L. The Triple Threat: Three Key Compliance Risks to Watch for in 2014-2015 and Must-Have Solutions

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THE TRIPLE THREAT:
THREE RISKS FOR YOUR COMPLIANCE
PROGRAM IN 2014

2014 AHLA FRAUD & COMPLIANCE FORUM
OCTOBER 6 & 7, 2014

<table>
<thead>
<tr>
<th>John E. Kelly, Esq.</th>
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<tr>
<td>Member</td>
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<td>Chief Compliance Officer, Senior Associate General Counsel, HIPAA Privacy Officer</td>
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Presentation Overview

The Triple Threat
Three Risks for Your Compliance Program in 2014

- Operationalizing the 2-Midnight Rule: One size approach does not fit all
- HIPAA cyber security: Your vendor is a back door to your server
- Meaningful use attestation compliance: Begin with the end in mind
- Are you in compliance? Solutions and best practices to remain in compliance
OPERATIONALIZING THE 2-MIDNIGHT RULE:

One size approach does not fit all

Danette Leigh Slevinski, JD, MPA, CHC, CHPC, CHRC
Vice President, Corporate Responsibility Officer
Bon Secours Charity Hospital System
Suffern, NY

Presentation Overview

- Current status of the 2-Midnight Rule
- 2-Midnight Rule Nuts and Bolts
- Response to the 2-Midnight Rule
- Challenges with the Operationalization of the 2-Midnight Rule
- Best practices and suggestions for success
- Note: Please refer to submitted manuscript for citations and reference materials
Is your crystal ball clear?

- [https://www.youtube.com/watch?v=eemfQkhashU](https://www.youtube.com/watch?v=eemfQkhashU)  
  (Created by Ronald Hirsch)

Current Status of the 2-Midnight Rule

- Intended to go into effect for dates of services as of October 1, 2013
- MAC Probe & Education activities to continue through March 31, 2015
- Recovery Auditors are prohibited from conducting inpatient hospital patient status reviews on claims with dates of admission October 1, 2013 through March 31, 2015
- As of May 12, 2014, MACs have completed most first probe reviews of 10 or 25 claims and are beginning to provide educational information related to the first probe
2-Midnight Rule Nuts and Bolts: The Rule

- Admissions for surgical procedures, diagnostic tests and other treatments “are generally appropriate for inpatient hospital admission and payment under Medicare Part A when
  - The physician expects the beneficiary to require a stay that crosses at least two midnights and
  - Admits the beneficiary based upon that expectation.”
- Sounds easy enough, right?
- Citing an anticipated increase in reimbursement for inpatient services, CMS instituted a 0.2% across the board cut for inpatient discharges occurring after October 1, 2013

2-Midnight Rule Nuts and Bolts: Unforeseen Circumstance

- If an unforeseen circumstance results in a stay of less than 2 Midnights in the case of
  - Transfer
    - To hospice (at patient election)
    - To another facility
  - Beneficiary leaving against medical advice (AMA)
  - Death
- After the physician ordered the patient’s admission based upon an appropriate expectation of a more than two midnight stay
- The order and sufficient documentation exists in the record
- The stay may be eligible for reimbursement as an inpatient admission
2-Midnight Rule Nuts and Bolts: Exceptions

• If a physician anticipates that the patient will have a less than 2 Midnight stay, it may still qualify as an inpatient stay if:
  • The admission is for a procedure on the CMS Inpatient-Only List for which inpatient care is deemed medically necessary
  • Email suggested exceptions for consideration to IPPSAdmissions@cms.hhs.gov and in the subject line write "Suggested Exceptions to the 2 Midnight Benchmark"
  • That the admission would otherwise satisfy any other inpatient admission criteria, standard or guideline such as MCG (Milliman) or InterQual does not matter if the patient is a Medicare patient

2-Midnight Rule Nuts and Bolts: What “Time” in the Hospital Counts

• The start time of outpatient services rendered if they are properly documented, until an inpatient admission order is entered
  • Not triage time or waiting time
• Time spent in inpatient status beginning from the execution of the admission order
• When using qualified outpatient time towards an inpatient admission, use Occurrence Span Code 72
2-Midnight Rule Nuts and Bolts: Benchmark vs. the Presumption

- The benchmark:
  - Is based on the physician’s decision to admit the patient;
  - It is the time when the Medicare patient receives inpatient services; and
  - It also includes qualifying outpatient services such as observation services, outpatient care, treatment in the ED or operating room

- The presumption:
  - Part A claims spanning 2 or more midnights after formal inpatient admission are presumed to meet the rule; and
  - Auditors will not give a claim of less than 2 midnights the benefit of the presumption. They will determine that the claim doesn’t meet inpatient criteria unless there is evidence of qualifying outpatient services prior to the inpatient admission or some other exception applies

2-Midnight Rule Nuts and Bolts: Certification Requirements

- The physician certification:
  - Authenticate the practitioner’s order by certifying that the care is medically necessary in an inpatient setting and that, unless on the CMS Inpatient Only list, the admission also meets the TMR criteria
  - Include the reasons for inpatient services and the estimated time that the beneficiary will be in the hospital
  - If care is provided in a critical access hospital, the physician must certify that the patient is expected to be discharged or transferred to a hospital within 96 hours
  - With limited exceptions, certification must be completed, signed and dated, as well as documented in the medical record prior to the patient’s discharge
  - Only (1) a doctor of osteopathy or doctor of medicine, (2) a dentist in limited circumstances, or (3) a doctor of podiatric medicine if the certification is for care that can be provided under a podiatric license, may sign the physician certification
  - Certification is closely linked to the practitioner order
2-Midnight Rule Nuts and Bolts: Admission Order Requirements

- The admitting inpatient order must:
  - Be made by a physician or qualifying practitioner with admitting privileges to the facility and knowledge of the patient
  - Clearly state that the beneficiary should be admitted for inpatient care and that inpatient care is medically necessary, and
  - Be completed at or before the time of inpatient admission
  - Note: Verbal inpatient admission orders must be signed dated and timed by the ordering practitioner or another practitioner with the required admitting qualifications.

Oops, Beneficiary Didn’t Really Meet Inpatient Criteria, Now What?: Beneficiary is Still In-House

- Appropriate Use of Condition Code 44
- If it is determined by the admitting physician or the utilization review committee, that the beneficiary did not meet inpatient criteria, the patient’s status can be changed if ALL of the following criteria are met:
  - the patient is still in the hospital;
  - the hospital has not yet submitted an inpatient admission claim to Medicare;
  - after a utilization review committee determined that the patient no longer meets inpatient criteria, a physician agrees with their decision; and
  - the physician documents that he or she agrees with the utilization review committee's decision
- Check state law to determine whether written notice to the patient is required and the content required for the notice
Oops, Beneficiary Didn’t Really Meet Inpatient Criteria, Now What?: Beneficiary is Discharged

- Status cannot be changed to outpatient or observation.
- Indicate Provider Liability period on the Part A claim by including Occurrence Span Code “M1” and the inpatient admission dates of service.
- The hospital should submit a bill using Type of Bill 12x for covered Part B Only services that were furnished to the inpatient.
- Medicare may still make payment for certain Part B services furnished to an inpatient of a hospital when payment cannot be made under Part A because an inpatient admission is determined not to be medically necessary.
- Information about Part B only services is located in the Medicare Benefit Policy Manual (Chapter 6, Section 10).
- You have one year: ready set, go!

Response to the 2-Midnight Rule

- The Center for Medicare Advocacy:
  - Bagnal v. Sebelius: does CMS’s policy of allowing hospitalized Medicare beneficiaries to be placed in “observation status,” rather than formally admitting them, deprive them of their Part A coverage in violation of the Medicare statute, the Administrative Procedure Act, the Freedom of Information Act, and the Due Process Clause?
  - Health Subcommittee of the House Committee of Ways and Means: discussions including the financial and rehabilitation coverage impact of the 2-Midnight Rule on beneficiaries
- Michigan Health and Hospital Association: the 2-Midnight rule places hospitals in a tough spot. Let the physician decide the appropriate setting for care.
- GNYHA: advocacy on multiple fronts, including encouraging commercial payors not to change to the 2-Midnight Rule criteria and sending letters articulating various concerns to CMS.
- Other physician advocacy and hospital advocacy associations throughout the country have weighed in as well.
Challenges With Operationalizing the 2-Midnight Rule: Financial Challenges (Universal Application)

- Universal Application of the 2-Midnight Rule can result in loss of revenue.
- Commercial and other payors may apply different inpatient admission criteria.
- Once EMTALA criteria is met, know whether the 2-Midnight Rule or other patient criteria is applied by the patient’s payor and communicate this information to the physician.
- Leverage EMR, case management tools or any other viable approach to provide all relevant information to the physician.

Challenges With Operationalizing the 2-Midnight Rule: Financial Challenges (What about the RACs)

- Litigation has delayed CMS from selecting new Recovery Auditors in Regions 1, 2 and 4.
- Utilize this time to update policies, identify issues and educate. Poll the staff (physicians, case managers, revenue integrity staff, coders):
  - What further information do they need to “get it right”?
  - What are the barriers to compliance and financial success exist?
- Auditors may still audit for medical necessity so any effort towards 2-Midnight Rule compliance is worth it!
Challenges With Operationalizing the 2-Midnight Rule: Financial Challenges (Selecting Outpatient Status Defensively)

- The University of Wisconsin's study, retrospectively applying the 2-Midnight Rule to claims between 1/1/12 and 2/28/13 found a 7.4% switch from inpatient to outpatient
- The “Two Midnight Dilemma”

<table>
<thead>
<tr>
<th>Top reasons for Medicare short stays</th>
<th>Observation pays this much less</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chest pain</td>
<td>$ 870.00</td>
</tr>
<tr>
<td>Circulatory disorders</td>
<td>$2,312.00</td>
</tr>
<tr>
<td>Coronary stent insertion</td>
<td>$2,007.00</td>
</tr>
<tr>
<td>Digestive disorders</td>
<td>$2,047.00</td>
</tr>
<tr>
<td>Dizziness</td>
<td>$1,320.00</td>
</tr>
<tr>
<td>Fainting</td>
<td>$1,890.00</td>
</tr>
<tr>
<td>Irregular heartbeat</td>
<td>$ 943.00</td>
</tr>
<tr>
<td>Irregular heartbeat (medium severity)</td>
<td>$2,444.00</td>
</tr>
<tr>
<td>Loss of blood flow to the brain</td>
<td>$1,677.00</td>
</tr>
<tr>
<td>Medical back problems</td>
<td>$2,085.00</td>
</tr>
<tr>
<td>Nutritional disorders</td>
<td>$1,977.00</td>
</tr>
<tr>
<td>Red blood cell disorders</td>
<td>$2,010.00</td>
</tr>
<tr>
<td>Respiratory signs and symptoms</td>
<td>$3,700.00</td>
</tr>
</tbody>
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Note: Adapted from an article by Bob Herman entitled “Hospitals' hope for relief from two-midnights purgatory in Modern Healthcare” citing data from the HHS Inspector General’s office. (See Bob Herman, Hospitals' hope for relief from two-midnight purgatory, MODERN HEALTHCARE (Aug. 21, 2014), http://www.modernhealthcare.com/article/20140821/NEWS/308219948)

Challenges With Operationalizing the 2-Midnight Rule: Compliance Challenges

- Challenges with changing status quo
- Inadequate staffing in departments such as case management
- EMRs, forms and templates that are not revised for success
- Physician order and certification issues including timing
- Appropriate application of Condition Code 44 and Occurrence Span Code 72
- Physician buy-in: they’re busy but you really need their support, ideas and understanding to get this right!
- The lurking whistleblower
Challenges With Operationalizing the 2-Midnight Rule: Patient/Family Demands

- Patient perspective: I was in a hospital bed what do you mean I was “under observation”
- Patient/family perspective: Make me an inpatient or else
- Center for Medicare Advocacy's Self Help Packet for Medicare “Observation Status” informs patients about the impact of observation status on patient financial responsibility and potential ineligibility for rehabilitation coverage
- News coverage regarding inpatient versus outpatient care encourages patients to not only be advocates for themselves but demand inpatient status
- What about CMS’s advice to beneficiaries? “Are you a Hospital Inpatient or Outpatient? If You Have Medicare - Ask!”

<table>
<thead>
<tr>
<th>Situation</th>
<th>Inpatient</th>
<th>Part A Pays</th>
<th>Part B Pays</th>
</tr>
</thead>
<tbody>
<tr>
<td>You're in the emergency department (ED), also known as the emergency room, or ER, and you're taken to the hospital with a doctor's order.</td>
<td>Outpatient</td>
<td>Your doctor services</td>
<td>Your doctor services</td>
</tr>
<tr>
<td>You visit the ED and are sent to the intensive care unit (ICU). Ask for a doctor's order.</td>
<td>Outpatient</td>
<td>Nothing</td>
<td>Your doctor services</td>
</tr>
<tr>
<td>You come to the ED with shortness of breath and the doctor orders you to be kept over the night. Your doctor orders you to stay in observation and the doctor writes an order for equivalent admission on the observation floor.</td>
<td>Outpatient</td>
<td>Your inpatient hospital stay</td>
<td>Doctor services and hospital expenses, ED visit, observation services, lab tests, or RX (prescription medicines)</td>
</tr>
<tr>
<td>You go to a hospital for outpatient surgery but stay overnight for high blood pressure. Your doctor does not write an order for equivalent admission on the observation floor.</td>
<td>Outpatient</td>
<td>Nothing</td>
<td>Doctor services and hospital expenses, RX (prescription medicines)</td>
</tr>
<tr>
<td>Your doctor writes an order for the hospital to treat you with observation status, but it's changing your hospital status. Ask for a doctor's order. Your doctor orders you to stay in observation; while you're still a hospital patient before being sent home, ask for your hospital status changed.</td>
<td>Outpatient</td>
<td>Nothing</td>
<td>Doctor services and hospital expenses</td>
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[ARE YOU A HOSPITAL INPATIENT OR OUTPATIENT? IF YOU HAVE MEDICARE - ASK!](https://www.medicare.gov/Pubs/pdf/11435.pdf)
Challenges With Operationalizing the 2-Midnight Rule: Patient/Family Demands

How would a hospital's observation services affect my SNF coverage? (continued)

Here are some common hospital situations that may affect your SNF coverage:

<table>
<thead>
<tr>
<th>Situation</th>
<th>Is my SNF stay covered?</th>
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<tbody>
<tr>
<td>You came to the ED and were formally admitted to the hospital with a doctor's order as an inpatient for 3 days. You were discharged on the 4th day.</td>
<td>Yes. You met the 3-day inpatient hospital stay requirement for a covered SNF stay.</td>
</tr>
<tr>
<td>You came to the ED and spent one day getting observation services. Then, you were formally admitted to the hospital as an inpatient for 2 more days.</td>
<td>No. Even though you spent 3 days in the hospital, you were considered an outpatient while getting ED and observation services. These days don't count toward the 3-day inpatient hospital stay requirement.</td>
</tr>
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- **ARE YOU A HOSPITAL INPATIENT OR OUTPATIENT? IF YOU HAVE MEDICARE – ASK** [https://www.medicare.gov/Pubs/pdf/11435.pdf]

Best Practices and Suggestions for Success: Take advantage of the CMS Settlement Offer

- Certain types of facilities, including Acute Care Hospitals and Critical Access Hospitals, can take advantage of a CMS settlement offer if they act on eligible claims by October 31, 2014.
- The purpose of this settlement opportunity is to address the large and growing number of claims appeals. CMS will settle all qualifying claims at 68 percent of the "net paid amount" of the claim.
- Qualifying claims include those that meet all of the following criteria:
  1. The facility qualifies for the settlement offer;
  2. The claim was not for items/services provided to a Medicare Part C enrollee;
  3. The claim was denied by an entity who conducted review on behalf of CMS (e.g., MAC, CERT, ZPIC);
  4. The claim was denied based on inappropriate patient status (or otherwise states that the services may have been reasonable and necessary but treatment on an inpatient basis was not);
  5. The first day of admission was before October 1, 2013;
  6. The denial was timely appealed by the hospital. As of the date the hospital signs and submits their first administrative agreement:
     a. The appeal decision was still pending at the MAC, Qualified Independent Contractor (QIC), Administrative Law Judge (ALJ), or Departmental Appeals Board (DAB); or
     b. The provider had not yet exhausted their appeal rights at the MAC, QIC, ALJ, or DAB levels; and
  7. The provider did not receive payment for the services as a Part B claim ("rebill").

- Don’t settle without evaluating whether this option is right for your facility. Balance what you give up for what you can gain.
Best Practices and Suggestions for Success

- Do Not Universally Apply the 2-Midnight Rule
- Review and Update Policies, Procedures and Forms (paper and electronic)
- Determine whether the Electronic Medical Record Can and Should be Updated to Make Compliance Easier
- Train and Educate All Relevant Staff
- Review available Data
  - Internal:
    - What are your most common and concerning compliance and finance issues
    - Are there patterns (DRGs, providers, days of the week) in which errors are more frequently made
  - External: Data such as RACTrac made available by the American Hospital Association

HIPAA CYBER SECURITY
YOUR VENDOR IS A BACK DOOR TO YOUR SERVER

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**Agenda**

- Provider Environment and Regulatory Framework
- Covered Entity’s Risks and Liabilities
- Mitigating a Covered Entity’s Risk

**Introduction to HIPAA Cyber Security: Provider Environment**

- Healthcare providers are becoming more reliant on third-party vendors to manage growing health information technology ("HIT") functions
- HIT platforms are increasingly the target for hackers and other cybercriminals
- Providers are more frequently finding themselves on the hook for their vendors’ security incidents and missteps because of recent regulatory changes
Regulatory Framework

- Extensive regulatory changes have occurred in the last 5 years that have drastically altered HIPAA compliance and enforcement
  - 2009 – the Health Information Technology for Economic and Clinical Health Act (“HITECH”)
    - Expanded the Office of Civil Rights” (“OCR”) enforcement tools
    - Created federal reporting obligations of PHI breaches
    - Altered the relationship between covered entities and business associates
  - 2013 – OCR’s Omnibus Final Rule implementing HITECH
    - Strengthened privacy and security protections for patient information

When is a BAA Necessary Post HITECH Act and Omnibus Rule?

- A business associate relationship exists when a vendor provides services for or on behalf of a covered entity that involve the disclosure of PHI to the vendor
  - For example, a software company that accesses PHI for troubleshooting and other support services is a business associate
  - Not a business associate if the vendor merely sells healthcare items and services
- Omnibus Rule expanded the definition of business associate to include:
  - An entity that maintains PHI, “even if the entity does not actually view the [PHI],” and an entity that transmits PHI (unless that entity merely has “random and infrequent” access to PHI), in connection with a function covered by the Privacy Rule
  - Subcontractors that provide services to business associates, to the extent they require access to PHI to perform such service
Covered Entity Liability for Acts of an Agent

- More is not necessarily better when it comes to BAAs
- The Omnibus Rule expanded an entity’s liability to the acts or omissions of its business associate if the vendor is acting as its agent within the scope of such agency
- OCR has not provided a clear definition of “agent” or “agency,” instead it relies on fact-specific determinations that turn on “the right or authority of a covered entity to control the business associate’s conduct.”
  - Likely considered a business associate when the covered entity has authority or control to direct how a particular function will be carried out after a relationship has been established
  - Likely **NOT** considered a business associate when a party merely has contractual obligations to carry out a particular function

Vendor’s Security Breach: Consequences for the Covered Entity or Business Associate

- HITECH introduced a federal reporting obligation in the event of a breach of unsecured PHI.
  - Vendor must notify the Covered Entity of a breach
  - If over 500 affected individuals entity must notify the media
  - Covered entity must notify affected individuals and HHS
  - Even if it’s a vendor error, the covered entity bears the financial and reputational burden of reporting the breach
Shifting Responsibility through Contractual Negotiations

- The covered entity and vendor may see advantages to shifting responsibility through a contractual arrangement, **but** that doesn’t come without risk.

- Covered entities should consider the following items when entering into any contract:
  1. Is there uncertainty about breach response and investigation/mitigation responsibilities that could expose the covered entity to increased risk?
  2. Does the covered entity wish to retain a right to review and approve material if the business associate takes responsibility of notification responsibilities?
  3. Which party retains responsibility for addressing inquiries from individuals seeking information on a breach?
  4. Is the contract drafted in such a way to increase the likelihood that OCR will view the vendor as the covered entity’s agent, thereby exposing the entity to increased risk?

Consequences Beyond the Breach

- Vendor security lapses can extend well beyond the costs of mitigating and responding to a breach.
  - OCR may open a compliance review to investigate any reported breach of unsecured PHI
  - HIPAA Compliance Audits
  - Class Action Litigation
OCR Investigations

- Recent OCR enforcement actions have stressed the importance of covered entities performing documented risk analysis
  - OCR guidance on the significance of a risk analysis states that it “form[s] the foundation upon which an entity’s necessary security activities are built.”

- In January 2013, OCR announced the first settlement in connection with a breach affecting fewer than 500 patients when the Hospice of North Idaho was required to pay $50,000 in connection with the 2010 theft of an unencrypted laptop containing PHI of 441 patients.
  - OCR investigation found that the hospice failed to conduct a risk analysis to identify threats to the security of electronic PHI maintained on the laptops.

- In May 2014, OCR reached a record $4.8 million settlement in May of this year against two health system providers when a security lapse allowed the PHI of roughly 6,800 patients to become accessible through internet search engines.
  - OCR found that the entities had not sufficiently performed a risk analysis to identify weaknesses in their HIT applications and databases, and failed to implement security measures sufficient to reduce the risks and vulnerabilities to a reasonable and appropriate level.

OCR Investigation Cont.

- A complete risk analysis:
  - Includes an accurate and thorough assessment of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of electronic PHI on an entity’s system;
  - Identifies potential threats to electronic PHI, assessing the entity’s current security measures, determining the likelihood and criticality of potential threats;
  - Implements security measures sufficient to reduce the risks and vulnerabilities to a reasonable and appropriate level; and
  - Is carried out on a continual basis.
OCR Investigation

• Conducting a risk analysis is not enough, OCR has demonstrated a willingness to hold covered entities and business associates liable for failing to implement protective measures in response to known threats.

  • In 2014, OCR reached a $1.73 million settlement with Concentra Health Services following the report of a breach involving a stolen, unencrypted laptop containing patient information. Concentra had documented, through multiple risk analyses, that PHI was vulnerable to threats based on a lack of encryption on company laptops, but it never took sufficient measures to reduce this threat by completing the encryption process across all company laptops at the time of the breach.

HIPAA Compliance Audits

• HITECH requires OCR to perform periodic audits assessing covered entities’ and business associates’ compliance with the privacy and security obligations of HIPAA.

  • In late 2012, OCR conducted a pilot audit during which select entities received a broad request for documentation relating to HIPAA and were subject to site visits between 3 and 10 business days in length.

  • OCR provided an audit report summarizing its findings, allowing the audited entity 10 days to review the report and describe corrective actions taken to address any identified issues.

  • OCR has indicated that the audits serve primarily as a compliance improvement activity, but if a serious compliance issue is identified, OCR may initiate a separate compliance review/investigation.

  • In Fall 2014, OCR will audit about 350 covered entities and 50 business associates, which include an increased focus on security rule compliance.
Class Action Litigation

- There is no private right of action under HIPAA, but recent case law has indicated that a breach or other incident affecting patient information can potentially serve as grounds for a common law claim, which has opened the door to class action litigation
  - **Tabata v. Charleston Area Medical Center**: In 2011, over 3,600 patients of the West Virginia hospital received notice of a breach occurring when a database operated by the hospital was accidentally placed on the Internet. The West Virginia Supreme Court of Appeals held that patients had standing to bring a cause of action against a hospital for breach of confidentiality caused by the hospital’s breach of PHI and further reversed the lower court’s ruling that the patients failed to meet the requirements for class certification.
  - **Stanford University Hospital & Clinics**: In March, 2014 Stanford and two of its vendors agreed to a settlement of a class action lawsuit, requiring them to pay over $4.1 million in total to settle claims in connection with a data breach that caused personal information of roughly 20,000 emergency room patients to be accessible on the Internet for nearly one year.

How to Mitigate the Risk

- With an increased focus on the health care industry’s vulnerabilities and OCRs reinvigorated efforts, covered entities should engage in the following to help limit risks:
  1. Track all vendor relationships to determine whether a business associate relationship is created
     - To limit to liability, do not hold a vendor out as a business associate if it is not appropriate
  2. Use contractual negotiations to spread risk to vendors. In particular, entities may seek indemnification from vendors for their breaches
  3. Maintain a heightened level of oversight that is tailored to specific vendors controlling, maintaining, or having access to a server containing patient information
  4. Integrate vendor oversight into overall HIPAA compliance program
  5. Focus on one’s own internal privacy and security procedures
MEANINGFULLY USE IT OR LOSE IT: 
BEGIN WITH THE END IN MIND TO ENSURE A 
TRUTHFUL ATTESTATION AND 
SUCCESSFUL AUDIT 

Robert G. Trusiak, Esq. 
Chief Compliance Officer, Senior Associate General Counsel, 
HIPAA Privacy Officer 
Kaleida Health 
Buffalo, NY

Agenda 

- Ramifications of a Failed Meaningful Use Exercise 
- What Is Meaningful Use? 
- Recommendations
Meaningful Use

1. Financial – The creation of objectives to quantitatively measure performance due to the receipt of federal funds
2. Quality of Care – The goal of EHR technology is not to digitize paper records. The goal is to improve care and reduce costs for unnecessary services.

Meaning: Providers Must Demonstrate Qualitative and Quantitative Use of Certified EHR Technology

Ramifications

CRIMINAL EXPOSURE

Joe White, Former CFO, Shelby Regional located in Center, TX
1. False Statement
2. Aggravated Identity Theft
If convicted, maximum 7 years
Forfeiture of Meaningful Use Incentive Payments

FINANCIAL EXPOSURE

Independent of Criminal or Civil Action
- EPs and Hospitals who do not upgrade technology by 2015 face reduction in Medicaid and Medicare reimbursement
- Reduction for Medicare FFS for EPs starts at 1% and increases yearly, up to 5% total
CMS Remedy: 2014 CEHRT Option

- Approximately 2,500 hospitals and 168,000 physicians met Stage 1 in 2011 or 2012. As of August 2014, roughly 100 hospitals and 3,000 physicians satisfied Stage 2.
- Ability to select 2014 CEHRT Option (1) is subject to credible demonstration the EHR vendor delayed 2014 Edition CEHRT availability, and (2) requires twofold attestation.
- Final Rule offers no relief for providers and hospitals in FY 2015.

CEHRT 2014 Option Certification

- Initial Attestation
  I certify that the foregoing information is true, accurate, and complete. I understand that the Medicare EHR Incentive Program payment I requested will be paid from Federal funds, and that the use of any false claims, statements, or documents, or the concealment of a material fact used to obtain a Medicare Incentive Program payment, may be prosecuted under Federal or State criminal laws and may also be subject to civil penalties.
- Additional Attestation
  Providers will be required to attest to their inability to fully implement 2014 Edition CEHRT as part of the attestation process should they select one of the options outlined in this final rule.
Assure, and Do Not Presume, Satisfaction of CMS Criteria for a Delay

Providers must initially demonstrate nexus between:

1. Problems based on software development, certification, implementation, testing or release of product
2. Failure to implement 2014 Edition CEHRT

Inadequate Reasons to Not Fully Implement 2014 Edition CEHRT

- Cost
- Inability to Meet One or More Measures
- Staff Turnover
- Delay or Inaction

Prepare For An Audit during Stage 1 and 2

- 20% of hospitals being selected for MU audit after attestation
- Audits random in nature, or target suspicious or anomalous data
- Documentation retention for six years post-attestation as per CMS
- Criminal consequences, including forfeiture
Dynamic and Not Static, so Document, Document, Document to Assure Extrinsic Proof

Stage 2
Eligible Hospital and Critical Access Hospital Meaningful Use Core Measures
Measure 6 of 16
Date Issued: October, 2012

Patient Electronic Access

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<tr>
<th>Objective</th>
<th>Provide patients the ability to view online, download, and transmit information about a hospital admission.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measure</td>
<td>1. More than 50 percent of all unique patients discharged from the inpatient or emergency departments of the eligible hospital or CAH (POS 21 or 23) during the EHR reporting period have their information available online within 36 hours of discharge.</td>
</tr>
<tr>
<td></td>
<td>2. More than 5 percent of all unique patients (or their authorized representatives) who are discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH view, download or transmit to a third party their information during the EHR reporting period.</td>
</tr>
<tr>
<td>Exclusion</td>
<td>Any eligible hospital or CAH that is located in a county that does not have 50 percent or more of its housing units with 3Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period is excluded from the second measure.</td>
</tr>
</tbody>
</table>

Dynamic and Not Static, so Document, Document, Document to Assure Extrinsic Proof

Eligible Hospital and Critical Access Hospital Meaningful Use Core Measures
Measure 6 of 16
Stage 2
Date Issued: August, 2014

Patient Electronic Access

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<tr>
<td>Measure</td>
<td>1. More than 50 percent of all unique patients discharged from the inpatient or emergency departments of the eligible hospital or CAH (POS 21 or 23) during the EHR reporting period have their information available online, with the ability to view, download, and transmit to a third party information about a hospital admission, within 36 hours of discharge.</td>
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<td>2. More than 5 percent of all patients (or their authorized representatives) who are discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH during the reporting period view, download or transmit to a third party their information.</td>
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Conducting an Efficient MU Review

1. Regularly Check CMS MU Measures and Retain All Documentation
2. Retain Duplicate Book of Evidence
3. Test Veracity of Claim by Certified EHR Representative
4. Ensure Certified EHR Provides Complete MU Attestation Compliance
5. Do No Harm
6. Test Operational Aspect of Core Measures
7. Do Not Increase Financial Exposure After a Failed Appeal

Beware of External Sources Affecting Data Integrity and Satisfaction of Thresholds

<table>
<thead>
<tr>
<th>Stage 2, Core Measure 6</th>
<th>Types of Care that Minors Can Receive in NYS Without Parental Consent</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Hospitals provide patients the ability to view, download and transmit information about their hospital admission</td>
<td>• Reproductive health services</td>
</tr>
<tr>
<td></td>
<td>• Certain mental health services</td>
</tr>
<tr>
<td></td>
<td>• Substance abuse treatment</td>
</tr>
<tr>
<td></td>
<td>• HIV testing</td>
</tr>
<tr>
<td></td>
<td>• Sexual assault treatment</td>
</tr>
</tbody>
</table>

**DECREASED NUMERATOR POOL, UNCHANGED DENOMINATOR**
Considerations

1. Meaningful Use attestation is difficult work that requires an integrated team.
2. Risk is multi-faceted due to dynamic measures and financial and criminal penalties.
3. Presume audit and ensure progression of measures and objectives on a regular basis during—not after—the attestation period.

How to Reach Us?

<table>
<thead>
<tr>
<th>John E. Kelly, Esq.</th>
<th>Danette Leigh Slevinski, JD, MPA, CHC, CHPC, CHRC</th>
<th>Robert G. Trusiak, Esq.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Member</td>
<td>Vice President, Corporate Responsibility Officer</td>
<td>Chief Compliance Officer and Privacy Officer, Senior Associate, General Counsel</td>
</tr>
<tr>
<td>Bass, Berry &amp; Sims, PLC</td>
<td>Bon Secours Charity Hospital System</td>
<td>Kaleida Health</td>
</tr>
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<td>Washington, DC</td>
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