



HEALTH AFFAIRS



TRICARE
Management
Activity

Privacy Essentials: Core Concepts

2007 Quarterly Training

TMA Privacy Office



Concepts under HIPAA Privacy Rule

Core Concepts

Objectives

- Upon completion of this module, you should be able to:
 - Describe a CE and the requirements for a CE
 - Explain what an Organized Health Care Arrangement (OHCA) is
 - Identify safeguards of PHI and sanctions
 - Identify the various types of health information
 - Explain Treatment, Payment, and Healthcare Operations (TPO) under the HIPAA Privacy Rule
 - Outline Patient Rights
 - Define the Minimum Necessary Requirement
 - Explain research and marketing under HIPAA

Core Concepts

Covered Entity

- Definition: Covered entities (CE) are health care providers who transmit health information in (standard) electronic transactions
- CE fall into four categories:
 - Health plans
 - Health care clearinghouses
 - Health care providers
 - Business associate relationships

Indirect Applicability: All organizations that exchange data with those directly covered under the HIPAA through Business Associate Agreements and/or contracts

Organized Health Care Arrangement (OHCA)

- Allows each of the CE in the OHCA to use the policies and procedures and the NoPP established by the OHCA as their own

- Includes:
 - MHS
 - Army
 - Navy
 - Air Force
 - Coast Guard

Safeguards and Sanctions (1 of 2)

- DoD 6025.18, Section C14.3
 - “A covered entity shall have in place appropriate administrative, technical, and physical safeguards to protect the privacy of protected health information.”
- Safeguards should:
 - Enforce HIPAA Privacy requirements
 - Limit incidental use and disclosure of PHI
- Develop and implement an appropriate sanction policy

Core Concepts

Safeguards and Sanctions (2 of 2)

- In addition to administrative and other actions, sanctions may include:
 - For members of the military; action under the Uniform Code of Military Justice
 - For civilians; sanctions consistent with Chapter 75 of Title 5, USC
 - For contractors; actions permissible under procurement regulations

Core Concepts

Health Information

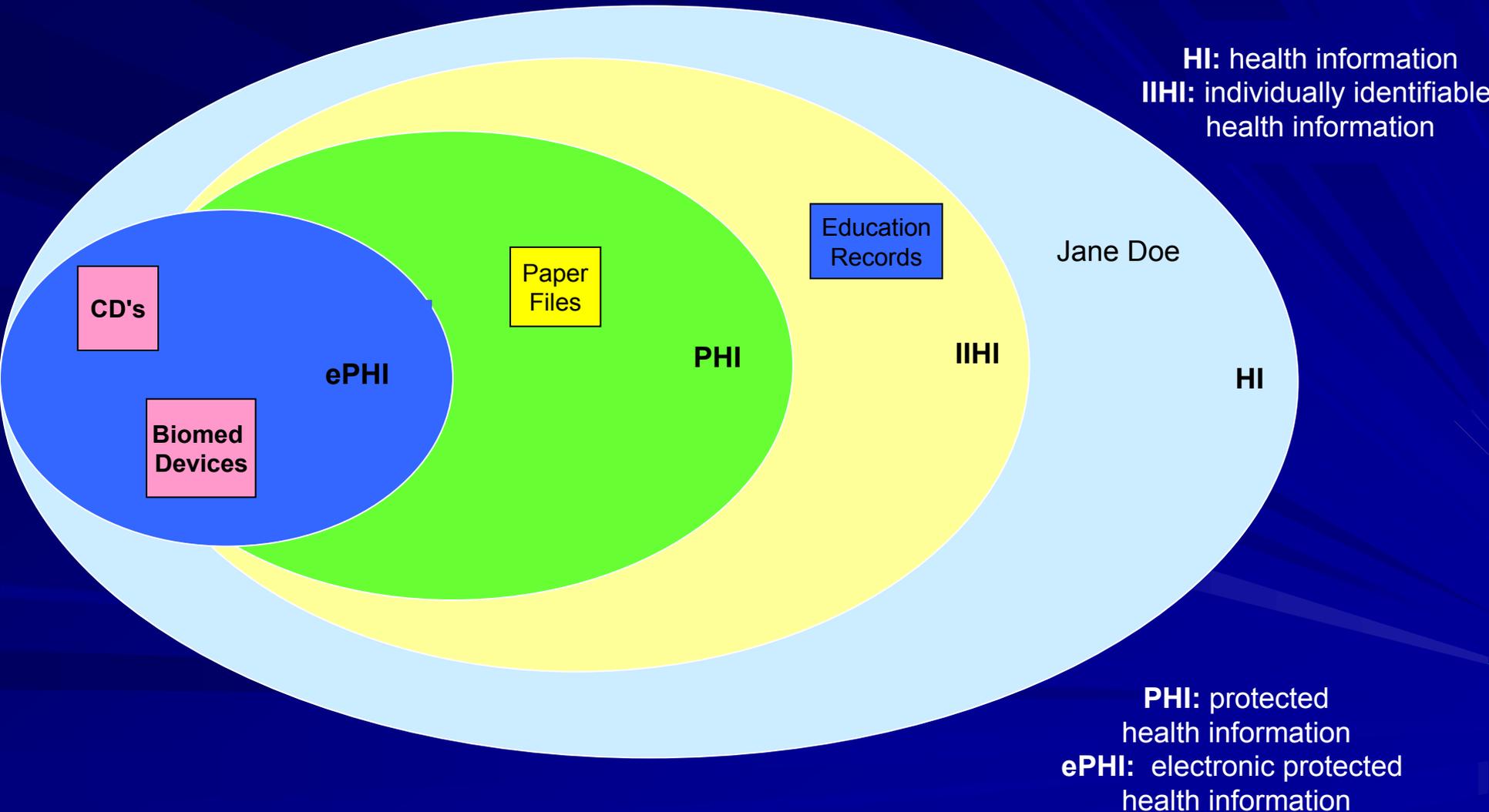
- Health Information (HI) is any information, whether oral or recorded in any form or medium, that:
 - Is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and
 - Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual

Types of Health Information

- Individually Identifiable Health Information (IIHI) is a subset of health information, including demographic information, collected from an individual, and is created or received by a health care provider, health plan, employer, or health care clearinghouse
- PHI is a specific type of health information collected from an individual that is created or received by a health provider, health plan, or employer that meets certain criteria
- ePHI is PHI in electronic form that is transmitted or maintained by electronic media

Core Concepts

The Universe of Health Information



Treatment, Payment and Healthcare Operations (TPO) (1 of 2)

- **Treatment** is the provision, coordination, or management of health care and related services by one or more health care providers
- **Payment** is those activities undertaken by health plans and providers to obtain premiums or provide reimbursement for services
- **Health care operations** are certain administrative, financial, legal, and quality improvement activities of a covered entity that are necessary to run its business and to support the core functions of treatment and payment

Treatment, Payment and Healthcare Operations (TPO) (2 of 2)

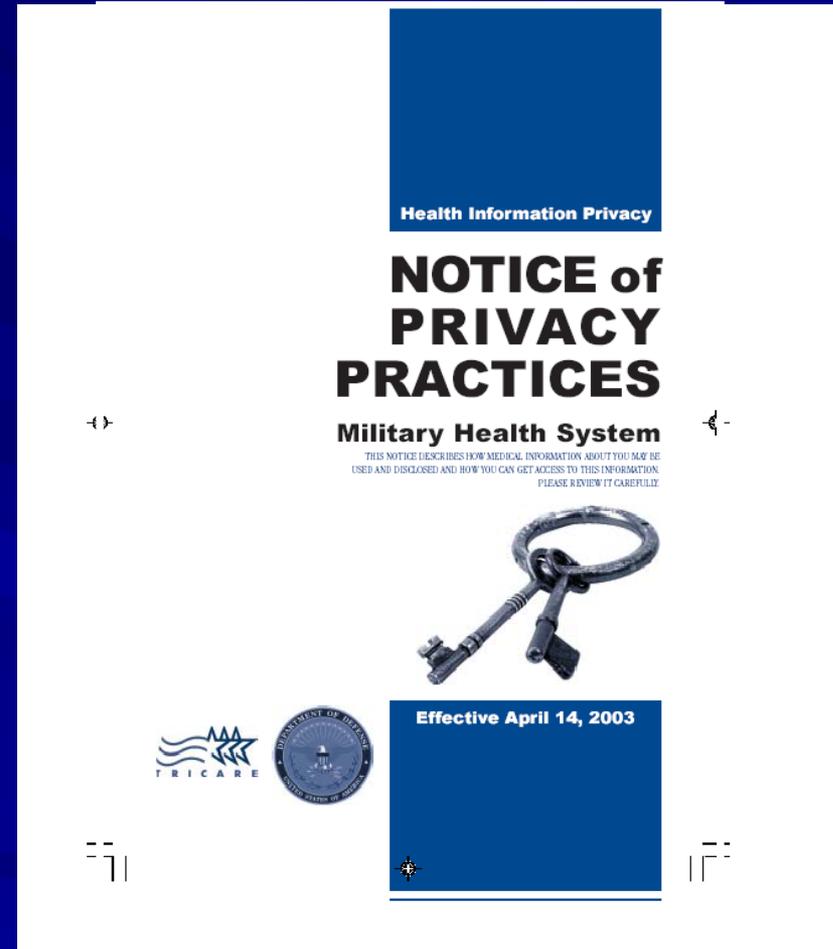
- HIPAA allows the use and disclosure of PHI for TPO without the patient's permission
- HIPAA Privacy is not meant to impede the provision of quality care
- Examples:
 - Walter Reed Army Medical Center (WRAMC) referring a patient to National Naval Medical Center Bethesda (NNMC) for test and requesting the results of the test
 - If a MTF submits a claim to TRICARE or another health insurer for payment

Core Concepts

Notice of Privacy Practices

■ Explains:

- MHS duty to protect health information
- How the MHS may use and disclose PHI
- Patients' rights
- Patient complaint procedures
- Contact information



Notice Contents (1 of 2)

- NoPP explains that MHS may use or disclose PHI:
 - For TPO
 - When required by law or for legal proceedings
 - For law enforcement purposes
 - To public health authorities
 - For health oversight
 - To the FDA
 - To coroners, funeral directors
 - For organ donations
 - For research

Core Concepts

Notice Contents (2 of 2)

- NoPP explains that MHS may use or disclose PHI:
 - For military activity and national security
 - To comply with worker's compensation laws
 - To correctional facilities regarding inmates
 - By the health plan
 - To parents or guardians

- NoPP explains that MHS may use or disclose PHI unless they object:
 - In MTF directories
 - To individuals involved in their health care

Core Concepts

Patient Rights Outlined in NoPP

- Right to receive a written NoPP
- Right to request access to PHI
- Right to request amendment of PHI
- Right to an accounting of disclosures of PHI
- Right to request confidential communications
- Right to request restrictions on uses and disclosures
- Right to complain to the MTF, TMA or DHHS

Core Concepts

Acknowledging the Notice

Acknowledgement of Military Health System Notice of Privacy Practices

The signature below only acknowledges receipt of the Military Health System Notice of Privacy Practices, effective date 14 April, 2003

Signature of Patient/Patient Representative

Date

Name of Patient/Representative

relationship to patient (if applicable)

FMP/SSN: _____ / _____ - _____ - _____

Patient/Representative declined to sign

_____ MTF staff initials

Core Concepts

How to use the Labels

- NoPP Acknowledgement labels must be placed on the outside cover of the medical / dental records in a vertical position in the center of the records jacket
 - This was agreed upon by the Services prior to April 14, 2003
- The patient must be given the option to sign and acknowledge on first out patient encounter
- If patient does not acknowledge, please check the “patient/representative declined to sign” box and MTF staff initial the label

Core Concepts

Minimum Necessary (1 of 2)

- Requires covered entities to take reasonable steps to limit the use or disclosure of, and requests for, PHI to the minimum necessary to accomplish the intended purpose
 - Limit information released to only what the person needs to know and release only the minimum amount of information
- Implementing the Requirement
 - Identify people or groups of people in the workforce who need access to PHI to do their work
 - Further identify the classes of PHI those individuals need to access

Core Concepts

Minimum Necessary (2 of 2)

■ Implementing the Requirement

- Create policies and procedures for **routine recurring** disclosures of PHI so that the information released is limited to the minimum to achieve the purpose of the disclosure
- Limit the PHI disclosed in **Non-routine** disclosures by developing criteria
- Review requests for PHI on an individual basis against the criteria

Core Concepts

Marketing

- “To make a communication about a product or service to encourage recipients of the communication to purchase or use the product or service”
- Marketing is:
 - Disclosing patient lists to third parties for independent marketing
 - Selling patient lists
- Marketing is **not**:
 - Communications related to care coordination
 - Alternative treatment recommendations
 - Describing participating providers or the plan
 - Describing services offered

Core Concepts

Marketing Rule

- All marketing efforts that do not meet one of the exceptions or exclusions specified in the rule require a prior written authorization
- Authorization must contain all of the HIPAA required fields and information
 - Approved authorization form is available on the TMA Privacy Office website
 - The correct form is the DD Form 2870
 - Retain according to local policies and procedures

Marketing Exclusions

- HIPAA excludes the following from the definition of marketing:
 - Information provided for the purpose of furthering or managing the treatment of an individual (ex. Information or recommendations about various treatment options, information about a smoking cessation program)
 - Information about coverage or payment (ex. Existing benefits as well as other products or services optionally available to a health plan enrollee)
 - Population-oriented communications that promote health in “a general manner” provided they do not endorse a specific product or service

Core Concepts

What is Research?

- Any systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalized knowledge
- Research does not include:
 - Quality assessment and improvement activities, such as outcomes evaluation or development of clinical guidelines
 - Activities for generalized knowledge for population health

Research in Relation to NoPP

- The MHS NoPP informs patients and beneficiaries that:
 - The MHS “may disclose your protected health information to researchers when authorized by law, for example, if their research has been approved by an institutional review board that has reviewed the research proposal and established protocols to ensure the privacy of your protected health information”

General Rule and Exceptions

- Research-related uses and disclosures of PHI require prior written authorization except when:
 - The PHI will not leave the CE, will be used solely for reviews in preparation for research, and the researcher represents to the covered entity that such access is essential
 - The PHI refers solely to deceased persons and the researcher again asserts to the CE that access is necessary for the research purpose
 - An Institutional Review Board (IRB) or a Privacy Board determines that a waiver of the authorization requirement is appropriate

Applicability of Other Rules

- The HIPAA rules regarding research do NOT replace other applicable laws such as the Common Rule and the FDA human subject protection rules
 - All requirements for informed consent and IRB review from these other regulations must be met
- The HIPAA rules regarding the use and disclosure of minimum necessary information apply to information used and disclosed for research

Core Concepts

Research- Disclosure Accounting

- Information disclosed for research is subject to the HIPAA disclosure accounting requirement
- For studies involving more than 50 records, the requirement may be met by providing individuals with:
 - A list of all protocols for which their PHI may have been disclosed pursuant to a waiver/exception
 - The purpose of those studies and the types of PHI sought
 - The timeframes of those disclosures
 - A researcher's name and contact information for each study

Core Concepts

Research- Data Access

- The individual's right to access their PHI may be suspended while the clinical trial is in progress if the individual agreed to the denial of access when consenting to participate
 - The individual must be informed that the right to access will be reinstated at the conclusion of the study
- CEs do not need an authorization or waiver from an IRB or Privacy board to release information for research if the information has been either de-identified or is part of a limited data set and the researcher has a Data Use Agreement (DUA)

Research Authorization (1 of 3)

- Research authorizations must meet all of the applicable HIPAA requirements for authorizations except that they do not require an expiration date
- Authorizations must be in writing, signed, and contain the following elements:
 - A description of the information to be used or disclosed in a specific or meaningful fashion
 - The name or specific identification of the person or class of persons authorized to make the requested use or disclosure

Research Authorization (2 of 3)

- Authorizations must be in writing, signed, and contain the following elements:
 - A description of each purpose of the requested use or disclosure (may be at the request of the individual when the individual initiates the authorization)
 - An expiration date or expiration event, except it may say “none” or “end of the research study” for research authorizations
 - Signature of the individual and date (and a description of the representative’s authority to act for the individual if signed by a personal representative)

Research Authorization (3 of 3)

- Authorizations must be in writing, signed, and contain the following elements:
 - The ability or inability to condition treatment, payment, enrollment or eligibility for benefits on the authorization. (While the CE may not normally condition treatment on obtaining an authorization they may condition “research related treatment”)
 - The potential for information disclosed pursuant to the authorization to be subject to re-disclosure by the recipient and no longer protected by HIPAA

Core Concepts

Transition Provisions

- PHI created or received prior to the compliance date may still be used or disclosed for specific studies if one of the following was obtained prior to the compliance date, April 14, 2003:
 - An authorization from the individual
 - The informed consent of the individual to participate in the study
 - A waiver by an IRB in accordance with the Common Rule or FDA's human subject protection regulations

Core Concepts

Summary

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