

E-Sign: Its Implications for Healthcare Providers and Vendors


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Contract Philosophy 101

- **Important agreements between parties are often in writing to eliminate/reduce confusion**
- **Historically, many ways to put one's "mark" to signify their agreement of the principles set forth in the writing. An "x", wax seal, initial, signature -- a unique identifier**



Contract Philosophy Meets the Computer Age

- At present, common technology does not and cannot assure that an agreement has been “electronically signed” by the party named on the agreement --
- You really don’t know who has “clicked” 
- Next Phase -- digital bitstreams encrypted with originator’s private key and decoded with the originator’s public key per HIPAA
- Some Day -- biometric devices will be in use and should reduce or eliminate this issue, e.g., retinal or fingerprint sensors

E-Sign: What is it? Why Do We Care?

A. Other Laws that Matter

- **Uniform Electronic Transactions Act (“UETA”) - adopted by National Conference of Commissioners on Uniform State Laws (adopted by more than 19 states) (see uetaonline.com)**
- **Uniform Computer Information Transaction Act (“UCITA”) (see ucitaonline.com)**
- **Other State Electronic Records/Signature Laws**
- **Special Federal Laws, e.g. HIPAA**

E-Sign: What is it? Why Do We Care?

B. E-Sign: The Law

- **Effective October 1, 2000, March 1, 2001 for government imposed records retention requirements (expect regulations)**
- **Preempts conflicting state laws, other than UETA**
 - **UETA is more complete which is why states are choosing to adopt it**



E-Sign: What is it? Why Do We Care?

- **Jurisdiction - transactions affecting interstate or foreign commerce**
- **Basic Impact:**
 - **Signature, contract or other record may not be denied legal effect, validity or enforceability solely because it is in electronic form**
 - **Don't have to use an electronic signature, but if you do it should be valid**
 - **Permits regulatory agencies to interpret E-sign provisions (to extent of their rulemaking authority)**



- **Record Maintenance**

- **Record maintenance requirements are satisfied by maintaining an electronic record that is**

- **Accurate**
- **Capable of being accurately reproduced, and**
- **Accessible by all legally entitled persons**

- **An electronic record can be considered an “original”**

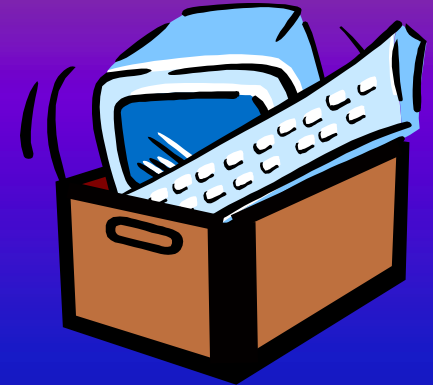
- **Notarizations/Acknowledgements**



- **Exceptions**
 - **Cancellation or termination of health insurance benefits**
 - **Wills, codicils, testamentary trusts**
 - **Documents governed by state laws concerning adoption, divorce, or other family law matters**
 - **Cancellation of utility services**
- **Notices of default, etc. under a mortgage**
- **Recall of certain products**
- **Documents that accompany hazardous materials**



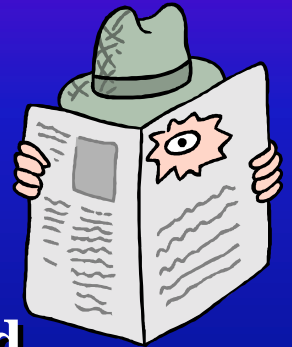
- **Consumer Protections**
 - **Affirmative consent to electronic transaction**
 - **Conspicuous notice to consumers of right to obtain record in non-electronic form**
 - **Right to withdraw consent to participate in electronic transaction (and related consequences)**
 - **How to update consumer contact information**



- **Pre-specifications of hardware and software requirements for access to and maintenance of electronic records**
- **Consumer confirms access to information in electronic form**
- **If hardware/software specifications change so there is a material risk that consumers cannot access or retain the electronic record, consumer is given right to withdraw consent**

What E-Sign Does Not Do

- It does not:
 - tell anybody how to sign
 - offer a way to authenticate that a signature actually belongs to the person named
 - affect any requirement by any federal or state regulatory agency that records be filed in accordance with specified standards or formats, i.e., Big Brother can refuse a filing made with an electronic signature



C. Special Laws:

1. E-Sign permits Federal regulatory agencies to interpret the provisions of E-Sign, but regulations must be:

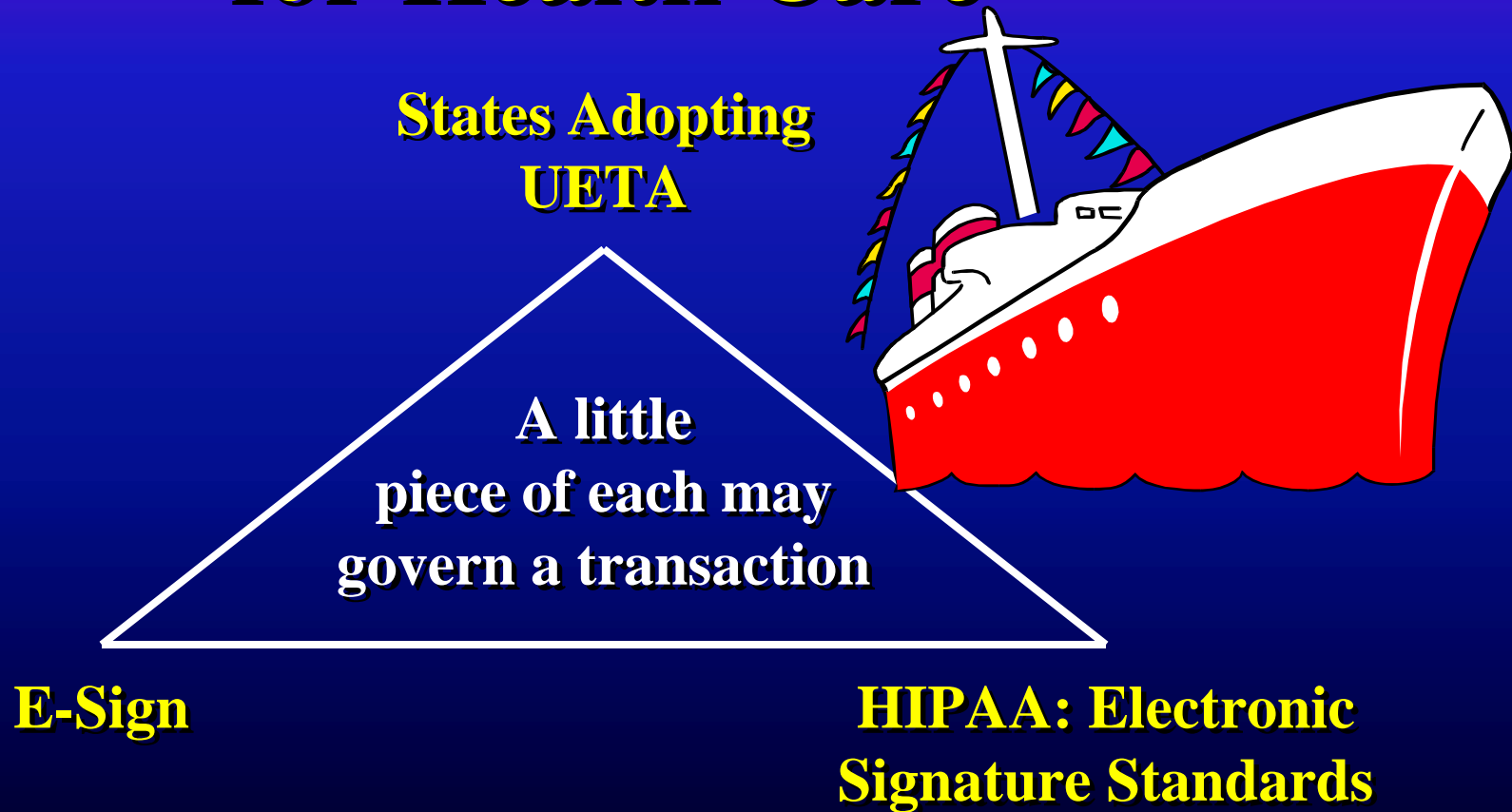
- consistent with E-Sign**
- cannot add requirements**
- substantial justification for the regulation**
- the methods prescribed to carry out their purpose are substantially equivalent to non-electronic records**
- do not impose unreasonable costs, and**
- must be technology neutral, unless serves an important governmental objective**



2. HIPAA - Security and Electronic Signature Standards (Proposed Rules, August 12, 1998)

- **Defines transaction**
- **HHS to coordinate with Department of Commerce concerning standards**
- **Principles for Electronic Signature Standards under HIPAA**
 - **Digital Signature**
 - **Message Integrity (assurance of unaltered transmission and receipt of message by intended recipient)**
 - **Repudiation (prevent parties from denying submission)**
 - **User authentication (assurance of claimed identity)**

The Bermuda Triangle for Health Care



Healthcare: The Practicalities and Realities of E-Sign

- Healthcare transactions are not included on the list of transactions excepted from E-Sign -- means “healthcare transactions” affecting interstate commerce can be validated by electronic signatures



Healthcare: The Practicalities and Realities of E-Sign

Implications -

- What is a “healthcare transaction” affecting interstate commerce?
- Could a patient electronically sign an advance directive before entering the hospital? Does an advance directive affect interstate commerce?
- Would a patient want to electronically sign an advance directive?
- Would the hospital want to accept an Electronic Signature for advance directives and matters involving informed consent?

- **Health Insurance and Health Plans**
 - **Can accept applications completed on-line, but cannot cancel contracts electronically (unless authorized by state law)**
 - **E-Sign protects insurance agents and brokers from liabilities arising from deficiencies in electronic procedures**

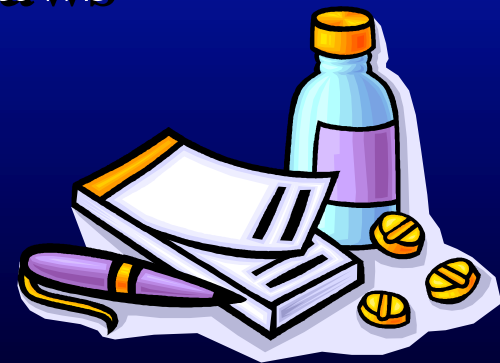


Implications -

- More consumers may unwittingly sign-on to a health plan without having the opportunity to ask questions of a broker**
- What happens if a consumer is harmed, but cannot hold agents and brokers responsible**

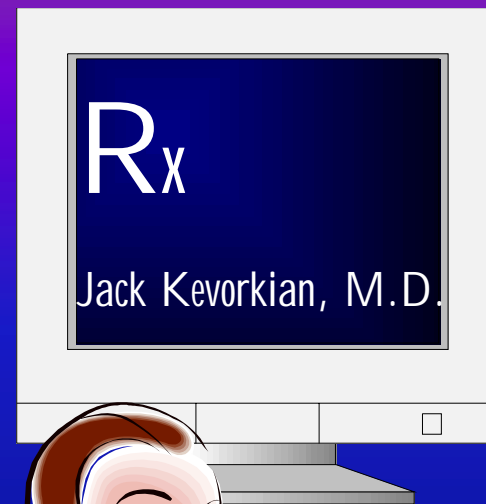
- **Prescriptions**

- **An electronic prescription, under E-Sign, should have the same legal effect as an original “paper” prescription**
- **Some states still require the presentation of an “original” paper prescription for controlled substances; are those laws preempted?**



Implications -

- Will on-line pharmacies accept an e-mail from a physician “prescribing” a drug for a patient?
- Can they?
- What about Federal DEA, FDA and state dispensing laws?



- **Physicians**

- **May be able to sign and validate orders and prescriptions remotely**
- **Promote and accomplish remote activity**

Implications -

- **Greater potential for medical errors**
- **Greater potential for liability**
- **Lacks opportunity for verification**
- **Increases opportunities for fraud**

- **Home Health Agencies**
 - **HCFA Form 485 requires original physician signature on care plans before a Home Health Agency can bill for services**
- **E-Sign does not supersede any requirement by a federal agency that records be filed with the agency in accordance with specified standards or format**

- **If HHS wants an original, you can most likely forget using that new wireless palm pilot to transmit/sign care plans (at least for now)**



What can you do?

What should you do?

What do you want to do?

- Can take steps to adopt new technology, but it's really not widely used yet -- must be how the first television writer felt
- You don't have to do anything



- **What does your business need -- must it by necessity obtain an electronic signature, or is this kind of interaction merely an added bonus?**
- **Where you can easily obtain an “electronic signature,” you should**

e.g., double-clicking on website terms/conditions is the most primitive of electronic signatures -- but it's a start



A few concluding thoughts:



- **With E-Sign, calligraphy is now a dead or dying art form**
- **Digital signatures probably will be (or at least should be) the next segment in Disney's Carousel of Progress**
- **Will probably forever change the way commerce and contractual relationships are conducted**
- **For Health Care -- will force the industry to invest more than ever before in information technology in order to keep up with other non-health related transactions**
- **Whether or not health care is different, it will not suffice to complain about being different. Participants will need to keep up -- by adopting technology and appropriately navigating the Bermuda Triangle -- E-Sign, UETA, HIPAA**