

Privacy and Confidentiality for Community Pharmacy

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Community Pharmacy : Privacy of Health Information

- At the Bench
- In the Mailbox
- In the Pharmacy's Database

The Pharmacy Bench

- A place of trusted professionalism with a “white coat” perception of a health care provider
- Pharmacists are repeatedly voted most trusted health care professionals
- Our patient has historically consented with her feet and, to some extent, by signing the consultation/third party log.
 - ◆ HIPAA gives us help on the implementation transition by permitting permission granted for payment to serve in the transition.

But Retail Pharmacy is also a place of business with:

- a typical daily script volume of over 450 prescriptions and growing
- 80% of prescription customers have a third party payor
- 50% of prescriptions are being called in from prescribers' offices
- The gambit of individual patients, family members, taxi drivers, neighbors, and friends coming in to pick up medications and other items

The Challenge of HIPAA to make an Environment of Privacy

- The 7/9/01 Office of Civil Rights Guidance tells us that we can make oral communications in this setting with reasonable safeguards such as “lowered voices”
- Pharmacies need a private face to face consultation area for communications

The Challenge of HIPAA to ensure privacy to an absent patient.

- Patients can be too ill, or otherwise unavailable leaving a privacy and consultation gap filled by the caretaker or friends and family.
- The Guidance tells a pharmacist to use professional judgment and experience with common practice to make reasonable inferences of the patient's best interest in allowing a person, other than the patient, to pick up a prescription (see § 164.510(b)).

More HIPAA Safety Nets

- Phone-in scripts –The Guidance says:

“ The Privacy Rule, as written, does not permit [filling a script] without prior patient consent. It poses a problem for first-time users of a particular pharmacy or pharmacy chain. The Department of Health and Human Services did not intend the rule to interfere with a pharmacist's normal activities in this way. *The Secretary is aware of this problem, and will propose modifications to fix it to ensure ready patient access to high quality health care.*”

- Advice on OTC

- ◆ Guidance says “No. A pharmacist may provide advice about over-the-counter medicines without obtaining the customers' prior consent, provided that the pharmacist does not create or keep a record of any PHI. In this case, the only interaction or disclosure of information is a conversation between the pharmacist and the customer. The pharmacist may disclose PHI about the customer to the customer without obtaining his or her consent (§ 164.502(a)(1)(i)), but may not otherwise use or disclose that information.”

Minimum Necessary Role under HIPAA

- Limits on access of persons (or classes of persons) in workforce
 - ◆ Even for treatment purposes, the minimum necessary criteria may demand different restrictions to information based on personnel job duties.
 - ◆ Distinguish a busy, high-volume environment from a slow, low-volume store.
- What about the PHI used to get the claim to “clear” for payment? The pharmacy is largely at the peril of the payor.

The Mailbox

(and other communications with Patients)

- Once Consent is on record, the pharmacy is able to conduct all activities within the rubric of treatment (including reminders to patients about compliance with medication therapies)
- Use of a mail fulfillment agent (as business associate) is acceptable under HIPAA
 - ◆ This is a strike against privacy tort plaintiffs such as in Elensys v. CVS et al.

But what about informing patients of matters beyond treatment:

- New dosage forms?
- Educational programs?
- Clinical trials ?

HIPAA demands more paperwork --- Marketing requires a Patient Authorization

- additional massive record keeping chore
- confusing to patient (Didn't I already sign something?)
- unworkable in instances: for example, how will you motivate customers to provide authorization?

Health Related Communications

The Answer may be:

(Section 164.415(e)(3)) There is a relevant exception to the authorization requirement when a pharmacy to make a "health-related" marketing communication which meets the requirements as follows:

- **it identifies the pharmacy as the party making the communication**
- **Prominently notifies the customer if the pharmacy is paid for the communication**
- **and contains instruction on how the individual may opt out of future marketing communications .**

Also, if the communication is targeted to a patient based on health status or condition, then, in addition to the above requirements,

" (A) The covered entity must make a determination prior to making the communication that the product or service being marketed may be beneficial to the health of the type or class of individual targeted;

and

(B) The communication must explain why the individual has been targeted and how the product or service relates to the health of the individual.

(iii) The covered entity must make reasonable efforts to ensure that individuals who decide to opt out of receiving future marketing communications, under paragraph (e)(3)(i)(C) of this section, are not sent such communications.

The Pharmacy Database

- **HIPAA makes de-identification a neat recipe or a professional judgment:**

- ◆ “ In the final rule, we reformulate the method for de-identification to more explicitly use the statutory standard of “a reasonable basis to believe that the information can be used to identify the individual”—just as information is “individually identifiable” if there is a reasonable basis to believe that it can be used to identify the individual, it is “de-identified” if there is no reasonable basis to believe it can be so used. We also define more precisely how the standard should be applied.”

HHS response to comments in Final Rule

- **HIPAA gives us a Safe Harbor for de-identification:**

- ◆ all dates directly related to the subject of the information must be removed or limited to the year, and zip codes must be removed or aggregated (in the form of most 3-digit zip codes) to include at least 20,000 people

HIPAA Accounting: Records of records of records.

- Pharmacy has always had a process for production of a patients prescription record
- HIPAA provides for a report to the patient (an “accounting”) with some exclusions of all record productions
- Includes all details, purpose, etc.
- How to automate this?
- The Pharmacy must also keep an accounting of the accounting.

Conclusion

- HHS Secretary Thompson inherited a legacy from the Clinton administration in the form of the Final Privacy Standards .
- After talk of the Bush Administration effectuating change, voices on privacy fell silent in Washington (or were over ridden by other voices) and the covered entities are going about the business of implementation of the standards. Secretary Thompson says that the Privacy rule will provide strong protections for personal health information while maintaining the high quality of care that Americans expect.
- But large questions remain in areas where the government has promised but not yet delivered guidance. Community Pharmacy awaits....knowing that good things come to those who wait.