

SECTION-BY-SECTION ANALYSIS

H.R. 6357, THE “PROTECTING RECORDS, OPTIMIZING TREATMENT, AND EASING COMMUNICATION THROUGH HEALTHCARE TECHNOLOGY ACT OF 2008”

Sec. 1. Short title; table of contents. Establishes the short title of H.R. [_____] as the “Protecting Records, Optimizing Treatment, and Easing Communication through Healthcare Technology Act of 2008” or the “PRO(TECH)T Act of 2008” and provides the table of contents of this Act.

TITLE I—HEALTH INFORMATION TECHNOLOGY

Subtitle A—Promotion of Health Information Technology

PART 1—IMPROVING HEALTH CARE QUALITY, SAFETY, AND EFFICIENCY

Section 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 technology.

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.

The National Coordinator is required to maintain and update the strategic plan on how to achieve these goals. The plan should include steps to encourage the utilization of an electronic health record for each person in the United States by 2014 and ensure the incorporation of adequate privacy and security protections into those electronic records. The National Coordinator is additionally charged with evaluating and reporting on progress toward these goals, barriers to access to technology, and the benefits and costs of health information technology including in medically underserved communities.

The National Coordinator shall develop a program for the voluntary certification of products as meeting the standards developed for the secure electronic exchange of health information.

\$66 million is authorized for appropriations for fiscal year 2009 for these purposes.

Section 3002. HIT Policy Committee. Establishes a federal advisory committee of public and private stakeholders to provide input and assistance to the National Coordinator. The HIT Policy Committee recommends a policy framework and prioritizes the technical standards necessary for the development of an HIT infrastructure towards the goal of having electronic health records for every American by 2014. The HIT Policy Committee must consider technologies and standards that protect the privacy and promote the security of health information. Their recommendations will then be forwarded to the HIT Standards Committee, a technical advisory committee.

Section 3003. HIT Standards Committee. Establishes a second federal advisory committee of public and private stakeholders to develop, recognize, or harmonize the technical standards necessary for the secure electronic exchange of health information.

Section 3004-3006. Process for adoption of endorsed recommendations; 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, 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.

Section 3007. 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.

PART 2—APPLICATION AND USE OF ADOPTED HEALTH INFORMATION TECHNOLOGY STANDARDS; REPORTS

Sec. 111. Coordination of Federal activities with adopted standards and implementation specifications. 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 Government 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.

Subtitle B—Incentives for the Use of Health Information Technology

Sec. 121. 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.

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 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) to work in coordination with the HIT Standards Committee to test technical standards. These are standards being developed or recognized for the electronic exchange of health information by the HIT Standards Committee. It additionally requires the director of NIST in coordination with the HIT Standards Committee 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.

Section 202. Research and development programs. Requires that the Director of NIST, in consultation with the Director of the National Science Foundation and other appropriate Federal agencies, to award competitive grants to institutes of higher education to research innovative approaches for the use of HIT in the delivery of health care. Additionally, it directs the National High-Performance Computing Program, created by the High Performance Computing Act of 1991, to coordinate Federal research and programs related to the development and deployment of HIT.

TITLE III—PRIVACY AND SECURITY PROVISIONS

Section 300. Definitions. These provisions define key terms related to the privacy and security provisions of this bill.

Subtitle A—Security Provisions

Section 301. Application of security provisions and penalties to business associates of covered entities; annual guidance on security provisions. This provision 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 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 302. Notification in the case of breach. This provision requires that, in the case of a breach of unencrypted 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 unencrypted 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.

Finally, the provision provides that this notification may be delayed if it could impede a criminal investigation or damage national security.

Section 303. Education on Health Information Privacy and report on compliance.

The provision 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 complaints of alleged violations. Finally, the provision requires that HHS implement an education program to enhance public transparency regarding the uses of health information.

Subtitle B—Improved Privacy Provisions and Additional Security Provisions

Section 311. Application of penalties to business associates of covered entities for violations of privacy contract requirements. The provision 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 312 Restrictions on certain disclosures of health information; accounting of certain protected health information disclosures. The provision 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.

The provision also requires covered entities to make reasonable effort to restrict the use, disclosure, or request of PHI to a 'limited data set' of information as defined in regulation. If the limited data set is insufficient, the covered entity must restrict the use, disclosure, or request of PHI to the minimum necessary to achieve the purpose. The provision also gives an individual the right to request an accounting of disclosures of PHI made by a covered entity to another party for treatment, payment, and health care operations in the six years prior to the request if that entity is utilizing an electronic medical record. Covered entities would not be required to make an accounting for uses of PHI or oral disclosures of such information.

Finally, this provision requires that a health care provider receive a patient's consent to use or disclose their protected health information for health care operations if that provider is utilizing an electronic medical record.

Section 313. Conditions on certain contacts as part of health care operations. The provision clarifies the definition of marketing under HIPAA and precludes direct payment to covered entities for the use of PHI to make certain communications.

Section 314. Study on application of privacy and security requirements to vendors of personal health records. The provision requires the Secretary, in consultation with the Federal Trade Commission (FTC) to submit recommendations to Congress regarding:

(1) the requirements relating to security, privacy, and notification in the case of a breach of protected health information, 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; and (2) the Federal agency best equipped to enforce those requirements.

Section 315. Temporary breach notification requirement for vendors of personal health records. In the case that an individual's unencrypted identifiable health information is breached, the provision requires that personal health record (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 two years after enactment of this bill.

Section 316. Business associate contracts required for certain entities. The provision requires organizations such as Health Information Exchanges, Regional Health Information Organizations, or E-prescribing Gateways to have business associate contracts.

Section 317. Guidance on implementation specification to de-identify protected health information. The provision requires the Secretary, in consultation with stakeholders, to issue guidance on how to best implement regulatory requirements for the de-identification of PHI.

Section 318. GAO report on treatment disclosures. The provision 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.

Section 319. Clarification of application of wrongful disclosures criminal penalties. The provision clarifies that criminal penalties for violations of HIPAA can be applied directly to individuals.

Subtitle C—Relationship to Other Laws; Clarification; Effective Date

Section 321. Relationship to other laws. The provision applies the preemption in Section 1178 of the Social Security Act to the provisions of title III of this bill and preserves the HIPAA and the regulations promulgated pursuant to that Act to the extent that they are consistent with Title III of this bill.

Section 322. Effective date. With the exception of certain specified provisions, this bill shall become effective 12 months after the date of enactment of this Act.