



May 1, 2015

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National Coordinator for Health Information Technology
Office of the National Coordinator for Health IT
200 Independence Avenue S.W.
Washington, D.C. 20201

Dear Dr. DeSalvo,

NextGen Healthcare appreciates the opportunity to respond to the ONC's draft *2015 Interoperability Standards Advisory*. As an EHR vendor with clients from over 4,000 healthcare organizations representing more than 40,000 providers, NextGen Healthcare shares the ONC's commitment to a connected healthcare system and to using the best available standards and implementation specifications to achieve this goal.

We join our colleagues in the EHR Association (EHRA) in welcoming the ONC's creation of the draft interoperability Standards Advisory. We actively participated in the drafting of the EHRA's public comments to the Standards Advisory and generally endorse the EHRA's comments, which inform our own public comments herein.

While we agree with most of ONC's recommendations for evaluating "best available standards", we submit our detailed comments with suggested improvements in the following areas:

1. ONC should further refine and clarify its intended use of the Interoperability Standard Advisory to avoid misinterpretations, especially in relation to regulation and the Interoperability Roadmap;
2. ONC should work with industry to define explicit principles to ensure stability/sustainability, and to promote long-term backward compatibility, such as:
 - a. Criteria for ongoing introduction/removal of standards from the advisory relevant to maturity of standards, availability of test tools;
 - b. A process for ensuring stability and backward compatibility of standards in subsequent releases of the Advisory;
3. Identification of appropriate body to conduct the comment resolution (we share the EHRA's concern that the "HIT Standards Committee or one of its sub-groups" is not the right body);
4. Greater consistency in placing standards and Implementation Specifications in the appropriate column;
5. Identification of another standard and Implementation Specification in the case of Publish and Subscribe, along with the suggestion of Implementation Guides for Imaging Exchange;
6. Inclusion in the 2015 Standards Advisory of only C-CDA R1.1, given the early stage of deployment of this standard and the still unresolved compatibility issues between C-CDA R1.1 and the proposed C-CDA R2.0.

Thank you for this opportunity to share our feedback and please find our detailed comments below.

Yours truly,

A handwritten signature in cursive script that reads "Sarah Corley MD, FACP".

Sarah Corley, M.D., FACP
Chief Medical Officer

NextGen Healthcare Comments on Draft 2015 Standards Advisory

1. [General] What other characteristics should be considered for including best available standards and implementation specifications in this list?

The Purpose of the Advisory is not entirely clear. The Executive Summary states two purposes:

“...provide the industry with a single, public list of the standards and implementation specifications that can best be used to achieve a specific clinical health information interoperability purpose.”

- **NextGen Healthcare Comment:** The judgment for “best” is ultimately that of ONC at a point in time (with input from a public consultation and review by the HIT Standards Committee). Nowhere is there a consideration for the expected stability/sustainability of the selection made over time. This consideration is critical as interoperability progresses only if stability and backward compatibility are ensured. We suggest that such a “policy commitment” should be added.

“...prompts dialogue, debate, and consensus among industry stakeholders when more than one standard or implementation specification could be listed as the best available.”

- **NextGen Healthcare Comment:** The dialogue is needed not only to arbitrate cases where alternative standards or implementation specifications exist, but equally about the criteria for introduction/removal from the Advisory (maturity, availability of test tools, piloting use, etc.). This second statement needs to be broadened with this point.
- **NextGen Healthcare Comment:** Although not in the executive summary, as stated in the body of the document, the present ONC intent is that the judgment for “best” be ultimately that of (1) ONC with input from and (2) a review by the HIT Standards Committee, and two (3) public consultations. (1) and (3) are appropriate, but NextGen Healthcare believes that the “HIT Standards Committee or one of its sub-groups” is not the right body to conduct the comment resolution. We believe that a dedicated committee for this task would be more effective and provide more technical rigor.
 - A broader and more expert representation is needed, as it is not a regulatory action.
 - Avoid confusion with the regulatory process
 - It is important to get input from the standards development organizations (SDOs) as sources of standards and implementation specifications.
 - Establish an explicit process to measure actual use.
 - Include other key stakeholders, including NCVHS for administrative standards and associations representing developers and providers.

The relationship with the regulatory process is not entirely clear. It is stated on page 4:

“While the standards and implementation specifications included in an advisory may also be adopted in regulation (already or in the future), required as part of a testing or certification program, or included as procurement conditions, an advisory is non-regulatory and non-binding in nature. Overall, an advisory is intended to provide clarity, consistency, and predictability for the public regarding ONC’s assessment of

the “best available” standards and implementation specifications for a given clinical health IT interoperability purpose.”

- **NextGen Healthcare Comment:** Non-regulatory and Non-Binding -- We understand that the Advisory is not intended to be an early heads-up about what standards and implementation specifications are intended to be included in certification in the future (although this action may happen, but is in no way assured or required). We suggest clarifications on the potential inferences that could be made or not made about the presence of a standard or implementation specification in relation to the regulatory process would be very helpful to set appropriate expectations.
- **NextGen Healthcare Comment:** The linking of the Interoperability Roadmap evolution process and the Standards Advisory evolution process is not described. It is quite important to decide if the Roadmap drives only the regulatory process and/or also the Standards Advisory. If it is the latter, the annual revision of the Standards Advisory may be out of synch with the Interoperability Roadmap for a given time period.

The Standards Advisory is proposed as a “point-in-time” assessment that is updated yearly.

- **NextGen Healthcare Comment:** The value of a snapshot is closely linked to its predictability. In healthcare, the deployment of connected IT solutions frequently takes several years across a wide range of distinct organizations to not only introduce the technology, but also align and update processes. When implementing best available standards, a period of stability is essential to remain interoperable for many years in the future to ensure that adherence to the Standards Advisory is a worthy investment.
- **NextGen Healthcare Comment:** We support the concept of an ONC statement expressing its perception of the current state of the “industry” or “market” for the best available standards/implementation specifications evaluated during the year prior to publication of the Standards Advisory. An annual update is appropriate, but many elements should remain unchanged if we collectively expect to improve interoperability and avoid constant change and churn.
- **NextGen Healthcare Comment:** A clear set of criteria associated with any recommendation for a standard/implementation specification is lacking in this document but required for its recommendations to be as credible as possible:
 - Standards and implementation specifications need to be stable and DSTUs should be avoided.
 - An active maintenance process must be in place.
 - Robust testing tools need to be available.
 - Some production piloting / early deployments need to have been performed.
- **NextGen Healthcare Comment:** In the tradeoff between the widest adopted standard and the better standard, one should generally prefer the widest adopted. This consideration should be part of the criteria.
- **NextGen Healthcare Comment:** Statements in the Standards Advisory about intent to consider adoption of a standard/implementation specification in a future Standards Advisory release may not be of significant value for the implementers. We recommend that the Standards Advisory use such

statements mainly when the standard or implementation guide cannot demonstrate sufficient piloting. Such statements, if made, should have an automatic expiration date of one or two years.

- **NextGen Healthcare Comment:** A standard or implementation specification should have a version number unless the standard or profiling body policy is explicit on ensuring backward compatibility during maintenance (e.g., IHE Profiles in final text status).
- **NextGen Healthcare Comment:** Delayed or non-adoption of a new version of a standard or implementation specification may often be appropriate, for example, to ensure longer term stability of the Standards Advisory. The rationale to adopt new versions of standards should be weighed against the usage impact in terms of upgrade and non-backward/forward compatibility
- **NextGen Healthcare Comment:** NextGen Healthcare suggests that the role of federal agencies and their choice of standards and implementation guides should not be given priority over other uses. Furthermore, DSTU or similar specifications should only be allowed and versioned for a temporary period with a one year expiration date, if no “normative” alternative exists.
- **NextGen Healthcare Comment:** We suggest adding an explicit list of criteria used to determine “best available” going forward with future versions of the Standards Advisory:
 - *Standards and Implementation Specifications in the lists were included as the “best available” based on the following characteristics:*
 - *Standards along with the needed Implementation Specifications have reached a “normative state (or equivalent labelled).*
 - *They have an active maintenance process in place.*
 - *They have testing tools covering the standards along with the needed implementation specifications that have been used by at least six software developers.*
 - *They have undergone at least two distinct pilot deployments with actual clinical usage for six months.*
 - *And they are explicitly labelled as “ready for national use” in the Standards Advisory.*
 - *Standards, along with the needed implementation specifications with an explicit version, have reached a “draft standard for trial use (or equivalent label) and there is no known alternative or available equivalent to that standard or implementation specification for a given purpose. They:*
 - *Have an active maintenance process in place;*
 - *Have testing tools covering the Standards along with the needed implementation specifications that have been used by at least six software developers;*
 - *Include an explicit label as “good enough for initial pilot only” in the Standards Advisory. Users are cautioned that non-backward updates may be required following pilot and progression as “normative or equivalent.”*
 - *A draft for trial use implementation specification is more acceptable when the underlying standards are normative/final.*
 - *When the Standards Advisory is updated and a standard and/or implementation specification that has reached a “normative state (or equivalent label)” is updated, backward and forward compatibility should be considered:*
 - *The two are incompatible and will coexist in the Advisory for an explicit period of time (at least a year) to ensure migration. A bridging solution between the two versions will be*

identified and piloted. In some cases (e.g., documents), there are situations where sunseting an older version may not be possible.

- *There is backward and forward compatibility between the two versions and will coexist in the Advisory for an explicit period of time (at least a year) to ensure migration.*
- *Testing tools for compatibility should be available.*

In either case, the benefits that make the update desirable will be explicitly documented.

2. [General] Besides the four standards categories included in this advisory, are there other overall standards categories that should be included?

- **NextGen Healthcare Comment:** The proposed categories are appropriate, but we NextGen Healthcare suggests a change in sequence as follows to improve flow and understanding:
 - Vocabulary
 - Data Structure
 - Services
 - Transport

- **NextGen Healthcare Comment:** The Standards Advisory would benefit from establishing a relationship with real-world use cases (e.g., as a matrix). This would be a more meaningful entry point and navigation aid into the categories.

Use Case(s)

Category

Purpose + Standard/Implementation Specification

- **NextGen Healthcare Comment:** Not all combinations across categories make sense or are not designed into the standards/implementation specifications. For example:
 - C-CDA specifies immunization value sets, so only that value set from this implementation specification may be used within C-CDA data structure. The transport used in XCA is specified within the IHE XCA Profile. It is consistent with the SOAP transport specified the transport category. No other transport is designed for use with the XCA profile. The split in categories is illustrative and should not be taken strictly, or some unintended combinations may emerge, making interoperability unnecessarily complex.

- **NextGen Healthcare Comment:** We recommend that ONC refines the section “Distinguishing between a Standard and an Implementation Specification” as a number of implementation specifications (actually most of them) are not based on a single standard (e.g., C-CDA is not based on CDA alone but also on several vocabularies such as LOINC, SNOMED, etc.). For example, ONC should use the phrase “one or more standards” instead of referring to “standard” in the singular.

3. [General] For sections I through IV, what “purposes” are missing? Please identify the standards or implementations specifications you believe should be identified as the best available for each additional purpose(s) suggested and why.

- **NextGen Healthcare Comment:** While not concerned with the Sexual Orientation and Gender Identity value sets per se, we need to have clarity on the purpose that they serve (i.e., what measures are they

being used for) and on privacy considerations. This is a case where the Standards Advisory needs to provide a linkage to use cases to clarify if and when certain elements need to be used or not.

4. [General] For sections I through IV, is a standard or implementation specification missing that should either be included alongside another standard or implementation specification already associated with a purpose?

- NextGen Healthcare Comment:** NextGen Healthcare is concerned with the smoking status values, as they do not appear to be harmonized with quality measures or Joint Commission reporting requirements.
- NextGen Healthcare Comment:** NextGen Healthcare suggests clarification regarding medication allergies. We feel strongly that the allergy section should be used for medication allergies only and that all other allergies be should be relegated to problem or diagnosis areas. This makes it easier to focus on generating relevant alerts only.
- NextGen Healthcare Comment:** Imaging Implementation Specifications are missing in Section IV. XDS-I and its counterpart in cross-community are widely implemented and used in several regional projects around the world (Canada, France, Netherlands, Austria, Denmark, Finland, Italy, Japan, and others). They are services built upon the “Query for documents outside a specific health information exchange domain” and the “Query for documents within a specific health information exchange domain” in the same category. Including these standards helps promote further adoption of imaging interoperability while not referenced by specific programs at this time.

Image exchange	Digital Imaging and Communications in Medicine (DICOM)	<p>within a specific health information exchange domain IHE-XDS-I (Cross-enterprise imaging information sharing)</p> <p>outside a specific health information exchange domain IHE-XCA-I (Cross-community imaging information sharing)</p>
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- NextGen Healthcare Comment:** There is no need for Imaging Implementation Guides in Section II, as those are specified by DICOM in the form of image technology specific “SOP Classes”. We suggest including a note in the last column.

Images	Digital Imaging and Communications in Medicine (DICOM)	<p>Use Image Acquisition Technology Specific Service/Object Pairs (SOP) Classes specified by DICOM.</p>
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- NextGen Healthcare Comment:** The Clinical Decision Support Knowledge Artifact implementation guide needs to move to the next column, while the standard that it is based on, needs to be put into the first column (it should be HL7 V3).
- NextGen Healthcare Comment:** For the Lab Orders, Results, Public Health electronic laboratory reporting, and electronic Directory of Services, a version should be listed in the standards column (e.g., “V2.5.1 and higher”) as the implementation guides use V2.5.1 as the base and then pre-adopt for select capabilities all the way up to V2.8.2. The Advisory should raise the point that implementers need to address the choice of profiles within the Implementation Guide to ensure interoperability.
- NextGen Healthcare Comment:** For the NWHIN specifications, IHE XDR, XDS, XCA, XCPD, FHIR, HPD, and CSD need to be moved, where relevant, to implementation specifications and document the underlying standards. Proposed changes are recorded below:

Purpose (listed alphabetically)	Standard(s)	Implementation Specification(s)
An unsolicited “push” of clinical health information to a known destination	[R] Applicability Statement for Secure Health Transport (“Direct”)	<ul style="list-style-type: none"> [R] XDR and XDM for Direct Messaging Specification [R] IG for Direct Edge Protocols IG for Delivery Notification in Direct
	[R] SOAP-Based Secure Transport Requirements Traceability Matrix (RTM) version 1.0 specification.	NwHIN Specification: Messaging Platform
	SOAP V2 and OASIS eb????? Registry Services 3.0	IHE-XDR (Cross-Enterprise Document Reliable Interchange)
	SAML v1.2, XSPA v1.0, WS-I v1.1	NwHIN Specification: Authorization Framework
Query for documents within a specific health information exchange domain	OASIS eb????? Registry Services v3.0	IHE-XDS (Cross-enterprise document sharing)
	HL7 V2.5 HL7 V3	IHE-PIX (Patient Identity Cross-Reference) or IHE-PIXV3 (Patient Identity Cross-Reference-HL7V3)
	HL7 V2.5 HL7 V3	IHE-PDQ (Patient Demographic Query) or IHE-PDQV3 (Patient Demographic Query-HL7V3)
Query for documents outside a specific health	OASIS eb ?????? Registry Services v3.0	IHE-XCA (Cross-Community Access)

Purpose (listed alphabetically)	Standard(s)	Implementation Specification(s)
information exchange domain	HL7 V3	IHE-XCPD (Cross-Community Patient Discovery)
	IHE-XCPD (Cross-Community Patient Discovery)	NwHIN Specification: Patient Discovery
	IHE-XCA (Cross-Community Access)	NwHIN Specification: Query for Documents
		NwHIN Specification: Retrieve Documents
Data element based query for clinical health information	Fast Healthcare Interoperability Resources (FHIR)	(Profiles under development)
Resource location	HTTP 1.1, XQuery 1.0, XForms 1.1 SOAP 1.2, IETF RFC 4791	IHE IT Infrastructure Technical Framework Supplement, Care Services Discovery (CSD), Trial Implementation
Provider directory	ISO 21091, LDAP, DSMLv2.0	IHE IT Infrastructure Technical Framework Supplement, Healthcare Provider Directory (HPD), Trial Implementation

5. [General] For sections I through IV, should any of the standards or implementation specifications listed thus far be removed from this list as the best available? If so, why?

- NextGen Healthcare Comment:** In Category IV, Publish and Subscribe proposed the NwHIN Specification: Health Information Event Messaging Production Specification. There is little deployment of this NwHIN Implementation Specification. This specification was written by a very small group and never gained acceptance. We suggest replacing the NwHIN Implementation Specification with the much more widely used IHE DSUB Profile:

(http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_Suppl_DSUB.pdf) and the following underlying base standards from the OASIS Web Services Notification Family of Standards:

(http://www.oasis-open.org/committees/tc_home.php?wg_abbrev=wsn)

- WS-BaseNotification 1.3 OASIS Standard

(http://docs.oasis-open.org/wsn/wsn-ws_base_notification-1.3-spec-os.pdf)

- WS-BrokeredNotification 1.3 OASIS Standard

(http://docs.oasis-open.org/wsn/wsn-ws_brokered_notification-1.3-spec-os.pdf)

- WS-Topics 1.3 OASIS Standard

(http://docs.oasis-open.org/wsn/wsn-ws_topics-1.3-spec-os.pdf)

Publish and subscribe	WS-BaseNotification 1.3 OASIS Standard 620 WS-BrokeredNotification 1.3 OASIS Standard WS-Topics 1.3 OASIS Standard	<u>IHE IT Infrastructure Technical Framework - Document Subscription Profile – Trial Implementation</u>
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- **NextGen Healthcare Comment:** NextGen Healthcare is concerned with including the Consolidated HL7 Implementation Guide: Data Segmentation for Privacy (DS4P), Release 1 as best available.
 - There is essentially no implementation (only a demonstration).
 - The only portion of DS4P that can be considered for wider deployment, such as 2015 Edition, is the subset of DS4P that was accepted into the IHE ITI US Realm. That is recognized with a specific set of vocabulary to be used as security tags (using confidentiality code element in XDS). These vocabularies have a well-defined meaning and expectation.
 - We believe that there still remains too much variance within this subset– i.e., the vocabulary is not universally understood and although some concepts are well-defined, others are completely unusable. There is a mix of codes that are just flags with other codes that are demands (obligations). This approach makes it unclear as to what should be done with them either on the publication side or the use side. Ultimately, even this subset of DS4P requires further implementation guidance or profiling. We recommend that the Advisory includes no more than the DS4P subset refined by the IHE IT Infrastructure Technical Framework Volume 4 – National Extensions – Section 3.1 Data Segmentation for Privacy (DS4P) (http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Vol4.pdf), noting that piloting is insufficient (see also CFR 42 part response to question 16).

On balance, considering the criteria NextGen Healthcare proposes whether to include a standard or implementation guide or not, NextGen Healthcare suggests removing this guide from the list until further maturation has occurred.

6. [Section I] Should more detailed value sets for race and ethnicity be identified as a standard or implementation specification?

- **NextGen Healthcare Comment:** No, currently identified value sets are appropriate. And the alternative coding systems would create unnecessary complexity. At the more granular level, we recommend that a single value set be agreed upon. Once this is done, the Advisory should be updated.

7. [Section I] Should more traditionally considered “administrative” standards (e.g., ICD-10) be removed from this list because of its focus on clinical health information interoperability purposes?

- **NextGen Healthcare Comment:** No. While SNOMED is best available for a number of areas, including problem lists, the SNOMED – ICD mapping remains a concern, and having clinician-friendly terminology that can be used on displays/reports that maps to SNOMED is desirable. Additionally, we need to resolve alignment on the level of granularity for particular purposes as that seem to vary across providers. On balance, we recommend against removal of ICD until quality measures and financial systems no longer use it, and a clear and robust mapping strategy is available.

8. [Section I] Should “Food allergies” be included as a purpose in this document or is there another approach for allergies that should be represented instead? Are there standards that can be called “best available” for this purpose?

- **NextGen Healthcare Comment:** Food allergies should be included as a purpose in this Advisory, as should other allergies, such as environmental or substance allergies (e.g., Latex). While UNII may support the necessary concepts, it would be more appropriate to suggest that ONC begin work to identify critical value sets for allergies, and begin mapping them to SNOMED CT. Accordingly, we can support allergies using SNOMED CT, with the exception of medication allergies. This approach should also allow tracking the source of the allergy (patient or provider). We recommend keeping the Standards Advisory silent until the above work is done.
- **NextGen Healthcare Comment:** We agree with using SNOMED-CT for Allergen Reactions (the term Allergy Reaction should be replaced by Allergen Reactions) and as indicated earlier. As there can be many aspects and categories of allergen reactions, we suggest this to be clarified and particularly indicate that Allergen Reactions is not limited to medication allergies, but also applies to food and other non-medication allergies.

9. [Section I] Should this purpose category be in this document? Should the International Classification of Functioning, Disability and Health (ICF) be included as a standard? Are there similar standards that should be considered for inclusion?

- **NextGen Healthcare Comment:** No comment.

10. [Section I] Should the MVX code set be included and listed in tandem with CVX codes?

- **NextGen Healthcare Comment:** Yes, it is appropriate to list multiple available standards as best available when neither standard is clearly the best. This would then also indicate the need and opportunity to invite the industry to either harmonize to a single standard, or improve clarity on which use case(s) use which standard.

11. [Section I] Public health stakeholders have noted the utility of NDC codes for inventory management as well as public health reporting when such information is known/recorded during the administration of a vaccine. Should vaccines administered be listed as a separate purpose with NDC as the code set?

- **NextGen Healthcare Comment:** Public health’s need to track vaccine inventory should not interfere with an EHR system’s primary purpose to track and enhance clinical care provided. The latter use is the purpose for which EHRs were originally designed, not inventory management. Vaccine utilization should be managed through other reporting mechanisms (i.e., those reporting mechanisms already existing at the state level).

12. [Section I] Is there a best available standard to represent industry and occupation that should be considered for inclusion in the 2016 Advisory?

- **NextGen Healthcare Comment:** No comment.

13. [Section I] If a preferred or specific value set exists for a specific purpose and the standard adopted for that purpose, should it be listed in the “implementation specification” column or should a new column be added for value sets?

- NextGen Healthcare Comment:** For Section I: Best Available Vocabulary/Code Set/Terminology Standards and Implementation Specifications, the column “Implementation Specification” should contain the value set (and a specific version, if desired), while the standard is the terminology standard from which the value set is derived. For example:

Allergy reactions	SNOMED-CT	<u>Value set is all entries from the Concept “Allergy Reaction”</u>
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or if the value set is fixed:

Allergy reactions	SNOMED-CT version/date.	<u>Value set is all entries from the Concept “Allergy Reaction”</u>
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14. [Section II] Several laboratory related standards for results, ordering, and electronic directory of services (eDOS) are presently being updated within HL7 processes. Should they be considered the best available for next year’s 2016 Advisory once finalized?

- NextGen Healthcare Comment:** The Lab Orders, Results, and Test Compendium versions referenced have not yet been published. For Results and Test Compendium, therefore, the currently published versions are effectively the best currently available. For Orders, the currently published version should not be considered as the best available, as it does not sufficiently match the Results Implementation Guide. The currently published Public Health Reportable Laboratory Results implementation guide is the best available.

15. [Section II] Are there best available standards for the purpose of “Patient preference/consent?” Should the NHIN Access Consent Specification v1.0 and/or IHE BPPC be considered?

- NextGen Healthcare Comment:** The NHIN Access Consent Specification is based on IHE BPPC and extends it with structured consents based on OASIS XACML.
 - The NHIN Access Consent Specification has only been implemented to our knowledge by a single project, thus making it quite specific and we believe not sufficiently piloted at this time
 - The general idea of inserting XACML inside the BPPC body has been used by a few HIEs and in some other countries.
 - The HL7 CDA Consent Directive is a more normative specification, and is managed by a standards organization. However, it not implemented in this specific way.
 - Specifically XACML is a general use policy language. It requires that a use-specific vocabulary is created to express concepts specific to the objects it will protect, the users and roles that it will be accessing, and the workflows in which these actions happen. An Implementation Guide or Profile is needed to define these concepts, and to enable the interoperable use of XACML.

- There is a proposal to do this work in IHE in 2015-2016 coming from vendors and national exchanges that have this experience. Until this is completed, we suggest not listing the NHIN Access Consent Specification.
- As most deployments of the “Query for documents within a specific health information exchange domain” in the category IV Services use BPPC in production today, it is proposed, at this time, that only the IHE BPPC profile be included (http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Vol1.pdf) as the standard and implementation specification.

Patient preference/consent	HL7 CDA Release 2	IHE IT Infrastructure Technical Framework Basic Patient Privacy Consents (BPPC)
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16. [Section II] For the specific purpose of exchanging behavioral health information protected by 42 CFR Part 2, does an alternative standard exist to the DS4P standard?

- **NextGen Healthcare Comment:** No. In addition, we emphasize that the full power of DS4P is unnecessary for behavioral health information. The only component that is necessary is the subset of DS4P that was accepted by IHE ITI into the US National Extension (IHE IT Infrastructure Technical Framework Volume 4 – National Extensions – Section 3.1 Data Segmentation for Privacy (DS4P), http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Vol4.pdf). This subset allows for the tagging of this sensitive information in a way that is appropriate to the use. Specific guidance on exactly what tags must be used, and exactly what behaviors are expected, would be very helpful to the community to assure accurate and proper handling of this data. We suggest adoption of the US Realm subset of DS4P from IHE: IHE IT Infrastructure Technical Framework Volume 4 – National Extensions – Section 3.1 Data Segmentation for Privacy (DS4P) (http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Vol4.pdf).

17. [Section II] For the 2015 list, should both Consolidated CDA® Release 1.1 and 2.0 be included for the “summary care record” purpose or just Release 2.0?

- **NextGen Healthcare Comment:** Given the deployment of C-CDA R1.1, which is still in an early stage, and the timing of the release 2.0 of C-CDA for 2017, NextGen Healthcare recommends inclusion in the 2015 Standards Advisory of only C-CDA R1.1. Indeed, the backward and forward compatibility issues between C-CDA R1.1 and the proposed C-CDA R2.0 are barriers that need to be specified with enough clarity and clearly documented for implementers to ensure a smooth transition. Any remaining issues need to be communicated to the clinicians. Until this need is addressed by HL7 (e.g., with a possible improved release of C-CDA), the inclusion in the advisory of C-CDA R2.0 is not appropriate. We expect that this compatibility issue has to be first resolved in the context of the 2015 edition certification regulation. At this time, the Standards Advisory should only include a “mature C-CDA R2.0”. NextGen Healthcare is available to validate the proposed cutover solution.

18. [Section IV] Should specific HL7 message types be listed? Or would they be applicable to other purposes as well? If so, which ones and why?

- **NextGen Healthcare Comment:** Rather than adding specific HL7 V2 messages in Category IV, we suggest adding in Category III the most common HL7 V2 Message Transport: HL7 Transport Specification - MLLP, Release 2. This will be especially useful for laboratory results and orders. We recognize that other HL7 V2 (e.g. SFTP for batch) and HL7 V3 (MLLP and WS) transport exists and are used in various degrees. It is not clear how the Standards Advisory should address those.