



Texas Consent Management Services Whitepaper
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Target Audience

This paper is targeted toward technical audiences such as systems integrators, software vendors, Texas Local Health Information Exchange (HIE) Grant Program HIE CTOs, other local HIE CTOs, and system architects. It may be of use for policy and planning purposes as it describes the technical capabilities that may be utilized to implement a variety of electronic health information exchange (HIE) consent policy decisions. This paper is not intended for use by a general consumer audience.

Scope

This paper defines and describes the primary design of the THSA's proposed Texas state-level consent architecture and the architecture proper. Although legal issues are discussed, this paper was written by, and for, lay people and should not be construed as legal advice. This paper is not intended to advocate any specific approach to consent policy (opt-in/opt-out, etc.).

Context

The Texas HIE Enterprise Architecture Blueprint (EAB) approved by the THSA Board of Directors in the summer of 2011 was a forward-looking document laying out the technical architecture vision for the next 7 years. One aspect of the blueprint was a consent management service component that was originally slated for delivery near the end of the 7-year plan.

Since then, Texas Local HIE Grant Program grantees have moved toward or completed their technology vendor selection process and toward implementation of HIE services. In some cases they have entered into live operation of their Local HIE. In order to serve the needs of the state's Local HIEs best, the THSA has intentionally been staggering its vendor selection and go-live implementation architecture to ensure the ability to determine Local HIEs' needs as accurately as possible based on their exact deployed capabilities. Toward that objective, the THSA has specifically asked Local HIEs "what do they need the THSA to deploy because it will be difficult or even impossible for them to do?" Resoundingly, one of the identified needs was to deploy state shared services for patient consent management across all Local HIEs.

Given that the THSA's consent management approach is very similar, in terms of technology components, to its approach to other identified Phase II state shared services, it has elected to accelerate the deployment of state-level consent management services from year 7 to year 1 to ensure that the needs of the state's Local HIEs are being met.

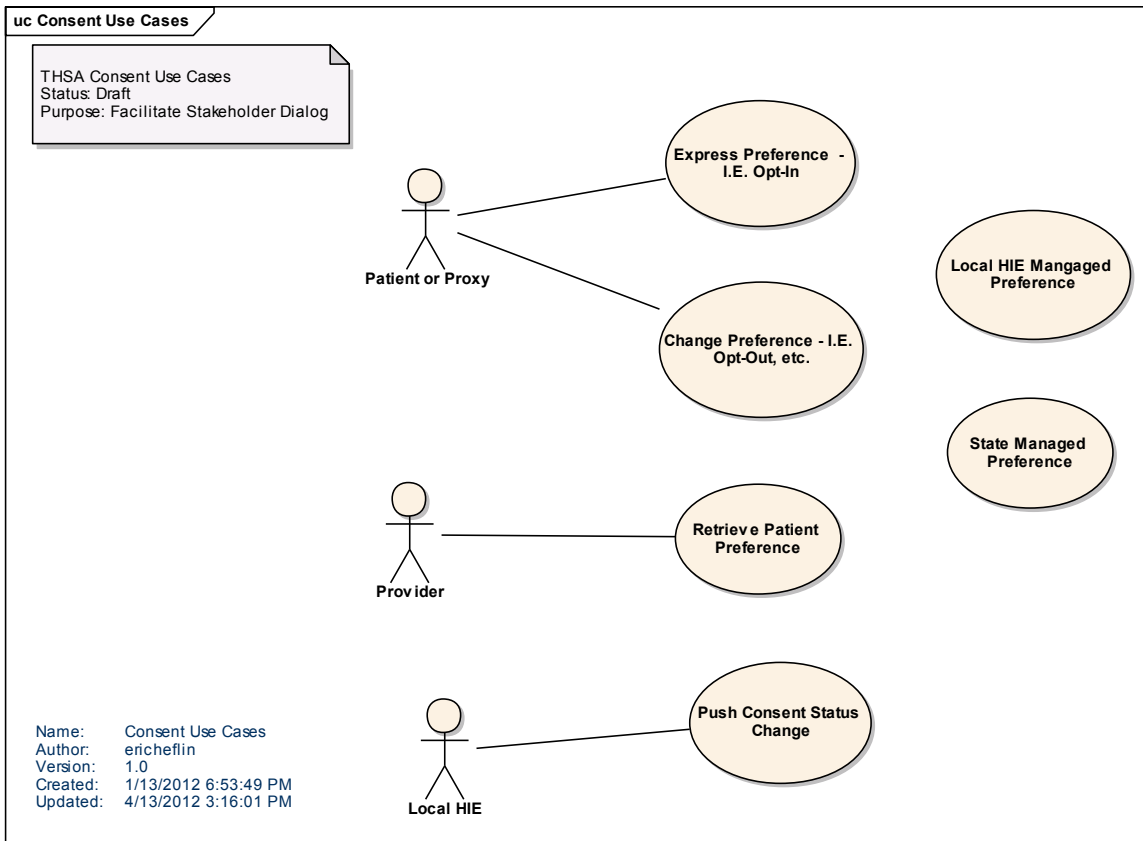
Problem Statement

Texas Local HIEs need a method to determine if a patient has expressed an “opt-out” or “opt-in” preference for exchange between HIEs. Local HIEs also need a way to determine if patients have acknowledged or exercised local fine-grained consent, authorization, or other policy. Automation of the access control decision is highly desirable and should be possible in most, if not all, cases using the envisioned services.

Priority Use Cases

The following use cases have been reviewed and agreed to in principle through the THSA’s collaborative stakeholder process:

- A patient wishes to express “all in” or “all out” consent for exchange between HIEs.
- A patient within a Local HIE Grant Program awardee expresses authorization for use of his/her data for research purposes.
- A responding gateway needs to determine if a patient has expressed a consent preference that would prevent access to a record.
- A patient wishes to change his/her consent preferences.
- A Direct Project-based exchange participant emails a THSA consent document to the state consent service.



High Level Components

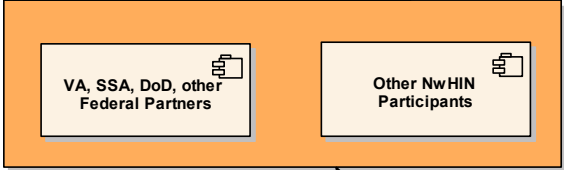
As explained in more detail in the RFP Functional Requirements Grid, the envisioned state consent services leverage industry standard components and technologies. IHE XDS.b is used to act as an index to and optional storage of consent documents. IHE Basic Patient Privacy Consent (BPPC) is used to represent the patient's consent expression. Direct is being used to receive consent documents from non-HIE/non-EHR sources. PKI is used to ensure security of each web services end-point of the exchange, and to ensure the communications channel is encrypted. The advantage of this leveraged approach is that the state consent services essentially re-use existing building blocks for a new purpose, allowing for substantial re-use of existing production products.

cmp Phase II Components

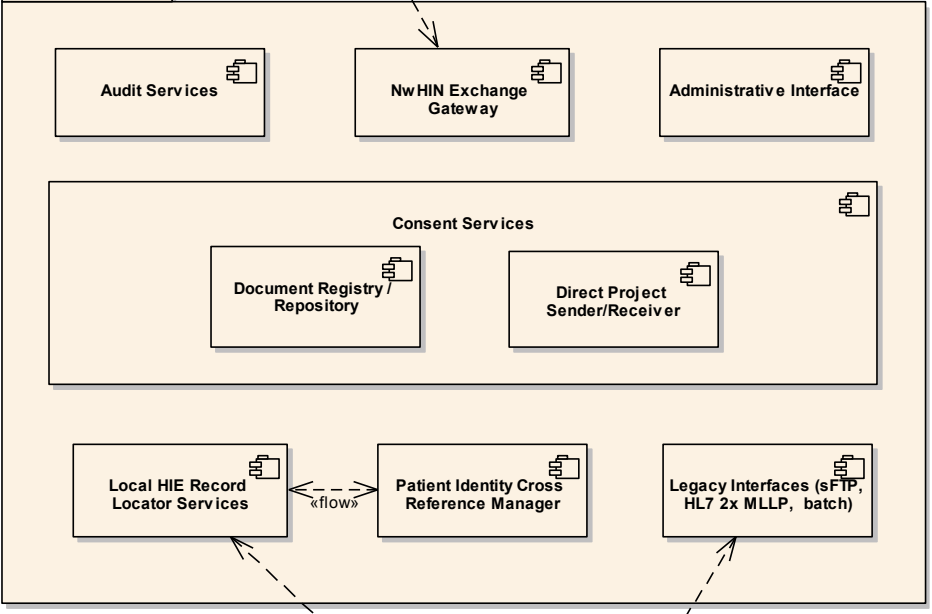
THSA Phase II High-Level Component Model
 Purpose: Overall scope communication
 Status: Draft

All data to be secure at all times in transit or at rest. Please see detailed architectural diagrams for more information.

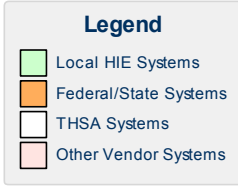
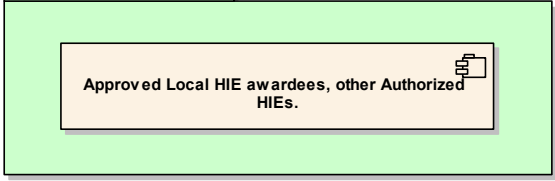
Nationwide Health Information Network Partners



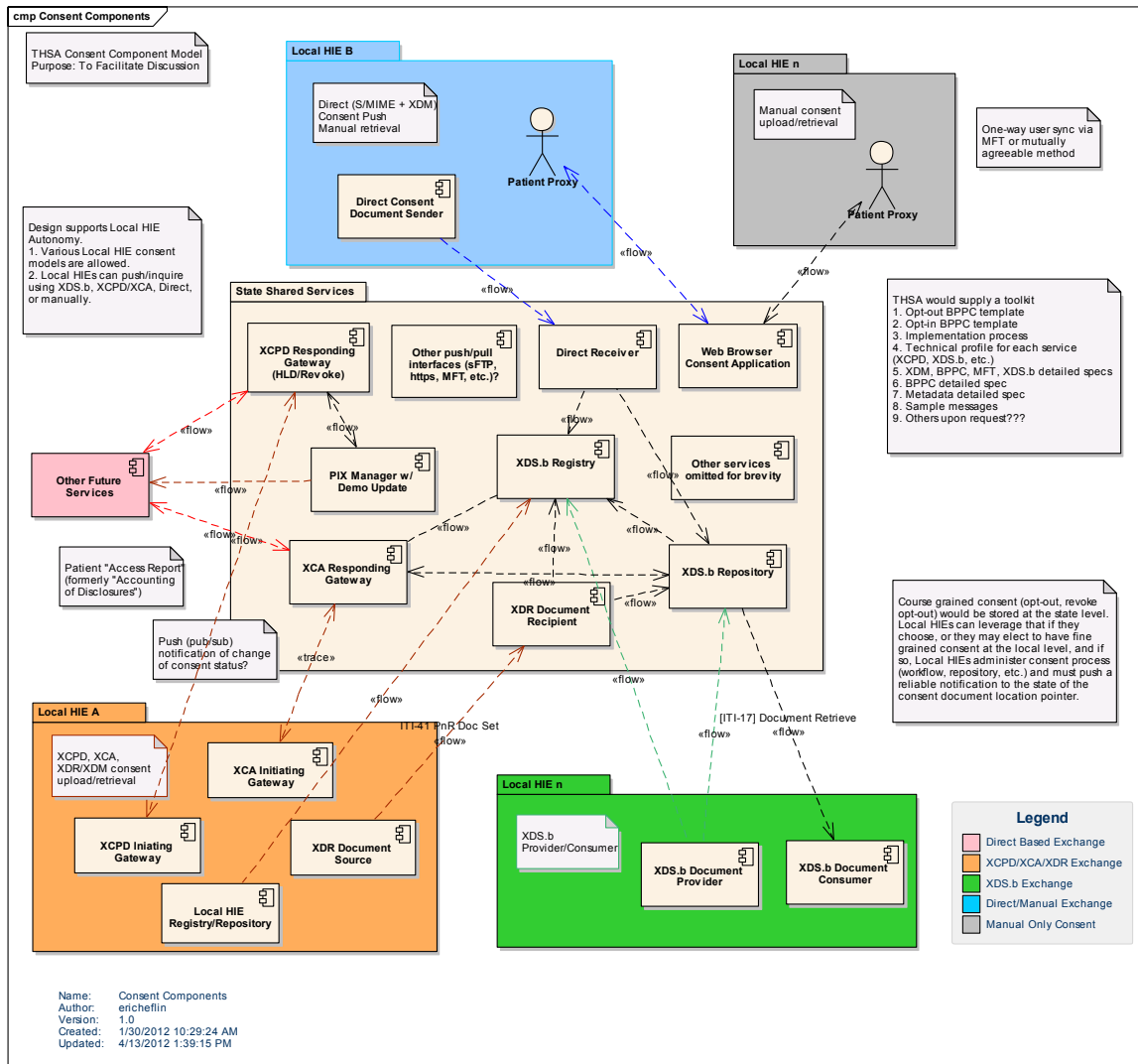
THSA Components



Texas Local HIE Grantees



Detailed Components



State-Wide Consent Vocabulary

In order to enable automated access control decisions regarding the release of a patient’s medical record from one HIE to another HIE, it is necessary for each of those HIEs to understand each other’s policy. Specifically, it is necessary for each HIE to have the ability to decide if a given patient’s policy preference allows or disallows access. In order to accomplish this, there must be a published and uniform vocabulary of each consent policy type used within the state. Thus, Phase II

state shared services includes a work stream to create such a statewide vocabulary of state, federal, and local HIE policy expressions.

The Selected Vendor for this work stream will be responsible for creating an inventory of each patient policy form for each Local HIE. Since most Local HIEs only have one to three policy forms, this is not anticipated to generate a large number of policies in the initial inventory. The vendor will add to this inventory all state and federal policies (of which there are also expected to be only a small number). Next, the vendor will reconcile similar policy documents and create the smallest possible list of discrete policies. This list will then be turned into a list of policy vocabulary identifiers (OIDs) that uniquely identifies each version of each policy in this statewide vocabulary.

Once the statewide policy vocabulary list has been created, only values from this list will be used by each patient's consent acknowledgement IHE BPPC document. Each request for each patient's medical information across HIE boundaries will result in the responding HIE gateway being required to search for, retrieve, and inspect any BPPC documents stored at the state policy servers. This allows the policy engines at each responding HIE to automatically determine if they will allow or deny the request based on their local policy and based on the knowledge of the policy the patient acknowledged.

Consent Toolkit

In order to facilitate implementation of this consent system, the THSA Selected Vendor will create an implementation "toolkit" of resources designed to simplify the policy implementation. The toolkit contents will be determined in coordination with Local HIEs and are expected to contain: 1) sample BPPC documents with and without optional scanned signature and digital signature components; 2) a list of the current policy OIDs along with references to the officially-maintained statewide list of policy OIDs; 3) use cases with diagrams; and 4) other documentation covering rules of use, scope, etc.

Key Standards Used

IHE BPPC
IHE XDS.b
IHE XCA
Direct (S/MIME)
IETF X.509/PKI
HL7 v2
HL7 v3
IHE PIX
IHE PDQ
IHE ATNA SN/SA/ARR

Detailed Use Case Diagrams

The following two use case diagrams are intended to be illustrative, not authoritative. That is, other use cases, and other methods of implementing these use cases, are anticipated. Note that these diagrams are embedded vector graphics, so the images can be resized to make them more readable. Both diagrams are UML models that are also available from the THSA in Enterprise Architect format.

In the first use case, the patient is presenting and has expressed a consent preference. The local practice captures the consent in a method consistent with local policy (verbal, electronic form, paper form, etc.) and enters the consent preference into its EMR/EHR. The EMR would send a notification, in a mutually agreed-to format, to the Local HIE. Common formats would include HL7 v2 CON message (consent) or CDA BPPC document. The Local HIE would record the preference, if needed as per local policy, and then would notify the state consent repository using a mutually agreed-to format if the consent expression could impact HIE-to-HIE exchange. Anticipated notification mechanisms include BPPC as a payload to an XDM/XDR push, a Direct email notification, or a file-oriented approach. The state consent services would index and store the consent pointer and, if appropriate, would store the consent document. If the consent is provided in a format other than via BPPC, then the consent would be transcoded into a BPPC document before it is submitted to the XDS.b registry/repository.

Business Rules

The following business/clinical rules have been identified. Others will likely be identified as the implementation planning process progresses.

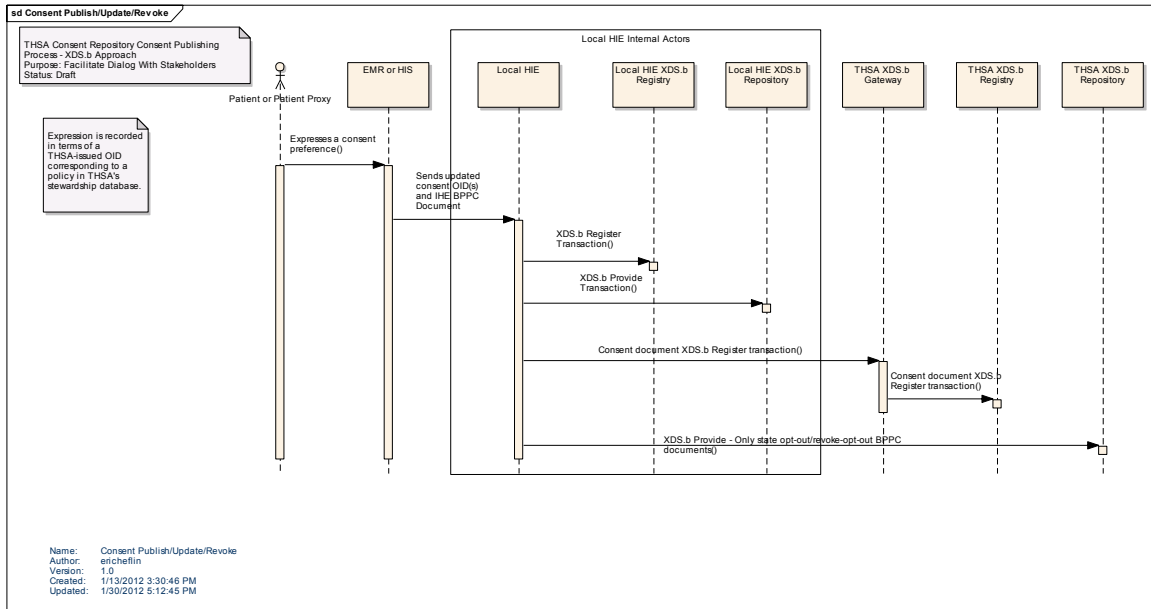
All communications will occur securely.

All data will be stored securely (using encryption).

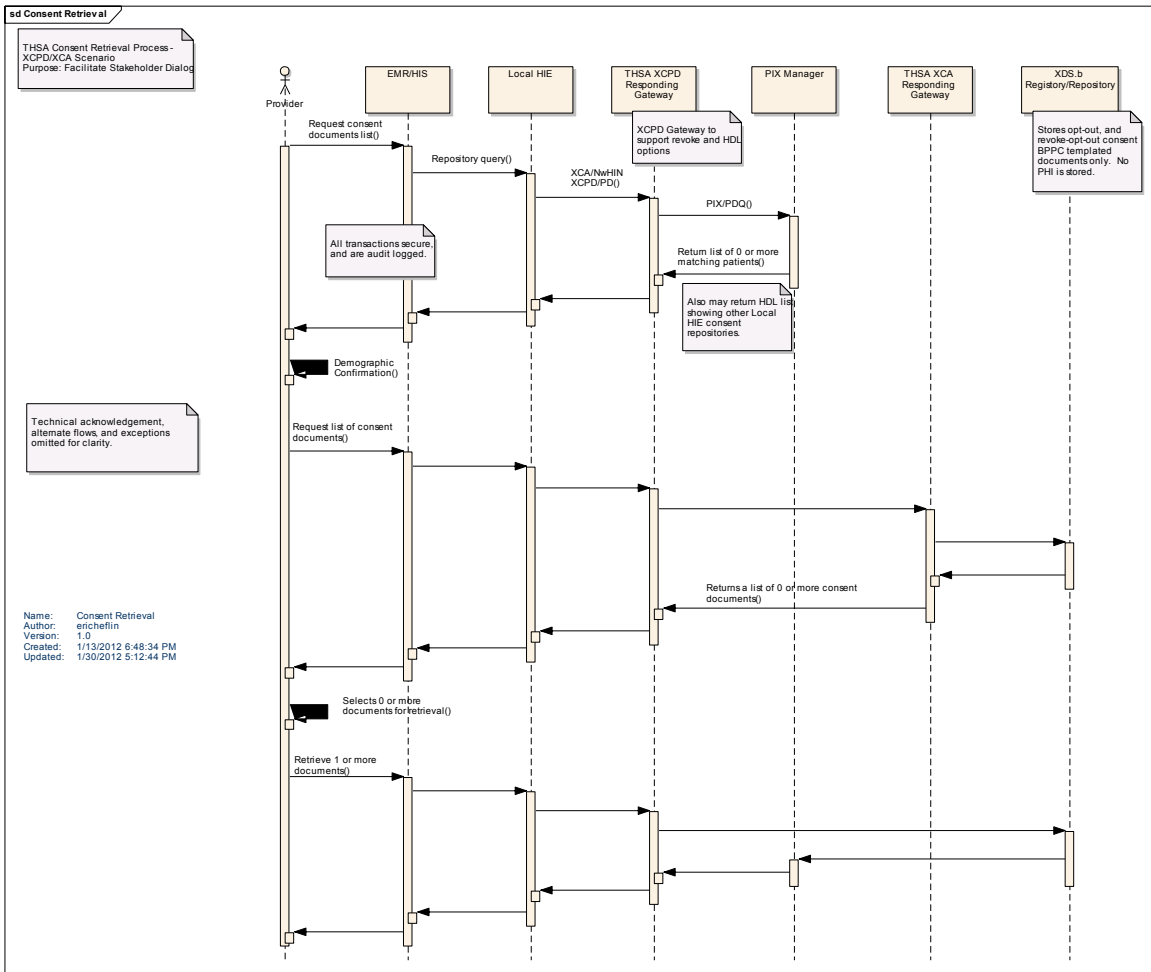
Consent documents would only be stored in the state consent service if the document does not contain PHI.

If a given consent document contains PHI, then the state consent service will index the patient and document, but will not store the consent document. Instead, a “pointer” or reference to the actual consent document will be indicated in the state consent service. This pointer will simply indicate that some type of consent document exists at a Local HIE for a given patient, and that the service consumer must access the consent document directly from the Local HIE.

Each Local HIE must send the consent expression to the state consent service only if the expression impacts exchange between HIEs. If the consent expression doesn't impact HIE-to-HIE exchange, then the consent document does not need to be sent to the state consent service.



The second use case is the logical follow-up to the first use case. Specifically, it shows one method to retrieve a state consent expression document.



XDS Mechanics/Metadata

XDS.b has metadata and objects beyond just the document itself. For example, XDS.b (referenced as XDS) can have both a registry and a repository. The registry stores an index to documents and associated objects, and the repository stores the actual documents. In addition, XDS has the concept of a folder (similar to a file system), submission sets (which group documents), associations (which can link documents) and document typeCode, classCode, confidentialityCode, version, and availabilityStatus. The THSA is not aware of standards describing how these concepts and data can be utilized for a consent repository and, thus, is seeking guidance from Selected Vendor(s) for appropriate methods through which to employ these concepts. For example, the THSA is seeking to work with the state's Local HIEs and Selected Vendor(s) to determine the life cycle of consent documents (version, availabilityStatus, associations, etc.).

Enabling Local HIEs

The State of Texas supports local autonomy, to the extent possible, for Local HIEs. The anticipated and realized result of this selected policy approach is that most of the state's Local HIEs have different consent policies in terms of defaults (opt-in, opt-out, etc.), purposes of use (treatment only, analytics, etc.), and use of various types of policy acknowledgements (consent form, consent plus authorization, authorization form only, etc.). The THSA's approach to state-level consent management fully supports that approach.

The state's Local HIEs will have an option, after the deployment of the state consent services, to continue to manage their patient policy acknowledgements in their current manner or to leverage the state consent services for their local policy acknowledgements. If a Local HIE is, for example, employing a course granularity "opt-in" or "opt-out" patient consent for HIE-to-HIE exchange, then the Local HIE may elect to store that acknowledgement 1) only at the Local HIE level; 2) only at the state level, or 3) in both locations. The THSA supports all three approaches and only imposes minimal restrictions that the Local HIE must: 1) push the acknowledgement or acknowledgement placeholder notification to the state if the document acknowledge will impact exchange across HIE boundaries; and 2) search and retrieve any patient acknowledgements or acknowledgement placeholders at the state level before making an HIE-to-HIE access control decision to ensure any patient preferences are honored. In other words, the Local HIEs will only need to inform or consult the state consent services for issues that impact exchange across HIE boundaries. Local policy applies for exchange within each individual HIE.

The Future

The THSA has taken into account several likely future uses of the consent management services and has attempted to provide a solution that is "future-proof" as much as is reasonable viable. The following are three areas we are specifically tracking closely.

Consumer Preferences

"Opt-in/opt-out" is a single attribute for a broader category of consumer consent preferences which include other settings such as DNR orders, Living Wills, Medical Proxies, Living Wills, Advanced Directives, ethnic preferences, religious preferences, scope of expression, etc. The now inactive federal Health Information Technology Standards Panel (HITSP) Security, Privacy and Infrastructure Workgroup created a draft requirements document that was designed to address the issues related to the next generation of consumer (patient) preferences. A copy of this never-published paper may be obtained from the THSA upon request and provides insight into where the industry may be headed.

Data Segmentation

The HL7 standards body is addressing the closely related issue of data segmentation in its workgroup of the same name. We are monitoring this workgroup and as their efforts result in viable approaches, we will consider adopting them.

Rules-Based and Attribute-Based Preferences

Another consideration taken into account by the THSA in regard to the design of the state consent services system is that rules-based preferences, such as those using OASIS XACML, and/or attribute-based preferences, such as those using OASIS XSPA, may become necessary and widely supported in the future. The system's current design is expected to be able to accommodate XACML-based and XSPA-based preference expressions with minimal changes (mostly related to the business operating rule, and to several new metadata values).

Summary

Currently, Local HIEs in Texas employ a variety of locally developed and supported approaches to patient electronic health information exchange consent. The THSA's goal in moving forward with development and deployment of state-level consent architecture is to create a mechanism for patient consent management to enable exchange of information beyond the boundaries of each Local HIE. The THSA anticipates that leveraging existing technologies, such as XDS, XCA, Direct, and others, will allow for a cost-effective and efficient solution that enables support of varying local approaches to patient consent preferences statewide.

In developing its state-level consent services architecture, the THSA is also interested in considering alternate approaches and encourages vendors to offer recommendations regarding such approaches.