

The Business Case for Electronic or Digital Signatures

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Who am I?

- Medical Information Scientist,
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 - Next Generation Internet (NGI) Contract,
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- co-chair Secure Transactions SIG
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Health Level Seven, Inc.
 - Secure HL7 Transactions using Internet Mail
 - The Unified Service Action Model (USAM) /
Reference Information Model (RIM)

Points to Make

- Digital Signatures are – in theory – more Secure, but hard to Manage.
 - PKI problem, Trust Structures
 - Practical Implementation on the Windows platform
- “Electronic signatures” are not secure at all, what counts is the trusted information systems on which they are implemented.
- HL7 Secure Transactions using Internet Mail
 - Mediated, layered accountability,
 - What do Signatures mean with medical information?
- HL7 version 3 support for Electronic and Digital Signatures
 - Direct Individual Accountability
 - Supporting both Electronic and Digital Signatures in the same Framework.

Digital Signatures: Gold Standard?

- Digital Signatures are Strong – in theory –
 - Cryptographically assured accountability
 - Problem Focused on Key Management
 - Is my private key compromised?
 - How can you prove that the public key is really mine?
 - I had a Verisign certificate as “John Doe”
 - We must understand the system to use it right.
 - Trust does not scale well.
 - Authority cannot be outsourced.
- ➔ Reuse conventional, local trust structures.

Regenstrief PKI (RPKI) Project

- Integrate a PKI into an existing user management system
 - reusing existing user management
 - technology (data bases, forms)
 - organizations, personnel (local MIS department)
 - policy (existing forms, countersignatures, application in person.)
- An RPKI certificate is only good for us
 - We do not accept e-shopping certificates.
 - We certify our people's access rights to our EMR.
 - We disclaim any warranty for other purposes.

Localized Trust Structures

- Healthcare is not just another e-business.
- Healthcare consists of personal, physical, rather long term relationships
 - Doctor sees Patient in person.
 - State authorities license healthcare professionals.
 - Employers get to see their employees.
 - Payers have contracts with providers.
- Multiple specialized PKIs
 - State Board of Health, DEA, AMA, can certify licensed Physicians with authority.
 - Institution can certify their employees with authority.
 - Doctors can certify their patients with authority.

Unsafe Implementations

- Microsoft Internet Explorer (4.0, 5.0, 5.5)
 - Widely available, supports SSL, and PKCS.
 - MSIE puts private keys at great risk
 - Allows exporting unencrypted private keys
 - “High Security” mode is a user’s nightmare: enter your password at every mouse click!
 - There are good implementations
 - Netscape or PGP
 - but the market forces us to work with unsafe implementations.
- ➔ In Practice, Digital Signatures may not be so secure.

Electronic Signatures are Bad?

“Enter your social Security Number to sign.”

“Type your initials here to sign.”

“By checking this box, I agree that ...”

“Sign in this field ...”

“You can fax your signed order.”

- There is reasonable doubt left.
 - Anyone can forge most *E-SIGNatures* easily.
 - Electronic signatures on the Web are weak.
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- How does this affect healthcare informatics?

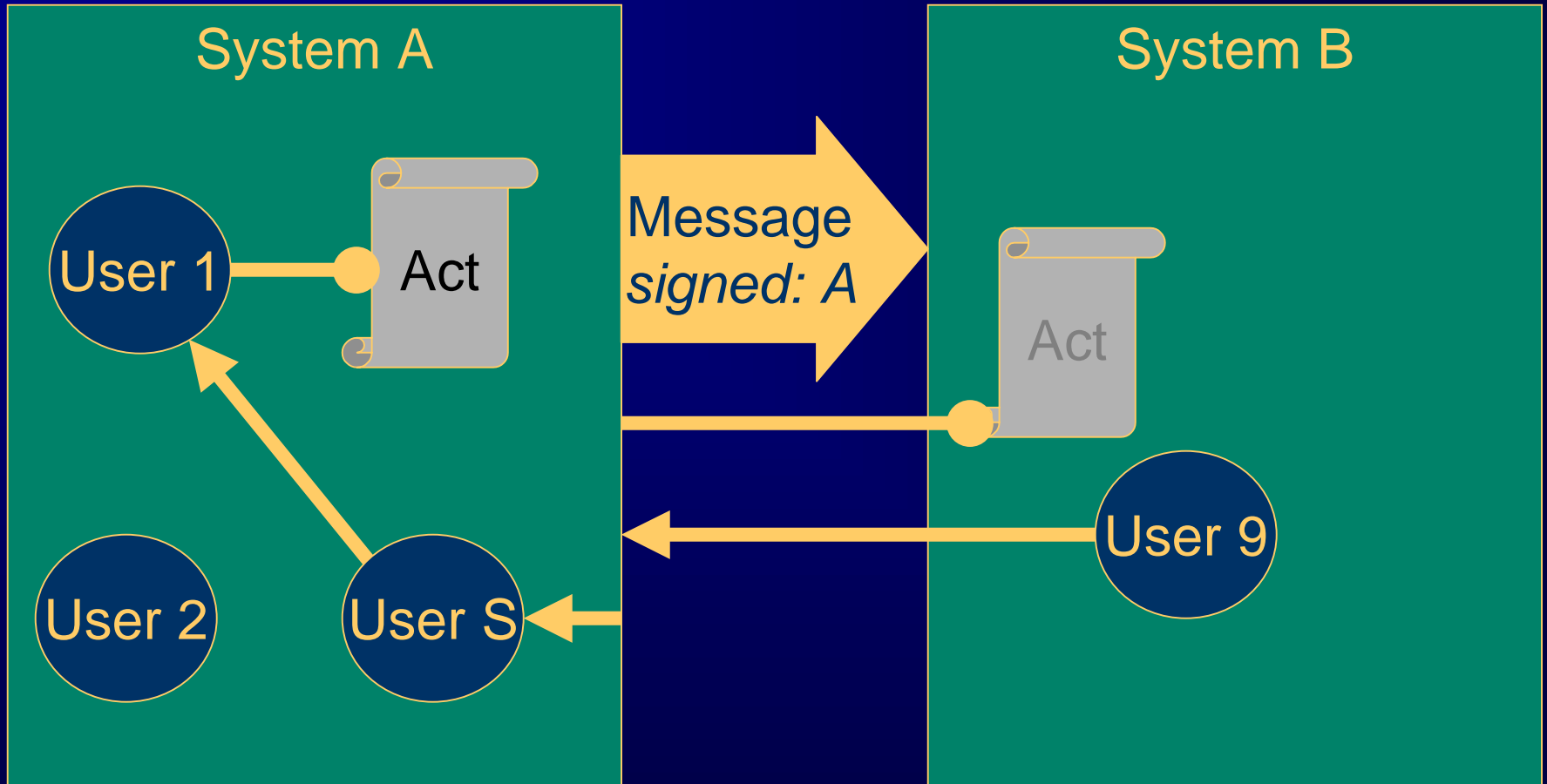
Authenticated Environment

- Relying on authenticated environment is safer than relying on pseudo e-signatures.
- Username/password authentication is state of the art and can be reasonably secure.
 - If done right ... as with any technical measure.
- Authenticated users are accountable for any of their actions taken at the system.
- The local system, its policies and procedures can establish trust beyond reasonable doubt.

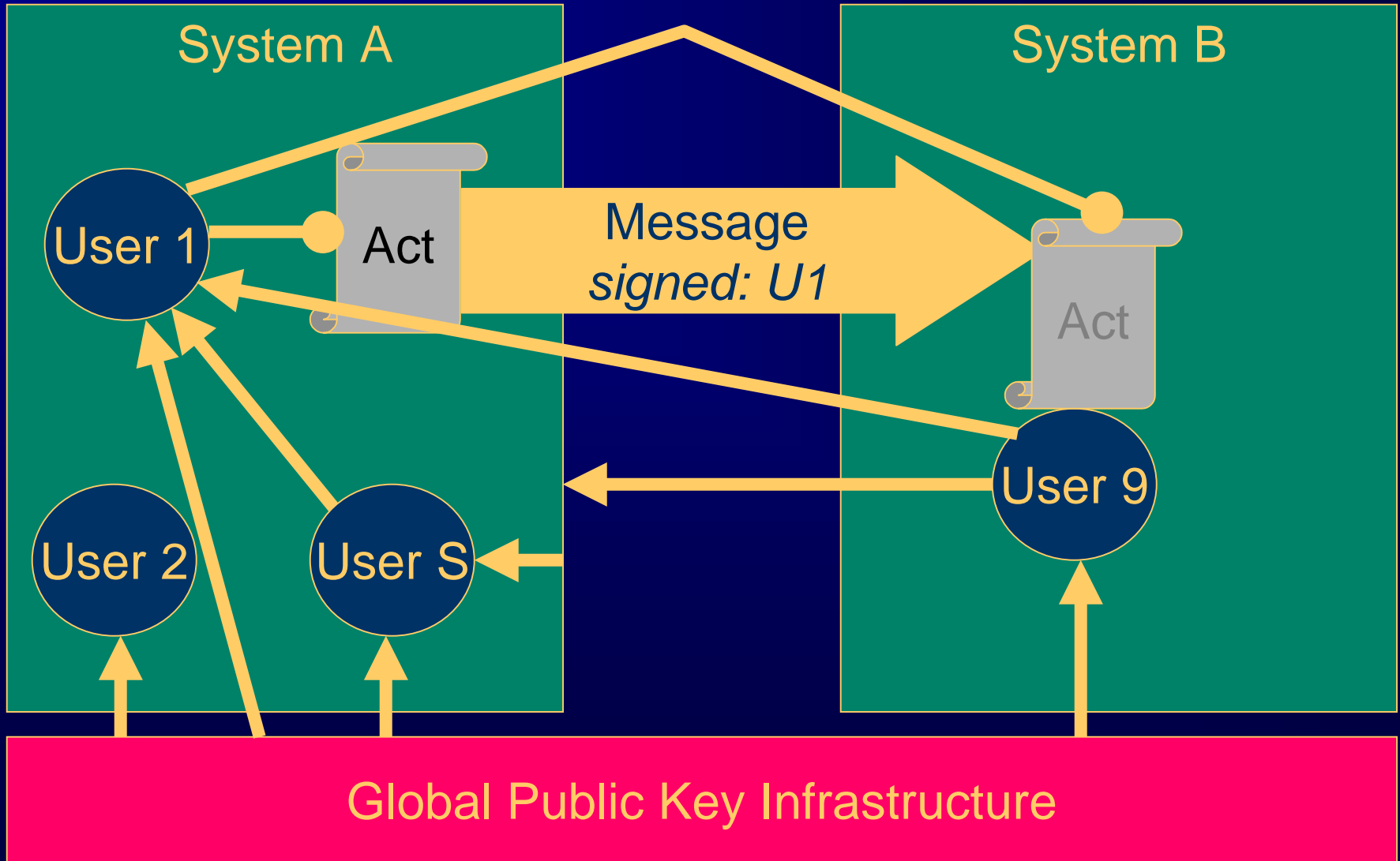
HL7 v2.x Secure Transactions

- Using Internet EDIINT Standards
 - Applies digital signatures over HL7 transactions.
- Who signs EDI transactions?
 - Individual users do not know about EDI transactions being sent in the background.
 - So, systems sign EDI transactions.
 - Systems are agents of organizations who run those systems.
 - Individual accountability is tracked within systems (user transaction audit log file.)
 - Organizational accountability tracked between systems (archive of signed messages.)

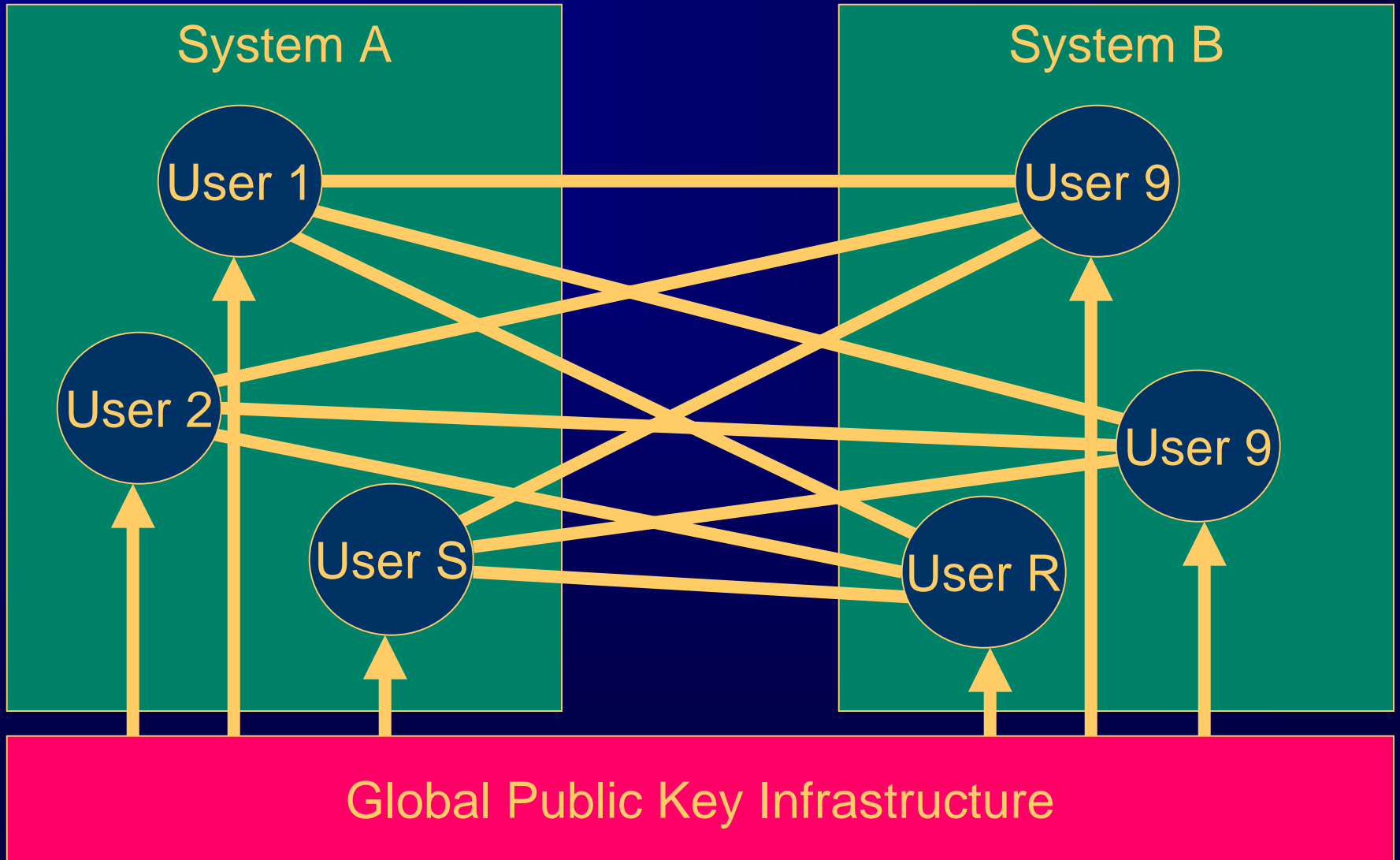
Local, Layered Accountability



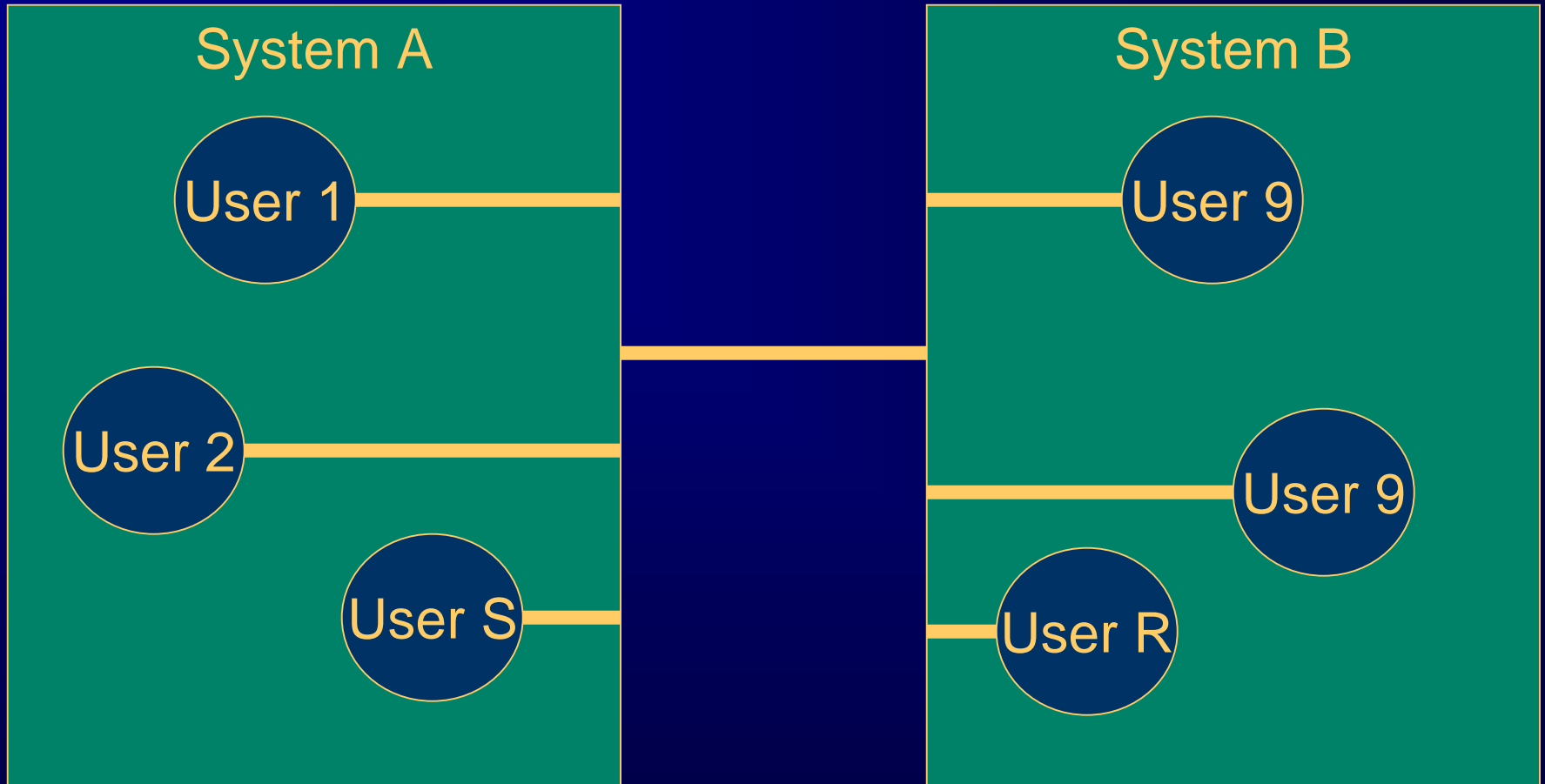
Non-Local Accountability



Individual Global Accountability



Mediated Local Accountability



HL7 v3 Digital Signature

- What do Signatures mean with medical information?
 - “Patient has fever, signed: XXX”
 - Did XXX make that observation?
 - Did XXX acknowledge the observation?
 - Did XXX record the observation?
- HL7 v2 signed messages signing system proxies accountability for entire transaction.
- In HL7 v3 signed acts can represent individualized and specialized accountability.

HL7 version 3 Signed Acts

Role

type_cd = *physician*
id : HL7.4.UPID.1846153

Person

type_cd = *human*
name: Dr. John Smith

Role_relationship

type_cd = *DEA cert*
id = DEA.4.19191919
cert_txt = (ED)

Participation

type_cd = *author*
signature_cd = *DS*
signature_txt: (ED) ...

Medication

mood_cd = *order*
id = HL7.3.RG.16.123434
service_cd = *MST*
strength_qty = 5 mg
dose_qty = 1
critical_time = H/6

Role

type_cd = *Healthcare cert. authority*

Organization

type_cd = *organization*
name = Drug Enforcement Agency

R_rel'ship

type_cd = *ca-cert*
cert_txt = (ED) ...

- What health applications are enabled by e-signatures?
 - all under HIPAA, d-signature good for prescriptions, order writing.
 - future: general attestation and patient consent
- What requirements must the signatures meet?
 - should track accountability beyond reasonable doubt
 - most e-signatures leave great doubt
 - the d-signature system is complex, has weak points too, doubts exist
- Are healthcare requirements different from other industries?
 - localized, personalized, long term relationships
 - more than just “you pay – I deliver”
 - healthcare system has a rich structure of accreditation and licensing – use it!
- How are we satisfying those requirements today, tomorrow?
 - individual accountability tracked locally in authenticated environments
 - organizational accountability tracked by d-signatures
 - organizations are accountability proxies for their individual users

- How important are standards in e-signatures?
 - important, but quality counts, not quantity
 - standards should be lean, intuitive, implementable and integrateable
 - HL7 v3 is truly technology neutral supports d- and e-signatures
- Are there d-signature solutions in other industries that can be used for healthcare?
 - yes, all technical, cryptographic standards
 - HL7 v3 uses XML DSIG, RSA, DSA, X.509, today, tomorrow?
 - however, fat and bloated frameworks are cumbersome, obscure

- What role should the government play?
 - government should support standards through participation and implementation
 - get involved in HL7, take responsibility (e.g., CDC, HCFA)
 - propagate localized and specialized PKI structures, governmental agencies should become PKI root CAs themselves (e.g., HCFA)
 - do not preempt the industry, continue careful legislation
- How does the E-SIGN act impact your work?
 - allows us to continue with our local accountability management using our existing systems and policies.

Thank you!