ASHRM AMERICAN SOCIETY FOR HEALTHCARE RISK MANAGEMENT
Monograph

A risk manager's tour of the ARRA

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INTRODUCTION

First there was TARP.(1) With President Obama signing the 406-page American Recovery and Reinvestment Act of 2009, "ARRA" became the second major economic intervention law in a matter of several months. For healthcare, however, ARRA (Public Law 111-5) means many changes.

At the very least the legislation portends many changes to HIPAA privacy *and* security.(2) It creates the context for change and a new approach to development of both electronic health records (EHR)(3) and personal health records (PHR).(4) The law includes incentives for physicians to adopt the use of EHR.(5) Moreover, it introduces what may become a new frontier in the debate on standards of care: comparative effectiveness.(6)

ARRA also introduces changes to COBRA, an issue of particular importance to healthcare organizations that are trimming employment.(7) One miscellaneous provision places moratoria on some Medicare regulations.(8)

ARRA is s dense piece of legislation. Reading it thoroughly demands close attention to detail. Notwithstanding the shear length of the legislation, it is useful to discern some of the risk management issues that emanate from ARRA. In doing so, healthcare risk management professionals working across the healthcare field can begin to put in place practical strategies to address the latest challenge for healthcare in the first decade of the 21st century.

What's included in the new law

ARRA is divided into two divisions, each including a number of titles. Division A, "Appropriation Provisions," includes:

- Title I – Agriculture, Rural Development, Food and Drug Administration and related agencies
- Title II – Commerce, Justice, Science, and Related Agencies
- Title III – Department of Defense
- Title IV – Energy and Water Development
- Title V – Financial Services and General Government

Title VI – Department of Homeland Security
Title VII – Interior, Environment and Related Agencies
Title VIII – Departments of Labor, Health and Human Services, and Education and Related Agencies
Title IX – Legislative Branch
Title X – Military Construction and Veterans Affairs and Related Agencies
Title XI – State, Foreign Operations and Related Programs
Title XII – Transportation, Housing and Urban Development and Related Agencies
Title XIII – Health Information Technology
Title XIV – State Fiscal Stabilization Fund
Title XV – Accountability and Transparency
Title XVI – General Provisions (this act)

Division B, "Tax, Unemployment Health, State Fiscal Relief, and Other Provisions," includes:

Title I – Tax Provisions
Title II – Assistance for Unemployed Workers and Struggling Families
Title III – Premium Assistance for COBRA Benefits
Title IV – Medicare and Medicaid health information technology; miscellaneous Medicare provisions
Title V– State Fiscal Relief
Title VI – Broadband Technology Opportunities Program
Title VII – Limits on Executive Compensation

Within the construct of this law is the creation of new bodies and positions, including the Federal Coordinating Council for Comparative Effectiveness Research,(9) the Health Information Technology Research Center,(10) the Office of the National Coordinator for Health Information Technology,(11), the position of the National Coordinator within the Department of Health and Human Services(12) and a new post of the Chief Privacy Officer of the Office of the National Coordinator.(13)

The ARRA gives the Secretary of Health and Human Services authority through rule-making or regulation to implement various aspects of the legislation. This includes standards and certification criteria for the electronic exchange and use of health information,(14) accounting of disclosures by a covered entity from an EHR of protected health information, notification of breaches of information,(15) and prohibitions on the sale of EHR-protected health information.(16)

Timeframes for implementation of sections of the law vary throughout ARRA. Similarly, a close reading of the legislation makes clear the importance of looking at terms and definitions. As with many complex laws, it is not uncommon to find provisions that indicate that a definition is specific to "this" section or subsection.

BIG ISSUES FOR HEALTHCARE RISK MANAGEMENT PROFESSIONALS

Although ARRA is complex, there are a few key provisions that stand out for risk management review. These include the changes to HIPAA privacy and security, the issue of psychotherapy notes, a type of electronic informed consent and the idea of comparative effectiveness.

HIPAA Privacy and Security

Changes to HIPAA Privacy and Security can be found in Subtitle D of the Health Information Technology for Economic and Clinical Health Act (the "HITECH Act"). Key provisions include:

- An expansion of the definition of "business associates"
- Expansion of some HIPAA Privacy and Security requirements to business associates
- Civil and criminal penalties under HIPAA that now apply to covered entities are expanded to address business associates
- A change to the minimum necessary rule in HIPAA
- A notification provision for a person's "unsecured" personal health information (PHI)
- A requirement that business associates inform a covered entity of any breach, including the identity of the individual whose PHI was or is believed to have been "accessed, acquired or disclosed during such breach"(17)
- Use of the media for notification for a breach of unsecured protected health information for 500 or more residents of a state or jurisdiction
- Immediate notification to the Secretary of Health and Human Services when "unsecured protected health information involves 500 or more individuals"
- Submission of a log on an annual basis to the Secretary of Health and Human Services by a covered entity of a data breach involving less than 500 individuals
- The imposition of new restrictions on selling protected health information
- Specific requirements for individual notice of a data breach that include:

  "(1) A brief description of what happened, including the date of the breach and the date of the discovery of the breach, if known

  (2) A description of the types of unsecured protected health information that were involved in the breach (such as full name, Social Security number, date of birth, home address, account number or disability code)

  (3) The steps individuals should take to protect themselves from potential harm resulting from the breach

  (4) A brief description of what the covered entity involved is doing to investigate the breach, to mitigate losses, and to protect against any further breaches

  (5) Contact procedures for individuals to ask questions or learn additional information, which shall include a toll- free telephone number, an e-mail address, Web site, or postal address.(18)
- The imposition of new restrictions on selling protected health information
- Completion of compliance audits by the Secretary of Health and Human Services of both covered entities and business associates.

To be certain that individuals understand their rights with respect to the uses of health information, ARRA requires that no later than a year from the enactment of the law, the Office of Civil Rights of the Department of Health and Human Services must

> *"develop and maintain a multi-faceted national education initiative to enhance public transparency regarding the uses of protected health information, including programs to educate individuals about the potential uses of their protected health information, the effects of such uses, and the rights of individuals with respect to such uses. Such programs shall be conducted in a variety of languages and present information in a clear and understandable manner."*(19)

Psychotherapy notes

An interesting issue in the evolution of HIPAA requirement is what constitutes psychotherapy notes. ARRA addresses this issue as follows:

> *"The Secretary shall study the definition of "psychotherapy notes" in section 164.501 of title 45, Code of Federal Regulations, with regard to including test data that is related to direct responses, scores, items, forms, protocols, manuals or other materials that are part of a mental health evaluation, as determined by the mental health professional providing treatment or evaluation in such definitions and may, based on such study, issue regulations to revise such definition."(20)*

In the Code of Federal Regulations the definition of psychotherapy notes states:

> *…"notes recorded (in any medium) by a healthcare provider who is a mental health professional documenting or analyzing the contents of conversation during a private counseling session or a group, joint, or family counseling session and that are separated from the rest of the individual's medical record. 'Psychotherapy notes' excludes medication prescription and monitoring, counseling session start and stop times, the modalities and frequencies of treatment furnished, results of clinical tests, and any summary of the following items: diagnosis, functional status, the treatment plan, symptoms, prognosis and progress to date."(21)*

That psychotherapy notes were singled out in the ARRA law suggests that changes may be forthcoming. As such, it is a privacy issue that bears watching as regulatory changes emerge from HHS.

A type of electronic informed consent

In a section of the ARRA dealing with studies, reports and guidance, the Government Accountability Office (GAO) has been tasked to complete a report

> *"…on the best practices related to the disclosure among healthcare providers of protected health information of an individual for purposes of treatment of such individual. Such report shall include an examination of the best practices implemented by States and by other entities, such as health information exchanges and regional health information organizations, an examination of the extent to which such best practices are successful with respect to the quality of the resulting healthcare provided to the individual and with respect to the ability of the healthcare provider to manage such best practices, and an examination of the use of electronic informed consent for disclosing protected health payment, and healthcare operations."(22)* [emphasis added]

The idea of an "e" informed consent for managing payment and operations disclosures is interesting. Those who recall the debates prior to the implementation of HIPAA may recall the "give and take" over an acknowledgement versus a consent. Here, however, the term is "informed consent." This will be an area to watch from a risk management standpoint, particularly if changes are made that trigger a need for refinement to organizational consent policies and procedures.

Comparative effectiveness

Not only does ARRA provide for the creation of the Federal Coordinating Council for Comparative Effectiveness Research, it provides for funding to the Institute of Medicine to help identify "national priorities" for comparative effectiveness research activity. The law itself indicates that funding for such research activity should be used to develop and disseminate

> *"…research assessing the comparative effectiveness of healthcare treatments and strategies, through efforts that: 1) conduct, support, or synthesize research that compares the clinical outcomes, effectiveness, and appropriateness of items, services and procedures that are used to prevent, diagnose or treat diseases, disorders, and other health conditions; and 2) encourage the development and use of clinical registries, clinical data networks, and other forms of electronic health data that can be used to generate or obtain outcomes data."*(23)

The "comparative effectiveness" provision is a tantalizing issue for risk management professionals. Will the first prong dealing with appropriateness of procedures become evidentiary fodder in cases in which plaintiff's counsel challenges the application of a standard of care? Could counsel argue that by departing from the "clinical effectiveness" findings, one breached a standard of care? On the other hand, could defense counsel respond by questioning the data from which the clinical effectiveness information was derived?

The second prong is also of interest to risk managers and quality professionals. How will the "clinical registries, clinical data networks and other forms of electronic health data" referenced under comparative clinical effectiveness stack up against Patient Safety Organizations? PSOs are also in the business of data analysis, using techniques that provide for comparison of similar cases in order to improve patient safety and quality healthcare delivery. The Final PSO Rule also addresses HIPAA issues.(24) Will there be some type of comparative effectiveness process based on the results from a PSO or a group of PSOs? What if a PSO analysis contradicts the results of research on comparative effectiveness designed to improve clinical outcomes?

These are not idle questions, especially in view of the stated purpose of the Office of the National Coordinator for Health Information Technology. In section 3001(b), ARRA states that

> *"The National Coordinator shall perform the duties … in a manner consistent with the development of a nationwide health information technology infrastructure that allows for the electronic use and exchange of information and that –*
> *"1) ensures that each patient's health information is secure and protected, in accordance with applicable law;*

> *"2) improves healthcare quality, reduces medical errors, reduces health disparities and advances the delivery of patient-centered medical care;*
> *"3) reduces healthcare costs resulting from inefficiency, medical errors, inappropriate care, duplicative care and incomplete information."(25)*
> [emphasis added]

This is a topic that merits scrutiny in future. At some point perhaps there will be some type of reconciliation between ARRA, the regulations promulgated under it, and the PSO Final Rule. The laws should not work at cross-purposes with one another. With a shared vision of quality, safe, efficient care, the goal should be to streamline federal regulation provisions.

RISK MANAGEMENT STRATEGIES FOR DEALING WITH ARRA

The healthcare information provisions in ARRA reflect the need for an enterprise approach to data management and technology. Indeed, the law defines the process as "enterprise integration," meaning

> *"the electronic linkage of healthcare providers, health plans, the government and other interested parties, to enable the electronic exchange and use of health information among all the components in the healthcare infrastructure in accordance with applicable law, and such term includes related application protocols and other related standards."(26)*

ARRA anticipates the need for interoperability of health information and the ability to complete research on quality and data outcomes. It provides the context for research on what it calls "health information enterprise management."(27) With the health information aspects of the law geared to reducing medical errors, improving quality and achieving efficiency, it is also about enterprise *risk* management. As such, there are some practical strategies to consider from a risk management perspective in addressing the health information management and comparative effectiveness aspects of ARRA.

These include the following:

1. Assemble the "ARRA" team

Work with colleagues in health information management, quality, patient safety and compliance to develop a team approach to analyzing the health information management and comparative effective aspects of the law.

2. Do an electronic "cut and paste"

Overcome the daunting task of going back and forth from the ARRA law to HIPAA Privacy and Security Rules. Take a few practical steps:

- Copy the relevant provisions of the ARRA law
- Copy those elements of the HIPAA Privacy and Security Regulations referenced in ARRA. (these regulations, like the ARRA law, are readily available, free of charge on federal Web sites)

- Insert the applicable HIPAA regulation where it is referenced in the ARRA law. Taking this step makes it easier to read the law and regulations in context.

3. Ask the ARRA team to prepare "key points"

Encourage the ARRA Team to develop some bullet points or "take-away" points for senior management and the board. Focus on what this means for the healthcare enterprise in terms of health information technology and risk management issues.

4. Encourage the development of an integrated enterprise information and enterprise risk management plan

Take note of the fact that an enterprise risk management plan is dependent upon good data, communication and analytics. Recognize that the same is true in what is mapped out in the health information aspects of ARRA. Work on areas of common interest such as:

- HIPAA Privacy
- HIPAA Security
- Breach Identification
- Breach Notification
- Business Associate Agreement terms and conditions.

5. Obtain advice on comparative effectiveness

Work with legal counsel on the roll out of ARRA level comparative effectiveness data as it relates to language in policies, procedures and practice routines. Think about how care providers should document exceptions with respect to "best practices" that emanate from comparative effectiveness data. Recognize, too, the importance of discussing with legal counsel how to frame the use of, and exceptions from, "comparative effectiveness" data with regard to managed care and health plan contracts.

6. Be prepared for multiple regulatory changes

Recognize that the next several years are apt to see the promulgation of a variety of regulations that address the health information management and comparativeness effectiveness aspects of ARRA. For health information this will mean the use of "certified EHR technology"(28) and a "certified electronic health record"(29) as discussed in the "HITECH" part of ARRA. Using an integrated health information and risk management enterprise approach:

- Analyze the requirements
- Do a gap analysis of the organization compared to the requirements
- Prepare a feasible action plan that encompasses revision to policies, procedures and practice routines and education
- Pilot the changes and fine-tune the requirements
- Monitor the full deployment of the revised system.

CONCLUSION

ARRA is a law filled with new opportunities and risk potentials for healthcare organizations. In his recent speech to a joint session of the U.S. Senate and the House of Representatives, the President noted the need to reduce fraud in the healthcare system. Recognizing that the type of data integration outlined in ARRA could help with increased enforcement efforts, there is yet another incentive to embark upon an integrated enterprise model for health information and risk management.

The results of such an endeavor may well serve to reduce waste. More importantly, it may help healthcare organizations achieve the goals of quality outcomes and reduced liability exposure.

ABOUT THE AUTHOR

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REFERENCES

1. Emergency Economic Stabilization Act of 2008, Public Law 110-343, includes TITLE I – Troubled Assets Relief Program or "TARP."
2. ARRA, Public Law 111-5 (2009), Sections 13400-13411.
3. Id. See, Health Information Technology for Economic and Clinical Health Act" or the "HITECH Act" in Title XIII Division A and Title IV of Division B.
4. Id.
5. Id. at Title IV, Subtitle A, Medicare Incentives in Section 4101Incentive for eligible professionals and Subtitle B, Medicaid Incentives, Section 4201 Medicaid provider, HIT adoption and operation payments; implementation funding.
6. Id at Section 804,Federal Coordinating Council for Comparative Effectiveness Research.
7. Id., Division B, Title III – Premium Assistance for COBRA Benefits.
8. Id., at Division B, Sec. 4301. Moratoria on Certain Medicare Regulations.
9. Id. at Sec. 804. Federal Coordinating Council for Comparative Effectiveness Research.
10. Id. at Sec.3012. Health Information Technology Implementation Assistance, (b). Health Information Technology Research Center.
11. Id. at Sec. 3001(a), Office of the National Coordinator for Health Information Technology.
12. Id.
13. Id at. Sec. 3001(e), Chief Privacy Officer of the Office of the National Coordinator.
14. Id. at Sec. 3004(a)(2).
15. Id at Sec. 13402.
16. Id. at Sec. 13405(d)(3).
17. Id., Sec. 13402(b). Notification in the Case of Breach.
18. Id., Sec. 13402 (f) Notification in the Case of Breach.

19. Id., Sec 13403(b). Education on Health Information Privacy.
20. Id., Sec. 13424(f). Studies, Reports, Guidance.
21. 45CFR §164.501 (2008) Privacy of Individually Identifiable Health Information.
22. Health Information Technology for Economic and Clinical Health Act" or the "HITECH Act" in Title XIII Division A and Title IV of Division B in ARRA, Public Law 111-5 (2009, Sec. 13424(d). Studies, Reports, Guidance.
23. ARRA, Public Law 111-5 (2009), Division A- Appropriations Provisions.
24. Patient Safety and Quality Improvement, Final Rule, Federal Register, 73(226): 70732-70814 November 21, 2008, effective January 19, 2009.
25. ARRA, Public Law 111-5 (2009), Sec. 3001(b).
26. Id., Sec. 3000.
27. 27 Id., Sec. 13202. Research and Development Programs.
28. Id., Sec. 3000.
29. Id., Sec. 3001(c)(5).

ADDITIONAL RESOURCES

Enterprise Risk Management: Defining the Concept; Getting an ERM Program Started; The Role of the Chief Risk Officer Monographs published February 2006 by the American Society for Healthcare Risk Management at www.ashrm.org.

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