HIPAA Special Considerations:
Individual Right to Request
Restriction of Uses and Disclosures of PHI –
Voluntary and Mandatory

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Patient Rights and Responsibilities under HIPAA

In case you missed it:

- 1996 = HIPAA - Health Insurance Portability and Accountability Act
- 2003 = HIPAA Privacy Rule/HIPAA Security Rule
- 2009 = HITECH Act - Health Information Technology for Economic and Clinical Health Act HIPAA
- October 2009 - Enforcement Interim Final Rule
- August 2009 = Breach Notification Interim Final
- January 25, 2013 = Final Omnibus HIPAA Rulemaking*

*HHS Title: “Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under the [HITECH Act] and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules; Final Rule”

Enforcement of all rules and updates in place by CEs and BAs by October of 2013.

*HIPAA Administrative Simplification Regulations can be found at 45 CFR Parts 160, 162, and 164, and includes: Transactions and Code Set Standards; Identifier Standards; Privacy Rule; Security Rule; Enforcement Rule; Breach Notification Rule
HIPAA - WHY DO YOU CARE?

<table>
<thead>
<tr>
<th>HIPAA Violation</th>
<th>Minimum Penalty</th>
<th>Maximum Penalty</th>
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<tbody>
<tr>
<td>Individual did not know (and by exercising reasonable</td>
<td>$100 per violation, with an annual maximum of $25,000 for repeat violations</td>
<td>$50,000 per violation, with an annual maximum of $1.5 million</td>
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<td>diligence would not have known) that he/she violated</td>
<td>(Note: maximum that can be imposed by AG regardless of the type of violation)</td>
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<td>HIPAA</td>
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<td>HIPAA violation due to reasonable cause and not due to</td>
<td>$1,000 per violation, with an annual maximum of $100,000 for repeat violations</td>
<td>$50,000 per violation, with an annual maximum of $1.5 million</td>
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<td>willful neglect</td>
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<td>HIPAA violation due to willful neglect but violation is</td>
<td>$10,000 per violation, with an annual maximum of $250,000 for repeat violations</td>
<td>$50,000 per violation, with an annual maximum of $1.5 million</td>
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<td>corrected within the required time period</td>
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<tr>
<td>HIPAA violation is due to willful neglect and is not</td>
<td>$50,000 per violation, with an annual maximum of $1.5 million</td>
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§164.522(a) Rights to request privacy protection for protected health information.

(1) Standard: Right of an individual to request restriction of uses and disclosures.

(i) A covered entity must permit an individual to request that the covered entity restrict:
   (A) Uses or disclosures of protected health information about the individual to carry out treatment, payment, or health care operations; and
   (B) Disclosures permitted under §164.510(b).

(ii) EXCEPT AS PROVIDED IN PARAGRAPH (A)(1)(VI) of this section, a covered entity is not required to agree to a restriction.
WHEN A PROVIDER VOLUNTARILY AGREES TO A RESTRICTION UNDER §45 C.F.R 164.522(a)(1)

- §45 C.F.R 164.522(a)(1)
  - (iii) A covered entity that agrees to a restriction under paragraph (a)(1)(i) of this section may not use or disclose protected health information in violation of such restriction, except that, if the individual who requested the restriction is in need of emergency treatment and the restricted protected health information is needed to provide the emergency treatment [use or disclosure ok for Treatment purposes].

- (iv) If restricted PHI is disclosed to a health care provider for emergency treatment under paragraph (a)(1)(iii) of this section, the covered entity must request that such health care provider not further use or disclose the information.

- (v) A restriction agreed to by a covered entity under paragraph (a) of this section, is not effective under this subpart to prevent uses or disclosures permitted or required under §164.502(a)(2)(ii) [Authorized by Patient], §164.510(a) [Directory] or §164.512 [Required].
Section 164.522(a):

While covered entities are not required to agree to such requests for restrictions, if a covered entity does agree to restrict the use or disclosure of an individual’s protected health information, the covered entity must abide by that restriction, except in emergency circumstances when the information is required for the treatment of the individual.

Noncompliance with agreed upon restrictions by providers is a violation of the HIPAA Privacy Rule and would be considered a Breach.
WHAT WILL HIPPA AUDITORS ASK WITH REGARD TO VOLUNTARY RESTRICTIONS?

- HAVE YOU PUT IN PLACE THE PROCESS TO NOTIFY YOUR PATIENTS OF THEIR RIGHT TO REQUEST VOLUNTARY RESTRICTIONS?
- HAVE YOU IMPLEMENTED A PROCESS FOR PATIENTS TO REQUEST VOLUNTARY RESTRICTIONS?
- HAVE YOU IMPLEMENTED A PROCESS FOR VOLUNTARY RESTRICTION REQUESTS TO BE EVALUATED AND EITHER APPROVED OR DENIED?
- ONCE APPROVED HAVE YOU PUT IN PLACE A PROCESS TO ENSURE THAT THE RESTRICTION IS CARRIED OUT?
- IF DENIED, HAVE YOU PUT IN PLACE A PROCESS TO ENSURE THAT THE DENIAL IS COMMUNICATED TO THE PATIENT?
WHERE THE FIRST PLACE THAT PATIENTS SHOULD SEE THESE RIGHTS?

- NOTICE OF PRIVACY PRACTICES (every HIPAA covered entity has to have one and every patient must receive one)
  
  - **Content of the Notice.** Covered entities are required to provide a notice in plain language that describes:
    
    - How the covered entity may use and disclose protected health information about an individual.
    
    - The individual’s rights with respect to the information and how the individual may exercise these rights, including how the individual may complain to the covered entity.
    
    - The covered entity’s legal duties with respect to the information, including a statement that the covered entity is required by law to maintain the privacy of protected health information.
    
    - Whom individuals can contact for further information about the covered entity’s privacy policies.
“Right to Request Restrictions on Uses and Disclosures

You have the right to request that we limit the use and disclosure of PHI about you for treatment, payment and health care operations.

Once we agree to your request, we must follow your restrictions (except if the information is necessary for emergency treatment). You may cancel the restrictions at any time. In addition, we may cancel a restriction at any time as long as we notify you of the cancellation and continue to apply the restriction to information collected before the cancellation.”
EXCEPT AS PROVIDED IN PARAGRAPH §164.522(a)(1)(vi)

- When Providers Must Abide by A Requested Restriction under §164.522(a)(1)(vi):

  THE SINGLE RESTRICTION TO WHICH CEs MUST AGREE
  
  (vi) A covered entity MUST agree to the request of an individual to restrict disclosure of protected health information about the individual to a health plan if:

  (A) The disclosure is for the purpose of carrying out payment or health care operations and is not otherwise required by law; and

  (B) The protected health information pertains solely to a health care item or service for which the individual, or person other than the health plan on behalf of the individual, has paid the covered entity in full.
MANDATORY RESTRICTION - THIS RIGHT SHOULD ALSO BE SPELLED OUT IN YOUR NPP

BASIC EXAMPLE OF MANDATORY RULE SPELLED OUT IN NOTICE OF PRIVACY PRACTICE:

- Right to Request Restrictions on Uses and Disclosures

You have the right to request that we limit the use and disclosure of PHI about you for treatment, payment and health care operations. Under federal law, we must agree to your request and comply with your requested restriction(s) if:

- Except as otherwise required by law, the disclosure is to a health plan for purpose of carrying out payment of health care operations (and is not for purposes of carrying out treatment); and,
- The PHI pertains solely to a health care item or service for which the health care provided involved has been paid out-of-pocket in full.
WHERE DID THIS REQUIREMENT ARISE?
THE HITECH ACT - ACTUAL LAW

§13405(a) of the Heath Information Technology for Economic and Clinical Health (HITECH) Act:

(a) Requested Restrictions on Certain Disclosures of Health Information.—In the case that an individual requests under paragraph (a)(1)(i)(A) of section 264.522 of title 45, Code of Federal Regulations, that a covered entity restrict the disclosure of the protected health information of the individual, notwithstanding paragraph (a)(1)(ii) of such section, the covered entity must comply with the requested restriction if—

(1) except as otherwise required by law, the disclosure is to a health plan for purposes of carrying out payment or health care operations (and is not for purposes of carrying out treatment); and

(2) the protected health information pertains solely to a health care item or service for which the health care provider involved has been paid out of pocket in full.
HHS INTERPRETATION OF THE HITECH ACT’S §13405(a)

- In the initial proposed rule, HHS stated that it interpreted § 13405(a) as giving the individual a right to determine for which health care items or services the individual wishes to pay out of pocket and restrict.

- As previously noted, this patient right is non-negotiable on the part of the Covered Entity and full compliance is required by HHS and enforced by CMS.
HHS SAYS:
HEALTH CARE PROVIDERS CANNOT BLOCK THE REQUEST FOR THIS RESTRICTION

HHS INTERPRETATION OF THE HITECH ACT’S §13405(a):

Thus, section 13405(a) would not permit a covered entity to require individuals who wish to restrict disclosures about only certain health care items or services to a health plan to restrict disclosures of PHI regarding all health care to the health plan.
CAVEAT: PAYMENT MADE DOES NOT COUNT TOWARDS CO-PAY

- With respect to an individual, or someone on behalf of the individual*, paying out of pocket for the health care item or service, HHS noted that the individual should not expect that this payment would count towards the individual’s out of pocket threshold with respect to his or her health plan benefits.

- *Requirement on CEs applies to payments in full received from both individuals and family members or friends of the individual paying for the individual’s health care item.
WHAT IF THE CHECK BOUNCES?

- HHS clarified that if an individual’s out of pocket payment for a health care item or service is not honored (e.g., the individual’s check bounces), the covered entity is not obligated to continue to abide by the requested restriction because the individual has not fulfilled the requirements necessary to obtain the restriction.

CEs DUTY TO FACILITATE ALTERNATIVE PAYMENT

- Notwithstanding the previous note, above, HHS stated its expectation in such cases that covered entities make some attempt to resolve any payment issues with the individual prior to sending the protected health information to the health plan, such as:
  - by notifying the individual that his or her payment did not go through and
  - giving the individual an opportunity to submit payment.
IMPLEMENTING REQUIRED RESTRICTIONS POSES OPERATIONAL CHALLENGES

- Creating a method for identifying the restricted information
- Defining the process for handling prescriptions (electronic vs. written)
- Identifying the specific location where a request for restriction may be received (at check-in; during appointment; after appointment; when patient returns home)
- Defining the time frame that the organization will give the patient to make the payment in full
- Establishing the process for how dishonored payments are handled (what are the reasonable attempts that the CE must make?)
- Outlining the process for sharing the restricted PHI with other providers for treatment purposes
- Educating the patient about possible additional costs when seeing other providers, if the information is necessary for continuing care
- Identifying records that have been restricted to avoid inadvertent release of information
Providers communicate concern to HHS on how to operationalize a restriction, generally:

- Concerned with having to **create separate records** to ensure that restricted data is not inadvertently sent to or accessible by a health plan.

- Argued that **having to segregate restricted and unrestricted information or redact restricted information** prior to disclosure would be burdensome as such a process would generally have to **occur manually**, and may result in **difficulties**.

- Concerned with having to **manually redact or create separate records** prior to a **health plan audit**, or **otherwise with withholding information** from a plan during an audit.
Concerns about application to Medicare, Medicaid and other government payors:

- Suggestions that providers would be prohibited from receiving cash payment from individuals for items or services otherwise covered by State or Federally funded programs, such as Medicare and Medicaid.

- Commenters asked that the “required by law” exception allow providers to disclose protected health information subject to a restriction for Medicare and Medicaid audits, because those insurers require complete, accurate records for audits.

Concerns about “balance billing” state laws:

- Commenters sought clarification on the effect of this provision where certain State laws prohibit “balance billing,” (billing the patient for any covered services over and above any permissible copayment, coinsurance or deductible amounts).
Concerns about splitting single visits and procedures:

- Commenters voiced concerns with applying a restriction to *only certain health care items or services provided during a single patient encounter or visit*.
- Commenters argued that *split billing is not possible for most providers* or that it may be obvious to a health plan if one item or service out of a bundle is restricted and that *unbundling services may be costly*. 
Concerns about communicating Restrictions to “downstream” providers.

Comments regarding HMOs:
- Some suggested that HMO patients would have to use an out-of-network provider to prevent disclosure to the HMO.
- Stated that State laws/provider contracts with an HMO may prohibit the provider from receiving a cash payment from an HMO patient above the patient’s cost sharing amount for the health care item or service.
- Others argued that individuals should not have to go out-of-network, and providers could and should treat the services as non-covered services.
- Asked for ample time for managed care contracts to be revised.
Comments on care paid out of pocket by family members/third parties:

- Commenters ask how to handle a family member, who pays for the individual’s care on behalf of the individual.
- Commenters also requested clarification that payment by any health plan would not constitute payment out of pocket by the individual, in order to avoid the situation where an individual has coverage under multiple plans, pays for care with a secondary plan, requests a restriction on disclosure to the primary plan, and then the secondary plan proceeds to obtain reimbursement from the primary plan disclosing the protected health information at issue.
Comments on provider responsibility when payments are rejected (the “bounced check” scenario):

- Expressed concern with the ability of a provider to bill a health plan for services following an individual’s inability to pay.
  - For example, when payor requires pre-certification for services
- Requested guidance on what constitutes a “reasonable effort” to obtain payment from an individual prior to billing a health plan for health care services where an individual’s payment fails:
  - Suggested that providers **should be able to set a deadline** for payment and then bill the plan if the patient’s payment fails
  - Requested a specific **timeframe in which providers must be paid** or the requested restriction is terminated
  - Suggested a “reasonable effort” should be based upon a CE making **one or two attempts to contact the patient**
  - Argued that providers **should not have to engage in any attempts** to resolve payment issues if an individual’s payment fails...
Commenters asked about how the restriction would apply to follow-up care:

- The majority of commenters supported the idea that if an individual does not request a restriction and pay out of pocket for follow up care, then the covered entity may disclose the protected health information necessary to obtain payment from the health plan for such follow up care, recognizing that some of the PHI may relate to and/or indicate that the individual received the underlying health care item or service to which a restriction applied.

- Asked whether individual authorization would be required to disclose previously restricted PHI to a health plan if the individual does not want to restrict the follow up care.

- A number of commenters expressed support for providers counseling patients on the consequences of not restricting follow-up care, but voiced concerns as to how a provider would know when such counseling was needed and what it should include...
Following consideration of the commentary, in January of 2013, HHS adopted the proposed rule as it was proposed, with no changes.
HHS PROVIDED CLARIFICATIONS AND RESPONSES TO COMMENTS WHEN PUBLISHING THE FINAL RULE

- HHS did provide clarifications in response to comments received from providers.

- **Major Clarification:**
  - HHS clarified that the provisions do not require that covered health care providers create separate medical records or otherwise segregate PHI subject to a restricted health care item or service.
  - However, covered providers will need to employ some method to flag or make a notation in the record with respect to the PHI that has been restricted to ensure that such information is not inadvertently sent to or made accessible to the health plan for payment or health care operations purposes, such as audits by the health plan.
HHS held tough on restricting disclosures to health plans under the existing “Minimum Necessary” rules:

- HHS commented that Covered entities should already have in place, and thus be familiar with applying, minimum necessary policies and procedures, which require limiting the protected health information disclosed to a health plan to the amount reasonably necessary to achieve the purpose of the disclosure.

- Thus, covered entities should already have mechanisms in place to appropriately limit the PHI that is disclosed to a health plan.
With respect to providers being able to continue to meet legal obligations, such as disclosing PHI to Medicare/Medicaid for audits:

- HHS responds that the statute and final rule continue to allow disclosures that are otherwise required by law, notwithstanding that an individual has requested a restriction on such disclosures.
  - Thus, a covered entity may disclose the protected health information necessary to meet the requirements of the law.

For purposes of “required by law”*, the definition includes Medicare conditions of participation with respect to health care providers participating in the program, and statutes and regulations that require the production of information if payment is sought under a government program providing public benefits.
  - Thus, if a covered entity is required by law to submit PHI to a Federal health plan, it may continue to do so as necessary to comply.

*Under the Privacy Rule, “required by law” is defined at § 164.103 as a mandate contained in law that compels a covered entity to make a use or disclosure of PHI and that is enforceable in a court of law.
With respect to commenters’ concerns about payment and claims requirements under State law, Medicare and Medicaid, HHS provided the following guidance:

- If a provider is required by State or other law to submit a claim to a health plan for a covered service provided to the individual, and there is no exception or procedure for individuals wishing to pay out of pocket for the service, then the disclosure is required by law and is an exception to an individual’s right to request a restriction to the health plan pursuant to § 154.522(a)(1)(vi) of the Rule.

- With respect to Medicare, the general rule is that when a physicians/suppliers are subject to the mandatory claim submission provisions of section 1848(g)(4) of the Social Security Act (the Act), then the physician/supplier must submit a claim to Medicare.

    ....BUT THAT’S NOT THE END OF THE MEDICARE STORY...
HHS clarified application of a Medicare Beneficiary patient’s right to restrict disclosure by paying out of pocket under Medicare as follows:

- **There is an exception to the rule** where a beneficiary (or the beneficiary’s legal representative) refuses, of his/her own free will, to authorize the submission of a bill to Medicare.

- In such cases, a **Medicare provider is not required to submit a claim to Medicare** for the covered service and may accept an out of pocket payment for the service from the beneficiary.

- The limits on what the provider may collect from the beneficiary continue to apply.

- **Thus, if a Medicare beneficiary requests a restriction** on the disclosure of PHI to Medicare for a covered service and **pays out of pocket for the service** (i.e., refuses to authorize the submission of a bill to Medicare), **the provider must restrict the disclosure of PHI regarding the service to Medicare in accordance with §164.522(a)(1)(vi).**
MORE HHS FINAL RULE CLARIFICATIONS
Splitting Treatments or a Single Encounter

- **HHS expects providers to counsel patients** on the ability of the provider to unbundle items/services and the impact of doing so (e.g., the health plan still may be able to determine that the restricted item or service was performed based on the context).

  - If a provider is able to unbundle items/services and accommodate the individual’s wishes after counseling the individual on the impact of unbundling,** it should do so.**
  
  - If a provider is not able to unbundle a group of items/services, the provider should **inform the individual and give the individual the opportunity to restrict and pay out of pocket for the entire bundle of items or services.**

*Where a provider is not able to unbundle a group of bundled items or services, we view such group of bundled items or services as one item or service for the purpose of applying §164.522(a)(1)(v).
MORE HHS FINAL RULE CLARIFICATIONS
Splitting Treatments or a Single Encounter

- HHS expects that a provider to accommodate an individual’s request for a restriction for separable and unbundled health care items or services, even if part of the same treatment encounter, such as with respect to the patient receiving both treatment for asthma and diabetes.

- Accordingly, HHS declined to provide as a general rule that an individual may only restrict either all or none of the health care items/services that are part of one treatment encounter.
MORE HHS FINAL RULE CLARIFICATIONS
Pharmacies and “Downstream” Providers

- Commenters indicated that there currently is not a widely available method for electronically notifying a pharmacy that a patient has requested a restriction.  
  - HHS Agreed.
- Commenters also argued that it is too costly, burdensome, and unworkable for a provider to attempt to notify all subsequent providers “downstream” of an individual’s restriction request, particularly given the lack of automated tools to make such notifications, and thus, it should remain the obligation of the individual to notify downstream providers.  
  - HHS agreed, given the lack of automated technologies to support such a requirement.
  - However, HHS encourages providers to counsel patients that they would need to request a restriction and pay out of pocket with other providers or “downstream” providers for the restriction to apply to the disclosures by such providers.
HHS example:
- Patient meeting with primary physician requests a restriction on tests that are being administered to determine if she has a heart condition.
- If, after conducting the tests, the patient’s primary physician refers the patient to a cardiologist, it is the patient’s obligation to request a restriction from the subsequent provider, the cardiologist, if she wishes to pay out of pocket rather than have her health plan billed for the visit.
- Although the primary physician may not be required to alert the cardiologist of the patient’s potential desire to request a restriction, HHS encourages providers to do so if feasible.
- Or, in the very least, HHS wants the physician to engage in a dialogue with the patient to ensure that he/she is aware that it is the patient’s obligation to request restrictions from subsequent providers.
HHS says:

- Providers operating within an HMO context and who are able under law to treat the health care services to which the restriction would apply as out-of-network services should do so in order to abide by the requested restriction.

- HHS does not consider a contractual requirement to submit a claim or otherwise disclose PHI to an HMO to exempt the provider from his or her obligations under this provision.

- Further, the final rule provides a 180-day compliance period beyond the effective date of these revisions to the Privacy Rule, during which provider contracts with HMOs can be updated as needed to be consistent with these new requirements.
HHS clarification regarding providers abiding by a restriction if an individual’s payment is dishonored:

- **HHS expects that providers will make a reasonable effort to contact individuals and obtain payment prior to billing a health plan.**
  - Does not prescribe the efforts a health care provider must make but leave that up to the provider’s policies and individual circumstances.

- **“Reasonable effort”** requirement is **not intended to place an additional burden on the provider** but is instead intended to **align with its current policies for contacting individuals to obtain an alternative form of payment** to one that was dishonored.

- **HHS does not require that the individual’s debt be placed in collection** before a provider is permitted to bill a health plan for the health care services.
MORE HHS FINAL RULE CLARIFICATIONS
“Pay Up Front” Requirement is OK

- A provider may choose to require payment in full at the time of the request for a restriction to avoid payment issues altogether.

- Similarly, **where precertification is required** for a health plan to pay for services, a provider may require the individual to settle payments for the care prior to providing the service and implementing a restriction.

http://www.condenaststore.com/-sp/It-s-my-ex-He-wants-to-pay-me-aconjugal-visit-New-Yorker-Cartoon-Prints_i8476578_.htm
MORE HHS FINAL RULE CLARIFICATIONS
Payment out-of-pocket from FSA or HSA

- Regarding whether payment with a **Flexible Spending Account (FSA) or Health Savings Account (HSA)** is considered a payment by a person on behalf of the individual:
  - HHS clarified that an **individual may use an FSA or HSA** to pay for the health care items/services that the individual wishes to have restricted from another plan;
  - However, in doing so the **individual may not restrict a disclosure to the FSA or HSA necessary to effectuate that payment.**
With respect to restrictions and follow-up care:

- If an individual has a restriction in place with respect to a health care service but does not pay out of pocket and request a restriction with regard to follow-up treatment, and the provider needs to include information that was previously restricted in the bill to the health plan in order to have the service deemed medically necessary or appropriate, then the provider is permitted to disclose such information so long as doing so is consistent with the provider’s minimum necessary policies and procedures.

- Such a disclosure would continue to be permitted for payment purposes and thus, would not require the individual’s written authorization.

- However, HHS “highly encourages” CEs to engage in open dialogue with patients to ensure awareness that previously restricted PHI may be disclosed to a health plan unless the patient requests an additional restriction and pays out of pocket for follow-up care.
MORE HHS FINAL RULE CLARIFICATIONS
§164.522(a)(1)(vi) Applies only to Disclosures to Health Plans

- In response to commenters’ concerns regarding *disclosure for payment or health care operations purposes to entities other than the health plan*:
  - HHS clarified that this provision **does not affect disclosures** to these other entities as **permitted by the Privacy Rule**.
MORE HHS FINAL RULE CLARIFICATIONS
§164.522(a)(1)(vi) Applies only to Providers

- Regarding what types of Covered Entities have to comply with the rule:
  - HHS clarified that the provision, in effect, will apply only to covered health care providers.
  - However, the provisions of § 164.522(a) apply to covered entities, generally.
MORE HHS FINAL RULE CLARIFICATIONS
Restriction Applies to BA of Health Plan

Regarding disclosures to Business Associates* of Health Plans

- HHS clarifies that when a restriction is requested:
  - **The Rule:**
    - Provider that is prohibited from disclosing protected health information to a health plan may not disclose such information to the health plan’s business associate.
  - **The Reasoning:**
    - It is the provider’s responsibility to know to whom and for what purposes it is making a disclosure.

*HHS clarified that a provider is not prohibited from disclosing PHI restricted from a health plan to its own business associates for the provider’s own purposes.
MORE HHS FINAL RULE CLARIFICATIONS
Disclosure in violation of rule is Breach

- Regarding what the liability is for a provider who discloses restricted protected health information to a plan:

  - HHS makes clear that a provider who discloses restricted protected health information to the health plan is making a disclosure in violation of the Privacy Rule and the HITECH Act, which, as with other impermissible disclosures is subject to

    - the imposition of possible criminal penalties,
    - civil money penalties,
    - or corrective action.
HHS responded to questions about the number of workforce members who must know about the mandatory restriction and indicated that this may create a risk for potential error with regard to the information:

- **Covered entities must identify those workforce members or class of persons who need access to particular PHI, and appropriately train their workforce members as necessary to comply with these new requirements.**
More HHS Final Rule Clarifications

Requirement to Document Restrictions

- Regarding Documentation Requirements for Providers under § 164.522(a)(3):
  - Agreed upon restrictions must be documented in writing in accordance with § 164.530(j).
  - Does not require a specific form of documentation; a note in the medical record or similar notation sufficient.
  - The documentation must be retained for six years from the date of its creation or the date when it last was in effect, whichever is later.

- No requirement to keep a record of all requests made, including those not agreed to, nor report requests to HHS.
  - Because there is no requirement to agree to a restriction, there is no reason to impose the burden to document requests that are denied.

- Under § 164.522, a covered entity could be found to be in violation of the Privacy Rule if it fails to put an agreed-upon restriction in writing and uses/discloses PHI inconsistent with the restriction.
TERMINATING A RESTRICTION, GENERALLY

- Section 164.522(a)(2) includes provisions for the termination of a voluntary restriction and requires that covered entities that have agreed to a restriction document the restriction in writing:

2. Implementation specifications: terminating a restriction. A covered entity may terminate its agreement to a restriction, if:
   i. The individual agrees to or requests the termination in writing;
   
   ii. The individual orally agrees to the termination and the oral agreement is documented; or
   
   iii. The covered entity informs the individual that it is terminating its agreement to a restriction, except that such termination is:
       A. Not effective for PHI restricted under paragraph (a)(1)(vi) of this section; and
       B. Only effective with respect to PHI created or received after it has so informed the individual.
Regarding the comment that providers will choose not to agree to voluntary restrictions based on the guidance of legal counsel and loss prevention managers:

- HHS asserted its belief that providers will do what is best for their patients, in accordance with their ethics codes, and will continue to find ways to accommodate requested restrictions when they believe that it is in the patients' best interests.

- HHS anticipates that providers who find such action to be of commercial benefit will notify consumers of their willingness to be responsive to such requests.

*In response to this comment, HHS stated “involving third parties could undermine the purpose of this provision, by causing the sharing, or appearance of sharing, of information for which individuals are seeking extra protection.”
BASIC BEST PRACTICES SUGGESTIONS

- **Ensure Notice of Privacy Practices** adequately spells out patient rights as required by the Final Omnibus Rule as of 2013 compliance date.

- **Ensure adequate administrative processes in place** for patients to request restrictions, requests to be reviewed and accepted or denied.
  - Use form (either electronic or paper) executed by requestor and formally acknowledged by administrative staff and billing professionals to ensure everyone
  - Ensure that mandatory or agreed upon restrictions flagged in paper records and/or electronic records
  - Ensure that all restrictions and terminations documented

- **Train employees** on when requested restriction must be accepted (only under §164.522(a)(1)) and when a requested restriction may be accepted or denied.
  - Implement internal processes for employees to easily determine which scenario applies
  - Patient education communication plan for all employees

- **Ensure HIPAA Compliance with other aspects of the Privacy Rule.**
  - Regular Audits done to ensure compliance process working and documented
  - If improper disclosure made in violation of a restriction, ensure that breach analysis done and appropriate and timely notification made to patient
As legal professionals serving health care providers and others within the health care industry, we provide compliance assistance.

If you don’t know whether you are in compliance, contact someone who knows the law and can help you comply.

PLEASE do not just pull information off of the internet -

- Many Notices of Privacy Practices and other HIPAA policies posted online are not in compliance with post Omnibus Rule requirements.
THE END

THANK YOU!

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