

# **An Empirical Investigation of Software Engineers' Ability to Classify Cross References**

Jeremy C. Maxwell, Allscripts

**Annie I. Antón, Georgia Institute of Technology**

Julie B. Earp, NC State University

# Outline

■ Background and Motivation

■ Research Design

■ Findings & Summary

# Problem Statement



Legal cross-references introduce challenges to regulatory compliance, including: ambiguities, exceptions and conflicts.



Software engineers need guidance as to how to address cross-reference to achieve compliance with legal requirements.

# Regulatory Impacts on Requirements Engineers

As laws change, software must be adapted to remain in compliance

Legacy systems may have to be rearchitected

New systems and upgrades may have to be deployed

Requirements engineers need guidance and tools to understand changes and impact to their software

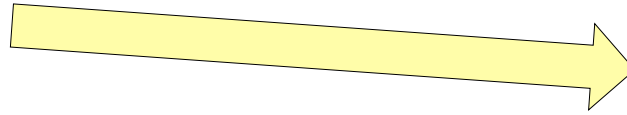
# Software Engineering

The application of a systematic approach to building, maintaining, and verifying software that must comply with laws and regulations.

# How U.S. Regulations are Developed



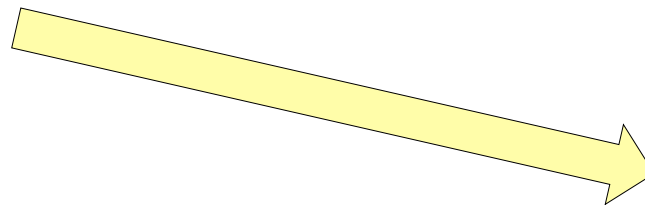
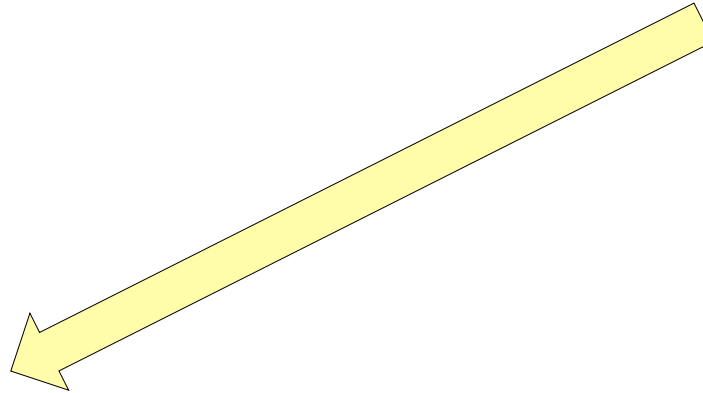
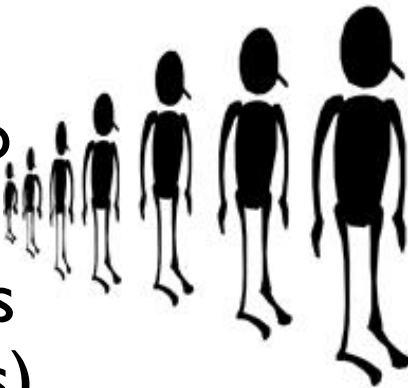
1. Congress passes a statute



2. Regulatory agency releases proposed regulations (rules) based on authority in statute

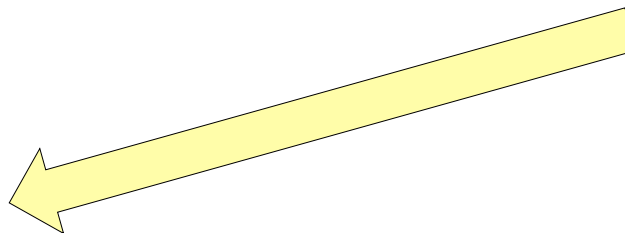


Public has opportunity to comment on proposed rules (usually 60 days)

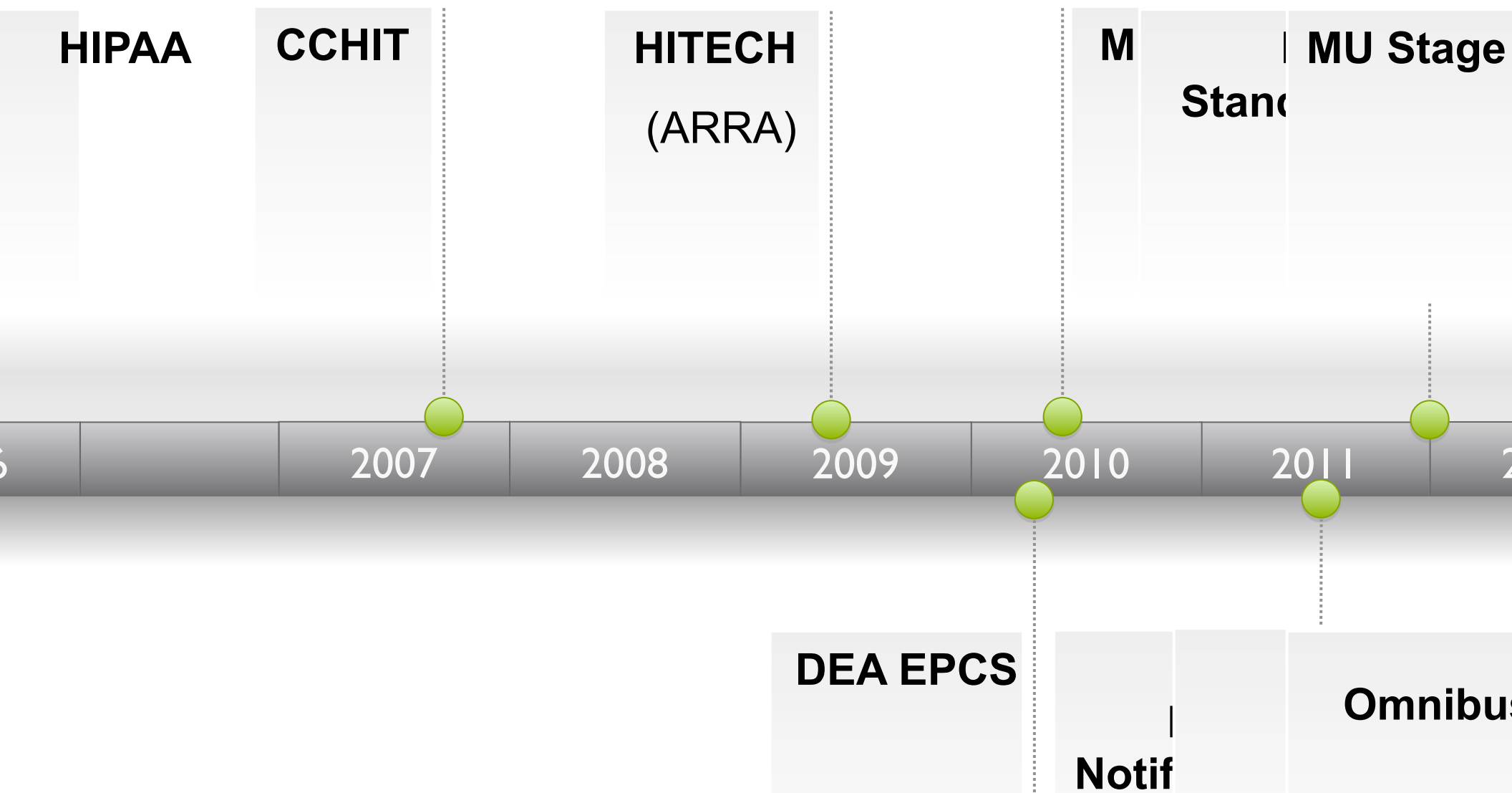


4. Regulatory agency responds to comments & releases final rules that are binding on regulated industry

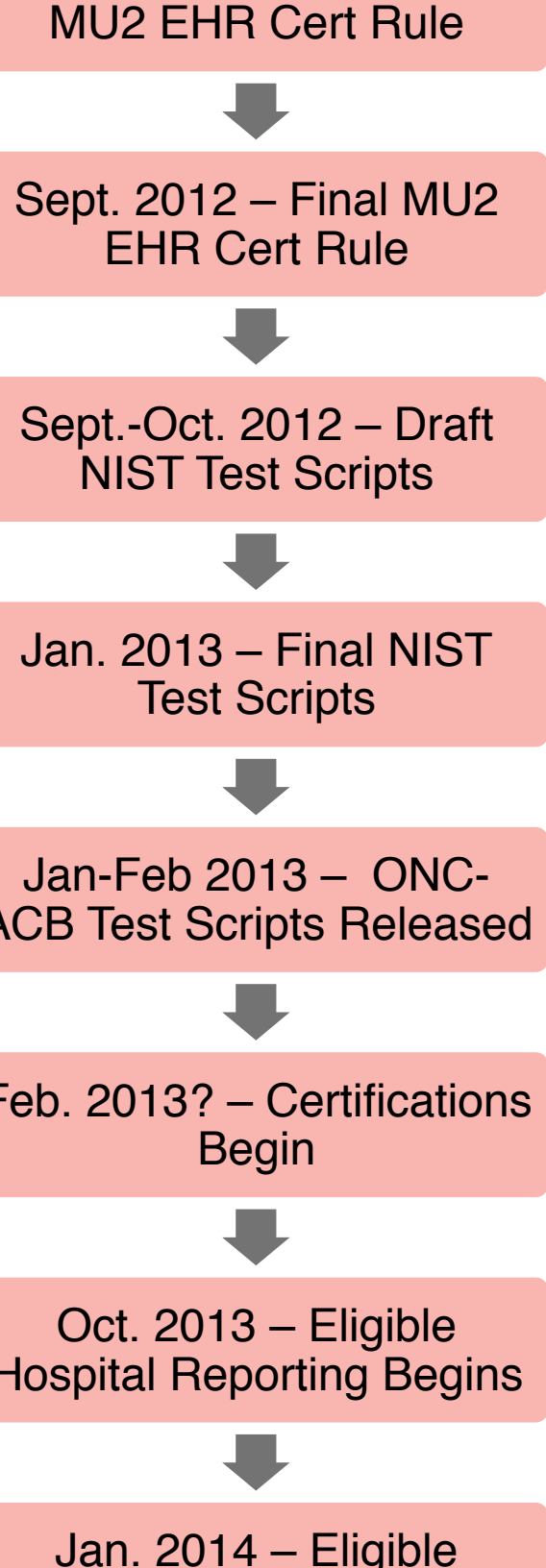
5. Industry must comply with rules by enforcement date



# Increasing U.S. Healthcare regulation



Various State Laws



# are Often Too Compressed

- ❑ EHR developers will have less than 8 months to develop features, certify their EHRs, and install at physician practices and hospitals
- ❑ When engineers miss compliance deadlines:
  - Financial penalties
  - Reputational damage
  - Lost sales



# Related Work

## Legal compliance in requirements engineering

Goals [AE04, GAP09, SPS09]

Frames [BA08, Bre09]

Traceability links [CCG10, GAP07, GAP09]

Internal cross-references [MOA09, MGL06]

Triage [MOA09, MSO11]

## Software and compliance requirements evolution

Software artifact evolution [AP03, Boh96, BL76, MS01, Par94]

Formal methods [Gho99, LX93, Nik09, ZO97]

Mining software repositories [KH07, YMN04, ZWD04]

## Knowledge representation

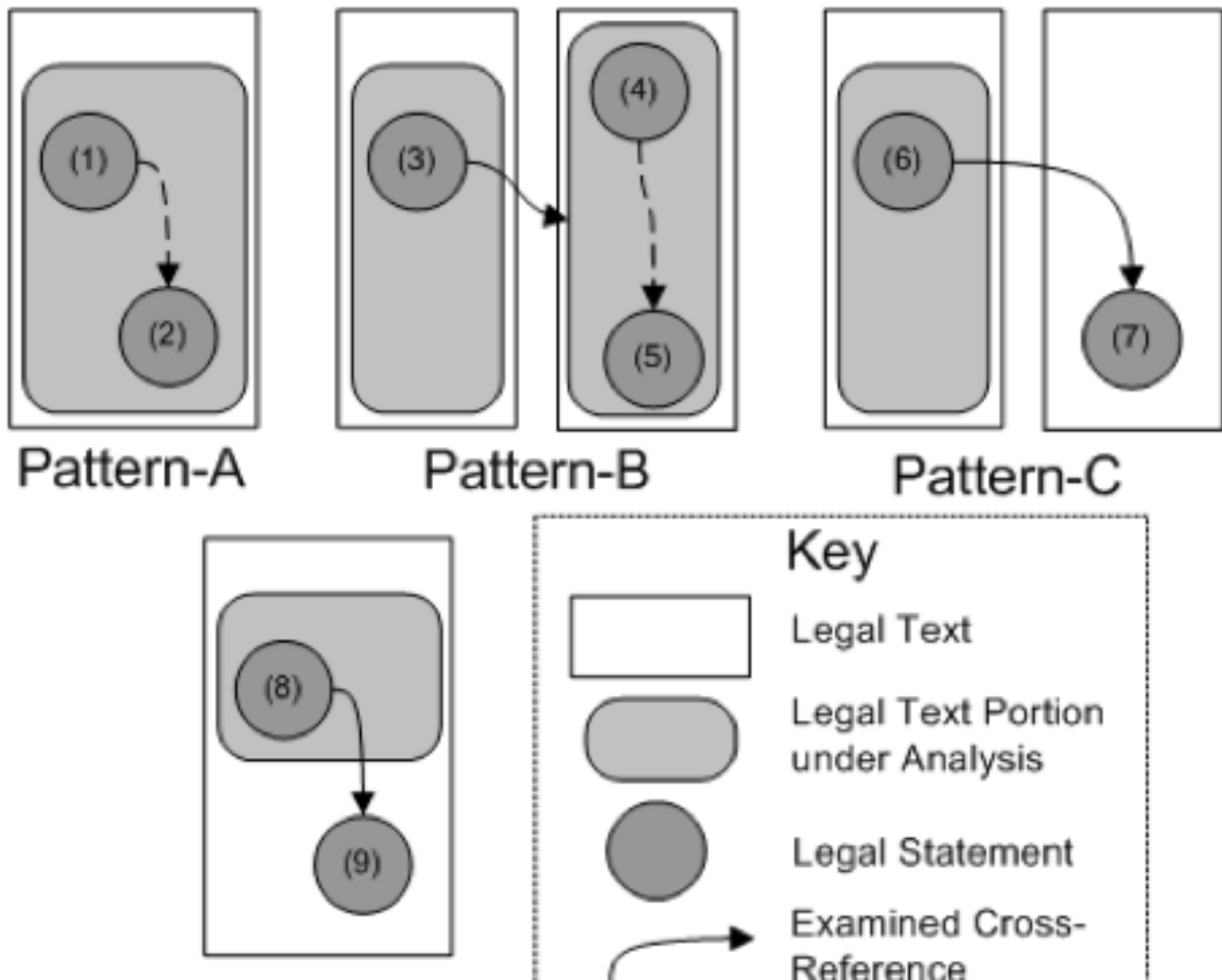
Logic programming [BRR87, SKB91, SSK86, She87]

# Engineers need precise specifications .....



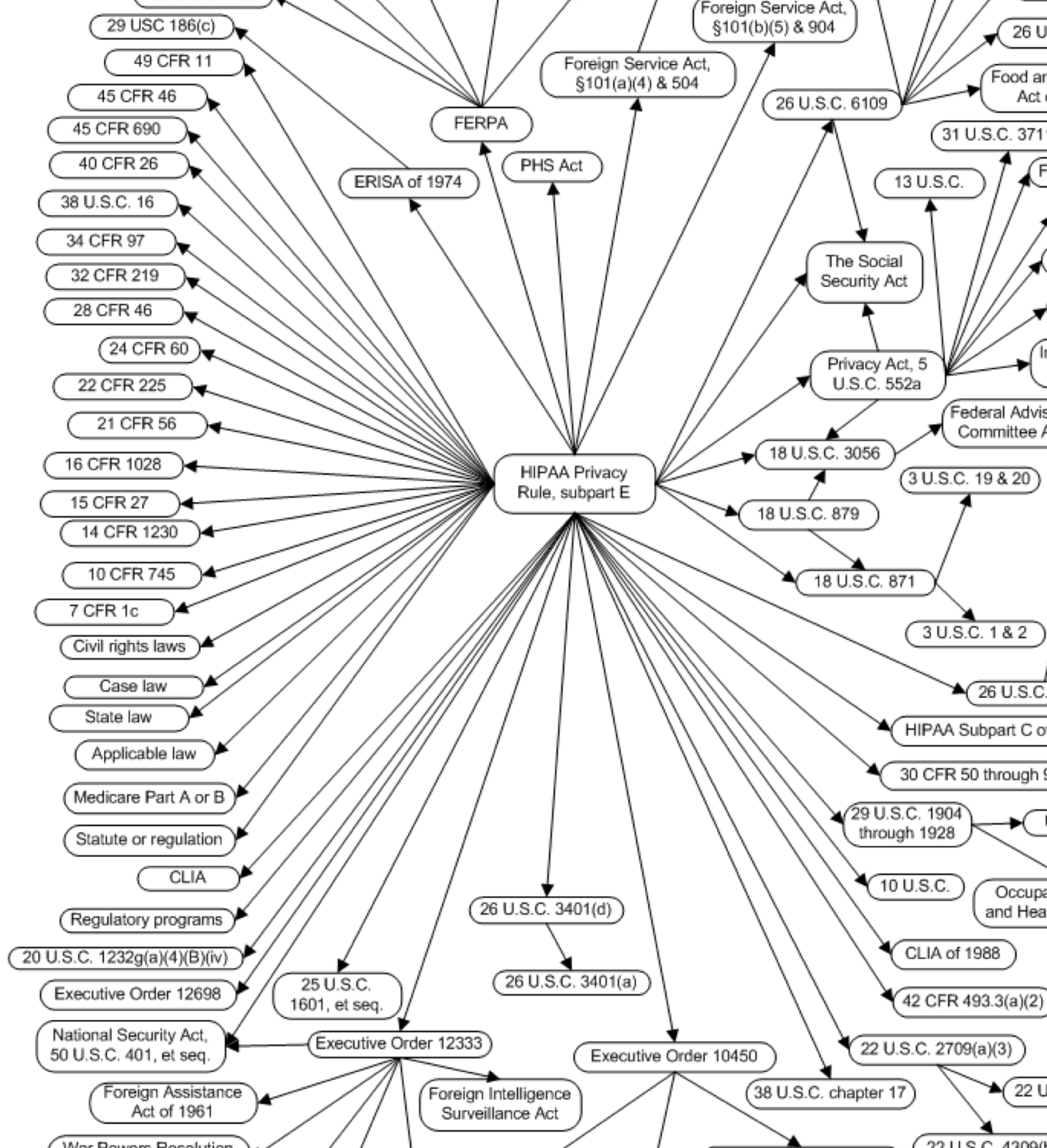
# Internal vs. External)

*EE Int'l Req'ts Eng. Conference, 2011]*



# External Cross- References the HIPAA Privacy Rule

EE Int'l Req'ts  
Conference,  
[1]



# taxonomy

*EE Int'l Req'ts Eng. Conference, 2011]*



## **Constraint**

Add additional constraints to existing compliance requirements

## **Exception**

Introduces an exception condition to an existing compliance requirement

## **Definition**

Introduces a definition or term

## **Unrelated**

The referencing or referenced legal texts do not yield software requirements

## **Incorrect**

Cite an incorrect portion of a legal text

## **General**

Do not cite a specific legal text but rather “applicable law”

## **Prioritization**

Position a new legal text with respect to an existing legal text

# Sample Cross Reference

## EHR MU1 Certification Rule

**170.210(a)(1)** (a) *Encryption and decryption of electronic health information—(1) General.* Any encryption algorithm identified **by the National Institute of Standards and Technology (NIST) as an approved security function in Annex A of the Federal Information Processing Standards (FIPS) Publication 140–2** (incorporated by reference in §170.299).

# Empirical Study Design

# Goal

Test the ability of software engineers, legal domain experts, and healthcare professionals to correctly classify cross-references using the cross-reference taxonomy we previously developed.



# aterials

Informed consent form & demographics survey

Tutorial

- Cross Reference Taxonomy w/ examples of each classification

10 legal statements from 4 healthcare and financial regulations

- Employed statements that were shorter in length
- Ensured each classification was exhibited by at least one cross-reference (w/ exception of incorrect CRs)

Participants asked to classify statements using our cross-references taxonomy

Online survey (Qualtrics<sup>3</sup>) — 30 days

# Null Hypothesis

$H_0$ : Individuals from the participant group have equivalent or greater precision than the expert classifications when classifying cross-references using the taxonomy.

# Target Population

Pilot — Realsearch & ThePrivacyPlace research groups (11 began survey; 7 completed)

- Experts — author, privacy prof., law prof., 2 PhD students

Participants recruited from 2 organizations

- An industry trade group of 41 EHR vendors
- A nonprofit consortium of 220 healthcare organization
- Participants — 56 began survey, 33 completed

# Typical Study Participants

		Pilot Study	Full Study
		(# in Role / Median Years Experience)	
Current Role	Req't Engineer	1 / 8	4 / 12.5
	Software Developer	3 / 3.75	17 / 15
	Quality Engineer	1 / 0	5 / 9.5
	Support / Services	0 / 0	1 / 7
	Network / IT	0 / 0	1 / 3
	Compliance / Legal	1 / 0	3 / 3
	Healthcare Practitioner	0 / 0	2 / 7.5
	Other	2 / 4.5	7 / 11
Previous Role	Req't Engineer	2 / 5	5 / 4
	Software Developer	4 / 4.25	20 / 16
	Quality Engineer	0 / 0	6 / 8.5
	Support / Services	0 / 0	8 / 3.5
	Network / IT	0 / 0	6 / 6.5
	Compliance / Legal	0 / 0	1 / 11
	Healthcare Practitioner	0 / 0	5 / 6
	Other	0 / 0	8 / 10

# Findings

# Empirical Study Observations

Median participant score: 5.5 (out of 10)

*Software engineers are not well equipped to understand the impact of cross-references on software requirements* ( $p=0.0002$ )

*Participants with more experience in regulatory domains perform better* ( $p = 0.0548$ )

Pilot participants performed better than software practitioners ( $p = 0.0374$ )

# Big Picture Takeaways ....

RCSE is a young, interdisciplinary field with lots of exciting research opportunities in security and privacy.

Software engineers are ill-equipped to understand legal cross-references & we know from other studies [MAS11] that SE students are ill-prepared to make legal implementation readiness decisions with any confidence.

Subject matter experts must be involved in legal compliance decisions.

# Next Steps ...

Plan to rerun the study in a graduate-level software engineering course

Two part survey:

1<sup>st</sup> part: 10 questions, then show participants how they did

2<sup>nd</sup> part: different set of 10 questions

**Our hypothesis:** with better training, participants will perform better than participants did in this first study



# Thank you!



# by Question

	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9
Pilot Study									
Constraint	71.4	12.5	12.5	0.0	28.6	11.1	0.0	0.0	75.0
Exception	0.0	0.0	87.5	0.0	0.0	11.1	50.0	0.0	0.0
Definition	28.6	0.0	0.0	87.5	0.0	0.0	50.0	87.5	0.0
Unrelated	0.0	12.5	0.0	12.5	42.9	0.0	0.0	12.5	12.5
Incorrect	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
General	0.0	0.0	0.0	0.0	28.6	66.7	0.0	0.0	0.0
Prioritization	0.0	75.0	0.0	0.0	0.0	11.1	0.0	0.0	12.5
Full Study									
Constraint	22.2	5.9	7.9	3.0	38.9	15.4	2.2	5.4	48.6
Exception	19.4	8.8	76.3	0.0	0.0	10.3	50.0	0.0	8.1
Definition	11.1	11.8	2.6	84.8	16.7	7.7	30.4	81.1	16.2
Unrelated	36.1	5.9	0.0	6.1	25.0	5.1	8.7	2.7	13.5
Incorrect	0.0	2.9	2.6	0.0	2.8	0.0	2.2	0.0	2.7
General	5.6	5.9	7.9	3.0	11.1	59.0	2.2	10.8	8.1
Prioritization	5.6	58.8	2.6	3.0	5.6	2.6	4.3	0.0	2.7