Meeting Objective: Consensus Regarding The NPRM Presentation To The HITPC

Health IT Implementation, Usability And Safety Work group presentation To The HIT Policy Committee: IUS Work group NPRM Comments

IUS Certification NPRM Assignments

Group 1
- Principles Of Proper Conduct For ONC-ACBs
- Surveillance And Maintenance
- Transparency And Disclosure Requirements
- Complaints Reporting
- Open Data Certified Health IT Product List (CHPL)
- Adaptations And Updates Of Certified Health IT
- Decertification

Group 2
- Safety-Enhanced Design
- Summative Testing
- Retesting
- Quality Management System
- Accessibility Technology Compatibility
- Accessibility-Centred Design

Group 3
- Pharmacogenomics Data – Request For Comment
- Sub part E – ONC Health IT Certification Program
- Modifications To The Program
- Removal Of Meaningful Use Measurement Certification Requirements
- Types Of Care And Practice Settings
- Base EHR Definition
- CEHRT Definition
- The ONC Health IT Certification Program And Health It Module
- Referencing The ONC Health IT Certification Program
- Design And Performance

Overarching Comments
The Approach Outlined In The NPRM Creates A Certification Program With Significantly Broader Scope And Applicability Across The Healthcare Eco-System To Be Inclusive Of Any Stakeholder That Sends And Receives Health Information.

While The EHR Incentive Program Targeted Specific Professionals And Providers, The Affordable Care Act And Goals Of Healthcare Reform Requires The Broader Healthcare Community To Use And Exchange Electronic Health Information To Reduce Care Fragmentation And Improve Coordination.

There Is Potential For The Modular Approach To Health IT Certification Described In The NPRM To Engage A Much Broader Set Of Stakeholders And Set Foundational Interoperability Requirements For Sending And Receiving Electronic Health Information.

Redesigning The Program Into A Modular Approach Provides The Flexibility To Increase Its
Applicability To The Various Stakeholders And Technologies That Must Interoperate.

The Program Will Likely Be More Complex, Particularly For Stakeholders Who Must Address Multiple Modules And Certification Requirements From Various Agencies. For This Reason, The Role Of ONC As A coordinator To Facilitate Alignment Between Federal Program Requirements And Related Health IT Modules Is Critical To Mitigate Complexity And Cost.

Also Recognize That This Is The Next Evolutionary Step For Certification That Will Include New Challenges And/OR Repercussions:

- A More Complex Program Will Likely Drive Up Costs For Certification Particularly Those Who Certify And Test To Multiple Health IT Modules That Might Be Considered A Single Large System.
- There May Be Challenges To Keeping The Modules And Their Requirements At The Foundational Level And Not Expand Their Scope Unnecessarily.
- Other Parties That Identify Certification Paths And/OR Require Compliance With A Certification Module(S) Could Erode The Foundation By Requiring A Module With Modifications And Add-Ons.

Utility Of CHPL-Comments

Appreciate The Recognition In The NPRM That Current Onc Certified Health IT Product List (CHPL) Is Difficult To Use. The NPRM Describes That ONC Will Rewrite The CHPL In Approximately 12 To 18 Months.

Evaluation Of The Significantly Expanded Dataset And Redesign Should Be Included In The Redesign Plans So That The Value To Purchasers, Developers, Usability Professionals Providers And Other Interested Parties Can Be Determined.

ONC Should Apply To The CHPL Development The User Centred Design Principles That It Is Asking Of Health IT Developers.

Other Software Sources

- Some Of The Committee Emphasized That Not All HIT Software Is Provided By Vendors. Providers Do Use Self-Developed Software And Open-Source Software.
- There Are Vendors With A Hybrid Of Software From Multiple Source-Types. As A Result, The Proposals May Be Inappropriate In Some Situations.
- The Proposals May Favour Some Sources Of Software Over Other Sources

Expansion Of The Use Of Certification

- Efforts Are Being Made To Expand The Use Of Certification To Address Public Policy Concerns Such As HIT Safety, Vendor Business Practices, And Helping Individuals With Disabilities.
- There Were Members Of The Work group Who Strongly Voiced The View That The Certification Process Is Not Appropriate To Address These Issues, Especially If Done By Attestation.
- A Member Of The WG Expressed Interest In Understanding Where In The Statute ONC Had The Authority To Expand The Certification Program Beyond The EHR Incentive Program

Shift From Functional Requirements To Interoperability And Privacy

- In Response To Industry Feedback, A Shift Away From Functional Requirements To Interoperability And Privacy/Security Requirements Is Noted.
- There Were Work group Members Who Suggested That In This Version, The Criteria Focused Solely, On Interoperability And Privacy/Security And That Functional Capabilities Should Not Be Included.
Time line
- The Time line Outlined In The NPRM May Not Allow Sufficient Time For Eligible Providers To Begin Their Reporting Period For Meaningful Use Stage 3 On January 1, 2017.
- While This Start Date Is Optional For Providers, Health IT Suppliers Would Have To Deliver Fully Operational Software To Providers Well In Advance Of That Date To Allow For Implementation By The Provider.
- While A Reduction In Scope Might Make This Time line Achievable, A Longer Development And Implementation Time line Could Well Improve Software Capabilities And Effective Implementation

Complexity
Some Work group Members Felt That This Version Of Certification Was Not Responsive To Feedback & That Previous Iterations Of Certification Were Too Complex.

Maturity Of Standards
- Work group Members Voiced Concerns That Proposed Standards Have Not Sufficiently Matured To Be Promulgated Through Regulations.
- Suggest That ONC And CMS Find Mechanisms Supportive Of Pilots And Limited Deployments In Production Environments. This Will Serve To Assess The Applicability, Practicality, And Consistent, Wide Deploy- Ability Of Standards And Implementation Prior To Being Considered For National Rule making And Avoid A Situation Where The Certification Rule Is In Effect Acting As A National Pilot Program.

Variations Among Partners
- Certification Requirements That Impact One Segments Of The Market Should Also Apply To The “partner” Segment To Be Certified. This Will Add Significant Cost And Complexity When Providers And EHR Developers Will Be Required To Develop And Implement Multiple Interfaces Rather Than One Standard Interface
- The Point Was Made Regarding How Certification Would Address The Challenges Of Interoperable Health IT Adoption By LTPAC And BH Providers Who Were Left Out Of The EHR Incentive Program.
- There Was Acknowledgement That The Sectors Requested This Approach In Hearings To The HIT Policy Committee, But Also Recognition That This Is One Approach While Others May Still Be Needed To Support Adoption.

Intent Of The Regulation And The Integrity Of A Sound UCD Process.

Developer Teams Must Carry Out Activities In An Iterative Manner That Are Aimed At Informing The Usability Goals, User Requirements And Design Of HIT And Include Actual End Users In That Process.

Developer Teams Must Carry Out Activities That Are Aimed At Evaluating The Success Of Meeting Usability Goals And Gathering Objective Performance Evidence That The Health IT Is Safe, Effective, Efficient, And Satisfying To Use.

The Certifying Boards Should Be Required To Demonstrate That They Are Equipped To Review And Evaluate Submissions In Regard To UCD.

Safety Enhanced Requirements
Missing In The Safety-Enhanced Design Requirements Is The Mechanism That Requires A Process That Includes All Of The Following:
- Identification Of Usage Errors & An Analysis Of Usage Errors
- Identifying And Implanting Mitigations Aimed At Reducing Risks Associated With Identified
Errors
- Tracking This Process Through Post-Market Surveillance.
- Inclusion Of Patient History As A Safety Element.

**Health IT Implementation, Usability, And Safety (IUS) Work group certification Nprm Comment Template**

(Group 1)

Surveillance and Maintenance of Certification

- The Process Must Be Reasonable And Considerate With Regard To Burden Placed On End User. It Is Unclear How This Will Be Evaluated In The Field, Especially In The Context Of The Uniqueness Of Each User Group And Context Of Use.
- When The EHR Is Not Working As Expected, The End User Is Not Easily Aware Of The Cause Of The Dysfunction.
- Agree With Intent Of The Statement “Requiring Complete EHR Developers To Take Corrective Action In Instances Where The Technology Fails To Conform To The Requirements Of Its Certification”.
- Caution That There Is The Potential For Unintended Consequences And Should Not Produce Additional Burdens To Providers Or Health System Purchasers.
- ACB Skill Set In This Area Is Lacking And Retraining Would Be Needed.

Areas Of Clarification Needed:

**HIPAA Impacts:**
1. On-site Surveillance
2. Patient/Provider Protections.
   - How Can The Audit Be Performed Without Disrupting Service To Patients?
   - What Weight Should Certifiers Give To Poor Product Implementation By Providers? How Can “poor” Or “good” Performance Be Objectively Determined? What Compels Providers To Participate?
   - Is This An Official “audit”?
   - What Federal Ruling Gives Certifiers The Authority To “audit” The Vendor Product Implementation At The Provider Site?
   - Is This Voluntary Or Mandatory On The Part Of A Provider?
   - How Will This Criteria Prevent “cherry Picking” Of Customers.

As Part Of Certifier Vendor Relationship, The New Surveillance Process Will Need To Be Built Into New Customer Agreements At The Time Of Application, And Current Vendor Customers Agreements Must Be Altered To Reflect New Charges This Could Add To Costs.

**Recommendation**
- Many Of The Concerns Can Be Addressed By A More Rigorous And Protocol Driven Complaint Process, With Periodic Public Reporting Mediated And Monitored By The ACB’s.
- ONC-ACBs Do Not Have Access To Vendor Customer Lists To Promote This On Their Own. But ONC, Working With CMS, Could Do This Effectively

**Transparency and Disclosure Requirements**
- WG Members Support The Notion Of A More Specific Cost Structure To Include All Costs And Fees Physicians Would Be Required To Pay For Any EHR Function Outside Monthly Service Contracts.
- In The Spirit Of Transparency, Vendors Should Collect HISP/HIE Fees And/Or Pricing Information And Provide It To Customers.
- ONC Should List This Information Publicly And Known Issues From Previous Implementations Shared Openly With Potential And Existing Customers.
- Contracts Should Not Prohibit Customers From Sharing Information On Their Own Including Screen Shots And Other Information Regarding Aspects Of A Custom Feature,
Training And Implementation Questions Or Reporting Tools, And Other Functional Elements.

- Some Members Felt That The Proposal Is Not Limited To EHR Vendors, But Also Impacts All HIT Vendors. It Represents A Major Expansion Of The Certification Program Scope It’s Burdensome And An Overreach.

Complaints Reporting

- The Work Group Is Generally Supportive And Agrees With Complaint Information Publicly Posted Online. In Order To Be Actionable And Meaningful, Vendor/Complainant Should Be Identified. However The Group Also Noted That This Seems To Suggest That All/Most Of The Issues Are Vendor Caused And/OR Fixable By The Vendor.
- The Broad Set Of Reasons For Complaint Would Need To Be Fully Considered Before This Would Be Implemented And The Expected Actions As A Result Of The Trend Analysis Would Need To Be Fully Assessed. Ultimately, The Value Of The Information Would Need To Be Weighed Against The Cost Of Creating It.
- This Exercise Must Be Carefully Thought Out, With Well-Defined Measurement Objectives, And Very Clearly Documented Methodologies. The Process Must Be Reasonable And Considerate In Regard To Burden Placed On End User As Well As The Vendor.
- A Process That Uses The ACB’s Through ANSI Accreditation Standards Might Include:
  o Publicly Available Records Of Customer Complaints And Their Outcomes.
  o Include Detailed Transparent Processes. (e.g. Standard Categories: By Product And Version Number).
  o Ease Of Complaint Process, Complaint Categorization Includes Certification Elements And Service Related Elements
  o User Complaints Within The Scope Of The Certification Criteria Or Testing Process Should Be The Priority,
  o Complaints About Problems Beyond The Scope Of Certification, Such As Poor Customer Service, Should Be Logged And Counted.

Open Data Certified Health IT Product List (CHPL)

- Some Work Group Members Thought It Best That Regulation Regarding Additional Data In The CHPL Should Be Postponed Until ONC Completes Its Redesign And Shows That The Data In The Chpl Is Used And Is Beneficial.
- Vendors Have Provided Significant Feedback To ONC Already To Make It More Usable.
- The Work group Is Supportive Of ONC’s Open Data Initiative.
- Opening The CHPL Up To Further Public Consumption Will Help The Industry And Health IT Consumers Compare And Contrast Products, Leading To Better Design And Enhanced Competition.
- There Is A Need For More Clarity On The API Functionality.
- Developers/Vendors At ATL/ACBS Should Know At Program Launch What The Open Data Elements Are And How Defined.
- The Work Group Believes That Additional Data Element Should Be Required In The Open Data File As An Important Step In Transparency And Consumer Choice.

Adaptations and Updates of Certified Health IT

- Some Work Group Members Felt This Proposal Was Redundant.
- Vendors Need To Provide Information To The ACB’s When They Update Their Solutions In The Current Environment. No New Process/Requirements Are Needed.
- Other Work group Members Are Supportive Of The New Principle Of Proper Conduct And Believe It Will Help Provide Updated Information To ACB’s On Status And Progress Of Health IT As It Improves.
- Distinctions Between “minor” And “major” Changes Need Definitions. These Methods Should Be Documented In A Protocol That All ATL/ACBS Follow.
- A Method For Understanding How This Variability Impacts The Utility Of The Data And Comparisons Should Be Identified And Piloted Prior To Mandating A Count Of Changes.
• There May Be Situations Where Health IT Vendors Make Small, Inconsequential Changes To Software Code - These May Or May Not Need To Be Reported And Could Add Undue Burden On Health IT Vendors.

Decertification” of Health IT – Request for Comment
• ONC Was Instructed By Congress To Report On Products Blocking Interoperability And To Decertify Them.
• Agree That This Concept Requires Further Consideration And Study. The Action Of Decertification Would Raise Real Concerns For All Stakeholders.
• There Would Almost Certainly Be Unintended Consequences Resulting From This Approach:
  o Concern For End Users, Using A Vendor’s System Only To Find They Are Not Able To Comply With The CMS EHR Incentive Program Because Their EHR Becomes Newly De-Certified.
  o Burden On Providers Who Must Spend Time And Funds To Purchase And Deploy A New EHR Or Accept A CMS Penalty If Vendor They Are Using Is Decertified.
  o Alternatives Should Be Considered.
  o Decertification Would Impact All Stakeholders:
    ▪ Vendors, Hospitals, Providers As Well As Patients Would All Likely Experience Disruptions.

• Information On Process And Planning For Consequences Must Be Outlined Before The Work group Could Support This Element.
• This New Measure Increases The Likelihood Of Decertification;
  o In A Situation Where A Health IT Product Is Marked For Decertification There Should Be Consideration Regarding The Circumstances Due Process, And Associated Remedies.

• The Decertification Process Must Be Well Thought Out:
  o Violations, Process, Review, Appeal, Notification And Other Possible Effects – Many Of Which Could Be More Harmful In The Big Picture.
  o There Is No Generally Accepted Definition Of Data Blocking.
    ▪ What Objective Information Would Be Used To Determine An Entity Is Blocking Information?
  o Acknowledge The Value Of Certification In Meeting Standards And Efficacy Of EHR's.
  o Would Like To Increase The Emphasis On Current Regulations That States The Expectation That Vendors Will Be Transparent In Their Requirements/Contractual Terms And Will Make Info Available To Their Customers And Prospects, Openly Portable And Transportable, As Well As The Proposal To Enhance The Information Available On The Chpl Site Addressed In Previous Comments.

Health IT Implementation, Usability, And Safety (IUS) Work group certification NPRM Comment Template (Group 2)

Safety-enhanced design
• Regarding Identify Industry Recognized/Federal User Centred Design (UCD) Standard:
  o Differences Of Opinion Existed Within The Group.
  o Most Members Of The Work Group Believed The NPRM Did Not Go Far Enough In This Area And That Following A UCD Process Will Be Applying Formative,
Iterative UCD Activities To Inform The Design & Conducting A Summative Test(S) To Validate Safe And Effective Use Of Production User Interface.

- Both Formative And Summative Activities Are Required As Part Of A UCD Process.

- Artefacts From Formative Activities May Be Appropriate As Evidence For Applying A UCD Process.
- Providing An Artefact From A Formative Usability Activity Is Not Going To “make The Product Better”.
- ONC-ACB Review For Certification Was Very Focused On Report Format And Inclusion Of Data Fields Not Related To Safe And Effective Use.
- Per The NPRM There Are Seven New Certification Criteria That Strengthen Safety-Enhanced Design. The Inclusion Of Additional Criteria With A Safety Focus Is A Positive Effort In The Right Direction.

There Also Needs To Be An Emphasis On Formative Evaluation. This May Be Covered When A Quality Management System Is Used, But Should Be Specifically Mentioned In This Section As Well.

The Following Information Must Be Submitted For Each Capability To Which User-Centred Design Processes Were Applied:

- Name And Version Of The Product; Date And Location Of The Test; Test Environment; Description Of The Intended Users; And Total Number Of Participants;
- Description Of Participants, Including: Sex; Age; Education; Occupation/Role; Professional Experience; Computer Experience; And Product Experience;
- Description Of The User Tasks That Were Tested And Association Of Each Task To Corresponding Certification Criteria;
- List Of The Specific Metrics Captured During The Testing, Including: Task Success (%); Task Failures (%); Task Standard Deviations (%); Task Performance Time; And User Satisfaction Rating;
- Results And Data Analysis Narrative, Including: Major Test Finding; Effectiveness; Efficiency; Satisfaction; And Areas For Improvement.

Submit Test Scenarios Used In Summative Usability Testing

- As Part Of A UCD Process, Teams Must Identify Intended Users Of Features/Prioritized Criteria And Recruit That User Role To Participate In Formative And Summative Activities.
- Regarding User Tasks: Recommend NIST Provide Standard Scenarios For Usability Test Tasks So Summative Test Reports Can Be Compared To Each Other.
- Risk-Based Analysis Of Test Tasks Should Be Included As Part Of The Test Task Description.
- Request Clarification On Whether This Portion Of The Rule Is Defining The Statistical Procedure To Use For Measuring Effectiveness Or The Effectiveness Metric (which Is Not Standard Deviations, But Simply Task Deviations).
- Task Performance Time: Needs Clarification- Mean Task Performance Time (and SD Of Task Performance Time).
- User Satisfaction Rating: Content Is Suggested As An Example And Is Not Representative Of An Industry Standard Questionnaire For Analysing Software Usability. The Primary Scientifically Recognized Single Task-Based Satisfaction Rating Is The Single Ease-Of-Use Question Which Uses A 7-Point Scale. The Work Group Also Recommends Supporting The Ability To Use Literature-Recognized Satisfaction Measures, All Of Which Use Different Measurement Scales And Do Not Specify Which Satisfaction Measure Is Used Nor Do They Specify Task-Based Satisfaction Measures Versus A Post-Session Satisfaction Measures.
• Results And Data Analysis Narrative: Asks For The Major Findings Related To Effectiveness, Efficiency, Satisfaction, And Areas Of Improvement. The Focus Is On Areas Identified To Be At Risk For Error, But No Requirement For Error Analysis As Part Of The Report? Recommend A Specific Results Section Be Required, Focused On Error Analysis.

• Number Of, And User Cohort For, Test Participants: Recommend The Establishment Of Minimum Number(S) And User Cohort(S) For Test Participants For The Purposes Of Testing And Certification To The 2015 Edition Under The ONC Health IT Certification Program.
• Recommendation That Organizations Follow Industry Accepted Guidelines On Compliance With A Number Of Test Participants For Formative Testing As Well As Summative Testing.
• The Work Group Recommends That A Minimum Of 15 Participants Should Be The Standard.
• Summative Testing Is A Benchmark Test So More Users Are Required;
• 15-20 Are Suggested Per User Group For Which The Application Is Being Designed. If Organizations Use Smaller Samples, Justification With Rationale Is Needed Since This Would Be Outside Industry Standards And Best Practice Recommendations.
• Need For Formative Testing With A Focus On Implementation Due To The Safety Issues That Arises From Customization Was Not Specifically Addressed In The NPRM, And The Work group Called Attention To This Omission.

Issues Of Hardship And Possible Need For Exceptions To The Above:
• Small Companies Producing Individual Modules- Might Not Have Enough Customers And Users Able To Participate In Testing.
• Self-Developed Software? A Programmer Creates A Customize Module
• Open Source Software.

• Applying A Nationally Recognized User Centred Design Process, Means Attesting To Carrying Out Formative Activities And Attesting To Conducting A Summative Usability Test.
• To Replace The Summative Usability Test With Only Formative Testing Is Prescribing A Process That Is Not A Nationally Recognized User Centred Design Process.
• Formative Activities Are Required As A Part Of Ucd Attestation.
• Formative Evaluation Must Be Required. Formative Activities Are Included When A Quality Management System Is Implemented.
• Both Formative And Summative Are Needed. Summative Testing With Summative Metrics Is The Only Standard For The Usability Validation. In Addition, The Work Group Also Believes Risk Management Processes If Implemented, Also Embrace Formative Testing.
• The Report Format Assumes Sound Practice Has Been Followed In The Design And Execution Of The Test.
• Test Procedures Which Produce Measures That Summarize Usability Should Be Used, I.E. The Test Is Summative In Nature. Some Usability Evaluation Methods, Such As Formative Tests, Are Intended To Identify Problems Rather Than Produce Measures; The Format Is Not Structured To Support The Results Of Such Testing Methods.
• Recommend Continued Use Of Summative Test Reports. It Is Important That Onc Show Evidence That Having That Information In The Chpl Is Useful To Health It Purchasers And Others.

Quality Management System
(a) For Each Capability That A Technology Includes And For Which That Capability's
Certification Is Sought, The Use Of A Quality Management System (QMS) In The Development, Testing, Implementation, And Maintenance Of That Capability Must Be Identified That Is:

1. Compliant With A QMS Established By The Federal Government Or A Standards Developing Organization; Or

(b) If A Single QMS Was Used For Applicable Capabilities, It Would Only Need To Be Identified Once.
(c) If Different QMS Were Applied To Specific Capabilities, Each QMS Applied Would Need To Be Identified.

Process Required Via A Certification Process

- Others Felt The Regulation Adds More Complexity To An Already Complicated Certification Process. It Increases The Cost Of Certification, But The Expenses Are Not Included In The NPRM's Cost Section. The Tie In To Self-Developed Software Or Open-Source Software Is Not Apparent.
- ONC’s Regulations Should Not Apply To All Software Sources And Not Penalize Any Potential Source.
- Recommend Against The Proposed Language Until ONC Completes Its Redesign Of The CHPL And Shows That The Information That It Is Already Gathering For Stage 2 Is Being Used By Purchasers Who Find It Effective.

Technology Compatibility

Accessibility Technology Compatibility. For Each Capability Technology Includes That Is Specified In The Certification Criteria At § 170.315(A), (b), And (e), The Capability Must Be Compatible With At Least One Accessibility Technology That Includes Text-To-Speech Functionality.

Regulation Is Burdensome And An Over-Reach. Text-To-Speech Capabilities Are Frequently Not Appropriate For Many Health Care Work-Flows, Especially When One Considers Privacy Issues.

Health IT Implementation, Usability, And Safety (US) Work group certification NPRM Comment Template (Group 3)

Pharmacogenomics Data – Request for Comment

- The Work group Encourages A Process That Highlights Priorities But Does Not Require Certification Criteria For Areas Where There Is A Lack Of Foundational Standards For A Certification Program.
- Issues Such As Pharmacogenomics Are Important To The Personalized Medicine Initiatives
- Early Prioritization Allows The Industry And/OR Onc To Address The Gaps Prior To Fully Integrating Into The Certification Program At A Future Date.

Sub part E – ONC Health IT Certification Program

The Work group Recognizes That Changes Are Needed To Support The Certification Program. Agree With The Changes Described In The NPRM, And Have No Concerns With The Following Revisions:

1. Replace The Term “HIT” With The Term “health IT”.
2. Replace The Term “ONC HIT Certification Program” With The Term “ONC Health IT Certification Program.”
3. Removal Of § 170.553 “Certification Of Health Information Technology Other Than Complete EHR's And EHR Models.
Modifications to ONC Health IT Certification Program

- The Work group Agrees That The ONC Health IT Certification Program Should Be Accessible To Health IT Beyond EHR Technology, And Healthcare Setting And Practices Not Directly Tied To The EHR Incentive Programs.
- Removing The EHR Module Definition And Replacing It With A Health IT Module Definition Is More Inclusive And Accommodates This Shift.
- The Work group Discussed The Need For Individual Modules To Be Interoperable With One Another And Not Just Stand Alone.
- The Work group Recognizes That Testing For This Is Difficult And Does Not See A Practical Way To Incorporate This Into The Certification Program.

Removal of MU Measurement Certification Requirements
1. Agree With The Rationale To Remove The Meaningful Use Measurement Certification Requirement To Make The Health IT Certification Process More Broadly Accessible Beyond The EHR Incentive Program.
2. This Approach Will Allow The Certification Program To Provide The Building Blocks And The Minimum Technology Needs To The Broad Healthcare Community.
3. Request Clarification That Removing The Capability To Calculate Meaningful Use Measurement Will Not Create Frustration For The Meaningful Use Program Providers If They Still Need To Report The Calculations As Part Of Program Requirements.
4. Have One Program For All Types Of Settings And Services In Healthcare Rather Than A Program Tied Only To Meaningful Use Eligible Providers.
5. Establishing A Base For All Will Provide A Better Foundation For Advancing And Testing Interoperability Across The Many Stakeholders Who Hold And Share Health Information.
6. There Are Additional Certification Criteria That Would Be Useful To The Settings Called Out In The NPRM Including Those Related To Identity Matching, Bi-Directional Exchange, Advanced Directives, Tele-health (including Personal Health Tracking/Monitoring Devices), And Assessments.
7. Encourage ONC And HHS To Align Federally Required Assessment Instruments For LTPAC And New Developments As A Result Of The Impact Act With The Certification Process.

Specifically Related To Behavioural Health Assessments, There Is An Opportunity To Incorporate Health IT Standards For SAMHSA Required Assessments And Reporting.

Regarding The Inclusion Of Smoking Status, Implantable Device List And Application Access To Common Clinical Data Set, Would Like To Highlight That The Information/Data May Not Be Applicable To The Expanded List Of Care Settings And Service Providers Targeted With The Proposed Program Modification.

ONC Should Consider Data Creation Separately From The Need To Receive/Handle These Types Of Data Elements. The Process Should Not Require Sharing Of A Full Data Set If The Data Is Not Relevant To The Care Provider And/Or Service Provider, Doing So Creates A Process Where The Setting/Service Collects Data That Is Not Appropriate And Creates An Unnecessary Burden.

The Approach Described In The NPRM To Engage A Broader Set Of Stakeholders Beyond Ambulatory And Inpatient Settings To Include Others That Also Have Systems Meeting Foundational Interoperability Requirements Will Allow Other Programs To Reference Certification Requirements And/Or Certified Health IT.

Also Aware That The Expansion Of The Program And Use Of Health IT Modules Will Likely Increase The Complexity Of The Program, And Drive Up Costs For Certification.