



## FACT SHEET

### **Protecting Records, Optimizing Treatment, and Easing Communication through Healthcare Technology Act of 2008 -- PRO(TECH)T Act**

**Background:** The House Committee on Energy & Commerce passed H.R. 6357, the [Protecting Records, Optimizing Treatment, and Easing Communication through Healthcare Technology Act of 2008 -- PRO\(TECH\)T Act](#), by a voice vote on July 23, 2008. The Committee on Science & Technology has waived their right to review this legislation and it has now been referred to the House Ways & Means Committee for consideration.

H.R. 6357 builds on a discussion draft released by Reps. John D. Dingell (D-MI) and Frank Pallone, Jr. (D-NJ), along with Reps. Joe Barton (R-TX), ranking member of the Committee on Energy and Commerce, and Nathan Deal (R-GA), ranking member of the Subcommittee on Health, on May 22, 2008. On June 4, 2008, the Subcommittee held a hearing in which witnesses from the Administration and representatives from consumer, technological, and privacy groups provided feedback on the draft legislation. HIMSS is closely monitoring this legislation, but has chosen not to endorse it since some provisions are contrary to our Board-approved 2008 Legislative Principles. Some of our concerns are specified in the analysis below:

#### **Section-by-Section Legislative Analysis: Title I - Health Information Technology**

##### **Part I: Improving Healthcare Quality, Safety and Efficiency**

##### **Section 3001. Office of the National Coordinator for Health Information Technology**

This section requires the National Coordinator to develop a new certification program, either directly or by contract. This provision seems to ignore the positive contributions of the Certification Commission on Health Information Technology (CCHIT) and does not seem to consider how CCHIT plays in the future of HIT adoption. The establishment of a new certification program for HIT could lead to uncertainty within the vendor and provider communities about certification; vendors could refrain from becoming certified under any certification program until the program was firmly established by law and validated by the vendor and provider communities. As a result of this section, the provider community might refrain from adopting CCHIT certified products until the new certification program became

validated by the vendor and provider communities. Both possible outcomes would result in a slower adoption rate of HIT throughout the United States.

### **Section 3002. HIT Policy Committee**

We believe that the HIT Policy Committee participation should require representation from the Nursing and Pharmacy professions to ensure full representation of the HIT Community. We support the transition of the American Health Information Community (AHIC) to AHIC 2.0 and believe that this section is duplicative of the progress already being made on HIT transformation.

### **Section 3003. HIT Standards Committee**

This section would eliminate the purpose of the Health Information Technology Standards Panel (HITSP), a group that industry is heavily involved in and has already proved successful in harmonizing standards and collaborating with standards development organizations. This section also does not reference the development and application of Use Cases that AHIC has been actively involved in developing and recommending to the HHS Secretary. As a result, it remains unknown whether or not the federal development and support of Use Cases would come to a halt.

### **Sec. 102. Transitions**

This section dissolves the AHIC, which when transitioned to AHIC 2.0 would reside in the private sector, one day prior to enactment of the Act, and establishes two federal advisory Committees. The need and value of these committees is not clear to the HIT industry. As a result, the momentum already achieved by AHIC could be lost during the formation of these two new Committees. HIMSS strongly supports the AHIC 2.0 initiative and would not support any legislation that would slow down this momentum.

## **TITLE III—PRIVACY AND SECURITY PROVISIONS**

### **Section 312 Restrictions on certain disclosures and Sales of health information; accounting of certain protected health information disclosures access to certain information in electronic format**

#### **(Subsection 312(c)) under the Amendment in a Nature of a Substitute to H.R. 6357 – Accounting of Certain Protected Health Information Disclosures Required if Covered Entity Uses Electronic Medical Record**

Section 312 (c) includes language for accounting for disclosures of personal health information. This would appear to include disclosures that are within the terms of ultimately permissible disclosures under the treatment, payment, and health care operations exclusions. It is hard to know what is and is not a disclosure under these permissible exclusions. There has previously

been no legal reason to make such distinctions in terms. This will open up numerous workability problems and needless administrative burdens.

The proposed legislation would require providers that utilize electronic medical records (EMR) to provide an individual, upon request, an accounting of disclosures of protected health information made within the past three years, including those made for the purposes of carrying out treatment, payment, or health care operations. While many entities that hold protected health information today have certain capabilities that allow them to track many types of uses and disclosures, the use of an EMR, as defined in the draft, does not necessarily imply the capability to track and account for every disclosure related to treatment, payment, and health care operations. Moreover, each individual tracking system – which may be parts of separate departments – would then need to be consolidated into the accounting for disclosure data base in a way that each PHI disclosure for an individual would need to be consolidated. Accounting for all disclosures is not as easy as clicking a button.

The actual disclosures that need to be tracked would appear to include faxes, papers, billing materials, emails, government forms, accreditation or licensing papers, accounting activities, fraud and abuse compliance papers, patient safety data, papers for internal reviews, grievances, disclosures to lawyers for legal defense, sales, transfers, mergers, business management papers, data storage under different contracts, communications among different providers, and much more. The obligation under the bill is that each covered entity be able to furnish a list of all of these disclosures for each individual. Presumably some information would be required like basic topic and dates.

The Amendment changes the required retention time to 3 years and has a complicated structure for effective dates. Under that structure, the dates you either first start using an EMR or upgrade an EMR could be a trigger for the requirement. The legislation does not define an upgrade and is therefore unclear on what would classify as an upgrade of an EMR. In addition, the added requirement for providers to retain health records for up to three years has no added value to a patient's privacy.

The definition of EMR is so broad that it is hard to know who would not be covered. One could argue an upgrade to a billing system is an upgrade to an EMR because it is really difficult to see a distinction under the definitions. Specifically, the term “electronic medical record” means an electronic record of individually identifiable health information on an individual that is created, gathered, managed, and consulted by authorized health care clinicians and staff within a single organization. This is hard to know what does not qualify. Regardless, the actual operative tracking requirement is for protected health information not the transfer or disclosure of an EMR.

Enforcement would be confusing but may subject covered entities to government inquiries regarding their purchases. The legal liabilities, however, for getting it wrong are substantial.

It should also be noted that during development of the HIPAA Rules, the Department of Health and Human Services (HHS) considered and accepted comments addressing the possibility of removing the current account exception for disclosures regarding treatment, payment, and health care operations. They ultimately rejected that approach on the basis that it would be unduly burdensome on covered entities and result in accountings of little added-value to the individual requesting such information.

**Subsection 312(d) under the Amendment in a Nature of a Substitute to H.R. 6357-  
Application of Consent Requirements for Certain Uses and Disclosures by Health Care  
Providers with Electronic Medical Records**

Proposed section 312(d) creates new unproductive restrictions on the use and disclosure of protected health information for health care operations. This paragraph is a substantial rewrite of the existing privacy regulations. Consider that health care operations includes among other activities quality assessment and improvement activities, reviewing the competence or qualification of health professionals, conducting training programs, licensing, credentialing, underwriting and premium rating, medical reviews, auditing for fraud and abuse, resolution of internal grievances, transfers and mergers, and even the creation of de-identified health information or limited data sets. A consent requirement cannot rationally work with most of these and would be a profound burden for all of these activities.

The basic issue is this: What happens when a patient does not provide consent? Modern healthcare is a sophisticated system of interactions and communications. Healthcare operations are critical to this system. If patients deny consent it is very unclear how this system can work. Under EMTALA, hospitals would appear to have an obligation to take patients for emergency. The overlap is not clear. Presumably any of those patients could deny consent for use of that information in health care operations. That means if an accreditation board wants to review the case record at an emergency room, many cases could be excluded from such review because of lack of consent. If there is a merger or acquisition of a provider group, the records of non-consenting individuals could not be transferred. Patient safety analyses and other work would have to be edited for non-consenting individuals. The list of problems is long.

What if it is a non-EMTALA situation? Can a provider under 312(d) not accept an individual who does not provide consent for healthcare operations? If the provision were referring to the authorization structure under 45 CFR 164.508, the answer would appear to be no. But under 45 CFR 164.506 that interpretation may be permissible. What kind of consent would that be really? Either answer is not a good situation. Is there a right of patients to not consent to use and disclosure for healthcare operations and still get treatment? This would set up an incredible set of workability and legal liability issues. If there is right of the provider to refuse treatment without consent this is probably better. Courts are going to explore what is the point of this provision.

This section tries to provide a mechanism for obtaining one-time consent. However, the whole concept still raises numerous questions and workability point. One issue arises from 10,000 different consent documents across the country. If each covered entity constructs a different consent form that is tailored to its healthcare operations, the movement of communication becomes an extraordinary burden. Forget the 50 conflicting State privacy rules. If the transmission of information varies according to its consent form you can give up the HIT vision and you can assume a massive set of new burdens for health care.

This section may impose burdens that dwarf the operation of the December 28, 2000, Clinton rule. As many recall, that rule imposed a consent requirement that was not described in the notice of proposed rulemaking. The rule met with a firestorm of criticism and was ultimately rescinded. Nonetheless, the 2000 rule had a number of important exceptions that H.R 6357 does not.<sup>1</sup> The most significant issue is the exception in the rule for indirect treatment relationship. Such exceptions are simply missing in H.R. 6357. Whether a provider has much incentive at the point of care to figure out all the potential health care operations of indirect providers is unclear.

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<sup>1</sup>In the 2000 rule provisions stated:

(2) A covered health care provider may, without consent, use or disclose protected health information to carry out treatment, payment, or health care operations, if:

(i) The covered health care provider has an indirect treatment relationship with the individual; or

(ii) The covered health care provider created or received the protected health information in the course of providing health care to an individual who is an inmate.

(3)(i) A covered health care provider may, without prior consent, use or disclose protected health information created or received under paragraph (a)(3)(i)(A)–(C) of this section to carry out treatment, payment, or health care operations:

(A) In emergency treatment situations, if the covered health care provider attempts to obtain such consent as soon as reasonably practicable after the delivery of such treatment;

(B) If the covered health care provider is required by law to treat the individual, and the covered health care provider attempts to obtain such consent but is unable to obtain such consent; or

(C) If a covered health care provider attempts to obtain such consent from the individual but is unable to obtain such consent due to substantial barriers to communicating with the individual, and the covered health care provider determines, in the exercise of professional judgment, that the individual's consent to receive treatment is clearly inferred from the circumstances.

At least the Clinton Administration understood this massive workability problem for indirect providers.

This section provides that: "...in the case that an individual revokes such consent, such revocation shall only apply to any information acquired by the covered entity after the date of such revocation."

This change from H.R. 6357 as introduced may be useful but is subject to a number of interpretations and problems. First, we need to ask about indirect providers. Does the rule apply to information that was first acquired by the primary provider before revocation and then acquired after revocation by a consulting provider? We also need to ask about derivative information. Let say a covered entity has a business associate reviewing medical records and comes back with a discussion that includes PHI. Was this newly acquired information for which a revocation might attach?

Under 312(d), a covered entity who is a health care provider may not use or disclose certain protected health information for purposes of health care operations unless the covered entity obtains consent. It would seem like health care providers are the ones to obtain PHI in the first instance. It would appear that the provision would ensnare not only the direct health care operations of the provider but also health care operations where providers participate jointly with other parties. For example, licensing or accrediting bodies may need to discuss real cases from a provider. Presumably, the provider may not disclose such information for this purpose without consent. And this means the accrediting body and the provider may both have a problem. It is difficult to see how the licensing or accrediting body could get the information elsewhere. It is difficult to read "the purposes of health care operations" as those functions residing exclusively with the providers. As one goes through the list of functions under the health care operations definition it would appear that, under 312(d) most all of these functions would be profoundly affected should the provider be unable to obtain consent for disclosure. And this means many other parties besides providers would be affected.

### **Subsection 312 (5) under the Amendment in a Nature of a Substitute to H.R. 6357-Regulations**

This provision has the possibility of the Secretary riding to the rescue during the rulemaking to exempt certain healthcare operations. It is hard to know on what basis the Secretary will exercise such authority and how to distinguish one set of the current healthcare operations from another. The legal standard "to ensure the integrity of protected health information in a reasonable and workable manner" does not seem to point to the value of the health care operation. So, for example, patient safety analysis or training activities at medical college hospitals are not really relevant or useful for ensuring the integrity of protected health information. If one did not do these activities protected health information would certainly be protected. Will the Secretary assume that such activities should proceed without the burden of

the consent provisions or will the Secretary just say it the burden of the consent provisions are workable for the objective of protecting health information? It is hard to see the Secretary able to select out certain health care operations from others in this regard.

### **Subsection 312, (7) under the Amendment in a Nature of a Substitute to H.R. 6357- Disclosures by Health Plans**

New paragraph (7) cements an ambiguity from the bill as introduced. Unfortunately, it operates in a manner antithetical to insurers and group health plans. This would seem to state that PHI transferred for treatment or payment purposes to another covered entity but subsequently used for health care operations needs consent. For example, let us say billing and coding information is transferred to Medicare for payment purposes. However, this very same information can be used by Medicare for health care operations purposes, and today is. Under 312(d) if the provider did not get consent Medicare would not be able to use the data base for other purposes, like pharmacovigilance activities or for fraud and abuse compliance purposes.

It is difficult to see much limitation from the language regarding EMRs. Virtually all health information will be initially obtained in a manner “created, gathered, managed, and consulted by authorized clinicians and staff within a single organization” The only limitation then would be the information loaded on to a computer at some point. It is hard to see how most of the health care operations could proceed without this being the case at some point in the process.

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### **Conclusion**

HIMSS has subject matter experts in all aspects of health information technology, including standards, interoperability, infrastructure, privacy and security and financial and would like to expand on this dialogue regarding the above provisions on the PRO(TECH)T Act. We look

forward to working with Congress to ensure that it positively helps in the transformation of healthcare for all Americans. Without critical changes to this legislation, HIMSS cannot endorse H.R. 6357. While this bipartisan legislation has the opportunity to bolster the adoption and use of HIT throughout the U.S., it also has some provisions that we believe may potentially set back much of the progress already achieved by the HIT community.

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