

Standards for Individually Identifiable Health Information: Prior Written Consent

National Committee on Vital & Health Statistics
Subcommittee on Privacy & Confidentiality
August 21, 2001

Susan C. Winckler, RPh, JD
Group Director, Policy and Advocacy
American Pharmaceutical Association



Pharmacy Operations Today

- Pharmacists abide by privacy standards
 - State Pharmacy Practice Acts
 - State Board of Pharmacy regulations
 - Other state laws
 - Pharmacist's Code of Ethics
- Many pharmacies have confidentiality policies
- Prior consent is not prevalent in current environment



Impact of Prior Written Consent

- Without prior written consent pharmacists may not:
 - Enter prescription information into the computer
 - Evaluate clinical appropriateness
 - drug or disease interaction review, assess dose and duration appropriateness, etc.
 - Prepare the prescription
 - Communicate with prescriber about the patient
 - Transmit information to third party payor



What Does This Mean?

- Scope: more than 3.1 billion prescriptions prepared in 2000
- Adding prior written consent
 - Erects barriers to the delivery of health care
 - Adversely affect patients because of delays and potential limits on use of information
 - Yield administrative and financial burdens



Impact on Non-Dispensing Activity

- Alert patients to contaminated, counterfeit, ineffective products
 - Pharmacist uses patient information to identify and contact patients
- Under privacy regulation
 - Could pharmacist use patient information without prior written consent?



Consent Restrictions

- Patients may restrict use and disclosure under consent
 - May increase patient risk
 - Erect barriers to patient care
- Example: Restrictions on mental health medication
 - Pharmacist identifies drug interaction
 - Cannot tell prescriber what medications the patient uses



Consent Restrictions

- Patients may not understand rights and restrictions
 - Granting some restrictions could conflict with responsibilities under state pharmacy practice acts
 - Patient may become accustomed to providing consent and sign forms without consideration
- May detract from regulation's goals
 - Distinction between treatment, payment and health care operations and “other activities” may be lost
 - Access to quality health care



Impact on Pharmacy

- Administrative and Financial Burden
 - Secure consent from every patient
 - Patients do not expect paperwork at the pharmacy
 - Pharmacists will have to explain consent form and Notice of Privacy Practices to each patient
 - Divert pharmacists from patient care
 - Exacerbate pharmacist shortage
- Vagueness still an issue
 - “Reasonable” precautions against accidental disclosures:
 - Log books
 - Public Address Systems
 - Semi-private counseling areas



Compliance: HHS Guidance Document

- Clarifies some areas of the rule
 - OTC medication questions
 - Can counsel without consent
 - If information not recorded
- Raises additional questions
 - Modify the regulation
 - Allow pharmacists to prepare phoned-in prescriptions without prior consent
 - No timeline for guidance or modifications



Recommendations

- Options to modify prior written consent requirement
 - Return to statutory authorization
 - Consent implied from prescription
 - Remove “prior”
 - One consent form for all treatment, payment, and health care operations
- Delay compliance date for 2 years after final modifications

