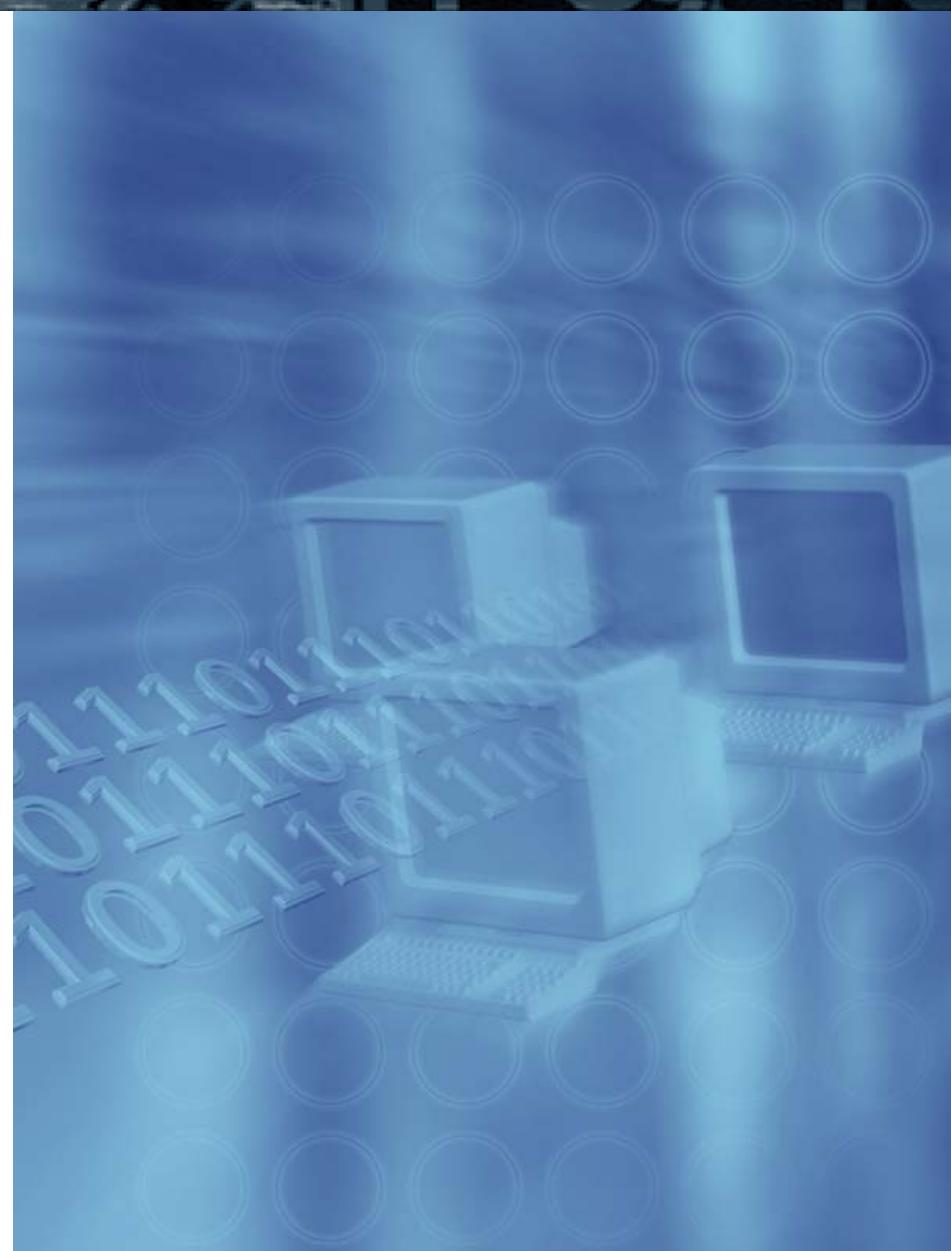


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HIPAA and Electronic Signatures

NCVHS

December 8, 2004
Kepa Zubeldia, M.D.



Topics

- HIPAA Statute Text
- Types of signature
- Encryption, Decryption, PKI
- Electronic vs. Digital signatures
- Digital Certificates
- PKI Standards
- Signature Standards

PL 104-191 HIPAA

Sec. 1173 (a)

- (1) IN GENERAL. The Secretary shall adopt standards for transactions, and data elements for such transactions, to enable health information to be exchanged electronically, that are appropriate for—
 - (A) the financial and administrative transactions described in paragraph (2); and
 - Other financial and administrative transactions determined appropriate by the Secretary, consistent with the goals of improving the operation of the health care system and reducing administrative costs.

Sec. 1173 (e) Electronic Signature

- Sec. 1173 (e) Electronic Signature.
 - (1) STANDARDS. The Secretary, in coordination with the Secretary of Commerce, shall adopt standards specifying procedures for the electronic transmission and authentication of signatures with respect to the transactions referred to in subsection (a)(1).
 - (2) EFFECT OF COMPLIANCE. Compliance with the standards adopted under paragraph (1) shall be deemed to satisfy Federal and State statutory requirements for written signatures with respect to the transactions referred to in subsection (a)(1).

Questions

- Standard procedures for “transmission” and “authentication” of signatures.
 - What did they mean ?
- For the HIPAA standard transactions
 - None of which require a signature today.
- But...
 - In the future some claims attachments may require signatures (e.g. consents).
 - In the future some new transactions may require signatures (e.g. scripts, medical record)

Food for thought

- HIPAA Signatures are separate from HIPAA Security requirements.
- Signature as a proof of “intent” rather than a security mechanism?
- What does it mean to “sign” an EDI file?
 - Most of the time the EDI data content is “obscure” to the untrained eye.
 - Intent?
 - Consent?
 - Assertion?
 - Or is it just a data integrity security protection?

Electronic Signature

- An electronic sound, symbol, or process, attached to or logically associated with a contract or other record and executed or adopted by the person with the intent to sign the record.

Electronic Signatures in Global and National Commerce (ESIGN) Act, Signed into law by President Bill Clinton on June 30, 2000

Electronic Signatures

- ESIGN Act passed in the summer of 2000
- Allows electronic record keeping
- Allows electronic signatures
 - Must have the “intent” to sign
 - Any electronic “mark” may be used
 - Technology independent
 - Risk of using “weak” methods
 - Simple to explain

Sample audio signature



- Legally valid. Effective.
- Low Tech. Easy to understand.
- Easy to capture by most PCs.
- Weakly bound to the document.
- Easy to forge.

Sample Electronic Signature

- Used by UPS drivers, CompUSA, Service Merchandise, etc.



Bart Simpson

- Simple implementations
 - Weak method, easy to copy.
- Strong technology is also available:
“Signature Dynamics”
 - Linked to the document
 - Prevents duplication
 - Can use a digital certificate

Geo Rogers
Joseph Howe,
John Brown.

Edward Fitzgerald,

Abd Haywood Jr.
James Lyell Fox
John Webster
William Brewster
Lyman Hall
Lydia Wallon.

John Hancock

Arnold Glass
Wm. Bass
Fitz Stone
Coch Fawcett & Agatha

George Wythe
Richard Henry Lee
Th Jefferson
Peter Harrison
John Adams
Samuel Adams
John Breton

Abd Morris
Benjamin Rush
Bog. Franklin
John Morton

Gottlieb Duttweiler
J. Smith

Geo Taylor
James Wilson
Geo. Washington
Genl Morris
Talley
Thom Ross

Ed. Livingston
Sam'l Morris
Lewis Morris

Nath. Jackson
Genl Washington
Genl Morris
John Ross
Ara Clark

Fish Burton
W. Whipple
Sam'l Adams
John Adams
Abd Frank Prince
Stringf. Jones

Step Hopkins
William Ellery L
Roger Sherman
John Huntington
Abd Quincy
Oliver Wolcott
Stephen Thompson



Signature Dynamics

- Signature characteristics captured in real time
 - X and Y coordinates
 - Pressure, Velocity, Acceleration
 - Time
- Signed with a stylus on a digitizing pad
- Associated with a specific signed document through a “hash”
 - If the document changes, signature is invalidated
- Signer’s identity can be determined
 - Forensic signature analysis as on paper signatures
 - Digital Certificate issued by a Certification Authority

Signature Dynamics in Practice

- Legally binding in all 50 states and in some foreign countries
 - ESIGN Act binding in USA
 - Used by the IRS for tax forms
- Technology-dependent
 - PenOp, Topaz, Cyber-SIGN, others
 - **No** interoperability among competing systems



Digital Home Port, Inc.

Devel

4028 Gulfview Dr., Spring Hill, FL 34607

Phone: 555-222-3333 Fax: 555-232-4444

Rx Prescription Rx

Date: 08-29-2003

Patient Name: Pyle, Gomer

Patient SSN#: 111-11-1111

DOB: 01-01-1940

Select Pharmacy:

Medication Name: acebutolol

Strength: 0.100 mg

Schedule: q4h

Pills: 10

Refills: 6

A handwritten signature in black ink, appearing to read "Ch. Damm".

SEND

| | | | | | | | |
|--|--|--|---|---------------------------|--|----------------------------|--|
| Pharmacy Stamp | | Age 10 yrs 3mths | Title, Forename, Surname & Address <i>Mr Peter Patient</i> | | | | |
| | | D.o.B 2/4/92 | <i>Flat 1 50 Stanhope Street Newtown TE22 1ST</i> | | | | |
| <p><i>Please don't stamp over age box</i></p> <table border="1"> <tr> <td>Number of days' treatment</td> <td></td> </tr> <tr> <td colspan="2">N.B. Ensure dose is stated</td> </tr> </table> | | | | Number of days' treatment | | N.B. Ensure dose is stated | |
| Number of days' treatment | | | | | | | |
| N.B. Ensure dose is stated | | | | | | | |
| Endorsements | | <i>Amoxicillin oral suspension 125mg/5mL sugar-free 125mg three times daily Supply: 100mL [No more items on this prescription]</i> | | | | | |
| | | Office use | | | | | |
| | |  | | | | | |
| Signature of Doctor | | Date 2/7/02 | | | | | |
| For dispenser No. of Prescns. on form | Anyborough Health Authority Dr D O Good 345543 7 High Street Anytown KBI CD2 Tel: 0111 222 333 | | | | | | |
| NHS PATIENTS – please read the notes overleaf | | | | | | | |



**NEW ENGLAND
EYE INSTITUTE**

1255 Boylston Street
Boston, Massachusetts 02215
Tel. (617) 262-2020
TDD (617) 236-4600

SPECTACLE PRESCRIPTION ONLY

FOR Daniel Smith DATE 10/3/94

ADDRESS _____

| Rx | | SPHERICAL | CYLINDRICAL | AXIS | PRISM | BASE |
|------|------|-----------|----------------|------|-------|------|
| D.V. | O.D. | -3.25 | -25 | 130 | | |
| | O.S. | +.50 | -1.00 | 80 | | |
| N.V. | O.D. | +2.00 | ADD | | | |
| | O.S. | +2.00 | | | | |

REMARKS _____ P.D. 1

DATE OF EXAM 10/3/94 EXPIRATION DATE _____

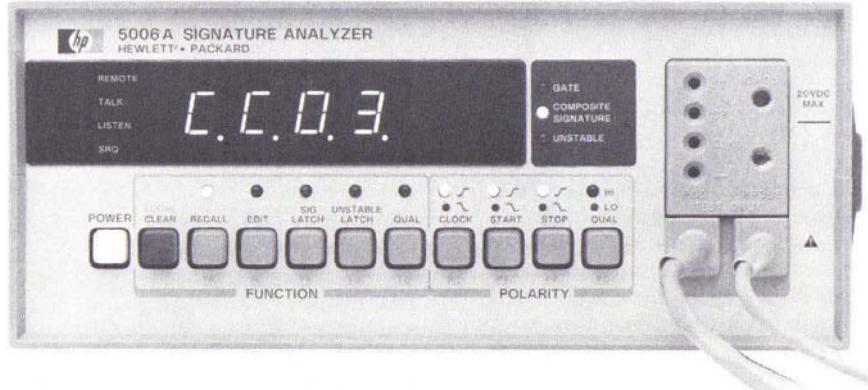
DR. X. Ghosh M LIC. # 3775

HIPAA Requirements

- Standard for electronic transmission
- Standard for authentication
- For HIPAA transactions



Electronic Signature (of another kind)



HP5006A Signature Analyzer

HP's patented Signature Analysis technique enables the HP5006A to generate a compressed, four digit "fingerprint" or signature of the digital data stream at a logic node. Any fault associated with a device connected through the node will force a change in the data stream and, consequently, produce an erroneous signature.

Message Digest

- One-way transformation of an entire message into a single number
 - Checksum
 - Simple algorithm produces 1 byte checksum
 - Validates a short number (credit card, NPI)
 - CRC
 - More complex algorithm produces 2-3 bytes
 - Validates longer data streams (TCP/IP, SNA)
 - Cryptographic hash
 - Complex algorithm produces 16-32 bytes
 - Validates large amounts of data

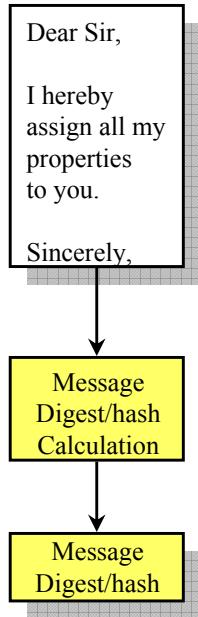
Message Digest (Hash) Properties

- Any change in the original data stream produces a different hash
- The transformation cannot be reversed: You cannot obtain the original data from the hash
- Changes are not predictable: Given a data set, you cannot predict what was changed from the hash
- No collisions: No two messages give the same hash
- Algorithm is well known (e.g., MD5, SHA-1)

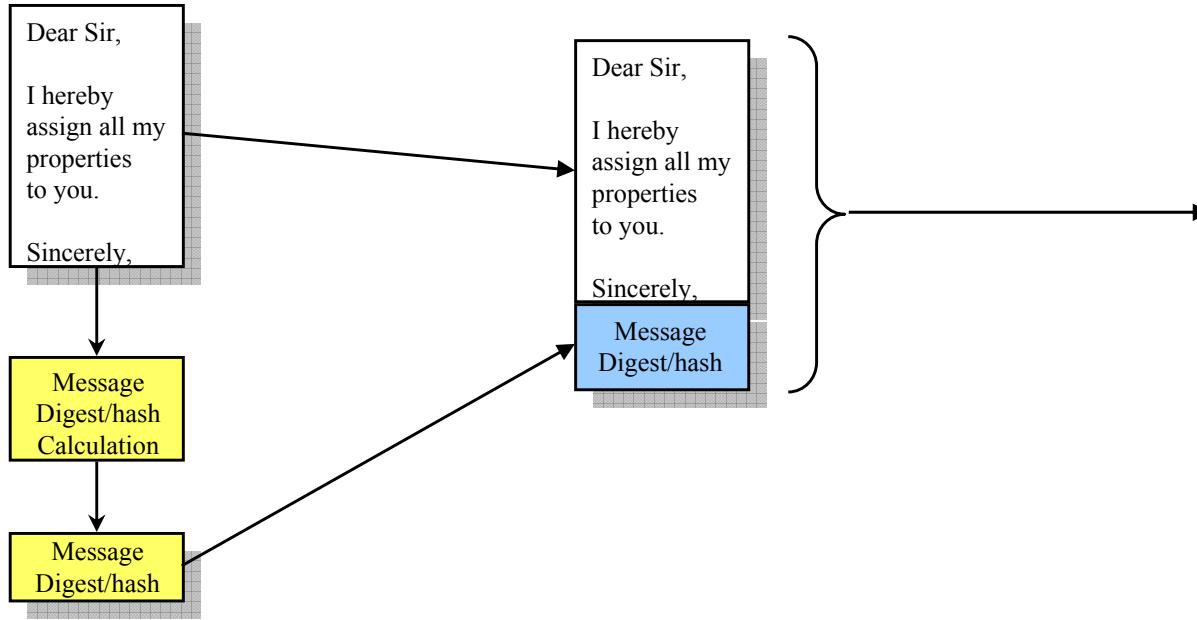
Examples of MD5 hash

- Text: “This is an example of MD5”
- MD5: 6090d33aa1c3b8885cfb2522c5d2189e
- Text: “This is another example of MD5”
- MD5: 19b9f4e9fe548830439332a520504f40
- Text: “This”
- MD5: a0311b12ed8180f815965a24044a3add
- Text: HR3103.PDF file (HIPAA Law)
- MD5: 35054013a8cd7ec700c0e903660183ed

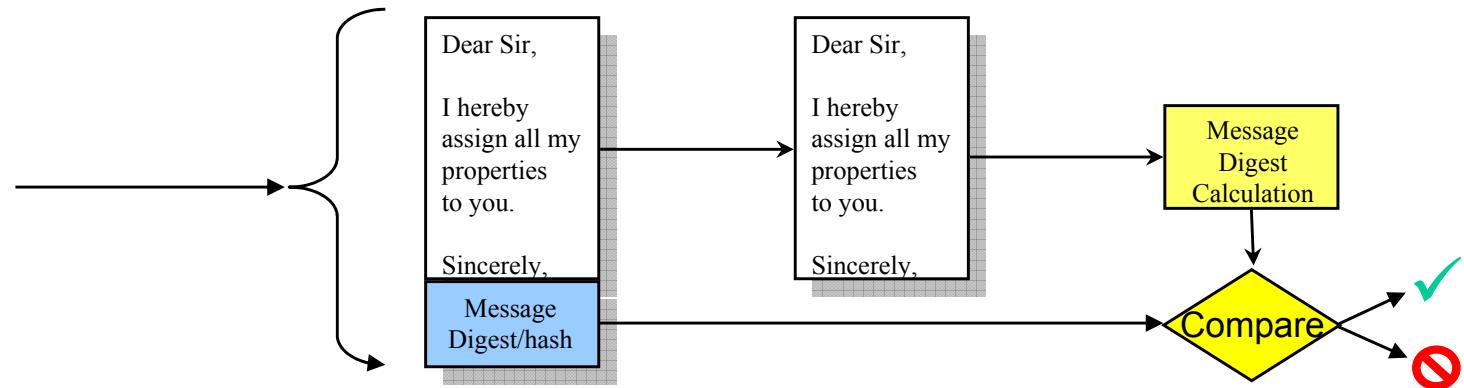
Message Digest Process



Message Digest Process



Integrity Verification



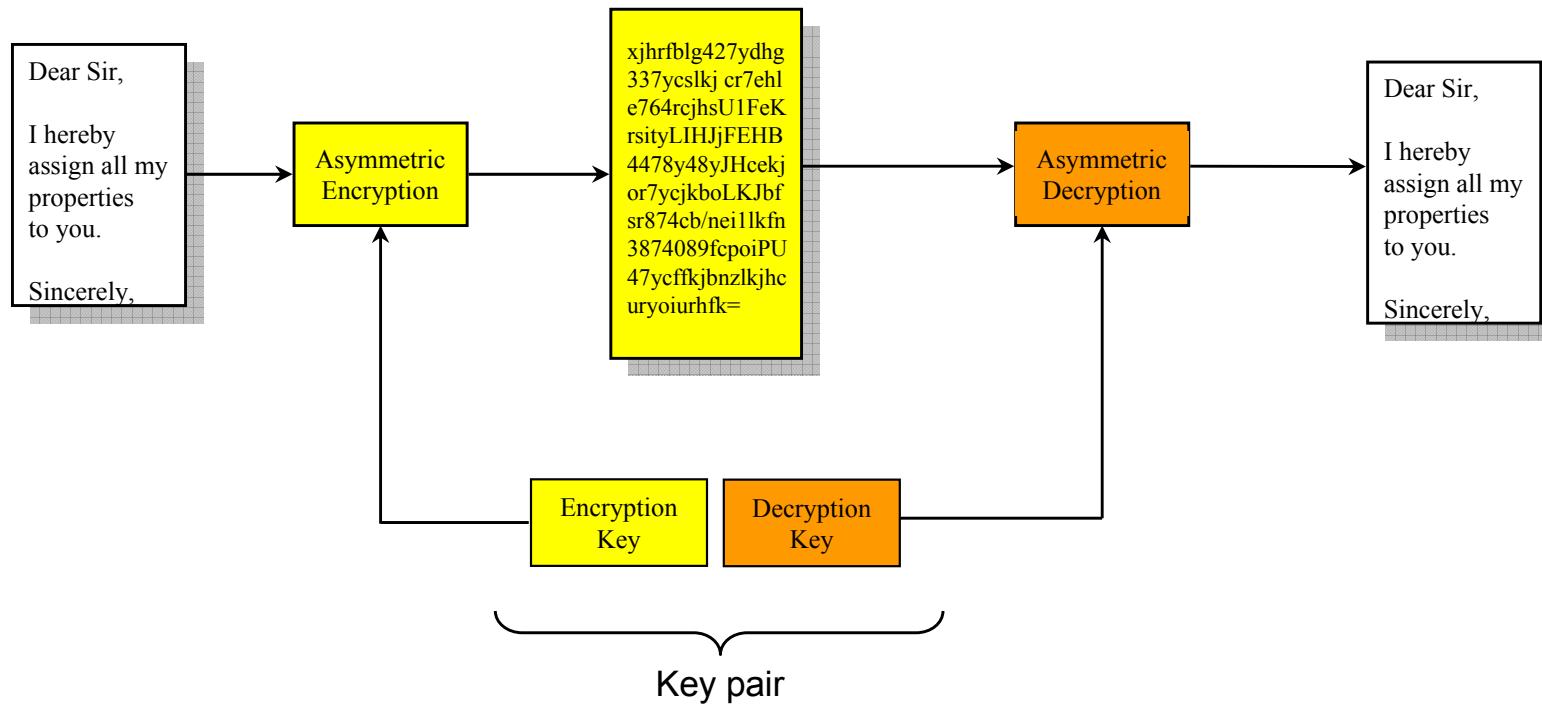
Concepts

- Message Digest / Hash is a “fingerprint” of the document(s)
- Any changes in the document will result in a different hash
- The hash does not prevent changes in the document, but detects the changes
- The hash helps preserve the integrity of the document and acts as a tamper-evident seal
 - Remember how the Tylenol tampering in the '80s forever changed how pharmaceutical products are packaged

Asymmetric Encryption

- Asymmetric, or Public Key Encryption
 - Each trading partner has a “key pair”, one of the keys of the pair can reverse the encryption operation of the other key of the pair. One key is made available publicly. The other key, kept private, cannot be derived from the public key.
 - One key per entity, scales linearly.
 - Encrypt/decrypt with asymmetric algorithms is a very slow process, usable only for short data sets

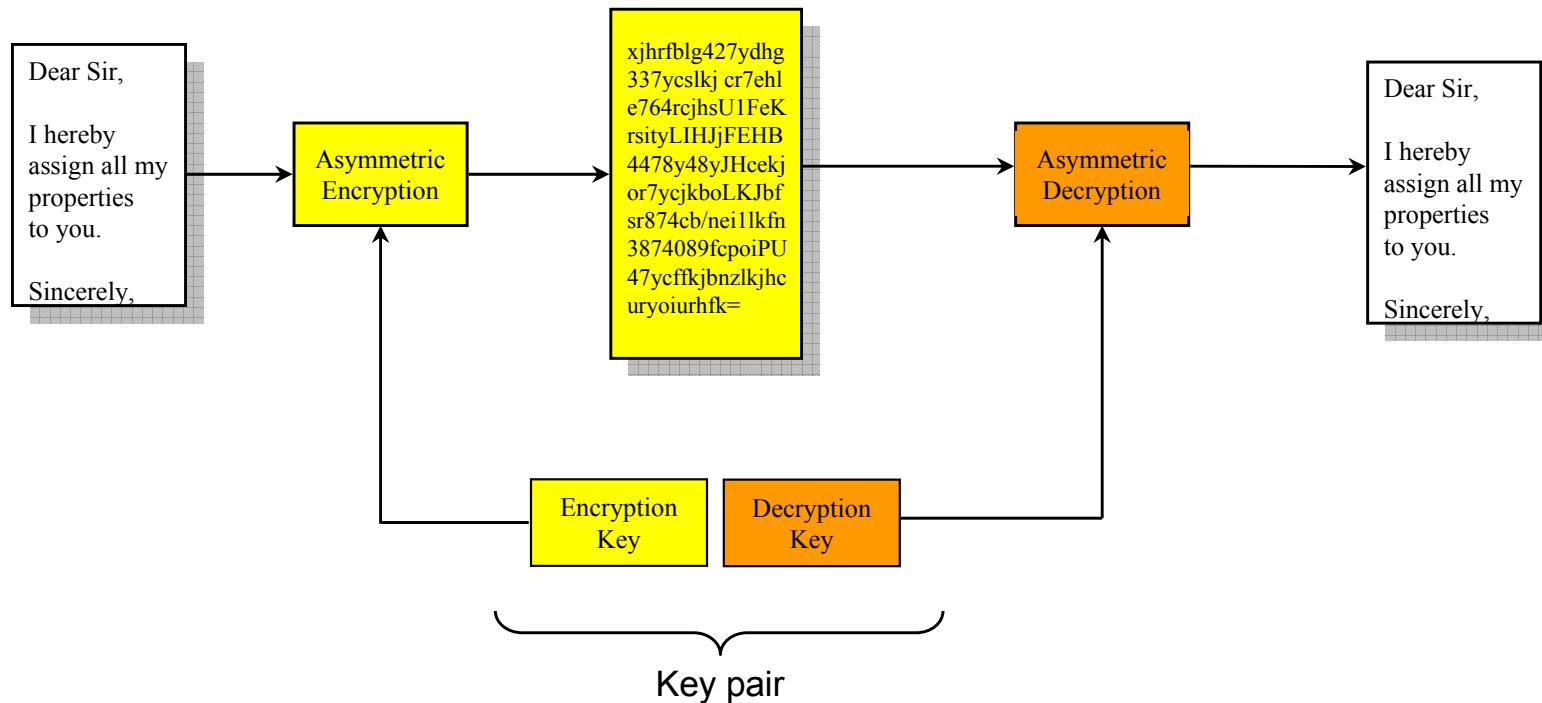
Asymmetric Encryption (not really...)



Asymmetric Encryption

- Matching pair of keys is unique
- Knowing one of the keys in the pair does not give any information about the other key
- One key in the pair can be published
 - I publish my decryption key to the world
 - Only I have the corresponding encryption key
 - Keep it as a closely guarded secret
 - You, or anybody else, can decrypt something from me using my published decryption key
 - Only I could have encrypted it with my secret key

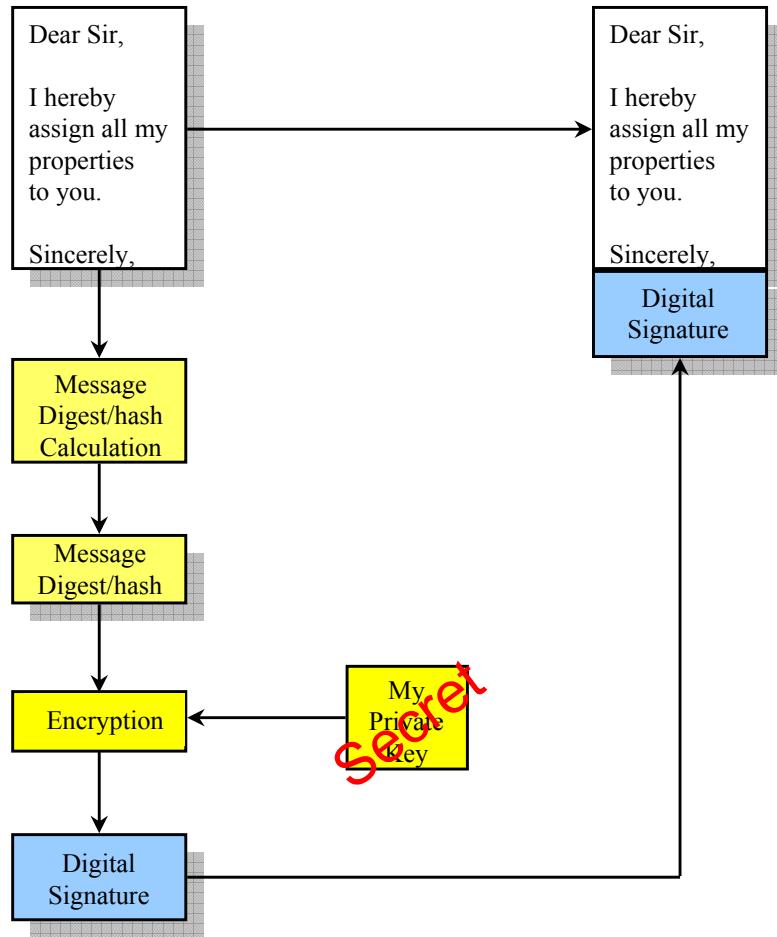
Asymmetric Encryption (not really...)



How is this useful?

- Putting both concepts together
 - Message Digest / Hash
 - Asymmetric encryption
 - Encrypt the hash
 - What do I get?

Digital Signature Process

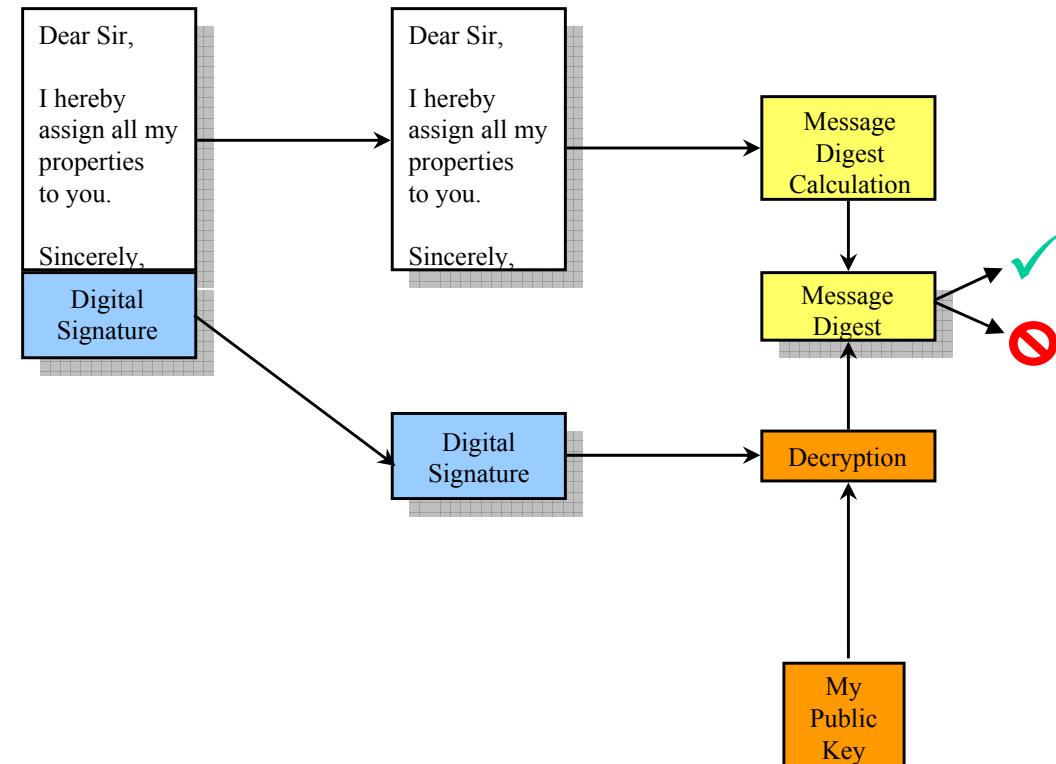


Only I could have
encrypted the hash in this
manner with my secret key.
Nobody else has a key like
mine.

Digital Signature Process

- Calculate the hash of the file or document to be signed.
 - Or part of a document if only that part is to be signed.
 - Example: HL7v3 “To be signed” tags
- Encrypt the hash with my private key to produce a “digital signature”
 - Combination of hash of the document and a secret that only I possess
- Attach the digital signature to the document

Signature Verification By Receiver



Digital Signature Verification Process

- Detach the “digital signature” from the document
- Decrypt the “digital signature” with the public key of the signer
 - I know who the presumed signer is
 - I have access to his/her public key
- Calculate the hash of the document
- Match the calculated hash with the one obtained from the digital signature
 - Match: Good signature
 - No a match: Either the document was tampered with or the signer’s secret key was not used

Sample PGP signed message

From: kepa.zubeldia@claredi.com
Date: Mon, 16 Nov 1998 19:03:30 -0600
Subject: Message signed with PGP
MIME-Version: 1.0
Content-Type: text/plain; charset=US-ASCII
Content-Transfer-Encoding: 7bit

-----BEGIN PGP SIGNED MESSAGE-----

Bill,

This is a message signed with PGP, so you can see how much overhead PGP signatures introduce. Compare this with a similar message signed with S/MIME. Does this make the point that we will have interoperability problems ?

Kepa

-----BEGIN PGP SIGNATURE-----

Version: PGP for Personal Privacy 5.0
Charset: noconv

iQCVAwUBM+oTwFcsAarXHFeRAQEsJgP/X3noON57U/6XVygOFjSY5lTpvAduPZ8M
aIFalUkCNuLLGxmtsbwRiDWLtCeWG3k+7zXDfx4YxuUcofGJn0QaTlk8b3nxADL0
O/EIvC/k8zJ6aGaPLB7rTIizamGOt5n6/08rPwwVkB03tmT8UNMAUCgoM02d6HX
rKvnc2aBPFI=
=mUaH

-----END PGP SIGNATURE-----

Sample S/MIME signature

```
From: kepa.zubeldia@claredi.com
Date: Mon, 16 Nov 1998 19:03:08 -0600
Subject: Message signed with S/MIME
MIME-Version: 1.0
Content-Type: multipart/mixed; boundary="simple boundary"
```

```
--simple boundary
Content-Type: text/plain; charset=US-ASCII
Content-Transfer-Encoding: 7bit
```

Bill,

This is a message signed with S/MIME, so you can see how much overhead S/MIME signatures introduce. Compare this with a similar message signed with PGP.
Does this make the point that we will have interoperability problems ?

Kepa

```
--simple boundary
Content-Type: application/octet-stream; name="smime.p7s"
Content-Transfer-Encoding: base64
Content-Disposition: attachment; filename="smime.p7s"
```

```
MIIQQwYJKoZIhvcNAQcCoIIQNDCCEDACAQExCzAJBgUrDgMCGgUAMAsGCSqGSIB3DQEHAaCCDnww
ggmGMIIJL6ADAgECAhBQQRR9a+DX0FHxFQOVHQhpPMA0GCSqGSIB3DQEBAUAMGiXETAPBqNVBAcT
CEludGVybmv0MRcwFQYDVQQKEw5WZXJpU2lnbiwgSW5jLjE0MDIGA1UECxMrVmVyaVNpZ24gQ2xh
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MzU5NTlaMIIBFzERMA8GA1UEbxMISW50ZXJuZXQxFzAVBqNVBAoTDlZlcmlTaWduLCBJbmMuMTQw
MgYDVQQLEytWZXJpU2lnbiBDbGFzcyAxIENBIC0gSW5kaXZpZHvhbCBTdWJzY3JpYmVyMUYwRAYD
```

VQQLEx13d3cudmVyaXNpZ24uY29tL3J1cG9zaXRvcnkVQ1BTIE1uY29yCC4gYnkgUmVmLiMSUFC
LkxURChjKTk2MSYwJAYDVQQLEX1EaWdpdGFsIE1EIE1ENsYXNzIDEgLSBOZXrZy2FwZTEWMBQGA1UE
AxMNS2VwYSBadWJ1bGRpYTERmCkGCSqGSIB3DQEJARYca2VwYS56dWJ1bGRpYUB1bnZveS1uZW1j
LmNvbTBcMA0GCSqGSIB3DQEBAQUAA0sAMEgCQQDTpPphGGti96yriSSzaje8HQXv9yCxWDFzFKQs
KAd8SRyC1Y7GjNJxbwQGddqNIUTy6NKBVAoDhhSvB4kaT+mPAgMBAAGjggcIMIIBDAJBgNVHRME
AjAAMIICHwYDVR0DBIICFjCCAhIwggIOMIICGgYLYIZIAyb4RQEHAQEWggH5FoIBp1RoaXMgY2Vy
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Y29tOyBvcibieSBtYWlsIGF0IFZ1cm1TaWduLApJbmMulCAyNTkzIENvYXN0IEF2ZS4sIE1vdW50
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bGljIFByaW1hcnkgQ2VydGlmaWNhdG1vbiBBdXR0b3JpdHkwgZ8wDQYJKoZIhvcNAQEBBQADgY0A
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xIwDet+c

--simple boundary--

The MIME signature block is much longer than the PGP signature because the MIME signature block includes both the signature itself and the corresponding digital certificate of the signer.

HIPAA Requirement

- Standard specifying procedures for electronic transmission of the signature



Where is the industry?

- Variety of hashing algorithms
 - MD5 and SHA-1 are the most common
 - Snefru, N-Hash, MD2, MD4, SHA, RIPE-MD, HAVAL, GOST, MDC-2, MDC-4, others
- Variety of signature encryption algorithms
 - RSA and DSA are the most common
 - ElGamal, GOST, Schnorr, Ong-Schnorr-Shamir, ESIGN, Elliptic Curve, others
- Variety of encryption key sizes
 - 1024 or 2048 bits recommended for RSA or DSA
- Variety of encodings of the resulting “signature”
 - ASN.1 and PGP are the most common, with base64 coding
 - XML and proprietary encodings are also used
- Variety of data content included in the “signature”
 - Hash, signature timestamp, signature usage indicators, digital certificate, etc.

Commercial Availability

- Most electronic mail software packages can digitally “sign” the entire message
 - Some can also digitally “sign” attachments
 - Very few can “sign” only a part of a message
- Other non-email software also implements signatures
 - Adobe Acrobat, PGP, PKZIP, signatures on Microsoft COM objects, signed Java beans, etc.
- X12 implements digital signature of an entire Transaction Set as part of the X12 syntax itself
- HL7 v3 has XML signature and authentication tags indicating the parts “to be signed” in the CDA
- **Interoperability of the signature** is the biggest problem

Authentication

- Signature Authentication
 - Was this signature written by this person?
 - Judge asks: “Is this your signature?”
- Document Authentication
 - Is this the document you signed?
- Entity Authentication
 - Is this the person whom he/she claims to be?
- Deeply inter-related concepts

HIPAA Requirement

- Standard specifying procedures for electronic authentication of the signature
 - Authentication of the signature vs. authentication of the context:
 - Signer (individual, program, hardware, entity)
 - Document being signed
 - Intent
 - Timestamp
- Thought... What is the use of a signature if we do not authenticate the context?

Traditional Signature Authentication

- Witnessed and personal knowledge
 - Witnessed signature
 - Signed in front of a State, Federal or other officer
 - Notary Public certification
- Signature Card
 - Used by banks
- Established record of the signer
 - Medical records, prescriptions
- Established by business context
 - Used in commerce, contracts, checks, etc.
- Expert witness
 - Forensic signature experts for court cases

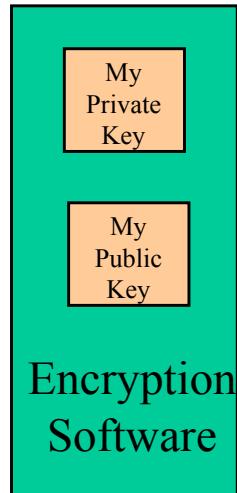
Authentication Technology

- Signature Dynamics
 - Compare signature dynamics with a registered template for that signer
 - Approximate comparison by forensics expert
 - Template can be “certified” by a Certification Authority
- Digital Signature
 - Compare the “public key” with a key registered for that signer
 - Exact comparison by a program
 - Key can be “certified” by Certification Authority

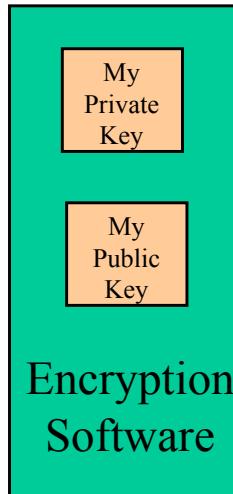
Authentication by a Third Party

- In addition to the **template** or the **public key**, other components may be authenticated by the Certification Authority
 - Legal Name
 - Validity dates of the certificate
 - Certified “attributes” of the signer
 - Identification number (DEA)
 - Access privileges, clearances
 - Signature privileges
 - Biometric (picture, fingerprint, retinal scan, etc.)
 - Other “certificate extensions”

Digital Certificate



Digital Certificate

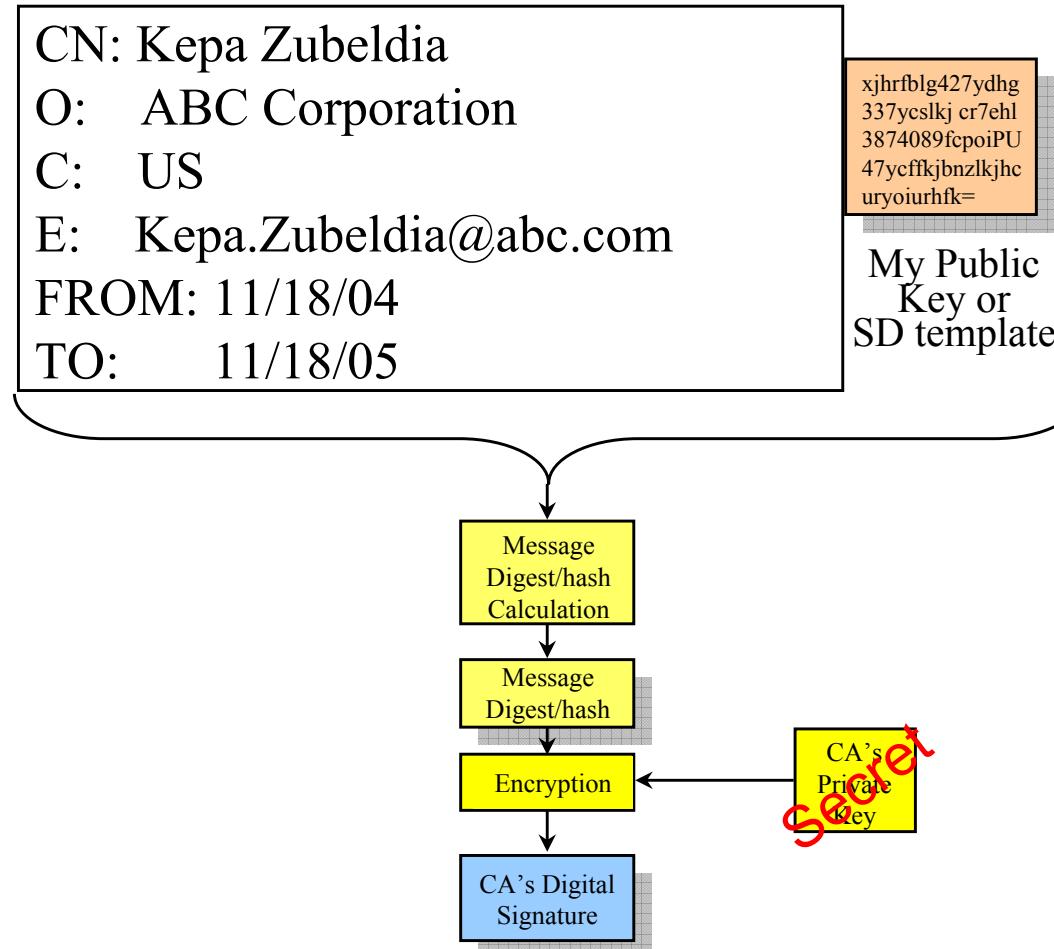


CN: Kepa Zubeldia
O: ABC Corporation
C: US
E: Kepa.Zubeldia@abc.com
FROM: 11/18/04
TO: 11/18/05

xjhrfbhg427ydhg
337yeslkj cr7ehl
3874089fcpoiPU
47ycffkjbnzlkjhc
uryoiurhfk=

My Public
Key or
SD template

Digital Certificate



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Certification
Authority's
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47ycfflkjbnzlkjhc
uryoiurhfk=

My Public
Key or
SD template

Certification
Authority's
Digital
Signature


My Digital Certificate
(encoded in ASN.1, PGP or XML)

Digital Certificate

- Binds the identity of an individual with a Public Key or a Signature Dynamics template.
 - Authenticates the owner of a Public Key or Signature Dynamics template.
- Electronic conveyor for transmission of a Public Key or Signature Dynamics template
 - Public Key or SD template incorporated inside certificate
 - Not a transmission of the signature
- Issued by a Trusted Third Party
 - Certification Authority (CA)
- May be revoked by the CA before the expiration date if the Private Key is compromised

Certificates and Digital Signatures

- Certificates attest to the identity of the owner of an encryption key or signature dynamics template
 - Issued by a Certification Authority.
- Certification Authority validates the identity of the signer
- Digital signatures “protect” a file or Email against tampering and identify the signer
 - Issued by the owner of the signed document
- The digital signature validates the document itself

Digital Certificate vs. Digital Signature

- Digital Certificate is a particular expression of one kind of digital signature
 - Signed material is included inside the certificate
 - Signed material may be a public key
 - Signed by a third party Certification Authority
 - But “self signed” certificates are also common
 - Well defined and universally used Digital Certificate standard format
 - X.509 Version 3
 - Variety of “certificate extensions” in use
 - These are not standard from implementation to implementation

Digital Signature

- Signed material totally variable
 - Entire text file, PDF, digital image, XML marked-up text, EDI transaction, or a part of it
- Signature and signed material relationship
 - Packaged as one file
 - Signature sent inside document (XML, HL7)
 - Document inside crypto-container (PGP, S/MIME)
 - Packaged as separate files
 - Interoperability with not-signature-enabled applications
- Signature and digital certificate relationship
 - Certificate included with each signature
 - Certificate available from a repository (CA, other)
- Signature encoding
 - No dominant standard
 - ASN.1, XML, PGP, S/MIME, etc.

Industry Progress

- PKI establishment
 - Certification Authorities
 - Root CA, Bridge CA, Federal PKI Bridge
 - Certification Policies
 - Authentication rules, CA operations, etc.
 - Certificate Revocation
 - Large CRLs, on-line certificate validation
 - Certificate Extensions
 - ASTM standard X.509v3 healthcare extensions
 - PKI software deployment
 - Supported by Microsoft and others

Problems

- Signature interoperability
 - **No** standards for digital or electronic signatures in universal use
- Certificate interoperability
 - Good. Some certificate extensions are “ignored”
- Certification Authority interoperability
 - Federal PKI Bridge
- Technology is very complex
 - Deployment has been much slower than originally predicted
 - AMA Digital Certificate, FDA certificates

PKI Benefits

- Increase trust in electronic transactions
- Certificates can be used for distribution of signature and encryption keys
- Enable secure transactions over the Internet
- Certificate and key management are simplified if there is a standard that everybody uses
- Cost of certificates should go down as volume increases with widespread adoption

PKI Issues

- The best interoperable results are produced by single vendor solutions
- Certificate maintenance is expensive
- I know my trading partners better than the CA
 - I want to be my own CA and reduce my costs
 - Forget interoperability, it works for me
- I have a digital certificate, now what?
 - No standards for signatures, encryption, single sign-on or other uses of the certificate

- Sec. 1173 (e) Electronic Signature.
 - (1) STANDARDS. The Secretary, in coordination with the Secretary of Commerce, shall adopt standards specifying procedures for the electronic transmission and authentication of signatures with respect to the transactions referred to in subsection (a)(1).
 - (2) EFFECT OF COMPLIANCE. Compliance with the standards adopted under paragraph (1) shall be deemed to satisfy Federal and State statutory requirements for written signatures with respect to the transactions referred to in subsection (a)(1).

Contact

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