The Business Case for Electronic or Digital Signatures

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Who am I?

- Medical Information Scientist, Regenstrief Institute for Health Care (Dr. Clem McDonald)
  - Next Generation Internet (NGI) Contract, Security and Public Key Infrastructure
- co-chair Secure Transactions SIG
  co-chair Orders and Observations
  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-SIGN*atures easily.
- Electronic signatures on the Web are weak.

- How does this affect healthcare informatics?

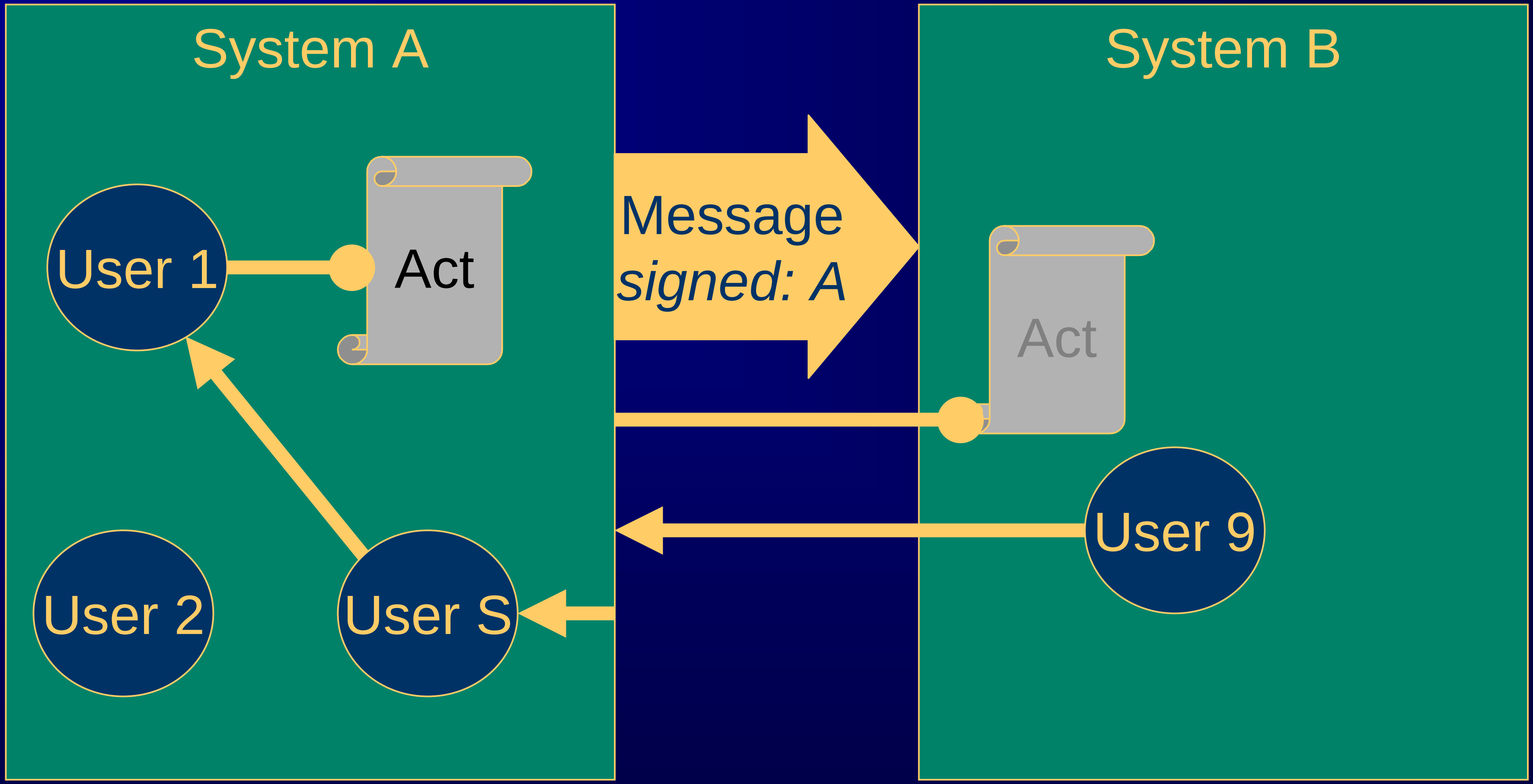
Authenticated Environment

- 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.

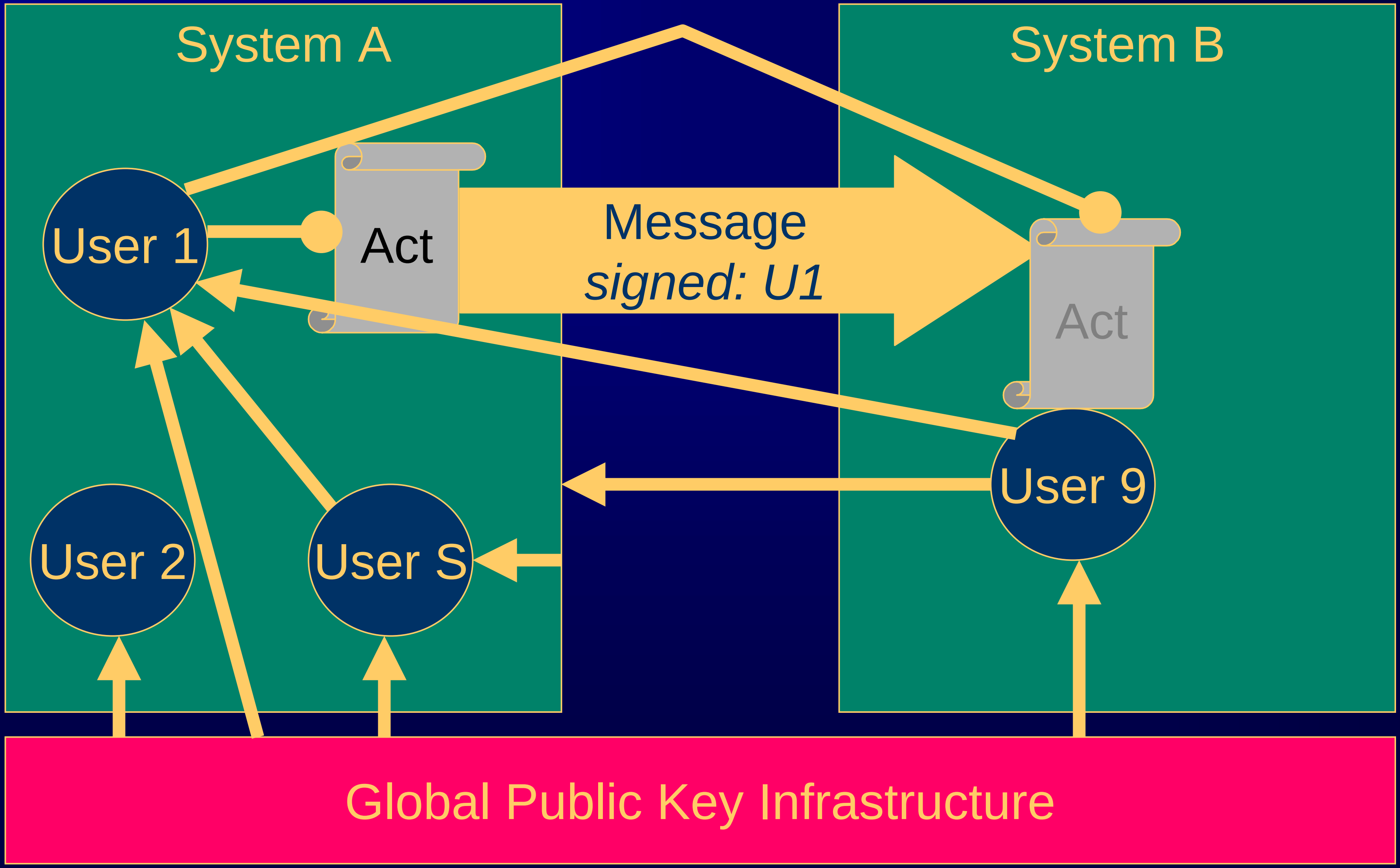
HL7 v2.x Secure Transactions

- 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.)

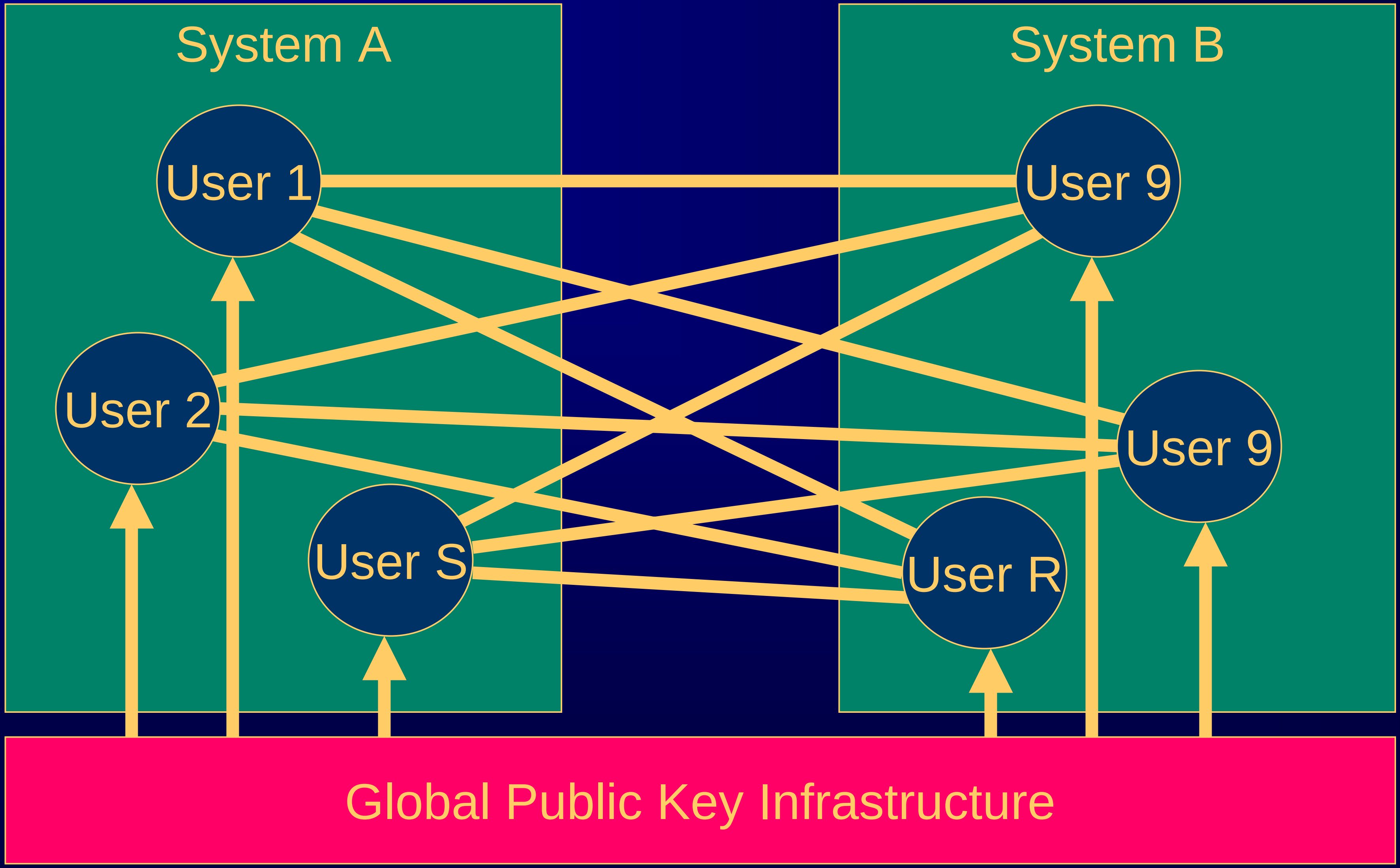
Local, Layered Accountability



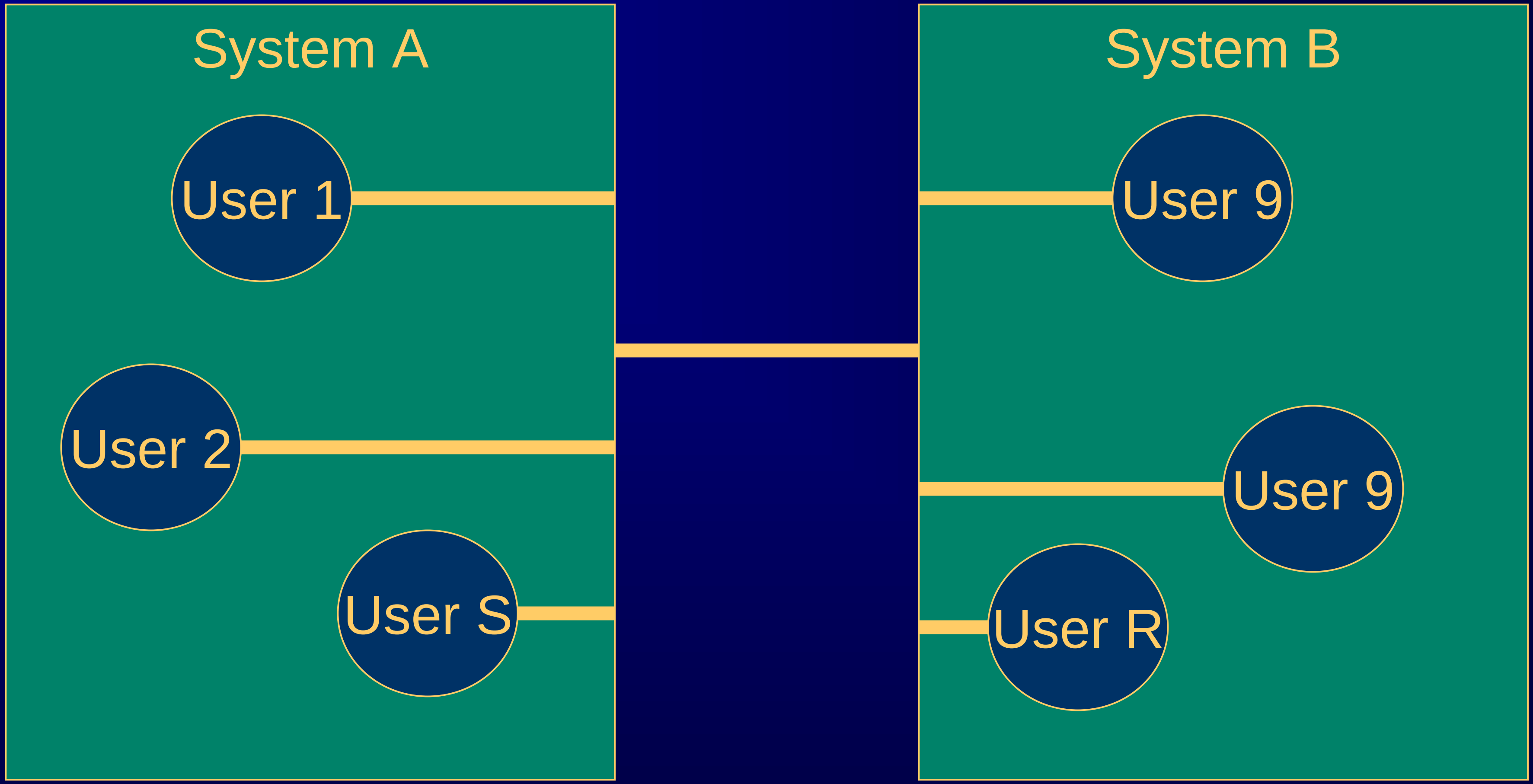
Non-Local Accountability



Individual Global Accountability



Mediated Local Accountability



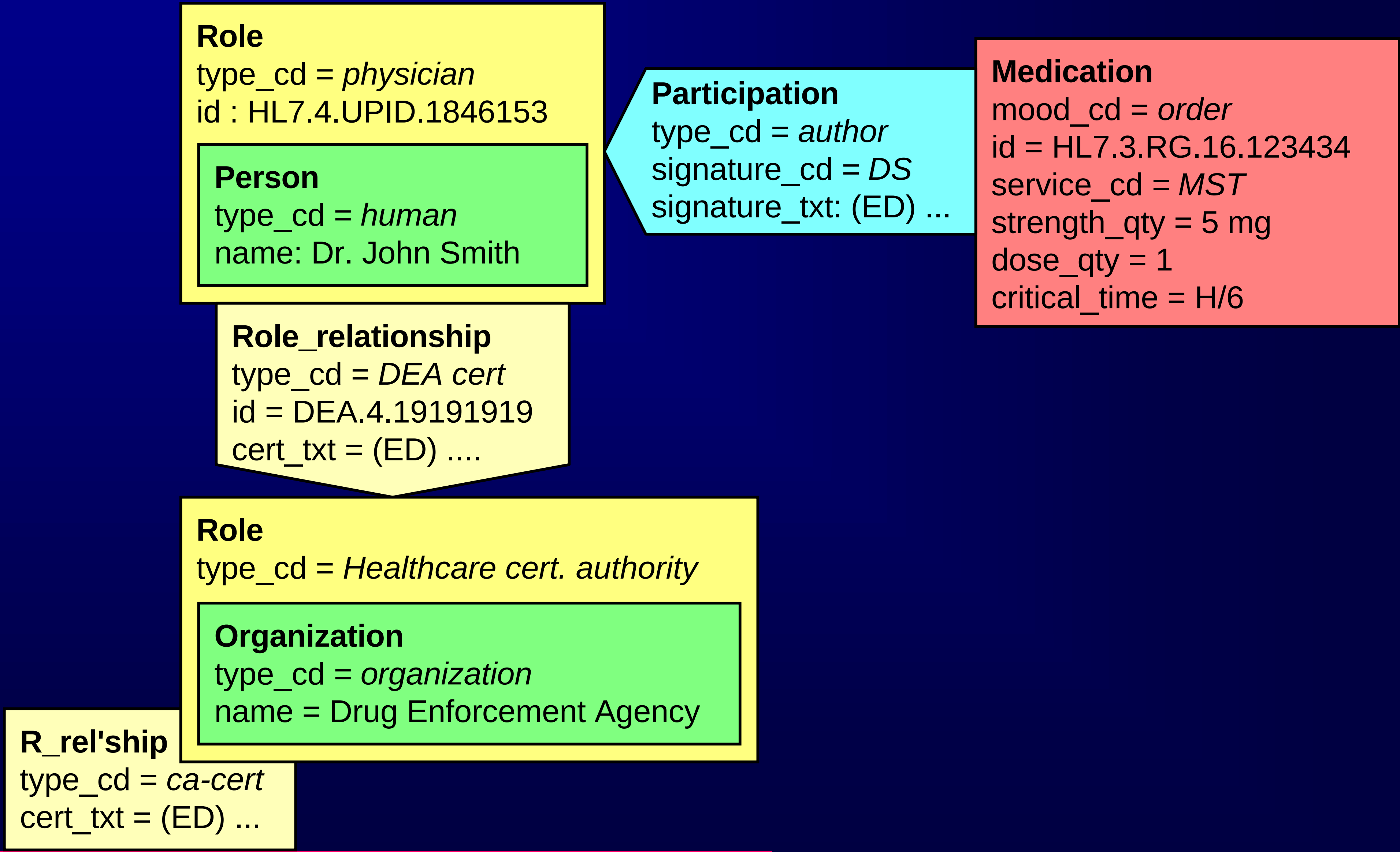
HL7 v3 Digital Signature

- 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

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

Role
type_cd = *Healthcare cert. authority*

Organization
type_cd = *organization*
name = Drug Enforcement Agency

R_rel'ship
type_cd = *ca-cert*
cert_txt = (ED) ...

Summary 1/3

- 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

Summary 2/3

- 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

Summary 3/3

- 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!