

APhA LEGISLATIVE SUMMARY

“The American Reinvestment and Recovery Act of 2009” (ARRA)

Summary of HIT and Privacy Provisions As of February 17, 2009

Health Care Information Technology Act (HITECH provisions) and Privacy Provisions

General overview

ARRA allocates a total of \$19 billion to implement health information technology (HIT) regional exchange networks.ⁱ Of this amount, \$17 billion includes incentive payments to physicians and hospitals enrolled in the Medicare and Medicaid programs to develop a complete system of electronic personal health records (PHR) by 2014. The remaining \$2 billion is allocated to begin immediately begin developing and improving the nation’s HIT infrastructure.ⁱⁱ

The goal of the HIT infrastructure is to ensure protection and privacy of health care information; improve patient care by reducing medical errors; reduce costs by removing administrative barriers that result in duplicative claims and services; and improve coordination of care among health care providers.ⁱⁱⁱ Other goals include improvement of public health services and emergency response systems, including bioterror events and infectious disease outbreaks. In coordination with other areas of the law, an integrated electronic system will also help to better expand and assess comparative effectiveness, a program that received over \$1 billion in funding to examine the appropriateness of certain therapies or treatment.^{iv} The initial publication of HIT implementation details and standards are due by December 2009.

Most of the HIT funding is in the form of bonus payments between \$44,000 and \$64,000 to physicians and as much as \$11 million to hospitals.^v Pharmacies will not receive direct funding or incentives for adopting electronic medical record technology. However, pharmacy schools are included among the list of approved graduate schools that may receive grants for incorporating electronic PHR technology into clinical education.^{vi}

The Secretary of Health and Human Services (HHS) and an Office of the National Coordinator for HIT (ONCHIT) will oversee the HIT infrastructure and policy issues. The HHS Secretary will appoint the ONCHIT coordinator. ONCHIT was first established by the Bush Administration and initially headed by David Brailer, MD, PhD, a well-known public health official in the area of HIT.^{vii} This new law expands, codifies, and funds the role of ONCHIT.



The HITECH provisions contain an roadmap regarding the Obama Administration's goal to in develop an HIT infrastructure in the Unites States in the next 5 years. These provisions build an existing framework developed over the past 5 years and also creates new incentives and approaches. An HIT infrastructure has been contemplated for some time in the United States, but uptake has been slow. Lack of standards, funding, and liability for breaches have all been cited for a lack of more proactive uptake of HIT in the past.^{viii} Even with funding and new regulations, Dr. Brailer recently noted that development costs for hospitals and physicians might exceed the funding levels.^{ix} Nevertheless, strong incentives exist to encourage HIT development, including Medicare and Medicaid funding reductions for physicians and hospitals that do not develop and use electronic PHR by 2014.^x

ARRA also updates existing HIPAA standards for health care privacy and security. These changes are the result of breaches of health information that have occurred since the implementation of HIPAA, the need to update standards and definitions for an HIT environment, and to address gaps that some consumer groups and researchers suggest still remain under HIPAA.^{xi} A recent study by the Institute of Medicine suggests that the current HIPAA privacy provisions do not provide sufficient protections to protect the privacy of medical information nor do the measures adequately encourage research and therefore recommends that Congress make improvements to strike a better balance.^{xii} ARRA seeks to implement this balance.

Under ARRA, covered entities, including health care providers such as pharmacists, and business associates must protect PHR from breaches. Covered entities must notify individuals of breaches. Business associates must report breaches to covered entities. HHS will also post breaches by covered entities and business associates involving more than 500 individuals on its website. Security breaches involving electronic health records that occur with vendors of HIT must be reported to the individual and to the Federal Trade Commission (FTC).^{xiii}

Business associates will be required to maintain and protect identifiable personal health information in the same manner as covered entities. Health care providers and business associates may have to evaluate their existing contract agreements and insurance policies to ensure compliance with the new provisions. However, the exact implications of these new provisions and requirements are not yet known. Regulations might help clarify the issue of whether new contractual requirements are necessary or whether the new procedures may be incorporated by reference into existing contracts.

The new privacy provisions clearly designate that the individual owns and controls his or her electronic personal health record that is portable for use in all health care environments.^{xiv} Individuals have the right to view all disclosures made by covered entities for a 3-year period.^{xv} While this provision is considered to be a victory for consumer groups that have long advocated for personal ownership of medical records, it could create controversy. Ownership will potentially allow modifications by patients that result in "corrections" to eliminate health information or make additions that might create

difficulty in determining a correct diagnosis or treatment. Consumer groups have also expressed concern if the electronic record contains errors, it could result in inappropriate health care determinations across multiple settings.

The exact implications of a fully electronic health care environment will not likely be known until uptake is greater. The goal of the ARRA for now is to begin encouraging implementation of HIT systems and to ensure that information is appropriately protected.

HITECH provisions

The Secretary of HHS will promulgate regulations that establish standards for certified medical records systems for PHR in ambulatory and hospital settings to electronically link health care providers and public and private payers through regional “enterprise integration” systems.^{xvi} The adoption of an HIT platform based on any standard recommended by HHS is voluntary for private health care entities.^{xvii} Providers that adopt an HIT system may be charged a nominal fee by ONCHIT.^{xviii}

The ONCHIT coordinator will develop HIT standards that will eventually be approved by HHS. Initially, the existing “Federal Health IT Strategic Plan” (first developed in June 2008) will be updated to include measurable goals to ensure privacy and security of health information and PHR, provide a system to accept recommendations, and ensure that special circumstances, populations, and systems receive appropriate accommodations. ONCHIT will maintain a public website to allow public review of existing recommendations, costs, benefits, certification, and updates. ONCHIT will also provide regular reports to Congress regarding the progress, costs, and financing needs associated with the programs.

HHS and ONCHIT will develop standards, rules and regulations in coordination with two appointed committees, the HIT Policy Committee and HIT Standards Committee. These committees will work to develop implementation specifications and standards including the names of standards, architecture, and software schemes for authentication and security of individually identifiable health information.^{xix} The ultimate goal is to enact comprehensive policies and standards that protect information and adapt to different propriety platforms.

The composition and specific responsibilities of each committee are described below.

The HIT Policy Committee is composed of the following members:

- Appointment by HHS Secretary
- Representative of Department of Veterans Affairs
- Representative of the Defense Department
- Appointment by the Majority Leader of the Senate
- Appointment by the Speaker of the House of Representatives
- Appointment by the Minority Leader of the House of Representatives
- Eleven members appointed by the United States Comptroller General including
 - Three patients or consumers
 - One health care provider

- One expert in health care privacy and security
- One member with expertise in vulnerable populations
- One representative from health plans or health insurers
- One representative from HIT vendors
- One representative from purchasers and employers; and
- One member with expertise in health care quality measurement and reporting.^{xx}

The committee will also work with outside advisors who have expertise in the areas of the committee members and also those with expertise in long-term care and aging and medical and clinical research.

Committee members will serve for a period of three years. The Comptroller General's initial appointees will serve staggered terms.

The HIT Policy Committee will also make specific recommendations for developing technology to:

- Collect data for quality measures and public reporting information;
- Collect information for biosurveillance and public health;
- Recommend technology that enhances medical and clinical research and public safety;
- Enhance the use of electronic patient information to reduce waiting times for care;
- Use telemedicine;
- Facilitate home health care systems;
- Reduce medical errors;
- Ensure continuity of care across settings;
- Meet the needs of diverse populations; and,
- Ensure ways for a caregiver or guardian to appropriately receive access to the information of a patient with dementia or another cognitive or age related disability.^{xxi}

The HIT Standards Committee will consist of participation of individuals that represent the spectrum of health care interests, including health care providers, ancillary health care workers, consumers, purchasers, health plans, technology vendors, government agencies, researchers, and individuals with HIT experience.^{xxii} Each sector shall be fairly represented so that no interest is overrepresented. This committee will also work with outside advisors with similar knowledge and backgrounds as described in HIT Policy Committee section. The process to develop standards will be open with public meetings announced in the *Federal Register*.

The legislation also provides for several reports that must be submitted to Congress, including one that examines nationwide adoption. The first report regarding nationwide adoption will be submitted two years after implementation and then subsequent reports will be submitted annually.^{xxiii} Another study will examine reimbursement systems necessary to improve health care quality in federal health centers, and rural and free clinics.^{xxiv} Finally, a study is required within two years examining technology for the

provision of aging services and to provide recommendations for new services in this area.^{xxv}

Steps to develop HIT infrastructure

HHS and ONCHIT have the authority to immediately begin distribution of \$2 billion to develop the IT infrastructure. This allocation includes \$300 million designated to regional efforts to begin the development of a health information exchange network.^{xxvi}

Regional “health information research technology centers” throughout the United States selected by HHS will assist in the development of infrastructure, provide technical assistance, and suggest best practices that support the adoption of HIT.^{xxvii} Non-profit institutions or organizations may apply for HHS funding and for the designation as a regional center.

States may seek planning and implementation grants to bolster HIT development. States may provide the grants to designated non-profit entities that can implement standards for HIT systems. States must provide matching funds to the federal dollars received. In the first years of implementation, as a percentage, state contributions compared to federal dollars will be less to encourage development of HIT infrastructure.^{xxviii}

Grants to pharmacy schools and other educational institutions for implementation of HIT into clinical education

The HHS Secretary will provide competitive grants to graduate schools of pharmacy, medicine, and other health professions for funding of up to 50% of the cost associated with incorporating certified HIT into clinical education.^{xxix} Interested schools must submit a grant application to the Secretary and provide a plan to use certified HIT to meet the goals of reducing medical errors, increasing the provision of safe health care delivery systems, increasing access to health care prevention, improving quality of care, and reducing chronic diseases.^{xxx} The plans must also show how the program will increase the likelihood of graduates adopting HIT into practice. This program will begin shortly after the effective date of the legislation and within one year, HHS must report to Congress regarding the programs implemented and provide recommendations for future programs or changes to programs.

Provision of assistance to universities to increase the number of HIT professionals

HHS will provide assistance of up to 50% of costs for colleges and universities to expand or implement medical informatics programs that provide certifications, undergraduate degrees, or master’s degrees for HIT education.^{xxxi} Priority will be given to programs that can be completed in less than six months.^{xxxii}

Privacy provisions

The new privacy provisions are designed to fill in gaps left by current HIPAA privacy and security provision. These provisions also update existing provisions to better protect

electronic PHR from breaches while allowing appropriate access by patients and health care providers. The legislation introduces several new terms to the HIPAA nomenclature:

- A specific definition for *breach* did not exist under the original HIPAA law and implementing regulations. This definition is necessary to help provide clarity to covered entities and business associates regarding the scope of actions considered breaches.

Breach is defined: “the unauthorized acquisition, access, use, or disclosure of protected health information which compromises the security, privacy, or integrity of protected health information maintained by or on behalf of a person. Such term does not include any unintentional acquisition, access, use, or disclosure of such information by an employee or agent of the covered entity or business associate involved if such acquisition, access, use, or disclosure, respectively, was made in good faith and within the course and scope of the employment or other contractual relationship of such employee or agent, respectively, with the covered entity or business associate and if such information is not further acquired, accessed, used, or disclosed by such employee or agent.”^{xxxiii}

- *Electronic health record* is defined as: “an electronic record of health-related information on an individual that is created, gathered, managed, and consulted by authorized health care clinicians and staff.”^{xxxiv}

- *Personal health record* is defined as “an electronic record of individually identifiable health information on an individual that can be drawn from multiple sources and that is managed, shared, and controlled by or for the individual.”^{xxxv}

- *Vendor of personal health records* is defined “an entity, other than a covered entity [*sic*] that offers or maintains a personal health record.”^{xxxvi}

Business associates must now maintain identifiable health information in the same manner as covered entities. The law requires that the new requirements for business associates be specifically identified in contractual agreements between covered entities and business associates.^{xxxvii} Business associates will also be civilly and criminally accountable for breaches in the same manner as covered entities.^{xxxviii}

Breaches of identifiable personal health information discovered by covered entities must be disclosed to individuals on the first known day of the breach. Business associates must disclose breaches on the first known day to covered entities.^{xxxix} In most cases, individuals must be notified of breaches in writing by covered via US mail or e-mail depending on preference.^{xl} Other ways of notification include a general notice posted on a website or in broadcast media.^{xli} HHS will post information on its website regarding breaches involving more than 500 individuals.^{xlii}

HHS will publish interim final rules on the privacy section of the law within six months of the implementation date. The legislative provisions regarding breach apply beginning 30 days after the implementation date (March 2009).^{xliii}

The law also seeks to clarify other controversial provisions associated with HIPAA, particularly in the area of disclosures of identifiable health information. ARRA provides individuals with the right to request a 3-year accounting of disclosures of identifiable health information released by covered entities. The legislation requires that HHS promulgate regulations regarding the description and scope of disclosures that require an accounting. Covered entities may charge a nominal fee to individuals who seek to review disclosures.^{xliv}

The legislation maintains and clarifies the ability of covered entities and business associates to receive remuneration for sales of electronic health information for treatment and health care purposes with authorization from the patient.^{xlv} Within 18 months of implementation, HHS will promulgate proposed regulations regarding the exact circumstances where these disclosures for remuneration may occur.^{xlvi} Implementation of these new provisions will occur within 6 months of the release of final regulations.

The legislation also preserves the ability of marketing communications to be made by covered entities, such as pharmacies, or their agents when an individual's treatment benefits from these disclosures.^{xlvii} For example, this provision will allow pharmacies to continue providing customers with refill reminders and to suggest products or services that might further benefit treatment for an existing condition. These communications must be made only to existing customers pursuant to authorization.

In summary, the enactment of the HITECH provisions is only the beginning of a 5-year process to develop EHR for all Americans. Most pharmacies already maintain electronic records. However, pharmacies have an incentive to understand the HIT standards and the potential impact to pharmacy practice. Pharmacies also might have opportunities to create partnerships with HIT vendors.

Pharmacists have an obligation to understand the new privacy provisions and should be aware of developments that might require modification of contractual or insurance liability provisions.

Summary of Health Care Provisions

General overview

ARRA provides a number of health care provisions other than the major provisions of the HIT sections and updates to the privacy rules. These provisions include increased funding for state Medicaid programs of approximately \$87 billion and also approximately \$20 billion additional funds to assist in providing Medicaid coverage or COBRA coverage

and health insurance premium tax credits to unemployed individuals. Other health care provisions include:

- \$1.1 billion for funding comparative effectiveness programs to provide assessments of different treatments, including medication therapy and other medical interventions such as surgery.
- Investment in telemedicine by allowing expanded coverage of broadband Internet services to rural areas and other underserved areas and to expand Medicare and Medicaid payments for telehealth services. The law provides grant programs through HRSA.
- \$400 million to fund upgrades and improvements at military health care facilities.
- \$85 million in direct funding to the Indian Health Service (IHS) to promote the adoption of HIT programs. This funding may be used for telehealth initiatives or for infrastructure. An additional \$415 million is allocated to IHS to upgrade health care facilities, including \$227 million for new construction.
- \$2.5 billion allocated to HRSA including the following:
 - \$1.5 billion for construction, renovation, equipment and HIT infrastructure for public health service centers.
 - \$500 million in unspecified grants for public health service centers
 - \$500 million for health care workforce shortage funding with \$75 million available until September 2011. Funds may be used for grants, scholarships, and loan repayment programs under the PHSA. *(These efforts are primarily focused on access to primary care physicians but pharmacy should further examine whether funds could be available.)*
 - Twenty percent of the funds allocated for the National Health Services Corps must be used for field operations.
- Allocates \$1 billion to repair, renovate, or construct existing non-federal research facilities.
- \$8.2 billion for further research initiatives associated with NIH and the Common Fund established under the PHSA.
- Increased funding of \$1 billion for health and wellness programs administered through HHS and the Public Health Service including \$300 million for efforts with CDC to improve immunization programs. An additional \$650 million will be used to fund evidence-based clinical and wellness strategies under the PHS to measure outcomes associated with chronic diseases.
- \$50 billion in funding to Veteran Benefits Administration for HIT systems and \$150 million to states for the construction and improvements of nursing homes, hospitals, and other VA approved domiciliary facilities.

Comparative effectiveness

The ARRA provisions allow HHS and NIH to work collectively to synthesize data and publish research, and clinical trials of medical procedures and services. The provisions encourage the development of electronic clinical trials registries and other data networks to generate outcomes data. By June 2009, the Institute of Medicine must provide a report to Congress on the national priorities for comparative effectiveness.

The law also establishes the Federal Coordinating Council for Comparative Effectiveness Research to provide recommendations for comparative effectiveness. The Council will include 15 presidential appointees from government agencies, including CMS, AHRQ, FDA, and the VA. The Council will provide recommendations on mechanisms that comparative effectiveness research may be used to reduce duplicative therapies and encourage complementary therapy.

According to the law and accompanying conference report, the recommendations by the Council and HHS will not be used to mandate clinical appropriateness or impact reimbursement under federal health care programs. Furthermore, the conference report notes that the recommendations should consider that treatment must be based on patient-specific measures and not simply clinical guidelines. *(Despite these assurances, patient groups, physicians, and the pharmaceutical industry remain concerned about the appropriateness of the scope of the studies and that the language is not strong enough to prevent CMS actions to reduce reimbursement. Beyond Medicare and Medicaid, the research could also potentially be used under a reformed health care system. The stimulus bill did not contain any provisions to that effect and therefore, advocates must remain vigilant about the implications under health care reform.)*

Health and wellness programs

ARRA allocates approximately \$5 billion in overall efforts to fund programs to improve health and wellness of Americans. Specifically, these efforts are targeted to training, education, and funding of programs to provide improved access to vaccines, prevent and fight obesity, smoking cessation, and other efforts aimed at reducing and preventing chronic diseases. Some of these funds will be distributed to the VA or the Indian Health Service for specific populations. The remaining funds will be distributed to NIH and HHS, including targeted funds for developing outcomes-based programs. *(Pharmacists have shown value in chronic disease management and prevention programs and should consider these programs as a way to obtain additional funding and expand the role of pharmacists in the health care system.)*

ⁱ HR 1 The American Reinvestment and Recovery Act of 2009 (ARRA) .HITECH Provisions §1301 *et seq.* Amends 42 USC §201 *et seq.* (Public Health Service Act (PHSA)) by adding Title XXX §3000 *et seq.*

ⁱⁱ Arvantes, J. Health IT, primary care come out ahead in stimulus bill. AAFP News Now: February 13, 2009. Available at <http://www.aafp.org/online/en/home/publications/news/news-now/government-medicine/20090213stimulus-passes.html>. Accessed February 17, 2009.

ⁱⁱⁱ *Ibid* at 1 PHSA §3001.

^{iv} *Ibid* at 1. ARRA§802.

^v Huslin A. Firms look to digital health records. LA Times: February 17, 2009. Available at <http://www.latimes.com/business/la-fi-health-records17-2009feb17,0,7014749.story>. Accessed February 17, 2009.

^{vi} *Ibid.* at 1 PHSA §3015.

^{vii} *Ibid.* at 2.

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- viii *Ibid* at 3.
- ix *Ibid* at 3.
- x *Ibid* at 3.
- xi Health information technology—consumer principles. Adopted March 2006. Available at http://www.nationalpartnership.org/site/DocServer/HIT_20-20Consumer_20Principles_20FINAL_20March_202006.pdf?docID=990. Accessed February 17, 2009.
- xii Beyond the HIPAA privacy rule: enhancing privacy, improving health through research. Institute of Medicine: February 4, 2009. Summary available at <http://www.iom.edu/?ID=61796>. Accessed February 18, 2009.
- xiii New PHR requirements in stimulus package. HDM Breaking News: February 17, 2009. Available at http://www.healthdatamanagement.com/news/PHR27728-1.html?ET=healthdatamanagement:e771:112652a:&st=email&channel=consumer_health. Accessed February 17, 2009.
- xiv *Ibid* at 1 ARRA 13400(11).
- xv *Ibid* §13405.
- xvi *Ibid* at 1 PHS §3001.
- xvii *Ibid* at 1 PHS §3006 (b).
- xviii *Ibid* at 1 PHS §3006(c).
- xix *Ibid* at 1 PHS §3002.
- xx *Ibid* at 1 PHS §3002.
- xxi *Ibid*.
- xxii *Ibid* at 1 PHS §3003.
- xxiii *Ibid* at 1 ARRA §13113.
- xxiv *Ibid* at §13113(b).
- xxv *Ibid* at §13113(c).
- xxvi *Ibid* at 1 PHS §3011.
- xxvii *Ibid* at 1 PHS §3012(c).
- xxviii *Ibid* §3013.
- xxix *Ibid* at 7.
- xxx *Ibid* §3015(b)(2).
- xxxi *Ibid* §3016.
- xxxii *Ibid*.
- xxxiii *Ibid* at 1 ARRA §13400 (1).
- xxxiv *Ibid* at §13400(5).
- xxxv *Ibid* at §13400(11).
- xxxvi *Ibid* §13400(18).
- xxxvii *Ibid* §13401.
- xxxviii *Ibid*.
- xxxix *Ibid* §13402.
- xl *Ibid* §13402(e).
- xli *Ibid*.
- xlii *Ibid*.
- xliii *Ibid* §13402(j).
- xliv *Ibid* §13405.
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^{xlv} *Ibid* §13405(e).

^{xlvi} *Ibid*.

^{xlvii} *Ibid* §13406.