Just the Facts...

Modifications to the Standards for Privacy of Individually Identifiable Health Information

Purpose: This fact sheet is to provide a brief summary of the final modifications The Department of Health and Human Services will publish on August 14, 2003.

Overview: The Privacy Rule (45 CFR Part 160 and 164) presents the first comprehensive Federal protection for the privacy of health information and provides patients with increased access to their medical records. Final modifications to the Privacy Rule ensure that the Rule provides strong privacy protection without impeding access to quality health care. The Standards for Privacy of Individually Identifiable Health Information (the Privacy Rule) took effect on April 14, 2001. As required by the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the Privacy Rule covers health plans, health care clearinghouses, and those health care providers who conduct certain financial and administrative transactions electronically. Most covered entities must comply with the Privacy Rule by April 14, 2003. Small health plans have until April 14, 2004 to comply with the Rule.

Final Modifications:

Incidental Use and Disclosure -- The final Rule acknowledges that various environments in which individuals receive health care or other services from covered entities, the potential for exists for an individual's health information to be disclosed incidentally. Such incidental uses or disclosures are not considered a violation of the Rule provided that the covered entity has met the reasonable safeguards and minimum necessary requirements [(45 CFR 164.530(c), 164.502(a) (1) (iii)]. For example, if these requirements are met, doctors' offices may use waiting room sign-in sheets, hospitals may keep patient charts at bedside, doctors can talk to patients in semi-private rooms, and doctors can confer at nurse's stations without fear of violating the rule if overheard by a passerby.

Minimum Necessary -- The final Rule requires covered entities to implement reasonable minimum policies and procedures that limit how much protected health information is used, disclosed and requested for certain purposes. The policies and procedures must limit who within the entity has access to protected information, and under what conditions, based on job responsibilities and the nature of the business. The minimum necessary standard does not apply to disclosures among health care providers for treatment purposes [45 CFR 164.502(b), 164.514(d)]. The Department clarifies in the preamble that the minimum necessary standard is not intended to impede disclosures necessary for workers' compensation programs. The Department will actively monitor to ensure that worker's compensation programs are not unduly affected by the Rule.

Personal Representatives -- The final Rule establishes a foundation of federally protected rights of the individual to control certain uses and disclosures of their protected health information. Under the Rule, a person authorized under state or applicable law) to act on the behalf of the individual in making heath care related decisions is the individual's "personal representative." The extent of the personal representative's power and situations requiring their involvement are addressed in 45 CFR 164.502(g) and 164.510(b) respectively.

The following chart displays who must be recognized as the personal representative by category of individuals:

If the Individual is:	The Personal Representative Is:
An Adult or An Emancipated Minor	A person with legal authority to make health care decisions on behalf of the individual *Examples*: Health care power of attorney, Court appointed legal guardian, General power of attorney
An Unemancipated Minor	A parent, guardian, or other person acting *in loco parentis* (collectively, "parent") with legal authority to make health care decisions on behalf of the individual *Exceptions*: See parent and minor discussion
Deceased	A person with legal authority to act on behalf of the decedent or the estate *Examples*: Executor of the estate, Next of kin or other family member

Generally, the Privacy Rule provides parents with new rights to control the health information about their minor children, with limited exceptions that are based on state or other applicable law and professional practice. For example, where a state has explicitly addressed disclosure of a minor's health information to a parent, or access to a child's medical record by a parent, the final Rule clarifies that state law governs. In addition, the final Rule clarifies that, in the special cases in which the minor controls his or her own health information under such law and that law does not define the parents' ability to access the child's health information a licensed health care provider continues to be able to exercise discretion to grant or deny such access as long as that decision is consistent with the state or other applicable law.

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Business Associates -- The final Rule allows covered providers and health plans to disclose protected health information to "business associates" if the provider or plan obtain satisfactory assurance that the business associate will use the information only for the purposes for which it was engaged by the covered entity, will safeguard the information from misuse, and will help the covered entity comply with some of the covered entity's duties under The Privacy Rule. The protected health information is not for the business associate's independent use or purposes, except for the proper management and administration of the business associate. The final Rule also gives covered entities (except small health plans) up to an additional year to change existing written contracts to come into compliance with the business associate requirements. The additional time will ease the burden of covered entities renegotiating contracts all at once. The Department has also provided sample business associate contract provisions.

Disclosures for Public Health Activities -- The final Rule permits covered entities to disclose protected health information without authorization for specific public health purposes to those legally authorized to receive those reports. The information may be used for the purpose of preventing or controlling disease, injury, or disability. At the direction of public health authorities, the covered entity may also disclose protected health information to foreign government agencies that are acting in collaboration with public health authorities.

Consent and Notice -- The Department makes changes to protect privacy while removing barriers to treatment by strengthening the notice requirement and making consent for treatment, payment, and health care operations optional. The Rule requires covered entities to provide patients with notice of the patient's privacy rights and the privacy practices of the covered entity. The strengthened notice requires direct treatment providers to make a good faith effort to obtain patient's written acknowledgement of the notice of privacy rights and practices. The final Rule promotes access to care by removing mandatory consent requirements that would inhibit patient access to health care while providing covered entities with the option of developing a consent process that works for that entity. The Rule also allows consent requirements already in place to continue.

Uses and Disclosures Regarding Food and Drug Administration (FDA)-Regulated Products and Activities -- The final Rule permits covered entities to disclose protected health information, without authorization, to a person subject to the jurisdiction of the FDA for public health purposes related to the quality, safety or effectiveness of FDA-regulated products or activities such as collecting or reporting adverse events, dangerous products, and defects or problems with FDA-regulated products. This assures that information will continue to be available to protect public health and safety, as it is today.

Research – Under the Privacy Rule, covered entities are permitted to use and disclose protected health information for research with individual authorization, or without individual authorization under limited circumstances set forth in the Privacy Rule. The final Rule facilitates researchers' use of a single combined form to obtain informed consent for the research and authorization to use or disclose protected health information for such research. The final Rule also clarifies the requirements relating to a researcher obtaining an IRB or Privacy Board waiver of authorization by streamlining the privacy waiver criteria to more closely follow the requirement of the "Common Rule," which governs federally funded research. The transition provisions have been expanded to prevent needless interruption of ongoing research.

Authorization -- The final Rule clarifies the authorization requirements to the Privacy Rule to, among other things, eliminate separate authorization requirements for covered entities. Patients will have to grant permission in advance for each type of non-routine use or disclosure, but providers will not have to use different types of forms. These modifications also consolidate and streamline core elements and notification requirements.

Marketing -- The final Rule requires a covered entity (health plans, health care clearinghouses and health care providers) to obtain an individual's prior written authorization to use his or her protected health information for marketing purposes except for a face-to-face meeting or a communication involving a promotional gift of nominal value. The Department defines marketing to distinguish between the types of communications that are and are not marketing, and makes clear that a covered entity is prohibited from selling lists of patients and enrollees to third parties or from disclosing protected health information to a third party for the marketing activities of the third party, without the individual's authorization. The Rule clarifies that doctors and other covered entities communicating with patients about treatment options or the covered entities own health-related products and services are not considered marketing.

Limited Data Set -- The final Rule permits the creation and dissemination of a limited data set (that does not include directly identifiable information) for research, public health, and health care operations. In addition, to further protect privacy, the final Rule conditions disclosure of the limited data set on a covered entity and the recipient entering into a data use agreement, in which the recipient would agree to limit the use of the data set for the purposes for which it was given, and to ensure the security of the data, as well as not to identify the information or use it to contact any individual.

Disclosure for Workers' Compensation Purposes – The final Rule permits covered entities to disclose protected health information to worker' compensation insurers, State administrators, employers and other persons or entities involved in workers compensation systems without the individual's authorization to the extent necessary to comply with laws regulating workers' compensation or similar programs; to the extent the disclosure is required by State or other law, or for the purpose of obtaining payment for any health care provided to the injured or ill worker. The covered entities may also disclose protected health information to workers' compensation insurers and others involved in the workers' compensation system with the individual's authorization for release of the information to the entity. The authorization must meet the requirements of 45 CFR 164.508.

Restrictions on Government Access to Health Information – The final Rule states that government-operated health plans must meet to a great extent the same requirements as private health plans. In addition, all federal agencies must also meet the requirements of the Privacy Act of 1974 restricting information about individual citizens that can be shared with other agencies and the public. The Rule also requires that health plans, hospitals and other covered entities cooperate with the efforts by the Department of Health and Human Services (HHS) Office for Civil Rights (OCR) to investigate complaints or otherwise ensure compliance.