The New Notice, and Old Consent, under HIPAA

Interpretational and Administrative Issues

Beth DeLair
Michael F. Brown
University of Wisconsin Hospital and Clinics

Comparison: New Notice and Old Consent

	NOTICE	CONSENT
Deadline	First "service" date (in-person, or electronic)	First use of any PHI
Way(s) to Comply	Written acknowledgement (signature not required); OR Good faith effort	Signed form
Tracking	No tracking after acknowl-edgement/good faith effort– no relation to TPO uses/disclosures **BUT RESTRICTIONS MUST BE TRACKED!	Must constantly be tracked for revocation, and tracked before TPO uses and disclosures

The (Old?) Consent Requirement

(Preparing for the Worst)

Preliminary Note: Problems in HIPAA Interpretation and Implementation

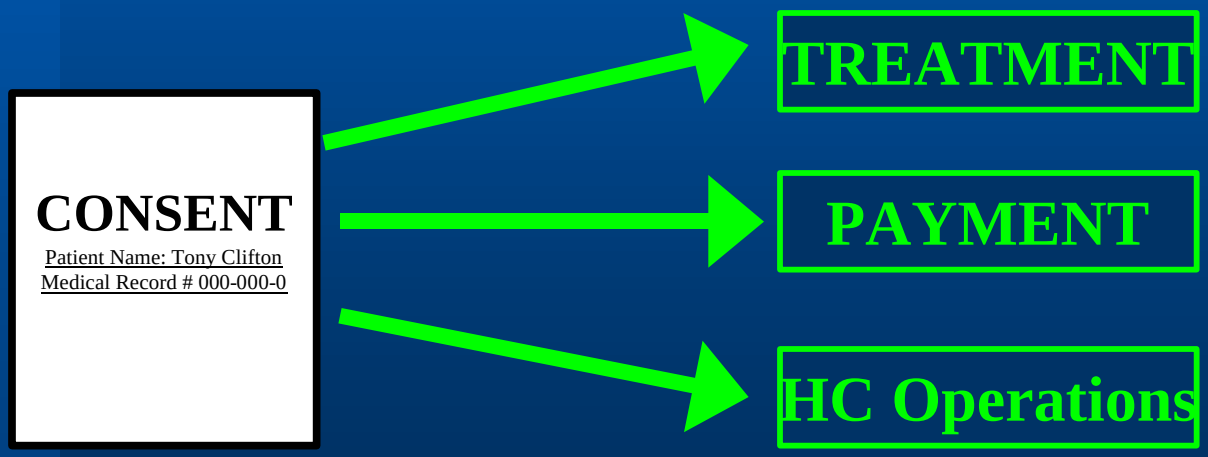
- **New Legislation**
  - Many contradictions and ambiguities.
  - No case law developed.
  - To what extent will penalties be enforced?
  - Will new penalties be developed (individual cause of action?)
  - Deadline.
- **Reasonableness and Efficiency Considerations**: How much flexibility allowed by HHS in meeting requirements?
- **Size and Complexity of Organization**
  - Small organization: e.g. cannot afford to hire HIPAA personnel.
  - Large organization: e.g. uses and disclosures of PHI too numerous and complex to efficiently interpret and implement.

Example: Privacy-Problematic Disclosure Allowable Under Plain Language "Treatment" Definition

- **Provider, without notifying patients, provides ten pharmacies with patients' names and illnesses; the pharmacies proceed to market specific drugs to those patients.**
  - Provider's disclosure fits "treatment" because pharmacy is a provider of health care, i.e. "sells drugs... in accordance with a prescription." Thus provider and pharmacy, in coordinating drug sales, are pursuing "treatment."

Old Consent: What Consent Allows

- If Patient signs written **consent** form, provider may make uses and disclosures for its own ***treatment***, ***payment***, and ***health care operations*** ***("TPO")***.
- Consent need only be signed once; valid until revoked.
- Provider can withhold health care if consent not given.



TREATMENT

- ***Treatment*** means:
  - the provision, coordination, or management of health care and related services by one or more health care providers;
  - the coordination or management of health care by a health care provider with a third party;
  - consultation between health care providers relating to a patient; or
  - the referral of a patient for health care from one health care provider to another.

- *Health care* includes, but is not limited to, the following:
- (1) Preventive, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care, and counseling, service, assessment, or procedure with respect to the physical or mental condition, or functional status, of an individual or that affects the structure or function of the body; and
- (2) Sale or dispensing of a drug, device, equipment, or other item in accordance with a prescription.

Old Consent: Treatment - "themed" PHI exchanges between providers do not require authorizations-- just 164.506 compliance.

** Except psychotherapy notes.

A's request is allowed because A is delivering health care to Patient (i.e. "treatment")

Provider A (has consent)
- Physician currently delivering health care to Patient.

Provider B (has consent)
- Has Patient PHI record from visit last year
- Not currently delivering health care to Patient

B's disclosure is allowed because B is involved in the "referral" and "coordination" of Patient's health care (i.e. "treatment").

Proposed Modifications: Maintain Special "Treatment" Niche, and Make it Explicit

- **New 164.506(c)(2) says a provider may disclose for another provider's treatment activities.**

WHAT TO DO… regardless of old or proposed rules…

… treatment – “themed” disclosures between providers do NOT require authorizations, if each meets 164.506.

PAYMENT

- ***Payment*** means:
  - A provider or plan's activities to obtain or provide reimbursement for health care provision, including but not limited to:
    - Billing, claims management, or collection activities;
    - Determinations of eligibility or coverage and adjudication of health benefit claims;
    - Review of health care services with respect to medical necessity, coverage under a health plan, appropriateness of care, or justification of charges;
    - Utilization review activities, including precertification and preauthorization of services; and
    - Disclosure to consumer reporting agencies of information relating to collection of premiums or reimbursement.

Health Care Operations

- ***Health care operations*** include, but are not limited to:

(1) quality assessment and improvement activities, population-based activities to improve health care or reduce costs, protocol development, case management and care

coordination, contacting providers or patients with information about treatment alternatives;

(2) Reviewing competence, performance or qualifications of health care professionals, reviewing performance of health plans, conducting training programs (for students, employees, including non-health care professionals) accreditation, certification, licensing, or credentialing activities.

New 164.506(c)(4)(ii): fraud and abuse detection and compliance

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(3) Underwriting, premium rating, and other activities relating to health insurance contracts or health benefits … securing … a contract for reinsurance of risk

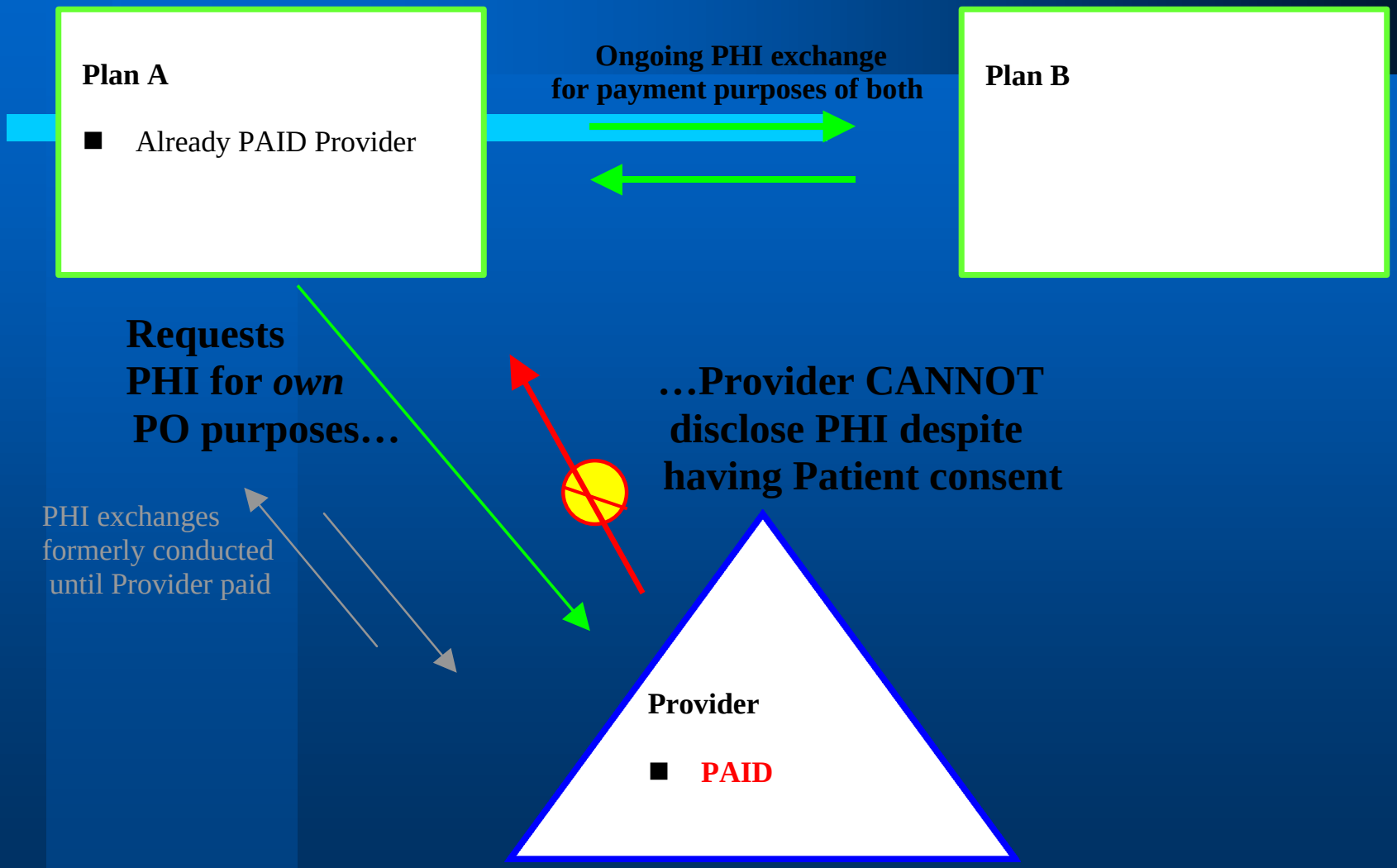
(4) Conducting medical review, legal services, and auditing;

(5) Business planning and development (e.g. cost-management, improvement of methods of payment or coverage policies; and

(6) Business management and general administrative activities (e.g.creating de-identified health information, fundraising, some types of marketing, customer service; resolution of internal grievances, etc.)

Old Consent: Limitations of Consent for PO

Some PO - "Themed" Exchanges between CEs are NOT allowed with consent:



Consent only allows uses and disclosures for provider's *own* PO purposes.

Old Consent: Beware of PO disclosures that are "favors" for other CEs: justify that your PO interests are advanced, or else an authorization may be required.

- **Basis for this rule (& preceding example):**
  - →**P. 12 July Guidance**
  - →**164.506(a)(5):** your consent does not permit another CE to use or disclose PHI for its TPO.
  - →**164.506(a)(1):** Your consent permits you to carry out TPO– this provision does not explicitly permit you to disclose PHI to another CE as a "favor," even if that CE is pursuing TPO.

Proposed Modifications: Good News for Providers-- Disclosures for Other CEs' PO (i.e. PO "favors") Are Allowed

- **PO "favors" are allowed by new 164.506(c)(3)-(4).**
  - **Exception: cannot disclose for another CE's activities falling between (3) and (6) of 164.501 "health care operations" definition.**

The New Notice Requirement: Relief for Providers

Notice and Consent Both Require Written Patient Confirmation: What's the "Advantage" Here Anyway?

- **Notice, unlike consent, is not required to "free up" TPO uses and disclosures.**
- **Notice, unlike consent, is NOT subject to patient revocation.**
- **Thus… Personnel in the "Trenches" Making TPO Uses and Disclosures Need NOT Check Patients' Notice Status.**

**** BUT RESTRICTIONS MUST BE TRACKED.**

Notice is not required to “free up” TPO uses and disclosures– it is a completely independent requirement, unlike old consent

- **Unlike consent, if notice is absent, subsequent TPO uses or disclosures do not “pile up” HIPAA violations, sanctions.**

Notice requirement, unlike consent, is NOT subject to patient revocation

- **Like consent, notice need only be secured one time. But unlike consent, the patient cannot revoke her acknowledgment, nor can she revoke good faith.**
- **After the provider has made an attempt in "good faith", the notice requirement is met, and need not be readdressed.**

So…Personnel Making TPO Uses and Disclosures Need NOT Check Patients' Notice Status

- **Thus, unlike consent documentation – which was required for all TPO and subject to revocation-- notice documentation need NOT be checked by health care personnel at the time of TPO uses or disclosures.**

  **** Again, restrictions must be checked, however.**

- **Rather, it is the HIPAA and registration staffs' responsibility to make sure notice– either acknowledgement OR good faith– is fulfilled before "service" is delivered.**

WHAT TO DO (if “old” consent remains)

- **Identify access points.**
- **Create a multidisciplinary team to evaluate the requirement and determine the process.**
  - **Advanced mailings?**
  - **Centralize the process?**
  - **Scan consents?**
  - **Determine where and how to track them (e.g., flag or report).**

WHAT TO DO (if “old” consent remains)

- **Determine process for maintaining or tracking**
  - **Scan it into EMR?**
  - **Have a place to document in a field?**
- **Determine process for communicating revocations and/or (possibly) restrictions with others in OHCA**
  - **Main database for all?**
  - **Main person to communicate restrictions or revocations?**

WHAT TO DO (if "old" consent remains)

- **Identify and document disclosures that are "favors," i.e. primarily address the other CE's TPO.**
  - **Especially favors identified between (3) and (6) of 164.501 "health care operations" definition**
- **Prepare to implement "(3) to (6)" authorizations, for certain.**
- **Don't forget <u>all</u> PO "favors" <u>may</u> require authorizations, so plan just in case.**

What to do with Notice of Privacy Practices

- **<u>Existing patients</u>: send/transmit notice and acknowledgment form well before 4/03.**
  - **Does sending Privacy Notice alone fulfill notice's "good faith requirement"?**
  - **Follow-up attempts bolster good faith effort.**
- **<u>New patients</u>:** provide notice as part of patient registration process (both on-site and electronic).
  - **Determine access points.**
  - **Establish entity-wide process for giving notice and obtaining acknowledgment.**

** Remember to document your efforts, and patient's response (or lack thereof).

What to do with Notice of Privacy Practices

- **Determine whether you will accept requests to restrict.**
  - **Is it operationally sound to do so?**
  - **Will there be negative publicity or customer service if you don't?**
  - **Which department(s) will accept the requested restrictions?**
  - **How will you communicate restrictions to other members of your OHCA?**

Anticipate, Document, And Justify Situations Where:

(1) The patient is new (i.e. didn’t receive mass mailer, electronic, or in-person notice);

(2) The patient receives “service” before she can receive notice via in-person or electronic registration; and

(3) The service does not concern an "emergency."

Example: Where "Service" Precedes Notice

- **Example 1: New patient, uncomfortably ill, makes phone call to schedule first appointment. During the call, nurse provides preliminary treatment advice, i.e. (arguably) delivers "service."**
- **Example 2: Clinic patient is seen once a year but has monthly labs drawn at other site, with results communicated to our staff. Patient follows-up with clinician about medication changes, new order, etc.**
- **Issue: How can the covered entity comply with notice requirement when first "service" occurs before first contact (in person, or electronic)?**

WHAT TO DO… possible arguments to justify service preceding notice…

- **LEGAL (Textual) Arguments**
  - Deadline is “date of” service, not “before” service (thus Ok to give/transmit notice later that day).
  - “Service” does not begin until physical visit, or electronic prescription, has occurred.
  - When first service is at same time as first contact, providing notice at registration meets “good faith.”
  - This is an “emergency.”

- **JUSTIFICATIONS (Policy Arguments)**

-- Purpose of consent removal was to avoid inefficiencies in treatment: notice problem in e.g. above was unintended by HHS.

-- Policy reason for good faith was to accommodate providers’ inefficiencies unforeseen by HHS.

Goal:

- **Anticipate, address, and document your notice requirements (and problems) ahead of time, so health care employees can assume it is taken care of.**

Questions or Comments?

- **Beth DeLair**
  - **(608) 262-4926**
  - **ce.delair@hosp.wisc.edu**
- **Michael Brown**
  - **(608) 263-9345**
  - **mf.brown@hosp.wisc.edu**