

Integrating the Healthcare Enterprise



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**IHE IT Infrastructure
Technical Framework**

Volume 4

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10

National Extensions

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Contents

	1	Introduction	3
30	1.1	Introduction to IHE	3
	1.2	Intended Audience	3
	1.3	Overview of Volume 4.....	3
	1.4	Comment Process.....	4
	1.5	Copyright Licenses	4
35	1.5.1	Copyright of Base Standards	4
	1.6	Trademark	4
	1.7	Disclaimer Regarding Patent Rights.....	4
	1.8	History of Document Changes.....	5
	2	Overview of National Extensions to the Technical Framework	6
40	2.1	Scope of National Extensions	6
	2.2	Process for Developing National Extensions.....	6
	2.3	Process for Proposing Revisions to the Technical Framework	7
	3	National Extensions for IHE USA	8
	3.1	Data Segmentation for Privacy (DS4P)	8
45	3.1.1	DS4P Document Content	10
	3.1.2	DS4P DocumentEntry	10
	3.1.2.1	DS4P DocumentEntry.confidentialityCode	10
	3.1.2.1.1	DS4P Confidentiality Security Classification Label	10
	3.1.2.1.2	DS4P Sensitivity Security Classification Label	10
50	3.1.2.1.3	DS4P Handling Caveats Security Category	10
	3.1.2.2	DS4P DocumentEntry.healthcareFacilityTypeCode	11
	3.1.2.3	DS4P DocumentEntry.practiceSettingCode.....	11
	3.1.2.4	DS4P DocumentEntry.typeCode	12
	3.1.3	DS4P SubmissionSet.....	12
55	3.1.3.1	DS4P SubmissionSet.intendedRecipient	12
	3.1.3.2	DS4P SubmissionSet.author.....	12
		Appendices.....	13
		Glossary	14

60 **1 Introduction**

This document, Volume 4, of the IHE IT Infrastructure (ITI) Technical Framework describes the country-specific extensions to ITI transactions and content modules.

1.1 Introduction to IHE

65 Integrating the Healthcare Enterprise (IHE) is an international initiative to promote the use of standards to achieve interoperability among health information technology (HIT) systems and effective use of electronic health records (EHRs). IHE provides a forum for care providers, HIT experts and other stakeholders in several clinical and operational domains to reach consensus on standards-based solutions to critical interoperability issues.

70 The primary output of IHE is system implementation guides, called IHE Profiles. IHE publishes each profile through a well-defined process of public review and trial implementation and gathers profiles that have reached final text status into an IHE Technical Framework, of which this volume is a part.

75 For more general information regarding IHE, refer to www.ihe.net. It is strongly recommended that, prior to reading this volume, readers familiarize themselves with the concepts defined in the *[IHE Technical Frameworks General Introduction](#)*.

1.2 Intended Audience

The intended audience of IHE Technical Frameworks Volume 4 is:

- Those interested in integrating healthcare information systems and workflows on an international or country basis
- 80 • IT departments of healthcare institutions
- Technical staff of vendors participating in the IHE initiative
- Experts involved in standards development

1.3 Overview of Volume 4

85 This volume contains information about the scope of national extensions to the transactions and/or content modules defined in the IHE IT Infrastructure (ITI) Technical Framework. Section 2 describes the permitted scope of national extensions and the process by which national IHE initiatives can propose such extensions for approval by the IHE Technical Committee and documentation in the IHE Technical Framework. Section 3 and beyond describe the national extensions, per country, which have been defined. Examples include specific transaction or
90 content changes for IHE Canada, IHE Germany, IHE Japan, for example..

1.4 Comment Process

IHE International welcomes comments on this document and the IHE initiative. They can be submitted by sending an email to the co-chairs and secretary of the IT Infrastructure domain committees. See http://ihe.net/ITI_Public_Comments.

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105 include materials owned or controlled by other parties, licenses to use those products are beyond the scope of this IHE document and would have to be obtained from that other party.

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135 **1.8 History of Document Changes**

Date	Document Revision	Change Summary
2014-09-23	11.0	Newly created Volume 4 - Create and add US Data Segmentation for Privacy (DS4P)

2 Overview of National Extensions to the Technical Framework

140 The goal of IHE is to promote implementation of standards-based solutions to improve workflow and access to information in support of optimal patient care. To that end, IHE encourages the development of IHE National Deployment Committees to address issues specific to local health systems, policies and traditions of care. The role of these organizations and information about how they are formed is available at http://ihe.net/Governance/#National_Deployment.

145 2.1 Scope of National Extensions

National extensions to the IHE Technical Framework are allowed in order to address specific local healthcare needs and promote the implementation of the IHE Technical Frameworks. They may add (though not relax) requirements that apply to the Technical Framework generally or to specific transactions, actors and integration profiles. Some examples of appropriate national extensions are:

- Require support of character sets and national languages
- Provide translation of IHE concepts or data fields from English into other national languages
- 155 • Extensions of patient or provider information to reflect policies regarding privacy and confidentiality
- Changes to institutional information and financial transactions to conform to national health system payment structures and support specific local care practices

All national extensions shall include concise descriptions of the local need they are intended to address. They shall identify the precise transactions, actors, integration profiles and sections of the Technical Framework to which they apply. And they must provide technical detail equivalent to that contained in the Technical Framework in describing the nature of the extension.

2.2 Process for Developing National Extensions

National extension documents are to be developed, approved and incorporated in the Technical Framework in coordination with the IHE Technical Committee and its annual cycle of activities in publishing and maintaining the Technical Framework. The first prerequisite for developing a national extension document is to establish a national IHE initiative and make information regarding its composition and activities available to other IHE initiatives.

170 Established IHE national initiatives may draft a document describing potential national extensions containing the general information outlined above. This draft document is submitted to the IHE Technical Committee for review and comment. Based on discussion with the Technical Committee, they prepare and submit finalized version of the document in appropriate format for incorporation into the Technical Framework. The publication of National Extensions is to be coordinated with the annual publication cycle of other Technical Framework documents in the relevant domain.

175 **2.3 Process for Proposing Revisions to the Technical Framework**

In addition to developing national extension documents to be incorporated in the Technical Framework, national IHE initiatives may also propose revisions to the global Technical Framework. These may take the form of changes to existing transactions, actors or integration profiles or the addition of new ones. Such general changes would be subject to approval by the IHE Technical and Planning Committees.

National extensions that are minor in scope, such as suggestions for clarifications or corrections to documentation, may be submitted throughout the year via the ongoing errata tracking process, called the [Change Proposal Process](#).

185 More substantial revision proposals, such as proposals to add new integration profiles or major country-based extensions, should be submitted directly to the IHE Technical and Planning Committees via the process for submitting new proposals called the [Profile Proposal Process](#).

3 National Extensions for IHE USA

190 The national extensions documented in this section shall be used in conjunction with the definitions of integration profiles, actors and transactions provided in Volumes 1 through 3 of the IHE ITI Technical Framework. This section includes extensions and restrictions to effectively support the regional practice of healthcare in the United States.

This ITI national extension document was authored under the sponsorship and supervision of IHE USA and the IT Infrastructure Technical Committee. Comments should be directed to:

195 [http://www.ihe.net/ITI Public Comments](http://www.ihe.net/ITI_Public_Comments)

3.1 Data Segmentation for Privacy (DS4P)

200 This National Extension shows how to use and interpret the Document Sharing Metadata Profiles (XDS.b, XCA, XDR, XDM, and MHD) in compliance with the requirements identified for Data Segmentation for Privacy (DS4P). Data Segmentation is the privacy and security concept for differentiating between data that are to be handled differently for privacy or security reasons. Data Segmentation for Privacy support in this context is the interoperability constraints to enable documents of various and different privacy and sensitivity to be communicated within a trust framework in a way that the sender can communicate necessary and specific privacy and security attributes and obligations in a way that the recipient can clearly understand them and act properly.

205 This national extension is intended to be used within a trust framework between communicating parties. This trust framework includes policy agreements to use this national extension to communicate segmented sensitive information. For each document that is communicated within this trust framework (PUSH or PULL) the following metadata constraints shall be used to communicate the highest sensitivity of the content as evaluated by the sender. The identified sensitivity level is then enforced by the recipient. Trust enforcement is expected to be defined and managed within that trust framework.

215 This USA National Extension addresses methods for sharing of segmented documents containing personally identifiable information (PII) as may be permitted by privacy policies or regulations. The privacy policies on which this National Extension is based do not explicitly address the clinical implications of giving patients control over the disclosure of their sensitive records. Standards development organizations are focused on the development of technical infrastructure specifications and remain agnostic on the appropriateness of a privacy policy.

220 Privacy policies are defined as limits on disclosure and use. Disclosure and use restrictions may originate from a patient, a service provider, or from jurisdictions where healthcare is delivered. Implementations should be prepared to extend functionality based on state, region, and local policies.

225 This USA National Extension is the result of a proposal from the US Department of Health and Human Services, Office of the National Coordinator for Health IT (ONC) to develop guidance for implementation of Data Segmentation Techniques, including RESTful patterns as defined in

230 the MHD Profile, using the standards, building blocks and principles documented in the Use Cases developed by the S&I DS4P stakeholder community, and the [NwHIN SOAP/Exchange version of the S&I DS4P Implementation Guide](#). Furthermore, this specification draws upon and cites specific instances of U.S. law such as 42 CFR Part 2, 38 CFR Part 1, etc. These specific references are intended to profile a specific set of users operating under realm specific law and goals. Nothing in this supplement is intended to prevent adoption or customization to meet the needs of other realms.

235 This USA National Extension is based on artifacts and the findings of [pilot implementations of the Data Segmentation for Privacy \(DS4P\) S&I Framework Initiative](#), specifically on the Use Cases developed by the stakeholder community, and the [NwHIN SOAP/Exchange version of the S&I DS4P Implementation Guide](#). Additionally, content from the HL7 DS4P Profiles (HL7_IG_DS4P_R1_CH1_CONTENT_N2_2014JAN, HL7_IG_DS4P_R1_CH2_DIRECT_N2_2014JAN, and HL7_IG_DS4P_R1_CH3_EXCHANGE_N2_2014JAN) which in turn reference IHE XDS are noted as important companion documents. For a detailed description of the project, refer to the S&I Initiative DS4P Project Executive Summary found at <http://wiki.siframework.org/Data+Segmentation+for+Privacy+Homepage>.

240 This USA National Extension defines constraints according to the requirements captured in the [Use Cases developed](#) by the Data Segmentation for Privacy (DS4P) S&I Framework Initiative stakeholder community and additional requirements that were identified by [pilot projects engaged](#) in validating the implementation guidance developed by the DS4P S&I Framework Initiative.

250 Conformance to the Document Sharing Profiles (XDS.b, XDR, XDM, XCA, and MHD) is expected with the following additional constraints based on privacy policies related to the type of document and the context of the exchange (requesting user, patient, consent, document, facility, purpose, communications mechanism, etc.).

- Document Entry constraints are given in Section 3.1.2 below. The constraints include:
 - Security tags (confidentialityCode) constraints
 - 255 • indicate the Confidentiality Level specified by using the designated HL7 Confidentiality vocabulary
 - indicate the Handling Caveats for Obligation Policy using a designated Obligation Policy vocabulary
 - indicate the Handling Caveats for Purpose of Use using a designated Purpose of Use vocabulary
 - 260 • indicate Handling Caveats for Refrain Policy using a designated Refrain Policy vocabulary
 - indicate the Authoring healthcare facility type using a designated restricted healthcare facility type vocabulary

- 265
- indicate the Document practice setting type using a designated restricted practice setting vocabulary
 - indicate the Low-level classification of the document (typeCode) using a designated restricted type code vocabulary
- 270
- SubmissionSet constraints are given in the Section 3.1.3 below. The constraints include:
 - Indicated as necessary the Targeted intended recipient (intendedRecipient)
 - Indicate the Submission set creator

3.1.1 DS4P Document Content

Any CDA document SHOULD comply with the CDA constraints defined in the HL7 CDA Privacy Segmented Document template (templateId: 2.16.840.1.113883.3.3251.1.1)

Other content types MAY be carried.

275 3.1.2 DS4P DocumentEntry

The following constraints apply to all documents in the submissionSet.

All the designated vocabulary and value sets are defined by HL7.

3.1.2.1 DS4P DocumentEntry.confidentialityCode

280 The confidentialityCode metadata SHALL use the “HL7 Healthcare Privacy and Security Classification System (HCS)” as defined in ITI TF-3:4.2.3.2.5

3.1.2.1.1 DS4P Confidentiality Security Classification Label

285 The confidentialityCode element SHALL contain exactly one value from the codesystem 2.16.840.1.113883.5.25 (i.e., U, L, M, N, R, or V) (aka, <http://hl7.org/implement/standards/fhir/v3/Confidentiality/index.html>), to indicate the Confidentiality coding of the content.

The confidentialityCode may also contain other values from other codesystems for which Sections 3.1.2.1.2 and 3.1.2.1.3 below are two examples.

The value represents the most restrictive content in the identified document (aka, High water mark).

290 3.1.2.1.2 DS4P Sensitivity Security Classification Label

The confidentialityCode SHOULD NOT contain a sensitivity indicator unless the trust framework policies indicate otherwise.

3.1.2.1.3 DS4P Handling Caveats Security Category

295 The confidentialityCode element SHALL contain any Obligation Handling Caveats deemed necessary.

If present, the Obligation values SHALL be selected from the ValueSet

HL7 ObligationPolicyCode 2.16.840.1.113883.1.11.20445

Also found at <http://hl7.org/implement/standards/fhir/v3/vs/ObligationPolicy/index.html>

If present, the Purpose Of Use values SHALL be selected from the ValueSet

300 HL7 PurposeOfUse 2.16.840.1.113883.1.11.20448

Also found at <http://hl7.org/implement/standards/fhir/v3/vs/PurposeOfUse/index.html>

If present, the Refrain Policy values SHALL be selected from the ValueSet

HL7 RefrainPolicy 2.16.840.1.113883.1.11.20446

Also found at <http://hl7.org/implement/standards/fhir/v3/vs/RefrainPolicy/index.html>

305 **3.1.2.2 DS4P DocumentEntry.healthcareFacilityTypeCode**

The healthcareFacilityTypeCode element contains an indicator of the type of facility that authored the document. The ValueSet designated is restricted to the subset of practice setting codes that will not disclose details about the healthcare facility that may be protected in a specific affinity domain, directed exchange, Health Information Exchange, etc. The HL7
310 RestrictedHealthcareFacilityTypeCode ValueSet meets this definition and is designated for this purpose.

The healthcareFacilityTypeCode element's value SHALL be selected from the ValueSet

HL7 RestrictedHealthcareFacilityTypeCode 2.16.840.1.113883.3.3251.3.2.1

315 This HL7 ValueSet is a dynamic ValueSet. An HL7 'dynamic' ValueSet is one that can change over time to adjust to changing policy landscapes, but is a managed ValueSet.

3.1.2.3 DS4P DocumentEntry.practiceSettingCode

The practiceSettingCode element contains an indicator of the type of practice setting. The ValueSet designated is restricted to the subset of practice setting codes that will not disclose details about the practice that may be protected in a specific affinity domain, directed exchange,
320 Health Information Exchange, etc. The HL7 RestrictedPracticeSettingCode ValueSet meets this definition and is designated for this purpose. The ValueSet is derived from SNOMED-CT codes in a way consistent with prevailing privacy policies.

The practiceSettingCode element's value SHALL be selected from the ValueSet

RestrictedPracticeSettingCode 2.16.840.1.113883.3.3251.3.2.2

325 This HL7 ValueSet is a dynamic ValueSet. An HL7 'dynamic' ValueSet is one that can change over time to adjust to changing policy landscapes, but is a managed ValueSet.

3.1.2.4 DS4P DocumentEntry.typeCode

330 The typeCode element identifies the type of document. The ValueSet designated avoids disclosing protected information. The HL7 RestrictedTypeCode ValueSet meets this definition and is designated for this purpose.

The typeCode element's value SHALL be selected from the ValueSet

RestrictedTypeCode 2.16.840.1.113883.3.3251.3.2.3

This HL7 ValueSet is a dynamic ValueSet. An HL7 'dynamic' ValueSet is one that can change over time to adjust to changing policy landscapes, but is a managed ValueSet.

3.1.3 DS4P SubmissionSet

The following constraints apply to the submissionSet containing the document entries

3.1.3.1 DS4P SubmissionSet.intendedRecipient

340 The intended recipient element's value MAY contain the intended recipient. When the exchange requires an intended recipient constraint, this element SHALL be populated. This element SHALL contain the e-mail address of that intended recipient unless the trust framework identifies an alternative encoding that is acceptable.

3.1.3.2 DS4P SubmissionSet.author

The Submission Set Author element's value SHALL contain at least the author of the submission set.

345 This element SHALL contain the e-mail address of the author of the submission set unless the trust framework identifies an alternative encoding that is acceptable.

The recipient utilizes the SubmissionSet author as the indicator of the sender for PUSH transactions, and as the provenance identifier of the submission. This information may be used by the recipient in policy decisions and enforcement.

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Appendices

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Glossary

360 The IHE Glossary can be found as an appendix to the *IHE Technical Frameworks General Introduction* at http://ihe.net/TF_Intro_Appendices.