



MARTIN | PRINGLE
ATTORNEYS AT LAW

Legislative Update HIPAA/HITECH

Richard C. Stevens, Attorney

Martin, Pringle, Oliver, Wallace & Bauer, LLP

<http://martinpringle.com>

Topics

n **Legislative Update**

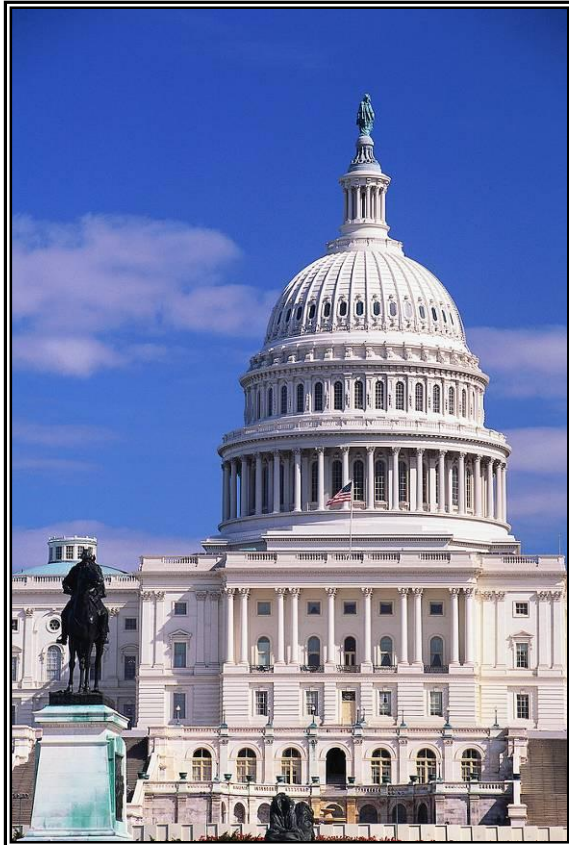
n **HIPAA/HITECH**

- q **Enforcement Activities**

- q **“Meaningful Use”**

- q **Business Associates (“BA”)**

Legislative Update



**“Politics is the
art of the
possible.”**

~Otto von Bismarck

Legislative Update

n WAPO

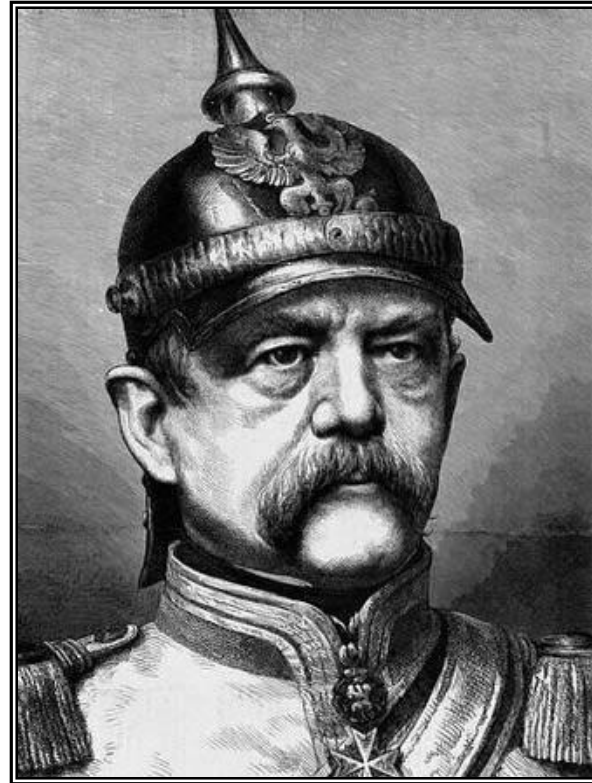
- q “Brown upsets Coakley in Massachusetts race”
1/19/2010
- q “Election dramatically alters the trajectory of
Obama's agenda” 1/19/2010

n WSJ

- q “Brown Wins Massachusetts Senate Seat”
1/19/2010
- q “Unions Cut Deal on Health Taxes”
1/15/2010

Legislative Update

“Laws are like sausages, it is better not to see them being made.”



~Otto von Bismarck

Links to H/S Bill comparisons

- n **Kaiser Family Foundation**

- q <http://www.kff.org/healthreform/sidebyside.cfm>

- n **New York Times**

- q <http://www.nytimes.com/interactive/2009/11/19/us/politics/119-plan-comparison.html>

- n **Politico**

- q http://www.politico.com/static/PPM136_100104_health_reform_conference.html

Legislative Update

n “In spite of all the activity that I know you're aware of in Massachusetts and the rest, we're still on course to resolving the differences between the House and the Senate bill. . . . So we're right on course, and we will have a health care reform bill.”

~Speaker Nancy Pelosi, 1/19/2010



Topics

n **Legislative Update**

n **HIPAA/HITECH**

q **Enforcement Activities**

q **“Meaningful Use”**

q **Business Associates (“BA”)**

New Statutory Req. of ARRA

(American Recovery and Reinvestment Act of 2009)

- n ARRA was signed 2-17-2009.
- n The law includes HITECH which Medicare and Medicaid incentive payments for the "meaningful use" of certified EHR.
 - q "Health Information Technology for Economic and Clinical Health"
 - q "Health Insurance Portability and Accountability Act" of 1996 (HIPAA)

New Statutory Req. of ARRA

- n CMS has a 3 roles in HITECH:
 - q Implementation of the EHR incentive programs, including defining “meaningful use”
 - q Standards, implementation specifications, and certification criteria for EHR technology
 - q Privacy and Security

New Statutory Req. of ARRA

- n Goal of EHR for everyone by 2014.
- n Debate about EHR privacy and security rules.
- n New federal requirements extend HIPAA coverage to Business Associates.

Impact

- n Biggest change since the 1st HIPAA.
- n Anticipation/expectation of a fundamentally different enforcement environment.
- n This is not a wholesale change to everything about HIPAA (forces re-evaluation).
- n Heightened tensions and ambiguities + more enforcement = disputes.

How Did We Get Here?

- n Incentives for EHR linked to “improved” privacy and security rules.
- n Questions exist regarding the rules effect and “stimulus” effects of EHR (long-term benefit?).
- n These provisions simply change the HIPAA structure/rules.

How Did We Get Here?

- n Stronger Enforcement Environment
- n Policy to promote health information technology, particularly EHR (HITECH).
- n Effective Date **February 17, 2010**

Topics

n **Legislative Update**

n **HIPAA/HITECH**

q **Enforcement Activities**

q **“Meaningful Use”**

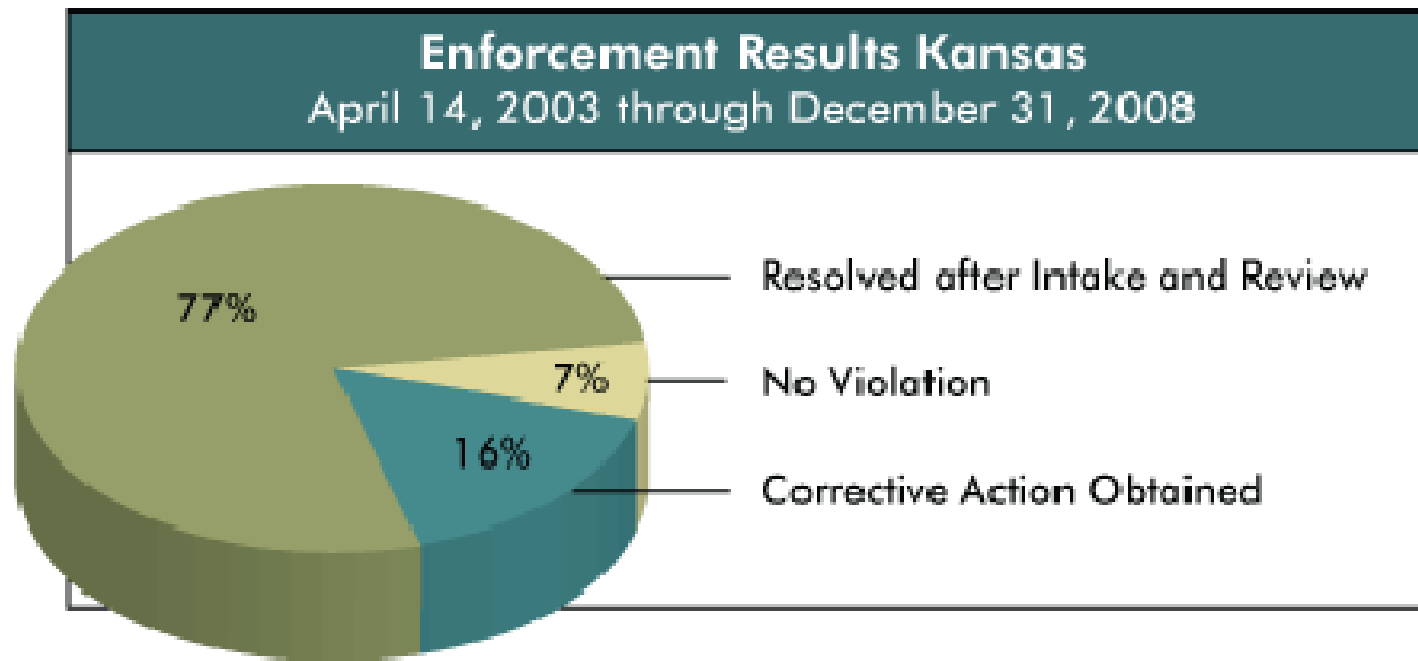
q **Business Associates (“BA”)**

Enforcement Issues

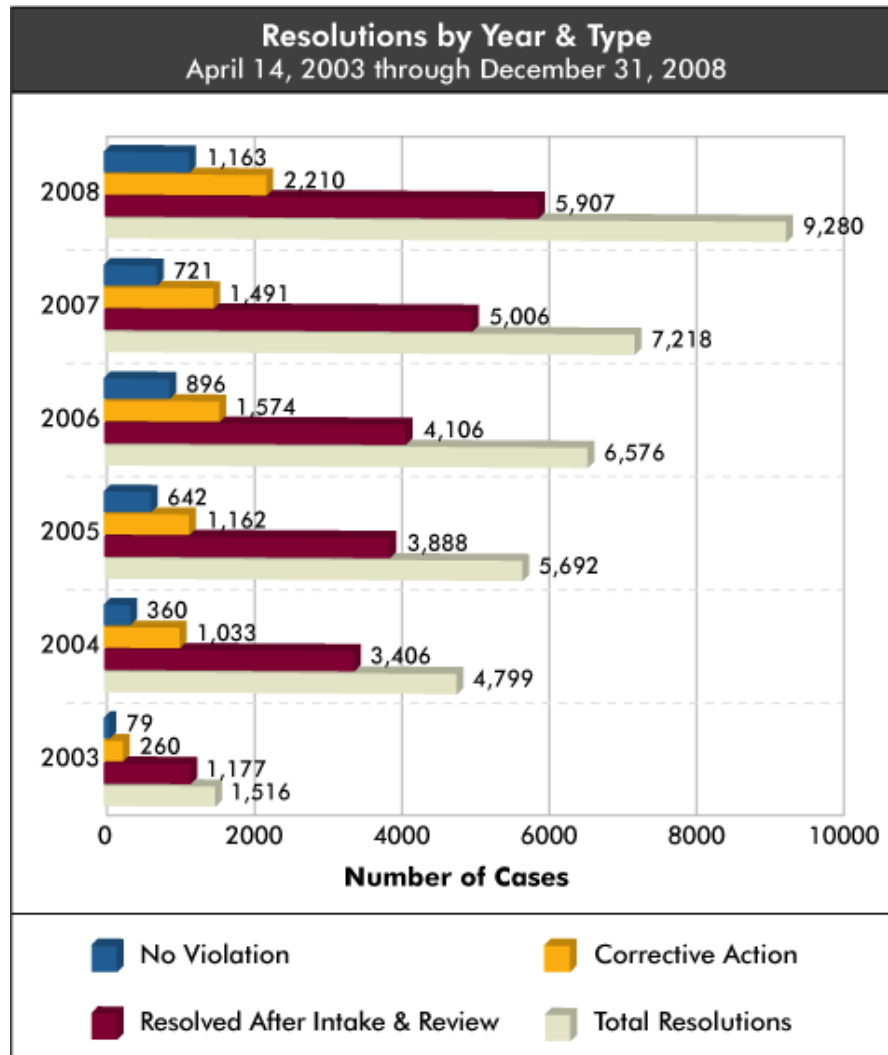
- n The Obama Administration may enforce the HIPAA Rules more aggressively than the Bush Administration.

- n Changes indicate that this new enforcement could be substantially different.

Enforcement Issues

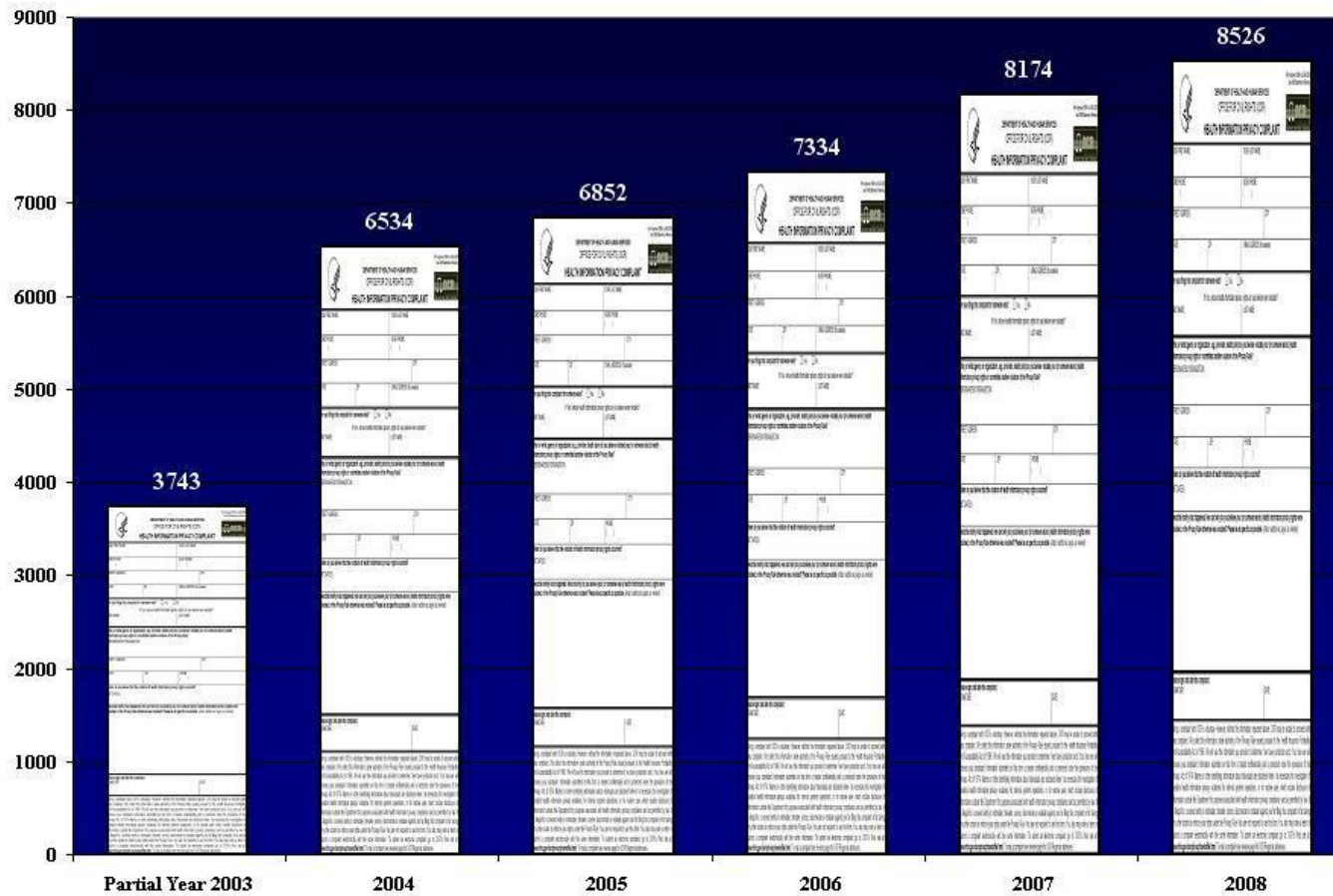


Enforcement Issues



<http://www.hhs.gov/ocr/privacy/hipaa/enforcement/data/historicalnumbers.html>

Enforcement Issues



<http://www.hhs.gov/ocr/privacy/hipaa/enforcement/data/complaintsyear.html#>

Enforcement Activity (Health Net)

- n **On January 13 the Connecticut AG sued Health Net of Connecticut, Inc.:**
 - q For failing to secure private patient medical records & financial information of 446,000 Connecticut enrollees
 - q For failing to promptly notify consumers endangered by the security breach
 - q For failing to effectively supervise and train its workforce on policies and procedures concerning the use and disclosure of PHI



Enforcement Activity (Health Net)

- n Connecticut is the first state to take advantage of the HITECH provisions that authorize state AGs to file lawsuits to enforce HIPAA:
 - q AGs may file suit to obtain statutory damages on behalf of any state residents for violations occurring after February 17, 2009
 - q Currently, per violation amounts are \$100 for each violation of a single requirement, up to a total of \$25,000 for violations of that requirement.
 - q The AG may seek injunctive relief to prevent future violations.
 - q An AG may also collect attorneys' fees from violators for pursuing civil actions.

Enhanced Penalties

- n Increased Monetary Penalties for Violations
 - q current maximum penalty \$25,000
 - q **new** penalty as much as . . . \$1,500,000

- n Effective February 17, 2010

Topics

- n **Legislative Update**

- n **HIPAA/HITECH**

 - q **Enforcement Activities**

 - q **“Meaningful Use”**

 - q **Business Associates (“BA”)**

“Meaningful Use”

- n January 13, 2010, CMS released a NPRM regarding “Meaningful Use” of Certified EHR technology.
- n “. . . shall be considered a meaningful EHR user for an EHR reporting period for a payment year if they meet the following three requirements:
 - q(1) Demonstrates use of certified EHR technology in a meaningful manner;
 - q(2) demonstrates to the satisfaction of the Secretary that certified EHR technology is connected in a manner that provides for the electronic exchange of health information to improve the quality of health care such as promoting care coordination, in accordance with all laws and standards applicable to the exchange of information; and
 - q(3) using its certified EHR technology, submits to the Secretary, in a form and manner specified by the Secretary, information on clinical quality measures and other measures specified by the Secretary.”



3 Stages

- n **“Under this phased approach to meaningful use, we intend to update the criteria of meaningful use through future rulemaking. We refer to the initial meaningful use criteria as “Stage 1.” We currently anticipate two additional updates, which we refer to as Stage 2 and Stage 3, respectively.**
- q Stage 1: The Stage 1 meaningful use criteria **focuses on electronically capturing health information in a coded format**; using that information to track key clinical conditions and communicating that information for care coordination purposes (whether that information is structured or unstructured, but in structured format whenever feasible); consistent with other provisions of Medicare and Medicaid law, **implementing clinical decision support tools** to facilitate disease and medication management; and reporting clinical quality measures and public health information.



Measures?

- n Implement drug-drug, drug-allergy, drug-formulary checks.
- n Input at least at least one diagnosis based on ICD-9-CM or SNOMED CT or an indication of none for 80% of all unique patients seen by the EP or admitted to an eligible hospital.
- n Maintain active medication lists for 80% of patients seen or admitted.
- n Record demographic info including preferred language; insurance type; gender; race; ethnicity and date of birth for 80% of patients seen or admitted
- n Record blood pressure and BMI and plot the growth chart for children age 2 to 20 years old for 80% of patients seen or admitted;
- n Record smoking status of 80% of patients age 13 or over;
- n Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research and outreach.
- n Implement five clinical decision support rules relevant to the relevant to specialty or high clinical priority, including for diagnostic test ordering, along with the ability to track compliance with those rules.



Measures?

- n Check insurance eligibility electronically for 80% of patients
- n Submit 80% of claims electronically
- n Provide summary of care record for at least 80% of transitions of care and referrals
- n Use computerized provider order entry (CPOE) for 80% of orders.
- n Transmit at least 75 percent of all permissible prescriptions electronically.
- n Report clinical quality measures as required by HHS.
- n Send electronic reminders to at least 50 percent of all unique patients seen by the EP that are 50 years of age and over.
- n Provide requested electronic copies of patients' health information within 48 hours of patient requests in 80% of cases.
- n Provide patients with timely electronic access to their health information (including diagnostic test results, problem list, medication lists, and allergies) within 96 hours of the information being available to the EP for at least 10 percent of all unique patients seen by the EP.
- n Provide clinical summaries to patients for each office visit for at least 80 percent of all office visits.



3 Stages

- n Stage 2: Our goals for the Stage 2 meaningful use criteria, consistent with other provisions of Medicare and Medicaid law, expand upon the Stage 1 criteria to encourage the use of health IT **for continuous quality improvement at the point of care and the exchange of information in the most structured format possible, such as the electronic transmission of orders entered using computerized provider order entry (CPOE)** and the electronic transmission of diagnostic test results (such as blood tests, microbiology, urinalysis, pathology tests, radiology, cardiac imaging, nuclear medicine tests, pulmonary function tests and other such data needed to diagnose and treat disease). Additionally we may consider applying the criteria more broadly to both the inpatient and outpatient hospital settings.
- n Stage 3: Our goals for the Stage 3 meaningful use criteria are, consistent with other provisions of Medicare and Medicaid law, **to focus on promoting improvements in quality, safety and efficiency, focusing on decision support for national high priority conditions, patient access to self management tools**, access to comprehensive patient data and improving population health.”



Standards

- n HHS also released an interim final rule (“IFR”) to adopt an initial set of standards, implementation specifications, and certification criteria.
- n This interim final rule represents the first step in an incremental approach to adopting standards, implementation specifications, and certification criteria to enhance the interoperability, functionality, utility, and security of health information technology and to support its meaningful use.
- n The certification criteria adopted in this initial set establish the capabilities and related standards that certified electronic health record (EHR) technology will need to include in order to, at a minimum, support the achievement of the proposed meaningful use Stage 1 (beginning in 2011) under the Medicare and Medicaid EHR Incentive Programs.



Standards

“III. Section-By-Section Description of the Interim Final Rule

- q A. Applicability

- q B. Definitions

- n 1. Definition of Standard

- n 2. Definition of Implementation Specification

- n 3. Definition of Certification Criteria

- n 4. Definition of Qualified Electronic Health Record (EHR)

- n 5. Definition of EHR Module

- n 6. Definition of Complete EHR

- n 7. Definition of Certified EHR Technology

- n 8. Definition of Disclosure C. Initial Set of Standards, Implementation Specifications, and Certification Criteria

- q 1. Adopted Certification Criteria

- q 2. Adopted Standards

- a. Transport Standards

- b. Content Exchange and Vocabulary Standards”



MARTIN | PRINGLE
ATTORNEYS AT LAW

Incentives

- n More than \$17 billion in incentives to acquire and implement EHR tech & the associated infrastructure
- n Physician practices are eligible to receive up to \$44,000 per physician for meaningful use of certified EHR technology:
 - q Up to \$18,000 for the first year (dropping to \$15,000 if first year is not 2011 or 2012); \$12,000 for the second year; \$8,000 in year 3, \$4,000 in year 4 and \$2,000 in year 5. (See table after the jump.)
 - q There will be no incentive payments for practices establishing their meaningful EHR use after 2014 (e.g., beginning 2015).



Incentives

- n There is a 10% premium for physicians with practices in under-serviced areas.
- n However, if a physician practice does not achieve meaningful EHR status by 2015, Medicare reimbursement fees will be reduced by 1% in 2015, 2% in 2016, 3% in 2017 and beyond; and the Secretary will have the right to reduce fees by 5% starting in 2018 for those practices where meaningful EHR use is under 75%.



Incentives

Physician Medicare Incentives							
Pay-Out Year							
Start Date	2011	2012	2013	2014	2015	2016	Totals
2011	18	12	8	4	2	0	44
2012		18	12	8	4	2	44
2013			15	12	8	4	39
2014				12	8	4	24
2015					0	0	0

(Courtesy of Mark J. Segal, *GE Healthcare*)



Incentives

- n (In lieu of Medicare) Certain physician practices may be also eligible to receive for up to \$65,000 in Medicaid reimbursement payments if they achieve standards of meaningful use.
- n States will reimburse up to 85% of the cost of implementation of EHR, possibly starting in 2011, but starting no later than 2016, with 2021 being the final year for Medicaid reimbursements.
- n First year's payment is capped at \$25,000 and may include reimbursed costs associated with purchase, implementation or upgrade of EHR technology, or, if provider achieves the meaningful user status, costs incurred if EHR technology is already implemented.
- n Subsequent annual reimbursements will not exceed \$10,000 per annual payment, and are intended to cover costs of operation and maintenance of EHR technology.

*** Physicians, unlike hospital systems, are specifically required to demonstrate the use of e-prescribing as part of their EHR use.**



Topics

- n **Legislative Update**

- n **HIPAA/HITECH**

 - q **Enforcement Activities**

 - q **“Meaningful Use”**

 - q **Business Associates**

Extension of HIPAA Requirements to Business Associates

n Business Associates

- q Person or entity that performs functions or activities involving use or disclosure of PHI (protected health information)

n Previous Requirements

- q Obtain satisfactory assurances through contract that BA complies with certain HIPAA rules

n New Requirements

- q Business associates are required by law to comply with all HIPAA provisions

Required Compliance

- n With:

- q Privacy Rule

- q Security Rule

- n Note: the “HIPAA Administrative Simplification” at

- <http://www.hhs.gov/ocr/privacy/hipaa/administrative/privacyrule/adminsimpregtext.pdf> is only **101** pages.



Security Rule

- n Requires administrative, physical and technical safeguards to protect the confidentiality, integrity, and availability of e-PHI
- n Requires covered entities to implement basic safeguards to protect electronic PHI from unauthorized access, alteration, deletion, and transmission
- n Now applied directly to Business Associates
- n Regulations and standards “shall be incorporated” into BA agreements
- n Business Associates subject to same civil and criminal penalties as covered entities

Privacy Rule

- n Establishes standards for authorized and required uses and disclosures of PHI
- n Business Associate may use and disclose PHI only in accordance with Privacy Rule
- n Privacy Rule regulations and standards “shall be incorporated” into BA agreements

Required Notice of Privacy and Security Breaches

- n **ARRA creates new federal security breach notification requirements**
- n **Covered entities and Business Associates must give notice of breach of “unsecured protected health information”**

Required Notice of Privacy and Security Breaches

- n Business Associates must notify the covered entity and identify all individuals affected or potentially affected
- n Breach is “discovered” as of the day the breach is known or reasonably should have been known to the covered entity or Business Associate
- n Notice must be given to each individual whose unsecured PHI has been or is reasonably believed to have been accessed, acquired, or disclosed as a result of the breach
- n Notice must be given without unreasonable delay, but no later than 60 calendar days from discovery of the breach

Required Notice of Breaches

- n Notice of security breach must also be given to the Secretary of HHS
- n Notice to the media
 - q Required when 500 residents are affected or believed to be affected by breach
- n Required reporting for wide range of breaches
 - q Any kind of personal information
 - q No “risk of harm” threshold or degree of risk analysis
- n Because requirements apply to “unsecured” PHI, covered entities and business associates may move toward greater use of **encryption** for wider range of health care information

Self-Pay Issues

- n If an individual requests that a covered entity restrict the disclosure of the PHI of the individual, the covered entity must comply with the requested restriction if –
 - q Except as otherwise required by law, the disclosure is to a health plan for purposes of carrying out payment or healthcare operations (and is not for purposes of carrying out treatment); and
 - q The PHI pertains solely to a healthcare item of service for which the healthcare provider involved has been paid out of pocket in full.

Accounting and Access Rules

- n Accounting Rule has been expanded under ARRA
- n Any use or disclosure of health care record for purposes of care and treatment and health care operations must be recorded for accounting purposes
- n Broadens individual's access rights pertaining to electronic health record use
- n Two ways to comply with accounting obligation by
 - q (1) providing an accounting of disclosures made by the covered entity and by a business associate on its behalf
 - q (2) providing an accounting of disclosures made by the covered entity and providing a list of business associates with their contact information

Developing BA Agreements

- n Federal law requires Privacy and Security Rule provisions be incorporated into existing Business Associate Agreements
- n Covered entities must work quickly to review and evaluate existing business associate agreements
- n Consider adding provisions to require business associate to provide notification of security breach within specific time period
- n Evaluate overall compliance (enhanced penalties)
- n Evaluate compliance procedures for preventing breaches, notification of breaches, and mitigating potential harm

Thank you.

<http://martinpringle.com>

rcstevens@martinpringle.com