Health Information Xperts

ARRA and Other Related Regulatory Overview

Health Information Xperts has compiled this document in order to provide summary updates and analysis of ARRA and other related regulatory changes as they continue to redefine healthcare record management, Privacy, Security and the EHR.

Kelly McLendon provides his analysis of components of ARRA that are of particular importance to Health Information Managers and Health Information Informatiscists. This analysis will be augmented with further thoughts as new information becomes available on these topics. This analysis is subject to revision as new understandings, clarifications and industry discussions are held. The information contained within this document is not intended as Legal Advice, for such advice contact your attorney.

Contact Kelly McLendon (kmclendon@hixperts.com) to advise of suggested changes or with any questions you may have.

Please note that Kelly McLendon offers professional services on ARRA related topics, as well as other electronic record areas of specialization.

Table of Contents

Health Information Xperts

1. ARRA and Regulatory Updates

Week of August 17 - 201, 2009 – This was a very active week as it marked the 6 month anniversary of ARRA being signed into law. The milestones required for this anniversary date have been met, but many more details are needed and expected in future rule making. Remember, many of these rules are still open to public comment, if you feel strongly that you wish to make a comment, please do so. More feedback is always better, how it will be expressed in future rules is never guaranteed, but make your voice heard if you feel strongly that you should do so.

Regional (Extension) Centers
According to the Washington post on 8/21 VP Biden announced that $1.2 billion in federal grants for EHR. $598 million will help establish technology extension centers (Regional Extension Centers). The grant floor is $1,000,000 and ceiling is $30,000,000. The Grants will fund a Health Information Technology Program (Extension Program) which consist of a Health Information Technology Research Center (HITRC) and Regional Extension Centers (Regional Centers). The funding announcement is for the creation of Regional Centers within the Extension Program. The grant announcement states that past experience has shown that local, robust technical assistance can result in effective implementation of EHR's and quality improvement throughout a defined geographic area. The grant announcement can be found on www.grants.gov at the following url;

http://www07.grants.gov/search/search.do;jsessionid=2LN6KR6TzJ4Q4NYygwrJRm7lnZ8JLyYKxn12lhTHLf6T2XKyWrjH!-1264077408?oppId=49167&mode=VIEW

HIPAA Breach Notification
Note this subject matter is NOW crucial for all readers as these regulations go into effect September 23th. However, enforcement is delayed until approximately February 18, 2010 to allow CE's and BA's time to put compliance technologies and processes in place.

In general the Interim Final Rule is consistent with ARRA language with a few changes. Below are some key elements:

- Encryption and destruction are not the only means of compliance with the HIPAA Security Rule; however they are key to understanding if Breach of 'Unsecured' PHI has occurred. Therefore, data encryption in any of its states is highly desired to prevent Breach Notification from being necessary.
- Access controls alone are not enough, they alone still require Breach reporting.
- Paper redaction does not exempt breach but can be used to render PHI non-PHI.

- Encryption keys should be kept on separate devices from data.
- The Breach notification applies to breaches that occur 30 days after this rule (September 23, 2009, although no enforcement until approximately February 23, 2010).
- BA's must report breaches to CE. Either party can notice the individual, this should be determined within the BAA.
- CE's needs to make 'harm threshold' analysis to determine if Breach needed. This must be documented. The assessment uses the following definition; 'Does the compromised Security or Privacy of PHI pose a significant risk of financial, reputational or other hard to the individual'.
    - CE has the burden to determine no hard, all must be documented.
- 18 identifiers comprise de-identification.
- The final rule has cost models and # of facilities potentially impacted.
- Snooping is definitely a breach, example outlined on page 31 of the interim final rule.
- EOB mistakenly sent to wrong addresses is a breach.
- Breach discovery remains when CE or BA knows or should have known it to exist. Proactive audits and controls are mandatory to be in compliance with this part of the rule. In no case (except exceptions like for law enforcement purposes) breaches must be reported in no more than 60 days and even 60 days can be too long, so faster is better.
    - CE's & BA's must have breach detection, in place
- Breach notification must be in plain, reasonable language.
- Notice of breaches must be sent to next of kin.
- Don't sent breach notices from both CE and BA, no multiple notices. Same is true for HIPAA and FTC notices for PHR's.
- CE's and BA's must develop and document Polices and Procedures, train workforce members, have sanctions for failure to comply, require CE to refrain from intimidation or retaliatory acts.

FTC Final Rule

The FTC final Rule for breach notification for PHR's is very similar to HHS's HIPAA rules, they have been harmonized to a large degree. The following points are key:

- Also takes effect September 18, 2009 but enforcement begins February 2010.
- PHR defined as medical information from multiple sources and which is controlled by the patient
- If a physician's office offers a PHR, they are not covered under the FTC rules, HHS rules will apply.

- Breach notice in a case of both FTC and HHS rules should come from the most direct contact to the individual, there must not be multiple notices for the same breach.
- Applies to foreign entities with US customers.
- Page 20; rebuttable presumption that access leads to unauthorized acquisition unless can otherwise be proven.
- Time period for posting notice on a website changed to 90 days.

CMS – Guidance on SA (State Survey Agencies) Surveying facilities that Use EHR – This guidance Ref: S&C-09-53 dated August 14, 2009 clarifies that providers who utilize EHR's must provide access to CMS surveyors. The surveyors role is to focus on how a EHR system is utilized within a facility, along with their other CMS enforcement activities. But they are not expected to evaluate the overall features of an EHR system for compliance with HIPAA Privacy and Security. The HHS OCR (Office of Civil Rights) manages enforcement of HIPAA Privacy and Security, not the SA surveyors. However, this communication makes it clear that SA's can report to OCR any suspected violations.

CCHIT

Dr. Blumenthal also said there may not be multiple certification bodies, that counters the earlier statements that have been made by The HIT Policy Committee this week that there should be multiple certification bodies. We'll just have to wait and see how that plays out, under all scenarios the time to start any other certification bodies would be significant so obviously CCHIT will continue to be a player and probably the only certification body really ready by the end of this year, through mid-next year when the market will need that capability to be actively running. CCHIT for their part has expended their options for certification and are working through a process that includes self developed and open source systems, along with more niche vendors that provide partial EHR functionality, more best of breed type approach. These ideas will continue to flesh out as well within CCHIT or any other certification bodies that are eventually tapped for inclusion.

Meaningful Use

Dr. Blumenthal (the ONC; Office of the national Coordinator) had a press conference on August 20th where he stated that the *final* definition of Meaningful Use, needed for EHR Incentive payments, will not be ready until mid or end of spring 2010. The interim final definitions will be out by the end of 2009, with a 60 day comment period. Remember the HIT Policy discussion of MU below is important, but not final.

This section is an updated on the HIT Policy Committee initial release (around July 16) of their MU matrix. The bullets listed below reflect the most recent version. The HIT Policy

Committee (and Standards Committee, but Policy Committee's work more accessible at this point, although still a draft recommendation) outlined their thoughts and a matrix on the subject of *Meaningful Use (MU)*. The Policy Committee accepted their workgroups recommendation; it now goes to ONC for his input prior to HHS for full review and rule issued by December.

It is very significant that any meaningful use (incentive) payments would be held until HIPAA Privacy and Security violations have been resolved. This is very key to understanding that HIPAA Privacy and Security need to be well monitored and compliance is mandatory and sites need to be very proactive.

See the HIT Policy Committee MU Matrix for more details:
http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_10741_878092_0_0_18/Proposed%20Revisions%20to%20Meaningful%20Use_08142009.pdf

- 2009 Data Capture and Sharing
- 2011 Advanced Clinical Processes
- 2015 Improved Outcomes

- Key Comment: Demonstrating the capability of reporting on MU measures and continuously improving its score would provide evidence of the organization's ability to use HIT to achieve goals of a transformed health system

The HIT Policy Committee recommends that incentives be paid according to an "adoption year" timeframe rather than a calendar year timeframe. Under this scenario, qualifying for the first-year incentive payment would be assessed using the "2011 Measures." The payment rate and phase out of payments would follow the calendar dates in the statute, but qualifying for incentives would use the "adoption-year" approach. i.e. 2011 measures apply for first adoption year, even if 2013 is the first year, those measure apply.

First, the new Matrix includes a requirement that by 2011 at least 10 percent of all orders for hospital services be rendered using CPOE directly *by a provider of care.* The 10 percent threshold applies to all orders in aggregate. The orders can be issued by physicians, nurse practitioners, and other eligible professionals. For ambulatory EHR 100% of the orders must be submitted directly by the provider, but the system does not have to interface to other systems and transmit those orders outside the source EHR product.

Second, the Workgroup recommended that late adopters not be held to the meaningful use criteria in place during their adoption year. Instead, the Workgroup recommended

that whatever meaningful use criteria are set for 2011 be the "Adoption Year 1" criteria applicable to all providers in the first year they apply for incentive payments.

Third, the new Matrix moves from 2013 to 2011 the requirement that patients have some level of access to their personal health information, and also moves from 2015 to 2013 the requirement for patients to have access to health data in real time (e.g., an EHR that immediately updates with lab results). *HIM watch out for patient access to their info on-line, HIPAA requests for amendments will go through the roof.*

The five accepted goals of certification were:

1. Focus Certification on Meaningful Use
2. Leverage Certification process to improve progress on Security, Privacy, and Interoperability
3. Improve objectivity and transparency of the certification process
4. Expand Certification to include a range of software sources: Open source, self-developed, etc.
5. Develop a Short-Term Transition plan

2011 Objectives

Providers (Hospital and Ambulatory):

- CPOE for all orders 10 % directly entered (Hospitals) by providers 9e.g. MD, DO, RN, PA, NP). 100% orders directly entered for Ambulatory (no external interfaces required).
- Institute Drug to Drug – Drug Allergy and Drug Formulary checks
- Record advanced directives
- Up to date problem list maintained of current and active diagnosis based on ICD-9 or SNOMED
- ePrescribing (Ambulatory)
- Maintain active medication list
- Maintain active allergy list
- Record demographics, allergies, vital signs (height, weight, blood pressure, BMI)
- Smoking status
- Structured labs incorporated into record
- Generate lists of patients with specific conditions for quality use (some differences between Ambulatory and Hospitals)
- Report ambulatory quality measures to CMS
- Send reminders to patients per patient preference for follow-up, preventive care
- Implement one clinical decision support rule (Ambulatory)
- Document a progress note for each encounter (Ambulatory)

- Check insurance eligibility from public and private payers where possible
- Submit claims electronically for public and private payers
- Provide patients with electronic copies of their information (labs, problem list, medication lists, allergies) *upon request*
- Provide patients with timely electronic access to their health information (labs, problem lists, medication lists, allergies)
- Provide clinical summaries for each encounter (Ambulatory)
- Provide access to patient specific education resources
- Able to provide key pieces of patient care info (meds, allergies, discharge summary, procedures, problem lists) to healthcare providers and patient authorized entities electronically (slight Ambulatory and Hospital differences)
- Provide medication reconciliation at relevant encounters and care transitions
- Capability to submit electronic immunization info to registries where possible
- Capability to provide syndromic surveillance information where possible
- Compliance with HIPAA Privacy and Security rules
- Compliance with Fair Data Sharing practices set forth in nationwide Privacy and Security Framework

How Hospitals are different than Ambulatory providers under MU

- 10% of all orders directly entered by providers
- No sending of reminders
- Generate lists of patients by specific conditions but not for quality improvement
- No documenting of progress note
- No provide electronic clinical summaries per encounter
- Capability to provide reportable lab results for syndromic surveillance

2011 Quality Measures

- Report Quality measures to CMS including:
    - % diabetics with A1C under control
    - Hypertensive patients with BP under control
    - % of patients with LDL under control
    - % of smokers offered cessation counseling
    - % patients with BMI recorded
    - % eligible patients who receive VTE prophylaxis
    - % orders entered directly by providers through CPOE
    - Use of high risk medication (Beers criteria) in the elderly
    - % patients over 50 with colorectal screening
    - % females over 50 receiving mammogram screening

- % patients at high risk for cardiac events on aspirin prophylaxis
- % patients who received flu vaccine
- % lab results entered into EHR in structured format
- Stratify reports by gender, race, insurance type, language, etc
- % of medications entered as generic when generic exists
- % of orders for high cost imaging with structured indications ordered
- % claims sent electronically to all payors
- % patient encounters with insurance eligibility confirmed
- % of all patients with access to personal health information electronically
- % patients with access to patient specific educational resources
- % of encounters where electronic clinical summaries were provided
- Report 30 day readmission rate
- % of encounters where med reconciliation was performed
- Implemented ability to exchange clinical information electronically with external clinical entity
- % of transitions of care for which summary is provided
- Report up to date status for childhood immunizations
- % reportable lab results submitted electronically
- Full Compliance with HIPAA Privacy and Security
- Conduct or update a HIPAA Security assessment and implement a security upgrades as necessary

2013 Objectives listed in the Table later in this report.

Red Flag Rules
Delayed until November 1, 2009.

August 4, 2009
OCR to Enforce HIPAA Security: The Department of Health and Human Services is moving enforcement authority for the HIPAA security rule to the HHS Office for Civil Rights.

The Centers for Medicare and Medicaid Services has enforced the security rule while OCR has handled privacy rule compliance. Combining privacy and security enforcement under one agency will eliminate duplication of work and increase efficiency, says HHS Secretary Kathleen Sebelius.HHS on Aug. 4 will publish in the Federal Register a notice on the change in security rule enforcement.

CMS continues to administer and enforce other parts of HIPAA's administrative

simplification provisions including the standards-based administrative/financial transaction sets.

CMS Rules related to Quality Measure reporting, among others: CMS-1406-F/IFC/1493-F/1337-F 54511. Electronic Health Records c. HITECH Act EHR Provisions On February 17, 2009, the President signed into law the ARRA, Pub. L. 111-5. The HITECH Act (Title IV of Division B of the ARRA, together with Title XIII of Division A of the ARRA) authorizes payment incentives under Medicare for the adoption and use of certified EHR technology beginning in FY 2011. Hospitals are eligible for these payment incentives if they meet the following three requirements: meaningful use of certified EHR technology; electronic exchange of health information; and reporting on measures using certified EHR technology (provided the Secretary has the capacity to receive such information electronically). With respect to this requirement, under section 1886(n)(3)(A)(ii) of the Act, as added by section 4102 of the HITECH Act, the Secretary shall select measures, including clinical quality measures, that hospitals must provide to CMS in order to be eligible for the EHR incentive payments. With respect to the clinical quality measures, section 1886(n)(3)(B)(i) of the Act requires the Secretary to give preference to those clinical quality measures that have been selected for the RHQDAPU …… Thus, the RHQDAPU program and the HITECH Act have important areas of overlap and synergy with respect to the reporting of quality measures using EHRs. We believe the financial incentives under the HITECH Act for the adoption and meaningful use of certified EHR technology by hospitals will encourage the adoption and use of certified EHRs for the reporting of clinical quality measures under the RHQDAPU program.

July 31, 2009

- If you want to see good CMS e-sig regs there was a transmittal dated June 5, 2009, subject Revised Appendix A, Interpretive Guide for Hospitals', this shows the CMS requirements for your e-sig. It is a related topic to EHR, not ARRA per say, but I thought I'd mention it as it's a great resource.
- FTC delayed, again, the Red Flag rules until Nov 1, 2009.
- According to an Allscripts slide show on HITECH (remember their CEO is on the HIT Policy Committee, so these are accurate statements:
    - 2008 Unsure of timeframe but 122 breaches investigated so far and 116 were actual braches. Most were unintentional from misdirected faxes, but there also was intentional snooping. (All sites had better be putting policies and procedures in place to educate, detect and correct these events from their staff). 800 breaches reported under a new California

law so far, all other sites had better be preparing for the flood from HIPAA.

- From a Privacy and Security Law Report (authors, Lisa Sotto, Aaron P. Simpson et al…of Privacy and Information Management Practice of Hunton & Williams, LLP) which is very well written entitled Proposed HHS Guidance on HITECH Act Breach there is a great amount of useable 'Breach' information. They list the following URLs as resources:
  - Proposed HHS guidance: www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/guidance_breachnotice.html
  - Both guidance and request for information: www.hhs.gov.privacy/hipaa/understanding/coverednetities/hitechrfi.pdf
  - FTC's Proposed Breach notification (PHR's) http://ftc.gov/os/2009/r911002healthbreach.pdf

Reminder: (42 USC §1320d-5), original HIPAA sets criminal penalties at up to $250,000 fine and 10 years in prison.

Breach notifications go into effect by Sept 15, 2009 GET READY! *This means you BA and BAA's need to be ready too, are they?*

Remember civil penalties are already in effect for Breaches.

July 28, 2009 – Per King & Spaulding Newsletter: "Health IT Standards Committee Adopts Recommendations on Standards and Quality Measures for Use of Electronic Health Records – The Health IT Standards Committee, a Department of Health and Human Services advisory panel, recommended quality measures and standards to enable meaningful use of EHR, with the goal of meeting the statutory mandates of the HITECH Act. The measures and standards adopted by the Standards Committee will be reviewed by the Office of the National Coordinator of Health IT, which will make final recommendations to CMS before its interim final rule on the EHR incentive program is issued in December".

April 17, 2009 - Federal Register issued guidelines for rendering PHI unreadable

Late May 2009 – ARRA HIT Implementation Plan from ONCHIT. Good comprehensive overview of plans for ARRA implementation. Many rules fall out by August. AOD, which is a big topic that everyone should be looking at now. For EHR's not in place before January 1, 2009, enforcement begins 30 days after interim final rule announced in August.

May 28 - Federal Register Regional Extension Centers comments solicited and more definition.

June 1, 2009 – Privacy & Security Requirements – Good information from King & Spaulding. Updated timeline in Privacy Subtitle D.

June 17 – HIT Policy Committee releases 22 'meaningful use' functionalities and says that initially the bar will be lower but will be raised over time. Also GE capital offering interest free loans to support GE EHR adoption.

July 3, 2009 – CCHIT announces three types of certification, including for home built systems and more open source orientation. Also recently the Drs lobbied for going slow with meaningful use.

July 10, 2009 – ONC communicated directly with Mr. McLendon that at this time Hospices are not eligible for ARRA incentive payments. But we still believe their physicians individually are.

July 15, 2009 – CCHIT is launching certification criteria for 2010 – 2011 or 2012 this fall, they have submitted criteria to the HIT Standards committee and are working to synch up with ARRA requirements. Work force funding is also be gin sought by AHIMA under Public health Title VII as a part of the healthcare reform package. HIE funding to come in next few months.

2. Dates of Implementation of ARRA Provisions

Most of the Acts provisions take effect one year after enactment (Feb 17, 2010), however penalties take effect immediately. There are numerous regulations and other actions that may require up to 2 - 3 years to implement.

This is by no means an all encompassing list of implementation dates for ARRA, but does include many key dates.

Timing after enactment	Established Deadlines
Immediately	**Section 13410** (d)(4) The amendments made by this subsection (civil monetary penalties) shall apply to violations occurring after the date of enactment of this Title.
30 days	**Section 804 as mentioned in Section 1013 of the Medicare Prescription Drug…** A 15-member Federal Coordinating Council for CER made up of senior representatives of AHRQ, CMS, FDA, ONC, VA, and other Federal agencies is established within 30 days.
45 days **April 1, 2009**	**Section 3001** (7) 45 days after enactment HIT Policy Committee is fully appointed or Secretary can appoint members.
60 days **April 17, 2009**	**Annual Updates** **Section 13402** (h)(2) Within 60 days of the enactment the HHS Secretary must issue guidance for breach Notification specifying technologies and methodologies that render health information unusable, unreadable. ONC w/ OCR & FTC. This encryption and rendering PHI unreadable without a key was issued via Federal Register on April 17, 2009.
90 days **May 17, 2009**	**Section 3003** (3) 90 days after enactment HIT Standards Committee shall develop a schedule for assessment of policy recommendations by the Policy Committee **Section 3003** (6)Within 90 days after enactment shall publish in the federal register a draft description of the program for creating Regional Extension Centers

	Section 3004 Date by which Secretary must review and decide whether or not to propose regulations for adoption of standards endorsed by the ONC.
June 30, 2009	**Section 1013 of the Medicare Prescription Drug…** The Institute of Medicine (IOM) is to submit a report to Congress and the Secretary by June 30, 2009 making recommendations on national priorities for CER. A 15-member Federal Coordinating Council for CER made up of senior representatives of AHRQ, CMS, FDA, ONC, VA, and other Federal agencies is established within 30 days; this Council reports to the President and Congress by June 30, 2009 regarding current Federal activities and recommendations regarding future CER.
August 2009	**Section 13405** (C)(2) The Secretary is to promulgate regulations on what information is to be included in the Accounting of Disclosure (AOD) within 6 months of adopting standards on accounting for disclosure; the regulations must take into account the interests of individuals and the administrative burden on CEs and BAs. – Breaches discovered 30 days after publication. Also interim final rule of breach requirements for entities not covered by HIPAA (i.e. PHR vendors)- FTC - Breaches discovered 30 days after publication effective. Regulation on data to be provided within the AOD – HHS – Jan 2011 for new systems, 2014 for existing systems (procured prior to January 1, 2009). **Section 13402** (a) Not more than 6 months after enactment the Secretary shall designate an individual in each Regional Office of HHS to offer guidance and education to CE's, BA's and individuals on their rights and responsibilities related to Federal privacy and security requirements for PHI. **Section 3012** Secretary shall publish in Federal Register a draft description of the programs for establishing Regional Extension Centers.

September 23, 2009	**Section 13405** September 2009 – *Notification required for Breaches discovered 30 days after publication of interim final rule in August*. Same time frame for non-HIPAA entities like PHR… Training for State Attorney General's.
December 31, 2009	**Section 3004** (b)(2) Not later than December 31, 2009 the Secretary shall adopt an initial set of standards addressing the areas outlined in 3002(b)(2)(B), implementation specifications and certification criteria; use of such standards is voluntary for the private sector. HHS. Update Federal Health IT Strategic plan: **Section 3001 (c), 3, (A), (B),(D)**. ONC. Define Meaningful Use of an EHR: **Section 4101.** Reiterate that HHS should have this rule out by December. Policy Committee has approved their workgroups matrix and ONC now has to approve (July 2009) Public Communications **Section 3001 (c), (3) (A) (B) (D).** ONC. Mechanisms established for communications to the public. Notification of funding availability for regional extension center grants will be published by the end of FY 2009, awards are anticipated to be made in early 2010. **Section 3014** (h)(2)(i) Loans for EHR adoption of a certified EHR cannot begin until January 1, 2010.
January 1, 2010	Date for loans for EHR adoption become available.
12 months February 17- 23, 2010	**Section 13424** (c) Within 12 months the Secretary is to issue guidance regarding de-identification of PHI. (d) Comptroller General issues a report on best practices related to the disclosure among health care providers of protected health information of an individual for treatment of such individual. **Section 3001** (3) ONC shall update federal IT Strategic Plan (developed as of June 3, 2008). (6) Date which ONC shall submit to House and Senate a report on any additional funding for ONC or HIT Policy or Standards Committees

	required to evaluate, develop standards, certification criteria or to achieve full participation of stakeholders…allows for electronic use and exchange of health information. Implementation Report from ONC that identifies lessons learned from major public and private health care systems in their implementation of HIT, including information on whether he technologies and practices developed by such systems may be applicable to and useable in whole or in part by healthcare providers. Also assess benefits and costs and to whom these benefits and costs accrue. Shall estimate and publish resources needed for resources to establish a HIT workforce sufficient to support this effort (including education programs in medical informatics and HIM). (e) 12 months after enactment Chief Privacy Officer shall be appointed to advise the National Coordinator on privacy, security and data stewardship and to coordinate with other Federal Agencies, with State, Regional and Foreign Countries. **Section 13401** (c) Annual guidance to be provided by the Secretary on most effective an appropriate technical safeguards to carry out Security in subsection (a) and the security standards in subpart C of part 164 of Title 45 including the use of standards developed under Section 3002 (b)(2)(B)(vi) of the Public Health Service Act. CMS w/ ONC. **Section 13402** Breach notification enforcement starts. Breach notification annual updates from OCR & FTC. Report to Congress on Breaches for which notice was provided to the Secretary. OCR **Section 1403** (b) Not later than 12 months after enactment OCR shall develop a national, multi-faceted education campaign to enhance public transparency regarding uses of PHI, etc. **Section 13404** Issue regulations to extend certain HIPAA Security Rule provisions to BA's. - CMS. *Compliance takes effect Feb 17, 2010.* **Section 13405**

	Issue regulations to modify the HIPAA Privacy Rule's provisions regarding right to request restrictions, minimum necessary, access. OCR. **Section 13406** Issue regulations to modify the HIPAA Privacy Rule's provisions regarding marketing and fundraising. OCR. **Section 13408** Issue regulations to clarify that certain entities are HIPAA Business Associates. OCR. **Section 13410** Issue regulations to modify the HIPAA Enforcement Rule to implement revised penalty structure. **Section 13411** HHS audits of HIPAA for CE and BA under new regulations may begin either Feb 17, 2010 or 2011. Be prudent and be ready for them by Feb 17, 2010. **Section 3015** Demonstration Project to Integrate Information Technology into Clinical Education. **Section 13423** *Except as otherwise noted provisions of Part I (Privacy) shall take effect 12 months after enactment*. BA's directly subjected to HIPAA rule, penalties and enforcement. RHIO's and HIE's and vendors who contract with CE's for PHR's must enter into BAA's. **Section 13424** Report to Congress on HIPAA privacy & Security compliance. OCR & CMS. Study and report to Congress on Privacy & Security requirements for entities that are not HIPAA CE or BA's. ONC w/OCR, CMS, FTC Issue guidance on HIPAA Privacy Rule's requirements for de-identification. OCR w/ ONC. Study the HIPAA Privacy Rule's definition of 'psychotherapy notes' with regard to including certain test data and mental health evaluations. OCR w/SAMHSA.

June 18, 2010	**Section 13405** Issue regulations to modify the HIPAA privacy Rule **AOD** provisions. OCR.
August 18, 2010	**Section 13405** (b)(B)Within 18 months the Secretary shall issue guidance on what constitutes 'minimum necessary' for purposes of the Privacy Rule and the limited data set guideline will then (C) sunset. Issue regulations to modify the HIPAA Privacy Rule to generally prohibit exchanging health information for remuneration without individual authorization. OCR. **Section 13410** Issue regulations to modify the HIPAA enforcement Rule to implement 'willful neglect' provisions. OCR w/CMS. (b)(2) 18 months for Secretary to promulgate regulations to implement such amendments.
180 days	**Section 13402** (j) Secretary shall promulgate interim final regulations regarding breaches within 180 days after enactment. The provisions of this section shall apply to breaches that are discovered on or after 30 days after publication of such final interim regulations. **Section 13407** (g)(1)The FTC is to promulgate interim final regulations regarding these breach notice obligations within 180 days, to take effect 30 days after publication. PHR's are covered as well.
No sooner than October 2010	Start hospital incentive payments
No sooner than January 2011	Start eligible professionals incentive payments (Medicare and Medicaid)

February 2011	**Section 1401** Bonus payments for 'meaningful use' of 'certified EHR's begins in 2011. ▪ 2011—100% of the amount of the incentive payment for which the hospital is eligible ▪ 2012—75% of the amount for which the hospital would otherwise be eligible ▪ 2013—50% of the amount for which the hospital would otherwise be eligible ▪ 2014—25% of the amount for which the hospital would otherwise be eligible ▪ 2015—No incentive payments **Section 13410** (b)(1) Amendments in this subsection shall apply to penalties imposed on or after a date that is 24 months after enactment. **Section 13113** (a) Study and reports. 2 years after enactment and annually thereafter the Secretary of HHS shall submit a report on adoption and barriers to adoption of a nationwide system for electronic use and exchange of health information. Grants and Loans begin in 2010.
Fiscal Year 2011	**Section 4102** Date by which hospitals may begin receiving incentives payments.

February 18, 2012	**Section 13410** Issue regulations to modify the HIPAA Enforcement Rule (c)(3) Methodology created for an individual who was harmed to receive % of civil monetary penalty is 3 years after enactment.
5 years	**Section 13424** ARRA impact on health insurance premiums, overall health costs, adoption, reduction in medical errors and other quality improvements.
2014 or 2011	**Section 13405** (4)(A)(B) If EHR acquired before January 1, 2009 AOD required by January 1, 2014, if acquired after this date January 1, 2011.
2014	**Section 3001** Every person in US has a certified EHR based electronic record.
2017	Penalties for no EHR adoption

3. ARRA's Table of Contents for Healthcare Sections

Title XIII of Division A and Title IV of Division B of ARRA constitute HITECH; Technology for Economic and Clinical Health Act. Subtitle D of HITECH deals with Privacy and Security.

Overall pages in Act that deal with HITECH and CER; HR- 112 – 165, HR – 353 – 382 and CER HR-63 – 74.

	Table of Contents Within ARRA's Healthcare Sections
Section 1	**Short Title –** HR 113 (page)
Section 2	**Table of Contents**
Division A	**Appropriations Provisions**
Title VIII	**Departments of Labor, Health and Human Services and Education and Related Branches**
Title XIII	**HITECH ACT (Health Information Technology for Economic and Clinical Health Act)** Section 13001 – 13101
Division B	**Tax, Unemployment, Health, State Fiscal Relief and Other Provisions**
Title XXX	**Health Information Technology and Quality** Section 3000
Subtitle A	**Promotion of Health Information Technology** Section 13101 - 13102 and Subtitle Sections 3001 – 3009
Part 2	**Application and Use of Adopted Health Information Technology Standards; Reports** Sections 13111 – 13113
Subtitle B	**Testing of Health Information Technology** Section 13201 – 13202
Subtitle C	**Grants and Loans Funding** Section 13301 and Subtitle Sections 3011 - 3018
Subtitle B	**Incentives for the use of Health Information Technology** Sections 3011 – 3018
Subtitle D	**Privacy –** HR 144 (page) Sections 13400 -

Part 1	**Improved Privacy Provisions and Security Provisions** Sections 13401 – 13411
Part 2	**Relationship to other Laws; Regulatory References; Effective Date; Reports** Sections 13421 - 13424
Section 3	**Purposes and Principals**

Health Information Xperts

4. Kelly McLendon's ARRA Overview and Analysis of Policies and Impacts; Concentrations on the HIM and EHR Perspectives

Mr. McLendon performed this analysis to serve as a reference tool encompassing the breadth of the new Economic Stimulus Plan (ESP), also more properly referred to by its formal name American Recovery and Reinvestment Act (ARRA), from President Obama and the One Hundred and Eleventh Congress signed into law on February 14, 2009. This is the first in an anticipated series of steps that this Administration envisions in order to achieve an often quoted 'healthcare reform'. The intention upon close read of ARRA is to lay foundational elements for a more interconnected national network of health information exchange, to allow much more penetration and use of electronic health records (EHRs) with their patient safety enhancing decision support tools (through incentive payments) and to facilitate an increasing amount of Comparative Effectiveness Research (CER) which will eventually spur empirical decisions on treatment approaches and drug / device effectiveness.

Certainly there were holes to plug with HIPAA, such as extension and refinement of regulations Business Associates (BA) and the newer Personal Health Records (PHR). However, the degree with which the notification requirements and Accounting of Disclosures (AOD) were expanded will have significant impacts on Health Information Management (HIM, formerly known as the Medical Record Department) operations; there will most likely be significant upticks in the workloads and volumes of requests processed. On a deeper level these new regulations should increase the level of review and control HIM and IT must exert on EHR security and privacy. Increase levels of monitoring processes, security audits and other forms of vigilance will be required. No more releases of *any* protected health information (PHI) from any provider source without adequate logging, this requirement alone will change many care process behaviors.

EHR adoption ranks very high within ARRA. The incentives for physicians can amount to $44,000+ each and $3.5 - $8,000,000+ for hospitals that can demonstrate meaningful use of certified EHRs.

Legal Health Records (LHR) have been a buzz in the industry and they will continue to be so, but ARRA will begin to take center stage as its regulations engage over the next year. There is a complex set of milestones mandated by The Act, (see Section 5 of this report) which will provide more clarification (supposedly) on various elements of The Act. National Standards bodies will be designated and begin to have influence on the exact details of how providers of care will have to manage these new, deeper, more complex regulations. ARRA is related to the LHR in many respects, privacy and security are at the

heart of protections for healthcare providers and are a part of any comprehensive LHR discussion. AOD, decision support with its templates, data exchange and several other ARRA provisions will impact the processes needed to insure the highest levels of compliance and well protected health information from litigation issues.

The intention of The Act, being it is a part of an economic stimulus package, will take years to fully effect the healthcare industry. EHR sales are currently in the doldrums and will take time to recover, even with incentives, the necessary EHR standards are not fully ripened and the regulations do not take effect for at times, 1 -2+ years. Therefore, while ARRA will help promote and stimulate sales and implementations of EHR systems, it will not be a fast process; there are few immediate benefits to be achieved in the near term.

One other topic that is rarely discussed is the common bias of standards organizations, physicians and IT professionals towards the clinical aspects of EHR systems. Back offices, HIM type functionalities, are of equal importance to address, especially given their role in information gathering and release. AOD, notifications, breaches, health information exchanges, increased roles for EHR systems and PHRs, all emphasized in ARRA, impact HIM squarely. There are many, many individuals and organizations that operate on assumptions that HIM as a department is 'going away' with electronic records, when the nothing if farther from the truth. Who will authenticate and secure for long term retention and management the exchanged data, both incoming and released? These *will not* be fully automated; hands off processes, there will be human intervention in the processes.

To date *almost all* core clinical applications have been developed with poor HIM functionality. The issue is endemic and result in HIM having to perform more workarounds and even manage their own record keeping systems, such an electronic document management (EDM) and Release of Information systems which are attached to but not necessarily part of the core systems. Core clinical systems have been designed with database that are optimized for decision support and physician usage with longitudinal views and poorly executed, snapshot, native format presentation, print and output routines. They don't have AOD capability and can have very unclear audit logs. All because the systems developers typically give short shrift to HIM functionalities. Due to their architectures the possibility that these core clinical systems will suddenly transform HIM processes into effect operations is slim. Therefore, it is crucial that National Standards organizations (CCHIT?) that are designated to set the standards for the 'certified EHRs' take into account and address the processes required by HIM to perform their roles.

It must be remembered that the EHR is concept of several or many systems working together to form records and structure to health information that facilitates efficiencies throughout the care process, including those on the back-end, administrative processes, such as HIM.