CONFIDENTIALITY, SECURITY, AND DOCUMENTATION



KIM C. STANGER Idaho Health Care Ass'n (4-22)



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OVERVIEW

- Confidentiality obligations
 - Use and disclosure rules
 - Breach reporting
- Security obligations
 - Cybersecurity threats
 - Relevant laws
 - Resources
- Patient rights, especially right of access
- Documentation suggestions





- The patient had no history of suicides.
- The patient refused autopsy.
- [Patient] has no rigors or shaking chills, but her husband states she was very hot in bed last night."
- The patient has been depressed since she began seeing me in 1993.
- MD order: "Walk in hell."
- Fecal heart tones heard.
- Large brown BM up walking in halls.
- Occasional, constant infrequent headaches.
- Patient was in his usual state of good health until his airplane ran out of gas and crashed.

HOLLAND& HOLLAND& HART.

- The patient is tearful and crying constantly. She also appears to be depressed.
- Patient had waffles for breakfast and anorexia for lunch.
- The skin was moist and dry.
- Skin: somewhat pale, but present.
- Patient was alert and unresponsive.
- Patient has two teenage children, but no other abnormalities.
- Patient lives at home with his mother, father, and pet turtle, who is presently enrolled in day care 3x a week.



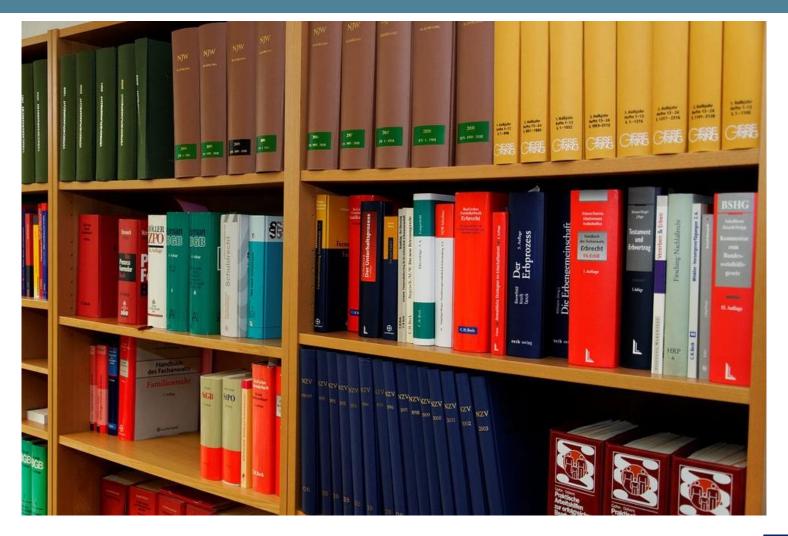
- Discharge status: Alive but without permission.
- Rectal exam revealed a normal size thyroid.
- [Patient] stated that she had been constipated for most of her life, until she got a divorce.
- I saw your patient today, who is still under our car for physical therapy.
- TheRapist in to see patient.
- The baby was delivered, the cord clamped and cut and handed to pediatrician, who breathed and cried immediately.



- Both breasts are equal and reactive to light and accommodation.
- The lab test indicated abnormal lover function.
- The pelvic exam will be done later on the floor.
- While in the ER, [patient] was examined, xrated, and sent home.
- Examination of genitalia was completely negative except for the right foot.
- Examination of genitalia reveals that he is circus sized.



CONFIDENTIALITY LAWS AND REGULATIONS





CONFIDENTIALITY REQUIREMENTS

- Health Insurance Portability and Accountability Act ("HIPAA"), 45 CFR part 164
 - Privacy
 - Security
 - Breach reporting
- Facility regs, e.g.,
 - SNFs: 42 CFR 483.70(i)
 - ALFs: IDAPA 16.03.22.550
 - HHA: 42 CFR 484.110(d)
 - Hospice: 42 CFR 418.104(c)

- Provider laws and regs.
- Substance Use Disorder records, 42 CFR part 2
- Common law privacy torts, e.g,
 - Public disclosure of private facts
 - İntrusion upon seclusion
- Negligence per se
 - Based on violation of statutory duty



SNF CONFIDENTIALITY

 "The facility must keep confidential all information contained in the resident's records, regardless of the form or storage method of the records, except when release is—

(i) To the individual, or their resident representative where permitted by applicable law;

(ii) Required by Law;

(iii) For treatment, payment, or health care operations, as permitted by and in compliance with 45 CFR 164.506;
(iv) For public health activities, reporting of abuse, neglect, or domestic violence, health oversight activities, judicial and administrative proceedings, law enforcement purposes, organ donation purposes, research purposes, or to coroners, medical examiners, funeral directors, and to avert a serious threat to health or safety as permitted by and in compliance with 45 CFR 164.512."

(42 CFR 483.70(i)(2); *see also id.* at 483.10(h)(3) and 483.20(f)(5); CMS SOM App. PP)



ALF CONFIDENTIALITY

 "Each resident must have the right to confidentiality of personal and clinical records."

(IDAPA 16.03.22.550.09)

 "Each resident must have ... the right to confidentiality and privacy concerning their medical or dental condition and treatment."

(IDAPA 16.03.22.550.12(c))

 "The facility must safeguard confidential information against loss, destruction, and unauthorized use."

(IDAPA 16.03.22.330.03)



HHA CONFIDENTIALITY

 "The patient has the right to ... have a confidential clinical record. Access to or release of patient information and clinical records is permitted in accordance with [HIPAA,] 45 CFR parts 160 and 164."

(42 CFR 484.50(c)(6); see also CMS SOM App.B)

 "The clinical record, its contents, and the information contained therein must be safeguarded against loss or unauthorized use. The HHA must be in compliance with the rules regarding personal health information set out at 45 CFR parts 160 and 164."

(42 CFR 484.110(d))



HOSPICE CONFIDENTIALITY

 "The patient has the right to ... have a confidential clinical record. Access to or release of patient information and clinical records is permitted in accordance with [HIPAA,] 45 CFR parts 160 and 164."

(42 CFR 418.52(c)(5); see also CMS SOM App. M)

 "The clinical record, its contents and the information contained therein must be safeguarded against loss or unauthorized use. The hospice must be in compliance with the Department's rules regarding personal health information as set out [in HIPAA, 45 CFR parts 160 and 164."

(42 CFR 418.104(c))



COMPLY WITH MOST RESTRICTIVE LAW



- HIPAA preempts less restrictive laws.
- Comply with more restrictive law, e.g.,
 - 42 CFR part 2
 - State licensing requirements
 - Federal regulations
 - Others?



HIPAA CRIMINAL PENALTIES

 Applies if employees or other individuals obtain or disclose protected health info from covered entity without authorization.

Conduct	Penalty
Knowingly obtain info in violation of the law	• \$50,000 fine • 1 year in prison
Committed under false pretenses	100,000 fine5 years in prison
Intent to sell, transfer, or use for commercial gain, personal gain, or malicious harm	\$250,000 fine10 years in prison
(42 USC 1320d-6(a))	HOLLAND&HART

HIPAA **CIVIL PENALTIES**

Conduct	Penalty
Did not know and should not have known of violation	 \$127* to \$63,973* per violation Up to \$25,630* per type per year No penalty if correct w/in 30 days OCR may waive or reduce penalty
Violation due to reasonable cause	 \$1,280* to \$63,973* per violation Up to \$102,522* per type per year No penalty if correct w/in 30 days OCR may waive or reduce penalty
Willful neglect, but correct w/in 30 days	 \$12,794* to \$63,973* per violation Up to \$256,305* per type per year Penalty is mandatory
Willful neglect, but do not correct w/in 30 days	 At least \$63,973* per violation Up to \$1,754,698* per type per year Penalty is mandatory
(45 CFR 102.3, 160.404; 85 FR 2879)	HOLLAND&HART

HIPAA ENFORCEMENT

- State attorney general can bring lawsuit.
 \$25,000 fine per violation + fees and costs
- Must sanction employees who violate HIPAA.
- Must self-report breaches of unsecured protected health info
 - To affected individuals.
 - To HHS.
 - To media if breach involves > 500 persons.
- Possible lawsuits by affected individuals or others.



HIPAA ENFORCEMENT

2009: HITECH Act requires HHS to establish a methodology for the distribution of a percentage of a civil monetary penalty or settlement collected for noncompliance with the HIPAA Rules to an individual harmed by the noncompliance. (42 USC 17939(c)(2)-(3))



- 4/6/22: OCR seeks comments on the regulation:
 - What "harm" will trigger damages
 - Method for allowing patients to recover percentage of fines or settlements.

(87 FR 19833)



HIPAA AVOIDING PENALTIES

You can likely avoid HIPAA penalties if you:

- Have required policies and safeguards in place.
- Execute business associate agreements.
- Train personnel and document training.
- Respond immediately to mitigate and correct any violation.
- Timely report breaches if required.

No "willful neglect" = No penalties if correct violation within 30 days.



HIPAA PROTECTED HEALTH INFO



PROTECTED HEALTH INFO

Protected health info ("PHI") =

- Individually identifiable health info, i.e., info that could be used to identify individual;
- Concerns physical or mental health, health care, or payment;
- Created or received by covered entity in its capacity as a healthcare provider; and
- -Maintained in any form or medium, e.g., oral, paper, electronic, images, etc.
- Not "de-identified" info.

(45 CFR 160.103)





IS IT PROTECTED HEALTH INFO?

- Facility directory that includes patient's name but no medical info?
- Text to doctor that refers to resident by initials?
- Info that does not include patient's name but does include record number or other medical info?
- Photo of patient so long as there is no name?
- Patient's financial info but no medical info?
- Response to negative internet review so long as no medical info disclosed?
- Employee's health record?



HIPAA AND EMPLOYMENT RECORDS

Employer rendered healthcare to employee (e.g., vaccination, drug test, etc.)

HIPAA applies

- To use/disclose PHI, need either:
 - Employee authorization, or
 - HIPAA exception.

(67 FR 53191)

Employer obtained info solely in its capacity as the employer (e.g., from employee or other provider)

- HIPAA does <u>not</u> apply.
 - "Employment records" excluded from definition of PHI.
- Other laws may apply, e.g., ADA.



ADA AND EMPLOYEE HEALTH INFO

Under ADA:

- Employer may ask about employee vaccination status.
- Employer must keep employee health info confidential, including vaccination status.
 - Store separately from personnel file.
 - May disclose to supervisors or managers to allow necessary accommodations.
 - May require those who are not vaccinated to wear a mask subject to reasonable accommodation.

(29 CFR 1630.14; EEOC Guidance (5/21))

- Maybe allow employee to display something confirming that they may work without a mask but do not require notice of vaccination status.
- Maybe allow voluntary vaccination stickers.

➤ Check local laws.



HIPAA PRIVACY RULE

Don't access if don't need to know. Don't disclose unless fit exception or have authorization

Implement reasonable safeguards



PROHIBITED ACTIONS

- Cannot use, access or disclose PHI unless:
 - -Permitted by HIPAA, or
 - -Have patient's or personal rep's authorization.
- Applies to
 - –Unauthorized disclosure <u>outside</u> covered entity.
 - –Unauthorized use <u>within</u> covered entity.
 - Unauthorized access from <u>within or</u> <u>outside</u> covered entity.

(45 CFR 164.502)



AUTHORIZATION

Must obtain a valid written authorization to use or disclose protected PHI:

- Psychotherapy notes.
- Marketing
- Sale of PHI
- Research
- For all other uses or disclosures unless a regulatory exception applies.
- Authorization may not be combined with other documents.
- Authorization must contain required elements and statements.
- Signed by patient or personal representative.
 (45 CFR 164.508)



PERSONAL REPRESENTATIVES

- Under HIPAA, treat the personal rep as if they were the patient.
- Personal rep may exercise patient rights.
- Personal rep = persons with authority under state law to:
 - Make healthcare decisions for patient, or
 - Make decisions for deceased patient's estate.

(45 CFR 164.502(g))

- In Idaho, personal reps =
 - Court appointed guardian
 - Ägent in DPOA
 - Spouse
 - Adult child
 - Parent
 - Delegation of parental authority
 - Other appropriate relative
 - Any other person responsible for patient's care

(IC 39-4504)



PERSONAL REPRESENTATIVES

- Not required to treat personal rep as patient (i.e., do not disclose PHI to them) if:
 - Minor has authority to consent to care.
 - Minor obtains care at the direction of a court or person appointed by the court.
 - Parent agrees that provider may have a confidential relationship.
 - Provider determines that treating personal rep as the patient is not in the best interest of patient, e.g., abuse.

(45 CFR 164.502)



TREATMENT, PAYMENT OR OPERATIONS

- May use/disclose PHI without patient's authorization for <u>your own</u>:
 - Treatment;
 - Payment; or
 - Health care operations.
- May disclose PHI to another covered entity for <u>other entity's</u>:
 - Treatment;
 - Payment; or
 - Certain healthcare operations if both have relationship with patient.
- Exception: psychotherapy notes.
 - Requires specific authorization for use by or disclosures to others.

(45 CFR 164.506. 164.508 and 164.522)



TREATMENT, PAYMENT OR OPERATIONS

 If agree with patient to limit use or disclosure for treatment, payment, or healthcare operations, you must abide by that agreement except in an emergency.

(45 CFR 164.506 and 164.522)

- Don't agree to limit disclosures for treatment, payment or operations.
 - *Exception: disclosure to insurers; see discussion below.*
- Beware asking patient for list of persons to whom disclosure may be made.
 - Creates inference that disclosures will not be made to others.
 - If list persons, ensure patient understands that we may disclose to others per HIPAA.



BUSINESS ASSOCIATES

 May disclose PHI to business associates if have valid business associate agreement ("BAA").

(45 CFR 164.502)

- Business associates =
 - Entities that create, receive, maintain, or transmit PHI on behalf of a covered entity.
 - Covered entities acting as business associates.
 - Subcontractors of business associates.
 - <u>Not</u> members of workforce.

(45 CFR 160.103)

- Failure to execute BAA = HIPAA violation
 - May subject you to HIPAA fines.
 - Based on recent settlements, may expose you to liability for business associate's misconduct.



<u>HTTPS://WWW.HHS.GOV/HIPAA/FOR-</u> <u>PROFESSIONALS/COVERED-ENTITIES/SAMPLE-BUSINESS-</u> <u>ASSOCIATE-AGREEMENT-PROVISIONS/INDEX.HTML</u>

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HIPAA for Professionals

Privacy	+
Security	+
Breach Notification	+
Compliance & Enforcement	+
Special Topics	+
Patient Safety	+
Covered Entities & Business Associates	-
Business Associates	
Business Associate Contracts	

Business Associate Contracts

SAMPLE BUSINESS ASSOCIATE AGREEMENT PROVISIONS

(Published January 25, 2013)

Introduction

A "business associate" is a person or entity, other than a member of the workforce of a covered entity, who performs functions or activities on behalf of, or provides certain services to, a covered entity that involve access by the business associate to protected health information. A "business associate" also is a subcontractor that creates, receives, maintains, or transmits protected health information on behalf of another business associate. The HIPAA Rules generally require that covered entities and business associates enter into contracts with their business associates to ensure that the business associates will appropriately safeguard protected health information. The business associate contract also serves to clarify and limit, as appropriate, the permissible uses and disclosures of protected health information by the business associate, based on the relationship between the parties and the activities or services being performed by the business associate. A business associate may use or disclose protected health information only as permitted or required by its business associate contract or as required by law. A business associate is directly liable under the HIPAA Rules and subject to civil and, in some cases, criminal penalties for making uses and disclosures of protected health information that are not authorized by its contract or required by law. A business associate also is directly liable and subject to civil penalties for failing to safeguard electronic protected health information in accordance with the HIPAA Security Rule.

A written contract between a covered entity and a business associate must: (1) establish the permitted and required uses and disclosures of protected health information by the business associate; (2) provide that the business associate will not use or further disclose the information other than as permitted or required by the contract or as required by law; (3) require the business associate to

BUSINESS ASSOCIATES

See also CMS regulations:

SNF: "The facility may release information that is resident-identifiable to an agent only in accordance with a contract under which the agent agrees not to use or disclose the information except to the extent the facility itself is permitted to do so."

(42 CFR 483.20(f)(5))

HHA: "The HHA and agent acting on behalf of the HHA in accordance with a written contract must ensure the confidentiality of all patient identifiable information contained in the clinical record..."

(42 CFR 484.40)



PERSONS INVOLVED IN CARE

- May use or disclose PHI to family or others involved in patient's care or payment for care:
 - If patient present, may disclose if:
 - Patient agrees to disclosure or has chance to object and does not object, or
 - Reasonable to infer agreement from circumstances.
 - If patient unable to agree, may disclose if:
 - Patient has not objected; and
 - You determine it is in the best interest of patient.
 - Limit disclosure to scope of person's involvement.
- Applies to disclosures after the patient is deceased.
 (45 CFR 164.510)



FACILITY DIRECTORY

- May disclose limited PHI for facility directory <u>if</u>:
 - Gave patient notice and patient does not object, and
 - Requestor asks for the person by name.
- If patient unable to agree or object, may use or disclose limited PHI for directory if:
 - Consistent with person's prior decisions, and
 - Determine that it is in patient's best interests
- Disclosure limited to:
 - Name
 - Location in facility
 - General condition
 - Religion, if disclosure to minister

(45 CFR 164.510)



EXCEPTIONS FOR PUBLIC HEALTH OR GOVERNMENT FUNCTIONS

- Another law requires disclosures
- Disclosures to prevent serious and imminent harm.
- Public health activities
- Health oversight activities
- Judicial or administrative proceedings
 - Court order or warrant
 - Subpoenas
- Law enforcement
 - Must satisfy specific requirements
- Workers compensation

(45 CFR 164.512)

Ensure you comply with specific regulatory requirements



VERIFICATION

- Before disclosing PHI:
 - Verify the identity and authority of person requesting info if he/she is not known.
 - E.g., ask for SSN or birthdate of patient, badge, credentials, etc.
 - Obtain any documents, representations, or statements required to make disclosure.
 - E.g., written satisfactory assurances accompanying a subpoena, or representations from police that they need info for immediate identification purposes.

(45 CFR 164.514(f))

 Portals should include appropriate access controls.
 (OCR Guidance on Patient's Right to Access Their Information) HOLLAND&HART

MINIMUM NECESSARY STANDARD

- Cannot use or disclose more PHI than is reasonably necessary for intended purpose.
- Minimum necessary standard does not apply to disclosures to:
 - Patient.
 - Provider for treatment.
 - Per individual's authorization.
 - As required by law.
- May rely on judgment of:
 - Another covered entity.
 - Professional within the covered entity.
 - Business associate for professional services.
 - Public official for permitted disclosure.

(45 CFR 164.502 and .514)



MINIMUM NECESSARY STANDARD

- Must adopt policies addressing—
 - Internal uses of PHI:
 - Identify persons who need access.
 - Draft policies to limit access accordingly.
 - External disclosures of PHI:
 - Routine disclosure: establish policies.
 - Non-routine disclosures: case-by-case review.
 - Requests for PHI:
 - Routine requests: establish policies.
 - Non-routine requests: case-by-case review.

(45 CFR 164.502 and .514)



HIPAA BREACH NOTIFICATION RULE





BREACH NOTIFICATION

- If there is "breach" of "unsecured PHI",
 - -Covered entity must notify:
 - Each individual whose unsecured PHI has been or reasonably believed to have been accessed, acquired, used, or disclosed.
 - HHS.
 - Local media, if breach involves > 500 persons in a state.
 - –Business associate must notify covered entity.
- (45 CFR 164.400 et seq.)



"BREACH" OF UNSECURED PHI

- Acquisition, access, use or disclosure of PHI in violation of privacy rule is presumed to be a breach unless the covered entity or business associate demonstrates that there is a low probability that the info has been compromised based on a risk assessment of the following factors:
 - nature and extent of PHI involved;
 - unauthorized person who used or received the PHI;
 - whether PHI was actually acquired or viewed; and
 - extent to which the risk to the PHI has been mitigated,

<u>unless</u> an exception applies.

(45 CFR 164.402)



"BREACH" OF UNSECURED PHI

- "Breach" defined to exclude the following:
 - Unintentional acquisition, access or use by workforce member if made in good faith, within scope of authority, and PHI not further disclosed in violation of HIPAA privacy rule.
 - Inadvertent disclosure by authorized person to another authorized person at same covered entity, business associate, or organized health care arrangement, and PHI not further used or disclosed in violation of privacy rule.
 - Disclosure of PHI where covered entity or business associate have good faith belief that unauthorized person receiving info would not reasonably be able to retain info

(45 CFR 164.402)



INCIDENTAL DISCLOSURES

- "Incidental disclosures" do not trigger breach reporting so long as the provider had reasonable safeguards in place.
 - Incidental disclosures do not violate the privacy rule, so they are not reportable "breach."
- Reasonable safeguards might include, e.g.,
 - Speaking quietly when discussing patient's condition to avoid others overhearing.
 - Avoiding use of patient names in public areas.
 - Isolating or locking file cabinets or records rooms.

(<u>https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/incidental-uses-and-disclosures/index.html</u>)





IS IT A REPORTABLE BREACH?

- In response to call, employee discloses that patient is receiving care, but no other info.
- Employee faxes patient medication info to wrong physician.
- Curious employee accesses PHI without a need to know.
- Employee responds to negative internet review about resident's care.
- Employee loses a smart phone that contains unencrypted PHI about a patient.
- Unencrypted laptop containing PHI is stolen from employee's home.
- Employee contacts family members to try to get them to pay for their mother's care.
- Visitor takes photos of his mother, but the photo includes other residents.
- Visitor overhears two CNAs talking about a patient.



NOTICE TO INDIVIDUAL

- Without unreasonable delay but no more than 60 days of discovery.
 - When known by anyone other than person who committed breach.
- Written notice to individual.
 - By mail.
 - Must contain elements, including:
 - Description of breach
 - Actions taken in response
 - Suggested action individual should take to protect themselves.

(45 CFR 164.404(d))



NOTICE TO HHS

- If breach involves fewer than 500 persons:
 - Submit to HHS annually within 60 days after end of calendar year in which breach was discovered (i.e., by March 1).
- If breach involves 500 or more persons:
 - Notify HHS contemporaneously with notice to individual or next of kin, i.e., without unreasonable delay but within 60 days.

(45 CFR 164.408)

Submit report at <u>http://www.hhs.gov/hipaa/for-professionals/breach-notification/breach-reporting/index.html</u>.



<u>HTTPS://WWW.HHS.GOV/HIPAA/FOR-</u> <u>PROFESSIONALS/BREACH-NOTIFICATION/BREACH-</u> <u>REPORTING/INDEX.HTML</u>

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	Privacy	+	Submitting N	lotice of a Breach	to the Secretary			
	Security	+	information. See 45 C.F.R.	A covered entity must notify the Secretary if it discovers a breach of unsecured protected health information. See <u>45 C.F.R. § 164.408</u> . All notifications must be submitted to the Secretary using the				
	Breach Notification	-	Web portal below.					
	Breach Reporting		more individuals or fewer t	notification obligations differ based or han 500 individuals. If the number of provision, the covered entity should n	individuals affected by a breach is	re		
	Guidance		additional information, sub	uncertain at the time of submission, the covered entity should provide an estimate, and, if it discovers additional information, submit updates in the manner specified below. If only one option is available in a particular submission category, the covered entity should pick the best option, and may provide				
	Reports to Congress		additional details in the fre	e text portion of the submission.				
	Regulation History		previously submitted notice	rs additional information that supplem e to the Secretary, it may submit an a	dditional form by checking the			
	Compliance & Enforcement	+	appropriate box to indicate that it is an addendum to the initial report, using the transaction number provided after its submission of the initial breach report.					
	Special Topics	+	Please review the instruction					
	Patient Safety	+		cting 500 or More Inc				
	Covered Entities & Business Associates		entity must notify the Secre 60 calendar days from the electronically by clicking or	rotected health information affects 50 etary of the breach without unreasona discovery of the breach. The coveren the link below and completing all of	able delay and in no case later than d entity must submit the notice			
	Training & Resources		notification form. Submit a Notice for a Brea	ch Affecting 500 or More Individuals				
	FAQs for Professionals		View a list of Breaches Affe	ecting 500 or More Individuals				
Other Administrative Simplification Rules				cting Fewer than 500 rotected health information affects fe				

entity must notify the Secretary of the breach within 60 days of the end of the calendar year in which

NOTICE TO HHS

HHS posts list of those with breaches involving more than 500 at <u>https://ocrportal.hhs.gov/ocr/breach/breach_report.jsfpersons</u>

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U.S. Department of Health and Human Services Office for Civil Rights

Breach Portal: Notice to the Secretary of HHS Breach of Unsecured Protected Health Information

Breaches Affecting 500 or More Individuals

As required by section 13402(e)(4) of the HITECH Act, the Secretary must post a list of breaches of unsecured protected health information affecting 500 or more individuals. These breaches are now posted in a new, more accessible format that allows users to search and sort the posted breaches. Additionally, this new format includes brief summaries of the breach cases that OCR has investigated and closed, as well as the names of private practice providers who have reported breaches of unsecured protected health information to the Secretary. The following breaches have been reported to the Secretary:

Show Advanced Options

			Breach	Report Results			🛌 🪣 🚣 🔤 🛛
	Name of Covered Entity \$	State \$	Covered Entity Type ≎	Individuals Affected ≎	Breach Submission Date ≎	Type of Breach	Location of Breached Information
O	Brooke Army Medical Center	ТХ	Healthcare Provider	1000	10/21/2009	Theft	Paper/Films
O	Mid America Kidney Stone Association, LLC	МО	Healthcare Provider	1000	10/28/2009	Theft	Network Server
O	Alaska Department of Health and Social Services	AK	Healthcare Provider	501	10/30/2009	Theft	Other, Other Portable Electronic Device
0	Health Services for Children with Special Needs, Inc.	DC	Health Plan	3800	11/17/2009	Loss	Laptop
0	Mark D. Lurie, MD	CA	Healthcare Provider	5166	11/20/2009	Theft	Desktop Computer
0	L. Douglas Carlson, M.D.	CA	Healthcare Provider	5257	11/20/2009	Theft	Desktop Computer
0	David I. Cohen, MD	CA	Healthcare Provider	857	11/20/2009	Theft	Desktop Computer
O	Michele Del Vicario, MD	CA	Healthcare Provider	6145	11/20/2009	Theft	Desktop Computer
0	Joseph F. Lopez, MD	CA	Healthcare Provider	952	11/20/2009	Theft	Desktop Computer
O	City of Hope National Medical Center	CA	Healthcare Provider	5900	11/23/2009	Theft	Laptop
O	The Children's Hospital of Philadelphia	PA	Healthcare Provider	943	11/24/2009	Theft	Laptop
O	Cogent Healthcare, Inc.	TN	Business Associate	6400	11/25/2009	Theft	Laptop
O	Democracy Data & Communications, LLC (VA	Business Associate	83000	12/08/2009	Other	Paper/Films
0	Kern Medical Center	CA	Healthcare Provider	596	12/10/2009	Theft	Other
0	Rick Lawson, Professional Computer Services	NC	Business Associate	2000	12/11/2009	Theft	Desktop Computer, Electronic Medical Record, Network Server
O	Detroit Department of Health and Wellness Promotion	MI	Healthcare Provider	646	12/15/2009	Theft	Desktop Computer, Laptop
O	Detroit Department of Health and Wellness Promotion	MI	Healthcare Provider	10000	12/15/2009	Theft	Other Portable Electronic Device



File a Breach | HHS | Office for Civil Rights | Contact

NOTICE TO MEDIA

- If breach involves unsecured PHI of more than 500 residents in a state, covered entity must notify prominent media outlets serving that state (e.g., issue press release).
 - Without unreasonable delay but no more than 60 days from discovery of breach.
 - Include same content as notice to individual.

(45 CFR 164.406)



IDAHO IDENTITY THEFT STATUTE

- Generally, requires all commercial entities to immediately investigate and notify subject persons if there is a
 - Breach of computer system
 - Resulting in illegal acquisition
 - Of certain unencrypted computerized personal info
 - Name + certain other identifiers (e.g., SSN, driver's license, credit card number + PIN or password, etc.)
 - Actual or reasonably likely misuse of personal info
- \$25,000 fine if fail to notify persons.
- Compliance with HIPAA likely satisfies Idaho statute.

(IC 28-51-104)



CYBERSECURITY





HIPAA SECURITY RULE

- Covered entities and business associates must:
- Risk assessment
- Implement safeguards.
 - -Administrative
 - -Technical, including encryption
 - Physical
- Execute business associate agreements.
 (45 CFR 164.301 et seq.)

Protect ePHI:

- Confidentiality
- Integrity
- Availability



FACILITY SECURITY REGULATIONS

- SNF must have "[a] system of medical documentation that preserves resident information, protects confidentiality of resident information, and secures and maintains the availability of records." (42 CFR 483.73(b)(5))
- ALF "must safeguard confidential information against loss, destruction, and unauthorized use." (IDAPA 16.03.22.330.03)
- HHA must have "[a] system of medical documentation that preserves patient information, protects confidentiality of patient information, and secures and maintains the availability of records." (42 CFR 484.102(b)(4))
- Hospice must have "[a] system of medical documentation that preserves patient information, protects confidentiality of patient information, and secures and maintains the availability of records." (42 CFR 484.102(b)(4))



CYBERSECURITY IN HEALTHCARE

- Ransomware encrypts your IT system so that you may not access it, including:
 - Patient records
 - Financial records
 - Employment records
- Hacker accesses data on your system
- Hacker manipulates or corrupts data on medical devices
- Employee error leads to access to thousands of patient records

What are the consequences to your organization?



CYBERSECURITY IN HEALTHCARE

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 - Patient records
 - Financial records
 - Employment records
- Hacker accesses data on your system
- Hacker manipulates or corrupts data on medical devices
- Employee error leads to access to thousands of patient records

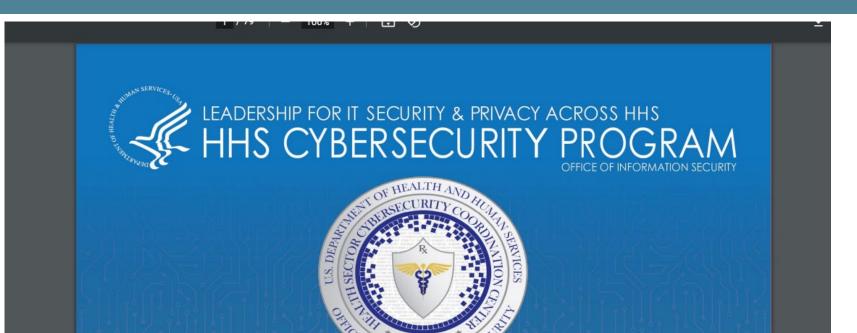


- Inability to access data
- Corruption of data
- Forced to move patients
- Disruption of operations
- Lost revenue
- Cost of response
- Loss or damage to equipment
- Bad public relations
- Fines and penalties
- Lawsuits
- Others?





<u>HTTPS://WWW.HHS.GOV/SITES/DEFAULT/FILES/2021-</u> <u>RETROSPECTIVE-AND-2022-LOOK-AHEAD-</u> <u>TLPWHITE.PDF</u>



Health Sector Cybersecurity: 2021 Retrospective and 2022 Look Ahead

OF INFORMATIC

03/03/2022

TLP: WHITE, ID# 202203031300

HHS CYBERSECURITY REPORT (3/22)

Healthcare Cybersecurity Events of Interest: July 2021, Part 3

IBM Annual Data Breach Cost Report

- IBM released their 2021 Cost of a Data Breach report
- They assessed that the data breaches in 2021 cost a company \$4.24 million per incident on average, which is the highest figure in the 17-year history of this report.
 - In the United States, data breach costs averaged about \$9 million per incident.
 - The cost of breaches increased about 10% in a year, and IBM largely attributes that to the remote workforce which has increasingly been in place since the beginning of the pandemic.
 - On that note, IBM also found that the average cost of a breach increased about \$1 million when remote work was a factor in the breach.
- The average healthcare breach was \$9.23 million, which was a dramatic increase, about 30%, from \$7.13 million in 2019.

11

Consecutive years healthcare had the highest industry cost of a breach

Healthcare organizations experienced the highest average cost of a data breach, for the eleventh year in a row.

\$180

Per record cost of personally identifiable information

Customer personally identifiable information (PII) was the most common type of record lost, included in 44% of breaches.

40

HHS CYBERSECURITY & PRIVACY ACROSS HHS

HHS CYBERSECURITY REPORT (3/22)

-

Healthcare Cybersecurity Events of Interest: December 2021, Part 5

Coveware Quarterly Ransomware Report: 2021 Q4

Average Ransom Amount up Sharply in Q4 2021

Average Ransom Payment

\$322,168 +130% from 03 2021

Median Ransom Payment

\$117,116 +63% from Q3 2021

The Most Common Ransomware Variants in Q4 2021

Rank	Ransomware Type	Market Share %	Change in Ranking from Q3 2021
1	Conti V2	19.4%	÷
2	LockBit 2.0	16.3%	+2
3	Hive	9.2%	+5
4	Mespinoza	4.1%	-2
5	Zeppelin	3.6%	+1
5	BlackMatter	3.6%	+4
6	Karakurt	3.1%	New in Top Variants
6	Suncrypt	3.1%	+2
6	AvosLocker	3.1%	New in Top Variants

Top 10: Market Share of the Ransomware attacks



HTTPS://WWW.HHS.GOV/BLOG/2022/02/28 /IMPROVING-CYBERSECURITY-POSTURE-HEALTHCARE-2022.HTML

HHS.gov

U.S. Department of Health & Human Services



OCR DIRECTOR PINO'S BLOG (2/28/22)

"I cannot underscore enough the importance of enterprisewide risk analysis.... You should fully understand where all electronic protected health information (ePHI) exists across your organization – from software, to connected devices, legacy systems, and elsewhere across your network.... Some best practices include:

- "Maintaining offline, encrypted backups of data and regularly test your backups;
- "Conducting regular scans to identify and address vulnerabilities, especially those on internet-facing devices, to limit the attack surface;
- "Regular patches and updates of software and Operating Systems; and
- "Training your employees regarding phishing and other common IT attacks."

(Lisa Pino, Director of Office for Civil Rights (2/28/22))



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Top Healthcare Cybersecurity Threats

- 1. E-mail phishing attacks
- 2. Ransomware attacks
- 3. Loss or theft of equipment or devices
- 4. Insider data loss
- 5. Connected medical



How To Spot A

What is Phishing? A technique used to fraudulently obtain usernames, passwords, credit card numbers, and other sensitive information.



Fraudulent emails typically ask you to:

- · Open an attachment or,
- · Click on a link, redirecting you to a malicious website.
- You may be prompted to enter personal information.

Types of Phishing Attacks

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Spear Phishing: A highly targeted form of phishing that hones in on a specific group of individuals or organization.



Whaling: A form of phishing, targeted at executive level individuals.



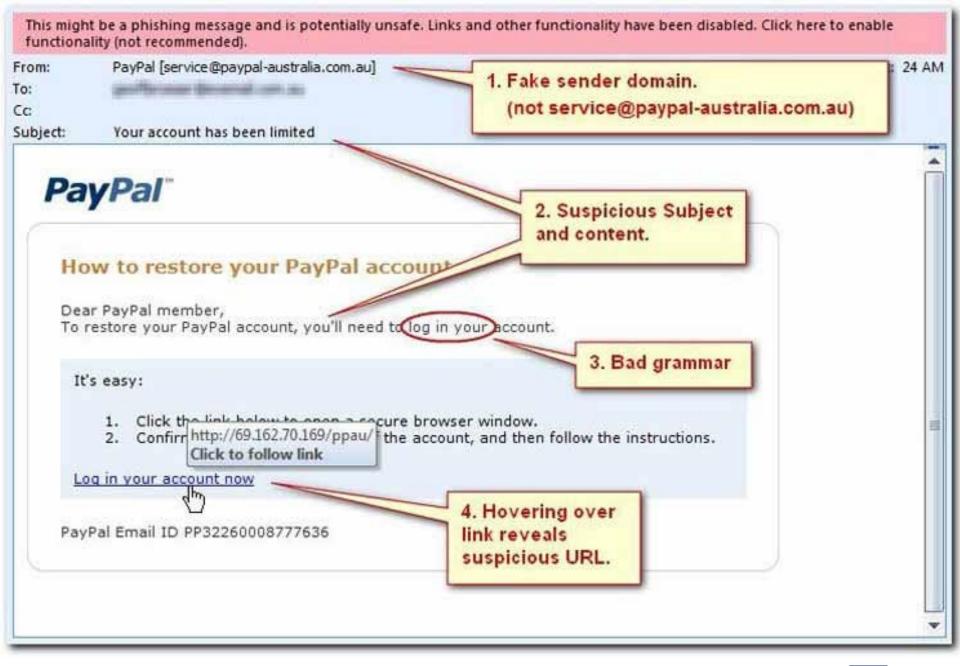
Cloning: Whereby a legitimate email is duplicated but, the content is replaced with malicious links or attachments.

S. FOUNDED BY BRICHAM AND WOMEN'S HOSPITAL AND MASSACHUSETTS GENERAL HOSPITAL

Anatomy of a Phishing Email

Contains links or attachments Poor grammar and spelling Requests personal or sensitive information High sense of urgency and/or privacy Discusses confidential subjects like salaries

For more information visit: www.ispo.partners.org.





From: Costco Shipping Agent <manager@cbcbuilding.com> Subject: Scheduled Home Delivery Problem Date: January 6, 2014 10:54:37 PM MST To: Reply-To: Costco Shipping Agent <manager@cbcbuilding.com>



Unfortunately the delivery of your order <u>COS-0077945599</u> was cancelled since the specified address of the recipient was not correct. You are recommended to complete <u>this form</u> and send it back with your reply to us.

Please do this within the period of one week - if we dont get your timely reply you will be paid your money back less 21% since your order was booked for Christmas.

1998 - 2013 Costco Wholesale Corporation All rights reserved



Hide

File	Message	∞ ?
From: To:	LinkedIn Accounts Amy B; Bryan; Dennis B; Gary; Jim C; Geff H; Louise K; Patty; Ihor M; Ted N; (Chris P;
Subject:	Account suspended!	
Li	nked in.	
	inkedIn accaunt was suspended due to spam messages. To unlock account open this link <u>www.llinked.ni a</u>	
Thank	you for using LinkedIn!	
The Li	inkedIn Team	





Refund Notification

Due to a sytem error you were double charged for your last order, A refund process was initiated but could not be completed due to errors in your billing information

REF CODE:2550CGE

You are required to provide us a valid billing address

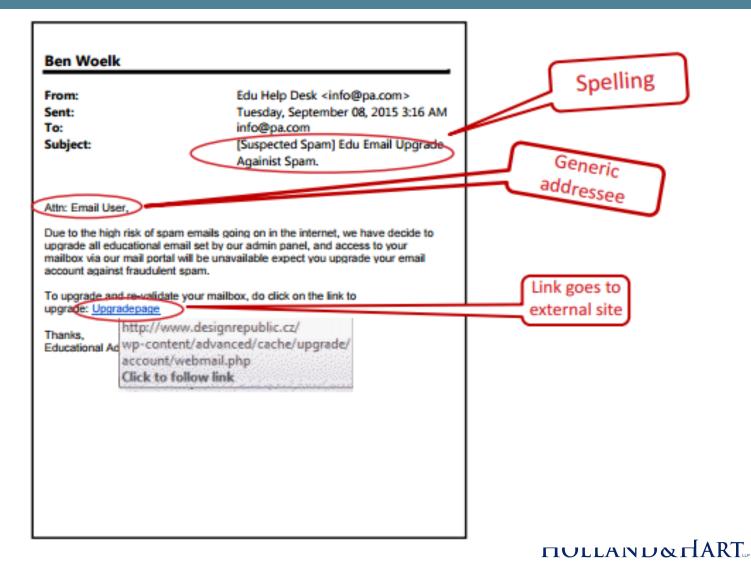
Click Here to Update Your Address

After your information has been validated you should get your refund within 3 business days

We hope to see you again soon. Amazon.com Email ID:



MAY ALSO APPEAR TO BE INTERNAL E-MAILS



From: HelpDesk [mailto:xxxxx@connect.ust.hk] Sent: Wednesday, April 12, 2017 2:23 PM To: *[redacted]* Subject: Validate Email Account

This is to notify all Students, Staffs of University that we are validating active accounts.

Kindly confirm that your account is still in use by clicking the validation link below:

Validate Email Account

Sincerely

IT Help Desk Office of Information Technology

The University



E-MAIL PHISHING ATTACKS

- Do you know the sender?
- Did you expect the e-mail?
- Is the subject generic, urgent, strange, or suspicious?
- Are there spelling, grammar, or other indicators that the tone or style is off?
- Does the e-mail require you to take some action, e.g.,
 - Disclose confidential info
 - Click on link
 - Open attachment
- Did you hover over link to see the URL destination?

DANGER DO NOT ENTER DANGER DO NOT ENTER DANGER DO DO NOT ENTER DO DO NOT ENTER DO COPEN attachment Click on link DO LOS



<u>HTTPS://WWW.HHS.GOV/HIPAA/FOR-</u> <u>PROFESSIONALS/SECURITY/GUIDANCE/CYBERSECURIT</u> <u>Y-NEWSLETTER-FIRST-QUARTER-2022/INDEX.HTML</u>

Regulatory Initiatives

- Key threats:
 - Phishing
 - Exploiting known vulnerabilities
 - Weak cyber practices
- Best practices to address threats
- Resources for covered entities

Other Administrative Simplification Rules

OCR Quarter 1 2022 Cybersecurity Newsletter

Throughout 2020 and 2021, hackers have targeted the health care industry seeking unauthorized access to valuable electronic protected health information (ePHI). The number of breaches of unsecured ePHI reported to the U.S Department of Health and Human Service's Office for Civil Rights (OCR) affecting 500 or more individuals due to hacking or IT incidents increased 45% from 2019 to 2020.¹ Further, the number of breaches due to hacking or IT incidents accounted for 66% of all breaches affecting 500 or more individuals reported to OCR in 2020.²

Although some attacks may be sophisticated and exploit previously unknown vulnerabilities (*i.e.*, zeroday attack), most cyber-attacks could be prevented or substantially mitigated if HIPAA covered entities and business associates ("regulated entities") implemented HIPAA Security Rule requirements to address the most common types of attacks, such as phishing emails, ³ exploitation of known vulnerabilities, and weak authentication protocols. If an attack is successful, the attacker often will encrypt a regulated entity's ePHI to hold it for ransom, or exfiltrate the data for future purposes including identify theft or blackmail. Cyber-attacks are especially critical in the health care sector as attacks on ePHI can disrupt the provision of health care services to patients. This newsletter explores preventative steps regulated entities can take to protect against some of the more common, and often successful, cyber-attack techniques.

Phishing

One of the most common attack vectors is phishing. Phishing is a type of cyber-attack used to trick individuals into divulging sensitive information via electronic communication, such as email, by impersonating a trustworthy source. ⁴ A recent report noted that 42% of ransomware attacks in Q2 2021 involved phishing. ⁵ All regulated entities' workforce members should understand they have an important role in protecting the ePHI their organization holds from cyber-attacks. Part of that role involves being able to detect and take appropriate action if one encounters suspicious email. To ensure workforce members can take appropriate action, regulated entities should train their workforce members to recognize phishing attacks and implement a protocol on what to do when such attacks or suspected attacks occur (*e.g.*, report suspicious emails to appropriate IT personnel).

The Security Rule requires regulated entities to implement a security awareness and training program for all workforce members. ⁶ A regulated entity's training program should be an ongoing, evolving process and be flexible enough to educate workforce members on new and current cybersecurity.

OCR CYBERSECURITY NEWSLETTER (4/22)

Phishing

- Train workforce how to recognize, respond to, and report phishing attacks or suspicious emails.
- Educate staff about current and evolving cyberthreats.
- Send periodic security reminders, e.g., simulated phishing e-mails to gauge awareness.
- Implement anti-phishing technologies, e.g.,
 - Flags external e-mails
 - Verifies e-mails do not originate from known malicious sites
 - Scanning links and attachments and removing them.



OCR CYBERSECURITY NEWSLETTER (4/22)

Weak Cybersecurity Practices

- Weak authentication, e.g., weak passwords or single factor authentication.
- Beware remote access; use stronger authentication, e.g., 2-factor authentication.
- Beware privileged access management systems.
- Conduct periodic assessments.



OCR CYBERSECURITY NEWSLETTER (4/22)

Exploiting Known Vulnerabilities

- Be aware of known vulnerabilities, e.g., subscribe to alerts from:
 - Cybersecurity and Infrastructure Security Agency ("CISA").
 - HHS Health Sector Cybersecurity Coordination Center ("HC3")
- Apply vendor patches.
- Upgrade or replace vulnerable apps and devices.
- Conduct risk assessment and periodic penetration tests.



SECURITY RISK ASSESSMENT

ov/providers-professionals/security-risk-assessment-tool



Security Risk Assessment

Guide to Privacy and Security of Electronic Health Information

Health IT Privacy and Security Resources

Mobile Device Privacy and Security

Model Notices of Privacy Practices

Patient Consent for eHIE

Privacy & Security Training Games

Cybersecurity

Security Risk Assessment

Security Risk Assessment Tool

What is the Security Risk Assessment Tool (SRA Tool)?

The Office of the National Coordinator for Health Information Technology (ONC) recognizes that conducting a risk assessment can be a challenging task. That's why ONC, in collaboration with the HHS Office for Civil Rights (OCR) and the HHS Office of the General Counsel (OGC),

developed a



downloadable SRA Tool [.exe - 69 MB] to help guide you through the process. This tool is not required by the HIPAA Security Rule, but is meant to assist providers and professionals as they perform a risk assessment.

We understand that users with Windows 8.1 Operating Systems may experience difficulties downloading the SRA Tool, we are working to resolve the issue and will post here when a resolution is identified and implemented.

Top 10 Myths of Security Risk Analysis

As with any new program or regulation, there may be misinformation making the rounds.

Read the top 10 list distinguishing fact from fiction.

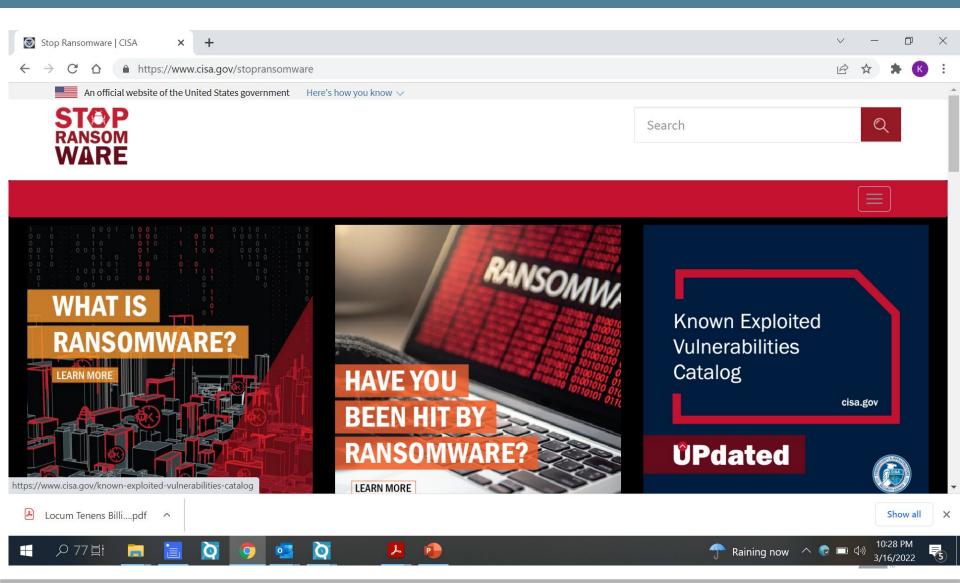
SRA Tool (Windows version)



Download Tool

Security Risk

<u>HTTPS://WWW.CISA.GOV/STOP</u> <u>RANSOMWARE</u>



HTTPS://WWW.JUSTICE.GOV/CRIMINAL-CIPS/FILE/872771/DOWNLOAD

How to Protect Your Networks fro X

https://www.justice.gov/criminal-ccips/file/872771/download

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- 1. Best practices for protecting your network
 - Educate personnel
 - Preventative measures
 - **Business continuity**
- 2. Suggestions for responding to ransomware
- 3. Law enforcement assistance



How to Protect Your Networks from RANSOMWARE

This document is a U.S. Government interagency technical guidance document aimed to inform Chief Information Officers and Chief Information Security Officers at critical infrastructure entities, including small, medium, and large organizations. This document provides an aggregate of already existing Federal

HTTPS://WWW.PHE.GOV/PREPAREDNESS/PLAN NING/405D/DOCUMENTS/HICP-MAIN-508.PDF

Recommended Practices

- 1. E-mail protection system
- 2. Endpoint protection system
- 3. Access management
- 4. Data protection and loss prevention
- 5. Network management
- 6. Vulnerability management
- 7. Incident response
- 8. Medical device security
- 9. Cybersecurity policies
- Sample Forms
- Resources

Preparedness/planning/405d/Documents/HICP-Main-508.pdf

Health Industry Cybersecurity Practices:

Managing Threats and Protecting Patients



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 Healthcare & Public Health Sector Coordinating Councils
 PUBLIC PRIVATE PARTNERSHIP

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	Assistant Secretary for Administration (ASA)				cybersecurity Coordination Center (HC3) esize AAA Print 🖶 Share 😭 💟			
	About ASA		Health Sector Cybersecurity Coordination Center (HC3)					
	EEO, Diversity & Inclusion	+	(1100)					
	Office of Business Management + & Transformation (OBMT)		A Prescription for Health Sector Cybersecurity					
	Office of Human Resources (OHR)	+	Health Sector Cybersecurity Coordination Center (HC3) was created by the Department of Health and Human Services to aid in the protection of vital, healthcare-related controlled information and ensure that cybersecurity information sharing is coordinated across the Health and Public Health Sector (HPH). HC3 Products					
	Office of the Chief Information Officer (OCIO)	-						
	About OCIO What We Do		Threat Brief	S	Sector Alerts			
	Our Mission		Highlights releva	nt cybersecurity topics	Provides high-level, situational background	L C		

and raise the UDU contaria situational information and contaxt for technical and

Our Mission



Privacy and Security

Health Information Privacy, Security, and Your EHR

Ensuring privacy and security of health information, including information in electronic health records (EHR), is a key component to building the trust required to realize the potential benefits of electronic health information exchange. If individuals and other participants in a network lack trust in electronic exchange of information due to perceived or actual risks to electronic health information or the accuracy and completeness of such information, it may affect their willingness to disclose necessary health information and could have life-threatening consequences.

Your practice, not your EHR vendor, is responsible for taking the steps needed to protect the confidentiality, integrity, and availability of health information in your EHR and comply with The Health Insurance Portability and Accountability Act of 1996 (HIPAA) Rules and CMS' Meaningful Use requirements.







Integrating Privacy & Security Into Your Medical Practice

The HIPAA Privacy and Security Rules protect the privacy and security of e health

Privacy & Security 10 Step Plan

Ensuring privacy and security of health information in an EHR is a vital part of Meaningful Use. Security risk analysis and management are foundational to

Privacy & Security and Meaningful Use

HIPAA privacy and security requirements are embedded in the Medicare and Medicaid EHR Incentive Programs through the following

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ionals/ehr-privacy-security

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/hipaa/for-professionals/security/guidance/index.html

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	HIPAA for Individuals		Filing a Complaint	HIPAA for Professionals		Newsro	om		
	HIPAA for Professionals	<u>ionais</u> > <u>5</u>	Security > Security Rule Guidance Material	Text Resize AAA	Print 🖶	Share f	¥ +		
	Privacy	+	Security Rule Guidance Material						
Security Summary of the Security Rule		-	In this section, you will find educational materials to help you learn more about the HIPAA Security Rule and other sources of standards for safeguarding electronic protected health information (e-PHI). <u>Security Risks to Electronic Health Information from Peer-to-Peer File Sharing Applications</u> -The Federal Trade Commission (FTC) has developed a guide to Peer-to-Peer (P2P) security issues for businesses that collect and store sensitive information.						
	Guidance Combined Text of All Rules								
	Breach Notification	Safeguarding Electronic Protected Health Information on Di Commission (FTC) has tips on how to safeguard sensitive of copiers.							
	Compliance & Enforcement	+	Security Rule Educational Paper Series						
Special Topics + Patient Safety +		+	The HIPAA Security Information Series is a group of educational papers which are designed to give HIPAA covered entities insight into the Security Rule and assistance with implementation of the						
		security standards.							
	Covered Entities & Business Associates		Security 101 for Covered Entities Administrative Safeguards						
	Training & Resources		Physical Safeguards						

<u>HTTPS://WWW.HEALTHIT.GOV/SITES/DEFAULT/FILES/P</u> <u>DF/PRIVACY/PRIVACY-AND-SECURITY-GUIDE.PDF</u>

1. Importance of Privacy and Security Matters

2. HIPAA Rules

3. Patient's Rights

4. EHR, HIPAA Security, and Cybersecurity

5. Meaningful Use Rules

6. 7-Step Approach for Security Management

7. Breach Notification Rules

The Office of the National Coordinator for Health Information Technology

Guide to Privacy and Security of Electronic Health Information

Version 2.0 April 2015

The information contained in this Guide is not intended to serve as legal advice nor should it substitute for legal counsel. The Guide is not exhaustive, and readers are encouraged to seek additional detailed technical guidance to supplement the information contained herein.



ENCRYPTION

- Encryption is an addressable standard per 45 CFR 164.312:
 - (e)(1) *Standard: Transmission security.* Implement technical security measures to guard against unauthorized access to [ePHI] that is being transmitted over an electronic communications network.
 - (2)(ii) *Encryption (Addressable).* Implement a mechanism to encrypt electronic protected health information whenever deemed appropriate.
- ePHI that is properly encrypted is "secured".
 - Not subject to breach reporting.
- OCR presumes that loss of unencrypted laptop, USB, mobile device is breach.



BEWARE MOBILE DEVICES









Share **F**

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<u>HHS</u> > <u>HIPAA Home</u> > <u>For Professionals</u> > <u>HIPAA Compliance and Enforcement</u> > <u>Resolution Agreements</u> > Business Associate's Failure to Safeguard PHI Leads to Settlement



Business Associate's Failure to Safeguard Nursing Home Residents' PHI Leads to \$650,000 HIPAA Settlement

Text Resize AAA

Print 📥

Catholic Health Care Services of the Archdiocese of Philadelphia (CHCS) has agreed to settle potential violations of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Security Rule after the theft of a CHCS mobile device compromised the protected health information (PHI) of hundreds of nursing home residents. CHCS provided management and information technology services as a business associate to six skilled nursing facilities. The total number of individuals affected by the combined breaches was 412. The settlement includes a monetary payment of \$650,000 and a corrective action plan.

"Business associates must implement the protections of the HIPAA Security Rule for the electronic protected health information they create, receive, maintain, or transmit from covered entities," said U.S. Department of Health and Human Services Office for Civil Rights (OCR) Director Jocelyn Samuels. "This includes an enterprise-wide risk analysis and corresponding risk management plan, which are the cornerstones of the HIPAA Security Rule." OCR initiated its investigation on April 17, 2014, after



BEWARE MOBILE DEVICES

oviders-professionals/your-mobile-device-and-health-information-privacy-and-security



Your Mobile Device and Health Information Privacy and Security



Physicians, health care providers and other health care professionals are using smartphones, laptops and tablets in their work. The U.S. Department of Health and Human Services has gathered these tips and information to help you protect and secure health information patients entrust to you when using mobile devices.



Read and Learn

- How Can You Protect and Secure Health Information When Using a Mobile Device?
- You, Your Organization and Your Mobile Device
- Five Steps Organizations Can Take To Manage Mobile Devices

Watch and Learn

- Worried About Using a Mobile Device for Work? Here's What To Do!
- Securing Your Mobile Device is Important!
- Dr. Anderson's Office Identifies a Risk



COMMUNICATING BY E-MAIL OR TEXT

≻General rule: must be secure, i.e., encrypted.

 <u>To patients</u>: may communicate via unsecure email or text if warned patient and they choose to receive unsecure.

(45 CFR 164.522(b); 78 FR 5634)

 <u>To providers, staff or other third parties</u>: must use secure platform.

(45 CFR 164.312; CMS letter dated 12/28/17)

 <u>Orders</u>: Medicare Conditions of Participation and Conditions for Coverage generally prohibit texting orders.

(CMS letter dated 12/28/17)



PATIENT RIGHTS, INCLUDING RIGHT TO ACCESS INFO





HIPAA PATIENT RIGHTS

- Notice of Privacy Practices
- Request restrictions on use or disclosure.
- Receive communications by alternative means.
- Access to info
- Amendment of info
- Accounting of disclosures of info

(45 CFR 164.520 et. seq.)



HIPAA RIGHT OF ACCESS

- Resident or personal rep generally has right to inspect and obtain copy of PHI in "designated record set, i.e., documents used to make decisions concerning healthcare or payment.
- Must respond within 30* days.
 - * Proposed rule would shorten to 15 days.
 - May need to respond sooner under other laws.
- Must provide records in requested form if readily producible, including electronic form.
- May charge reasonable cost-based fee, i.e., cost of actual labor and materials in making copies, not administrative or retrieval fee.
- Limited exceptions to right to access. (45 CFR 164.524)



HIPAA DISCLOSURE DIRECTED BY PATIENT

- Individual or personal representative has right to direct that a copy of the record be transmitted to a third party.
- Written request signed by individual or personal representative and clearly identifies recipient and recipient's address.
 - Limits on charges apply.
 - Must transmit in manner, form and format requested if readily producible.
- Compare authorization:
 - Individual requests transmittal: individual request rules in 45 CFR 164.524 apply.
 - Third party requests transmittal: authorization rules in 45 CFR 164.508 apply.

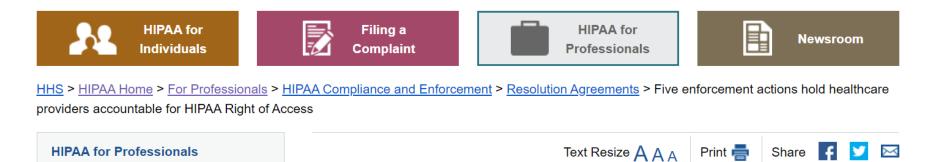
(45 CFR 164.524; OCR Guidance on Access)



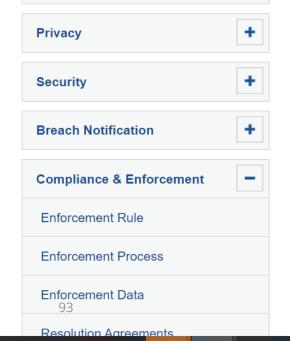
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☆

OCR RIGHT OF ACCESS INITIATIVE



Regulatory Initiatives



Five enforcement actions hold healthcare providers accountable for HIPAA Right of Access

The Office for Civil Rights (OCR) at the U.S. Department of Health and Human Services (HHS) announced the resolution of five investigations in its HIPAA Right of Access Initiative, bringing the total number of these enforcement actions to twenty-five since the initiative began. The Health Insurance Portability and Accountability Act, or HIPAA, for short, gives people the right to see and get copies of their health information from their healthcare providers and health plans. After receiving a request, a HIPAA covered entity has 30 days (or 60 days if an extension is applicable) to provide an individual or their representative with their records in a timely manner. OCR has taken the following enforcement actions that underscore the importance and necessity of compliance with the HIPAA Right of Access:

- Read the HHS Press Release
- Read the <u>Advanced Spine & Pain Management (ASPM)</u> Resolution Agreement and Correction Action Plan
- Read the <u>Denver Retina Center</u> Resolution Agreement and Correction Action Plan

SNF RIGHT OF ACCESS

SNF

- "The facility must provide the resident with access to personal and medical records pertaining to him or herself, upon an oral or written request, in the form and format requested by the individual, if it is readily producible ... (including in an electronic form or format when such records are maintained electronically); or, if not, in a readable hard copy form or such other form and format as agreed to by the facility and the individual, within 24 hours (excluding weekends and holidays); and
- "The facility must allow the resident to obtain a copy of the records or any portions thereof (including in an electronic form or format when such records are maintained electronically) upon request and 2 working days advance notice to the facility."

(42 CFR 483.10(g)(2))



SNF RIGHT OF ACCESS

- SNF: "The facility may impose a reasonable, cost-based fee on the provision of copies, provided that the fee includes only the cost of:
 - (A) Labor for copying the records requested by the individual, whether in paper or electronic form;
 - (B) Supplies for creating the paper copy or electronic media if the individual requests that the electronic copy be provided on portable media; and
 - (C) Postage, when the individual has requested the copy be mailed."

(42 CFR 483.10(g)(2))



ALF RIGHT OF ACCESS

 ALF: "Upon request, a resident or others authorized by law, must be provided immediate access to information in their record, and copies of information within two (2) business days."

(IDAPA 16.03.22.550.01)



HOME HEALTH AND HOSPICE RIGHT OF ACCESS

 HHA: "The patient has the right to ... have a confidential clinical record. Access to or release of patient information and clinical records is permitted in accordance with [HIPAA,] 45 CFR parts 160 and 164."

(42 CFR 484.50(c)(6); see also CMS SOM App.B)

 Hospice: "The patient has the right to ... have a confidential clinical record. Access to or release of patient information and clinical records is permitted in accordance with [HIPAA,] 45 CFR parts 160 and 164."

(42 CFR 418.52(c)(5); see also CMS SOM App. M)



INFO BLOCKING RULE

- Applies to "actors"
 - Healthcare providers.
 - Developers or offerors of certified health IT.
 - Not providers who develop their own IT.
- Health info network/exchange. (45 CFR 171.101)

 Prohibits info blocking, i.e., practice that is likely to interfere with access, exchange, or use of electronic health info,

and

- Provider: <u>knows</u> practice is unreasonable and likely to interfere.
- Developer/HIN/HIE: <u>knows or should know</u> practice is likely to interfere.

(45 CFR 171.103)



INFO BLOCKING RULE: PENALTIES

Developers, HIN, HIE

- Complaints to ONC
 - <u>https://www.healthit.g</u>
 <u>ov/topic/information-</u>
 <u>blocking</u>.
- ONC investigations
- Proposed rule:
 - Civil monetary penalties of up to \$1,000,000 per violation

(85 FR 22979 (4/24/2020); proposed 42 CFR 1003.1420)

Healthcare Providers

- "Appropriate disincentives to be established by HHS."
- Waiting for rule.





INFO BLOCKING: EXAMPLES

- Refusing to timely respond to requests.
- Charging excessive fees.
- Imposing unreasonable administrative hurdles.
- Imposing unreasonable contract terms, e.g., EHR agreements, BAAs, etc.
- Implementing health IT in nonstandard ways that increase the burden.

Others?



INFO BLOCKING EXCEPTIONS





TIME FOR RESPONDING TO PATIENT REQUESTS

"Q: When would a delay in fulfilling a request for access [to] EHI be considered an interference under the [IBR]?

"A determination as to whether a delay would be an interference ... would require a fact-based, case-by-case assessment of the circumstances....

"Unlikely to be an Interference: If the delay is necessary to enable the access, exchange, or use of EHI, it is unlikely to be considered an interference For example, if the release of EHI is delayed ... to ensure that the release complies with state law, it is unlikely to be considered an interference so long as the delay is no longer than necessary. Longer delays might also be possible ... if no longer than necessary, in scenarios where EHI must be manually retrieved and moved from one system to another system

"Likely to be an Interference: It would likely be considered an interference ... if a health care provider established an organizational policy that, for example, imposed delays on the release of lab results for any period of time in order to allow an ordering clinician to review the results or in order to personally inform the patient of the results before a patient can electronically access such results.... [I]t also would likely be considered an interference where a delay in providing access ... occurs after a patient logs in to a patient portal to access EHI that a health care provider has (including, for example, lab results) and such EHI is not available—for any period of time—through the portal."

HTTPS://WWW.HEALTHIT.GOV/TOPIC /INFORMATION-BLOCKING

Information Blocking HealthIT.g	~ – @ X				
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	NEW: Health IT Feedback Portal	CONTACT EMAIL UPDATES			
	Official Website of The Office of the National Coordinator for Health Information Technology (ONC)	Connect with us: in 🎔 🛗 🔊			
Health IT .gov	TOPICS BLOG NEWS DATA ABOUT ONC	Search O Q			
HealthIT.gov > Topics > Information Blocking					

Information Blocking Report Information Blocking

-

Information Blocking

What is information blocking?

exchange, or use of electronic health information (EHI).

i

Additional Resources

- Fact Sheets
- Webinars
- FAQs
- Report Information Blocking

Rain/snow 🔿 😨 💷 🕬

Show all

3/16/2022

Have questions about information blocking? View our Information Blocking Frequently Asked Questions (FAQs)

Human Services (HHS) as a reasonable and necessary activity, is likely to interfere with access,

In general, information blocking is a practice by a health IT developer of certified health IT, health information network, health information exchange, or health care

provider that, except as required by law or specified by the Secretary of Health and

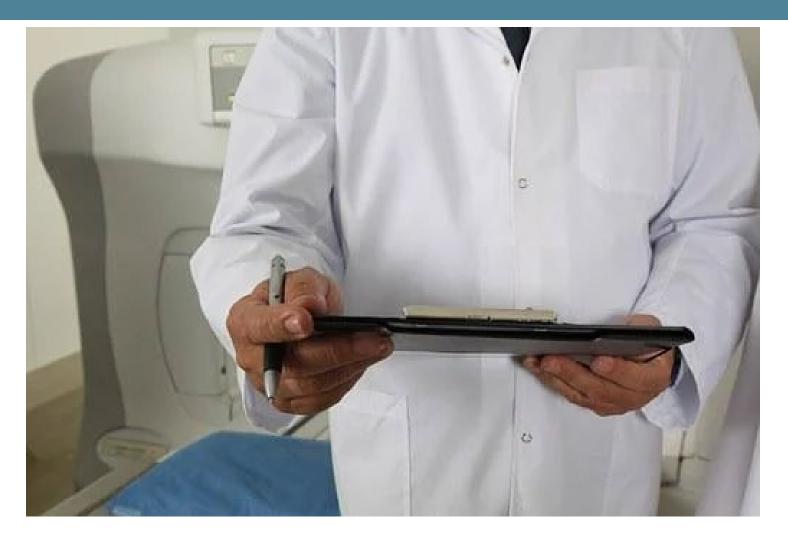
What are examples of practices that could constitute information blocking?

Section 4004 of the Cures Act specifies certain practices that could constitute information blocking:

Practices that restrict authorized access, exchange, or use under applicable state or federal law
of such information for treatment and other permitted purposes under such applicable law



PATIENT CHARTING





GOOD MEDICAL RECORDS ARE IMPORTANT

- Proper medical records are essential to—
 - Proper patient care
 - -Proof of proper conduct
 - -Regulatory compliance
 - Payment and reimbursement
- Even more important given patients' right to access info.





BAD MEDICAL RECORDS

- Criminal fines and penalties
 - Criminal negligence, fraud, false claims, etc.
- Civil lawsuits, fines, and penalties
 - Malpractice, fraud and abuse, lack of consent, privacy violation, etc.
- Administrative penalties
 - Licensing board actions, civil monetary penalties, program exclusion, etc.
- Adverse business consequences
 - Poor care, denied payment, patient relation problems, loss of privileges, loss of employment, etc.



PRACTICAL STANDARDS

- Practical standards defined by purpose for medical records.
 - Document patient's health and treatment.
 - Communicate patient's status and care to other practitioners.
 - Provide basis for evaluating adequacy and appropriateness of care.
 - Support claims for payment or reimbursement.
 - Protect legal interests of patient and provider.
 - Provide data for planning, research, education.
- Make sure chart is sufficient to accomplish these purposes.



REMEMBER THE PRESUMPTIONS...

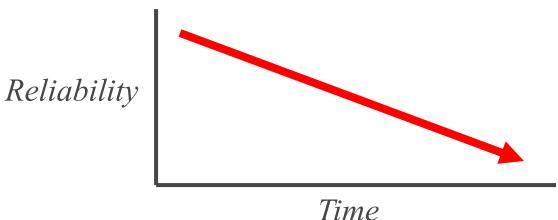
- If it's not in the chart, it didn't happen.
- If the chart has been altered, you must be guilty.
- If the chart can't be found, it must have contained bad stuff.





PROMPT CHARTING

Document as soon as possible.



- Easy to forget details with time.
- Exact time of entry may be very important.
- Evidentiary exception for "business record" requires that record is made at or near the time.
- Others may rely on record in meantime.



LATE ENTRIES

- Late entries are okay.
 - May be unavoidable.
 - Better than no, incomplete, or incorrect entry.
 - Subject to scrutiny.
- To make late entry—
 - Add entry at first available line.
 - Reference "late entry"
 - Identify the date, time, and name of person making entry.



MISTAKEN ENTRIES AND CORRECTIONS



- Corrections and amendments are okay.
 - Truthfully document patient care and status.
 - Better than incorrect entry.
 - Still subject to scrutiny.
- Corrections should preserve original entry.
 - For mistaken entry, draw single line through entry, designate it as "*mistaken entry*", and initial with date, time, and reason for change if reason not obvious.
 - Avoid using "error"
 - Do not write over original entry.
 - For additions, initial the addition and state the date, time, title, and reason for change if not obvious.



MISTAKEN ENTRIES AND CORRECTIONS

- Be careful about making entries after notice of potential claim or complication.
 - May create inference of "padding" the record.
 - Opposing counsel may already have copy of original claim.
 - Consult with risk manager or attorney.
- Correction may still be appropriate if necessary to provide effective patient care.



CHART FACTS

- Remain objective and document facts.
 - What you see, hear, smell, feel, measure and count.
 - <u>Not</u> what you opine, infer, or assume, or speculate.
 - * "Just the facts, ma'am"





BE SPECIFIC

- Document observations in specific, quantifiable terms if possible.
- Avoid vague terms, e.g., *light, moderate, heavy, occasional, frequent.*
 - Subject to broad interpretation.
- Compare:
 - "Output adequate" → "Output 1,200 ml"
 - "Pt. appears to be in pain" → "Pt. requested pain medication after complaining of severe lower back pain radiating to right leg."

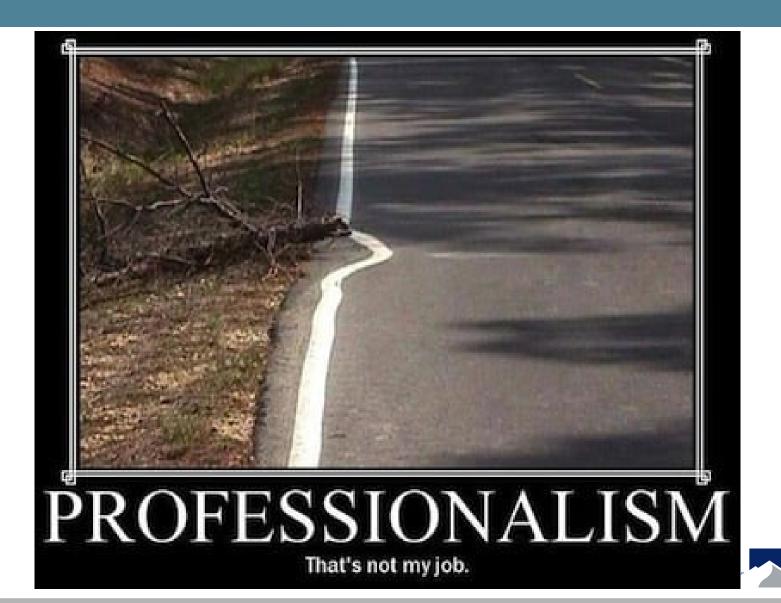


DOCUMENT EXACT QUOTES

- Document quotes, especially when they contain significant information, e.g., Patient states, "I slipped as I was trying to get out of bed."
 - Exact quotes are more credible.
 - Exact quotes avoid inference of bias.



BE PROFESSIONAL



BE PROFESSIONAL

- Always be professional in comments.
- Describe patient <u>behavior</u> objectively;
- Do not label the <u>patient</u> negatively,
 - e.g., complainer, malingerer, frequent flyer, alcoholic, abusive, bizarre, obnoxious, problem patient, rude, uncooperative, disagreeable, drunk, etc.
 - Creates impression of anti-patient bias.
 - Suggests that patient received substandard care because the nurse disliked the patient.
- Avoid flippant remarks, e.g., "PBBB"
- * Assume that patient or jury may read your notes at some future time.



DON'T BLAME

- In chart, do not—
 - -Blame or accuse others
 - -Admit fault
- * You may not know all the facts.
- There may be other times or places where such discussions may occur, but the chart is not the place for such comments.



FROM PATIENT CHARTS...

- Primary nursing could not be given because nurse patient ratio 1:20
- Patient in extreme pain because night shift refused to give prescribed medication
- If [the doctor] doesn't start returning calls, he's going to kill a patient.
- Patient going into shock. Could not get Dr. [X] to come. We never can!!!
- If nurses around here would read medication orders, we'd have fewer emergencies.
- Patient fell out of bed because nurse left the side rail down.



REPORTING INCIDENTS

- Document incidents in separate incident report.
 - Subject to peer review privilege.
- Document incidents immediately.
 - Time
 - What happened
 - Name and time physician notified
 - Follow-up care
 - Patient's response

- Remember: do not
 - -Opine
 - -Speculate
 - -Blame
 - -Admit



DOCUMENT NON-TREATMENT

- Phone calls
- Missed medications
- Missed appointments
- Missed treatment
- Failure to follow advice
- Failure to take medication
- Non-compliance with treatment
- Misconduct by patient
- * Include warnings or notice of risks, e.g.,
 - "Patient refused fetal monitor; limitation on our ability to identify fetal distress emphasized."
- * Remember: be objective and professional.



TAMPERING WITH MEDICAL RECORDS

- Tampering includes—
 - Rewriting/altering record without notation.
 - Addition to chart at later time without notation.
 - Placing inaccurate info in the record.
 - Intentionally omitting significant facts.
 - Dating entry to appear as if written at earlier time.
 - Destroying records.
 - Adding to someone else's entry.
- Relatively easy to detect tampering.





TAMPERING WITH MEDICAL RECORDS

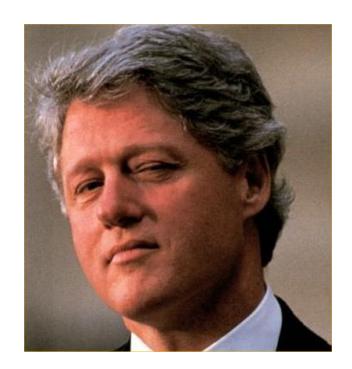


- Tampering may be worse than the actions it is designed to hide.
 - Creates inference of improper conduct.
 - May constitute spoliation of evidence.
 - May justify punitive damages.
 - May subject you to criminal penalties.



TAMPERING WITH MEDICAL RECORDS

- People are very forgiving of those who acknowledge and accept responsibility for mistakes.
- People do not easily forgive dishonesty.
- Once lost, credibility is nearly impossible to restore.





ADDITIONAL RESOURCES





https://www.hollandhart.com/healthcare#overview

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Secure https://www.hollandhart.com/healthcare#overview



OVERVIEW PRACTICES/INDUSTRIES NEWS & INSIGHTS

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LTH LAW BLO

Access to previous webinar recordings, publications, and more.

The Healthcare II this sector now n stand ready to he

Issues such as rising h innovations in healthc minds of many of our opportunities that ari:

Clients We Serve

- Hospitals
- Individual medical providers
- Medical groups
- Managed care organizations (MCOs)
- Third-party administrators (TPAs)
- Health information exchanges (HIEs)
- Practice managers and administrators

nd facilities

ons (IPAs)

Imaging centers Ambulatory surgery centers

Past Webinars

Publications



QUESTIONS?

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