

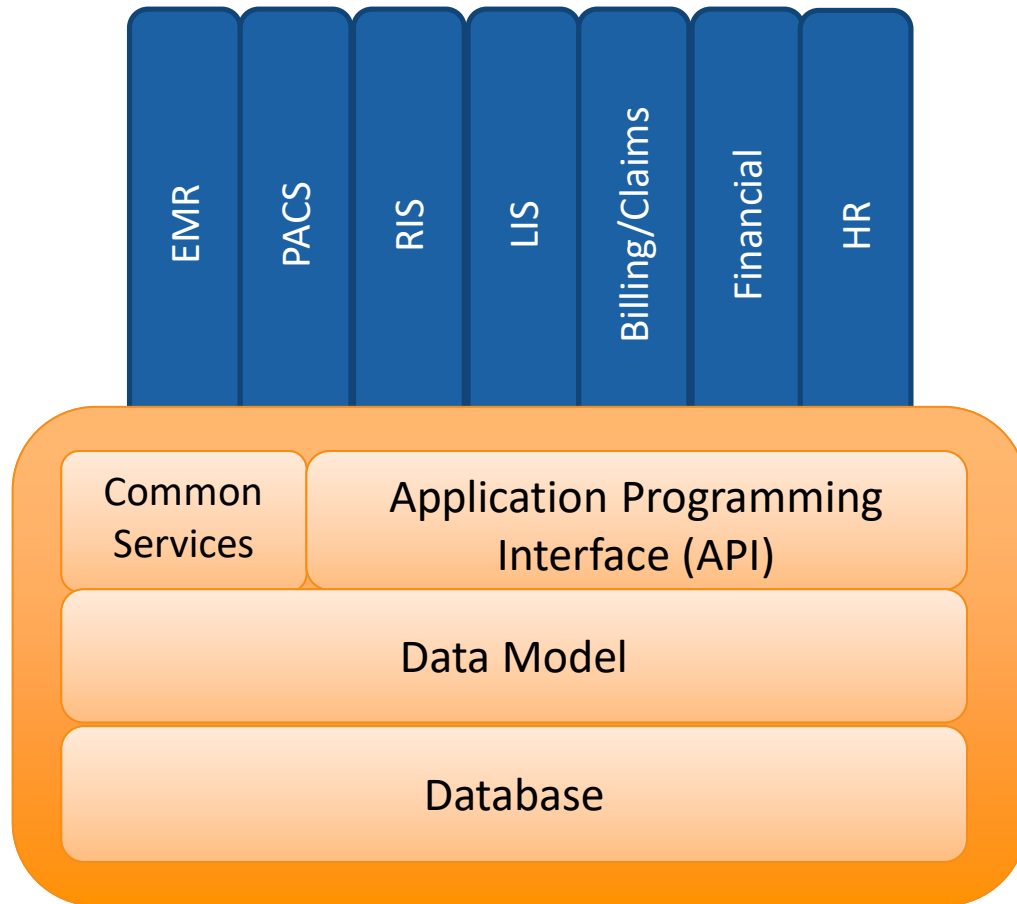
Use of Health IT Standards and Certification in the U.S. Market

November 21, 2017

Why Have Standards in Health IT?

- To require certain implementations within a system
 - Example: Data encryption
 - Goal: Ensure data security and privacy
 - Standard: NIST FIPS 140 standard for data encryption
- To enable interoperability between systems
 - Example: Clinical document exchange
 - Goal: Share data to improve quality and cost
 - Standard: HL7 Consolidated Clinical Document Architecture (C-CDA)

Internal System Standards



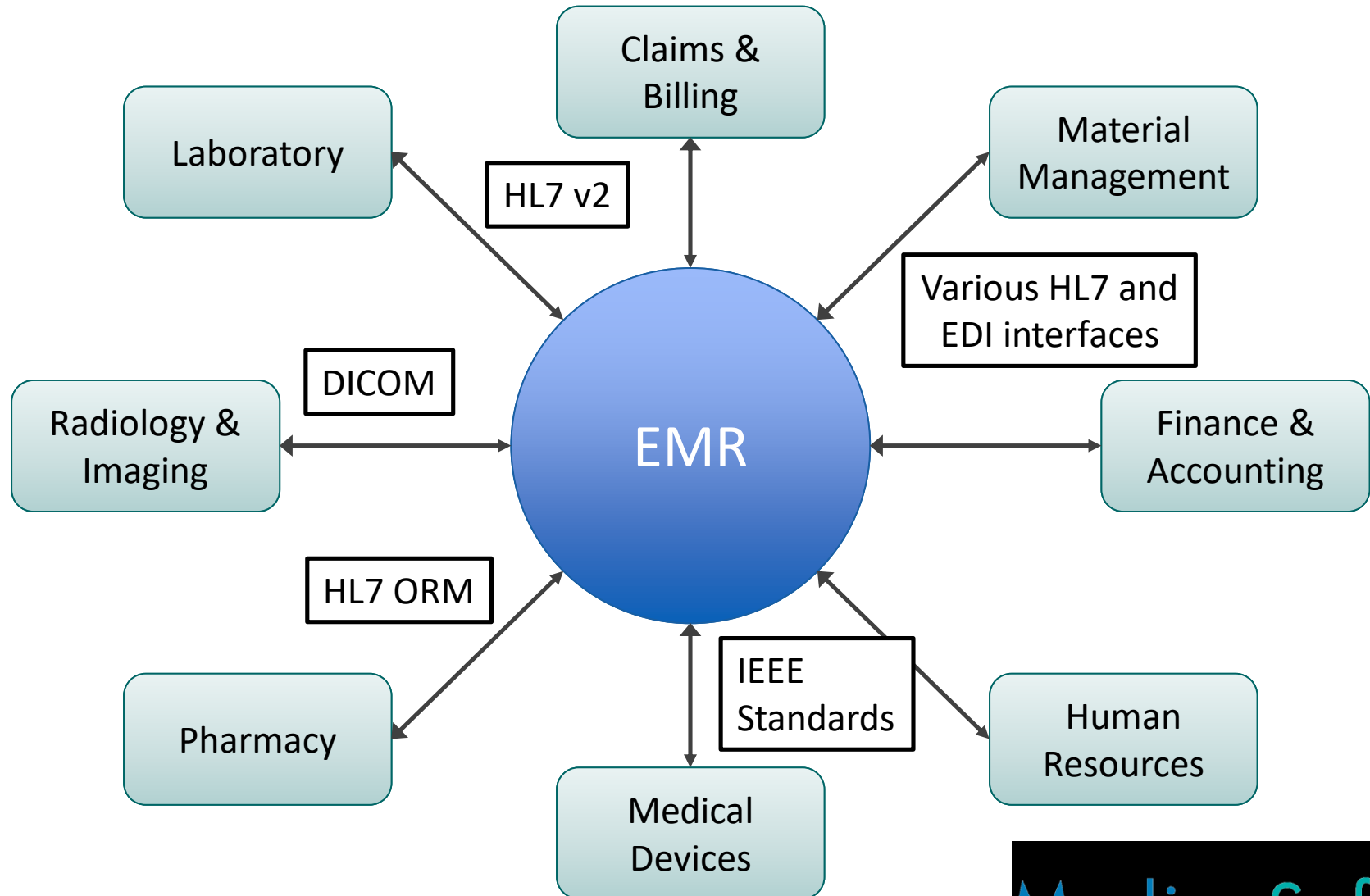
At every layer, Health IT software has many standards to choose from. Some examples:

HL7 FHIR, .NET, OAuth, SAML

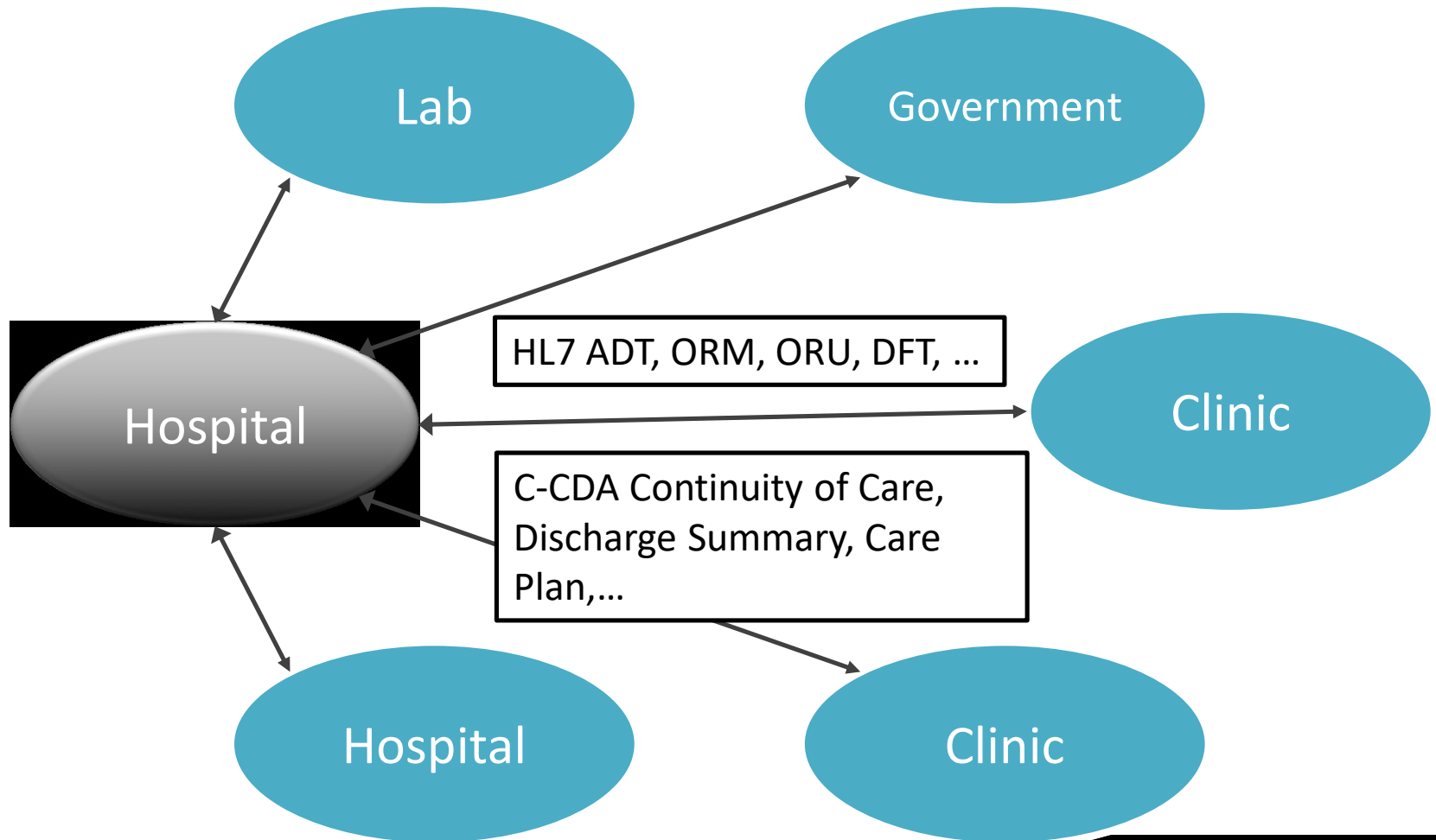
HL7 FHIR, HL7 v2

NIST 140-2

Interoperability Standards Within One Hospital



Interoperability Standards Between Facilities



How Can We Provide Guidance?

- Voluntary
 - Healthcare providers and vendors sometimes have a natural motivation to implement standards
 - Implementation guides, voluntary workgroups, and other non-required activities can assist
- Mandatory
 - Some standards affect security, privacy, or patient safety and cannot be left up to voluntary compliance
 - When incentive money or penalties are involved, voluntary compliance may not be appropriate
 - Certification may be required to enforce compliance

Voluntary Implementation of Standards

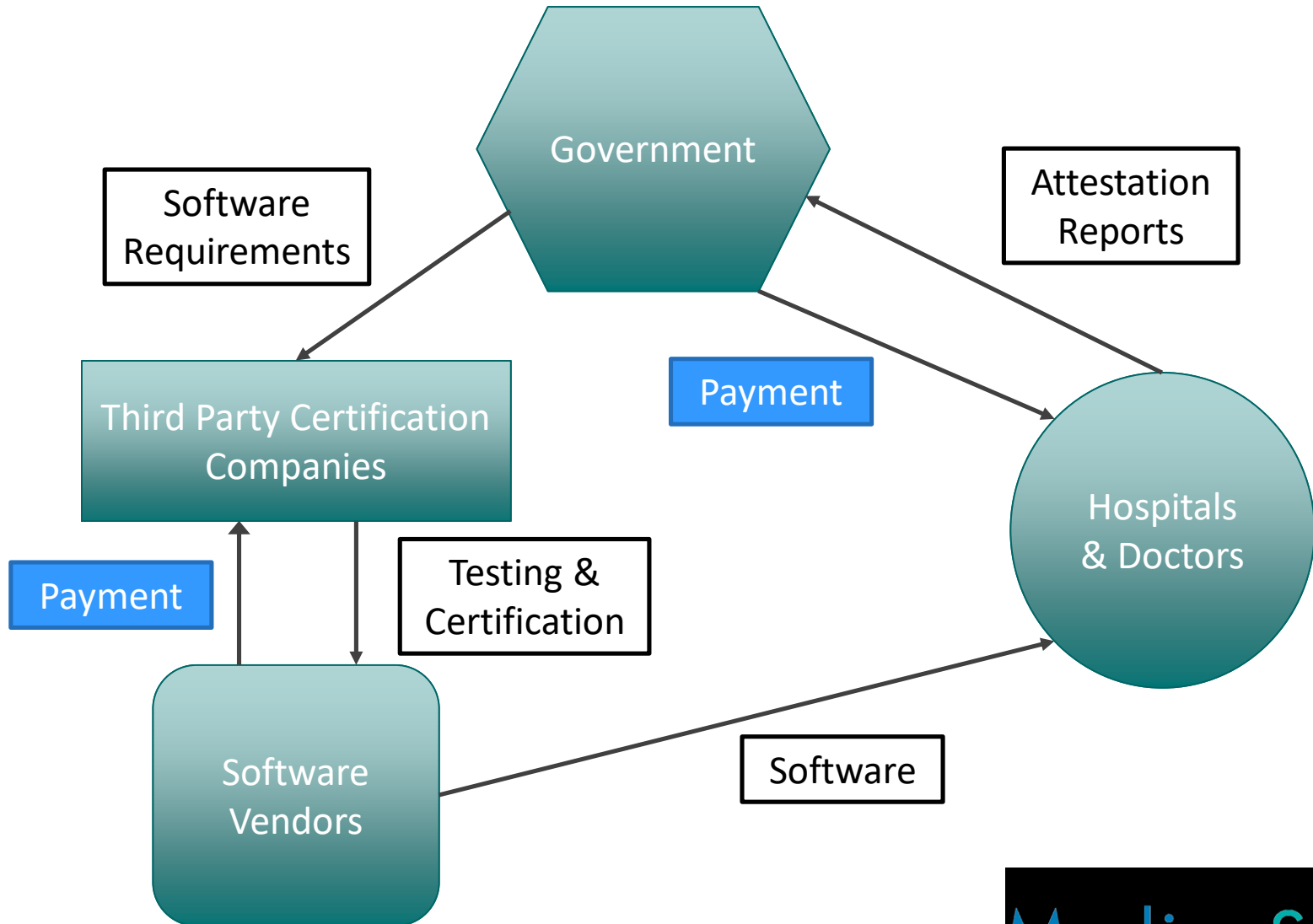
- HL7 Argonaut Project
 - Private sector organization, about 100 companies
 - Accelerate adoption of HL7 FHIR standard
 - Companies test their implementations with each other
- OSEHRA Open Source EHR Foundation
 - Government & private sector members
 - Collaborate on technical and policy issues
 - Participate in standards discussions and implementations

Meaningful Use

Certification & Attestation

- The US Government offers incentives (and penalties) to encourage adoption of EMR software
- Software vendors *certify* their software
- Hospitals & doctors choose certified software and *attest* that they are using it in a “meaningful way”
- Government assesses payments and penalties

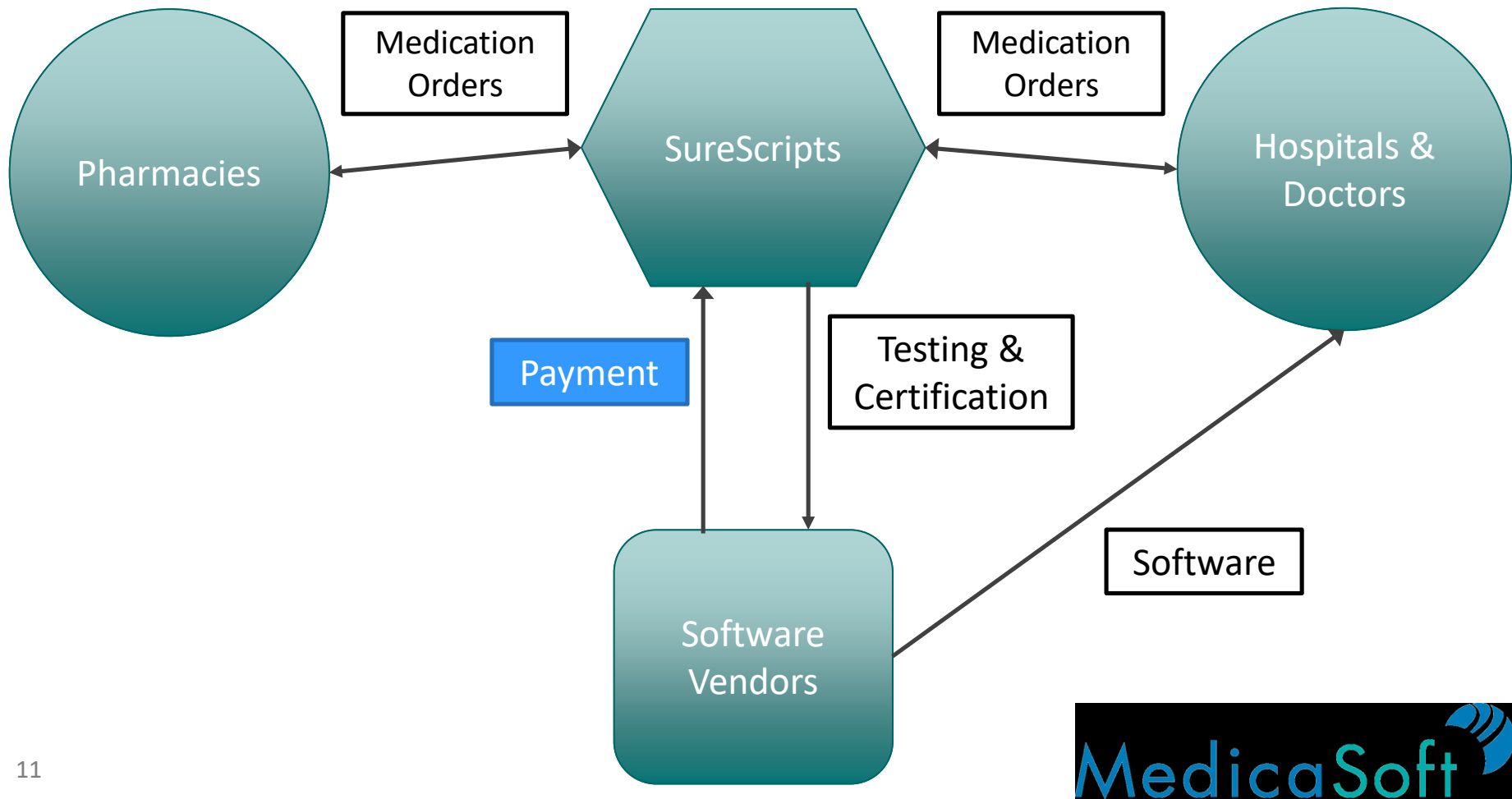
Meaningful Use



SureScripts Certification

- Large electronic medication prescribing network in the U.S.
- Strict compliance with ePrescribing standards is critical to patient safety
- SureScripts certifies software vendors before their software is allowed to connect to the ePrescribing network
- Any software changes requires re-certification

SureScripts Certification



Summary

- Health IT standards improve quality, security, safety, and cost
- A large number of health IT standards are available to healthcare providers and vendors
- Many opportunities to promote the adoption of standards
- Enable voluntary organizations and projects
- Establish certification processes and incentives