HL7 FAST Consent Management Implementation Guide Reportout

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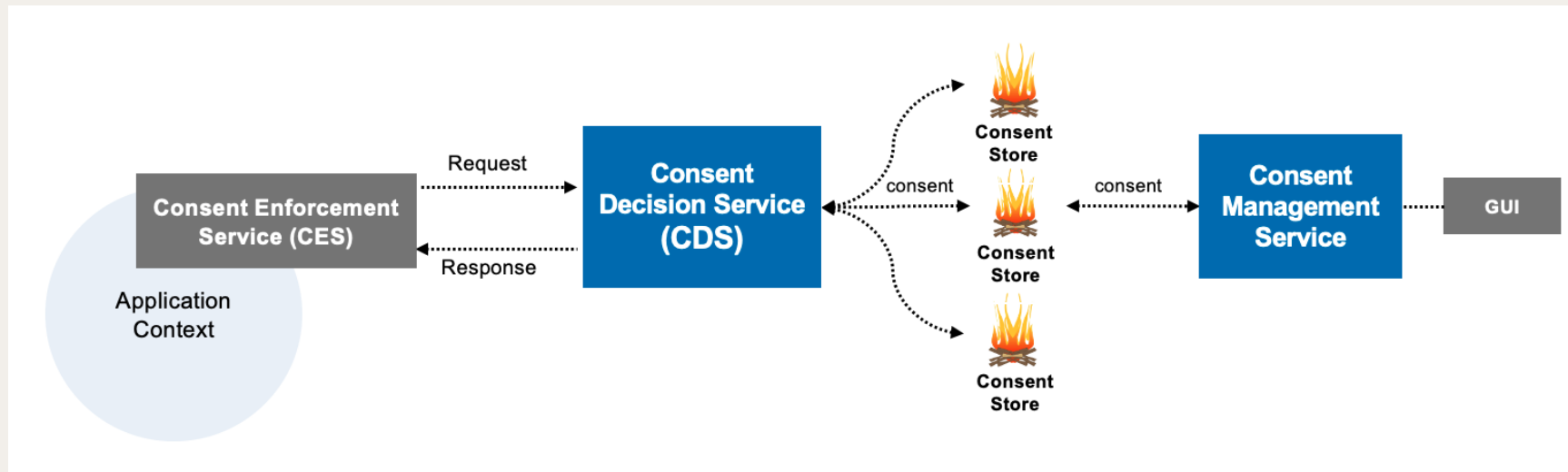
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HL7 FAST Consent Management IG

- Following an environment scan in summer of 2023
- Identifying the area of consent management and administration as a gap in existing specifications
- FHIR-based specification

Actors

- Consenter:
  - patient, social services client, research participant, etc.
  - substitute decision maker
- Administrator:
  - admin at healthcare provider, social services organization, etc.

Use Cases

- Request Consent
- Review Consent
- Sign/File Consent
- Browse Consents
- Review Consent Provenance
- Revoke Consent
- Disclosure Audit
- Propagate Consent Events
- Delegate

Request Consent

- An authorized admin requests a consent from a consenter
  - The consent form may be selected manually or be implied by the workflow.
  - The admin must be able to identify the consenter
    - Implied by context/workflow, or
    - manual selection/discovery
  - The consenter may be individually selected or as part of a group
  - The consenter should be notified about the request
  - The identity of the consenter must be consistent between the consent administration system and the admin client

- A Questionnaire resource captures the consent form to be reviewed by the consenter.
- A Task resource records the assignment of the request to the consenter and tracks its status.
- A Subscription resource is used to subscribe the requester to the events about this consent.
  - Subscription on pre-consent events are optional
  - Subscription R5 backport IG
- Provenance resource captures the event as part of the consent provenance

Review Consent

- A consenter navigates and reviews the consent form
  - It may be based on a request or self-initiated.
  - The form may be completed over multiple sessions and its state needs to be preserved.
 - Some fields may need to be pre-populated.

- A QuestionnaireResponse resource captures the partially- or fully completed form.
- A Task resource records the state of the process.
- Provenance resource captures the event as part of the consent provenance.

Sign/File Consent

- A consenter signs (and thereby activates) a completed consent form.

- A QuestionnaireResponse resource captures fully completed form.

- A Task resource records the completion of the process.

- A Consent resource records the final computable active consent.
  - $extract operation from the SDC IG
  - Consent profiles corresponding to the form

- A Provenance resource captures the event.

From Form to Computable Consent
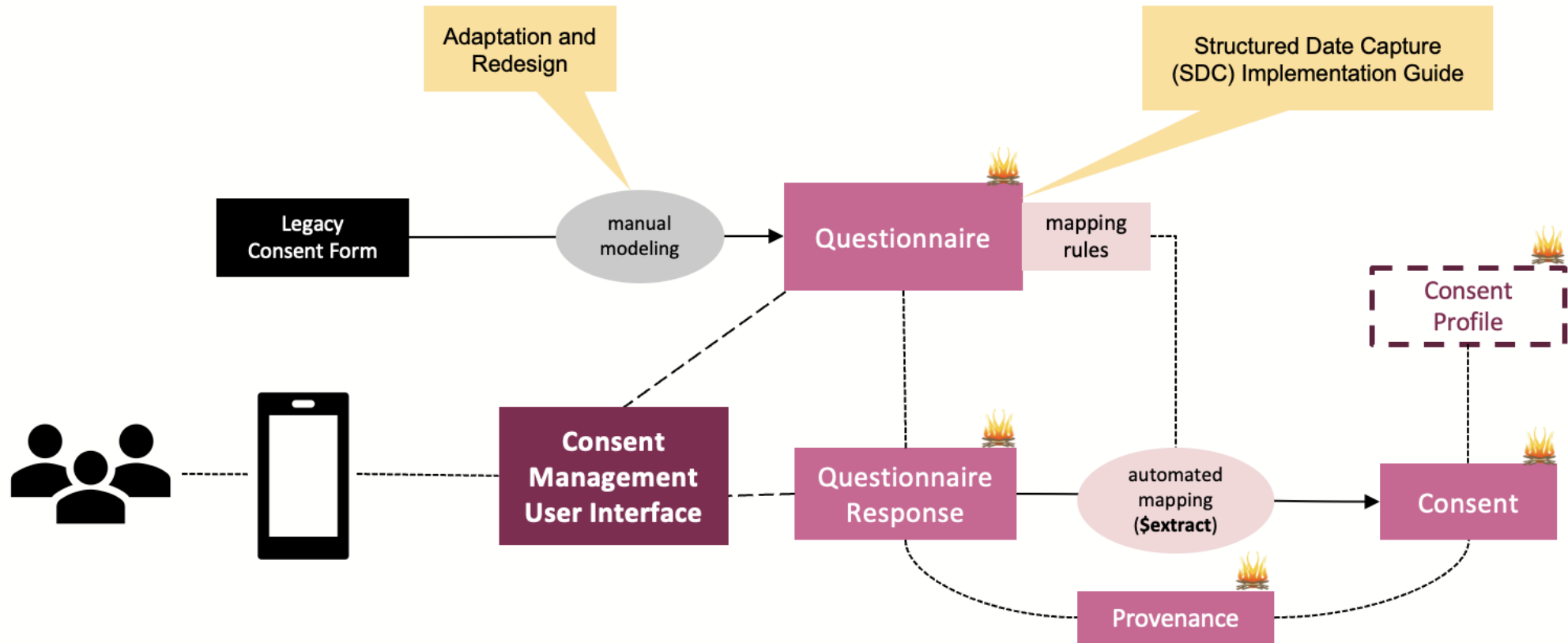
Browse Consents

- A consenter or admin can browse and review existing consents.
  - Requested consents (in progress)
  - Active Consents
  - Expired and Revoked Consents

- QuestionnaireResponse captures the original response to the form

- A Document resource can capture a print-friendly version (e.g., PDF)

- A Consent resource records the computable form.

Review Consent Provenance

- Admin or Consenter can review consent Provenance including a record of lifecycle events for each consent
  - Requested by whom and when
  - Date/time of signing
  - Date/time of revocation
  - Record of sharing the consent with other parties.

- Provenance resources capture the record of lifecycle events to show.
- AuditEvent resources capture the events of sharing the consent with other parties.

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Revoke Consent

- A consenter can revoke an existing active consent.
  - The consenter must be able to find and review existing active consents.
  - The consenter may be required to sign a form to formalize the request to revoke.

- A Consent resource records the change in the status of the consent.

- A Provenance resource to capture the revocation event.

- Questionnaire and QuestionnaireResponse resources may be used to capture the revocation record if required by policy.

Disclosure Audit (optional)

- A consenter or admin can see a record of disclosures permitted or denied based on each consent.

- AuditEvent captures the record of a permit/deny decision based on the consent.

- Subscription resource captures how to receive such events from other systems.

Propagate Consent Events

- Consent lifecycle events:
  - request (optional)
  - Review (optional)
  - sign/file,
  - revocation

- Provenance captures the record of lifecycle events.

- Subscription resource captures how to share such events to other parties.

Delegate

- A consenter can assign a delegate to make consent decisions on their behalf.
  - The identity of the delegate should be discoverable.

- Questionnaire and QuestionnaireResponse resources can capture the delegation form.

- A Consent resource can capture the computable form of the delegation policy.

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