

Use and Disclosure of PHI- Overview and Update on Significant Issues

Marc D. Goldstone, Esq.

Hoagland, Longo, Moran, Dunst & Doukas, LLP

40 Paterson Street

P.O. Box 480

New Brunswick, NJ 08903

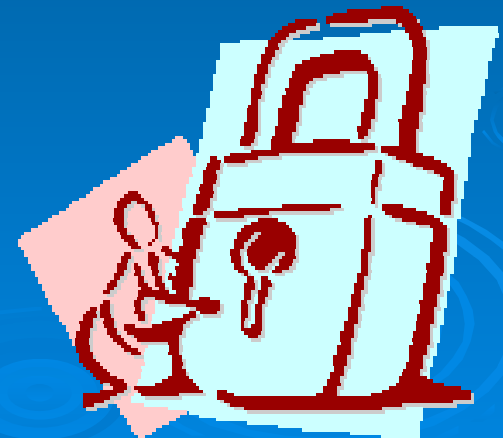
732-545-4717

732-545-4579 (fax)

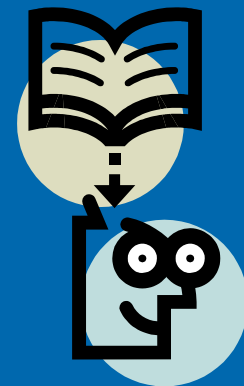
MGOLDSTONE@HOAGLANDLONGO.COM

OVERVIEW

➤ CEs may not use or disclose PHI (hard copy OR E-PHI) except as the final Privacy Rule allows or requires.



Privacy Rule Definitions



- Disclosure = release, transfer, provision of access to or the divulging in any manner of information outside the entity holding the information
- Use = sharing, employment, application, utilization, examination or analysis of PHI within the entity that maintains the information
- If you can find a way to manipulate these definitions so that your particular transfer of PHI is NOT a use or disclosure, I want to know about it!

Mandatory Disclosures

- ✓ The Privacy Rule only **REQUIRES** disclosure of PHI in two situations:
 1. A CE **MUST** disclose PHI to a patient or their personal representative, when they ask for access to or for an accounting of disclosures of the patient's PHI
 2. A CE **MUST** disclose PHI to DHHS when DHHS is engaged in a compliance investigation or review.
- ✓ **ALL** other uses/disclosures of PHI contemplated by the Privacy Rule are “permissive” (i.e., “may” disclose, “can disclose”, etc.)

Is it for TPO?

- TPO: In general, a CE may use and disclose PHI for the CE's treatment of the patient, to obtain payment for the care provided to the patient, and to facilitate the CE's healthcare operations (TPO)
 - This use/disclosure is NOT mandatory
 - This use/disclosure does not require the patient's authorization

Common Misconceptions- Healthcare Operations?

- ✓ Healthcare operations: As specified in the Privacy Rule, but ONLY to the extent that the activities are related to the CE's functions:
 - Quality Assurance Activities (i.e., outcome evaluation, case management, care coordination, development of clinical guidelines, etc.)
 - Professional Competency Activities (i.e., training, evaluation, credentialing, etc.)
 - Insurance Activities (i.e., underwriting, rating, etc.)
 - Compliance Activities (medical reviews, legal services, auditing, etc.)

Healthcare Operations-Con't.

- Business Activities (i.e., arranging for medical reviews, fraud and abuse detection, planning and development, business management, general administration, customer service, due diligence, creating de-identified health information.) Fundraising and marketing (to the extent that an individual authorization are not required) are also included.
- ✓ BUT-Before you declare “everything under the sun” to be Healthcare Operations, see the 2/28/03 OCR Letter to Greater NY Hosp. Assn.:
 - “the definition of healthcare operations is designed to identify those activities of a covered entity that support that entity’s ability to provide treatment to individuals or to pay or be paid for such health care”
 - This is a substantial narrowing of the definition contained in the Privacy Rule, in terms of OCR’s enforcement authority and workplan.

De-Identified Information

- ✓ De-identified Information does not identify an individual and for which there is no reasonable basis to believe that it may be used to identify an individual. De-identified information, by definition, is NOT PHI.



De-Identified Information- Continued

- ✓ How to De-Identify Information-It's Not Very Easy:
 - Statistically determine that the information has be de-identified.
 - Hire a specially trained expert statistician to provide a report documenting the methods and results of the analysis, and concluding that the risk is very small that the de-identified information could be used to identify a person. Not cheap! OR ...
 - Safe Harbor: remove the following elements
 - Names
 - Geographic subdivisions smaller than a state (3 digit zip codes are permitted)
 - All elements of date related to the individual (birth date, admission date, discharge date, date of death, ages over 89, etc.)
 - Telephone numbers
 - Fax numbers
 - E-mail addresses

De-Identified Information- Continued

✓ Safe Harbor-Continued:

- Social Security Numbers
- Medical Record Number
- Health Plan Numbers
- Account Numbers
- Certificate/License Numbers
- Vehicle Identifiers/Serial Numbers; License Plate Numbers
- Device Identifiers and Serial Numbers
- URLs (i.e., [HTTP://WWW.WEBSITE.COM](http://www.website.com))
- Internet Addresses (i.e., Name@Domain.Com)
- Biometric Identifiers, including finger and voice prints
- Full Face Photographic Images (and comparable images)
- Any other unique identifying number, characteristic or code

Can you de-identify PHI “a little bit”? Limited Data Set is an Option.

- ✓ Limited Data Set (LDS) = PHI stripped of 16 listed identifiers. LDS PHI may contain:
 - Admission Date
 - Discharge Date
 - Date(s) of Service
 - Date of Death
 - Age (including age 90 and over)
 - Five digit zip codes



Limited Data Set-Continued

- ✓ CE must obtain a Data Use Agreement from the recipient of LDS PHI. The “DUA” agreement must include:
 - Permitted uses and disclosures of data; prohibition on use of LDS PHI to violate the final Privacy Rule
 - Permitted recipients of data
 - LDS PHI recipient must not use or further disclose data other than as provided for in agreement or as required by law
 - Recipient must use appropriate safeguards to prevent further use or disclosure of data
 - Recipient must report to CE any use or disclosure of the data that is NOT provided for in the agreement
 - Recipient must ensure that agents/subcontractors with access to the LDS data will agree to same restrictions as Recipient
 - Recipient will not identify the information or attempt to contact the patients
- ✓ From a practical perspective, LDS data has little use to the entities that need PHI to carry out their business activities.

Marketing Disclosures-Are they Worth It?

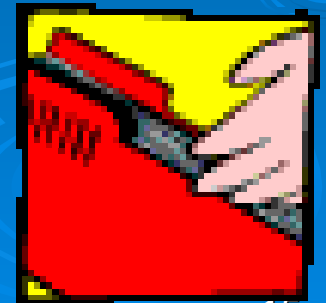
- ✓ In general, a CE must obtain an authorization from the patient for any use or disclosure for marketing purposes
 - If a CE seeks an authorization for marketing related to a “fiscal arrangement” with a third party, the authorization must ALSO state that the CE will be paid for the disclosure, and must set forth the amount that will be paid.
 - Who the heck will want to do that?

Disclosures for Marketing-Common Misconceptions

- ✓ Exclusions: Marketing does not include-
 - Face to Face communications
 - Promotional gift of nominal value
 - Health-related activities
- ✓ Health-related activities include:
 - Communications to describe health-related services or products, or payment for such services or products that are provided for or included in a benefit plan of the CE, including services only available to health plan enrollees that add value to, but are not a part of a health benefit plan.
 - Communications for the treatment of a patient
 - Communications for the patient's case management/care coordination

Disclosure Pursuant to an Authorization

- ✓ Except as otherwise permitted or required by the final Privacy Rule, a CE may not use or disclose PHI without a valid authorization from the patient. A valid authorization must contain the following elements:
 - Meaningful description of the PHI to be used or disclosed
 - Identity of the entity or class of entities authorized to make the disclosure
 - Identity of the entity or class of entities to whom the disclosure may be made
 - The purpose of the disclosure



Disclosure Pursuant to an Authorization

- ✓ Valid Authorization Elements-Continued:
 - The expiration date/event of the authorization (which may be limited by state law; may be “end of research” or “none” for research authorizations)
 - Notice to the patient that the authorization may be revoked in writing, and that such revocation will not affect uses and disclosures made pursuant to the authorization BEFORE the revocation
 - If the authorization is for compensated marketing, the CE’s remuneration must be set forth
 - The authorization must be dated and signed by the patient or the patient’s personal representative.

Exception to the Authorization Rule

✓ “Common Practice” Exception: CE may release-

- Prescriptions
- X-Rays
- Medical Supplies
- Similar Items

to a person “acting on the patient’s behalf” if the CE, “applying professional judgment and *experience with common practice*” reasonably infers that allowing the person to pick up the items in the individual’s best interest.

Disclosures Without the Opportunity to Object

- ✓ The final Privacy Rule permits use/disclosure of PHI for a variety of *public benefit* purposes.
- ✓ A CE must:
 - VERIFY the identity of the person seeking PHI pursuant to a “public benefit” exception AND
 - ESTABLISH the authority of the person to receive the PHI
 - BEFORE releasing the PHI requested, if the requester is unknown to the CE.

Disclosures Without the Opportunity to Object-Continued

- ✓ Public Benefit disclosures include:
 - “Required by Law” (NOT as “permitted by law”)
 - Public Health Activities-
 - Disease/Communicable Disease Reporting
 - Vital Statistics Reporting
 - FDA reports
 - Employer “work-safety” reports about an employee

Disclosures Without the Opportunity to Object-Continued

- Victims of Abuse, Neglect, or Domestic Violence (“reasonable belief” standard)-limited to the extent that the disclosure is required by law AND agreed to by the individual; however, the consent may be waived if, in the CE’s professional judgment:
 - The disclosure is necessary to prevent serious harm to the patient or other potential victims OR
 - The individual is unable to agree due to “incapacity”
 - Notification must be to governmental authority (inc. social service agency) authorized by law to receive such reports
 - CE MUST notify the individual of the disclosure, unless in the CE’s professional judgment, informing the patient would place them at risk of serious harm OR, in the case of a personal representative, the CE reasonably believes that the personal representative is “responsible for” the abuse.

Disclosures Without the Opportunity to Object-Continued

- Health Oversight Activities-
 - Audits
 - Civil, criminal, administrative investigations
 - Inspections
 - Licensure
 - Disciplinary Actions
 - Other Health Oversight Activities
- Not Applicable when the investigation does not “arise out of and is not directly related to the receipt of healthcare, a claim for public benefits or qualifications for public benefits.”
- Duty to Inquire?

Disclosures Without the Opportunity to Object-Continued

- Judicial/Administrative Proceedings-
 - In response to a Court Order (NOT an attorney-signed subpoena)
 - In response to a subpoena, discovery demand or other “lawful process” if accompanied by a Court Order (or patient authorization)
 - In response to a subpoena if “satisfactory assurances” are received
 - Caselaw on discovery of PHI rapidly evolving; Crescenzo v. Crane 350 N.J. Super. 431 (App. Div. 2002) is one example.

Disclosures Without the Opportunity to Object-Continued

- Law Enforcement Purposes-
 - May disclose to a law enforcement official, as required by law
 - As required by law for the reporting of certain types of injuries or wounds
 - In accordance with a court-ordered warrant or grand-jury subpoena
 - In accordance with an administrative subpoena
 - The information sought must be relevant in and material to a legitimate enforcement inquiry, the request must be specific to the PHI sought, AND de-identified information could not reasonably be used
 - These are PERMISSIVE disclosures; HIPAA itself does NOT require the disclosures.

Disclosures Without the Opportunity to Object-Continued

- Decedents
 - May disclose PHI to a coroner, medical examiner or funeral director to identify a decedent, determining cause of death, or other duties as authorized by law
- Organ, Eye or Tissue Donation purposes
 - May use or disclose PHI to organ procurement organizations or other entities engaged in the procurement, banking or transplantation of organs, eyes or tissues

Disclosures Without the Opportunity to Object-Continued

- Research Purposes
 - May disclose PHI if a waiver of consent is received from an IRB/PB
- To Avert a Serious Threat to the Public
 - A CE, consistent with applicable laws and standards of ethical conduct may use or disclose PHI if the CE believes, in good faith, that the disclosure is necessary to prevent or minimize a “serious and imminent threat” to the health and safety of a person or the public
- Specialized Government Function
 - A CE may disclose or use PHI as authorized by law for specialized government functions such as military, secret service (dignitary protection), etc.

Disclosures Without the Opportunity to Object-Continued

- Worker's Compensation
 - A CE may disclose PHI as authorized by law, to the extent necessary to comply with the laws governing worker's compensation programs and similar programs

The Pre-Emption Quagmire

- HIPAA expressly supersedes any contrary provision of State law. 45 C.F.R. § 160.203
 - EXCEPT that, pursuant to 45 C.F.R. § 160.203(b)) HIPAA does not preempt contrary state law, if:
 - the state law "relates to the privacy of individually identifiable health information," AND
 - the state law is "more stringent" than HIPAA's requirements.
- ✓ If a disclosure is mandated by state law, but the mandate is less protective of personal privacy than HIPAA, then EVEN if the state law demand falls into one of the "public benefit" exceptions in the Privacy Rule, the disclosure is PROHIBITED because the underlying state-law disclosure authority is pre-empted.
- ✓ Say that three times fast; I dare you.
- ✓ The published cases struggle with this concept.

Minimum Necessary



- ✓ A CE must use, disclose, and/or request from other CEs the “minimum necessary” amount of PHI to accomplish the purpose of the use, disclosure or request.
 - A CE may rely, if reasonable under the circumstances, on the scope of the request for PHI from another CE as presumptive proof of the “minimum necessary” standard
 - This includes professionals (attorneys, accountants, etc.) employed by the CE or the CE’s BAs if they represent that they seek the minimum necessary PHI.
 - A CE may also rely on the scope of requests from public officials who represent that they seek only the minimum necessary PHI

Minimum Necessary-Continued

- ✓ In general, the patient's ENTIRE medical record is NOT considered the "minimum necessary" for most purposes, unless established otherwise
- ✓ TIP-Have a "canned form" for use by requesters that appropriately represents that the request is authorized, for an appropriate purpose, and seeks the minimum necessary PHI for the purpose of the request. E-mail me for an example.

Request for Restriction on Use or Disclosure

- ✓ Patients have the right to request that a CE restrict its use and/or disclosures of the patient's PHI.
 - The CE is under no duty to agree to such requests.
 - If the CE agrees, it must honor the agreement except in medical emergencies
 - The CE may terminate such an agreement by notice to the patient-the CE must honor the agreement prior to the termination.
 - The patient's request USUALLY cannot trump a public safety demand that is permitted by HIPAA AND required by State Law.

Requests for Restriction-Con't

- ✓ Unless a CE's particular customer service/competition needs require, it is recommended that CE's NOT elect to accept these optional patient requests; accepting them will likely be the cause of a HIPAA violation at some point! (they will be "statistical outliers", and patients will be on the lookout for your explicit and specific compliance with their wishes).

What do the Cases Say?

- ✓ State Courts are beginning to see cases involving the Privacy Rule; the reported decisions are not entirely harmonious:
 - **Helping Hand, LLC v. Baltimore County**-2003 District of Md. methadone clinic exclusionary zoning case. Defendants sought patient medical records in discovery. Whether or not patients were “disabled” under the ADA was germane to the cause of action. Plaintiffs objected pursuant to HIPAA and Md. Psych/pt privilege law.
 - Held: Federal cause of action, so privilege argument inapposite. Under Section 512(e), may disclose pursuant to a court order or agreement of the parties that provides for protection of the information outside of litigation and return of the info once proceedings are concluded.
 - Order: Depose plaintiff’s president and other officers, but may not inquire regarding “specific medical or personal circumstances of patients.”
 - I’m not sure that I agree with the court’s conclusions regarding section 512(e); rather, I think that ANY order under 512(e)(1)(i) is enough to compel disclosure (with or without “protections”) however, the result was correct, so the language in the decision is not too bothersome.

What do the Cases Say?

- ✓ **Campos v. Payne**-2nd Cir 2003 Defendants asked the court to issue a Judicial Subpoena Duces Tecum to Staten Island University Hospital, seeking the production of all medical records relating to plaintiff's medical treatment at the hospital as a result of an automobile accident, as well as all records subsequent and prior to that date. Recently modified New York State law no longer required a court order for the service of a discovery subpoena duces tecum on a nonparty; rather, New York State law requires:

- service of a notice or subpoena duces tecum

- a 21 day objection period. If no objection is filed during the period, then compliance with the subpoena is required.

- HOWEVER, the rule also states that "A medical provider served with a subpoena duces tecum requesting the production of a patient's medical records ... need not respond or object to the subpoena if [it] is not accompanied by a written authorization by the patient." Any subpoena so served **MUST** state in conspicuous bold-faced type "that the records shall not be provided unless the subpoena is accompanied by a written authorization by the patient."

The subpoena presented in this case neither contained the required statement nor the authorization of the plaintiff. Accordingly, the Court couldn't "so order" the subpoena without the authorization of the party whose records are sought. **"To do so would be to sanction an end run around the privacy protections established both by Congress and the State legislature."**

The Court made multiple references to HIPAA and to Federal privacy policy to support the ruling, even though it was really a matter of state law on the facts.

What do the Cases Say?

- ✓ **IN RE PPA LITIGATION** (Opinion on HIPAA Preemption of Stempler v. Speidell)
2003 NJ Trial Court decision: Stempler Interviews are informal *ex parte* conferences with a non-party treating physician, on notice to the plaintiff patient. It's essentially "cheap" discovery (as opposed to a deposition on the record). Plaintiff's counsel should provide written authorization for the interviews. If authorizations are withheld unreasonably, they can be compelled. The rules require reasonable notice of the time and place of the proposed interviews & the anticipated scope of the interview. The notice MUST "communicate with unmistakable clarity" the fact that the physician's participation in an *ex parte* interview is voluntary. Plaintiff may seek a protective order if a proposed interview threatens substantial prejudice. Such order could require the presence of plaintiff's counsel during the interview or, **in extreme cases**, require defendant's counsel to proceed by deposition.
The joint defendants in a consolidated mass tort action made a motion to compel Stempler interviews, about eighteen years after the Stempler decision, and shortly after the implementation of the final Privacy Rule. The plaintiffs objected, arguing that Stempler was "less stringent" than the final Privacy Rule's requirements, and thus was preempted. The Court ruled that the actual mechanism of the disclosure of PHI—a Stempler interview itself—was not preempted by HIPAA. However, the Court also ruled that the final Privacy Rule's authorization requirements were more stringent than those specified by the Stempler ruling, and the Court declared that the "drafting of a new HIPAA compliant authorization must be undertaken." The defendants could have depositions on the record if they wanted to, though, in this matter. The fact that the cases were almost ready to go to trial weighed in the decision.
- ✓ Decision just approved for publication; will be precedential case law in NJ

Grand Jury Subpoenas?

- ✓ §164.5129(a) “A covered entity may use or disclose protected health information to the extent that such use or disclosure is required by law and the use or disclosure complies with and is limited to the relevant requirements of such law.” §164.501 defines “required by law” to include “subpoenas or summons issued by a court, grand jury, a governmental or tribal inspector general.”
- ✓ Conflicts with State Law abound. For example, N.J.R.E. 506 provides for a qualified privilege with respect to confidential “physician patient” communications
- ✓ State v. Long, 575 A.2d 435, (N.J. 1990). ‘Prior to trial the State obtained, through the use of grand-jury subpoenas issued by representatives of the prosecutor's office, defendant's medical records Defendant ... argues that the seizure of his medical records amounted to misconduct so egregious as to require the dismissal of the indictment. A review of the record indicates that there was no taint or advantage given to the prosecution from the **unlawful seizure of the records**. “ 575 A.2d 435, 453.
- ✓ Prosecutors obtain a search warrant pursuant to N.J.R. 3:5-5(a), specifying the seizure of the PHI sought by the Grand Jury subpoena as a “work-around”.
- ✓ BUT-When in Texas, see: Harmon v. State, 2003 WL 21665488 (Tex. App. Hous. 1st Dist. 7/17/03) (grand jury subpoena for defendant's blood alcohol levels permitted, as in accordance with §512(f)). “the State's power to issue grand-jury subpoenas in a criminal investigation, disclosure of medical records under HIPAA is permissible without an individual's permission when the information is disclosed for law enforcement purposes and is obtained pursuant to a grand-jury subpoena.” Pre-Privacy Rule Implementation Case.

Criminal Subpoenas and Fees

- ✓ N.J.R. 1:9-1, regarding subpoenas, provides that “If the witness is to testify in a criminal action for the State or an indigent defendant, the subpoena shall so note, and shall contain an order to appear without the prepayment of any witness fee.” Similar provisions in most states. Public Defender demands copies of medical records “for free,” via subpoena, for discovery use.
- ✓ §164.524(c): Fees. If the individual requests a copy of the protected health information or agrees to a summary or explanation of such information, the covered entity may impose a reasonable, cost-based fee, provided that the fee includes only the cost of:
 - Copying, including the cost of supplies for and labor of copying, the protected health information requested by the individual;
 - Postage, when the individual has requested the copy, or the summary or explanation, be mailed; and
 - Preparing an explanation or summary of the protected health information, if agreed to by the individual as required by paragraph (c)(2)(ii) of this section.
- ✓ Refuse, Object, or Seek Protective Order and/or Order for “reasonable copying costs”.

Thanks!

➤ Thanks for your kind attention!!!!!!!!!!!!!!!!!!!!!!!!!!!!

Marc D. Goldstone, Esq.

Hoagland, Longo, Moran, Dunst & Doukas, LLP

40 Paterson Street

P.O. Box 480

New Brunswick, NJ 08903

(732) 545-4717

(732) 545-4579 (FAX)

MGoldstone@Hoaglandlongo.com

www.healthlawnj.com

www.hipaasurvivalkit.com