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HITECH Act: Analysis of Policy Implications, Requirements of Health IT Stimulus Provisions

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INTRODUCTION

The Health Information Technology for Economic and Clinical Health Act (HITECH Act)¹ is part of the American Recovery and Reinvestment Act of 2009 (the Act), which was signed by President Barack Obama on Feb. 17 (Pub. L. No. 111-5). The Act includes approximately \$20 billion allocated to health information technology (IT) projects, including the investment in health IT infrastructure to facilitate a nationwide health information network, the endorsement of stan-

¹ H.R. 1, S.1, American Recovery and Reinvestment Act of 2009, Health Information Technology for Economic and Clinical Health Act (the HITECH Act), § 13001, et seq. (Feb. 17, 2009).

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dards to assist in this endeavor, and the provision of incentives through Medicare and Medicaid reimbursement to assist physicians and hospitals in acquiring electronic health record (EHR) technology.

The policy implications of the funding and incentive package promote education and dissemination of best practices through administrative and infrastructure changes.

In addition, the HITECH Act codifies the Office of the National Coordinator of Health Information Technology (ONC) under the Department of Health and Human Services (HHS) and provides an administrative process to coordinate health IT policy and standards. The HITECH Act also expands the reach of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), extending it to business associates. It imposes a nationwide security breach notification law for entities that possess electronic protected health information (PHI) and it makes other significant modifications to HIPAA.

The policy implications of the stimulus package for health IT have the potential to transform the delivery of health care. The provisions of the HITECH Act are consistent with President Obama's emphasis on health IT as part of his overall health care plan and are carefully aligned with ONC's goals, which include the following:

- ensuring that each patient's health information is secure and protected;
- improving health care quality, reducing medical errors, reducing health disparities and advancing the delivery of patient-centered medical care;

- reducing health care costs resulting from inefficiency, medical errors, inappropriate care, duplicative care and incomplete information; and
- facilitating health and clinical research and health care quality.²

This paper summarizes the major provisions of the HITECH Act and offers preliminary analysis on how the provisions will affect health care providers, hospitals and those who serve the health care industry.

The HITECH Act is complicated legislation that includes different effective dates for different provisions. In addition, it requires HHS to issue regulations and reports on numerous health IT topics.

Attached as Appendix A is a chart setting forth the timing requirements of most of the provisions within the HITECH Act.

Part I: ADMINISTRATIVE MATTERS

Office of the National Coordinator for Health Information Technology

The HITECH Act establishes a permanent Office of the National Coordinator for Health Information Technology, to be headed by a National Coordinator. The HITECH Act provides ONC with \$2 billion to fulfill its duties consistent with the development of a nationwide health IT infrastructure through the development of standards and certification criteria and the coordination of health IT policies through a federal health IT strategic plan.³

The HITECH Act requires ONC to update the strategic plan to include specific milestones with respect to numerous policy matters, including, without limitation, the following:

- the electronic exchange and use of health information;
- the integration of information among health care providers, health plans, the government and other interested parties;
- the utilization of an EHR for each person in the United States by 2014;
- the incorporation of privacy and security protections for the electronic exchange of individually identifiable health information;
- ensuring security methods for appropriate authentication of health information and specifying encryption technologies;
- implementing strategies to enhance the use of health IT in improving the quality of care, reducing medical errors, reducing health disparities, improving public health, increasing prevention and coordination with community resources, and improving the continuity of care among health care settings.⁴

In connection with the strategic goals, ONC is promoting interoperability through standard setting and the endorsement of such standards. The HITECH Act requires ONC to coordinate with the National Institute of Standards and Technology (NIST) to develop a program to certify health IT as being compliant with the

endorsed standards.⁵ (See also HIT Standards Committee and Standard Setting discussion set out below).

To further the privacy and security policies of ONC, HHS must appoint a Chief Privacy Officer of ONC. The Privacy Officer shall advise ONC and work with state and regional efforts concerning privacy, security and data stewardship of electronic health information.⁶ It is unclear, at this point, how the Chief Privacy Officer will interact with privacy and security enforcement that is conducted through the Office for Civil Rights (OCR) and the Center for Medicare & Medicaid Services (CMS).

HIT Policy Committee

The HITECH Act establishes a federal advisory committee, known as the HIT Policy Committee, to make recommendations to the National Coordinator relating to the implementation of a nationwide health IT infrastructure.⁷ The HIT Policy Committee shall recommend areas in which standards, implementation specifications and certification criteria are needed for the electronic exchange and use of health information, such as technologies that protect privacy and promote security in EHRs or encryption technologies.

The HIT Policy Committee shall also make recommendations as to the appropriate uses of a nationwide health information infrastructure, including, for instance, to collect quality data, conduct bio-surveillance activities, and facilitate public health activities or clinical research. The HIT Policy Committee is comprised of members from a variety of health care sectors, including public health officials, patient advocates, health care providers and privacy experts.⁸

HIT Standards Committee and Standard Setting

The HITECH Act establishes a second federal advisory committee, known as the HIT Standards Committee, to recommend standards, implementation specifications and certification criteria for the electronic exchange and use of health information in accordance with the policies developed by the HIT Policy Committee.⁹ As appropriate, the HIT Standards Committee shall arrange for NIST to test the standards.¹⁰

Like the HIT Policy Committee, the HIT Standards Committee is to serve as a forum for participation by a broad range of stakeholders to provide input on the development, harmonization and recognition of standards necessary for the development and adoption of a nationwide health IT infrastructure that allows for the electronic use and exchange of health information.¹¹

⁵ HITECH Act, § 13101 (to be codified at 42 U.S.C. § 3001(c)(5)).

⁶ HITECH Act, § 13101 (to be codified at 42 U.S.C. § 3001(e)).

⁷ HITECH Act, § 13101 (to be codified at 42 U.S.C. § 3002(a) – (b)).

⁸ HITECH Act, § 13101 (to be codified at 42 U.S.C. § 3002(c)).

⁹ HITECH Act, § 13101 (to be codified at 42 U.S.C. § 3003(a)).

¹⁰ HITECH Act, § 13201(a).

¹¹ HITECH Act, § 13101 (to be codified at 42 U.S.C. § 3003(b) – (c)). Note also that the HITECH Act specifically states that the National eHealth Collaborative may modify its charter to allow HHS to recognize NeHC as the HIT Policy Committee or the HIT Standards Committee. (HITECH Act, § 13101 (to be codified at 42 U.S.C. § 3008(b))).

² HITECH Act, § 13101 (to be codified at 42 U.S.C. § 3001(b)).

³ HITECH Act, § 13101 (to be codified at 42 U.S.C. § 3001(a) – (c)).

⁴ HITECH Act, § 13101 (to be codified at 42 U.S.C. § 3001(c)(3)).

By Dec. 31, 2009, HHS shall adopt an initial set of standards with respect to the areas that the HIT Policy Committee addresses. Standards that have already been adopted by ONC may be applied towards this requirement.¹² For instance, ONC may adopt the standards established by the Certification Commission for Healthcare Information Technology (CCHIT) or by the Healthcare Information Technology Standards Panel (HITSP).

NIST is required to test the standards to assure the efficient implementation and use of the standards, but it may do so through a program to accredit independent, non-federal laboratories that perform testing of the standards and certification programs.¹³ For instance, NIST could accredit organizations such as CCHIT or HITSP to perform the testing of the standards and certification criteria.

Education Components

Health IT Extension Program. The HITECH Act requires HHS to provide implementation support through the creation of a Health IT Research Center (the Research Center), which will provide technical assistance and develop best practices to accelerate efforts to adopt, implement and effectively utilize health IT. The Research Center will work with regional extension centers to accomplish these purposes. Specifically, the regional extension centers will provide assistance with implementation, effective use, upgrading and ongoing maintenance of health IT, and are directed to focus their efforts on public or not-for-profit hospitals or critical-access hospitals, federally qualified health centers and entities located in areas that serve uninsured or underinsured populations.

To perform these tasks and achieve these aims, regional extension centers will affiliate with nonprofit organizations that apply for and are awarded financial assistance by HHS. The financial assistance will not exceed 50 percent of the capital and annual operating and maintenance funds required to create and maintain a regional extension center, except in the event of national economic conditions that would render the cost-share requirement detrimental to the program.¹⁴ It seems that entities that are currently coordinating regional health information exchanges will be well poised to serve as regional extension centers.

Grants for Academic Programs. HHS may award grants to carry out demonstration projects to develop academic curricula integrating certified EHR technology in the clinical education of health professionals. Graduate health professions schools (such as schools of medicine, dentistry or pharmacy) that desire a grant must submit a strategic plan for integrating certified EHR technology in the clinical education to reduce medical errors, increase access to prevention, reduce chronic diseases and enhance health care quality. The grant may not provide more than 50 percent of the costs of any activity, except in the event of national economic conditions that would render the cost-share requirement detrimental to the program.¹⁵

¹² HITECH Act, § 13101 (to be codified at 42 U.S.C. § 3004(b)).

¹³ HITECH Act, § 13201(b).

¹⁴ HITECH Act, § 13301 (to be codified at 42 U.S.C. § 3012).

¹⁵ HITECH Act, § 13301 (to be codified at 42 U.S.C. § 3015).

In addition, HHS, in consultation with the National Science Foundation, shall provide assistance to institutions of higher education to establish or expand medical health informatics education programs for health care and IT students to ensure the rapid and effective utilization and development of health IT.¹⁶

NIST, in consultation with the National Science Foundation and other appropriate federal agencies, shall establish a program of assistance to institutions of higher education to establish multidisciplinary Centers for Health Care Enterprise Integration.¹⁷ These Centers shall generate innovative approaches to health care information enterprise integration through cutting-edge, multidisciplinary research on the systems challenges to health care delivery and the development and use of health IT.¹⁸ Institutions of higher education that desire to seek funding shall submit an application to NIST in accordance with a process to be developed by NIST.

Privacy Education. HHS must designate an individual in each regional office to offer guidance and education to covered entities, business associates and individuals on their rights and responsibilities related to privacy and security requirements for PHI.¹⁹ Furthermore, OCR must develop and maintain a national education initiative to enhance public transparency regarding the uses of PHI, including programs to educate individuals about the potential uses of their PHI, the effects of such uses and the rights of individuals with respect to such uses.²⁰

Federal Promotion of Health IT

ONC is also promoting the adoption and use by federal agencies of health IT that meets the applicable standards. Federal agencies that implement, acquire or upgrade health IT systems used for the direct exchange of individually identifiable health information between agencies and non-federal agencies shall utilize, where available, health IT that meets the standards.²¹ In addition, each agency shall require in contracts with health care providers, health plans or health insurance issuers that, as each of the foregoing implements, acquires or upgrades health IT systems, it shall utilize health IT systems that meet the standards.²²

The National Coordinator shall support the development and routine updating of qualified EHR technology and make such technology available, unless the Secretary of HHS determines through an assessment that the needs and demands of providers are being substantially and adequately met through the marketplace. In making this technology available, the qualified EHR technology must be certified to be in compliance with applicable standards.²³

¹⁶ HITECH Act, § 13301 (to be codified at 42 U.S.C. § 3016).

¹⁷ “Enterprise Integration” is defined as the electronic linkage of health care 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 health care infrastructure in accordance with applicable law, and such term includes related application protocols and other related standards. (HITECH Act, § 13101 (to be codified at 42 U.S.C. § 3000(2))).

¹⁸ HITECH Act, § 13202.

¹⁹ HITECH Act, § 13403(a).

²⁰ HITECH Act, § 13403(b).

²¹ HITECH Act, § 13111.

²² HITECH Act, § 13112.

²³ HITECH Act, § 13101 (to be codified at 42 U.S.C. § 3007).

Clearly, a major component of the HITECH Act is the emphasis on the building of policy and infrastructure as a platform to set the stage for future, effective health IT implementation by physicians, hospitals and other health care providers. While similar efforts have been supported at both the federal and state levels for the past few years through programs such as the Health Information Security and Privacy Collaboration (HISPC), there has not been the same kind of systematic outline and direction as that contemplated by the HITECH Act. While this kind of direction and funding is critically important, the tasks to be accomplished are multi-faceted, will involve many participants and are forward looking, yet will take significant time to implement and remain subject to supplemental regulations that will refine and direct the overall process.

Part II: PRIVACY AND SECURITY MATTERS

Application of the HIPAA Security Provisions to Business Associates

One of the most significant changes to HIPAA made by the HITECH Act is the extension of certain HIPAA requirements to business associates. More specifically, the HITECH Act applies the administrative, physical and technical safeguard requirements of the security regulations to business associates and imposes additional obligations related to policies and procedures and documentation. In addition, business associates that are aware of a pattern of activity that constitutes a violation of HIPAA must take steps to cure the violation.²⁴ Furthermore, civil and criminal penalties that apply to covered entities for violations of the security and privacy regulations also apply to business associates.²⁵

The implications of this modification to HIPAA are significant in that they will impact thousands of organizations that support the health care industry as business associates. These entities traditionally were required, by contract, to agree to certain safeguards with respect to the use or disclosure of PHI. Now, they will also be required under law to develop and implement robust written privacy and security policies and procedures with respect to the handling of PHI. They may also need to upgrade significantly their technological infrastructure to comply with these safeguards.

Security Breach Notification Requirements

In addition to extending HIPAA's privacy and security rules to cover business associates, the HITECH Act also requires covered entities, business associates, vendors of Personal Health Records (PHR)²⁶ and certain third-party service providers to notify individuals and/or entities when unsecured PHI or unsecured PHR identifiable health information is subject to a security breach.²⁷ A "breach" is defined broadly to include the unauthorized acquisition, access, use or disclosure of PHI that compromises its security, privacy or integrity.

However, the term "security breach" does not include instances in which there has been an inadvertent disclosure from an authorized individual and the information is not further acquired, accessed, used or disclosed.²⁸

Although the statute does not define "unsecured" PHI or PHR identifiable health information, it directs HHS to issue guidance within six months specifying the technologies and methodologies that render PHI or PHR identifiable health information unusable, unreadable or indecipherable to unauthorized individuals. If HHS does not issue the guidance within 60 days of enactment, the definition of unsecured PHI shall mean PHI that is not secured by a technology standard that renders such information unusable, unreadable or indecipherable to unauthorized individuals and is developed or endorsed by a standards-developing organization that is accredited by the American National Standards Institute.²⁹

This approach is significantly different from the typical approach adopted at the state level, in that the subject data need only be a person's name, for example, and would not need to include any sensitive information (such as a Social Security number) to constitute a security breach. As a result, and depending on the ultimate definition of "unsecured PHI," one would anticipate the health care industry and those vendors who support it as business associates to incur significant time and expense in either implementing enhanced methods to secure PHI and/or to incur significant time and expense managing the notice requirements associated with security breaches.

Events that Require Notice. In the event of a security breach, the HITECH Act requires covered entities to notify each individual whose unsecured PHI has been (or is reasonably believed to have been) accessed, acquired or disclosed. Further, business associates must notify covered entities in the event of a security breach and include in the notification the identification of affected individuals.³⁰

Vendors of PHRs, entities that offer products or services through the website of a vendor of PHRs and/or covered entities that offer individuals PHRs, and entities that access information in, or send information to, a PHR must also notify affected individuals and the Federal Trade Commission (FTC) following discovery of a breach of security of unsecured PHR identifiable health information.³¹ Finally, the HITECH Act requires third-party service providers that provide services to vendors of PHRs (or those that offer products or services through the websites of vendors of PHRs or covered entities) to notify the vendor or entity of a security breach, which includes the identification of affected individuals.³²

Time Requirements for Notice. Covered entities, business associates, vendors of PHRs and certain third-party service providers must make the required notifications without unreasonable delay and within 60 calendar days after the discovery of a breach.³³ A breach is treated as discovered on the first day it is known (or

²⁴ HITECH Act, § 13404.

²⁵ HITECH Act, § 13401(a); 13404(c).

²⁶ "Personal Health Record" means an electronic record of PHR identifiable health information on an individual that can be drawn from multiple sources and that is managed, shared and controlled by or primarily for the individual. (HITECH Act, § 13400(11)).

²⁷ HITECH Act, § 13402(a)-(b); § 13407(a)-(b).

²⁸ HITECH Act, § 13400(1).

²⁹ HITECH Act, § 13402(h)(1)(B)).

³⁰ HITECH Act, § 13402(a) - (b).

³¹ HITECH Act, § 13407(a).

³² HITECH Act, § 13407(b).

³³ HITECH Act, § 13402(d); 13407(c).

reasonably should have been known) to occur by the covered entity, business associate, vendor or third-party service provider.³⁴ However, these entities may delay notification if a law-enforcement official determines that it would impede a criminal investigation or cause damage to national security.³⁵

Permissible Methods of Notice. Notice must be provided in writing by first-class mail to the affected individuals or by electronic mail if specified as a preference by the individual. In circumstances where there are 10 or more individuals with out-of-date contact information, a conspicuous posting on the covered entity's internet home page or notice in major print or broadcast media may serve as a substitute form of notice. If the breach has affected the unsecured PHI of more than 500 residents, notice must also be provided to prominent media outlets following the discovery of a breach. Further, the covered entity must notify HHS when unsecured PHI has been acquired or disclosed in a breach; notice to the Secretary must be immediate if it affects 500 or more individuals. HHS will post on its website a list of covered entities involved in a breach in which the unsecured PHI of more than 500 individuals is acquired or disclosed.³⁶

Content of Notifications. To the extent possible, notice of a security breach must include a brief description of: (1) the events that occurred; (2) the types of unsecured PHI that were involved; and (3) actions performed by the covered entity to investigate the breach, to mitigate losses and to protect against further breaches. Notices should also include recommended steps individuals should take to protect themselves from potential harm and contact procedures for individuals to ask questions or obtain additional information.³⁷

Effective Dates. The HITECH Act directs HHS and FTC to promulgate interim final regulations within 180 days after the enactment of the bill to implement these security breach notification requirements. These notification provisions apply to breaches that are discovered on or after 30 days after the date of publication of such interim final regulations.³⁸ However, the provisions pertaining to vendors of PHRs and entities that offer products or services through the website of a vendor of PHRs and/or covered entities that offer individuals PHRs, are set to sunset when either HHS or FTC promulgates standards for non-covered entities.³⁹

Changes to Business Associate Agreements

The additional requirements of the HITECH Act that relate to privacy will be applicable to business associates and must be incorporated into Business Associate Agreements between the business associate and the covered entity. Both covered entities and business associates should re-examine their Business Associate Agreements so they can amend them to the extent required.⁴⁰

³⁴ HITECH Act, § 13402(c); 13407(c).

³⁵ HITECH Act, § 13402(f); 13407(c).

³⁶ HITECH Act, § 13402(e); 13407(c).

³⁷ HITECH Act, § 13402(f); 13407(c).

³⁸ HITECH Act, § 13402(j).

³⁹ HITECH Act, § 13407(g).

⁴⁰ HITECH Act, § 13404.

Restrictions on Certain Disclosures of Health Information: Out-of-Pocket Payment and Limited Data Set/Minimum Necessary

The HITECH Act permits an individual to request a covered entity to restrict the disclosure of its PHI if the disclosure is to a health plan for purposes of carrying out payment or health care operations (and is not for treatment purposes), and the PHI pertains solely to a health care item or service that was paid for fully out-of-pocket by the individual.⁴¹ In addition, when required to comply with the minimum necessary doctrine, the HITECH Act requires covered entities to limit the use, disclosure or request of PHI to the limited data set, to the extent practicable, or, if needed by such entity, to the minimum necessary to accomplish the intended purpose. Further, the HITECH Act directs HHS to issue guidance on what constitutes "minimum necessary" not later than 18 months after the date of enactment.⁴²

Accounting of Disclosures

The HITECH Act newly requires covered entities with EHRs to produce, upon an individual's request, an accounting of all disclosures of the individual's PHI, including disclosures made for treatment, payment and health care operations, over a three-year period. This expands current law, which limits accounting of disclosures requests to non-routine disclosures such as those for research. The Secretary is directed to promulgate regulations not later than six months after the Secretary adopts standards on accounting for disclosures. The regulations must specify what information should be included about each disclosure for treatment, payment and health care operations and must consider the interests of individuals in learning about how their PHI is disclosed and the administrative burden of accounting for disclosures.

In addition, covered entities must either account for disclosures of PHI made by their business associates or provide to the individual making a request for an accounting of disclosures a list of, and contact information for, all business associates acting on behalf of the covered entity. Business associates are newly required to provide individuals, upon their request, with an accounting of disclosures of PHI for treatment, payment and health care operations.⁴³

With respect to the effective date, covered entities with EHRs as of Jan. 1, 2009, must have the capacity to produce an accounting of disclosures of PHI for treatment, payment and health care operations made on and after Jan. 1, 2014. The Secretary has the authority to set a later effective date for such covered entities, but the later date may not be after 2016. For covered entities that adopt EHRs after Jan. 1, 2009, the covered entity must honor requests for accountings of disclosures of PHI for treatment, payment and health care operations made on or after the later of Jan. 1, 2011, or the date that the covered entity acquires an electronic record. The Secretary has the authority to set a later date for covered entities acquiring EHRs after Jan. 1, 2009, but the later date may not be later than 2013.⁴⁴

The expansion of the current accounting for disclosures requirement to include routine disclosures for

⁴¹ HITECH Act, § 13405(a).

⁴² HITECH Act, § 13405(b).

⁴³ HITECH Act, § 13405(c).

⁴⁴ HITECH Act, § 13405(c).

treatment, payment and health care operations newly requires covered entities to have the capacity to track, store and compile a vast amount of information. Producing an accounting of disclosures report could be technologically challenging and operationally burdensome, particularly for early adopters of EHRs with multiple information systems. One estimate of compliance costs for a large health system is in the tens of millions of dollars for programming, storage, infrastructure development and maintenance, as well as personnel costs. It will be important for those health systems and others who would experience a large compliance burden to comment on the forthcoming regulations, urging that the Secretary minimize the information about each disclosure that needs to be in the accounting report and highlighting both the administrative burdens of compliance and describing other ways that individuals can learn about how their PHI is disclosed.

Prohibitions on Sale of EHRs or PHI

The HITECH Act introduces a new affirmative prohibition on the direct or indirect receipt of remuneration by a covered entity or a business associate in exchange for any PHI without a HIPAA authorization from the applicable individual(s). The term “remuneration” is not defined. This provision also provides six exceptions to the prohibition and authorizes the Secretary to develop others, through the promulgation of regulations, so long as they are similar in necessity and appropriateness to those prescribed in the HITECH Act itself. The exceptions allow the sale of PHI for the following purposes:

- public health activities (as defined in the HIPAA regulations);⁴⁵
- research (as defined in the HIPAA regulations)⁴⁶, if the “price” charged reflects the costs of preparation and transmittal of the data;
- treatment of the applicable individual(s) (subject to any additional protections against inappropriate access, use or disclosure of the PHI that the Secretary may impose by future regulations);
- a transaction (and corresponding due diligence) involving the sale, transfer, merger or consolidation of all or part of the applicable covered entity with another covered entity, or an entity that following such transaction will become a covered entity;⁴⁷
- payment by a covered entity to a business associate for HIPAA-permissible services provided for the covered entity;
- provisions to the applicable individual(s) of a copy of the individual(s)’ record.

Significantly, the exception for a sale, merger, consolidation or other transfer transaction draws on only one among the many components of the broad defini-

⁴⁵ “Public Health Activities” include preventing or controlling disease, injury or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations and public health interventions. (45 CFR § 164.512(b)).

⁴⁶ “Research” is defined as a systematic investigation, including research development, testing and evaluation, designed to develop or to contribute to generalizable knowledge. (45 CFR § 164.501 and 164.512(i)).

⁴⁷ 45 CFR § 164.501(6)(iv).

tion of Health Care Operations⁴⁸ under the current HIPAA regulations.

Among the changes made just before the HITECH Act was finalized was the separation of the exceptions for public-health activities and the exception for research. The effect of this change was to apply the condition concerning the price charged to the exception for research.

At the same time, however, language was added both to require the Secretary to consider, when promulgating regulations to implement this section of the HITECH Act, the impact of the “price-charged” condition on the exceptions for both research and public health activities, and to authorize the Secretary to add this condition to the public health activities exception if he finds that it will not impede such activities. These additions suggest the possibility that such a condition may either be imposed upon both exceptions or eliminated altogether in the future.

Worth noting is the use of the HIPAA term “protected health information” in this section. As defined under HIPAA, such term does not include data that is fully “de-identified” within the meaning of HIPAA, but it does include data in the form of a HIPAA-defined “limited data set.”

On its face, therefore, and in the absence of implementing regulations that add exceptions or expand the existing exception for research, the HITECH Act has the potential for significantly limiting the flexibility HIPAA previously provided by allowing use of data and tissue repositories in a limited data set format for research without HIPAA authorizations.

Further, depending upon whether and how the implementing regulations define remuneration or add exceptions, many of the economic arrangements that may be considered necessary and appropriate to foster and support the creation, establishment and operation of large-scale data and tissue repositories (e.g., the right to access and use of information in a repository in return for contributions of capital, data and tissue to the repository) will likely trigger the need for authorizations that can significantly impede such important electronic-information initiatives.

Marketing and Fundraising

The HITECH Act removes certain marketing communications from the definition of “health care opera-

⁴⁸ See 45 CFR § 164.501 for a complete definition and see Footnote 49 for further discussion relating to Health Care Operations. Among other things, “Health Care Operations” is defined as any of the following activities of the covered entity to the extent that the activities are related to covered functions: (1) conducting quality-assessment and improvement activities, population-based activities relating to improving health or reducing health care costs, case management, and care coordination and related functions that do not include treatment; (2) reviewing the competence or qualifications of health care professionals, evaluating health-plan performance, accreditation, certification, licensing or credentialing activities; (3) underwriting activities; (4) conducting or arranging for medical review, legal services and auditing functions, including fraud and abuse detection; (5) business planning and development; and (6) business management and general administrative activities of the entity, including the sale, transfer, merger or consolidation of all or part of the covered entity with another covered entity.

tions.”⁴⁹ Communications by a covered entity or business associate that encourage the purchase or use of a product or service shall not be considered a health care operation unless the communication is made to describe a health-related product or service (including payment) that is provided by, or included in a plan of benefits of, the covered entity making the communication; for the treatment of the individual; or for case management or care coordination for the individual, or to direct or recommend alternative treatments, therapies, health care providers or settings of care to the individual.⁵⁰

These exceptions do not apply (and, therefore, the communications would not fall under the definition of “health care operations”) if the covered entity receives direct or indirect payment in exchange for making such communications, unless the communication describes a drug or biologic that has been prescribed and the payment is reasonable, is made by the covered entity with a valid authorization from the recipient, or is made by a business associate on behalf of the covered entity and the communication is consistent with the Business Associate Agreement.⁵¹ Further, the HITECH Act provides individuals the option to opt out from any communication that relates to fundraising.⁵²

Business Associate Contracts Required for Certain Entities

The HITECH Act clarifies that organizations that provide data transmission of PHI to covered entities, such as Health Information Exchange Organizations, Regional Health Information Organizations or an e-Prescribing Gateway, or a vendor that contracts with a covered entity to allow that covered entity to offer a PHR to patients as part of its EHR, are required to enter into Business Associate Agreements with covered entities.⁵³ This confirms the approach that many of these entities already use.

Penalties and Enforcement

In addition to creating new requirements applicable to covered entities, business associates and other orga-

⁴⁹ Under current law, covered entities may use and disclose protected health information for treatment, payment and health care operations purposes without the individual’s specific authorization. While early versions of both the House and Senate bills would have directed the Secretary to narrow the definition of health care operations to exclude those activities that could reasonably be conducted with de-identified information or that should require a valid authorization, the final version of the HITECH Act does not include this provision. This means that the Secretary is not directed to narrow the definition of health care operations, which includes numerous functions of covered entities, including quality assessment and improvement activities, care coordination, reviewing provider competence and qualifications, etc. However, as discussed, the Act does not tighten the definition of marketing and newly affords individuals the opportunity to opt out of fundraising. In a related provision, the U.S. Government Accountability Office is directed to report to Congress within one year of enactment on the use of electronic informed consent for disclosing protected health information for treatment, payment, and health care operations. This report must also examine best practices related to disclosures among health care providers of PHI for purposes of treatment.

⁵⁰ HITECH Act, § 13406(a)(1).

⁵¹ HITECH Act, § 13406(a)(2).

⁵² HITECH Act, § 13406(b).

⁵³ HITECH Act, § 13408.

nizations, the HITECH Act also revises and expands the penalties applicable when either HIPAA or these new requirements are violated. These organizations may now be penalized for violating any of these provisions due to willful neglect. Further, in place of the current penalty of \$100 per violation, the HITECH Act adds a new tiered-penalty structure based on the organization’s level of knowledge of the violation:

- In circumstances in which the entity did not know (and, by exercising reasonable diligence, would not have known) that it violated these provisions, the entity will be subject to a penalty of at least \$100 per violation, not to exceed \$25,000 per calendar year for all violations of an identical requirement or prohibition.
- If a violation is due to reasonable cause and not to willful neglect, the entity will be subject to a penalty of at least \$1,000 per violation, not to exceed \$100,000 per calendar year for all violations of an identical requirement or prohibition.
- If a violation is due to willful neglect and the failure to comply is corrected within 30 days of when the entity knew or should have known that the failure to comply occurred, the entity is subject to a penalty of \$10,000 per violation, not to exceed \$250,000 per calendar year for all violations of an identical requirement or prohibition.
- However, if the violation is due to willful neglect and the violation is not corrected within 30 days, the entity is subject to a penalty of at least \$50,000 per violation, not to exceed \$1.5 million per calendar year for all violations of an identical requirement or prohibition.⁵⁴

The HITECH Act also provides for enforcement by the State Attorneys General to enjoin further violation or obtain damages on behalf of the residents of the state in an amount equal to \$100 per violation (for a maximum of \$25,000 per year).⁵⁵

Miscellaneous Reports and Guidance

In addition, HHS must prepare reports to Congress concerning: (1) complaints of alleged violations of the provisions contained in the HITECH Act and in HIPAA, and (2) privacy and security requirements for entities that are not covered entities or business associates. HHS must also issue guidance on how best to implement requirements as well as issue guidance on how best to implement requirements for the de-identification of PHI.⁵⁶

Part III: FUNDING AND HIT INCENTIVES

The HITECH Act also contains funding for certain strategic health IT projects and incentive payments for physicians and hospitals designed to encourage the use of certified EHR systems.

General Investment in Infrastructure

The HITECH Act provides immediate funding to various federal agencies to invest in the infrastructure necessary to promote the electronic exchange and use of health information. In particular, the funding to federal agencies is to be used to support the following:

⁵⁴ HITECH Act, § 13410.

⁵⁵ HITECH Act, § 13410(e).

⁵⁶ HITECH Act, § 13424.

- health IT architecture that will support the nationwide electronic exchange and use of health information in a secure, private and accurate manner, including connecting health information exchanges;
- development and adoption of appropriate certified EHRs;
- training on and dissemination of information on best practices to integrate health IT into a provider's delivery of care;
- infrastructure and tools for the promotion of telemedicine;
- promotion of the interoperability of clinical data repositories or registries;
- promotion of technologies and best practices that enhance the protection of health information by all holders of individually identifiable health information; and
- improvement and expansion of the use of health IT by public health departments.⁵⁷

State Grants to Promote Health IT

HITECH requires HHS, acting through ONC, to establish a program to facilitate and expand the electronic movement and use of health IT among organizations according to nationally recognized standards. This program shall be administered through grants to states or qualified not-for-profit entities that are designated by the state. Possible activities to be funded by the grants include:

- enhancing broad and varied participation in the nationwide electronic use and exchange of health information;
- providing technical assistance for the development and dissemination of solutions to barriers to the exchange of electronic health information; and
- promoting the use of EHRs for quality improvement.⁵⁸

Beginning in 2011, states will be required to make available non-federal contributions towards the cost of the grant.⁵⁹ Prior to 2011, HHS may determine the extent to which there shall be required non-federal contributions from states receiving grants.

Loan Programs to Facilitate Adoption of Certified EHR Technology

Commencing Jan. 1, 2010, the National Coordinator may award grants to states or Indian tribes to establish loan programs for health care providers to be used to support the following activities:

- facilitating the purchase of certified EHR technology;
- enhancing the utilization of certified EHR technology;
- training personnel in the use of such technology; and
- improving the secure electronic exchange of health information.

⁵⁷ HITECH Act, § 13301 (to be codified at 42 U.S.C. § 3011).

⁵⁸ HITECH Act, § 13301 (to be codified at 42 U.S.C. § 3013).

⁵⁹ The non-federal contributions shall be in the following amounts: (a) in fiscal year 2011, at least \$1 for each \$10 of federal funds; (b) in fiscal year 2012, at least \$1 for each \$7 of federal funds; and (c) in fiscal year 2013 and each subsequent year, at least \$1 for each \$3 of federal funds. (HITECH Act, § 13301 (to be codified at 42 U.S.C. § 3013(i))).

States or Indian tribes are encouraged to establish a certified EHR technology loan fund (Loan Fund) to award loans or loan guarantees in accordance with a strategic plan that it submits to identify the intended uses of the Loan Fund. The state or Indian tribe must make available non-federal contributions in cash to the costs of carrying out the activities for which the grant is awarded in an amount equal to at least \$1 for each \$5 of federal funds provided under the grant.⁶⁰

Medicare Incentives

Incentives to Physicians. Commencing in 2011 and for the first five years, the Act will compensate physicians who are "meaningful EHR users" in an amount equal to an *additional* 75 percent of the allowed charge for professional services furnished by the physicians.⁶¹ The payments are capped, with maximum amounts being \$18,000 per year (for 2011 and 2012) and decreasing each year thereafter.⁶² No incentive payments will be made after 2016 and physicians for whom the first payment year is after 2014 receive no incentive payment.⁶³ Physicians who practice in an area that is designated as a health professional shortage area shall receive an additional 10 percent incentive.⁶⁴ Hospital-based physicians are not eligible for these incentives.⁶⁵

"Meaningful EHR users" are physicians who demonstrate to HHS that they are using certified EHR technology in a meaningful manner, including use of electronic prescribing; demonstrate that the certified EHR technology is connected in a manner that provides for the electronic exchange of health information to improve the quality of health care (consistent with law and standards); and will submit information to HHS on clinical-quality measures and other measures determined by HHS.⁶⁶

Beginning in 2015, unless the Secretary exempts a physician due to a significant hardship, physicians who are not meaningful EHR users will find their Medicare reimbursements reduced by 1 to 3 percent each year, with authority granted to HHS to reduce further the reimbursement rate beginning in 2018 if the proportion of eligible professionals who are meaningful EHR users is less than 75 percent.⁶⁷

Incentives to Physicians for Certain Medicare Advantage Organizations. Similarly, commencing in 2011, the same incentives and penalties will apply to eligible professionals of a qualified MA organization⁶⁸ who the organization attests to be meaningful EHR users. In this

⁶⁰ HITECH Act, § 13301 (to be codified at 42 U.S.C. § 3014).

⁶¹ HITECH Act, § 4101 (to be codified at 42 U.S.C. § 1395w-4 (o)(1)(A)(i)).

⁶² HITECH Act, § 4101 (to be codified at 42 U.S.C. § 1395w-4 (o)(1)(B)).

⁶³ HITECH Act, § 4101 (to be codified at 42 U.S.C. § 1395w-4 (o)(1)(A)(ii)); § 1395w-4 (o)(1)(B)(v)).

⁶⁴ HITECH Act, § 4101 (to be codified at 42 U.S.C. § 1395w-4 (o)(1)(B)(iv)).

⁶⁵ HITECH Act, § 4101 (to be codified at 42 U.S.C. § 1395w-4 (o)(1)(C)).

⁶⁶ HITECH Act, § 4101 (to be codified at 42 U.S.C. § 1395w-4 (o)(2)).

⁶⁷ HITECH Act, § 4101 (to be codified at 42 U.S.C. § 1395w-4 (o)(7)).

⁶⁸ A "qualifying MA organization" means a Medicare Advantage organization that is organized as a health maintenance organization.

case, eligible professionals are physicians who furnish, on average, at least 20 hours per week of patient-care services and who are either of the following:

- Employed by a qualifying MA organization
- Employed by, or are partners of, an entity that through contract with the MA organization furnishes at least 80 percent of the entity's Medicare patient care services to enrollees of such MA organizations, and who furnish at least 80 percent of the professional services of the eligible professional services to enrollees of the organizations⁶⁹

Incentives For Hospitals. Commencing in 2011 and for the first five years, the HITECH Act will compensate eligible hospitals that are "meaningful EHR users" by an amount calculated under a formula based on the proportion of Medicare patients. This formula is explained in detail in Appendix B. The incentives decrease each year after 2011. Hospitals that begin utilizing an EHR after 2013 have a lower rate of incentives and hospitals for which the first payment year is after 2015 receive no incentive payment.⁷⁰

For purposes of these incentives, "meaningful EHR users" are hospitals that can demonstrate to HHS that they are using certified EHR technology in a meaningful manner, that the certified EHR technology is connected in a manner that provides for the electronic exchange of health information to improve the quality of health care (consistent with law and standards), and that they will submit information to HHS on clinical quality measures and other measures determined by HHS.⁷¹

Beginning in 2015, hospitals that are not meaningful EHR users will find their Market Basket Adjustment percentage reduced (as described in Appendix B). In some cases, HHS may exempt hospitals from becoming meaningful EHR users if that requirement would result in a significant hardship, such as in the case of a hospital in a rural area without sufficient internet access. States are also required to adjust payments to each hospital in the state that is not a meaningful EHR user.⁷²

Incentives for Certain Eligible Hospitals Under Common Governance with MA Organizations. Similarly, commencing in 2011, the same incentives and penalties will apply to eligible hospitals of a qualified MA organization which the organization attests to be meaningful EHR users. An eligible hospital of a qualified MA organization is a hospital that is under common corporate governance with such organization and serves individuals enrolled under an MA plan offered by such organization.⁷³

Medicaid Incentives

States are also authorized to make payments to certain Medicaid providers to encourage the adoption and use of certified EHR technology. States may provide in-

⁶⁹ HITECH Act, § 4101 (to be codified at 42 U.S.C. § 1395w-23 (l)(2)).

⁷⁰ HITECH Act, § 4102 (to be codified at 42 U.S.C. § 1395ww (n)(2)(E)).

⁷¹ HITECH Act, § 4102 (to be codified at 42 U.S.C. 1395ww (n)(3)).

⁷² HITECH Act, § 4102 (to be codified at 42 U.S.C. 1395ww(b)(3)(B)).

⁷³ HITECH Act, § 4102 (to be codified at 42 U.S.C. 1395w-23 (m)(2)).

centives up to 85 percent of net average allowable costs⁷⁴ for certified EHR technology to eligible professionals (i.e., physicians, dentists, certified nurse midwives, nurse practitioners, and physician assistants insofar as the assistant is practicing in a rural health clinic that is led by a physician assistant or is practicing in a federally qualified health center that is so led):

- (i) Who are not hospital-based and for whom at least 30 percent of the professional's patient volume is attributable to individuals who are receiving medical assistance;
- (ii) Who are not described in (i), who are pediatricians, who are not hospital-based and for whom at least 20 percent of the professional's patient volume is attributable to individuals who are receiving medical assistance ("Medicaid Pediatricians");
- (iii) Who practice predominantly in a federally qualified health center or rural health clinic and for whom at least 30 percent of the professional's patient volume is attributable to needy individuals.⁷⁵

Incentives are capped at \$25,000 the first year (which may not be later than 2016), with a decreasing schedule thereafter. Medicaid Pediatricians are eligible for two-thirds of the amounts otherwise specified. No payments shall be made after 2021 or over a period of longer than 5 years.⁷⁶

Medicaid providers that may receive incentives in accordance with Appendix B include the following:

- (i) children's hospitals;
- (ii) acute-care hospitals that are not described in clause (i) and for which at least 10 percent of the hospital's patient volume is attributable to individuals who are receiving medical assistance.⁷⁷

In no case shall payments be made after 2016 and over a period of more than 6 years of payment.⁷⁸

CONCLUSION

The HITECH Act's multi-pronged approach should not be surprising to the health IT world. It represents a composite effort that marries efforts to support the development of state-based health IT infrastructure (with

⁷⁴ "Net average allowable costs" means average allowable costs reduced by any payment that is made to such Medicaid provider from any other source that is directly attributable to payment for certified EHR technology or support services. (HITECH Act, § 4201 (to be codified at 42 U.S.C. § 1396b (§ 1903(t)(3)(E))). "Average allowable costs" means, with respect to certified EHR technology for (i) the first year of payment, the average costs for the purchase and implementation or upgrade of such technology (and support services including training that is for, or is necessary for the adoption and initial operation of, such technology); and (ii) a subsequent year of payment, the average costs not described in clause (i) relating to the operation, maintenance and use of such technology for such providers. (HITECH Act, § 4201 (to be codified at 42 U.S.C. § 1396b (§ 1903(t)(3)(C))).

⁷⁵ HITECH Act, § 4201 (to be codified at 42 U.S.C. § 1396b (§ 1903(t))).

⁷⁶ HITECH Act, § 4201 (to be codified at 42 U.S.C. § 1396b (§ 1903(t)(4)(A))).

⁷⁷ HITECH Act, § 4201 (to be codified at 42 U.S.C. § 1396b (§ 1903(t))).

⁷⁸ HITECH Act, § 4201 (to be codified at 42 U.S.C. § 1396b (§ 1903(t)(4)(D))).

an emphasis on regional and local health information exchange to further patient care and quality) to Medicare and Medicaid funding (to incentivize providers to accelerate the implementation and use of EHRs), while enhancing or making more complex (depending on one's perspective) methods of protecting and securing health information. None of these concepts or implementation steps are new, and are, in part, natural extensions of both private and public efforts undertaken during the past three to five years to prepare the health care industry to expand its use of technology to improve quality of care and reduce costs.

While the HITECH Act appears to have been built on the experience of a variety of federal and state pilot projects focused on EHRs, health information exchange

and associated privacy/security considerations, the legislation properly recognizes the need for greater infrastructure and a more robust regulatory framework before the health care of all patients can be managed electronically in order to improve quality, reduce errors, and reduce cost.

The legislation is complex in parts, too simplistic in others, lacks detail in certain respects and presents uncertainties throughout. It is, however, a thoughtful attempt to direct a multi-constituent process, with funding to create a comprehensive effort to stimulate the modernization of the U.S. health care system—an investment that simultaneously reduces the cost of care while improving health outcomes.

APPENDIX A

Effective Dates of Provisions in HITECH

Topic	Section Reference	Effective Date	Implementing Regulations/Agency Guidance
Part I: Administrative Matters			
Office of the National Coordinator for Health Information Technology	§ 13101 (§ 3001 of Public Health Service Act (PHSA))	[None specified – presumably, effective immediately.]	<p>The National Coordinator will maintain and update a website with information on the work, schedules, reports, recommendations and other information to ensure transparency.</p> <p>No later than February 17, 2010, the National Coordinator will submit to Congress a report on any additional funding or authority required to evaluate and develop standards, implementation specifications and certification criteria.</p> <p>The National Coordinator will prepare a report that identifies lessons learned from major public and private health care systems in their implementation of health information technology.</p> <p>The National Coordinator will assess and publish the impact of health information technology in communities with health disparities and identify practices to increase the adoption of technology.</p> <p>The National Coordinator will evaluate and publish evidence on the benefits and costs of the electronic use and exchange of health information.</p> <p>The National Coordinator will estimate and publish resources required annually to reach the goal of utilization of an EHR by every person in the United States by 2014.</p>

Topic	Section Reference	Effective Date	Implementing Regulations/Agency Guidance
HIT Policy Committee	§ 13101 (§ 3002 of PHSA)	The HIT Policy Committee is established effective immediately. HHS will adopt policy standards on or before December 31, 2009.	HHS will publish the policy recommendations made by the HIT Policy Committee in the Federal Register and on the ONCHIT website. HHS will adopt an initial set of standards with respect to the areas that the HIT Policy Committee addresses on or before December 31, 2009.
HIT Standards Committee and Standards Setting	§ 13101 (§ 3003 of PHSA)	The HIT Standards Committee is established effective immediately.	HHS will publish the policy recommendations made by the HIT Standards Committee in the Federal Register and on the ONCHIT website.
Health IT Extension Program	§ 13001 (§ 3012 of PHSA)	[None specified – presumably, effective immediately.]	HHS will publish a draft description of the program for establishing regional centers by May 16, 2009.
Grants for Academic Programs	§ 13001 (§ 3011 of PHSA)	[None specified – presumably, effective immediately.]	No later than February 17, 2010, and annually thereafter, HHS will submit to Congress a report that describes the specific projects established under this section and contains recommendations for Congress based on the evaluation of the projects.
Privacy Education	§ 13403	No later than August 17, 2009.	HHS will designate an individual in each regional office of HHS to offer guidance and education on privacy and security requirements, no later than August 17, 2009. No later than February 17, 2010, OCR will develop and maintain a national education initiative to enhance public transparency regarding the uses of PHI.
Federal Promotion of Health IT	§ 13101 (§ 3002 of PHSA)	[None specified – presumably, effective immediately.]	[No regulations.]
Part II: Privacy and Security Matters			
Application of the HIPAA Security and Privacy Provisions to Business Associates	§ 13401 § 13404	February 17, 2010.	HHS will annually issue guidance on the most effective and appropriate technical safeguards for use with the security standards.

Topic	Section Reference	Effective Date	Implementing Regulations/Agency Guidance
Security Breach Notification Requirements for Covered Entities and Business Associates	§ 13402 § 13407	No later than September 15, 2009.	<p>HHS and FTC will promulgate interim final regulations no later than August 16, 2009.</p> <p>The security breach notification requirements will apply to breaches that are discovered on or after 30 days after the date of the publication of the regulations, which is no later than September 15, 2009.</p> <p>HHS regulations will apply to covered entities and business associates. FTC regulations will apply to vendors of PHRs, entities that offer products or services through the website of a vendor of PHRs and/or covered entities that offer individuals PHRs; and entities that access information in, or send information to, a PHR.</p> <p>By February 17, 2010, HHS and FTC must conduct a study and submit a report on recommendations for federal privacy and security requirements to apply to non-HIPAA covered entities, including PHR vendors.</p>
Restrictions on Certain Disclosures of Health Information: Out-of-Pocket Payment	§ 13405(a)	February 17, 2010.	[No regulations.]
Restrictions on Certain Disclosures of Health Information: Limited Data Set / Minimum Necessary	§ 13405(b)	February 17, 2010	This requirement sunsets once HHS issues guidance, due not later than August 17, 2010, as to what constitutes "minimum necessary."
Accounting of Disclosures	§ 13405(c)	<p>Covered entities that acquired an EHR on or before January 1, 2009 must comply by January 1, 2014.</p> <p>Covered entities that acquired an EHR after January 1, 2009, must comply by the later of January 1, 2011, or the date that it acquires an EHR.</p>	<p>HHS must promulgate regulations on what information must be collected about disclosures by June 30, 2010 (within six months of the date on which HHS adopts HIT technical standards for accounting of disclosures, December 31, 2009).</p> <p>These regulations will only require such information to be collected through an EHR in a manner that takes into account the interests of the individuals in learning the circumstances under which their PHI is being disclosed and the administrative burden of accounting for such disclosures.</p> <p>HHS may delay the compliance date for covered entities that acquired an EHR on or before January 1, 2009, until December 31, 2016, and those that acquired an EHR after January 1, 2009, until December 31, 2013.</p>

Topic	Section Reference	Effective Date	Implementing Regulations/Agency Guidance
Prohibition on Sale of EHRs or PHI	§ 13405	No later than February 17, 2011.	<p>HHS must develop regulations by August 17, 2010, to be effective six months after they are promulgated, which is no later than February 17, 2011.</p> <p>When developing these regulations, HHS is directed to evaluate the impact of the “price-charged” condition on the exceptions for both research and public-health activities.</p> <p>HHS may add the price-charged condition to the exception for public health activities if it determines that the condition will not impede such activities by August 17, 2010.</p>
Marketing and Fundraising	§ 13406	February 17, 2010.	[No regulations.]
Business Associate Contracts Required for RHIOs and other HIEs	§ 13408	February 17, 2010.	[No regulations.]
Penalties and Enforcement	§ 13409 § 13410	<p>The provisions concerning noncompliance due to willful neglect will be effective by February 17, 2011.</p> <p>The provisions concerning the tiered increase in amount of civil monetary penalties and the enforcement powers of the state attorneys general are effective immediately.</p>	<p>HHS will promulgate regulations concerning noncompliance due to willful neglect no later than August 17, 2010.</p> <p>No later than August 17, 2010., the GAO will submit a report to HHS which includes recommendations for a methodology under which an individual who is harmed may receive a percentage of any civil monetary penalty or monetary settlement collected. No later than February 17, 2012, HHS will promulgate related regulations.</p>
Education and Studies	§ 13424	No later than February 17, 2010.	<p>GAO must report to Congress by February 17, 2010 on the use of electronic informed consent for disclosing PHI for treatment, payment and health care operations.</p> <p>HHS must prepare a report to Congress concerning complaints of alleged violations of the provisions contained in the Stimulus Package and HIPAA annually beginning February 17, 2010.</p> <p>HHS must prepare a report to Congress concerning privacy and security requirements for non-covered entities no later than February 17, 2010.</p> <p>HHS must issue guidance on how best to implement requirements for the de-identification of PHI no later than February 17, 2010.</p>
Part III: Funding and HIT Incentives			
General Investment in Infrastructure	§ 13001 (§ 3011 of PHSA)	Effective immediately.	[No regulations.]
State Grants to Promote Health IT	§ 13001 (§ 3011 of PHSA)	[None specified – presumably, effective immediately.]	HHS will annually evaluate the grants made to states and implement the lessons learned to subsequent awards.

Topic	Section Reference	Effective Date	Implementing Regulations/Agency Guidance
Loan Programs to Facilitate Adoption of Certified EHR Technology	§ 13001 (§ 3014 of PHSA)	An award will not be made prior to January 1, 2010.	The National Coordinator will publish guidance and promulgate regulations to ensure that each eligible entity commits and expends funds allotted to the entity as efficiently as possible and to prevent waste, fraud and abuse.
Medicare Incentives	§ 4101- § 4104	Incentive payment will become available in 2011.	No later than June 17, 2009, HHS will submit a report to Congress on the findings and conclusions of a study to the extent to which payment incentives could be made available to professionals who are not eligible for HIT incentive payments and serve Medicare patients. HHS will post on its website a list of names of eligible hospitals and professionals that are meaningful EHR users.
Medicaid Incentives	§ 4201	For purposes of carrying out this section, the bill appropriates to CMS \$40 million for each year between FY 2009 and FY 2015 and \$20 million for FY 2016.	HHS will periodically submit reports to Congress on the status, progress and oversight of payments. These reports will also describe the extent of adoption of certified EHRs among Medicaid providers and any improvement in health outcomes, clinical quality or efficiency resulting from such adoption.

APPENDIX B

Formula for Calculating Hospital Incentives

The formula is equal to the product of the following: (a) Initial Amount; (b) Medicare Share; (c) Transition Factor.⁷⁹ Each is defined as follows:

- The “Initial Amount” means the sum of \$2,000,000 plus the Discharge-Related Amount for the 12 month period selected by HHS with respect to such payment year. The “Discharge-Related Amount” means the sum of the amount for each discharge during a 12 month period up to the 23,000th discharge as follows: (i) first through 1,149th discharge, \$0; (ii) 1,150th through 23,000th discharge, \$200; and (iii) for any discharge greater than the 23,000th, \$0.⁸⁰
- The “Medicare Share” means the following fraction, where
 - (i) the *numerator* is the *sum* of (A) estimated inpatient-bed days which are attributable to individuals with respect to whom payment may be made under Part A; and (B) the estimated number of inpatient-bed-days which are attributable to individuals who are enrolled with a Medicare Advantage organization under Part C
 - (ii) the *denominator* is the *product* of (A) the estimated total number of inpatient bed days; and (B)(I) the estimated total amount of charges minus charges that are attributable to charity

⁷⁹ HITECH Act, § 4102 (to be codified at 42 U.S.C. § 1395ww (n)(2)).

⁸⁰ HITECH Act, § 4102 (to be codified at 42 U.S.C. 1395ww (n)(2)(B) – (C)).

care, divided by (II) the estimated total amount of the hospital’s charges.⁸¹

- The “Transition Factor” means for the first payment year, 1.0; for the second payment year, $\frac{3}{4}$; for the third payment year, $\frac{1}{2}$; for the fourth payment year, $\frac{1}{4}$; and for any succeeding payment year, 0.⁸²

Formula for Reducing Reimbursements for Hospitals Beginning 2015

Three-quarters of the Market Basket Adjustment percentage increase otherwise applicable for such fiscal year shall be reduced by 33-1/3 percent for fiscal year 2015, 66-2/3 percent for fiscal year 2016 and 100 percent for fiscal year 2017.⁸³

Formula for Calculating Medicaid Incentives for Children’s Hospitals or Acute Care Hospitals

These incentives are capped in the aggregate as the product of the overall Hospital EHR Amount and the Medicaid Share. This amount shall be capped at 50 percent of such product any year; and capped at 90 percent of such product in any two-year period.

- The “Hospital EHR Amount” is the sum of the amount specified for an eligible hospital under the Medicare incentives, determined as if the Medicare Share were 1. The HITECH Act also provides guidance for calculating the Discharge-Related Amount.

⁸¹ HITECH Act, § 4102 (to be codified at 42 U.S.C. 1395ww(n)(2)(D)).

⁸² HITECH Act, § 4102 (to be codified at 42 U.S.C. 1395ww (n)(2)(E)).

⁸³ HITECH Act, § 4102 (to be codified at 42 U.S.C. 1395ww(b)(3)(B)(ix)(I)).

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- The “Medicaid Share” is calculated in the same manner as the Medicare Share for such a hospital, except that the numerator shall take into account the estimated inpatient-bed-days that are attribut-

able to individuals who are receiving medical assistance rather than who are enrolled in Medicare.⁸⁴

⁸⁴ HITECH Act, § 4201 (to be codified at 42 U.S.C. 1396b).