Compliance in the Age of Electronic Health Records (EHR)

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Regulatory Landscape
Increased Claims Scrutiny

- Medicare
- Medicaid
- Private Payor

Medicare Auditing Activity

- Medicare Affiliated Contractor ("MAC")
- Recovery Audit Contractor ("RAC")
- Program Safeguard Contractor ("PSC")/Zone Program Integrity Contractor ("ZPIC")
Medicare RACs

- RACs are companies contracted by Medicare, tasked to identify and correct Medicare improper payments.
- RACs are compensated on a contingency fee basis.
  - The RAC program initially began as a demonstration authorized by Section 306 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (“MMA”).
  - The RAC program was made permanent and expanded nationwide pursuant to Section 302 of the Tax Relief and Health Care Act of 2006.
  - Section 6411 of the Affordable Care Act expands the RAC program to include Medicare Part C and D claims.

Zone Program Integrity Contractor (“ZPIC”) / Program Safeguard Contractor (“PSC”) Audits

- Responsible to perform benefit integrity functions:
  - Fraud and abuse investigation and detection
  - Overpayment identification
  - Case resolution (e.g., coordination of overpayment recovery; referral to law enforcement)
- Authorized to:
  - Conduct prepayment reviews
  - Recommend suspensions of payment
  - Conduct post-payment audits
  - Extrapolate the amounts of alleged overpayments identified by way of post-payment audit
- **Not** compensated on a contingency-fee basis
Medicaid Auditing Activity

- Recovery Audit Contractor (“RAC”)
- Medicaid Integrity Contractor (“MIC”)

Medicaid RACs

- Section 6411 of the Affordable Care Act expands the RAC program to include Medicaid claims
Medicaid Integrity Contractors (“MICs”)

• The Deficit Reduction Act of 2005 added Section 1936 to the Social Security Act, which created the Medicaid Integrity Program (“MIP”) and required CMS to procure contractors to:
  – Review provider actions
  – Audit claims
  – Identify overpayments
  – Educate providers and others with respect to program integrity and quality of care

• To perform the functions above, CMS awarded contracts to Medicaid Integrity Contractors (“MICs”), including Audit MICs
• Focus on providers with “truly aberrant” billing
• Not compensated on a contingency-fee basis

The Healthcare Reform Statutes

• The Patient Protection and Affordable Care Act (PPACA), Pub. L. 111-148
  – Enacted on March 23, 2010
  – CBO estimate of $940M cost during first 10 years
    • Paid for, in part, by eliminating fraud, abuse and waste in Federal health care programs

• The Health Care and Education Reconciliation Act of 2010 (Reconciliation Act), Pub. L. 111-152
  – Enacted into law on March 30, 2010
  – Makes changes to 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

• “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)
Mandatory Return of Overpayments Provision

- EHR may make it easier for hospitals and other providers to establish medical necessity

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

EHRs and Accountable Care Organizations

- Section 3022 of PPACA requires HHS to establish, by January 1, 2012 a shared savings program utilizing ACOs

- Secretary has authority to waive provisions of the CMP Statute, Stark, and AKS

- Among other requirements, ACOs are required to define processes to promote evidence-based medicine and patient engagement, report on quality and cost measures, and coordinate care, such as through the use of telehealth, remote patient monitoring, and other such enabling technologies.
EHRs and Accountable Care Organizations

Secretary shall determine appropriate measures to assess the quality of care furnished by the ACO, such as measures of—
(i) clinical processes and outcomes;
(ii) patient and, where practicable, caregiver experience of care; and
(iii) utilization (such as rates of hospital admissions for ambulatory care sensitive conditions).

EHRs and Accountable Care Organizations

• ACOs must submit data in a form and manner specified by the Secretary 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 EHR
EHRs and Accountable Care Organizations

EHRs will play an important role in

- physician/hospital alignment strategy
- clinical integration
- ACOs’ ability to measure and report quality and cost data to CMS

Would-be ACOs need to evaluate their IT capability before plunging headfirst into a shared savings program.

Stark Exception/AKS Safe Harbor for Electronic Prescribing and Electronic Health Records

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
- E-Rx exception and safe harbor mandated by MMA of 2003
Stark Exception/AKS Safe Harbor for Electronic Prescribing and Electronic Health Records

Requirements of EHR exception/safe harbor

- 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 Exception/AKS Safe Harbor for Electronic Prescribing and Electronic Health Records

Requirements of EHR exception/safe harbor (cont’d)

• 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 (or other business generated between the parties).

• donor does not know that recipient already possesses equivalent items or services

• items and services do not include staffing of physician

• Any software must contain an E-Rx component

• Exception/safe harbor sunset 12/31/13
Stark Exception/AKS Safe Harbor for Electronic Prescribing and Electronic Health Records

What has been the effect of the final rule?

HIPAA and EHR

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

Per 45 CFR 164.402, unsecured PHI is PHI that is not rendered unusable, unreadable or indecipherable to unauthorized individuals through guidance issued on the HHS web site.
HIPAA and EHR

“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.

- “compromises the security or privacy of the [PHI] means poses a significant risk of financial, reputational, or other harm to the individual.”

- harm standard is controversial

Not all HIPAA violations are “breach” but where 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
Civil Penalties for improper disclosure

45 CFR 160.404
• 3-tiered system for penalties for violations occurring after 02/18/2009, keyed to the culpability of the individual or entity making the violation
• The fines start at $100 for violations without fault, and go up to $50,000 per violation for willful neglect
  - Cap of $1.5 million for identical violations per CY

45 CFR 160.406
• Affirmative defenses

Compliance issues caused or exacerbated by EHR

• more records in one place (e.g., laptop), = 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

• implications for e-discovery in malpractice cases
HIPAA and EHR

**Compliance issues caused or exacerbated by EHR**

- need business associate agreement with software vendor

- Software vendor’s access to PHI – may argue for broader indemnity, e.g., for breach of business associate obligations under HIPAA

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**Overview of Incentives to Adopt EHR**
EHR and meaningful use

• 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.
• 15 core measures, 5 menu measures
• $44,000 carrot will promote EHR use, introduce compliance risks

Overview of EHR Programs
Some common features

- EHRs can be client server based, web based or hybrid
- Most are written in Microsoft DotNet platform and are SQL server based.
- Tablets, lap tops commonly used pose data breach risks... Need to be set up with passwords.
- Data input options are web portal, scanning OMR forms, Kiosks, Direct entry, stored phrases, typing and voice recognition. Good EHRs offer all these.
- Certification assures capability but not ease of use

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)
Compliance Issues with EHR

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
Compliance Issues with EHR

- Signature block issues
- Self-populating fields
- Documentation of services rendered
  - Documenting medical necessity
  - Template issues/customization

Case Studies
Audit Issue: Provider Signatures

Otherwise normal colonoscopy to cecum
Recommendations: Colonoscopy in 5 years
High Fiber Diet
Additional notes: polyps were removed by different techniques based on size and app

Thank you for allowing me to participate in the case of

[Signature]

Case Investigated on 6/24/2017 3:53 PM
CC: [Redacted]
Patient: [Redacted]

Audit Issue: Self-Populating Fields

First Visit

Date: Wednesday, July 12, 2017
Birth Date: [Redacted] (71 years)
ID #: 0109

Patient: [Redacted]
Physician(s): [Redacted]
Ref. Phys.: INTERNAL MEDICINE

Chief Complaint: Weight Loss, Constipation

Present Illness: PT is here today because of weight loss. PT has lost about 40 pounds since August without trying. Also he mentions that he had problems with constipation over the last year or so. He states that this is somewhat unlike him as he had been regular prior to that. He also states that he feels as if there is a large piece of food blocking the rectum. Observer present he has a "normal bow," he has a lot of fiber as he has a history of diverticulosis. He understands that the pre-medications he takes are also contributing to his symptoms. Discussed significant abdominal pain, but he has not had any suprapubic tenderness. He has had more gas and bloating with this as well. Discussed bowel in the colon

Past Medical History:

Diagnostic studies:

- Colonoscopy on 1/20/2016 reporting Diverticulosis of the sigmoid colon and anal
- Descending colon, Polyp in the mid-descending colon, Polyp in the sigmoid colon,
- Visualized masses unreported in the colon, Diverticulosis of the sigmoid colon and  descending colon, Normal mucosa in the cecum, Polyp in the transverse colon,
- Polyp in the rectum, Polyp in the transverse colon
Audit Issue: Self-populating Fields
Inconsistent Documentation

Audit Issue: Templates
Inconsistent Documentation

First Visit
Date: 04/15/2009
Patient: [redacted]
Physician(s): [redacted] FNP
Ref. Phys.: [redacted]
Chief Complaint: Hemorrhoids, IRC 84
Present Illness: Pt still bothered by his hemorrhoids He can't ride his lawnmower He complains every 15 seconds
Past Medical History
Audit Issue: Templates Customized Records

Date: 11/02/2019
Patient: [Redacted]
History: [Redacted]
Number of visits to date: 3
Address/Review: [Redacted]

Diagnosis: Laminectomy and decompression of lumbar spine.
Number of visits to date: 3
Diagnosis: [Redacted]
Number of visits to date: 4

Audit Issue: Templates Customized Records

More Compliance Risks and possible solutions

- Authorship risks
- Audit log risks
- Integrity risks
- Too much information risks
- Inappropriate content risks
- Contradiction risks
- Action/documentation dissociation risks
Authorship Risks

• CMS guidelines
  ➢ Provider has to obtain HPI, perform EXAM and be the DECISION MAKER
• Staff entry issues
• Another Provider entry assumed as own
  ➢ “Make it my note feature”
• EHRs should not allow this or have the ability to turn this feature off.

Logging on 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
Audit Log Risk -
Time Stamping of Activities

- Resident/PA signs in and does the note
- Attending checks and finishes the note and bills under his name
  - Who did the note? Where does this show?
  - Did the provider do the full note?
  - Does it meet CMS requirements?
- How to deal with this and prevent it?
- 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
- If bill before documentation complete, potential claim of Fraud
- After 48 hours, accuracy questionable
- Time stamp can show this
- Changes in findings after that valid?
- Does the EHR have lock down capability?
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.
“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.

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
- EHR should use risk based and ICD-9 combination to prevent this.
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.

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 EMR 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
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.

Effective Appeals Strategies

- If faced with an unfavorable audit determination related to EHR issues, effective appeals strategies include:
  - Provider affidavits
  - Affidavits from EHR software vendor
Compliance Tips

• Compliance audits
  – This will involve a careful review of EHR documentation for compliance with documentation guidelines (including signature requirements, medical necessity, etc.)

• Education of workforce regarding EHR compliance issues

• Training of workforce regarding appropriate use of EHR

Questions?

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