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May 22, 2008

MEMORANDUM

TO: Members of the Subcommittee on Health
Committee on Energy and Commerce

FROM: John D. Dingell, Chairman
Joe Barton, Ranking Member
Committee on Energy and Commerce

Frank Pallone, Jr., Chairman
Nathan Deal, Ranking Member
Subcommittee on Health

SUBJECT: Health Information Technology/Privacy Discussion Draft

INTRODUCTION

Most bank records, bill payments, and personal communications are currently maintained in electronic form. Health information, however, continues to be held primarily in paper records. Many believe that needs to change. Health Information Technology (HIT), such as electronic medical records (EMRs), electronic prescribing, and decision support software, hold the promise of improving the quality of care, reducing medical errors, and decreasing costs within the healthcare system.

Attached is a Discussion Draft of legislation to amend the Public Health Service Act to promote the adoption of health information technology, and for other purposes. This Discussion Draft was prepared to provide a roadmap for how to best integrate the Federal Government's role in the promotion of HIT. It further sets forth stronger privacy protections as our Nation's healthcare system moves into the electronic exchange and use of information.

This Discussion Draft is intended to promote discussion with interested parties and stakeholders to assist in the further development of legislation. The Discussion Draft builds on several sources: a number of related bills introduced this Congress, such as H.R.1952 (Rep. Gonzalez), H.R. 2406 (Reps. Gordon and Gingrey), H.R. 3800 (Reps. Eshoo and Rogers of Michigan), and H.R. 5442 (Reps. Markey and Emanuel); H.R. 4157 (Rep. Johnson of CT) from the 109th Congress, including amendments offered to this bill during Committee consideration and markup (Reps. Capps and Towns); findings from hearings held by the Committee on Energy and Commerce; reports by the Institute of Medicine, the National Committee on Vital and Health Statistics, and others; and input from key stakeholders.

HEALTH INFORMATION TECHNOLOGY PROMOTION

Background

On April 27, 2004, President George W. Bush issued an Executive Order promoting the development and implementation of a nationwide health information technology infrastructure. The order established an Office of the National Coordinator of Health Information Technology (ONCHIT) within the U.S. Department of Health and Human Services (HHS). The purpose of the office is to promote the use of EMRs and the electronic exchange of health information. In 2006, President Bush issued another Executive Order requiring agencies implementing, acquiring, or upgrading HIT systems to utilize products that meet recognized standards.

Discussion Draft Provisions

Codification of ONCHIT. In order to provide continued support for the promotion of HIT, the Discussion Draft would make ONCHIT permanent and provide more resources and support for that office. ONCHIT will develop a strategic plan for the development, adoption, use, and certification of HIT. The strategic plan, developed in collaboration with public and private entities, will lay out a plan to encourage the utilization of EMRs in the United States by 2014. Furthermore, this plan must include adequate privacy and security protections for the electronic exchange of an individual's health information.

ONCHIT will provide a report on various healthcare systems and their implementation of HIT. The report will evaluate the costs and benefits of using technology. ONCHIT will also assess the effect HIT has in communities with health disparities and medically underserved areas with the goal of increasing the adoption of HIT.

Development of policies and standards for electronic exchange and use of information. The Discussion Draft establishes two Federal advisory committees for expert stakeholders to provide input and assist ONCHIT in the development and implementation of a nationwide HIT infrastructure.

An HIT Policy Committee is established to recommend a policy framework and prioritize standards necessary for the development of an HIT infrastructure. Their recommendations will then be forwarded to the HIT Standards Committee. The HIT Standards Committee is established to develop and recommend the technical standards, implementation specifications, and certification criteria.

Adoption of standards. The Secretary, in consultation with other relevant agencies, will review the standards and specifications recommended by the HIT Standards Committee and where appropriate provide for adoption by the Government. The standards would be voluntary for private entities.

Federal activities. To promote the electronic exchange and use of information, the Discussion Draft directs Federal agencies to use standards developed by the HIT Standards Committee. Once adopted by the Government, the goal is to drive the marketplace towards use of those standards.

Voluntary certification and testing of products. In order to promote the use of quality standards, ONCHIT and the Director of the National Institute of Standards and Technology (NIST) will work together to create a program allowing industry to voluntarily submit products to be tested and certified as meeting the standards.

HIT resource center. The Discussion Draft establishes a HIT resource center to provide technical assistance and serve as a forum for the exchange of knowledge and experience.

Financial incentives. To further support and encourage the widespread use of HIT, the Discussion Draft creates incentives in the nature of three separate competitive grant programs. The first program will offer direct financial support for providers to purchase HIT. Preference will be given to small healthcare providers, those in medically underserved areas, and others that may have difficulty acquiring HIT on their own. The second program is for States and Tribes and is a loan program that will leverage private-sector funds to provide low interest loans to healthcare providers to purchase HIT. The third grant program provides support for local or regional organizations to develop HIT plans. These plans must provide direction for the exchange of health information among physicians, pharmacies, hospitals, health centers, and others within a given region.

Education. The Discussion Draft also creates a demonstration program to integrate HIT into the clinical education of healthcare professionals. Funding will be offered to healthcare educational institutions to provide for training on the use of HIT that promotes quality of care.

Research. An important final component of the Discussion Draft is the creation of Health Information Enterprise Integration Research Centers through NIST. The Discussion Draft directs NIST to award competitive grants to institutes of higher education to research innovative approaches for the use of HIT in the delivery of health care.

PRIVACY AND SECURITY

Background

In 1996 Congress enacted the Health Insurance Portability and Accountability Act (HIPAA), which established a privacy and security framework for health information. Pursuant to this Act, on August 14, 2002, HHS promulgated the first comprehensive Federal protections for the privacy of health information (the Privacy Rule). In addition, on February 20, 2003, HHS promulgated national security standards (the Security Rule) specifying a series of security procedures for Covered Entities (CEs), defined as providers, health plans, and healthcare clearinghouses.

Discussion Draft Provisions

Accountability and enforcement for privacy and security. Under current law, the HIPAA Privacy and Security Rules apply to CEs, defined as providers (physicians, hospitals, etc.), health plans (HMOs, health insurance companies), and healthcare clearinghouses (bill and claims processing). These rules require CEs to enter into written contracts with Business Associates (BAs) (entities that assist providers, e.g. bill collection, legal services). These contracts include security and privacy requirements for the protection of electronic health information. CEs are not required to monitor whether or not BAs carry out privacy safeguards or the extent to which the BAs abides by the privacy requirements of the contract. In addition, the Government is not permitted to enforce privacy safeguards against BAs directly.

The Discussion Draft subjects the BAs to the security safeguards directly and holds BAs directly accountable to the Federal Government for violations of minimum contract requirements outlined in both the Security and Privacy Rules. The Discussion Draft also requires notification to be provided to the patient in the case of a data breach. Currently there is no breach notification requirement in the HIPAA Privacy or Security Rule. The Discussion Draft requires the HHS Secretary to designate an individual in each regional office to offer guidance and education to the CEs, BAs, and the public on their rights and responsibilities related to their protected health information. This provision also requires the Secretary to compile a report on compliance and includes an authorization for appropriations to fund a public education initiative on the uses of health information.

Greater protections on information. Currently the HIPAA Privacy Rule permits providers and health plans that receive protected health information from a patient to share that patient's information with other providers for treatment without the patient's authorization. In addition, the covered entities can share with others the minimum amount of such information necessary for payment and for the entity's healthcare operations, such as quality improvement and assessment activities. Beyond that, authorization from a patient must be secured before sharing the patient's information. Finally, the Privacy Rule includes a set of exceptions to the authorization requirement for certain situations such as law enforcement purposes or when required by law.

The Discussion Draft provides patients with more transparency and gives providers a new tool to ensure that the least amount of data necessary is shared with additional entities. Rather than relying on the "minimum necessary" standard, which is subjective, the Discussion Draft language encourages the use of the limited data set as defined in the current regulations. A limited data set strips a record of obvious identifiers such as name and social security number. If the limited data set does not provide enough information to fulfill the healthcare operation, the covered entity can provide additional information, but still adhering to the minimum necessary requirement. If a patient requests and chooses to pay out-of-pocket for a service, no disclosure is allowed for payment. In addition, where a covered entity has an electronic medical record, this legislation requires that covered entity to maintain a log of all disclosures for treatment, payment and healthcare operations. This gives the patient greater ability to know where and when their Protected Health Information (PHI) is released.

The Discussion Draft would close a loophole that allows disclosure of PHI for "treatment alternatives" and has been used in the past to send marketing materials to patients without their authorization.

RHIOs, HIEs, and PHR vendors. Over the past decade new entities have come into existence that handle patients PHI for purposes such as holding or networking electronic medical or patient records. These entities are not covered by the HIPAA Privacy and Security Rules.

The Discussion Draft requires Health Information Exchanges (HIEs), also referred to as Regional Health Information Organizations (RHIOs), which are organizations that facilitate electronic communication among providers and entities, to have BA contracts for the purpose of applying privacy standards. The Discussion Draft subjects Personal Health Record (PHR) vendors (e.g., Google, Microsoft) that have products that allow individuals to store their health information in one place to a breach notification requirement. The Federal Trade Commission (FTC) will have the authority to enforce that requirement for an interim period. During that period, the HHS Secretary, in consultation with the FTC, must submit recommendations to Congress on the security, privacy, and breach notification standards that should apply to Personal Health Record vendors. It should also recommend the Federal agency that should have enforcement authority over these vendors.

De-identified information. De-identifying information is deleting identifying characteristics from information to the point that a person cannot be identified by it. Currently, de-identified information can be released without a patient's authorization and can be useful for things such as research. The definition of "de-identified" is, however, not clear. The Discussion Draft requires the HHS Secretary to issue guidance on how to best implement the requirements for the de-identification of Protected Health Information.

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If you have any questions, please contact us or have your staff contact Bridgett Taylor, Amy Hall, Purvee Kempf, or Yvette Fontenot with the Majority Committee staff at ext. 5-2927, or Ryan Long, Melissa Bartlett, or Brian McCullough with the Minority Committee staff at ext. 5-3641.