

Protecting Clients & Their Information

**American Association of
Diabetes Educators (AADE)
Salt Lake City UT – August 9, 2003**

Understanding & Implementing HIPAA (How to Avoid Civil & Criminal Penalties)

A Presentation by:

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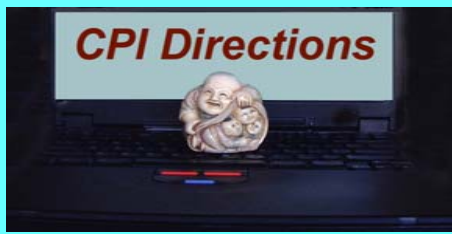
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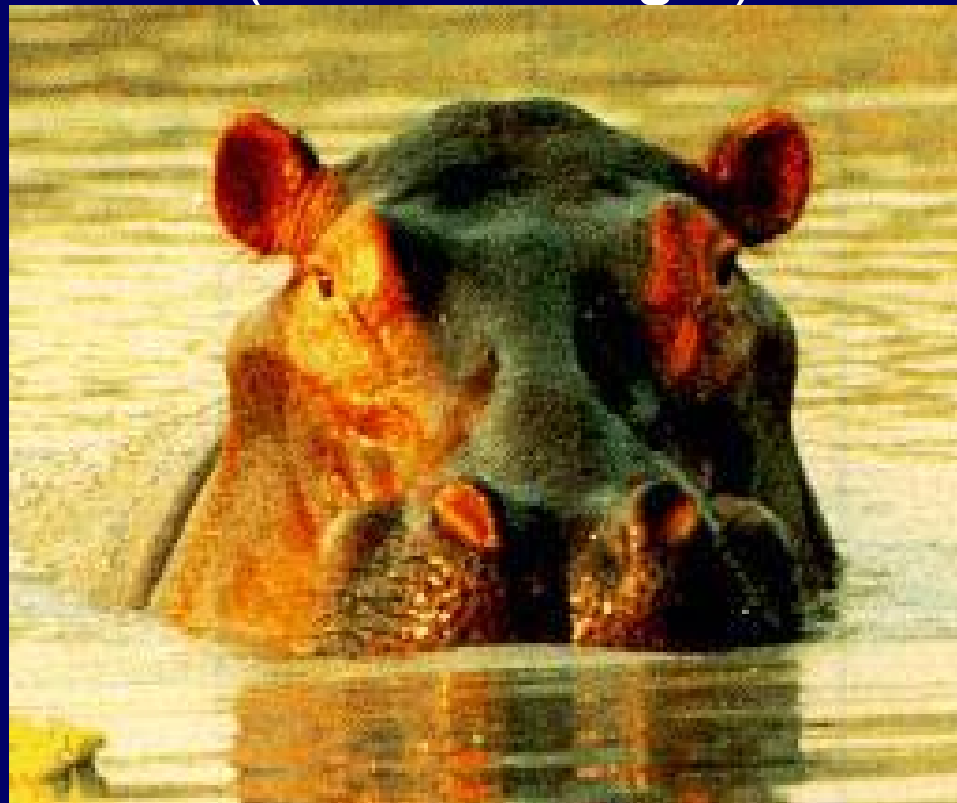
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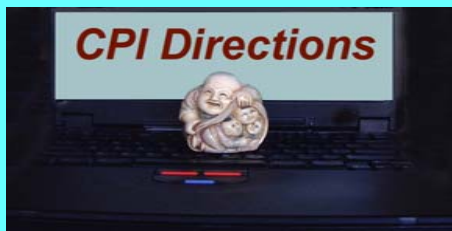
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Health Insurance Portability & Accountability Act of 1996 **(HIPAA is Huge!)**



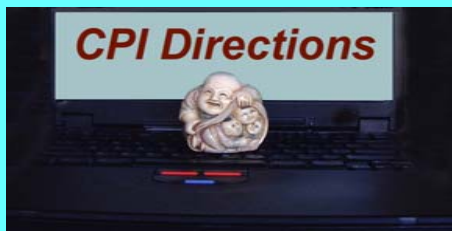


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HIPAA is Huge

Impacts all aspects of treatment, payment and operations:

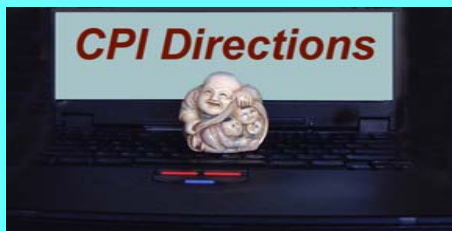
- ***Cultural Change***: whose info is it? Patient's? Providers? Insurer's?
- ***Y2K*** = single event with no punitive legal actions
- ***HIPAA*** = possibility of on-going erosion of profit margins + civil, criminal penalties (including prison)
- ***Push toward standard electronic transactions***: major restructuring of administration of paper processes & staffing
- ***Corporate restructuring & firewalls***: requires legal, administrative, technical, & physical-space transformations
- Implementation cost: ***\$22B over 5 years*** for hospitals alone (AHA)
- ***Minimum Necessary rule***: prohibits common practices, ranging from *talking in elevators* to providing insurance companies with *whole chart*
- ***Pre-empts State laws*** that provide less privacy



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HIPAA Timeline & Deadlines

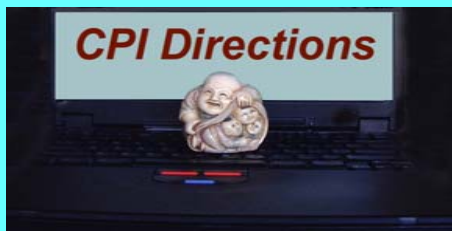
- **August 1996:** Congress passes HIPAA
- **August 1998:** Congress fails deadline to publish HIPAA implementation rules; HHS takes over the process
- **1998-9:** Proposed HIPAA rules formulated & published
- **August 2000:** Final *Transaction Rules* published
- **December 2000:** Final *Privacy Rules* published
- **December 2001:** ASCA - Final *TCS Rule* extension to 10-2003, if implementation plan filed by 10-15-02 & testing begun by 4-15-03
- **March 2002:** HHS proposes changes to Final *Privacy Rule*
- **May 2002:** Final Rule *Employer ID Rule*, comply by 7-30-2004
- **May 2002:** HHS proposes changes to Final *Transactions Rule*
- **August 2002:** Final Privacy Rules revisions, comply by 4-14-2003
- **October 15, 2002:** 1-Yr TCS extension requests to be filed by Midnight
- **February 20, 2003:** Final Security Rules published, comply by 4-20-2005
- **April 17, 2003:** Interim Enforcement Rules published, effect. 5-19-2003



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Some recent **HORROR** stories

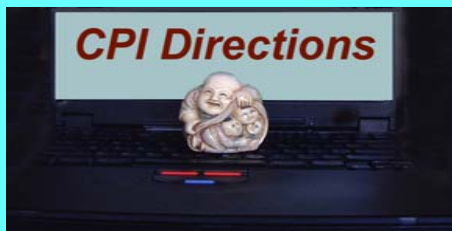
- Large Pharmaceutical Company: Revealed >600 patient e-mail addresses when it sent a message to every individual registered to receive reminders about taking Prozac.
- Major Medical Research University: 1) Mistakenly posted the MH records of 20 children on a public Web site. 2) Mailed a survey to 1200 transplant recipients participating in a long-term research study and mistakenly revealed the names of those who had donated their kidney to the recipients.
- National Retail Drug Chain: Customers pick up prescriptions and sign a log to indicate that they do not want counseling of the pharmacist. Drug chain staff takes the signature (written on a gum-backed sticker) and puts it on a form authorizing the drug store to use the customer's prescription record for promotions.



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Some General HIPAA Terms

- **Covered Entity (CE)**: Health Plans, Clearinghouses, Healthcare Providers that transact PHI electronically
- **Business Associate (BA)**: Indirectly covered - Attorneys, IT vendors, consultants, transcription services, etc.
- **Protected Health Information (PHI)**: individually identifiable health info that relates to past, present, or future health; written, oral, stored in any media
- **TPO**: routine uses and disclosures for Treatment, Payment, Healthcare Operations
- ***Authorization*** to use / disclose PHI non-TPO activities
- ***Minimum Necessary***: Role-, use-based *need to know*



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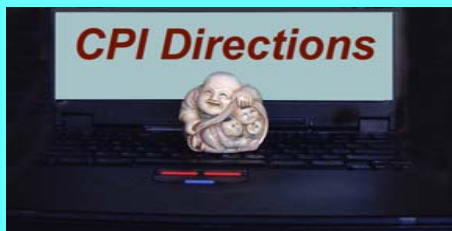
Uses & Disclosures of PHI

Minimum necessary principle

Reasonable efforts to ensure that only *minimum necessary* PHI is used/ disclosed, except:

- **To provider for treatment**
- **To the patient**
- **To HHS pursuant to a privacy investigation**
- **As required by Federal or other law**

Categorize workforce by *need to know* and establish P&P's to limit inappropriate use & disclosure. CE must limit its own requests for PHI (from other CE's) to the *minimum* needed.

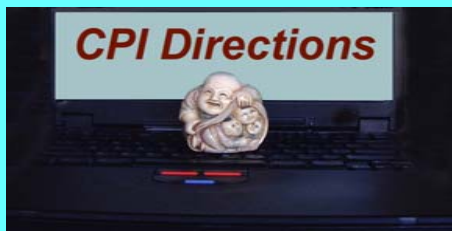


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Designated Record Set

A group of records maintained by or for a CE that is:

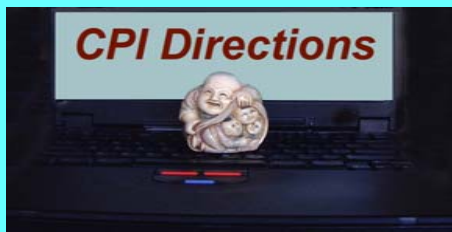
- The medical records and billing records about individuals maintained by or for a covered health care provider, or
- The enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan, or
- Used, in whole or in part, by or for the CE to make decisions about individuals.



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Overview of 5 HIPAA Rule-Sets

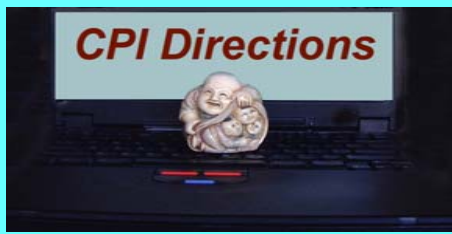
- **Transaction Standards**: standardizes and reduces the current # of electronic formats (claims, eligibility, etc.)
- **Privacy Standards**: provides that our *PHI* will be protected from *bad* uses and disclosures, and provides the patient/client with certain *controls* and *rights*
- **Security Standards**: aim is to provide administrative, technical, and physical-space safeguards
- **Employer/Provider Unique IDs**: unique identifiers for providers & employers to facilitate transfer of information to/from health plans, clearinghouses, payers, etc.
- **Enforcement Standards**: HHS & OCR oversight & enforcement methodologies, penalties for non-compliance



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Patient Rights! & Needed P&P's

- **Notice of privacy practices (NPP)**: Right to be notified of the CE's uses & disclosures of PHI, individual's rights, and CE's legal duties with respect to PHI.
- **Signed-Acknowledgements** (for receipt of ***NPP***): Direct treatment providers to make "***good faith effort***" to obtain signed-acknowledgement by initial visit.
- **Confidential communications**: Right to request communications of PHI from the CE by alternative means or at alternative locations ("***don't call me at home!***")



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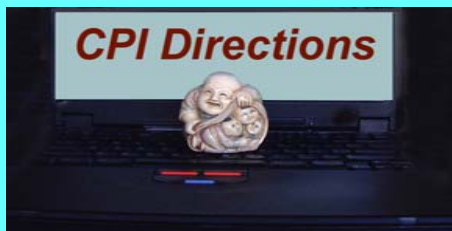
TPO: What is meant by Treatment?

Provision, coordination, or management of health care, & related services by health care provider, including:

- **Coordination or management of healthcare by a provider with a 3rd party consultation(s) among providers relating to a patient**
- **Referral of a patient for health care from one health care provider to another**

Direct treatment relationship: E.g., hands-on exam, verbal assessments (in-person or even on the telephone), filling an Rx at the pharmacy.

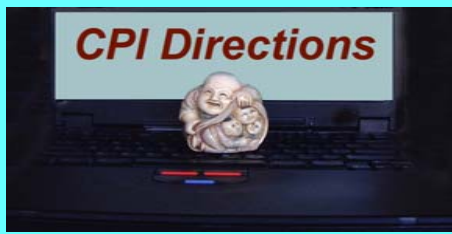
Indirect treatment relationship: E.g., remote consults, diagnoses, laboratory work-ups, and radiological readings.



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TPO: What is meant by Payment?

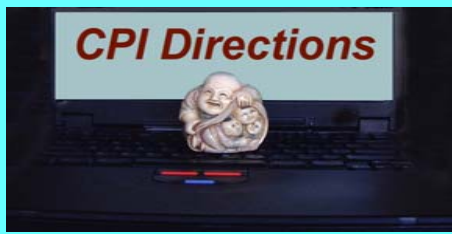
- Review of care for medical necessity, health plan coverage, appropriateness of care, justification of charges
- UR activities, pre-certification and preauthorization of services, concurrent and retrospective review of services
- Determinations of eligibility or coverage, coordination of benefits and adjudication of claims
- Billing, claims management, collection activities
- Disclosures to reporting agencies re collection of payments: Name, address, SSN, DOB, payment hx, acc' #, name and address of provider and/or health plan
- Risk adjustments of amounts due based on enrollee health status and demographic characteristics



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TPO: What are Health Care Operations?

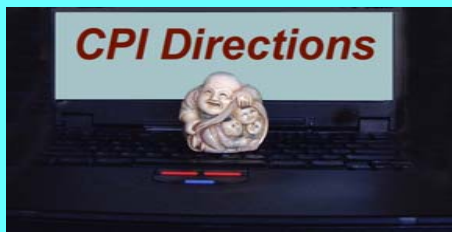
- **Case management/coordination, contacting providers & patients re treatment alternatives, related functions**
- **Workforce evaluation, training, activities re accreditation, certification, licensing, credentialing**
- **Peer review, legal services, auditing functions re fraud, abuse detection, compliance**
- **Outcomes analysis, activities re performance improvement**
- **Formulary development and administration**
- **Grievance resolution**
- **Due diligence in connection with the sale or transfer of assets**
- **HIPAA implementation & compliance**



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HIPAA Requirements

- **Policies and procedures**: Create & implement a privacy P&P **set**. Having a “policy” is **not adequate**; P&P ***set*** must take into account the CE’s size and type of operations
- **Privacy Official**: Requires (documented) appointment of an individual to be accountable for the development implementation of privacy policies & procedures
- **Training**: All workforce members. Initial, and on-going as privacy P&P’s change. Workforce includes Board, employees, volunteers, trainees, etc.



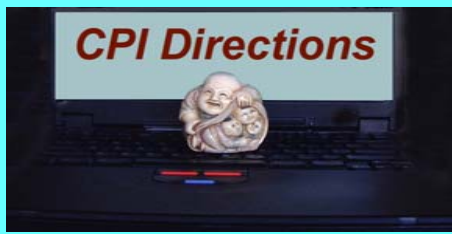
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More Patient Rights! & Needed P&P's

Access to PHI: Access, inspect, and obtain a copy of the individual's PHI in the ***designated record set***. There are exceptions to this requirement, time frames for compliance, and specific required processes that must be implemented.

Right to amend: Amend the PHI. Requirements for addressing requests include timely action, accepting or denying the amendment, informing the individual, etc.

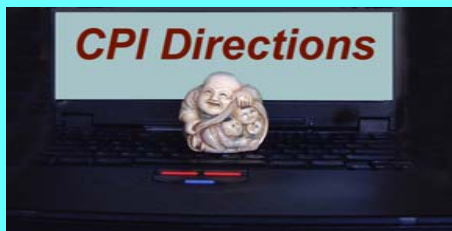
Right to accounting of disclosures of PHI: Right to an accounting of PHI disclosures within the last 6 years, or since compliance was first required for the CE. Exceptions for disclosures for **TPO**, disclosures pursuant to an authorization



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Accountings of PHI Disclosures

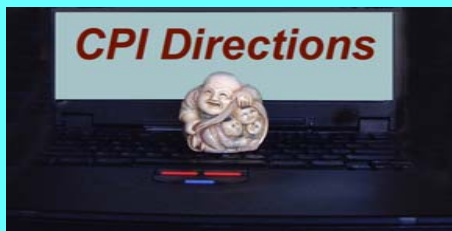
- Research pursuant to IRB waivers
- Suspected abuse reporting
- Underage pregnancy reporting
- Communicable disease reporting
- Disclosures to law enforcement
- State neonatal reporting
- Birth defects registry
- Batch P.H. disclosures to State
- Cancer registry
- Trauma registry
- Death registry
- Poison control
- County medical examiner
- Disclosures to funeral homes
- Reporting to FDA
- Privacy Breaches



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And Yet More Required P&P's!

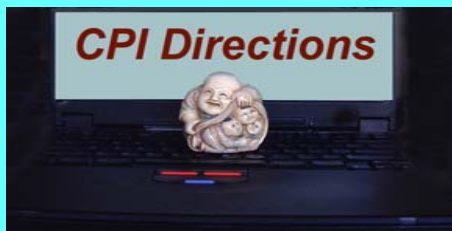
- **Sanctions**: Corrective & disciplinary actions
- **Mitigation**: Positive actions to minimize *harmful effects* of Privacy breaches. BA's to notify CE of breaches
- **Safeguards**: *Appropriate & reasonable* administrative, technical, and physical safeguards
- **Contingency Plans**: Assess systems for anticipated risks; plan to detail how data will be maintained and duplicated
- **Complaints**: Complaints to CE & HHS/OCR



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Business Associate Contracts (BAC): CE to ensure BA's appropriately handle shared PHI

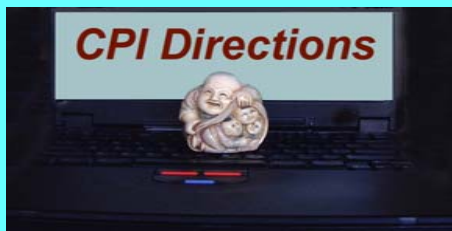
- Signatures, contract start/expiration or review dates
- Terms & conditions, including conditions for disclosure of PHI, data rights of each party, minimum security
- Procedures for reporting breaches and time frame
- Method of recording breaches: incident logs
- Penalties: intentional vs. unintentional breaches
- P&P for the retention and/or destruction of data
- Language requiring subcontractors to be compliant
- TCS certification to be attached (when appropriate)



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Research, as Defined by HIPAA

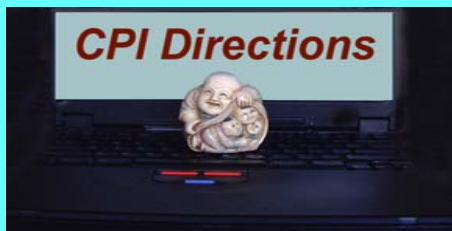
“.....a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.”



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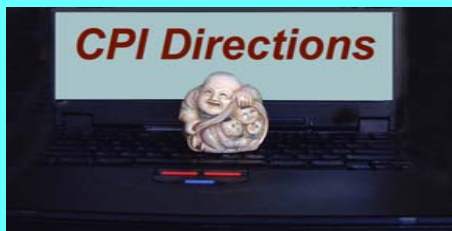
Research WithOUT an Authorization

- Written IRB or Privacy Board approval
- Preparatory to Research
- Research on PHI of Decedents
- De-identified Data Sets
- *Limited Data Set & Data Use Agreement*



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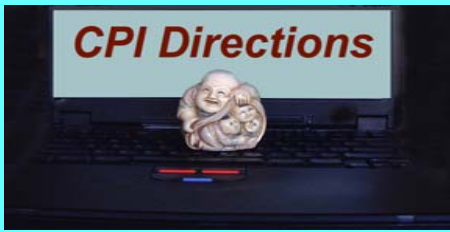
<u>Identifier</u>	<u>De-ID'd</u>	<u>LDS</u>
• Name	X	X
• Address components	X	Town, State Zip code OK
• All elements of dates	X	Dates OK
• Telephone or fax number	X	X
• E-mail, URL, IP addresses	X	X
• Social Security number	X	X
• Driver's license number	X	X
• Medical record number(s)	X	X
• Health plan numbers	X	X
• Account numbers	X	X
• Certificate, license #'s	X	X
• Vehicle identifiers	X	X
• Medical device identifiers	X	X
• Biometric identifier	X	X
• Photographic images	X	X
• Other unique identifiers	X	Minimum Necessary Rule



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Contents of a Data Use Agreement (DUA):

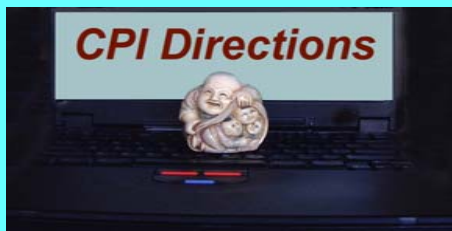
- Establish who is permitted to use or receive the LDS
- Establish permitted use / disclosure by the researcher
- May not authorize the researcher to (re)disclose the LDS in manner that would violate HIPAA
- State appropriate safeguards to prevent use or disclosure of the information other than as provided for by the DUA (including safeguards implemented by agents & subcontractors)
- Require reporting to the CE of any use / disclosure not provided for by the DUA
- May not (re)identify the LDS or contact subjects



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Research WITH an Authorization

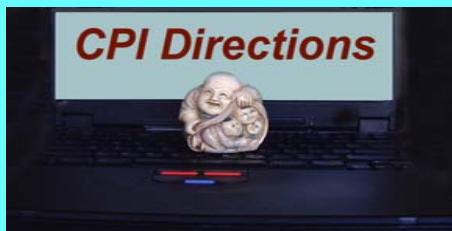
- Requires *HIPAA* compliant “authorization”, but with some differences.....
- Possibility of “open ended” expiration date
- May be combined with a consent to participate in the research



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Authorizations for use & disclosure

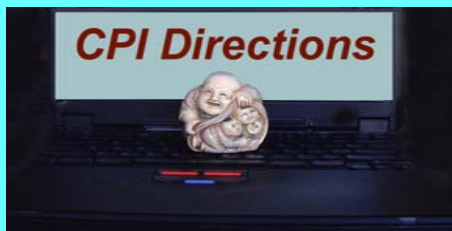
- Required prior to using or disclosing PHI for most non-TPO purposes.
- Patient has right to revoke authorization.
- Examples: Research without an IRB waiver, press events featuring patients, most marketing activities, disclosure of psychotherapy notes



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Components of Authorization Form:

- A description of the PHI to be used or disclosed
- ID's persons authorized who make disclosures
- ID's the persons who may use, or to whom the CE may make the disclosure
- Description of purpose of the use or disclosure
- Expiration date or expiration event that relates to the individual or purpose of the use or disclosure.
- Signature of the individual and date

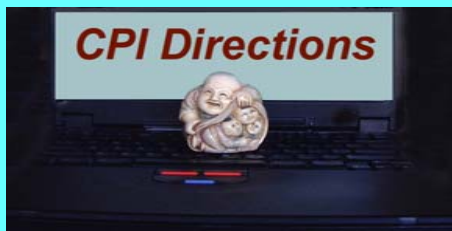


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Uses & Disclosures of PHI for Marketing

“To make a communication about a product or service that encourages recipients of the communication to purchase or use the product or service...” Exceptions for:

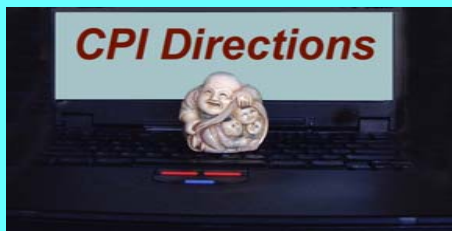
- Descriptions of products or services
- Replacements or enhancements of products or services
- Treatment communications
- Most face-to-face communications
- Providing items of nominal value (e.g., calendars, pens with provider's name)



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Tracking the HIPAA HIPPO

- NPPs & Acknowledgements
- Authorizations
- Patient requests, denials, and complaints
- Workforce Awareness Training
- Disclosure accountings
- Confidential communications
- Agreed-upon restrictions
- Opt-outs from fundraising
- Opt-outs from facility directory
- BACs, DUAs, LDSs
- Amendments of PHI in various sections of the medical record, electronic databases, and already disclosed to other providers & BAs
- Identifiers of PHI in various places in the Designated Record Set (DRS)
- *Breaches* in HIPAA rules
- Etc., etc., etc., etc.

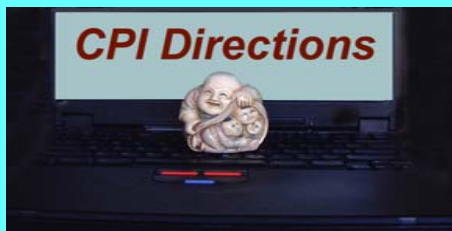


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HIPAA Privacy Costs (Average per Year)

SIC	Industry	Yr 1	Yrs 2-10
8010	Doctors Office	\$3,703	\$2,086
8050	Nursing Care	\$8,301	\$4,676
8060	Hospitals	\$101,999	\$38,244
8070	Medical & Dental Labs	\$3,169	\$1,785
5910	Pharmacies	\$6,436	\$3,625

***Source: Office of Advocacy, U.S. Small Business Administration, from data provided by the Bureau of the Census, Statistics of U.S. Businesses, 1997**



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Penalties for Privacy Breaches

➤ Civil monetary fines:

Up to \$100 per person, per violation

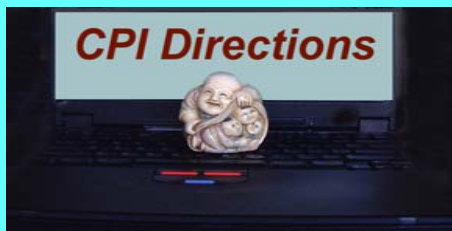
Up to \$25K per person, per standard, per year

➤ Criminal penalties:

Up to \$50K + 1 yr prison: (knowing actions)

Up to \$100K + 5 yrs prison: (false pretense)

Up to \$250K + 10 yrs prison: (sale, malicious harm)



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For additional information, please contact:

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