

## The Protecting Records, Optimizing Treatment, and Easing Communication through Healthcare Technology Act of 2008 (PROTECH [T] Act - HR 6357)

Introduced on June 24, 2008, by House Energy and Commerce Committee Chair John Dingell (D-MI-15) with 12 bi-partisan co-sponsors, the PRO(TECH)T Act is intended to strengthen the quality of healthcare, reduce medical errors and costs by encouraging the adoption of health information technology (HIT), and further protect the privacy and security of health information in the electronic age. The Energy and Commerce Health Subcommittee approved HR 6357 on June 25 and full Committee approval followed on July 23. However, passage of health IT legislation this year is unlikely, given limited legislative time remaining, yet-to-occur action by the House Ways and Means Committee that has jurisdiction over portions of the IT issue and failure of the Senate to act thus far on Committee-approved legislation. This bill is a likely starting point in the 111<sup>th</sup> Congress for health IT legislation and its role in the overall healthcare reform debate. The paragraphs below highlight key provisions of HR 6357 and comment on the implications for CIOs.

### I. Promotion of Health Information Technology

#### ***Office of the National Coordinator for Health Information Technology (ONC).***

Originally created by Executive Order #13335 in April 2004, this office has functioned as a national focal point for advancement of health IT. To assure continuation of this effort, HR 6357 establishes in law a Federal HIT office within the U.S. Department of Health and Human Services (HHS) with leadership by the National Coordinator.

ONC has responsibility to:

- Assure the development of standards, such as interoperability;
- Coordinate HIT policy and programs within DHHS;
- Maintain and update the health IT strategic plan to include the 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; and
- Develop a program for the voluntary certification of products as meeting the standards developed for the secure electronic exchange of health information.

***Comment.*** Within the role of the National Coordinator, the bill calls for collaboration with many of the same public/private partners that are currently working together. It is unclear, however, how the work of current partners (American Health Information Community/AHIC, AHIC Successor organization/AHIC 2.0, Health Information Technology Standards Panel/HITSP, and Commission on the Certification of HIT/CCHIT) would integrate with the new strategic planning process to enable reporting of overall national progress to achieve the mutual goal of a nationwide interoperable health information technology infrastructure.

Establishing a national focal point for the advancement of health IT through legislation recognizes the critical need of having one agency function as the authority on standards. Current differences across States and conflicting definitions and requirements of Federal and State programs act as disincentives, add to the costs of and discourage health IT adoption

by providers.

***HIT Policy and Standards Committees.*** The PRO(TECH)T Act establishes two federal advisory bodies to assist ONC. The role of the HIT Policy Committee of public and private stakeholders is to recommend a policy framework and prioritize the technical standards necessary for the development of an HIT infrastructure as well as recommend standards to protect the privacy and security of health information. Second, the Act establishes a 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.

***Comment.*** The role of AHIC, AHIC 2.0, HITSP and CCHIT in these new committee structures is unclear. For example, HR 6357 states that no new entities are required and consistency with the current AHIC is recommended, yet it is not apparent which working partnership will be considered the “authority and voice.” Currently, AHIC 2.0, HITSP and CCHIT have strong working relationships with industry, government and consumers. Trust has been established and products are being delivered, including standards that best serve the needs of the federal government. While the two proposed new Federal Advisory Committee Act (FACA) committees require greater involvement of Congress and the Federal Government in their establishment and work, the current structure appears to be working. Changing this structure may not necessarily produce better results.

***Process for Adoption of Endorsed Recommendations by Federal Agencies and Private Entities.*** After receipt of recommended standards, implementation specifications or certification criteria, the Secretary has 90 days to call for adoption by the Government through a rulemaking process. Private entities may adopt standards voluntarily.

***Comment.*** This provision raises several questions including whether or not this timeframe is consistent with the current review and adoption process used by HITSP. Second, AHIC 2.0 may address future standards development and adoption that may be a priority for the private sector, while currently standards are selected based on Government priorities.

***Health Information Technology Resource Center.*** The National Coordinator is directed 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.

***Comment.*** At present the Center is operated by the Agency for Healthcare Research and Quality (AHRQ) through a contract. The proposed Health Information Technology Resource Center will serve as a valuable national resource for information, resource exchange and technical assistance. Establishing the Center as a matter of law will continue its value as a learning community for HIT adoption and utilization. Assistance to underserved communities should be added as an area of focus as a means to expand the knowledge base of this critical constituency.

***Transitions.*** The legislation recognizes that a transition is needed to allow for the development and harmonization of standards currently taking place once ONC is codified and the current AHIC is subsumed by the HIT Policy and Standards Committees.

***Comment.*** A clear articulation on how the transition takes place is not indicated. To address this issue, the PRO(TECH)T Act should provide for formal acceptance of current AHIC recommendations by the HIT Standards Committee.

***Use of Adopted Health Information Technology Standards for Public and Private Sectors.*** When implementing, acquiring, or upgrading HIT systems for the electronic exchange of identifiable health information, Federal agencies are required to use HIT products adopted by the Government. Activities involving the collection and submission of

health information must also be consistent with these standards. Private entities contracting with the Federal Government for health activities must adopt these standards. ***Comment.*** Such consistency will serve to promote interoperability across a range of care settings and improve care.

***Reports by the Secretary.*** Among HHS responsibilities, the Secretary is required to submit an annual report to Congress on the efforts toward, and barriers to, facilitating the electronic exchange of health information nationwide. The Secretary is also required to study methods to create efficient reimbursement incentives for improving healthcare quality in Federally-qualified health centers, rural health clinics, and free clinics.

***Comment.*** As noted above, the Secretary's report should address how partnerships, including those with the AHIC 2.0, HITSP, CCHIT and the new entity created by the PRO(TECH)T Act are proceeding toward adoption and a national infrastructure. As CHIME members look for connectivity in the community through Federally Qualified Health Centers (FQHCs), rural Clinics and free clinics—the study on incentives will be important to inform the process of interoperability in the community at-large.

***Incentives for the Use of Health Information Technology.*** To encourage the widespread adoption of health information technology, the legislation creates three separate competitive grant programs as well as a demonstration. These programs include matching funds for healthcare providers to encourage purchase of qualified health information technology; funds to States and Indian Tribes to develop loan programs that will leverage private-sector funds to provide low interest loans to healthcare providers; and support for local or regional organizations to develop health information technology plans. Preference in awarding 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 each year through fiscal year 2013.

***Comment.*** These grant programs are essential to move toward a national infrastructure and show commitment on the part of the Federal government to partner with states, organizations and communities toward this goal. This funding is a minimal effort to assist communities in working together and the suggested matches encourage buy-in commitment to adopt HIT.

***Clinical Education Demonstration Program.*** To encourage integration of information technology into clinical education, HR 6357 creates a demonstration program for the education of healthcare professionals with an authorization of \$10 million for fiscal years 2009-2011. Funding will be offered on a competitive basis to healthcare educational institutions providing training on the use of HIT that promotes quality of care.

***Comment.*** This effort is an important step in educating the future healthcare workforce on use of HIT tools. In addition, education grants are needed in underserved areas and through telemedicine and other venues to facilitate connectivity and access to the tools of HIT beyond academic medical centers.

## **II. Testing of Health Information Technology**

***National Institute for Standards and Technology Testing.*** The National Institute for Standards and Technology (NIST) is charged with working in coordination with the HIT Standards Committee to test technical standards being developed or recognized for the electronic exchange of health information by the HIT Standards Committee. Additionally, the PRO(TECH)T Act 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 meet standards for the electronic exchange of information.

***Comment.*** HITSP, formed for the purpose of harmonizing and integrating standards to meet clinical and business needs for sharing information among organizations and systems, is already engaged in similar activities. For example, on Electronic Health Record (EHR) Laboratory Results Reporting, HITSP defines specific standards to support the interoperability between electronic health records and laboratory systems. HR 6357 permits NIST to accredit non-Federal laboratories to perform testing. Presumably NIST could contract with HITSP to perform this work. Since HITSP is already performing this activity, it is questionable that this provision is necessary.

### III. Privacy and Security

***Security Provisions and Penalties to Business Associates of Covered Entities and Annual Guidance.*** This provision requires that the Health Insurance Portability and Accountability Act of 1996 (HIPAA) security safeguards and the penalties for violation of those safeguards apply to business associates under HIPAA 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.

***Comment.*** The increased adoption of EHRs involves a range of parties, including RHIOs and various other entities. Application of penalties to business associates for violation of safeguards addresses this expanded range of entities to assure protection of patient privacy.

***Notification in the Case of Breach.*** In the case of a breach of unencrypted Protected Health Information (PHI), a covered entity must notify each individual whose information is reasonably believed to have been breached. Should the breach of unencrypted PHI occur while 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 both on the content and required methods for notifying an individual. Notification may be delayed if it could impede a criminal investigation or damage national security.

***Comment.*** The language of this section addresses unintentional acquisition and provides some flexibility for compliance. At the same time, the language may be overly broad. Inadvertent disclosure of information may occur between business associates that is resolved and contained between a small number of parties involved. No further action would be necessary at this point. One way to address this is to require the Secretary to develop risk-based standards to ensure that any breach under this law includes a reasonable likelihood of substantial harm to the individual as a result of the unauthorized disclosure.

***Accounting for Certain Protected Health Information Disclosures and Use of an Electronic Medical Record.*** All covered entities using an EHR must account for disclosures of PHI (except for oral disclosures) made in the course of treatment, payment and healthcare operations. This information must be retained for a period of three years.

***Comment.*** These activities were excluded from the original, broader HIPAA requirement because the burden of collecting and maintaining this information far outweighed any potential benefit. Audit trails allow for tracking disclosures when using EHRs, but the enormous amount of information involved in direct patient care activities, payment and healthcare operations, and the storage capacity and required would render this unworkable. The resulting information is not likely to be useful for patients and the resource requirements necessary to retain this information, transform it into a form understandable by a patient and manage this process will add to the overall cost of care.

***Consent Requirements for Certain Uses and Disclosure of Healthcare Operations.***

Providers covered under this provision must obtain consent for each specified use and disclosure of protected health information for healthcare operations.

***Comment.*** Under HIPAA regulations, HHS rejected this approach, instead using the current process in which patients provide implied consent for the purpose of treatment, payment and healthcare operations. This approach has provided for confidentiality while permitting the sharing of information that is an integral part of today's healthcare environment. For example, such sharing is necessary for quality reporting to the Joint Commission; submitting data on quality measures through the Hospital Quality Alliance (HQA) to the Hospital Compare website maintained by CMS; complying with public health reporting requirements; submitting sentinel event data; and auditing for fraud and abuse. De-identified health data or limited data sets would be unworkable in most of these cases, while adding a significant burden to these important activities.

***Concluding Comments***

The PRO(TECH)T Act includes a number of provisions that would advance efforts to encourage the adoption of health IT with a goal of improving the quality and value of healthcare. Codifying the Office of the National Coordinator within HHS is perhaps the most critical step to assure the continuation of high-level Federal leadership and coordination essential to this endeavor. Grants and loans will provide incentives to encourage adoption by small physician practices and other providers needing assistance. Other areas of the legislation raise concerns. Certain privacy and security provisions could undermine the overall intent of the legislation and should be revised to assure they protect the confidentiality of patient information without hindering the delivery of high-quality and timely care. CHIME is committed to leveraging the knowledge of chief information officers and working with the Committee and other Members of Congress toward legislation that fully realizes the benefits of HIT for transforming the healthcare system.