Compliance Risks with EHR implementation and how to minimize them

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Overview

- Brief summary of Laws and implications for EHRs.
- Review of Major risk areas associated with EHR implementation.
- AREAS to focus on during set up and implementation to minimize these risks
- Questions

LAWS and Implications for EHRs

- Stark and Anti-kick back
- PPACA …ACOs
- HITECH and HIPAA
- ARRA and Meaningful Use
EHRs and Stark safe harbor and Anti kick back exception

- On August 8, 2006 CMS and OIG published Stark exceptions and Anti-Kickback Safe harbors for E-Rx and for EHR
  - Separate exceptions for E-Rx and EHR, and separate safe harbors for E-Rx and EHR
  - Requirements of exceptions are almost identical to corresponding safe harbors

- EHR exception/safe harbor allow donation of software or information technology and training services necessary and used predominantly to create, maintain, transmit, or receive EHR
  - No hardware
  - Donation may be made by any type of entity
  - Any software donated is interoperable
  - Recipient pays, before receipt, at least 15% of donor’s cost
  - **Signed, written agreement that specifies items and services**, the donor’s cost/recipient’s, and which covers all of the EHR items and services provided by the donor

Stark and Ant kickback  ..continued

- Neither the eligibility of a physician for the items or services, nor the amount or nature of the items or services, is determined in a manner that directly takes into account the volume or value of referrals
  - Recipient must not already possesses equivalent items or services
  - Cannot include staffing costs of physician

- Software must contain an E-Rx component

- Exception/safe harbor sunset 12/31/13
PPACA...Overpayments and EHR

• “Overpayment” is defined in section 6402 of the PPACA as any funds a person receives or retains under Medicare or Medicaid to which the person, “after applicable reconciliation,” is not entitled.

• Any overpayment retained past the deadline is an “obligation” (as defined in, and for purposes of, the reverse false claims provision of the False Claims Act)

• EHR may make it easier for providers to establish medical necessity

• EHR may make it easier for providers and suppliers to discover overpayments and to quantify the overpayment

PPACA...Mandatory Return of Overpayments Provision

• Section 6402 of PPACA adds section 1128J to the Social Security Act (“Medicare and Medicaid Program Integrity Provisions”)

• Among those provisions is new section 1128J(d) "Reporting and Returning of Overpayments"

• The provision provides that a person or entity receiving an "overpayment" is required to
  ➢ report and return it to the Secretary or the State Medicaid Agency or the appropriate contractor; and
  ➢ notify the agency or contractor of the reason for the overpayment

• Overpayment must be reported and returned within 60 days of the date on which it was identified, or the date any corresponding cost report is due (if applicable), whichever is later
EHRs and Accountable Care Organizations

• ACOs must submit data on measures the Secretary determines necessary to evaluate the quality of care furnished by the ACO. Secretary may incorporate reporting requirements and incentive payments related to PQRI initiative, including such requirements and such payments related to E-Rx and HER

• EHRs will be absolutely critical to success of ACOs in shared savings program and will play an important role in:
  • Physician/hospital alignment strategy
  • Clinical integration to improve coordination of care and reduce costs
  • ACOs’ ability to measure and report quality and cost data to CMS

EHRs and HITECH & HIPAA

• HITECH defines “unsecured protected health information” as PHI that is not secured through the use of a technology or methodology specified by the Secretary

• “breach” of PHI is defined in 45 CFR 164.402 as: the acquisition, access, use, or disclosure of PHI in a manner not permitted and which compromises the security or privacy of the PHI.

• More records in one place (e.g., laptop), \( \geq \) risk of improper disclosure of more records (e.g., greater than 500)

• Software tracking features will allow authorities to see who accessed the EHR and when, making it easier to show improper viewing of PHI
HITECH and Breach

- If there has been a “breach,” there are notification requirements:
  - Less than or equal to 500 individuals affected:
    - Notify the individuals and Secretary
    - Breach is listed on annual report to Secretary, due 60 days after new calendar year
  - Greater than 500 individuals of a State affected:
    - Must also notify prominent media outlets in the State

EHR and meaningful use

*HITeCH act has changed the landscape and pushed providers to adopt EHRs*

- To be implemented in 3 stages.
- The Stage 1- electronically capturing health information in a coded format, using that information to track key clinical conditions, communicating that information for care coordination purposes, and initiating the reporting of clinical quality measures and public health information.
- $44,000 carrot will promote EHR use, introduce compliance risks
All EHRs are not same

- Data entry in some is cumbersome and rigid.
- Templates are the heart of the product - need to be carefully set up.
- Interfaces are critical for efficiency
- Specialty content important
- Web portal, security, work flow set up and support are key areas that determine successful adoption by physicians
- Bad implementations are costly - $120k plus $100k in lost revenues (McIntyre AAOS Feb 2011)

“MAGNIFICENT SEVEN”

COMPLIANCE ISSUES WITH EHRs
OIG Compliance Program Guidance
Physician Documentation Guidelines

- Timely, accurate and complete documentation is important to clinical patient care. Medical records should support the medical necessity for the service billed and should:
  - Be complete and legible;
  - Document each patient encounter (including the reason for encounter, relevant history; physical exam findings; diagnostic test results; assessment; clinical impression/diagnosis; plan of care; date and legible identity of provider);
  - Provide the rationale for ordering diagnostic tests and other ancillary services (or it should be easily inferred);
  - Support the CPT and ICD-9 codes;
  - Identify risk factors; and
  - Document the patient’s progress, his or her response to, and any changes in, treatment, and any revision in diagnosis is documented.

http://oig.hhs.gov/authorities/docs/physician.pdf

7 Major Compliance Risks associated with EHR use

1. Authorship risks
2. Audit log risks
3. Integrity risks
4. Too much information risks
5. Inappropriate content risks
6. Contradiction risks
7. Action/documentation dissociation risks
1. Authorship Risks

- CMS guidelines
  - Provider has to obtain HPI, perform EXAM and be the DECISION MAKER
- Staff entry issues. Entering information not supposed to enter.
- Unauthorized E-Prescribing by staff
- EHRs should not allow this and staff privileges should be carefully assigned.

Authorship Risk – Shared Password

“The patient fell at his building and injured his foot, breaking his metacarpal. He was seen in ER and given medications. He feels good and now comes to Dr M’s office for casting”

- Who made this note?
- Where is that shown?
- Does it meet CMS requirements?
- Can this be accepted as Doctor’s entry?
- How do you avoid this? Role of EHRs
2...Audit Log Risk -
Time Stamping of Activities

- Resident/PA signs in and does most of the note
- Attending checks and finishes the note and bills under his name
- How to deal with this and prevent it?

QUESTIONS
- Who did the note? Where does this show?
- Did the provider do the full note?
- Does it meet CMS requirements?
- Does EHR clearly show this?

Audit Log Risk -
Timely Note Completion

- Timely completion can be traced
- Technically, cannot bill for any service that is not provided.
- If not documented, it is considered not done
- After 48 hours, accuracy questionable
- Time stamp can show this
- Changes in findings after that valid?
- Does the EHR have lock down capability?
3. Integrity Risk and role of EHRs

- Cut-and-paste another provider note
- Carry forward another provider note
- Copy another provider note
  - Charges of Plagiarism/ Fraud
- Same note for different patients
- Copy your own note for different visit
- Cut-and-paste your own note from one patient to another
  - Misrepresentation?

Cloned Documentation

- Little to distinguish one patient encounter from another.
- Undermines establishment of medical necessity
- Risk of improper, inappropriate or irrelevant documentation
- EHRs can and should be set up to avoid this
- OK to carry forward PH/FH/PMH from a prior visit
- SHOULD NEVER be used for HPI, exam or decision-making. EHRs should not permit this.
Audit Issue: Templates Customized Records

Date: 11/4/2005
Patient:...
Diagnosis: 708.45 Right shoulder impingement and rotator cuff injury.
Number of visits to Date: 3
Number of missed visits: 0

Audit Issue: Templates Customized Records

Date: 11/4/2005
Patient:...
Diagnosis: 708.45 Right shoulder impingement and rotator cuff injury.
Number of visits to Date: 4
Number of missed visits: 0

“Exploding” Documentation

- Clicking a checkbox such as triggers documentation of a complete exam, etc.
- “Takes over” documentation from the physician
- Does not allow physician to choose description of his or her actions and findings
- Templates need to be set up or modified to not allow this type of trigger and yet allow efficiency.
Audit Issue: Self-Populating Fields

5. Inappropriate Information

- Examination of lower extremities for Trigger Finger
- 10 system review for Trigger Finger
- Discussion of carpal tunnel release when diagnosis is Trigger Finger
Inappropriate Information....

- The testes are normal in size and shape with no evidence of enlarged prostate on rectal exam.
  
  Problem: patient is a 30 year old female

- Problem is EHR in this case uses same Review of system for all patients.

6. Contradiction risks
Contradiction Risks....... 

- Patient presents with Right shoulder pain.

- There is history of Hemiplegia resulting in Left sided weakness

- Exam reveals 5/5 strength in Left upper extremity muscles.

7. Action/Documentation Mismatch Risk

- 4 views ordered, 3 done.
- Short arm plaster cast applied, billed as short arm fiberglass cast
- MRI ordered but not documented
- Injection 40 mgs DepoMedrol, documented as 80 mgs
- This can be and should be addressed in EHR set up.
Prove that it was done

• How to prove examination done and not blown in?
  ➢ Show that template is blank until actually picked by provider
• How to prove informed consent done?
  • Should require active action
  • Should be relevant.

What Should Be Done?

• Remember that EHR is a Tool
• Very helpful, will be required, can protect
• Teach proper use - educate providers
• Well built tool easier to use - built in safeguards
• One tool for all situations not a good choice - need options with controls
  ➢ EDUCATE,
  ➢ REINFORCE,
  ➢ RE-EDUCATE
How to minimize these risks?

- Must have a compliance professional involved in EHR implementation.
- Update your Compliance Plan incorporating EHR risks.
- Must carefully review TEMPLATES
- Do E/M audit of various types and E/M level notes on a test patients.
- Educate/ re-educate the providers.

Compliance Risk – HPI

- Provider has to obtain HPI
  - Scribe?
  - Separate section
- Impossible to template
- Must have room to add/change easily
Compliance Risk – No Narrative

- Make sure EHR provides space in templates to allow additional narrative description of a positive finding on review of systems.
- Remind providers that a “check” to validate a diagnostic test is not sufficient – make sure additional information is allowed to support the Medical necessity for diagnostic tests ordered.
- EHR should be set up to allow proper documentation of examination and plan items.

Compliance Risk - Identification

- Make sure there is space for the author of the note to properly identify their documentation (signature and date, etc.)
- For multiple page templates make sure each page of the template has patient identification in case a page becomes lost from the original chart.
Compliance Risk – Too Much info

- Medical decision making more complex than presenting problem warrants
  - Data review over-utilized, inconsistent with depth of history or exam
  - *Cigna Government Services* “Copied & pasted and/or cloned documentation that is not medically necessary should not be counted towards the service level billed.”
- EHRs should have specific interactive risk based code guidance

Compliance Risk – Irrelevance

- Prior or subsequent notes but no mention of presenting problem status
- Extensive documentation unrelated to the presenting problem
- Extensive documentation but impression says condition resolved, plan states follow up prn
- Medical decision making consisting of only a problem list – no plan of care
- Template and training issue in EHR set up
E&M-incident to... Issues

- Evaluation of "incident to" Services.
  - Testing to determine if Medicare standards are met for medical necessity, documentation, and quality of care.
  - Not for hospital work or new patients
  - Provider on site
  - State signature requirements
  - Plan documented
  - Physician involved

- EHR should clearly show who saw the patient and who was the supervising provider

Injection Documentation

- Informed Consent
- Site
- Who injected
- Drug name and code
- Quantity
- Instructions
- Lot number, expiration

Recommend a separate note covering all these items and EHR should have these fields
Meaningful use risks mitigation

- Careful Planning and workflow adjustments
- Select measures carefully
- Look at risk areas carefully
- Monitor progress monthly
- Ensure attestations are accurate

EP’s must meet ...

- Meaningful Use Objectives
  - 25 objectives in total
    - 15 “core set”
      - EP must report on all measures
    - 10 “menu set”
      - EP must meet at least 5 and may defer up to 5
- Clinical Quality Measures
  - 3 “core” measures OR
  - 3 “alternate core” measures
  - PLUS 3 additional measures from a set of 38
Meaningful use ..denominator issues

- If no physical or telemedicine encounter and minimal service like interpreting a test, can choose to include or not as long as consistent.
- If seen more than once in reporting period, counted as only one.
- Patient encounters in ASC/ satellite offices count in denominator totals.
- 50% of patient encounters have to be in locations equipped with certified technology

HITECH Breach Risk mitigation

- Policies and Procedures
- Staff and Provider Education
- Firewall
- Virus/Spyware/Malware
- Contingency plans for “breach”
- Back up
- Disaster recovery
EHR Implementation..

- Method
  - Big Bang. All at once
  - Gradual. Groups one at a time
  - Hybrid
    - Office staff
    - Early adopters
    - Majority
    - Resistant Physicians

6 key steps

1. Selecting Project manager, core group of users, physician champion and early physician adopters.
2. Introducing vendor team to core group
3. Formulating a Project plan, evaluating IT infrastructure, selecting workflow and documentation processes
4. Reviewing templates with compliance staff and providers
5. Practicing Dry run to make sure integrations work and staff familiar
6. Going live with reduced patient load
6 common mistakes

1. Not selecting the right project manager, physician champion and core group of users
2. Not training office staff before physicians go live
3. Not involving compliance and billing staff
4. Physicians not reviewing templates and workflow before going live
5. Not budgeting enough training days.. 1-2 per provider
6. Not reducing workload first week of go live

Support is the key

- Do not under estimate the challenge
- Each physician is individual
- Murphy’s law works
- Need on site support
- Fix “stuff on the fly”
- Have extra help and back up plan
- Expect challenges, hope for smooth sailing
THANK YOU

- Questions?