ISA Section Referenced	ISA Line # Referenced	Critical / Substantive / Administrative	Comments
Table of Contents	NA	Critical	PROBLEM: The ONC ISA is recommending an interoperability mapping requirement using SNOMED CT ® and LOINC® integrated in the National Library of Medicine (NLM) Unified Medical Language System (UMLS) Metathesaurus (consisting of nearly 200 different vocabularies). On the other hand, CMS is requiring a separate coding strategy for reimbursement using ICD-10. By ONC requiring a separate mapping strategy for interoperability from CMS reimbursement terminologies, ONC creates a back and forth mapping that is expensive, cumbersome on the business owner, and adds to semantic ambiguity. RECOMMEND: ONC resolve the conflicting reimbursement strategies. Reimbursement and interoperability are using conflicting code sets. Clinical point of care terminologies with concept definitions and defined relationships between concepts preserves meanings and concept names and are essential to achieve the ONC goals of a semantically interoperable healthcare ecosystem without "special effort".
Introduction	NA	Critical	PROBLEM: ONC recommended with the Health Information Technology for Economic and Clinical Health (HITECH)Act and 'Meaningful Use' the federal reimbursement of clinical services based upon Eligible Professional (EP) existing coded strategies that generate revenue Data collection of the nursing contribution to national healthcare quality was omitted because, in 2020, nursing remains in the room rate and is not revenue generating. The ONC continues to obscure the nursing contribution to healthcare quality by omitting nursing point of care terminology. The nursing point of care terminologies in SNOMED CT® and LOINC® mix multiple terminologies without definitions or linking concept relationship and perpetuate the impression that interoperability is a complete framework for clinical information exchange. RECOMMEND: ONC recommend to CMS reimbursement for nursing services to promote interoperability. Incorporate and integrate the use of federally-funded, public domain, U.S. Department of Health and Human Services (HHS) approved, NLM Metathesaurus nursing terminology, the Clinical Care Classification (CCC) System https://careclassification.org/ as an alternative to SNOMED CT® and LOINC®. Enhanced nursing data for interoperability to achieve care goals can subsequently be considered for nursing services reimbursement.
Introduction	NA	Critical	PROBLEM: The ONC recommendation for mapping to the NLM Metathesaurus SNOMED CT® and LOINC® has a substantial, indirect cost. The reference terminology mapping for interoperability adds cost to the electronic health record, requires preparation time to 'clean' and verify data for interoperability and requires human and technical resources to perform mapping with no objective means to validate mapping quality, accuracy, or consistency. Currently, there is no federal reimbursement for interoperability mapping. RECOMMEND: ONC accept all coding strategies for reimbursement as well as point of care terminologies.
Nursing	page 21	Critical	PROBLEM: Appears as if the ISA does not recognize the previous recommendations of other federal standards advisory groups (e.g. American Health Information Committee or Healthcare Information Technology Information Standards Panel (HITSP)) who have developed and published standards in these areas. The ISA terminologies referenced have no framework or definitions with which to structure nursing concepts for interoperability. SNOMED CT® and LOINC® specifications proposed for Clinical Nursing Assessments, p. 21; Nursing Interventions, p. 21; and Outcomes for Nursing, p. 22 and Patient Problems for Nursing, p. 22; Patient Clinical "Problems"(i.e. conditions), p. 23 do not follow the nursing professional information model or framework for care data. RECOMMEND: Incorporate and integrate the use of federally-funded, public domain, U.S. Department of Health and Human Services (HHS) approved, NLM Metathesaurus nursing terminology, the Clinical Care Classification (CCC) System https://careclassification.org/ as an alternative to SNOMED CT® and LOINC®. Enhanced nursing data for interoperability to achieve care goals can subsequently be considered for nursing services reimbursement.
Section II: Content/Structure Standards and Implementation Specifications	Pages 43 - 114	Critical	Critical: For content/structure standards which include "HL7 Implementation Guide for CDA Release 2: Consolidated CDA Templates for Clinical Notes (US Realm) Draft Standard for Trial Use, Release 2.1" as an Implementation Specification, add the "HL7 CDA® R2 IG: C-CDA Templates for Clinical Notes R2.1 **Companion Guide,** Release 2 - US Realm" (https://www.hl7.org/implement/standards/product_brief.cfm?product_id=447) as an Implementation Specification.
Section II: Content/Structure Standards and Implementation Specifications	Pages 43 - 114	Critical	Critical: For content/structure standards which include "HL7 Implementation Guide for CDA Release 2: Consolidated CDA Templates for Clinical Notes (US Realm) Draft Standard for Trial Use, Release 2.1" as an Implementation Specification, add the "Commonwell Health Alliance and Carequality Concise Consolidated CDA: Deploying Encounter Summary CDA Documents with Clinical Notes June 2018" (http://www.commonwellalliance.org/wp-content/uploads/2018/07/Carequality_CommonWell_Improve_C-CDA_06-15-2018_V1.pdf) as an Emerging Implementation Specification.
Patient Dental Encounters	page 0	substantive	There is a current ballot in HL7 to extend the use of diagnosis from within the dental community to the broader medical community and to cross reference SNOMED and SNODENT terms so there is evidence of progress toward dental-medical interoperability (a very positive move) which would lower the adoption level over all but may raise adoption across the community through collaboration and best practice adoption.
Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications/Allergies and Intolerances (p. 2)	page 2	Substantive	Allowing SNOMED CT finding/disorder value sets (and/or CPT value sets) is not advised for recording allergies to substances (whether for foods, environmental substances or medications). The simplest way to document allergic substances is to document using the codes for those substances (i.e. RxNorm codes for medications, SNOMED CT codes for food allergies, environmental allergies, and drug class allergies). Using SNOMED CT findings codes or CPT procedure codes adds a level of indirection and complexity that has the potential to compromise patient safety. SNOMED CT itself will presumably contain links and relationships between the allergy findings and the corresponding allergy substances. But this is not guaranteed to be the case at all times for all substances. Substance codes should be used to record allergies to substances.

Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications/Allergies and Intolerances (p. 2)	page 2	Substantive	Applicable Value Sets and Starter Sets: Adverse Clinical Reaction' value set (OID: 2.16.840.1.113883.3.2074.1.1.30) contains SNOMED CT findings and disorders resulting from reactions to substances. 118927008 Thrombotic disorder (navigational concept) - should SNOMED CT's navigational concepts be allowed in VSAC value sets for Allergic Reactions? Not sure if SNOMED CT intends these to be used in value sets.
Interoperability Needs: Allergy and Intolerances-Medications	page 3	Substantive	Is the intent of the MED-RT to replace the VA NDF-RT and stand as the industry standard? Where does it sit with regard to RxNorm and SNOMEED-CT?
Interoperability Needs: Allergy and Intolerances-Medications	page 3	Substantive	Is there a plan to add an adverse drug reaction standard to provide easily reported and standardized reporting capability on a national level? Any state/locally specific requirements would have to be considered however the benefit of easy access and use could extend the data available to address ADEs in a more comprehensive way than is currently practiced
Clinical Notes	page 4	substantive	Most EHRs support clinical notes-the ongoing challenge is capturing narrative in a meaningful way that communicates the providers through process in the face of the desire to codify data so that it is maching readable and computable. It seems that there is still a tendancy to support codification over narrative and the emmission of codified documention is often non-sensical to the person that wrote it let along the person who is trying to interpret it. As natural language processing matures, and the transformation of medicine from analog to digital progresses, capturing the thought process of the author of clinical notes should become richer-many opportunities for improvement in this area.
Cognitive Status	page 5	substantive	The lack of agreement withing the mental, behavioral and social health community is a barrier to information sharing that would improve provider team members (primary care and so on) with a more comprehensive understanding of a patient's state, teatment successes/failures and a path toward improved outcomes.
Demographics	page 6	substantive	Can a default phone number and e-mail be designated as patients may have several and using their preferred communications channel (default phone first, default e-mail as a back up etc.)?
Dietary	Page 7	substantive	Unable to look at UMLS references-account applied for…it appears that this area of healthcare is being taken seriously and progressing
Dietary and Nutritional Needs-Interoperability Need: Representing Nutrition Assessment, Diagnosis, Interventions and Monitoring/Evaluation: Standard eNCPT	Page 7	substantive	The electronic Nutrition Care Process Terminology (eNCPT) cannot be evaluated for cost due to technical/administrative issues associated with its website for GFE laptop. I believe as a government employee, when a cost is identified for implementating any standard, a reasonable expectation is to easily and readily identify at least a ballpark estimate of cost, even if it's a variable range and not just use the $ sign to indicate cost without further elaboration.
Emergency Medical Services	Page 8	substantive	As a general comment for all products like NEMSIS, is there a review committee or team that can sample documents in use, or a feedback mechanism to capture usability problems or burdensome processes in use for improving the products as well as a process to review the current state of usefulness of the data collected for decision making, patient care, public health or research?
Emergency Medical Services	Page 8	Substantive	Interoperability Need: Representing Health Care Data for Emergency Medical Services-NEMSIS-data is collected by EMS practitioners at the point of care and includes information on the EMS system response, scene characteristics, patient demographics, patient condition, medical treatment provided, transport decision, patient and incident disposition and EMS system times. I believe collection of vital data should also distinguish the type of practitioner collecting the data since less experienced EMS Practitioners such as ambulance technicians may not have the experience to decide the relevant data for the patient as well as the more educated and advanced Paramedics. This could potentially be a patient safety issue.
Encounter, Diagnosis, Assessment, Plan	Page 9	substantive	Ease of use and conformance (or not) are precursors/barriers to adoption-burden of use is also a barrier-what efforts are being made to elicit this information from the user community and what methods are used to analyze the value of those documents that are currently used for communicating encounter diagnosis, assessment and plan?
Interoperability Need: Representing Patient Dental Encounter Diagnosis-Standard SNODENT	Page 9	substantive	I believe as a government employee, when a cost is identified for implementating any standard, a reasonable expectation is to easily and readily identify at least a ballpark estimate of cost, even if it's a variable range and not just use the $ sign to indicate cost without further elaboration. It is somwhat confusing when the content under Limitations, Dependencies, and Preconditions for Consideration indicates --> The SNODENT code set is available under license at no cost for non-commercial use yet the Cost column is indicating Cost via the $ sign.
Section I		substantive	Add the Note Activity template included in the C-CDA Companion Guide Release 2, with maturity of "final"
Section I		substantive	Adding "Assessment" to Encounter "Diagnosis" as a data class is appropriate Adding "Assessment and Plan" to Encounter "Diagnosis" as a data class is not appropriate. The observation/value pair of LOINC/SNOMED CT is appropriate for Assessments and Diagnoses, but the "Plan" portion would likely be represented differently, probably with procedure or encounter terminology codes
Section I		substantive	For CDA - recommend referencing the "Provenance - Author Participation" template in C-CDA Companion Guide Release 2 For FHIR - recommend referencing US FHIR Core 3.1.0 Provenance profile - http://hl7.org/fhir/us/core/STU3.1.1/StructureDefinition-us-core-provenance.htmlhttp://hl7.org/fhir/us/core/STU3.1.1/StructureDefinition-us-core-provenance.html I believe both of the above should be flagged as "Federally Required" per ONC's Final Rule in support of the 21st Century Cures Act
Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications/**Encounter Diagnosis, Assessment and Plan** (p. 9)	page 9	Substantive	Encounter Diagnosis, Assessment and Plan->Representing Dental Encounter Diagnosis. Add an additional type of just plain SNOMED CT. Recent work has been done through the SNOMED CT Dentistry Clinical Reference Group on diagnosis and dental body structure.

Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications/Family Health History (p. 11)	page 11	Substantive	1. Under “Applicable Value Set(s) and Starter Set(s)”, the value set for “Problem Type” is mislabeled as “(LOINC code system”). The Value Set referenced is a SNOMED CT value set. 2. Under “Applicable Value Set(s) and Starter Set(s)”, two value sets are presented for family relationships and roles. It would seem reasonable also to mention that SNOMED CT can be used to represent family relationships, particularly as in this section, SNOMED CT is listed as a standard for observation values, and depending on the information model used, family relationship may be one of the observation values recorded (in addition to the diagnosis or condition).
Family Health History	Page 11	Substantive	For clinical genomics purposes, the Human Phenotype Ontology (HPO) developed by Robinson, et al. and uses information from the Online Mendelian Inheritance in Man to generate its terms. It is popular within the genomics community, and is used by some organizations to describe "phenotypic abnormalities". What does popular within the genomics community mean? Popular should be replaced with a more specific statiscally relevant term. Even the term genomics community is somewhat subjective, in my opinion. If I run a biomarker lab test, am I a member of th genomics community?
Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications/**Health Concerns** (p. 15)	page 15	Substantive	1. The “Interoperability need” is phrased as “Representing Patient Health Concerns”. I would suggest it be rephrased as “Representing Patient or Caregiver Health Concerns” to reflect that in many cases (e.g. pediatric care and care of adults with limited cognitive capacity, referral or transfer of a patient from another health care provider or facility), someone other than the patient is articulating the concern. 2. While LOINC is listed as a standard for observation, there does not seem to be a LOINC code that corresponds to health concerns (the closest is a document title LOINC, 75310-3). However, there are LOINCs for “chief complaint” (see above). The current limitation in semantic coverage of LOINC in this area could be mentioned in the “Limitations, Dependencies…” section. 3. SNOMED CT is appropriate to list as a standard for Observation Values; It may be helpful to identify a value set that limits SNOMED CT to the “clinical finding” and “situation with explicit context” hierarchies to discourage use of other SNOMED CT hierarchies that aren’t semantically aligned with “health concerns” but might be tempting to use for users not familiar with ontologic structures and semantic types. For instance, for a patient presenting to request a sterilization procedure, it would be more appropriate to represent the “health concern” with SNOMED CT 183996000, “sterilization requested”, than SNOMED CT 703145006, “sterilization procedure”.
Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications/**Immunizations** (p. 16)	page 16	Substantive	1. Under “Limitations, Dependencies…” the statement “RxNorm is an acceptable alternative code set for local use” is confusing, as it isn’t clear what the ISA is saying it’s an alternative to; Furthermore, the only two possibilities from the standards listed are CVX and NDC, both of which are noted to be Federally required. 2. It would be worth referencing the ISA section(s) related to prescribing and/or recording medication administration if they contain information about how to represent route and site of administration, since this often needs to be recorded when documenting immunization administration.
Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications/Laboratory/Representing **Laboratory Values/Results** (p. 20)	page 20		It is unclear how this differs from the preceding section, “Representing Laboratory Tests”. Both sections provide information relevant to representing both the test and result. It might be helpful to combine these into one section.
Medications	Page 20	substantive	Interoperability Need: Representing Patient Medications-Standard RxNorm-RxNorm is often used for the exchange of information; however, it may not be available for export and import by end users. Reference to endusers should be more specific to categories of users: Physicians, pharmacists insurance companies, data scientists/researchers, possibly even patients or other categories.
Sex at Birth, Sexual Orientation and Gender Identity	Page 29	substantive	My opinion is that this is a highly sensitve area and needs further elaboration in Limitations, Dependencies, and Preconditions for Consideration - with respect to differentiation of birth sex, self-identified sex, and administrative sex.
Patient Identified Sexual Orientation	page 31	substantive	There is a longstanding contention that the gender designation (and sexual orientation) are administrative roles, within HL7, which is a barrier to captureing reliable information about sexual orientation and in the case of transgender patients, what their original gender was (are they at risk for prostate cancer, uterine cancer etc.) to effectively address their healthcare needs beyond the administrative information that is captured. While solving for a techincal requirement, the clinical reality is minimized or ignored and surfacing in the literature, JAMA and AFP, as problematic.

Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications/Social, Psychological, and Behavioral Data/**Representing Alcohol Use** (p. 32)	page 32	Substantive	1. The hyperlink for text "Alcohol Use Disorder Identification Test - Consumption [AUDIT-C]" is broken (does not reference the AUDIT-C). 2. The bottom two LOINC codes referenced in this section appear to be for the full World Health Organization AUDIT assessment, instead of the screening assessment, the AUDIT-C. Recommend removing these codes or noting that they are for reference only to avoid user confusion. 3. With respect to the use of SNOMED CT to represent AUDIT-C data elements: There is currently one AUDIT-C concept in SNOMED CT to represent the total score, but no concepts to represent the individual question-answer pairs. SNOMED CT would need to create each of the question-answer pairs as pre-coordinated concepts. This might be challenging given that this content may fall outside of SNOMED CT editorial policy (e.g., use of numeric ranges and references to time). Also, SNOMED CT would require intellectual property rights permissions from the AUDIT-C creator(s) to include this content. If SNOMED CT concepts are created, then to support user adoption, it is suggested these concepts be maintained in a NLM VSAC value set.
Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications/Social, Psychological, and Behavioral Data/**Representing Depression** (p. 32)	page 32	Substantive	1. The hyperlink for text "Patient Health Questionnaire 2 item (PHQ-2)" appears to be broken. 2. Since the recommendation is to use the PHQ-2, it's not clear why the LOINC code for the PHQ-9 is listed (PHQ-9 panel LOINC code 44249-1). Suggest removing this code or noting that it is for reference to avoid user confusion.
Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications/Social, Psychological, and Behavioral Data/**Representing Drug Use** (p. 33)	page 33	Substantive	With respect to the use of SNOMED CT to represent DAST-10 data elements, there does not appear to be equivalent SNOMED CT content to represent the DAST-10 data elements. SNOMED CT would need to create each of the question-answer pairs as pre-coordinated concepts. This might be challenging given that this content may fall outside of SNOMED CT editorial policy (e.g., disjunction, complex questions). Also, SNOMED CT would require intellectual property rights permissions from the DAST-10 creator(s) to include this content. If SNOMED CT concepts are created, then to support user adoption, it is suggested these concepts be maintained in a NLM VSAC value set.
Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications/Social, Psychological, and Behavioral Data/**Representing Financial Resource Strain** (p. 34)	page 34	Substantive	Suggest that the ONC ISA and Gravity Project align on the specifications for representing financial resource strain, food insecurity, and housing insecurity.
Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications/Social, Psychological, and Behavioral Data/Representing Financial Resource Strain (p. 34)	page 34	Substantive	The hyperlink for text "Coronary Artery Risk Development in Young Adults (CARDIA) study" is broken.
Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications/Social, Psychological, and Behavioral Data/**Representing Food Insecurity** (p. 34)	page 34	Substantive	1. The text for the first LOINC code is correct, but the hyperlink points to the a different (incorrect) LOINC code and should be corrected. 2. It is not clear how the PRAPARE panel should be used (i.e., which specific data elements pertain to food insecurity and which specific LOINC or other standard codes should be used). Suggest removing this reference until clear guidance for its use has been better defined. 3. As CMS supports the Hunger Vital Sign screening tool and LOINC has available codes to support this tool, it is recommended to use this tool and these LOINC codes. It is not clear how SNOMED CT, ICD, CPT, or HCPCS support this data element at this time. Unless specific assessment data elements, standardized vocabulary codes, use cases, etc. are proposed and can be reviewed, suggest removing these standards and focus on LOINC usage to improve adoption and reduce user confusion. Using multiple standards can reduce interoperability if organizations are implementing multiple different standardized vocabularies.
Financial Resource Strain, Food and Housing Insecurity	pages 34-35	substantive	The gap in SDOH documentation and consideration, while acknowledged, is one that can make a big difference in outcomes so moving toward. On a national allocation of resources note…perhaps, as other countries do, the US could look at how it spends its $3.XT on healthcare and consider shifting that to addres SDOHs to improve outcomes.
Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications/Social, Psychological, and Behavioral Data/**Representing Housing Insecurity** (p. 35)	page 35	Substantive	It is not clear how SNOMED CT, ICD, CPT, or HCPCS support this data element at this time. Unless specific data elements, standardized vocabulary codes, use cases, etc. are proposed and can be reviewed, suggest removing these standards and focus on LOINC usage to improve adoption and reduce user confusion. Using multiple standards can reduce interoperability if organizations are implementing multiple different standardized vocabularies.
Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications/Social, Psychological, and Behavioral Data/**Representing Transportation Insecurity** (p. 38)	page 38	Substantive	It is not clear how SNOMED CT or ICD support this data element at this time. Unless specific assessment data elements, standardized vocabulary codes, use cases, etc. are proposed and can be reviewed, suggest removing these standards and focus on LOINC usage to improve adoption and reduce user confusion. Using multiple standards can reduce interoperability if organizations are implementing multiple different standardized vocabularies.
Transportation Insecurity	page 38	substantive	This non-federally required need is mature and widely adopted (no informatino on quality notwithstanding)-what makes it so and other required categories not widely adopted…to my point above on understanding the differences for the purpose of moving required categories from nascent/poorly adopted to mature and widely adopted.
Tobacco Use	page 39	substantive	As a leading cause of death, smoke/smokeless tobacco and associated products should be included in US Core and USCDIS categories to reflect type (incuding emerging types-vaping, marijuana etc., duration and quauntity used to effectively address individual patiet needs as well as public health and research goals

Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications/Tobacco Use (Smoking Status)/**Representing Patient Second Hand Tobacco Smoke Exposure** (p. 39)	page 39	Substantive	Recommend the use of SNOMED CT to represent tobacco use data elements, and specifically second hand tobacco smoke exposure. SNOMED CT has more than sufficient content to represent values for this data element and new concepts can be created as needed.
Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications/Tobacco Use (Smoking Status)/Representing Patient Electronic Cigarette Use (Vaping) (p. 39)	page 39	Substantive	1. Recommend the use of SNOMED CT to represent tobacco use data elements, and specifically electronic cigarette use. SNOMED CT has a substantial amount of content to represent the values for this data element and new concepts can be created as needed. 2. Three of the four SNOMED CT codes listed refer to the actual types of electronic cigarettes ("physical object" concepts in SNOMED CT), as opposed to all other recommended concepts in the Tobacco Use section which refer to SNOMED CT "finding" or "situation" concepts. For consistency, suggest removing codes 722498003, 735240008, and 735239006 in this section and replacing with the following codes: 785889008 |Nicotine-filled electronic cigarette user (finding)| and 786063001 |Non-nicotine-filled electronic cigarette user (finding)|.
Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications/Tobacco Use (Smoking Status)/**Representing Patient Tobacco Use (Smoking Status)** (p. 40)	page 40	Substantive	1. Suggest that all SNOMED CT concepts listed reference the "fully specified name" (the formal, official concept name) rather than a synonym. 2. Some of the SNOMED CT concepts listed have incorrect descriptions: "Former smoker" is no longer an active description for 8517006. "Never smoker" is not a description for 266919005. "Smoker, current status unknown" is not a description for 77176002. "Unknown if ever smoked" is not a description for 266927001.
Vital Signs-Interoperability Need: Representing Patient Vital Signs	Page 42	Substantive	In my opinion, a special reference to pacemakers and/or fibrillators and dialysis devices should be identified here since they are highly signicant in the scope of chronic and serious medical conditions.
Referral to a Specialist	page 45	substantive	The concept of a closed loop process and messaging that reflects actionable data/documentation, is long overdue as a workflow/process component of healthcare delivery-applications to consults/referrals/prescritinos/lab-rad-diagnostic studies etc.
Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications/Documenting and Sharing Care Plans for a Single Clinical Context (p. 47)	page 47	Substantive	Recommendation for additional standard: VA Office of Nursing Informatics supports the use of the Clinical Care Classification (CCC) code set for representing Nursing content in care plans.
Interoperability Need: Push Patient-Generated Health Data into Integrated HER	Page 126	Substantive	In my opinion, this section doesn't appear to distinguish PGHD that is auto-generated by devices within the patient's possession vice PGHD that the patient is self-reporting via a patient portal
General Comment	throughout	substantive	The categories that are evaluated:
General Comment	throughout	substantive	Implementation maturity-pilot to production: Many standards in production do not effectively support interoperabllity as the implementations are divergent so that the intention of interoperability is not met, even though the specified standard is widely distributed in production. Another measure, conformance, would be helpful to assess as it should reflect the proper use of a standard in a uniform manner.
General Comment	throughout	substantive	Standards Process maturity-the 3 categories: Final, Balloted Draft and In Development reflect the stage of development but nothing about the level of interoperability that the specified standard supports. An analogy would be the state of EHR adoption-do you have one? yes, does it communicate with any others? yes, no, maybe...and what level of interoperability is achieved by the EHR (or in this case, the specified standard)
General Comment	throughout	substantive	Adoption levels-Feedback requested-as this is provided with many of the identified standards/areas of use-is there an active solicitaiton for feedback from user groups (patients, providers/clinicians, insurers, and so on such that it is widely known, input collected as provided by users and acted on?
General Comment	throughout	substantive	Adoption low-high/widespread: there is no qualitative assesment of the nature of adoption-is it just included in a platform? Is it used and to what degree and conformance? What is the quality of the data and documentation/image that is shared and to what level of interoperability does the widespread adoption attain?
General Comment	throughout	substantive	There are many instances of federally required standards that have low adoption and not requrired that have high adoption (qualitative assessments aside) That looks like an opportunity to evaluate what the barriers to adoption are for required standards and the widespread adoptoin of non-required standards.