t expect a turnkey solution without involvement
    • Be knowledgeable about interfaces to other systems and likelihood of success
    • Consider fully integrated solution that includes EHR, PMS, etc. if interfacing with other systems is essential
    • Call references in advance
    • Has vendor implemented similar practices (i.e., is the technology directed to large practices instead of small practices? Is the technology appropriate for the volumes you have?)

• Workflow Matters
  • Part of early site assessment – nurses, staff and physicians should be involved
  • Have key stakeholders involved in the selection process and implementation process
  • Learn how the software impacts daily operations and interactions with patients
  • Prepare for slowdown
  • Prepare for learning curve
  • Can the software be adapted to fit your workflow?
  • Can you adapt your workflow for the software?
EHR challenges and solutions

• Privacy and Security
  • Internal uses and disclosures (treatment, payment and healthcare operations)
  • Uses and disclosures with other participants (treatment, payment and healthcare operations)
  • Other uses and disclosures?
  • Quality assurance, clinical trends, clinical research
  • HIE / RHIOs
  • Cross jurisdictional issues if crossing state lines
  • Establishment of rules of the road
  • Enforcement
  • “EHR Committee” – Physician stakeholders, donors, perhaps patient representatives

EHR challenges and solutions

• Data protection
  • Develop comprehensive data management program
    • Realistic
    • Scaleable
    • Flexible
  • Varies depending on where data is located and stored
    • Central locations such as servers
    • Disparate locations such as laptops, memory sticks, PDAs, desks
    • Third party vendors
    • Off-shore storage

EHR challenges and solutions

• Determine how to protect the data and who should be responsible
  • Adherence to industry standards
  • Encryption, passwords, firewalls
  • Audit trails
  • May vary depending on the type of data
  • Develop plan for responding to a security breach
EHR challenges and solutions

- Risk allocation and transfer
- Due Diligence
  - Who will hold the data? Does the vendor outsource?
  - Policies and procedures
  - Site visits
  - Disaster recovery plan
  - Insurance: request evidence of coverage and what it covers and does not cover

EHR challenges and solutions

- Contract Steps
  - Obtain review and attach documentation: policies and procedures, disaster recovery plan, insurance certificates
  - Supplement with own policies and procedures
  - Obtain right to audit
  - Require training
- Ongoing Operational Steps
  - Periodic audits
  - View audit logs
  - Attend training

EHR challenges and solutions

- HIPAA Security
  - Covered entity requirements
  - Business associate requirements
  - Reasonable and appropriate technical, administrative and physical safeguards to protect the availability, confidentiality and availability of electronic Protected Health Information
  - Safeguards may vary depending on type of data and purposes for which data is used and/or disclosed
- HIEs and RHIOs
  - Who should bear risk of security breach and cost of insurance?
    - Vendor, provider
  - Affect of security breaches on patient care, patient confidence in system
Establishing a Stark- and AKS-compliant contractual relationship with a hospital system

A success story

Physician Health Partners

• Founded in 1996, Physician Health Partners (PHP) is a management services organization that believes physicians have the capability and responsibility to drive high quality, cost-effective healthcare.

• Our innovative services create solutions for the healthcare market by delivering performance tools and expertise to:
  - improve healthcare quality
  - reduce overall system costs and
  - increase our clients’ business success.

• Our current customers include two adult primary care IPAs, a multi-specialty pediatric IPA, and three self-funded government contracts.

• Primary Physician Partners (PPP), the largest IPA we serve, currently has 183 primary care physicians mostly in northwest Denver metro
  - PPP has led the charge on EHR adoption.
Pre-Stark status

- Primary Physician Partners (PPP) member physicians can select EHRs independently
  - Several PPP and PHP representatives attended the 2005 TEIPR Conference in Salt Lake City
  - Realized widespread EHR adoption could represent market strategy
    - Clinical Integration pursuit as Board policy with EHR adoption a core element
  - In Fall 2005, PPP asked PHP as their management company to conduct due diligence and recommend preferred EHR solution
    - PPP physician reps on EHR Committee met bi-weekly for about 1 year

Pre-Stark status

- Evaluated
  - Exam Room functionality
  - Underlying technology
  - Configuration options (ASP vs. self-hosted)
  - Price
- Recommended NextGen in ASP environment
  - September 2006
- PPP Board approved direct contract with NextGen and ASP vendor

...Then the Hospital Called

Initial hospital discussions

- Centura Health, Colorado’s largest hospital system, expressed interest in engaging in a Stark/AKS arrangement with PPP
  - Initially offered ambulatory EHR paired with its inpatient EHR at nominal cost
  - Offer declined by PPP physicians for functionality concerns
  - Serendipitous occurrence with another IPA affiliated with Centura resulted in offer to support NextGen in existing ASP environment
    - Local NextGen ASP instance had been three years in the making, and live for about 1½ years
    - Had federal grant through FQHC member to help fund development
    - Initial efforts of IPA slow until IT/Project Management consultant brought in
Hospital offer

- Hospital offered to support NextGen or LSS (Meditech companion ambulatory EHR)
- Financial assistance
  - Allowance towards Training and Implementation (T&I) on per provider basis
  - Subsidize monthly costs, physicians pay 15%
    - Local IT support
    - Data center/host
    - NextGen maintenance and support fee
- Local IT operations for NextGen subsumed into Centura IT Department
- Original local consultant continued Training and Implementation work with PPP physicians

Contract issues to be considered

- Contract negotiations took a year to complete
  - Uncharted territory for hospital, but kept plugging forward
- Stark compliance
  - 85% max for hospitals
  - Terms for inclusion/exclusion
  - IRS considerations for non-profit hospitals
  - Sublicense or equivalent
  - Governance/control over modifications
  - Billing
  - Support

Contract issues to be considered

- Inclusions/exclusions
  - Service Level Agreements (SLA) including penalties
  - Hospital as IT vendor to practice
  - Add-on software, e.g., patient web portal
  - Interfaces
- Cost/financial terms
  - Initial
    - Term of subsidy, initial commitment for practice, hospital
    - Exit strategy
    - Concluded contract negotiations in December 2007

15
Current state and initial goals

- 7 PPP practices, 34 physicians in various stages of T&I
- 1st year just basic competence
- True ROI a multi-year endeavor
- Goal (and track record)
  - < 3-5% productivity drop during T&I period
  - 15% increase in average charge capture 6 months post-go live
  - Same average daily caseload per provider with 100% EHR use

Other lessons learned

- Interoperability needs to be stressed, addressed
  - Get RHIOs on the radar early
  - Fewer EHR platforms may aid RHIO development
  - ASP hosting also an advantage
  - Competing offers from other hospitals likely to follow
- Must keep focus on ultimate goal of community good
  - Cooperation among competitors will be a necessity
  - Push collaboration among practice, hospitals, other sources of clinical data/messages
- Self-hosting of EHR at practice can lead to “islands of data”
  - Inefficient
  - Risk of catastrophic data loss
- Carefully consider implementation methodologies that minimize productivity loss
  - Multiple strategies

Questions?