

# Keys to Electronic Records Implementation Compliance

HCCA's 13<sup>th</sup> Annual Compliance Institute

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## Overview

- Vendor Contracts
- HIPAA and System Design
- How to Enlist Provider Participation
- Questions/Discussion

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## Current Environment

*The Times They Are A Changin'*  
– Bob Dylan, 1964

- Confluence of events means...
- that the way health care providers have used IT in the past
  - And the measures they have taken to protect the privacy of health information and the security of electronic health information
  - Are no longer acceptable

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## Current Environment

Key component of President Obama's campaign platform

*The Obama plan will lower health care costs by \$2500 for a typical family by investing in health information technology, prevention and care coordination.*

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## Current Environment

Key component of President Obama's Economic Recovery Plan — Radio Address, December 6, 2008

*In addition to connecting our libraries and schools to the Internet, we must also insure that our hospitals are connected to each other through the Internet. That is why the economic recovery plan I'm proposing will help modernize our health care system—and that won't just save jobs, it will save lives. We will make sure that every doctor's office and hospital in this country is using cutting edge technology and electronic medical records so that we can cut red tape, prevent medical mistakes, and help save billions of dollars each year.*

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## Current Environment

- Increase in enforcement of HIPAA privacy and security along with possibility (probability?) of additional federal privacy regulation.
- Since 2005, reported breaches of data security compromised over 250 million records.
- October 27, 2008 memo from HHS OIG criticizing CMS actions to assure implementation of the HIPAA Security Rule.

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## Current Environment

- Providence Health & Services enters into Resolution Agreement agreeing to pay \$100,000 fine for failing to adequately protect backup tapes, optical disks and laptops, all containing unencrypted electronic PHI. All were stolen and compromised PHI of 368,000 patients.
- Two bills to increase protections for PHI introduced in Congress in 2008.

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## Current Environment

- 44 States and the District of Columbia have enacted data breach notification laws. Most do not specifically address health or medical information but beginning to be specifically addressed (Arkansas, Delaware, California).
- Nevada and Massachusetts now require encryption of transmitted personal information.
- FTC Red Flag rules.

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## Vendor Contract Issues

Risk Allocation – past, standard contract language no longer acceptable.

*Warranty – The above is a limited warranty and it is the only warranty made by licensor. Licensor makes and licensee receives no warranty express or implied and there are expressly excluded all warranties of merchantability and fitness for a particular purpose. Licensor shall have no liability with respect to its obligations under this agreement for consequential, exemplary, or incidental damages even if it has been advised of the possibility of such damages. The stated express warranty is in lieu of all liabilities or obligations of licensor for damages arising out of or in connection with the delivery, use, or performance of the software systems.*

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**Vendor Contract Issues**

**LIMITATION OF LIABILITY –**

*Licensors shall have no liability with respect to its obligations under this agreement or otherwise for consequential, exemplary, special, indirect, incidental or punitive damages even if it has been advised of the possibility of such damages. This limitation applies to all causes of action or claims in the aggregate, including without limitation to breach of contract, breach of warranty, indemnity, negligence, strict liability, misrepresentation, and other torts. Both parties understand and agree that the remedies, exclusions and limitations herein allocate the risks of product and service non-conformity between the parties as authorized by the uniform commercial code and/or other applicable laws. The royalty-free license herein reflects, and is set in reliance upon, this allocation of risk and the exclusion of consequential damages and limitations of liability set forth in this agreement.*

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**Vendor Contract Issues**

- Who Bears Risk
  - Consequential Damages
  - Customer Damages
  - Defense
  - Required Notifications
  - Cost of Remediation/Fixes
  - Fines and Penalties
  - Lost Profits, Goodwill, Reputation
  - Criminal or Willful Conduct
  - Gross Negligence

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**Vendor Contract Issues**

- Subcontractor
  - What standards apply
  - Who is responsible for compliance
  - Who bears risk

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**Vendor Contract Issues**

- New Legislation/Regulations
  - Flexibility to address
  - Who bears the cost

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**Vendor Contract Issues**

- Compliance – Can you afford to be “hands off” regarding whether a vendor is complying with privacy/security requirements?

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**HIPAA and System Design**

- Audit and Logging Capabilities
- End-User/Employee Security

*We have met the enemy and he is us.*  
- Pogo, 1970

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### Other Issues

- What is the Medical Record?
- Record retention and management – what are you legally obligated to retain?

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### Enlisting Providers Overcoming Inertia – Action Plan

- Mission critical emphasis
- Publicize early success stories
- Recruit a physician leader to educate physician community
- Involve Medical Staff Board
- Consider potential role in P4P goals

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### Enlisting Providers Overcoming Inertia - Benefits

- Greater efficiency, easier access to records
- Easier to read other practitioners' notes
- Compare to other tech advances (Blackberry, MS Office calendar)

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**Enlisting Providers  
Overview of Take Aways**

- Interoperability
  - software is technologically capable
  - freedom to use with others
- Documentation
- Not a condition of doing business
- Not related to referrals or generating business
- Physician pays at least 15% of donor’s cost without donor financing (EHR)

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**Enlisting Providers  
Overview of Main Authorities**

- Stark Exceptions
  - Electronic Prescribing, 42 CFR 411.357(v)
  - Electronic Health Records, 42 CFR 411.357(w)
  - Community-Wide HIS, 42 CFR 411.357(u)
  - Others
- Anti-Kickback Safe Harbor
  - Electronic Prescribing, 42 CFR 1001.952(x)
  - Electronic Health Records, 42 CFR 1001.952(y)
- Tax Exempt Status
  - May 11, 2007 IRS Memorandum
  - <http://www.irs.gov/pub/irs-tege/ehrdirective.pdf>

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**Enlisting Providers  
Stark: Electronic Prescribing**

- provided by: hospital to member of medical staff, group to group member, PDP sponsor or MA organization to prescribing physician;
- program meets Part D requirements at time provided (42 CFR 423.160)
- interoperability not restricted
- physician free to use with any patient regardless of payor

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**Enlisting Providers  
Stark: Electronic Prescribing (con't)**

- receipt/amount of IT not a condition of physician doing business with donor
- eligibility and amount provided does not take into account volume or value of referrals or business generated
- written signed agreement that specifies items/services, donor's cost, and cross reference, incorporation, or master list of all items/services provided
- not duplicating physician's existing items/services (reckless disregard)

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**Enlisting Providers  
Stark: EHR**

- items/services provided by entity furnishing DHS
- software interoperable (deeming provisions)
- no limit or restriction on use with other systems
- physician pays 15% of donor's cost before receipt (no loans)
- not a condition of physician doing business with donor
- eligibility and amount provided does not take into account volume or value of referrals or business generated (deeming provisions)
- written signed agreement that specifies items/services, donor's cost, physician contribution, and cross reference, incorporation, or master list of all items/services provided

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**Enlisting Providers  
Stark: EHR (con't)**

- not duplicating physician's existing items/services (reckless disregard)
- physician free to use with any patient regardless of payor
- no office staffing or primary use unrelated to medical practice
- electronic prescribing capability meets Part D standards (42 CFR 423.160)
- no violation of federal or state billing or claims submission law
- done by December 31, 2013

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**Enlisting Providers**  
**Stark: Community-Wide HIS**

- covers hardware and software
- items or services must be available as necessary to enable physician participation
- principally used by physician as part of community system
- doesn't take into account volume or value of referrals or other business generated
- available to all who wish to participate
- no violation of federal or state billing or claims submission law

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**Enlisting Providers**  
**Stark: Other Exceptions**

- Non-Monetary Compensation up to \$300, 42 CFR 411.357(k)
- Fair Market Value Compensation, 42 CFR 411.357(l)
- Medical Staff Incidental Benefits, 42 CFR 411.357(m)

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**Enlisting Providers**  
**AKA**

- Electronic Prescribing, 42 CFR 1001.952(x)
- Electronic Health Records, 42 CFR 1001.952(y)
- Requirements similar, but not identical, to Stark exception requirements

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### Enlisting Providers Tax Exempt Status

- May 11, 2007 IRS Memorandum
  - must meet EHR Regulations, plus:
  - Health IT Subsidy Arrangements
    - both parties will comply with EHR Regulations
    - hospital access to all records created with system
    - IT and services available to all medical staff physicians
    - same subsidy level available to all medical staff physicians or level varies by criteria related to community needs

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### Enlisting Providers Take Aways

- Interoperability
  - software is technologically capable
  - freedom to use with others
- Documentation
- Not a condition of doing business
- Not related to referrals or generating business (document offering to all)
- Physician pays at least 15% of donor's cost without donor financing (EHR)

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### Enlisting Providers Pop Quiz

- medical staff use of dedicated computer terminal in hospital for treatment of hospital patients
- physician requests that hospital provide her with an external hard drive to facilitate storage of EHR

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# Thank you!

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