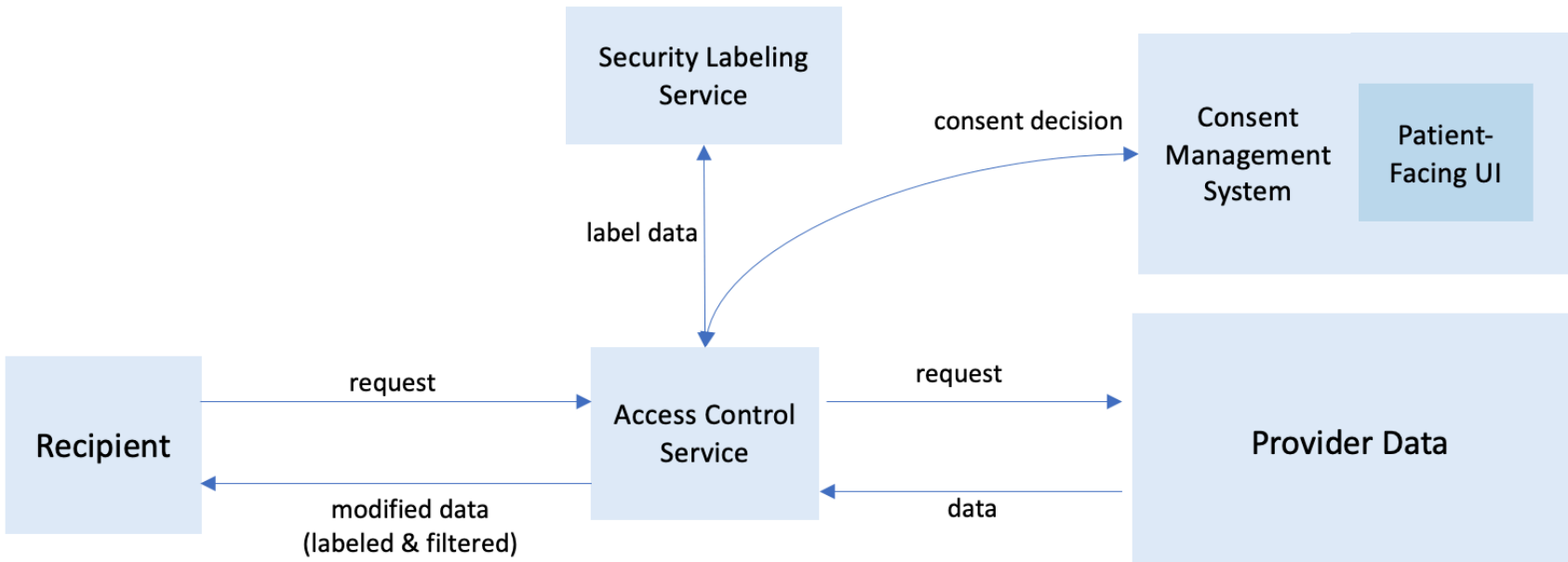
- Tight coupling between patient preferences (consent) and data segmentation
  - Patient preferences (consent) is where the granular policy rules are recorded; data segmentation identifies the granular segments of data subject to the rules.
- The need a cohesive view of granular patient preferences (consent) and data segmentation as components of one system
- At a minimal level, it is possible to enforce patient preferences while keeping data segmentation internal to the organization
  - No support for exchanging labeled data


Security Labeling Service
consent decision
Consent Management System
Patient-Facing UI
label data
Recipient
request
Access Control Service
request
Provider Data
modified data
(labeled & filtered)
data

- Standard labels are key
  - Standard labels provide a *language* for expressing patient granular preferences (consent) –and other policies
  - Consent enforcement and segmentation methods can be proprietary, but the labels need to be interoperable
- Agreement on the meaning of labels is essential for consistent enforcement
- The need for selecting a well-defined subset of existing standard codes for security labels
  - Confidentiality labels
    - e.g., Unclassified, Normal, and Restricted
  - Obligations and Refrains
  - Sensitivity labels
    - e.g., Substance Use, Behavioral Health, Reproductive Health

- The semantic link between sensitivity classes and clinical concepts
- The need for guidance on the underlying clinical concepts for each sensitivity class
  - Without a common understanding there is a risk of inconsistent enforcement of any policy that is based on sensitivity labels.
  - Is this an acceptable risk?

- Data can flow in different forms and through different gateways
  - Enforcement should be implemented in all exchanges
- The need for a cross-paradigm framework for data segmentation
  - v2, CCDA, and FHIR with a common vocabulary for labels
  - There are individual implementation guides but currently there are no specifications for harmonized cross-paradigm DS4P

- Implementation can/should be incremental
  - Advanced data segmentation/consent enforcement may not be feasible to implement in one phase
- The need for a maturity model and a road map for implementing data segmentation and granular consent

Existing Standards and Implementation Guides	Standard Vocabulary	Consent/Policy Integration	Cross-Paradigm Guidance	Maturity Model
HL7 Healthcare Privacy and Security Classification System (HCS) *Abstract, high-level, and conceptual guidance on security tags.*	x	x	abstract	x
Clinical Document Architecture (CDA®) Data Segmentation for Privacy (DS4P) Implementation Guide *Guidance on labeling CDA documents and sections.*	✓	x	CDA documents	x
FHIR Data Segmentation for Privacy (DS4P) Implementation Guide *Guidance on labeling FHIR resources (and resource portions). Standard value sets for different security labels based on the HL7 terminology.*	✓	some guidance	FHIR	x (roadmap)
HL7 Messaging Version 2.9 *Guidance on labeling for v2 messages (Batch Header Segment, File Header Segment, and the Message Header Segment).*	some	x	v2	x
IHE Privacy Consent on FHIR (PCF) (emerging specification) *Guidance on recording and enforcing consent.*	N/A	✓	N/A	some

Conclusions

- At a minimum level, it is possible to require enforcing granular patient preferences while the details of segmentation remains internal to the organization.
- There is sufficient implementation guidance for recording security labels in FHIR, CDA, and v2.
- Well-defined labels that are unambiguously understood by all parties are essential in consistent labeling and policy enforcement:
  - Confidentiality labels: e.g., Unclassified, Restricted, and Normal
  - Common Obligations and Refrains: e.g., do-not-redisclose, purpose of use
  - The precise subset should be determined based on feedback from different stakeholders.
- While there is sufficient guidance on how to *record* sensitivity labels, there is a risk of inconsistency in *assigning* sensitivity labels due to lack of guidance on a common understanding of the underlying the clinical concepts.