

**TOP LINE CHANGES BETWEEN THE HIT/PRIVACY DISCUSSION DRAFT
AND THE PROTECTING RECORDS, OPTIMIZING TREATMENT, AND EASING
COMMUNICATION THROUGH HEALTHCARE TECHNOLOGY ACT OF 2008
PRO(TECH)T ACT OF 2008**

Title I

Definition of Health Plan. In response to comments, the PRO(TECH)T Act ensures that all health plans, including safety net plans, are incorporated into the definition of “health plan” for the purposes of the membership in the HIT Standards Committee and the regional or local health information technology plans.

Office of the National Coordinator for Health Information Technology. In response to comments, the PRO(TECH)T Act adds to the role of the National Coordinator to ensure meaningful input into the development of the Nation’s health information infrastructure. In addition, it requires the National Coordinator to consider continuity of care among different health settings, health and clinical research, and privacy and security protections in updating the strategic plan.

HIT Policy Committee and HIT Standards Committee. In response to comments, the PRO(TECH)T Act provides for input from additional entities such as a public health official, a physician, and a researcher. In addition, provisions governing the Committees such as quorum requirements and appointments for vacancies were synchronized. Also, the PRO(TECH)T Act clarifies that the HIT Standards Committee cannot only develop, but also can recognize and harmonize standards developed by other entities for the electronic use and exchange of health information.

Incentives for the Use of Health Information Technology. In response to comments, the PRO(TECH)T Act ensures that providers receiving grants under Title I provide notification to affected individuals where individually identifiable health information in their possession has been breached in accordance with Title III. In addition, the PRO(TECH)T Act authorizes an appropriation of 115 million each year through 2013 for the grant programs in section 121. It specifies a \$10 million authorization for appropriation for the demonstration program in section 121 that integrates information technology into clinical education.

Title III

Definition of Breach. In response to comments, the PRO(TECH)T Act improves the definition of breach by clarifying that good faith acquisition of personal information by an employee or agent of the person or business for the purposes of the person or business is not a breach of the security of the system, provided that the personal information is not used or subject to further unauthorized disclosure.

Definition of Vendor of Personal Health Record. In response to comments, the PRO(TECH)T Act improves the definition of a vendor of personal health record by clarifying that it does not include covered entities under the Health Insurance Portability and Accountability Act of 1996.

Annual guidance on the latest safeguard technologies. In response to comments, the PRO(TECH)T Act will require the Secretary to consult with stakeholders when developing annual guidance on the latest safeguard technologies for carrying out the security provisions.

Breach notification. In response to comments, the PRO(TECH)T Act adopts the model in California's breach notification law and requires notification of a breach of any unencrypted protected health information. The PRO(TECH)T Act also allows the Secretary of Health and Human Services to authorize the use of technologies that are equally or more effective than encryption at rendering protected health information in a record readily indecipherable or unusable. In response to comments, rather than requiring notification within 15 days of a discovered breach, the PRO(TECH)T Act requires notification without unreasonable delay or within 60 calendar days, whichever is earlier. The PRO(TECH)T Act allows notification by first class mail or by electronic mail if that is the stated preference of the patient or provides greater flexibility about the other potential means of notification. Finally, the PRO(TECH)T Act requires the Secretary of Health and Human Services to publish a listing of any entity that has suffered a breach affecting more than 1,000 people on the HHS Web site.

Requested restrictions for out-of-pocket payment. In response to comments, the PRO(TECH)T Act improves the provision that limits the disclosure of information if a patient is paying out-of-pocket by requiring that the payment cover the cost of the service in full. In addition, it improves on this provision by precluding the disclosure of protected health information for payment purposes, as well as for healthcare operations if the patient pays out-of-pocket for the service in full, unless otherwise required by law.

Accounting of disclosures for treatment, payment, and health care operations. In response to comments, the PRO(TECH)T Act improves the workability of this provision by making clear that disclosures made orally do not have to be included in the accounting and by allowing 12 months for the implementation of this provision.

Study on application of privacy and security requirements to vendors of personal health records. In response to comments, the PRO(TECH)T Act clarifies that this provision only applies to non-covered entities as defined in the Health Insurance Portability and Accountability Act of 1996 and applies to third-party service providers that the vendor makes available to individuals with personal health records.

Temporary breach notification requirement for vendors of personal health records. In response to comments, the PRO(TECH)T Act improves this provision by making clear that it applies to third-party service providers and by making it consistent with the breach notification provision implemented by the PRO(TECH)T Act for covered entities as defined in the Health Insurance Portability and Accountability Act of 1996.

Guidance on implementation specification to de-identify protected health information. In response to comments, the PRO(TECH)T Act improves this provision by allowing 12 rather than 6 months for completion of guidance on the implementation of the requirement for the de-identification of protected health information and by requiring the Secretary to consult with stakeholders.

Conditions on certain contacts. In order to further guard against the misuse of protected health information, the PRO(TECH)T Act prohibits direct payment to covered entities as defined in the Health Insurance Portability and Accountability Act of 1996 for certain communications about health care items or services. For example, a provider would be precluded from receiving direct payment for communications made for treatment purposes using a patient's protected health information.

Clarification of application of wrongful disclosures criminal penalties. In order to strengthen enforcement of the privacy requirements in the Health Insurance Portability and Accountability Act of 1996, the PRO(TECH)T Act clarifies that the criminal penalties can be applied to an individual. This is intended to address an opinion issued by the Department of Justice's Office of Legal Counsel that has prevented prosecutors from charging people criminally for disclosing protected health information unless the defendant is a covered entity under the Health Insurance Portability and Accountability Act of 1996.

Consent provision. In order to strengthen a patient's ability to control their protected health information, the legislation includes a provision which requires that a health care provider receive a patient's consent to use or disclose their protected health information for health care operations such as sending the information to others for quality reviews. This applies to providers utilizing an electronic medical record.