PRELIMINARY ANALYSIS OF PROPOSED HIPAA RULE STANDARDS OF 3 NOV 1999 FOR PRIVACY OF CERTAIN ELECTRONIC HEALTH INFORMATION

Applicability	Substantive Provisions	Miscellaneous	Enforcement
Entities covered: The proposed regulations apply to: • health plans • health care clearinghouses • certain health care providers (those who transmit covered health information in connection with HIPAA standard transactions) Proposed 45 CFR 160.102 *Subject matter covered:* The proposed regulations apply to "protected health information". Proposed 45 CFR 164.502. The term is defined as any individually identifiable health information that is or *has* been electronically transmitted or maintained by a covered entity. Proposed 45 CFR 164.504. [i]	The proposed regulations: (1) define and limit the circumstances in which covered entities may use and disclose covered health information; (2) establish individual rights with respect to the covered health information; and (3) require covered entities to adopt safeguards to protect the confidentiality of covered health information and protect against unauthorized access. See below for further analysis.	This column summarizes certain additional aspects of the proposed regulations. 1. Minimum Necessary Disclosure Except in certain circumstances, covered entities must make all reasonable efforts not to use or disclose more than the minimum amount of covered health information necessary to achieve the intended purpose of the use or disclosure. Proposed 45 CFR 164.506 (b)(1). 2. Business Partners Except for purposes of consultation or referral for treatment, covered entities are required to enter into written contracts with business partners before protected health information can be shared. The regulations establish the requirements for those contracts. Proposed 45 CFR 164.506 (e)(1). [ii]	The HIPAA grants the Secretary of the Department of Health and Human Services the authority to impose civil monetary penalties against covered entities which fail to comply with the requirements of the proposed rule, and also establishes criminal penalties for certain wrongful disclosures of covered health information. The civil fines are capped at $25,000 for each calendar year for each standard that is violated. The criminal penalties are graduated, increasing if the offense is committed under false pretenses, or with the intent to sell the information or reap other personal gain. The statute does not provide for a private right of action for individuals.

Substantive Provisions	Analysis
Use and Disclosure Restrictions	I. The General Rule Under the proposed regulations, a covered entity is prohibited in most cases from using or disclosing an individual's protected health information without individual consent. Proposed 45 CFR 164.506 (a)(1). II. Exceptions There are two types of exceptions to this prohibition: permissive disclosures and mandatory disclosures. *A. Permissive Disclosures* Proposed 45 CFR 164.506 (a)(1) A covered entity is permitted to use or disclose protected health information without individual authorization: (1) to carry out treatment, payment or health care operations (research information unrelated to treatment and psychotherapy notes are excluded), and (2) for certain national priority purposes (such as research, public health and oversight), but only under defined circumstances. Proposed 45 CFR 164.510. *B. Mandatory Disclosures* Proposed 45 CFR 164.506 (a)(2) A covered entity is required to disclose protected health information without individual authorization in two circumstances: (1) in response to a request by an individual to inspect, and obtain a copy of, his protected health information pursuant to Proposed 45 CFR 164.514; and (2) in connection with an enforcement action or compliance review brought by the Secretary of the HHS pursuant to Proposed 45 CFR 164.522.

Substantive Provisions	Analysis
	III. Uses and Disclosures with Individual Authorization Proposed 45 CFR 164.508 Except in certain circumstances (see above), covered entities are required to obtain an individual's explicit consent before using or disclosing protected health information about that individual. The proposed regulations contemplate two situations in which individual authorization can occur, either it can be initiated at the individual's request or be prompted by a covered entity's request. The conditions governing the authorization differ depending on which situation is involved. *A. Requirement for Authorizations Requested by Individuals* Proposed 45 CFR 164.508(c) The individual requesting a use or disclosure must submit an authorization form to the covered entity. The form must: (1) provide a specific description of the information to be used or disclosed; (2) name the covered entity authorized to make the requested use or disclosure; (3) name the party to whom the covered entity may make the requested use or disclosure; (4) provide an expiration date; (5) be signed and dated; (6) be in plain language if the model form at the end of the proposed regulations is not used. *B. Requirements for Authorizations Requested by Covered Entities* Proposed 45 CFR 164.508(d) Covered entities making a request are also required to obtain an authorization form. The authorization must meet the requirements for requests made by individuals and contain certain additional elements such as statements concerning: (1) the purpose for which the request was made, (2) the right of the individual to inspect or copy the information, (3) the right of the individual to refuse treatment, and (4) whether authorization will result in financial gain for the covered entity. In addition, the covered entity is required to have procedures in place to limit the scope of the request to the minimum amount of information needed to achieve the purpose for which the information is requested. *C. An authorization made pursuant to either type of request is revocable at any time.* Proposed 45 CFR 164.508(e).

Substantive Provisions	Analysis
Individual Rights	I. Introduction The proposed regulations establish basic rights for individuals with respect to their protected health information. The rights created are: (1) the right to notice of information practices Proposed 45 CFR 164.512; (2) the right to obtain access to protected health information, including the right to inspect and copy protected health information Proposed 45 CFR 164.514; (3) the right to receive an accounting of how an individual's protected health information has been disclosed Proposed 45 CFR 164.515; and (4) the right to request amendment or correction of protected health information that is inaccurate or incomplete Proposed 45 CFR 164.516. [iii] [iv] II. Right to Notice The proposed regulations provide individuals with a right to an adequate notice of the information practices of covered health plans and providers. The notice is required to include: (1) an explanation of the way the entity uses and discloses protected health information; (2) basic statements relating to individual rights, such as the disclosure of an individual's right to access protected health information and the right of the covered entity to change its policies and procedures; (3) the identification of a contact person for complaints and additional information; and (4) the date the notice was produced. Covered health plans and providers are required to update their notices when they make material changes to their information practices. Proposed 45 CFR 164.512 (d)(2). Furthermore, covered health plans and providers are required to follow the information practices specified in their most current notice. An otherwise lawful use or disclosure that does not appear in the entity's notice would not be permitted. Comments to the Proposed Regulations, p. 59926.

Substantive Provisions	Analysis
	III. Right to Inspect and Copy The proposed regulations limit the right of an individual to access information about him to protected health information that is maintained in a designated record set. Under Proposed 45 CFR 164.504, a designated record set is defines as "a group of any records under the control of any covered entity from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual." Individuals also have a right of access to protected health information maintained by a business partner of a covered plan or provider when such information is not a duplicate of the information held by the plan or provider. Proposed 45 CFR 164.514(a). Covered plans and providers may deny a request to inspect or copy protected health information under very limited circumstances. 45 CFR 164.514 (b).
Safeguards	I. Requirements In order to protect identifiable health information from inappropriate access, use or disclosure, covered entities are required to develop and implement safeguards. The proposed regulations require covered entities to (1) develop and implement basic administrative procedures to protect the confidentiality of health information and the rights of individuals (Proposed 45 CFR 164.518) and (2) maintain documentation of the policies and procedures used by covered entities to comply with the requirements of the proposed rule (Proposed 45 CFR 164.520). The administrative procedures required of covered entities are: (1) the designation of a privacy official; (2) the establishment of training programs for employees; (3) the implementation of safeguards to protect health information from intentional or accidental misuses; (4) the development of a system for individuals to lodge complaints about an entity's information practices (covered entities must maintain a record of any complaints made); and (5) the development of a system of sanctions for employees and business partners who violate the entity's policies.

[i] The following points should be noted regarding the definition of protected health information. First, the protections afforded under the proposed regulations start when the information becomes electronic and stay with the information as long as it is held by a covered entity. Second, as the definition indicates, the proposed regulation applies to the information itself, and not to the particular records in which the information is recorded. Combined, these two points mean that once the information has been maintained or transmitted electronically by a covered entity, the protections follow the information in whatever form, including paper records, in which it exists (while it is held by a covered entity). Comments to the Proposed Regulation, p. 59924.

[ii] The proposed regulations also contain a provision for the de-identification of covered health information. According to Proposed 45 CFR 164.506 (d)(1), covered entities are permitted to strip identifiers from health information and use and disclose such de-identified information in any way, provided that (1) they do not disclose the key or mechanism that would enable the information to be re-identified, and (2) they have no reason to believe that such use or disclosure will result in the use or disclosure of covered health information.

[iii] The rights created apply to health plans and health providers in all cases. Clearinghouses are exempted from the notice requirement as well as the obligation to provide access for inspection, copying, amendment or correction.

[iv] The proposed regulations also provide individuals with a right to request that a covered entity restrict further uses and disclosures of protected health information for treatment, payment or health care operations. Proposed CFR 45 164.506 (c). Agreeing to restrict further use is optional on the part of a covered entity, but once an agreement has been reached between the parties, it is binding on the covered entity. The right to restrict uses and disclosures does not apply to disclosures made pursuant to Proposed 45 CFR 164.510 or disclosures made for emergency purposes.