2015 ONC Interoperability Roadmap IPO Comments

Chg #	Section/Page Number	Recommended Change
1	2nd sentence, 2nd paragraph, Page 102	Consider revising, "ONC will continue to support and coordinate (Delete/Modify: data collection) with federal partners on health exchange and interoperability."
2	4th sentence, 2nd paragraph, Page 102	Recommend Modification: "Identifying and remediating gaps can only occur through collective input by stakeholders, and monitoring their progress."
3	5th sentence, 2nd paragraph, Page 102	Consider Revising: "Measuring progress affects diverse individuals and entities, such as end-users (e.g., providers, individuals), entities enabling exchange and payers, amongst others. "
4	1st sentence, 3rd paragraph, Page 102	Consider Acronym or Capitalizing for "The measurement and evaluation proposed framework" MEPF?, since it is used collectively as a descriptive framework
5	5th sentence, 1st Paragraph, Page 106	Consider revising: "Measuring whether there is the level of interoperability in place to ensure quality measures can be consistently and accurately implemented across various systems, can shed light on the infrastructure and standards that are in place."
6	Bullet 2, Page 107	Recommend term "Integration" instead of "Penetration" for bullet 2
7	1st Sentence, 3rd Full Paragraph, Page 108	Verbose, Consider revising: "As progress on interoperability is made, measuring impacts in areas that have shown some promise of being affected by increased use of health information exchange may serve as a way to begin to understand the early effects of expanded interoperability. "
8	2nd sentence, 1st full paragraph, page 109	Consider Revising to: "After assessing the current landscape to identify potential measures that may be in use, measurement pilots may need to be conducted to develop and test metrics used locally, in order to assess scalability."
9	Bullet List, page 109	Consider Adding Something on Healthcare Quality, See IOM's STEEEP (Safety, Timely, Effective, Efficient, Equitable, Patient Centered)

10	2nd Full Paragraph, page 109	Consider Revising to: "Stakeholder involvement of entities that promote and enable healthcare information exchange (health information organizations, HISPs, health IT developers, healthcare centers, etc.), payers and providers will be critical to the development and testing of measures."
11	pg 102, 3rd para, Measurement and Evaluation Proposed FW; Defining Success	**Input:** The reference of the first domain is described less completely than when referenced elsewhere in the Chapter **Recommended Change:** To improve alignment with the content of Fig 9, the first of the three domains should pick the best reference and stick with it through out whether that is of infrastructure, standards, services and policies from the Fig 9 or of technology and policy matching the content in the 3rd para or of technology, standards, infrastructure and policies on pg 106. **Rationale:** Gain consistency which promotes imprinting the message which is valid.
12	pg 102, 4th para, Measurement and Evaluation Proposed FW; Defining Success	**Input:** Governance Monitoring is mentioned as distinct from monitoring progress though there may be overlap in in specific measures. Recommend offering examples of Governance Monitoring **Recommended Change:** Recommend offering examples of Governance Monitoring where different and where there are examples of overlap **Rationale:** Examples make plain or obvious the distinctions between Governance monitoring vs. monitoring progress. Though a lesser scale, but just as interoperability has been described many different ways, governance is another area easily misunderstood. Examples overcome possible confusion

13	pg 104	**Input:** Current content presents a vague picture of just which (federal) partners are a part of what's gained via referenced data sources, and without links to the referenced data (results / surveys) different understanding is likely **Recommended Change:** Given the higher level Fed Health IT Strategic Plan references certain partners recommend the same are referenced in similar manner here. Recommend offering via links what data is currently made available that represent national monitoring **Rationale:** This will ensure the ties between the two are much more obvious and it will force the named partners (DoD and VA for example via the IPO) to confirm their intent to align with the expectation and/or counter Links to what is it that is results of national monitoring will make it easier for the higher volume of educated but less informed staffs to readily participate
14	pg 105 Table 11	**Input:** Table is the right idea to convey examples but what's offered (LTC & Behavioral health) seems more aligned with 6yr vs. 3yr **Recommended Change:** Recommend selection of metrics from healthcare areas that are more prevalent amongst the widest possible net of users **Rationale:** The more accurate the examples are to the period (short) the more this will resonate
15	pg 107, Exchange Activity or Availability & Use	**Input:** The content in both is appreciated / valid but stimulates the interest on whether the reference of 'use cases' should be more explicitly referenced **Recommended Change:** Addition of Use Case Alignment should be considered **Rationale:** More views point to the value of working in measures as driven by use cases and where there are many, (as App H shows), 'prioritized use cases. Perhaps the manner the use cases are presented (as able) be presented in the 3, 6 10year categories
16	pg 107, Exchange Activity or Availability & Use	**Input:** Exchange Activity examples are solid. Source is absent **Recommended Change:** Consider adding 'source' **Rationale:** Addition of source will be sure to point out completeness / depth and while that might be as important at the national level, it is important among exchange partners and those who manage & oversee

17	Overarching	Input: Subsets of Populations Recommended Change: Where possible,, make references to the DoD to VA to Private Sector as a subset of our population Rationale: This done more and more, will likely help improve the way monitoring occurs which largely excludes the DoD, VA and their private sector association which very much exists but by 'captured care' is minimally captured and is to gain a lot of technology attention to be addressed.
18	Page 38	"…the federal government is unique in its market reach, but is still limited in its capacity to drive standardization." • Why is it limited? HHS has the power to address this, but it will likely step on lobbyists' toes.
19	Page 39	"Additional policy levers across the public and private sector could also be leveraged…" • "levers… could… be leveraged" Too much jargon! "2) requirements/penalties that raise the costs of not moving to interoperable systems." • This will be important. Consider not paying for an x-ray when another one was done recently at another facility and there is no clinical indication for a repeat. The patient would get socked with the bill and that would drive reform in a hurry!
20	Page 40	"…physicians will be required to utilize certified health IT to furnish certain services to beneficiaries." • This approach is unlikely to be effective for several reasons: 1. The requirement to adopt "certified" health IT may force Providers to adopt health IT that is poorly suited to their workflow, reducing efficiency and provider satisfaction. 2. It is difficult to create certification criteria that accurately reflect a given technology's ability to effectively exchange information. 3. Simply adopting certified technology does not guarantee the HIE capabilities will be used. "…measures of health IT adoption and interoperability…" • Developing measures of health IT interoperability is problematic. ONC has an opportunity to provide leadership in this area.

21	Page 42	"…similar to current measures that seek to drive consumers toward providers that deliver high-value services." • Not sure what the "current measures" are. One approach could be to score medical practices and provide these ratings to consumers. Examples of measures might be rates of redundant tests and patient ratings of care transitions. "…by collaborating with other purchasers, providers and consumers." • Absolutely. If two large purchasers in a given region decide they want to make it easy for patients to transition between their contracted provider networks, they could pressure those networks to adopt interoperable health IT.
22	Page 43	"…in a manner that does not limit competition." • How will this be assessed?
23	Page 44	"Roughly half of states should enact state- autonomous policies to advance interoperability that go beyond their current efforts." • I'm skeptical of equating progress with increased legislation. "…Purchasers should consider health plans' commitment" • How will this be measured?
24	Page 45	"in10shared" • Please correct
25	Page 46	"Moving Forward" • I would like to see the discussion shift toward making the patient the owner and steward of his or her own health care record. The practitioner would be responsible for helping the patient understand what the contents mean and what are the optimum choices for managing his or her health. The record should be stored in a standardized format in the cloud, and accessible through standard browsers.

26	Page 48	"Call to action: Providers should encourage their patients to access their health information online and will enable patients to view, download and transmit that information to a destination of the patient's choice." • Some medical practices provide patients with this capability but discourage its use by charging extra for it. Insurance companies can affect this by their reimbursement policies. For example, insurers might pay only for procedures for which the patient can download the report for free and for an unlimited time. "ONC and government ensure that patients understand their ability to access, send and receive health information." • How will this be achieved? Perhaps CMMS could tie payments to attestation that a practice provides a health IT consultant or access to such services.
27	Page 49	"…help the majority understand the value of health IT for managing their health…" • How will this be measured?
28	Page 52	"Call to action: Providers should recognize that valuable clinical information about their patients may reside with patients or caregivers themselves and that they may need to incorporate that information into their decision making." • This is basic medical practice and this recommendation adds nothing. If by "valuable clinical information" you mean documentation, then you might be saying something useful. Most practices already do this at least at a basic level, such as utilizing history forms completed by the patient. We need to focus on making it easier for patients to submit their own information (and not to have to do it repeatedly), and for this information to be more effectively integrated into the provider's workflow. "Providers should regularly use and have access to the most relevant, integrated information, appropriate notifications." • How will this be measured? (This sentence has a grammatical error and I'm not sure what it means.)

29	Page 53	"…Health care systems" • I'm not sure how providers could accomplish this or how it will be measured. My comment applies to all references to "providers" in this section. "…use standard metrics for interoperability" • Who will develop these standards? "….information required from their diplomats " • What type of information does this refer to? My board does not require me to supply patient information. This item seems out of scope for this Roadmap.
30	Page 8	General Comment: The roadmap is heavily focused on the relationship between HHS/ONC/CMS and commercial providers. Although the roadmap for the relationship noted above seems reasonable, it occurs to me that it lacks a cogent strategy to incentivize and include the largest provider of healthcare, the Federal Government (via DoD and VA). I think it's critical to the success of the roadmap to address this gap.
31	Page 13	I don't see any incentives in this paragraph (starting with "Advance incentives for sharing…") that will motivate large, key federal providers like DoD or VA. I suggest designing and implementing a plan to appropriately incentivize these Federal Stakeholders.
32	Page 13	Also, Incentives need to be devised to incentivize EHR Vendors to make their COTS products interoperable or at least "able" to exchange information.
33	Page 16	I like the strategic plan and applaud the intent. That said, the large Federal Healthcare Providers (DoD and VA) will require special consideration when providing incentives because they do not operate on a fee for service basis. Hence, an alternate incentive strategy must be devised.
34	Page 20	(Guiding Principles No.4 "Leverage the Market") Great concept in the commercial market, but large Federal Providers don't compete. Their patients are a captive audience. Suggest identifying an alternate incentive.
35	Page 23	(LHS Requirement B) It occurs to me that a "supportive business environment" is the key driver of the Roadmap. Since large Federal Healthcare Organizations (DoD and VA) don't bill for services, it occurs to me that a strategy to incentivize these players should be included in the roadmap.

36	Page 29	Consider inserting a section called “Interagency Governmental Governance”. The Governmental Governance Section above relates primarily to Governmental governance over the commercial sector, but does not address governance between Federal Departments/Agencies. From my perspective, this is particularly relevant for DoD and VA, but ideally would include HHS, ONC, CMS and others.
37	Page 40	Consider inserting a paragraph about actions that can be taken by federal partners (DoD and VA) to advance interoperability as the largest healthcare provider (not just a large purchaser).
38	Page 43	(B1.Federal Actions)Consider inserting DoD and VA Actions here or perhaps separate these out in a different section (e.g. B2).
39	Page 77	Recommend including a strategy to standardize PHI security standards across Federal Health (DoD, VA, IHS) and the commercial sector as differences in security standards currently prevent exchange of information. Changed “The consistent implementation and use of standards as well as broad access to technology services is foundational for a learning health system to mature over the next 10 years.” To “The consistent implementation and use of standards and broad access to technology services is foundational for a learning health system to mature over the next 10 years.” This is an admirable goal but not sure that it will actually happen even if ONC recommends it. Would we be setting everyone up for failure here?
40	Page 80	Should there not be a clear and concise list of exactly which standards should be followed rather than expecting the developers to figure it out independently? This comment seems to be counter to the way ONC operates. ONC cannot meaningfully dictate a single set of standards for everyone to use. Their movement towards recommending a set of standards is a step in the right direction but they need to walk the fine line of providing guidance while not limiting future innovation on use cases that have not even been conceived yet.
41	Page 85	This section serves to provide a good overview of the current state but really does not provide guidance- “these are all the things that are out there try to figure it out” Where is the oversight who has the final say?

42	Page 89	Perhaps this could be discussed further as the concept of trust is foundational but difficult to implement between facilities who do not regularly interact. Just because two facilities are not familiar with each other the patient's records should not be impeded/rejected. What about the encryption of the individual message itself? If I intercept a message I should not be able to read it unless I am authorized. Formatting just makes it easier for me to figure out where the patient's information is found-I see this as a gap.
43	Page 90	(Table 12) This is an interesting chart but I think it would be more powerful if the responsible parties with contact information were added.
44	Page 99	This discussion seems odd as they have already discussed formats which can handle the query and response (HL7). Unclear what is odd and what we'd want to get from the discussion, if anything. Applies to a few comments down the line as well.
45	Page 104	The office-based physician will have the most difficult time adapting as many are smaller businesses – if facilities and labs convert – they will come.
46	Page 107	(Sentence beginning with "If information flows ") "In a secure manner" should be added before the phrase "information should be available". This section (Interoperability of Data and Systems) does not add anything.
47	Page 113	Suggest reorganizing appendices such that funding is not the first thing discussed. The appendix B would seem much more appropriate for the first Appendix.
48	Page 166	The majority of the items listed are categories of events rather than individual events from which use cases may be built.
49	Page 29	• Concern: Several pages of this document contains font that does not match the rest of the text (this is just one example). • Recommendation: Make sure all text font is consistent. Instead of including the text in a text box over the image, set the image wrapping to "Behind Text" and keep the text all in the body of the document itself.

50	Page 31	"Where individuals clearly instruct a data holder to release information about them to others, the data holder should comply with that directive." • Concern: This is not feasible for the DoD because the DoD must have access to all active duty health records to confirm readiness level. • Recommendation: Include a governance principle or an exception for the DoD to allow the organization to have the ability to access active duty health records for readiness purposes.
51	Page 32	"clear and simple choices regarding what restrictions an individual can and cannot place on the collection, sharing, or use of that individual's health information." • Concern: "Clear and simple choices" is not specific enough and makes it difficult to determine whether data holders and entities are following this guidance. • Recommendation: Develop a common base set of choices for the individuals to choose from. ecommends the following language: "If possible, the multi-stakeholder coordinated governance process should develop a set of these simple choices that all data holders and entities that facilitate the interoperability of health IT could use as a common core set of choices offered." "Data holders and entities should provide clear information to health information trading partners about technical error rates (e.g., for improper individual matching) and other information (for example results of independent audits of security controls) about information interoperability that may have diverged from expected practices." • Concern: Total transparency regarding technical error rates could be risky for the DoD and VA and have legal implications. • Recommendation: Soften the language and instead require data holders and entities to provide escalation paths (i.e. Who should I talk to about this concern?). Recommends the following language: "Data holders

52	Page 33	"open access" • Concern: How open is "open"? Complete "open access" to exchange services could be risky to the providers. • Recommendation: A "happy medium" to open access might be a better route to go. The Engineering Team recommends further discussion over this language to verify this is really what ONC and DoD/VA want to do. "Where available and appropriate for the desired exchange of health information federal vocabulary, content, transport and security standards and associated implementation specifications are used." • Concern: Limiting data holders and entities to federal vocabulary, content, transport, and security standards could discourage innovation of better methods of information exchange. • Recommendation: Support for the federal vocabulary, content, transport, and security standards and associated implementation specifications should be a "minimum standard" provided, but that shouldn't prohibit or discourage trading partners from innovating and adopting more powerful or efficient methods for information exchange as well.
53	Page 37	"Rules that govern how health and care is paid for must create a context in which interoperability is not just philanthropic, but is a good business decision." • Concern: The LHS requirement does not match the LHS requirement listed in the table on page 23. • Recommendation: Use the exact same language when referring to the LHS requirement to avoid confusion.
54	Page 49	"Providers work together with patients to routinely assess and incorporate patient preferences and goals into care plans that achieve measurable value for the individual and the population." • Concern: The LHS requirement does not match the LHS requirement listed in the table on page 23. • Recommendation: Use the exact same language when referring to the LHS requirement to avoid confusion.

55	Page 52	Table 4: Critical Actions for Care Providers Partner with Individuals to Deliver High Value Care • Remove excess space to stay consistent with the other tables.
56	Page 56	"Moving Forward and Critical Actions" • Recommendation: Add language stating that data holders must follow the most restrictive guidance. Incorporating the following language: "The DoD/IA Electronic Health Record (EHR) applicable sets of baseline IA controls are DoD (DODI 8500.2) MAC II Sensitive levels and VA FIPS 199 'High'. The EHR baseline IA controls are the more restrictive security requirements of each agency. All new EHR capabilities must address the baseline IA control requirements."
57	Page 74	• Concern: The LHS requirement does not match the LHS requirement listed in the table on page 24. • Recommendation: Use the exact same language when referring to the LHS requirement to avoid confusion.
58	Page 82	• Concern: How feasible is this recommendation?

59	Page 57	Table 5: 1. ONC will work with OCR to release an updated Security Risk Assessment tool and hold appropriate educational and outreach programs. • Recommendation: The Security Risk Assessment tool should also include guidance on how to mitigate identified risks. Additionally, it would be helpful if it were tied to use cases. Table 5: Encryption • Concern: Why is encryption called out above the other aspects of cyber security (encryption is normally one aspect of a cyber security plan)? Since this is the only aspect called out, we assume that it is because encryption is part of the recommendations in HIPAA that often doesn't happen, at least while data is at rest (note recent Anthem breach). • Recommendation: Since the current HIPAA standard for encryption is considered an "addressable implementation specification" and not a requirement, guidance should be enhanced to identify when it is considered a risk. Additionally, more information should be provided as to what "standards" are included. Finally, "carrots and sticks" should be identified to make encryption a higher priority for providers. • Recommendation: Mobile device encryption should be addressed as well. Table 5: 4. ONC will work with payers to explore the availability of private sector financial incentives to increase the rate of encrypting, starting with discussions with casualty insurance carriers who offer cyber security insurance. • Recommendation: Incentives should be investigated beyond just insurance providers.
60	Page 59	"Authentication is the process of establishing confidence in the identity presented to gain access to a system. Authentication sometimes utilizes tokens (also called factors for authentication) that a participant provides to demonstrate they are the person who should have access. Tokens can be something a participant knows (a password), something a participant has (ID badge or hardware token/fob), or something a participant is (typically a biometric like a fingerprint). Depending on the risks of authentication errors, one or more factors may be required for authentication." • Recommendation: The term "multi-factor authentication" should be introduced in this paragraph with its definition. The term is used later on in the document without the supporting definition, which could cause confusion to readers.

61	Page 60	"multi-factor authentication" • Recommendation: As stated above, the term "multi-factor authentication" should be introduced in the Authentication paragraph with its definition to avoid any confusion.
62	Page 66	"Granular choice refers, therefore, not only to granular choice among clinical conditions that are protected by laws in addition to HIPAA, but eventually, granular choice, should a patient wish to express it, regarding other data distinctions to be determined, but which are consistent with a learning health system, such as research purposes in which an individual has chosen to participate." • Concern: This sentence is awkward and hard to digest. • Recommendation: Simplify the definition to make it clearer to the reader. Consider breaking it up into multiple sentences.
63	Page 69	Table 7: 2.adopt technical standards regarding how to ensure individuals are offered Basic Choice in a manner that can be captured electronically and in a manner in which the individual's choice persists over time and in downstream environments, unless the individual makes a different choice. • Concern: In educating individuals it is important they understand the trade-offs that may exist in their choice. For instance, while not granting access, an individual's privacy will be enhanced, but their care may be impacted. • Recommendation: Add a third goal related to educating individuals on the implications of their choice as it relates to increased security. For instance, with increased security, there is an additional risk to patient care. Table 7: begin revising regulations, policies and programs for granular choice to align with the consensus categories of sensitive health information and rules for granular choice that establish consensus background rules for the nation. • Concern: Individuals should be made aware of the trade-offs between sharing and care ability when making their choice to understand the potential implications to their patient care. • Recommendation: As part of this effort, the trade-off between sharing and care ability should be defined and individuals should be made aware of this trade-off. Algorithms for assessing data for privacy adjudication need to sophisticated enough to recognize nuances in care. For instance, a medication that is used typically for depression may be prescribed for smoking cessation. If the individual has indicated they do not wish to share mental health information, it is possible the medication is left off of the medication list creating

General Comments:
2015 Interoperability Roadmap Comments

Overall the interoperability documents are very vague, without any specific action items or milestones to target. This makes it relatively high-level and not used by the IPO and thus not currently of particular operational or tactical use.

Appendix H lists the priority use cases submitted to ONC through public comment, listening sessions, and federal agency discussions. The list is too lengthy and needs further prioritization. Please submit 3 priority use cases from this list that should inform priorities for the development of technical standards, policies and implementation specifications.

The specifics within the roadmap on content standards are appropriate. There is no mention of testing for semantic interoperability, which is confusing because this is an area that is of interest to the DoD and VA, which are placing a heavy reliance on the ability to perform this type of testing.

There is no specific language or reference to the behavioral aspects of interoperability, and the specific influences ONC can apply in these aspects. While some mention of financial influences are included, there is not enough specifics on areas of behavioral psychology that impact the need and desire to implement different types of interoperable solutions

Building Block #2, with its specific focus on ONC in its role as a convener, could provide to be somewhat problematic as this may be beyond the scope of ONC's abilities. While this would be helpful for the IPO's purposes it is not clear it would actually work in practice.

It would probably be more ideal to use a different structure for levels of interoperability, or remove this section. By establishing these levels, it can run contradictory to other efforts to define interoperability that have already been made by various organizations. Because ONC does not have a specific adoption model it can apply to these levels, it reads as a somewhat confusing section of the document

ONC should ideally consider the possibility of coordinating a 3/6/10 year requirements for privacy and security as well as the other building blocks listed.

ONC should attempt to recognize in the document that there are wide varieties of standards that can be used and applied to a wide variety of scenarios, and it would be advisable at some point to create a leadership collaborative of leading health standards organizations to help manage competing or redundant efforts.

The draft interoperability roadmap includes a call to action for health IT stakeholders to come together to establish a coordinated governance process for nationwide interoperability. ONC would like to recognize and support this process once it is established. How does ONC plan to have industry do this?

Address the need to develop a national patient identifier to facilitate data sharing with outside healthcare providers.

Ensure interoperability standards, moving forward, support healthcare areas not typically supported (e.g., long-term care, behavioral health, etc.). Also, ensure that incentives for becoming interoperable are available for all physicians. These areas will help ensure that the DoD and VA can receive data from all healthcare providers.

Ensure DoD/VA participation in standard development workgroups. The DoD/ VA healthcare beneficiaries represent a large population with unique healthcare needs. To ensure success meeting DoD/VA interoperability requirements, standards must support their need to moving forward. For example, C-CDA currently does not support how the DoD and VA plans to use shared data. Similarly, terminology standards do not fully support their clinical needs.

Develop metrics to make it easy for patients to provide information electronically to help staff record the data more accurately.

If it is unrealistic to expect a single organization to keep track of all of the services available and the API details of each one, then ONC needs to determine which services are needed to make it easier for tracking and eliminate the ones not needed. This would allow organization's to operate more efficiently and remain accurate and up-to-date with the services offered.