

**The Hon. Pete Stark, Chairman, Committee on Ways and Means,
Subcommittee on Health**

SECTION-BY-SECTION ANALYSIS

“The Health-e Information Technology Act of 2008”

TITLE 1—PROMOTION OF HEALTH INFORMATION TECHNOLOGY

Subtitle A—Improving Health Care Quality, Safety, and Efficiency

Sec. 101. ONCHIT; standards development and adoption; health information technology resource center.

Section 3000. Definitions. These provisions define key terms related to the promotion of health information technologies.

Section 3001. Office of the National Coordinator for Health Information Technology. The Office of the National Coordinator of Health Information Technology (ONCHIT), which was originally created by Executive Order 13335, is codified into statute within the U.S. Department of Health and Human Services (HHS). The head of ONCHIT (the National Coordinator) will lead the efforts for the development of policies and recognition of standards to allow for the secure electronic exchange of health information that leads to improvements in the quality of clinical care.

The National Coordinator is charged with the following duties:

- Within 12 months, develop and maintain a strategic plan on how to achieve widespread adoption and use of interoperable, secure, and clinically useful electronic health records. The National Coordinator is required to annually evaluate and publicly report on progress toward achieving these goals, barriers to access to technology, and the benefits and costs of health information technology including in medically underserved communities.
- Recommend standards and guidance to the Secretary to ensure interoperability, security/privacy, and clinical utility of electronic health information. Such recommendations will be developed with input from the HIT Advisory Committee and should be consistent with the strategic plan.
- Develop a program for the voluntary certification of products as meeting the standards adopted by the Secretary for the secure electronic exchange of health information.

- Coordinate the development of an open source health information technology system that will be certified as meeting all relevant standards for the secure electronic exchange of health information. Such system will be available to providers for a nominal fee within nine months of the adoption of an initial set of standards.
- Ensure the development of a nationwide health information network through the expansion and coordination of sub-national health information organizations.

Funding is authorized annually for appropriations for fiscal years 2009 through 2013 for these purposes.

In addition to the amounts authorized for appropriations, there shall be 1 percent transferred from amounts appropriated for purposes of health IT to other agencies within HHS to the Office of the National Coordinator to promote collaboration.

Section 3002. HIT Advisory Committee. Establishes a federal advisory committee of public and private stakeholders to provide input and assistance to the National Coordinator. The HIT Advisory Committee will serve as a forum for input and expertise in the area of health information technology. The HIT Advisory Committee will provide advice and make recommendations to the National Coordinator on how best to promote interoperability, privacy and security, and clinical utility of electronic health information.

Section 3003-3005. Process for adoption of recommended standards and guidance; Application and use of adopted standards and implementation specifications by Federal agencies; Voluntary application and use of adopted standards and implementation specifications by private entities. Directs the Secretary, in consultation with other relevant agencies, to review standards and guidance and, where appropriate, provide for adoption by the Government through a rulemaking process. These standards would not be binding on private entities, but may be voluntarily adopted. Also directs the Secretary to adopt through rulemaking an initial set of standards for interoperability, privacy and security, and clinical utility no later than September 30, 2011.

Section 3006. Health Information Technology Resource Center. Directs the National Coordinator to establish a HIT Resource Center to provide technical assistance, develop best practices, and serve as a forum for the exchange of knowledge and experience with regard to the adoption of HIT.

Sec. 102. Transitions. Provides for transitions to allow for the development and harmonization of standards currently taking place to continue to occur as ONCHIT is codified and the functions of the current AHIC are subsumed by the HIT Policy and Standards Committees.

SUBTITLE B—Application and Use of Adopted Health Information Technology Standards; Reports

Sec. 111. Coordination of Federal activities with adopted standards. Requires that Federal agencies implementing, acquiring, or upgrading HIT systems for the electronic exchange of identifiable health information use HIT products meeting standards adopted by the Secretary of HHS in accordance with this bill. It also requires that the President ensure that Federal activities involving the collection and submission of health information be consistent with standards established under this bill for the electronic exchange of health information.

Sec. 112. Application to private entities. Requires that private entities contracting with the Federal Government to carry out health activities adopt the standards established under this bill for the electronic exchange of health information.

Sec. 113. Reports. Requires the Secretary to submit an annual report to Congress on the efforts toward, and barriers to, facilitating the electronic exchange of health information nationwide. It also requires the Secretary to study methods to create efficient reimbursement incentives for improving healthcare quality in Federally-qualified health centers, rural health clinics, and free clinics.

TITLE II—TESTING OF HEALTH INFORMATION TECHNOLOGY

Sec. 201. National Institute for Standards and Technology testing. Requires that the National Institute for Standards and Technology (NIST) work in coordination with the Office of the National Coordinator to test standards. These are standards being developed or recognized for the electronic exchange of health information by the Office of National Coordinator. It additionally requires the director of NIST in coordination with the Office of the National Coordinator to support the establishment of accredited testing laboratories for the voluntary testing of products for certification by the National Coordinator that they meet standards for the electronic exchange of information.

TITLE III—INCENTIVES FOR ADOPTION OF HEALTH INFORMATION TECHNOLOGY

SUBTITLE A—Medicare Program

Sec. 301. Incentive Payments for Eligible Professionals. Provides incentive payments to certain physicians who adopt and utilize a certified electronic medical record system. Following the availability of the open source electronic health record system developed by HHS, but no later than 2013, physicians who demonstrate they have adopted a certified health IT system are eligible for incentive payments through Part B of the Medicare program.

In order to receive the incentive payments, physicians must bill under the physician fee schedule and demonstrate that they are utilizing the clinical functions of an approved health IT system. The Secretary may pro-rate the incentive payment for physicians that are meaningful HIT users for a portion of the year. The incentive payments are phased out over five years. Medicare payments are then reduced by a percent of allowed charges for any physician who is not utilizing a certified system by 2016.

GAO shall conduct a study to determine the extent to which payment incentives and other funding for health IT adoption should be made available to health care providers that are receiving minimal or no payments under this Act, titles XVIII or XIX of the Social Security Act, or otherwise.

Sec. 302. Incentive Payments for Hospitals. Provides incentive payments to Section 1886(d) hospitals that adopt and utilize a certified electronic medical record system. By the first fiscal year after the open source electronic health record system developed by HHS is available, but no later than 2013, hospitals that demonstrate they have adopted and are utilizing an approved health IT system are eligible to receive incentive payments through Part A of the Medicare program. Meaningful users of health IT are those hospitals that demonstrate they are utilizing the clinical functions of a certified health information technology consistent with standards set by the Secretary.

All hospitals that meet the standards for meaningful HIT user receive a base payment. Hospitals receive additional payments based on total discharges, at a declining rate per discharge, up to a maximum number of discharges. All payments are adjusted by Medicare share, taking into account the level of charity care provided by the hospital. The Secretary may pro-rate the incentive payment for hospitals that are a meaningful HIT user for a portion of the year. The incentive payments are phased out over three years, and the market basket update is reduced for any eligible hospital that has not adopted a certified system by 2016. Hospitals that are under common corporate governance with a Medicare Advantage plan are eligible for incentive payments.

GAO shall conduct a study to determine the extent to which payment incentives and other funding for HIT adoption should be made available to health care settings that are receiving minimal or no payments under this Act, titles XVIII or XIX of the Social Security Act, or otherwise.

Sec. 303. Incentive Payments for Certain Medicare Advantage Plans. Provides incentive payments to certain Medicare Advantage plans that adopt and utilize a certified electronic medical record. Only closed network or staff model plans whose Medicare providers would otherwise not receive payments are eligible for the payments. Once the open source electronic health record system developed by HHS is available, but no later than 2013, plans that demonstrate they have adopted and are utilizing an approved electronic health record system are eligible to receive incentive payments. Incentive payments will be phased out over time, and payments will be reduced for these plans that have not adopted a certified system by 2016.

SUBTITLE B—Other Incentives for the Implementation and Use of Health Information Technology

Sec. 311. Grant, loan, and demonstration programs.

Section 3011. Grants and loans to facilitate the widespread adoption of qualified health information technology. Incentivizes the widespread adoption and use of

electronic health records through the creation of three separate competitive grant programs.

The first grant program offers matching funds to eligible healthcare providers for the purchase of qualified health information technology. Preferences in awarding the grants is given to providers who serve low-income areas, rural areas, and medically underserved areas, as well as non-profit facilities, and providers who receive little or no Medicare incentives.

The second competitive grant program offers funds to States and Indian Tribes to develop loan programs that will leverage private-sector funds to provide low interest loans to healthcare providers to purchase health information technology as described above.

The third grant program provides support for local or regional organizations to develop health information technology plans. These plans must provide for the exchange of health information among physicians, pharmacies, hospitals, health centers, health plans, and others within a given region.

Preference in awarding these grants will be given to small healthcare providers, those in medically underserved or rural areas, and others who may have difficulty acquiring electronic health records on their own.

\$115 million is authorized for appropriations each year through fiscal year 2013 for these grants.

Section 3012. Demonstration program to integrate information technology into clinical education. Creates a demonstration program to integrate HIT into the clinical education of healthcare professionals with an authorization of appropriation of \$10 million for fiscal years 2009-2011. Funding will be offered on a competitive basis to healthcare educational institutions to provide for training on the use of HIT that promotes quality of care.

TITLE IV—PRIVACY AND SECURITY PROVISIONS

Section 400. Definitions. These provisions define key terms related to the privacy and security provisions of this bill.

Subtitle A—Improved Privacy Provisions and Security Provisions

Section 401. Application of security provisions and penalties to business associates of covered entities; annual guidance on security provisions. Requires that security safeguards promulgated pursuant to Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the penalties for violation of those safeguards apply to business associates under HIPAA (see note below) in the same manner as applied to covered entities. This provision also requires that the Secretary, in consultation with stakeholders, annually issue guidance on the latest privacy and security safeguard technologies for protecting information. [NOTE: Covered entities are

defined as providers, such as physicians, health plans and healthcare clearinghouses, such as claims processors. Business associates are entities that assist covered entities with particular routine business functions, including quality efforts.]

Section 402. Notification in the case of breach. Requires that, in the case of a breach of unsecured Protected Health Information (PHI), a covered entity must notify each individual whose information has been, or is reasonably believed to have been, breached. In the case of a breach of unsecured PHI that is under the control of a business associate, that business associate is required to notify the covered entity. All breach notifications must be made without unreasonable delay and no later than 60 calendar days after discovery. The provision provides instruction for the required methods by which an individual must be notified and the content of the notification. However, this notification may be delayed if it could impede a criminal investigation or damage national security.

The Secretary is also required to issue guidance within 60 days, and annually thereafter, as to the technologies or methodologies that meet the standard of making information secure (i.e. unusable, unreadable, or indecipherable). If the Secretary fails to issue guidance within 60 days, PHI will be considered secure if it is protected by technology standards developed or endorsed by a standards developing organization that is accredited by the American National Standards Institute (ANSI).

Finally, the Secretary is required each year to compile and analyze the number and nature of breaches reported to the Secretary and issue a report to Congress concerning the scope of the problem and steps that have or will be taken to address it at a Federal level and through guidance on best practices for covered entities and business associates.

Section 403. Education on Health Information Privacy and report on compliance. Requires that the Secretary designate an individual in each regional HHS office to offer education and guidance on privacy requirements regarding PHI. It requires that the Secretary annually report to Congress on the number and nature of complaints of alleged violation and how they were resolved, including the imposition and amount of civil money penalties; the number of covered entities receiving technical assistance from the Secretary in order to achieve compliance, as well as the types of technical assistance provided. Finally, the provision requires that HHS implement an education program to enhance public transparency regarding the uses of health information.

Section 404. Application of penalties to business associates of covered entities for violations of privacy contract requirements. Requires that the penalties for violating the business associate contract standard in the HIPAA Privacy Rule apply to business associates under HIPAA in the same manner as applied to covered entities.

Section 405. Restrictions on certain uses and disclosures of health information; accounting of certain protected health information disclosures; access to certain information in electronic format. Permits a patient to request that their PHI regarding a specific healthcare item or service not be disclosed by a covered entity to a health plan for purposes of payment or healthcare operations, unless otherwise required by law, if that patient has paid in full out-of-

pocket for that item or service. In such a circumstance, the covered entity is required to honor the patient's request.

While the use, request, and disclosure of de-identified data is encouraged when practicable, this provision allows for the disclosure of PHI as long it is limited to the minimum necessary for a given purpose. This provision also deems the use, disclosure, or request of a 'limited data set' of information as defined in regulation to fulfill the minimum necessary requirement until such time as the Secretary issues guidance or regulations to the contrary.

This provision also clarifies that in the event of disagreement, the entity which holds the PHI—rather than the entity requesting the PHI—retains the discretion to make its own minimum necessary determination, in a manner that is consistent with and does not override professional judgment.

The provision also gives an individual the right to request an accounting of disclosures of PHI made by a covered entity or business associate to another party for treatment, payment, and health care operations in the three years prior to the request if that entity is utilizing an electronic medical record or electronic health record. Covered entities would not be required to make an accounting for uses of PHI or oral disclosures of such information.

Additionally, this provision clarifies that certain uses and disclosures of PHI are not permitted without a valid authorization, such as the sale of PHI (except to recoup the costs associated with preparing data for public health and research purposes) and the unauthorized re-identification of de-identified data or the limited data set.

This provision also gives individuals the right to receive electronic copies of their PHI used or maintained by a covered entity in electronic format and without charge if the entity uses an electronic medical record or electronic health record.

Finally, this provision authorizes the Secretary to revise the timeframes and deadlines by which covered entities will be required to act when individuals request amendments to their PHI maintained in an electronic medical record or electronic health record.

Section 406. Limitations on certain activities as part of health care operations. Clarifies the definition of health care operations under HIPAA by limiting the conditions under which marketing is considered a health care operation, and precluding fundraising and direct payment to covered entities for the use of PHI to make certain communications without valid authorization. This provision also requires the Secretary to promulgate regulations to eliminate from the definition of health care operations those activities that can reasonably and efficiently be conducted through the use of de-identified data or that should require a valid authorization for use and disclosure. Finally, this provision clarifies that treatment cannot be conditioned on the provision of a valid authorization for these activities.

Section 407. Study on application of privacy and security requirements to vendors of personal health records. Requires the Secretary, in consultation with the Federal Trade Commission (FTC) to conduct a study on the privacy and security requirements for vendors of personal health records and submit its findings to Congress regarding: (1) the requirements relating to security, privacy, and notification in the case of a breach of PHI, including the

applicability of an exemption to notification in the case of PHI that has been rendered indecipherable through the use of encryption or alternative technologies, with respect to personal health record vendors; (2) the Federal agency best equipped to enforce those requirements; and (3) a timeframe for when these requirements will be implemented by such agency through rulemaking.

Section 408. Temporary breach notification requirement for vendors of personal health records. In the case that an individual's unsecured personal health record (PHR) identifiable health information is breached, requires that PHR vendors notify that individual along with the FTC. The provision requires that the notification requirements applicable to covered entities under section 302 of this bill be applied to notifications required under this section and that FTC notify HHS of breach notices received by FTC. The provision gives the FTC enforcement authority regarding breaches of health information maintained by PHR vendors. The provision sunsets when either HHS or FTC adopt privacy and security standards specific to PHRs and other non-HIPAA covered entities and those standards take effect.

Section 409. Requirements regarding business associates. Requires organizations such as Health Information Exchanges, Regional Health Information Organizations, E-prescribing Gateways, and vendors of PHRs who have entered into contracts with covered entities to have business associate contracts. It also specifies that covered entities will be subject to civil monetary penalties if the Office for Civil Rights (OCR) within the Department of Health and Human Services (HHS) determines that they reasonably should have known of a business associate's pattern of activity or practice not in compliance with the terms of the contract and did not take the actions required under regulation to address it.

Section 410. Guidance on implementation specification to de-identify protected health information. Requires the Secretary, in consultation with stakeholders, to issue guidance on how to best implement regulatory requirements for the de-identification of PHI.

Section 411. GAO report on treatment, payment, and health care operations uses and disclosures. Directs GAO to submit a report to Congress on best practices related to the disclosure of PHI among health care providers for the purposes of treatment and best practices for determining the minimum necessary set of PHI for the purposes of the most common payment and health care operations, including recommendations on which healthcare operations can be accomplished with de-identified data .

Section 412. Clarification of application of wrongful disclosures criminal penalties. Clarifies that criminal penalties for violations of HIPAA can be applied directly to individuals, whether they are employees of covered entities or have no relationship to covered entities.

Section 413. Improved enforcement. Improves enforcement of the Federal health privacy law by the OCR at HHS by requiring a formal investigation of complaints and the imposition of civil monetary penalties for violations that rise to the level of willful neglect or other violations that are not corrected within 30 days. The provision also increases the amount of civil monetary penalties and authorizes a percentage of the penalty to accrue to the individual(s) harmed and the

OCR, through the application of a methodology to be developed by the GAO and adopted by the Secretary.

Preserves OCR's current tools for informal resolution, technical assistance, and correction within 30 days without the imposition of a penalty in situations where the violation was due to a reasonable cause. Currently, all complaints and violations can be handled informally and without the imposition of civil monetary penalties.

In addition, this provision permits OCR to pursue an investigation and the imposition of civil monetary penalties against any individual for an alleged criminal violation of the Federal health privacy law if the Department of Justice has not prosecuted the individual.

Finally, this provision authorizes the state attorneys general to enforce Federal privacy and security laws.

Section 414. Audits. Directs the Secretary to perform periodic audits to oversee compliance with the privacy and security provisions.

Subtitle B—Chief Privacy Officer; Standards and Guidance Recommendations Related to Privacy and Security

Section 421. Chief Privacy Officer of the Office of the National Coordinator. To ensure coordinated and comprehensive development and oversight of privacy and security policies across the federal government, this provision requires the Secretary to appoint a chief privacy officer within ONC and designate chief privacy officers within HHS agencies to assist the National Coordinator in carrying out all duties relating to the privacy and security of health information. This provision also encourages the ONC Chief Privacy Officer to consult with officials in other Federal agencies who have primary responsibility relating to the privacy and security issues.

Section 422. Additional standards and guidance recommendations related to privacy and security. Requires the ONC to institute an ongoing process whereby standards and guidance related to ensuring the privacy and security of health information are continually recommended to the Secretary and periodically updated, as necessary, to keep pace with issues that emerge as the electronic health care marketplace evolves.

Subtitle C—Relationship to Other Laws; Regulatory References; Effective Date

Section 431. Relationship to other laws. Applies the preemption in Section 1178 of the Social Security Act to the provisions of title IV of this bill and preserves the HIPAA and the regulations promulgated pursuant to that Act to the extent that they are consistent with Title IV of this bill.

Section 433. Effective date. With the exception of certain specified provisions, this bill shall become effective 12 months after the date of enactment of this Act.