Federal Programs and the Next-Generation Health IT Ecosystem:

Innovation in standards, implementation, testing, and engagement

October 19, 2016

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Medical Officer
Office of the National Coordinator for Health IT
Objectives

• Recall improvements in the ONC 2015 Edition Certification Program
• Understand the Interoperability Standards Advisory, IMPACT Act, PAMA 218, CPCI and MACRA/MIPS Programs
• Discuss next-generation standards maturation of for clinical quality and decision support as planned by CMS and ONC
Meaningful Use is/was a Building Block

Use technology to gather information

Use information to transform

Enhanced access and continuity
- Data utilized to improve delivery and outcomes
- Patient self management
- Patient engaged, community resources
- Patient centered care coordination
- Team based care, case management
- Registries to manage patient populations
- Privacy & security protections
- Structured data utilized for Quality Improvement
- Connect to Public Health
- Evidenced based medicine
- Registries for disease management
- Privacy & security protections
- Connect to Public Health
- Patient engaged
- Care coordination
- Basic EHR functionality, structured data
- Connect to Public Health
- Privacy & security protections
- Structured data utilized for Quality Improvement
- Connect to Public Health
- 3-Part Aim
- PCMHs
- Stage 1 MU
- Stage 2 MU
- ACOs
- Stage 3 MU

Office of the National Coordinator for Health Information Technology

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Nationwide Interoperability Roadmap:

3 Year Agenda (2015-2017)
Send, receive, find and use a common clinical data set to improve health and health care quality

6 Year Agenda (2018-2020)
Expand interoperable health IT and users to improve health and lower cost

10 Year Agenda (2021-2024)
Achieve a nationwide learning health system

BUILD UPON EXISTING HEALTH IT INFRASTRUCTURE
CONSIDER THE CURRENT ENVIRONMENT AND SUPPORT MULTIPLE LEVELS OF ADVANCEMENT
PROTECT PRIVACY AND SECURITY IN ALL ASPECTS OF INTEROPERABILITY

MAINTAIN MODULARITY
EMPOWER INDIVIDUALS
LEVERAGE THE MARKET

ONE SIZE DOES NOT FIT ALL
SIMPLIFY
FOCUS ON VALUE

SCALABILITY AND UNIVERSAL ACCESS

LEARNING HEALTH SYSTEM
Better Care
Smarter Spending
Healthier People
Product trends on this graph are reflective of the last 2 years of program operations. Date range 10/24/2012 – 10/24/2014
## Supporting the Broader Care Continuum: 2015 Edition

### The Past (2011 and 2014 Editions)

- ONC included **policy** that supported the EHR Incentive Programs in its previous Editions
  - Defined the Certified EHR Technology (CEHRT) definition on behalf of CMS
  - Required “meaningful use measurement” criteria
  - Specified the minimum number of clinical quality measures developers must certify to in order to participate in the EHR Incentive Programs
  - Specified criteria as “ambulatory” or “inpatient”

### The Future (2015 and Future Editions)

- ONC does not include **policy** to support the EHR Incentive Programs in its Editions
  - Each program sets its own requirements (e.g., CMS defines the CEHRT definition in its final rule)
  - **The ONC Health IT Certification Program** is “agnostic” to settings and programs, but can support many different use cases and needs
  - This allows the ONC Health IT Certification Program to support multiple program and setting needs, for example:
    - EHR Incentive Programs
    - Long-term and post-acute care
    - Chronic care management
    - Behavioral health
    - Other public and private programs
2015 Edition
Specific Health IT Goals

- Improve Interoperability
- Facilitate Data Access and Exchange
- Ensure Privacy and Security Capabilities
- Improve Patient Safety
- Reduce Health Disparities
- Improve the Reliability and Transparency of Certified Health IT
- Use the ONC Health IT Certification Program to Support the Care Continuum
- Support Stage 3 of the EHR Incentive Programs
## 2015 Base EHR Definition

* Red - New to the Base EHR Definition as compared to the 2014 Edition

** Privacy and security removed – now attached to the applicable certification criteria

<table>
<thead>
<tr>
<th>Base EHR Capabilities</th>
<th>Certification Criteria</th>
</tr>
</thead>
</table>
| Includes patient demographic and clinical health information, such as medical history and problem lists | Demographics § 170.315(a)(5)  
Problem List § 170.315(a)(6)  
Medication List § 170.315(a)(7)  
Medication Allergy List § 170.315(a)(8)  
Smoking Status § 170.315(a)(11)  
Implantable Device List § 170.315(a)(14) |
| Capacity to provide clinical decision support                                          | Clinical Decision Support § 170.315(a)(9)                                              |
| Capacity to support physician order entry                                              | Computerized Provider Order Entry (medications, laboratory, or diagnostic imaging) § 170.315(a)(1), (2) or (3) |
| Capacity to capture and query information relevant to health care quality              | Clinical Quality Measures – Record and Export § 170.315(c)(1)                           |
| Capacity to exchange electronic health information with, and integrate such information from other sources | Transitions of Care § 170.315(b)(1)  
Data Export § 170.315(b)(6)  
Application Access – Patient Selection § 170.315(g)(7)  
Application Access – Data Category Request § 170.315(g)(8)  
Application Access – All Data Request § 170.315(g)(9)  
Direct Project § 170.315(h)(1) or Direct Project, Edge Protocol, and XDR/XDM § 170.315(h)(2) |
Common Clinical Data Set

- Renamed the “Common MU Data Set.” This does not impact 2014 Edition certification.
- Includes key health data that should be accessible and available for exchange.
- Data must conform with specified vocabulary standards and code sets, as applicable.

<table>
<thead>
<tr>
<th>Patient name</th>
<th>Lab tests</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td>Lab values/results</td>
</tr>
<tr>
<td>Date of birth</td>
<td><strong>Vital signs (changed from proposed rule)</strong></td>
</tr>
<tr>
<td>Race</td>
<td>Procedures</td>
</tr>
<tr>
<td>Ethnicity</td>
<td>Care team members</td>
</tr>
<tr>
<td>Preferred language</td>
<td><strong>Immunizations</strong></td>
</tr>
<tr>
<td>Problems</td>
<td><strong>Unique device identifiers for implantable devices</strong></td>
</tr>
<tr>
<td>Smoking Status</td>
<td><strong>Assessment and plan of treatment</strong></td>
</tr>
<tr>
<td>Medications</td>
<td>Goals</td>
</tr>
<tr>
<td>Medication allergies</td>
<td><strong>Health concerns</strong></td>
</tr>
</tbody>
</table>

ONC Interoperability Roadmap Goal

2015-2017
Send, receive, find and use priority data domains to improve health and health quality

Red = New data added to data set (+ standards for immunizations)
Blue = Only new standards for data
Increased Measure Coverage

- Greater than 80% eCQM test case logic coverage
- Patient test decks will increase in size
- C2 Import and Calculate will now require automated ingest of QRDA Cat III
- Patient test decks will only be used for a single measure
• Optional – Certify an EHR’s ability to:
  – Record the data listed in paragraph (c)(4)(iii) of this section in accordance with the identified standards, where specified
  – Filter CQM results at the patient and aggregate levels by each one and any combination of the data listed in paragraph (c)(4)(iii) of this section and be able to:
    • Create a data file of the filtered data
    • Display the filtered data results in human readable format

(c)(4)(iii)
A) Taxpayer Identification Number.
(B) National Provider Identifier
(C) Provider type
(D) Practice site address
(E) Patient insurance
(F) Patient age
(G) Patient sex
(H) Patient race and ethnicity
(I) Patient problem list
Surveillance of Certified Health IT

- New requirements for “in-the-field” surveillance under the ONC Health IT Certification Program

- ONC-ACBs should ensure that certified Health IT Modules can perform certified capabilities in a production environment (when implemented and used)
  - Reactive surveillance (e.g., complaints)
  - Randomized surveillance

- Enhanced surveillance of mandatory transparency requirements

- Non-conformity and corrective action reported to the CHPL beginning in CY 2016
Objectives

• Recall improvements in the ONC 2015 Edition Certification Program

• **Understand the Interoperability Standards Advisory, IMPACT Act, PAMA 218, CPCI and MACRA/MIPS Programs**

• Discuss next-generation standards maturation of for clinical quality and decision support as planned by CMS and ONC
Contains Proposed Standards For:

- Vocabulary/Terminology
- Content and Structure
- Transport
- Services
- Implementation Guidance

Includes an open process for annual updates
2017 Draft Interoperability Standards Advisory: 
http://www.healthit.gov/standards-advisory/draft-2017

Draft 2017 Interoperability Standards Advisory

Available for public comment!

<table>
<thead>
<tr>
<th>Section I</th>
<th>Section II</th>
<th>Section III</th>
</tr>
</thead>
<tbody>
<tr>
<td>I-A: Allergies</td>
<td>I-B: Encounter Diagnosis</td>
<td>I-C: Family Health History</td>
</tr>
<tr>
<td>I-D: Functional Status/Disability</td>
<td>I-E: Health Care Provider</td>
<td>I-F: Imaging (Diagnostics, interventions and procedures)</td>
</tr>
<tr>
<td>I-J: Medications</td>
<td>I-K: Numerical References &amp; Values</td>
<td>I-L: Nursing</td>
</tr>
<tr>
<td>I-M: Patient Clinical “Problems” (i.e., conditions)</td>
<td>I-N: Preferred Language</td>
<td>I-O: Procedures</td>
</tr>
<tr>
<td>I-P: Race and Ethnicity</td>
<td>I-Q: Research</td>
<td>I-R: Sexual Orientation and Gender Identity</td>
</tr>
<tr>
<td>I-S: Social Determinants</td>
<td>I-T: Tobacco Use</td>
<td>I-U: Unique Device Identification</td>
</tr>
</tbody>
</table>

COMMENT ON THE WHOLE ISA

- Draft 2017 Interoperability Standards Advisory
  - Introduction
  - Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications
  - Section II: Content/Structure Standards and Implementation Specifications
  - Section III: Standards and Implementation Specifications for Services
  - Section IV: Questions and Requests for Stakeholder Feedback
  - Appendix I – Sources of Security
CMS PROGRAMS RELATED TO CLINICAL QUALITY AND PERFORMANCE
### CMS quality and performance programs (2014)

#### Hospital Quality
- Medicare and Medicaid EHR Incentive Program
- PPS-Exempt Cancer Hospitals
- Inpatient Psychiatric Facilities
- Inpatient Quality Reporting
- HAC reduction program
- Readmission reduction program
- Outpatient Quality Reporting
- Ambulatory Surgical Centers

#### Physician Quality Reporting
- Medicare and Medicaid EHR Incentive Program
- PQRS
- eRx quality reporting

#### PAC and Other Setting Quality Reporting
- Inpatient Rehabilitation Facility
- Nursing Home Compare Measures
- LTCH Quality Reporting
- Hospice Quality Reporting
- Home Health Quality Reporting

#### Payment Model Reporting
- Medicare Shared Savings Program
- Hospital Value-based Purchasing
- Physician Feedback/Value-based Modifier*
- ESRD QIP

#### “Population” Quality Reporting
- Medicaid Adult Quality Reporting*
- CHIPRA Quality Reporting*
- Health Insurance Exchange Quality Reporting*
- Medicare Part C*
- Medicare Part D*

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*Denotes that the program did not meet the statutory inclusion criteria for pre-rulemaking, but was included to foster alignment of program measures.
Mandated coordination across agencies and programs:
HHS Measurement Alignment

MU, PQRS, IQR, ACO, VBP, HRSA, CDC

Unified Outcome Measures

EHR as primary reporting platform, with secondary reporting from registry, claims
• IMPACT Act added new section 1899(B) to Title XVIII of the Social Security Act (SSA)

• Post-Acute Care (PAC) providers must report:
  – Standardized assessment data
  – **Data on quality measures**
  – Data on resource use and other measures

• The data must be standardized and interoperable to allow for the:
  – Exchange of data using common standards and definitions
  – Facilitation of care coordination
  – Improvement of Medicare beneficiary outcomes

• PAC assessment instruments must be modified to:
  – Enable the submission of standardized data
  – Compare data across all applicable providers
IMPACT ACT: Quality Measure Domains

• **Requirements:**
  – Measures must be uniform/standardized across the 4 settings
  – Measures will be risk adjusted, as determined appropriate by the Secretary

• **Domains:**
  – Functional status, cognitive function, and changes in function and cognitive function
  – Skin integrity and changes in skin integrity
  – Medication reconciliation
  – Incidence of major falls
  – Communicating the existence of and providing for the transfer of health information and care preferences
• Section 218(b) of the PAMA amended Title XVIII of the Act, to establish a program to promote the use of appropriate use criteria (AUC) for advanced imaging services.

• The legislation requires in 2018 that every claim for advanced radiologic studies would include both:
  – Evidence that the user had utilized some form of approved clinical decision support that supported “appropriate use” of the advanced radiologic study
  – Evidence as to whether the user adhered to that advice or not
The Shared Savings Program is part of CMS’ strategy to promote delivery of health care aimed at reducing fragmentation, improving population health, and lowering overall growth in expenditures by:

– Promoting accountability for the care of Medicare fee-for-service beneficiaries
– Improving coordination of care for services provided under Medicare Parts A and B
– Encouraging investment in infrastructure and redesigned care processes
Medicare Shared Savings Program

- Section 3022 of the Affordable Care Act.
- Voluntary national program.
- Medicare-enrolled providers and suppliers to join together to form Accountable Care Organizations.
- 3-year agreement, choice of Track
- Required to develop processes to promote evidence-based medicine, patient engagement, care coordination, and internally report on cost and quality.
- ACOs that meet quality and cost goals share in savings generated.
As of January 2016 there were 434 Shared Savings Program ACOs in 49 states plus Washington DC:

- 180,000 participating physicians and other practitioners.
- ACOs serve over 7.7 million assigned Medicare fee-for-service beneficiaries.

- ACO quality reporting satisfies PQRS and VM reporting requirements for eligible practitioners participating in the ACO.

Most recent results (performance year 2015) show continued quality improvement and more ACOs share savings over time.

- In 2015, Medicare Shared Savings Program ACOs had a combined total program savings of $429 million.
- ACOs that reported quality in both 2014 and 2015 improved on 84 percent of the quality measures that were in the measure set in both years. Average quality performance improved by over 15 percent on several measures, including blood pressure screening and follow up.
Appropriate Use Criteria for Advanced Diagnostic Imaging Services

• Proposed Priority Clinical Areas:
  – Lung cancer
  – Headache
  – Low back pain
  – Altered mental status
  - Cervical/neck pain
  - Chest pain
  - Abdominal pain
  - Suspected stroke

• In 2019 Congress mandated that CMS start to require preauthorization of radiologic studies for entities and individuals found to be regularly ordering studies deemed “inappropriate” according to the established “appropriate use” criteria
• In 2015 CMS established the requirements for the creation of “appropriate use criteria” (AUC) for advanced radiologic studies

• Requires that either an integrated or a web-based service is consulted prior to any advanced imaging (e.g. CT, MRI, PET, SPECT)

Comprehensive Primary Care (+/- Plus)

Track 1

Up to 2,500 primary care practices.

Pathway for practices ready to build the capabilities to deliver comprehensive primary care.

Track 2

Up to 2,500 primary care practices.

Pathway for practices poised to increase the comprehensiveness of care through enhanced health IT, improve care of patients with complex needs, and inventory resources and supports to meet patients’ psychosocial needs.
Comprehensive Primary Care (+/- Plus)

**Access and Continuity**
- 24/7 patient access
- Assigned care teams

**Care Management**
- Risk stratify patient population
- Short and long-term care management

**Comprehensiveness and Coordination**
- Identify high volume/cost specialists serving population
- Follow-up on patient hospitalizations

**Track 1**
- E-visits
- Expanded office hours

**Track 2**
- Care plans for high-risk chronic disease patients
- Behavioral health integration
- Psychosocial needs assessment and inventory resources and supports
## Comprehensive Primary Care (+/- Plus)

<table>
<thead>
<tr>
<th></th>
<th>Care Management Fee (PBPM)</th>
<th>Performance-Based Incentive Payment</th>
<th>Underlying Payment Structure</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Track 1</strong></td>
<td>$15 average</td>
<td>$2.50 opportunity</td>
<td>Standard FFS</td>
</tr>
<tr>
<td><strong>Track 2</strong></td>
<td>$28 average; including $100 to support patients with complex needs</td>
<td>$4.00 opportunity</td>
<td>Reduced FFS with prospective “Comprehensive Primary Care Payment” (CPCP)</td>
</tr>
</tbody>
</table>
Beginning in 2019, all current Medicare payment, including incentive programs, will be combined into one Merit-Based Incentive Payment System (MIPS), replacing all Medicare reimbursement for eligible professionals.

The MIPS program will use four performance measures to determine reimbursement, which will begin in 2019:

• Quality;
• Resource use;
• Clinical practice improvement activities; and
• Meaningful use of certified EHR technology.

Privacy and security including HIPAA are also requirements and failure to adhere to required standards results in penalties.
Clinicians who receive a substantial portion of their revenues (at least 25% of Medicare revenue in 2018-2019 but threshold will increase over time) from qualifying alternative payment mechanisms will not be subject to MIPS.

While the definition of a qualifying APM has yet to be determined, MACRA outlines criteria which includes but is not limited to:

**Quality Measures**
- Use of certified EHR technology
- Risk-sharing

**Merit-Based Incentive Payment System (MIPS)**

Adjustments based on the composite performance score of each eligible physician or other health professional on a 0-100 point scale based on the following performance measures. All scores noted below are for the first MIPS year and are subject to adjustment. Additional positive adjustment available for exceptional performance.

- **Quality**
  - (50% of MIPS score for first 2 years)

- **Clinical Practice Improvement Activities**
  - (15%)

- **Resource Use**
  - (10% 1st year)

- **Meaningful Use of certified HER**
  - (15%)
MIPS-Eligible Professionals (EP)

**Notable Dates**

**July 1, 2017**
CMS must make available timely confidential feedback reports to each MIPS EP

**Qualifying EPs 2019-20**
- Physicians
- PAs
- Certified RN Anesthetists
- NPs
- Clinical Nurse Specialists
- Groups that include such professionals

**July 1, 2018**
CMS must make available to each MIPS EP information about items and services furnished to the EP’s patients by other providers and suppliers for which payment is made under Medicare

**2017**
**2018**
**2019**
**2020**
**2021**

**2021 & Onward**
Secretary can add EPs to MIPS
MIPS Penalties

Failing to perform to the program minimums results in payment penalties:

- 2019 - 4% maximum penalty
- 2020 - 5% maximum penalty
- 2021 - 7% maximum penalty
- 2022 - 9% maximum penalty

Eligible professionals with higher performance scores receive an incentive up to three times the annual cap for negative payment adjustments.

Nationwide interoperability is a requirement by December 31, 2018*
MACRA/MIPS Opportunities and Risks

• Current final rule leaves a lot of uncertainty regarding technical requirements
• CMS intends to use subregulatory guidance to further specify requirements
• Flexibility could be used by providers and developers to advance next-generation standards (yes, FHIR!)
• CMS has announced its intention to offer an API for MIPS reporting
Objectives

• Review ONC strategy and vision
• Learn about ONC 2015 Edition Certification Program
• Understand the purpose and function of the Interoperability Standards Advisory
• Discuss next-generation standards maturation of the electronic clinical quality measures supported by CMS
The Current State vs the HHS Future Vision for Clinical Quality Improvement

Current State
• CQMs and CDS are separate
• Each vendor develops their own CDS artifacts
• CQMs are focused on retrospective data
• CDS is an afterthought

Future Vision
• CDS drives care activities
• Performance is consistently improved through CDS
• CQM data capture is automatic
• CQMs are available with paired optional CDS artifacts
Standards improvement and harmonization: Clinical Quality Measurement and Clinical Decision Support

CQM Specific Standards
- HQMF
- QRDA Category-1
- QRDA Category-3
- QDM

Common Metadata Standard

Common Data Model Standard (QUICK)*

Common Expression Logic Standard (CQL)**

CDS Specific Standards
- HeD
- vMR

* Quality Improvement and Clinical Knowledge
** Clinical Quality Language
Authors use CQL to produce libraries containing human-readable yet precise logic.

ELM XML documents contain machine-friendly rendering of the CQL logic. This is the intended mechanism for distribution of libraries.

Implementation environments will either directly execute the ELM, or perform translation from ELM to their target environment language.
• Staged approach to introduction of harmonized content starting with the Clinical Quality Language (CQL-based HQMF)

• **Current Measure Authoring Tool and Bonnie alpha releases support CQL-based HQMF (Oct 2016)**

• Future HHS programs could allow optional FHIR reporting before requiring a transition

• Use of APIs and maps could facilitate consistent translation from one standard to another without loss of meaning
Proposed 2018 Standards Evolution for CMS eCQM Specifications
Proposed Next Generation Standard?
Stroke 10/102 Rehab Therapy

Type: Implementation Problem
Priority: Minor
Component/s: Guidance
Labels: ValueSet
Secondary Title: Order and/or Assessment
Summary/Title: Clarification on reporting data
Solution: Thank you for your question. The measure logic reads:

OR: Union of:

"Procedure, Performed: Rehabilitation Assessment"
"Procedure, Performed: Rehabilitation Therapy"
"Procedure, Performed not done: Patient Refusal" for "Rehabilitation Assessment"
starts during Occurrence A of 5EncountersPatientNonElective

Assignee: Mathematica EH CQM Team
Reporter: mitzi graham
Tracker Notification: mitzi graham
Votes: 0 Vote for this issue
Watchers: 1 Start watching this issue
Created: 09/Jun/16 11:19 AM
Updated: 10/Jun/16 3:33 PM
Solution Posted On: 10/Jun/16 3:33 PM

View on Board
What is the eCQI Resource Center?

• The Resource Center is designed to act as a central hub for storing and collating resources surrounding the eCQMs and CDS standards, measures, tools, and guidance.

• It is cosponsored by CMS and ONC

• It will continue to add functionality and additional related content over time

• We welcome your feedback!
Welcome to the Interoperability Proving Ground!

The Interoperability Proving Ground (IPG) is an open, community platform where you can share, learn, and be inspired by interoperability projects occurring in the United States (and around the world).

Use the Active and Complete buttons to change the project view displayed below.

Active Projects

Click the map to see where interoperability projects are taking place.

Add a Project  Show 25 entries  Showing 1 to 25 of 237 entries  Previous  Next  Export
How will “ONC Tech Lab” be organized?

Area 1: Interoperability Proving Ground – Focus on Pilots (e.g. HEART Profile)

Area 2: Supporting Interoperability Testing - Test tools, Utilities, etc. to support interoperability issues (e.g. Open ID server)

Area 3: Coordinating Standards Development – New versions of standards (e.g. HEART Profiles)

Area 4: Innovation activities to improve healthcare thru IT – New ways of engaging developers (e.g. Patient Matching Challenges)
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Questions and Feedback

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• Contact us at: onc.request@hhs.gov

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