The following comments are submitted by Quest Diagnostics

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| Key measurement areas that ONC has identified include: tracking whether interoperability standards are contained in health IT products and services; and the subsequent use of standards by end users1 (e.g., providers), including whether end users are customizing their use of the standards. |
| Comment:Currently EHR systems may be certified, but do not actually implement interfaces in support of the certification requirements; this occurred with lab results interface (LRI) required for the 2014 Edition Certification. Therefore, beyond tracking if interoperability standards are contained in EHR systems, measuring the deployment to end users is critical. We support ONC is their efforts to enforce that certified EHR Systems function as intended. |

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| Measuring standards customization/conformance will provide insights into the variability in how standards are implemented in the field including where this variability is occurring and potentially impeding interoperability. |
| Comment:Please identify the preferred method to report certified EHR system requests to laboratories to deviate from the certification standards cited by ONC. For example, EHR vendors have requested labs to disable features required for the EHR system to pass MU certification test. |

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| ONC has identified, through discussions with various key stakeholders, two key measurement areas where moving towards uniform implementation and use measures as outlined in the framework will support the ability to measure nationwide interoperability progress: 1) Implementation of standards in a health IT product; 2) Use of standards, including customization of the standards, by end users to meet specific interoperability needs.  |
| Comment:Item 2) “specific interoperability needs” needs to be defined to avoid misuse. For example, an EHR vendor requested a laboratory to exclude SNOMED CT terminology (required under 2014 certification) because they did not need it for reporting in their state; the vendor would likely assert this is their “specific interoperability need”. Unfortunately, this meant customization of the interface. This approach moves us away from a cost effective national standards, toward expensive point to point customizations.Suggest a higher threshold for exclusions from ONC cited standards. If the standard is deficient, a change should be proposed to the steward Standards Development Organization (SDO). Another option is use of profiles to support different requirements for different use cases, but still within the boundaries of the defined standard/implementation guide. |

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| Measurement Areas1. *Level of conformance/customization of interoperability standards*: Stakeholders have limited experience to date in measuring this area. As a result, additional foundational work is essential to identify the best approach(es) to track the conformance and customization of standards after implementation in the field. ONC requests stakeholder feedback on the best methods to measure this area.
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| Comment:Suggest ONC coordinate with SDOs for those standards that maintain a comment tracker/change request methodology. For example, several of the HL7 standards named for 2014 and 2015 certification are “standards for trial use [STU]” which have an ongoing comment [tracker](http://www.hl7.org/dstucomments/?ref=nav). While this may not mean implementers were forced to customize, it provides a measure of implementation issues.A simple methodology to report/register customization requests/deviations from standard/implementation to ONC, based on a cited standard, may have the effect of deterring unnecessary customizations. |

| Pg. 10 Questions |
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| 1) Is a voluntary, industry-based measure reporting system the best means to implement this framework? What barriers might exist to a voluntary, industry-based measure reporting system, and what mechanisms or approaches could be considered to maximize this system’s value to stakeholders?  |
| Comment:Often vendors do not implement standards unless there is a federal mandate, and may have contract obligations to implement federally mandate standards. The validation tools provided by NIST are helpful to implementers and have potential to speed the process of implementation, e.g. ability to create a properly formed message can be validated prior to attempting to exchange messages. However, validation tools require a corresponding sufficiently specified standard/implementation guide. If the end ‘product’, e.g. the exchange, isn’t mandated, it can be expensive to implement and organizations must determine if there will be a return on investment. Without implementation, there can be no measurement. |

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| 2) What other alternative mechanisms to reporting on the measurement framework should be considered (for example, ONC partnering with industry on an annual survey)?  |
| Comment:Assessing common deviations from standards/implementation guides would be useful; this could be useful to collect via survey but only if the information is disseminated back to the community.  |

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| 3) Does the proposed measurement framework include the correct set of objectives, goals, and measurement areas to inform progress on whether the technical requirements are in place to support interoperability?  |
| Comment:Technical requirements may not be adopted unless proven through demos and pilots. Unless there is significant return on investment that warrants replacing an older, but functional, information exchange, no matter how good or ideal, there may not be traction to adopt. |

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| 5) Are the appropriate stakeholders identified who can support collection of needed data? If not, who should be added?  |
| Comment:Suggest consulting with appropriate industry groups, such as the American Clinical Laboratory Association (ACLA) for laboratory interoperability |

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| 6) Would health IT developers, exchange networks, or other organizations who are data holders be able to monitor the implementation and use of measures outlined in the report? If not, what challenges might they face in developing and reporting on these measures?  |
| Comment:Laboratories might be able to provide information re: the status of information exchange. |

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| 7) Ideally, the implementation and use of interoperability standards could be reported on an annual basis in order to inform the Interoperability Standards Advisory (ISA), which publishes a reference edition annually. Is reporting on the implementation and/or use of interoperability standards on an annual basis feasible? If not, what potential challenges exist to reporting annually? What would be a more viable frequency of measurement given these considerations?  |
| Comment:Suggest consulting with EHR system developers re: their product development/planning cycle to effectively synch. This information may inform whether annual, or every 18 or 24 months is a more effective timeframe. |

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| 8) Given that it will likely not be possible to apply the measurement framework to all available standards, what processes should be put in place to determine the standards that should be monitored?  |
| Comment:Mandated standards/implementation guides are first priority. Beyond that, it seems standards/IGs that are supposed to be mature or heavily adopted could be second priority. |

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| 9) How should ONC work with data holders to collaborate on the measures and address such questions as: How will standards be selected for measurement? How will measures be specified so that there is a common definition used by all data holders for consistent reporting?  |
| Comment:Since laboratory results are frequently used to measure eCQMs, we suggest that any selection of LOINC codes or other measures to interpret laboratory results must be validated and corroborated by a lab consortium, such as the American Clinical Laboratory Association (ACLA). |

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| 10) What measures should be used to track the level of “conformance” with or customization of standards after implementation in the field?  |
| Comment:If validation tools are available, such as NIST validation tool for US Realm Laboratory Guides, self-reporting to a central “self service” registry could be facilitated using the validation result scores. Note: full vocabulary would need to be loaded to avoid ‘false failure’ error messages due to missing vocabulary master. |