



Consent: Challenges, Opportunities, and Future Direction

ONC Annual Meeting 2020

Monday, January 27, 2020

Rose-Marie Nsahlai, ONC (OS/OTECH)

Johnathan Coleman, Security Risk Solutions Inc.

Jay Nakashima, eHealth Exchange

Doug Burke, Cognitive Medicine

Daniel Chavez, San Diego Health Connect

John Moehrke, ByLight Professional IT Services

The Office of the National Coordinator for
Health Information Technology

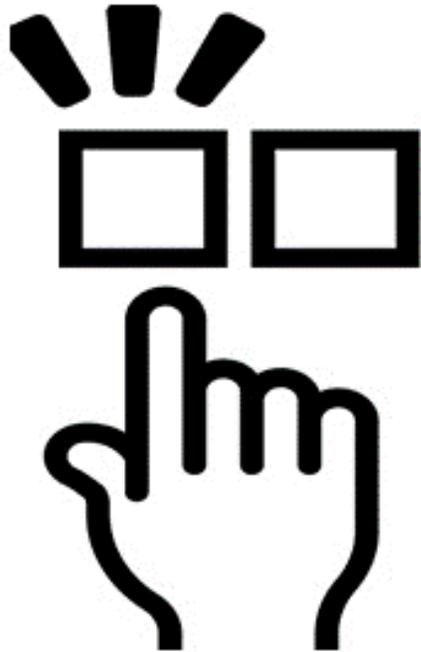


Consent: Challenges, Opportunities, and Future Direction - Speakers

- Panel Kick-Off: Rose-Marie Nsahlai, Office of the National Coordinator for Health Information Technology, Office of Technology, Security and Services Branch
- Panel Moderator: Johnathan Coleman, Security Risk Solutions, Inc.
- Panelists:
 - Jay Nakashima, eHealth Exchange
 - Daniel Chavez, San Diego Regional Health Information Exchange/San Diego Health Connect
 - Doug Burke, Cognitive Medicine
 - John Moehrke, ByLight Professional IT Services

Considerations for electronic consent in different settings

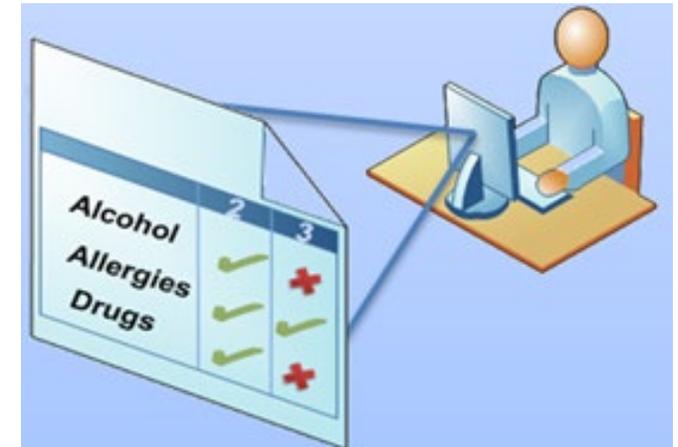
Opt-in, Opt-out



Regulatory Considerations, e.g. 42 CFR Part 2



Other Considerations, e.g. Granular Choice



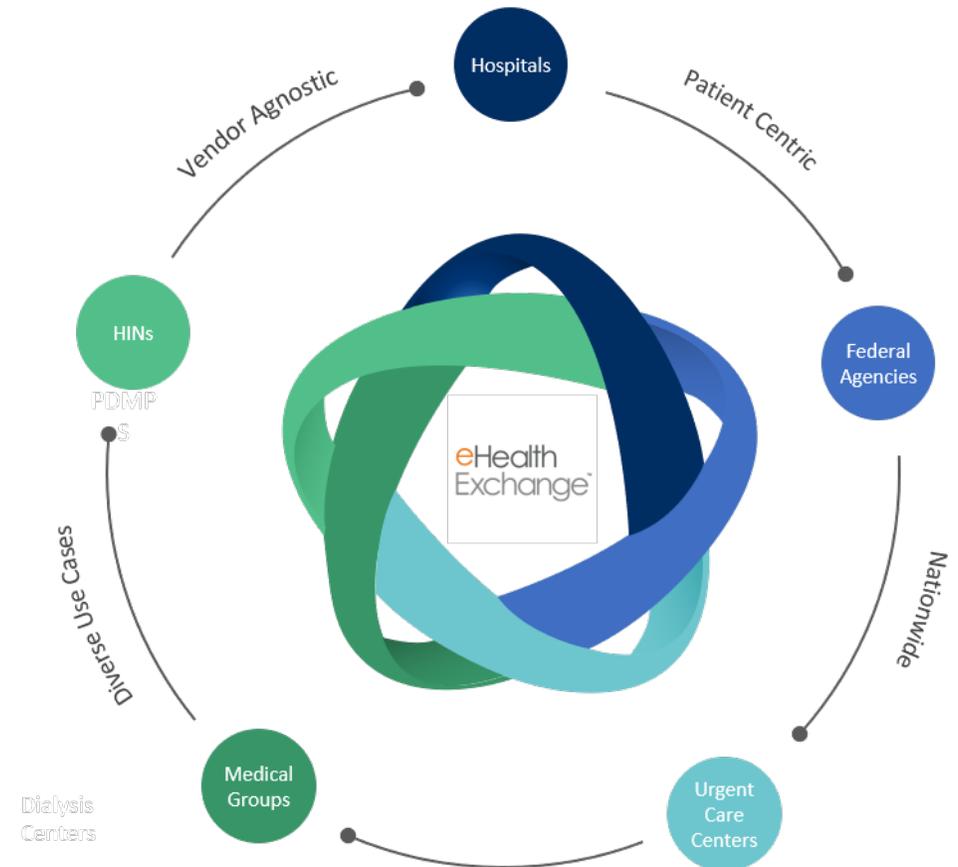


eHealth Exchange

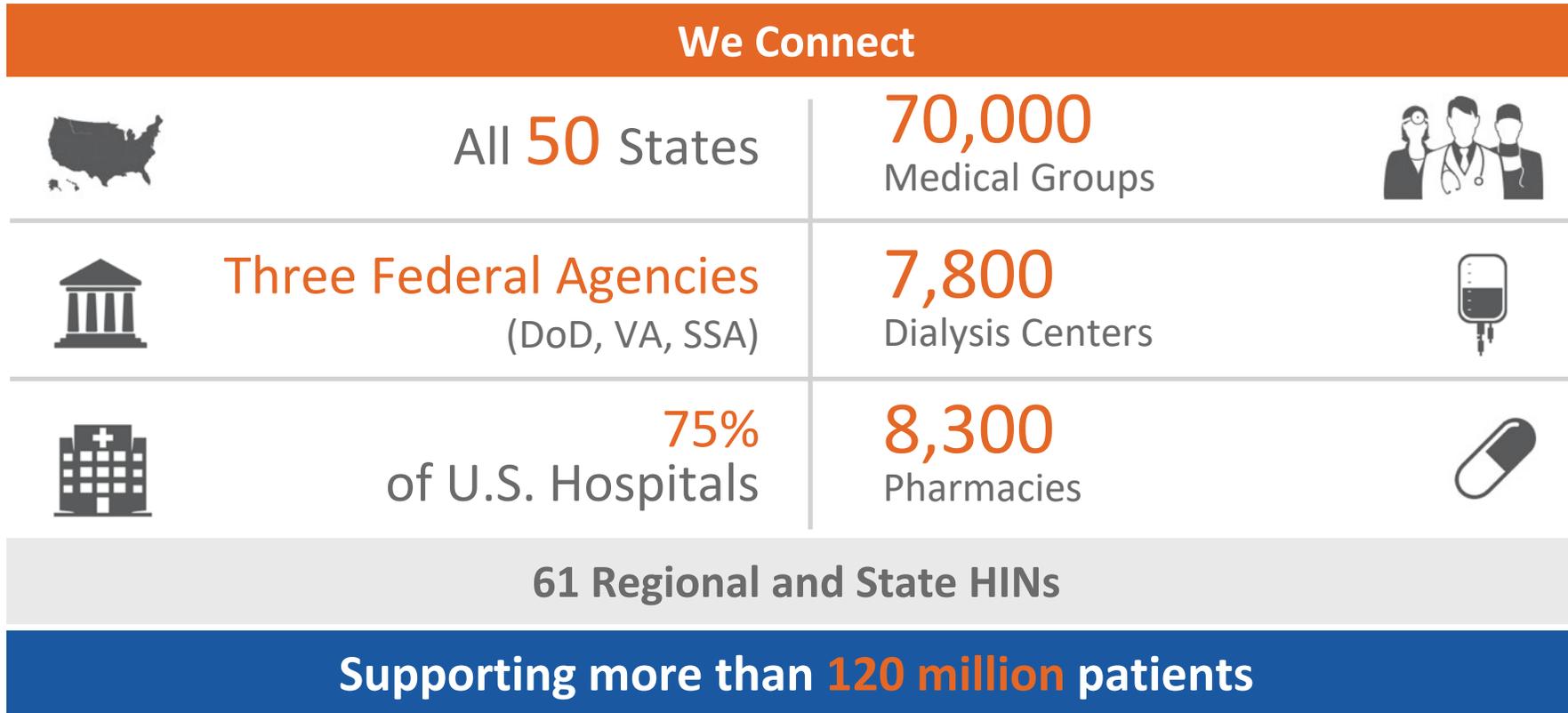
Jay Nakashima

eHealth Exchange

- Facilitates electronic exchange of patients' medical information
- Improves the speed, quality, safety, and cost of patient care
- Informs clinical decisions **when seconds and minutes matter**



eHealth Exchange



Connecting federal agencies & the private sector in all 50 states

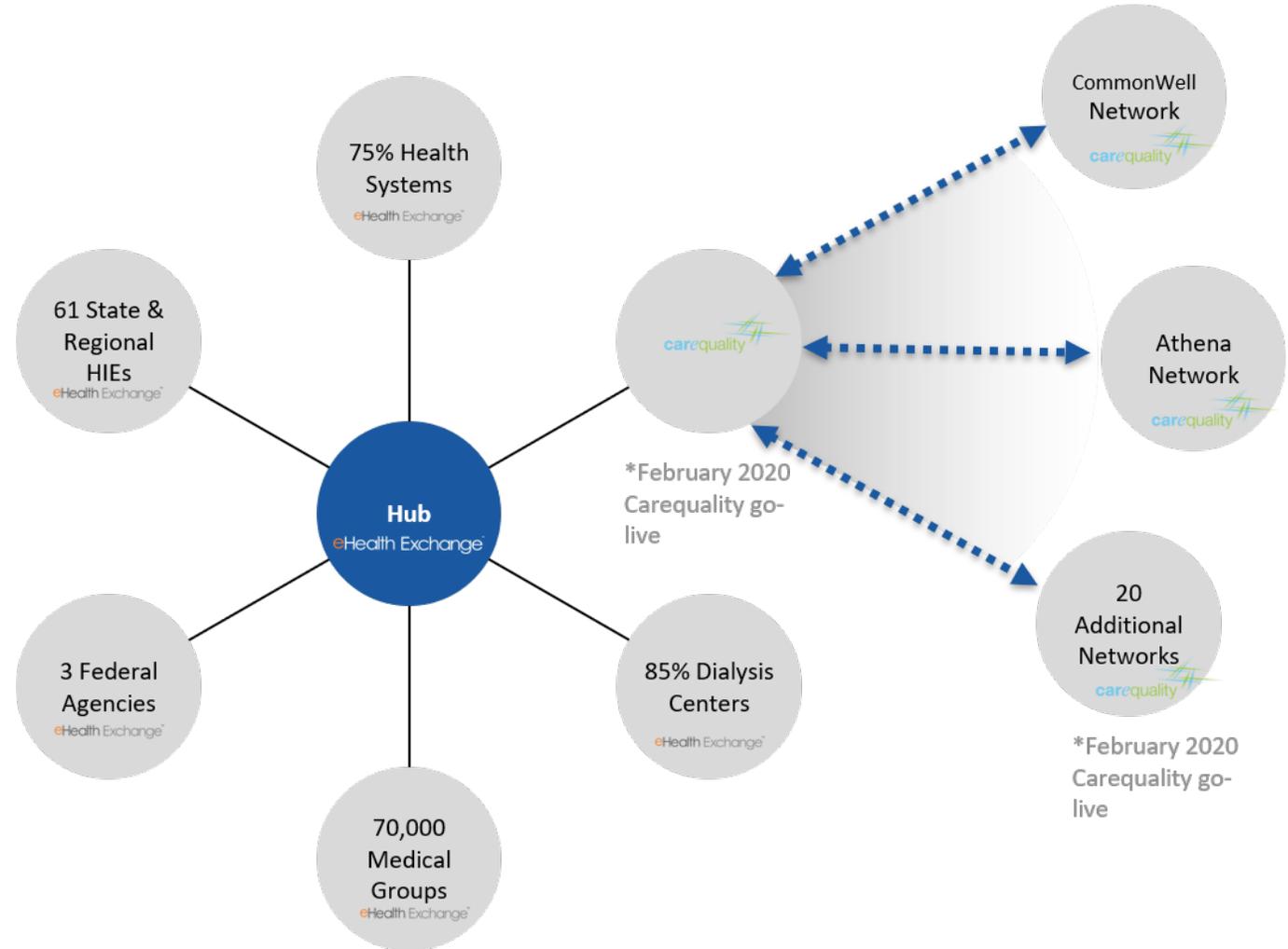
eHealth Exchange

Who Manages Consent?

Each eHealth Exchange Participant is responsible for adhering to applicable law, eHealth Exchange policies, etc before disclosing PHI

Complexities:

- Opt-in States
- Opt-in Providers in Opt-Out States
- Sensitive Conditions
- Consents vs Authorizations





ONC LEAP Consent Registry Utility

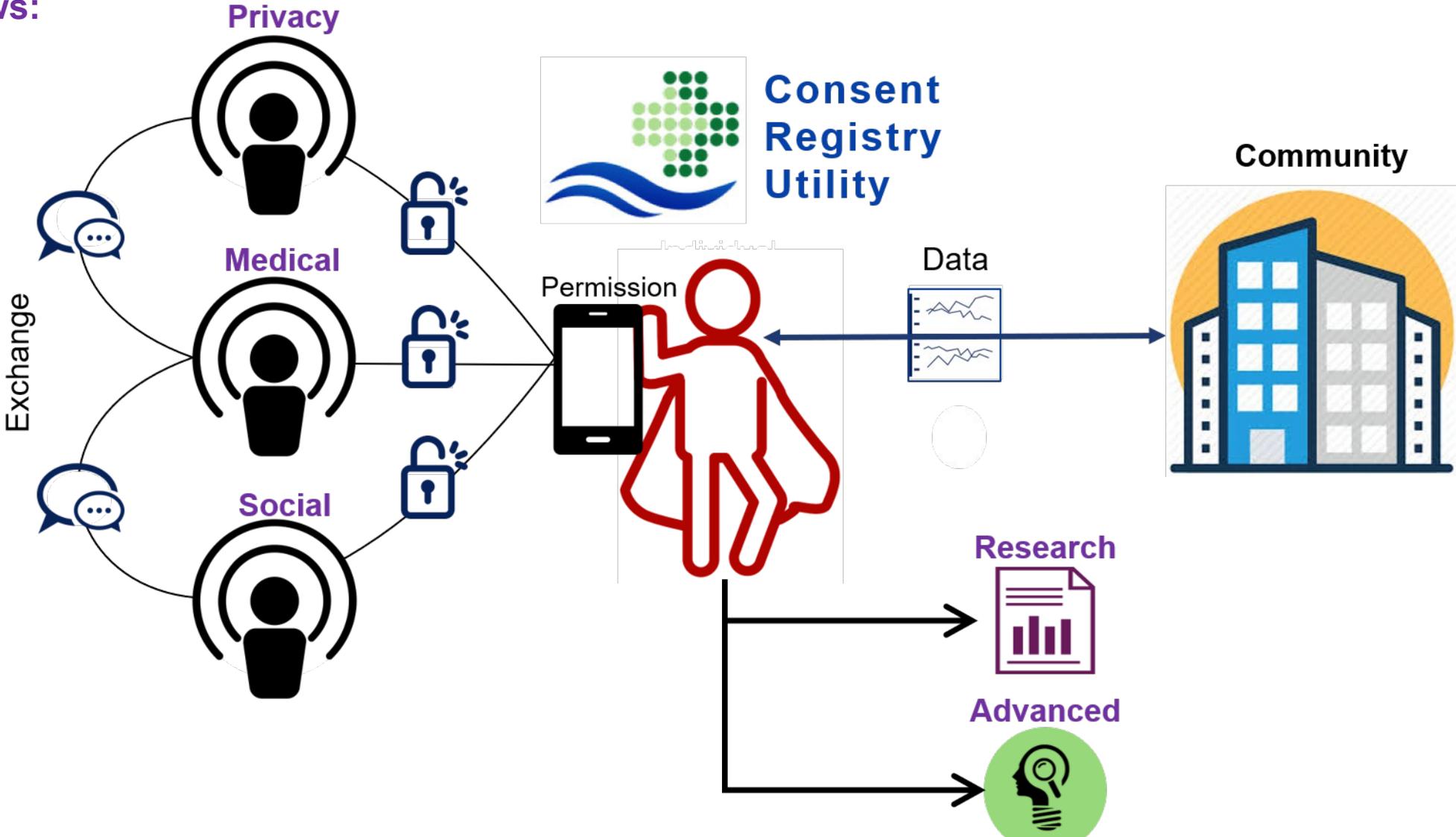
Dan Chavez, Doug Burke



Today, **facilities**, not humans, determine what information is shared with whom, when and under what conditions.

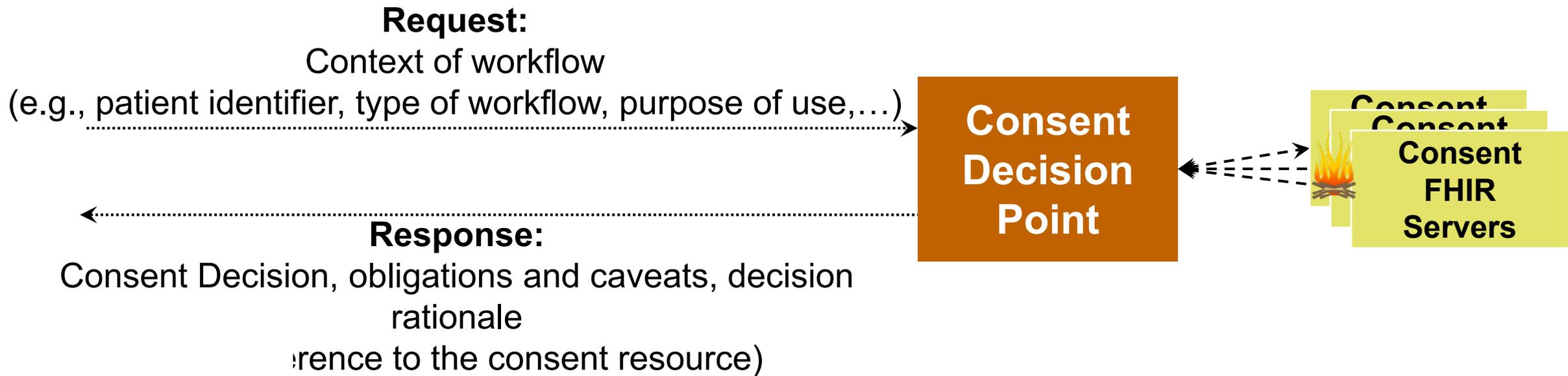


Workflows:



Consent Decision Point

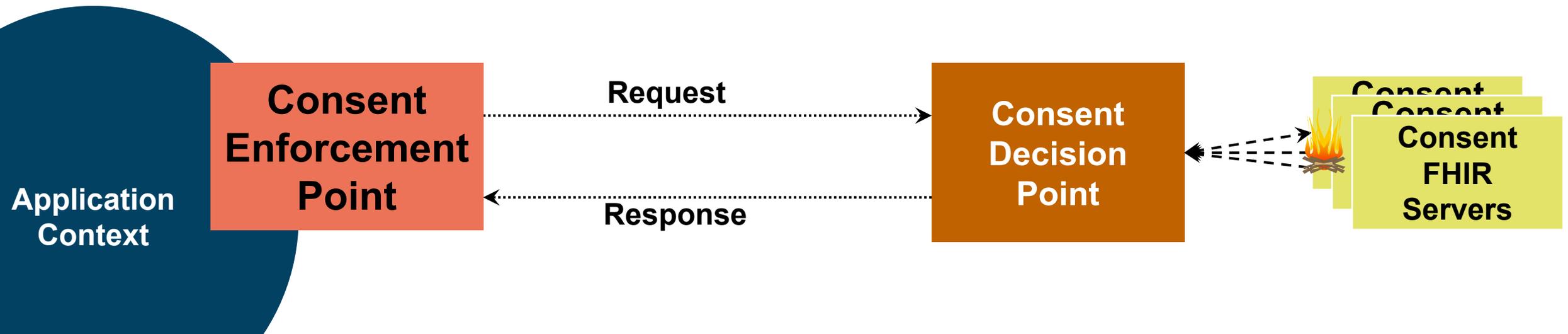
A microservice providing an interface for inquiring about patient consent (backed by FHIR-based consent repositories)



Consent Enforcement Point

Individual modules integrating with different application contexts to enforce consent decisions

- Capture and report the context of the workflow in the form of a query
- Receive and process the response
- Apply and enforce the decision in the workflow





HL7 FHIR Consent

John Moehrke

HL7 FHIR Consent

- Consent Resource - useful for many consent types
- Positive and Negative - not just consent but dissent
- Not just classic consent - also Authorizations
- Depends on Local Policy meaning and enforcement
- Just captures and records facts
- Absence of a Consent means?
- Questionnaire may be used in workflow to obtain Consent
- Includes a RULE encoding customized to FHIR



Consent Maturity

1. Consent resource just points at scanned paper
2. Consent resource just points at QuestionnaireResponse
3. Consent encodes .provisions
4. Consent w/ depth .provisions (PERMIT vs DENY)
5. Consent using external rules encoding (XACML)

Vectors:

- Timeframe of validity
- Organization consent applies to
- Regulation consent applies to
- Local Policy agreed to





FHIR Consent

- Type - permit/deny
- Context affected
- Actors affected
- Data selection
- Obligations

provision	Σ	0..1	BackboneElement	Constraints to the base Consent.policyRule
type	Σ	0..1	code	deny permit ConsentProvisionType (Required)
period	Σ	0..1	Period	Timeframe for this rule
actor		0..*	BackboneElement	Who what controlled by this rule (or group, by role)
role		1..1	CodeableConcept	How the actor is involved SecurityRoleType (Extensible)
reference		1..1	Reference(Device Group CareTeam Organization Patient Practitioner RelatedPerson PractitionerRole)	Resource for the actor (or group, by role)
action	Σ	0..*	CodeableConcept	Actions controlled by this rule Consent Action Codes (Example)
securityLabel	Σ	0..*	Coding	Security Labels that define affected resources SecurityLabels (Extensible)
purpose	Σ	0..*	Coding	Context of activities covered by this rule V3 Value SetPurposeOfUse (Extensible)
class	Σ	0..*	Coding	e.g. Resource Type, Profile, CDA, etc. Consent Content Class (Extensible)
code	Σ	0..*	CodeableConcept	e.g. LOINC or SNOMED CT code, etc. in the content Consent Content Codes (Example)
dataPeriod	Σ	0..1	Period	Timeframe for data controlled by this rule
data	Σ	0..*	BackboneElement	Data controlled by this rule
meaning	Σ	1..1	code	instance related dependents authoredby ConsentDataMeaning (Required)
reference	Σ	1..1	Reference(Any)	The actual data reference
provision		0..*	see provision	Nested Exception Rules



Audience Q&A



The Office of the National Coordinator for
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Contact ONC

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