The Office of the National Coordinator for Health Information Technology

Federal Programs and the Next-Generation Health IT Ecosystem:

Innovation in standards, implementation, testing, and engagement

October 19, 2016

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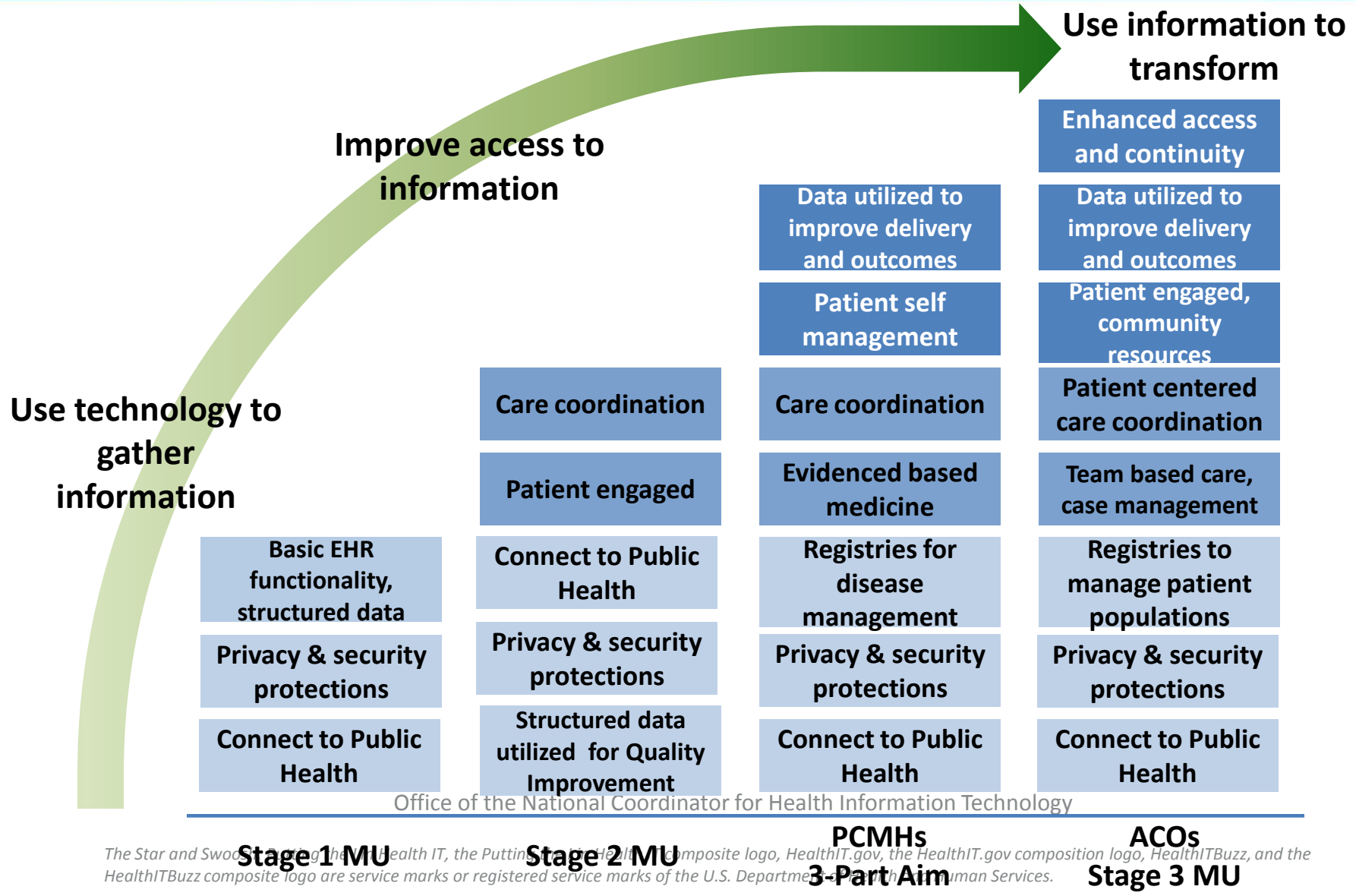
Objectives

- **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



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Nationwide Interoperability Roadmap:

www.healthit.gov/sites/default/files/shared_nationwide_interoperability_roadmap.pdf

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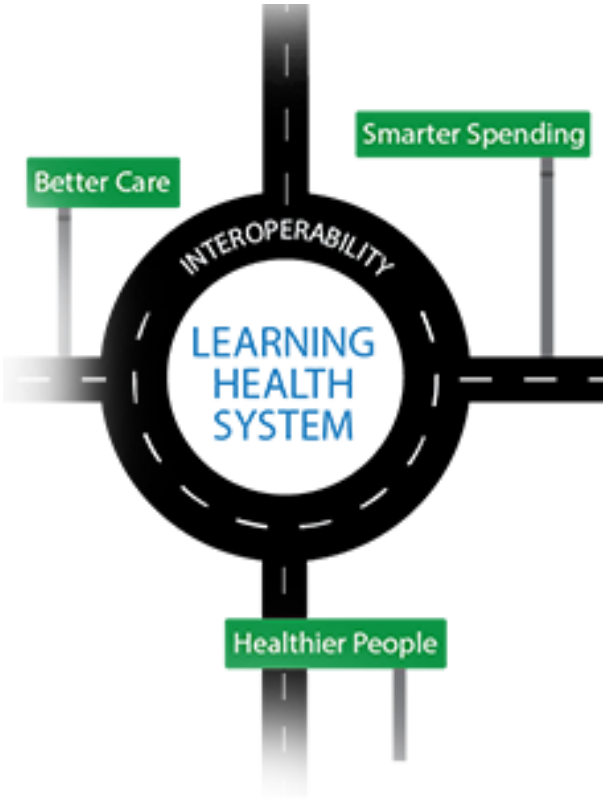
3 Year Agenda (2015-2017)
Send, receive, find and use a common clinical data set to improve health and health care quality

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

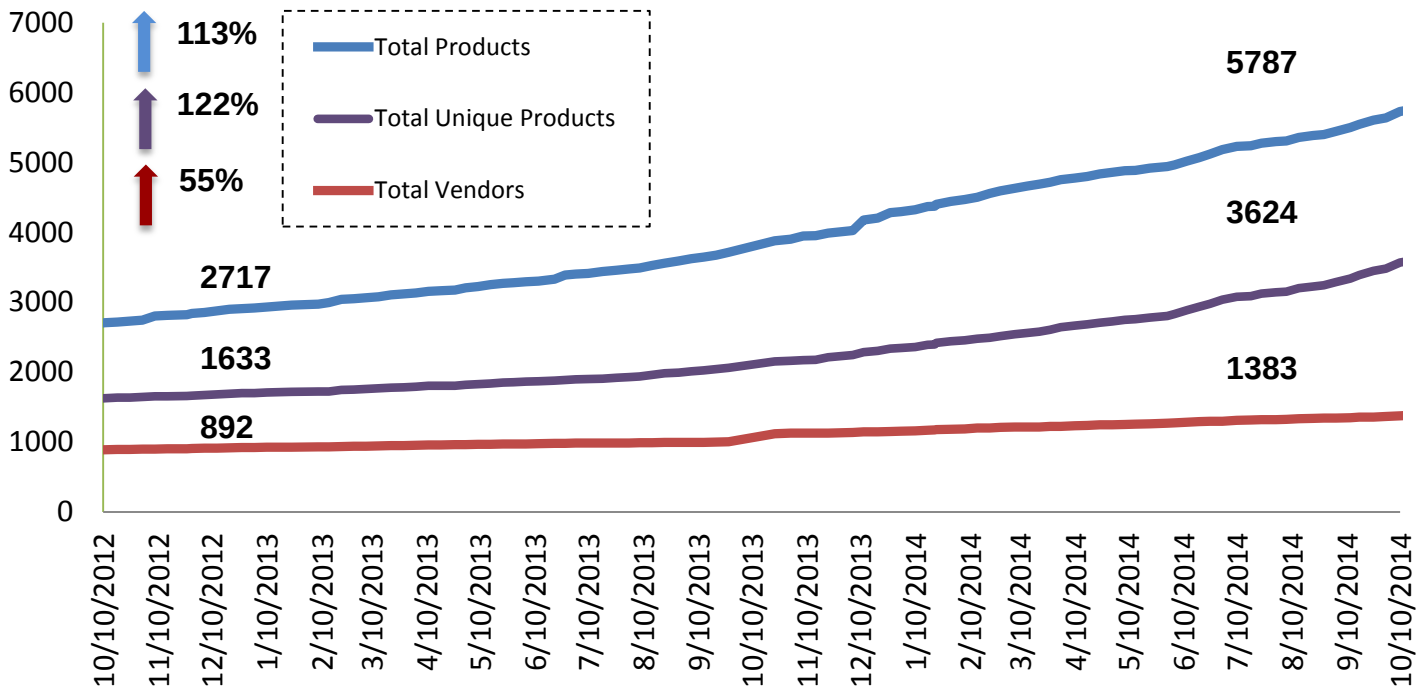
10 Year Agenda (2021-2024)
Achieve a nationwide learning health system

- BUILD UPON EXISTING HEALTH IT INFRASTRUCTURE
- MAINTAIN MODULARITY
- ONE SIZE DOES NOT FIT ALL
- CONSIDER THE CURRENT ENVIRONMENT AND SUPPORT MULTIPLE LEVELS OF ADVANCEMENT
- EMPOWER INDIVIDUALS
- SIMPLIFY
- PROTECT PRIVACY AND SECURITY IN ALL ASPECTS OF INTEROPERABILITY
- LEVERAGE THE MARKET
- FOCUS ON VALUE
- SCALABILITY AND UNIVERSAL ACCESS



Certified Health IT Product and Vendor Trends

10/24/2014



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)	The Future (2015 and Future 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"
	• 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

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- 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

Base EHR Capabilities	Certification Criteria
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.

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

ONC Interoperability Roadmap Goal

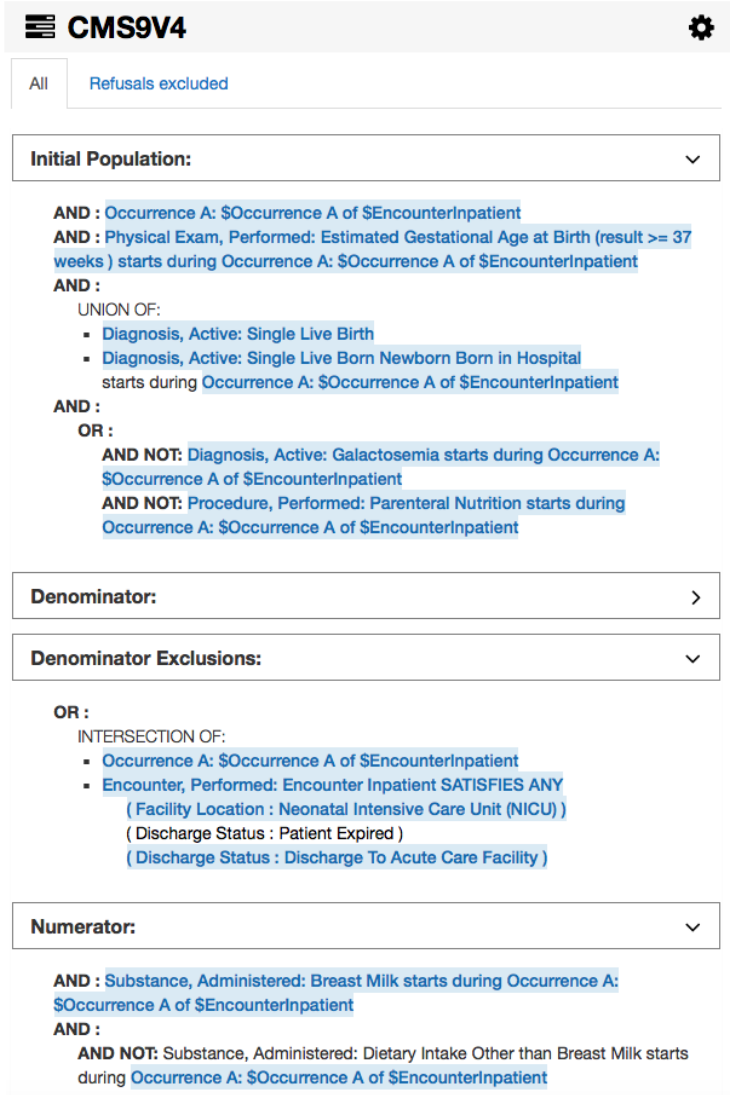
2015-2017

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



C4 Test - Clinical quality measures – filter

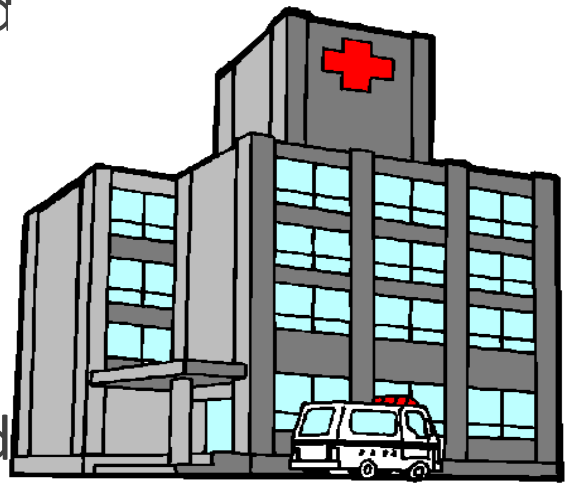
- Optional – Certify an EHR's ability to:
  - Record the data listed in paragraph (c)(4)(iii) of this section in accordance with the identified standards, where specified
  - Filter CQM results at the patient and aggregate levels by each one and any combination of the data listed in paragraph (c)(4)(iii) 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



Improve the Reliability and Transparency of Certified Health IT

Improve Patient Safety

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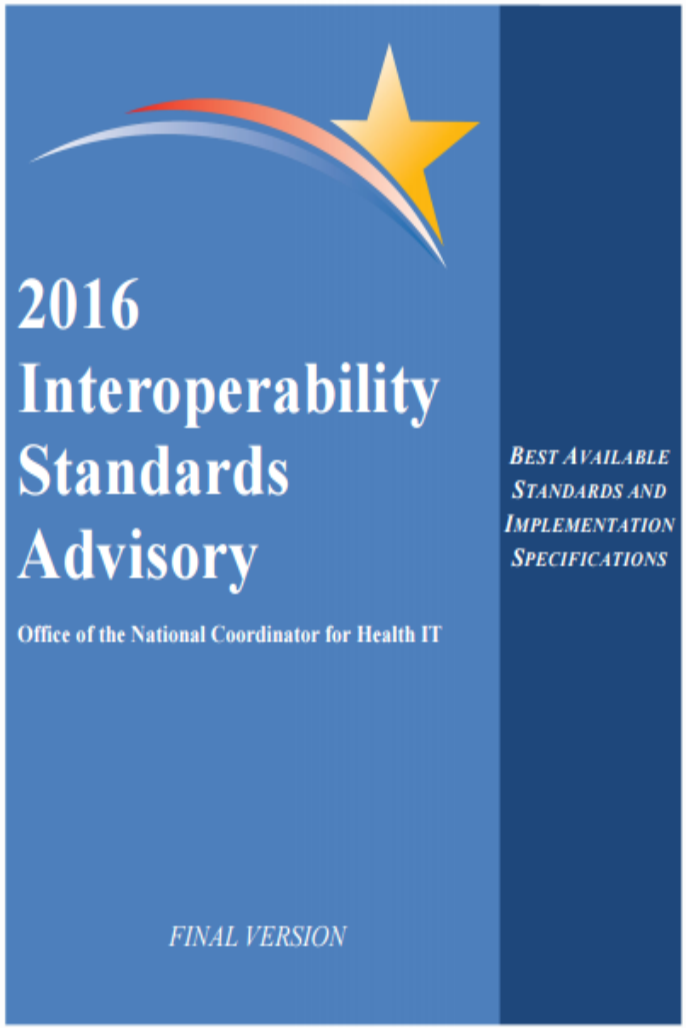
2016 Interoperability Standards Advisory: http://www.healthit.gov/standards-advisory/2016



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

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Draft 2017 Interoperability Standards Advisory

Available for public comment!

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

Section I | Section II | Section III

I-A: Allergies	I-B: Encounter Diagnosis	I-C: Family Health History
I-D: Functional Status/Disability	I-E: Health Care Provider	I-F: Imaging (Diagnostics, interventions and procedures)
I-G: Immunizations	I-H: Industry and Occupation	I-I: Lab Tests
I-J: Medications	I-K: Numerical References & Values	I-L: Nursing
I-M: Patient Clinical "Problems" (i.e., conditions)	I-N: Preferred Language	I-O: Procedures
I-P: Race and Ethnicity	I-Q: Research	I-R: Sexual Orientation and Gender Identity
I-S: Social Determinants	I-T: Tobacco Use	I-U: Unique Device Identification

CMS PROGRAMS RELATED TO CLINICAL QUALITY AND PERFORMANCE

CMS quality and performance programs (2014)

Hospital Quality	Physician Quality Reporting	PAC and Other Setting Quality Reporting	Payment Model Reporting	"Population" Quality Reporting
• Medicare and Medicaid EHR Incentive Program	• Medicare and Medicaid EHR Incentive Program	• Inpatient Rehabilitation Facility	• Medicare Shared Savings Program	• Medicaid Adult Quality Reporting*
• PPS-Exempt Cancer Hospitals	• PQRS	• Nursing Home Compare Measures	• Hospital Value-based Purchasing	• CHIPRA Quality Reporting*
• Inpatient Psychiatric Facilities	• eRx quality reporting	• LTCH Quality Reporting	• Physician Feedback/ Value-based Modifier*	• Health Insurance Exchange Quality Reporting*
• Inpatient Quality Reporting		• Hospice Quality Reporting	• ESRD QIP	• Medicare Part C*
• HAC reduction program		• Home Health Quality Reporting		• Medicare Part D*
• Readmission reduction program				
• Outpatient Quality Reporting				
• Ambulatory Surgical Centers				

** 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

current

EHR as primary reporting platform, with secondary reporting from registry, claims

Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014

- 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

Appropriate Use Criteria for Advanced Diagnostic Imaging Services

- 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

Medicare Shared Savings Program

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.

Medicare Shared Savings Program

- 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 - Cervical/neck pain
  - Headache - Chest pain
  - Low back pain - Abdominal pain
  - Altered mental status - 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

Appropriate Use Criteria for Advanced Diagnostic Imaging Services

- 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)
- Current proposed rule describes the criteria for Clinical Decision Support Mechanisms (CDSMs): https://www.gpo.gov/fdsys/pkg/FR-2016-07-15/pdf/2016-16097.pdf

Comprehensive Primary Care (+/- Plus)

Track 1

Up to **2,500** primary care practices.

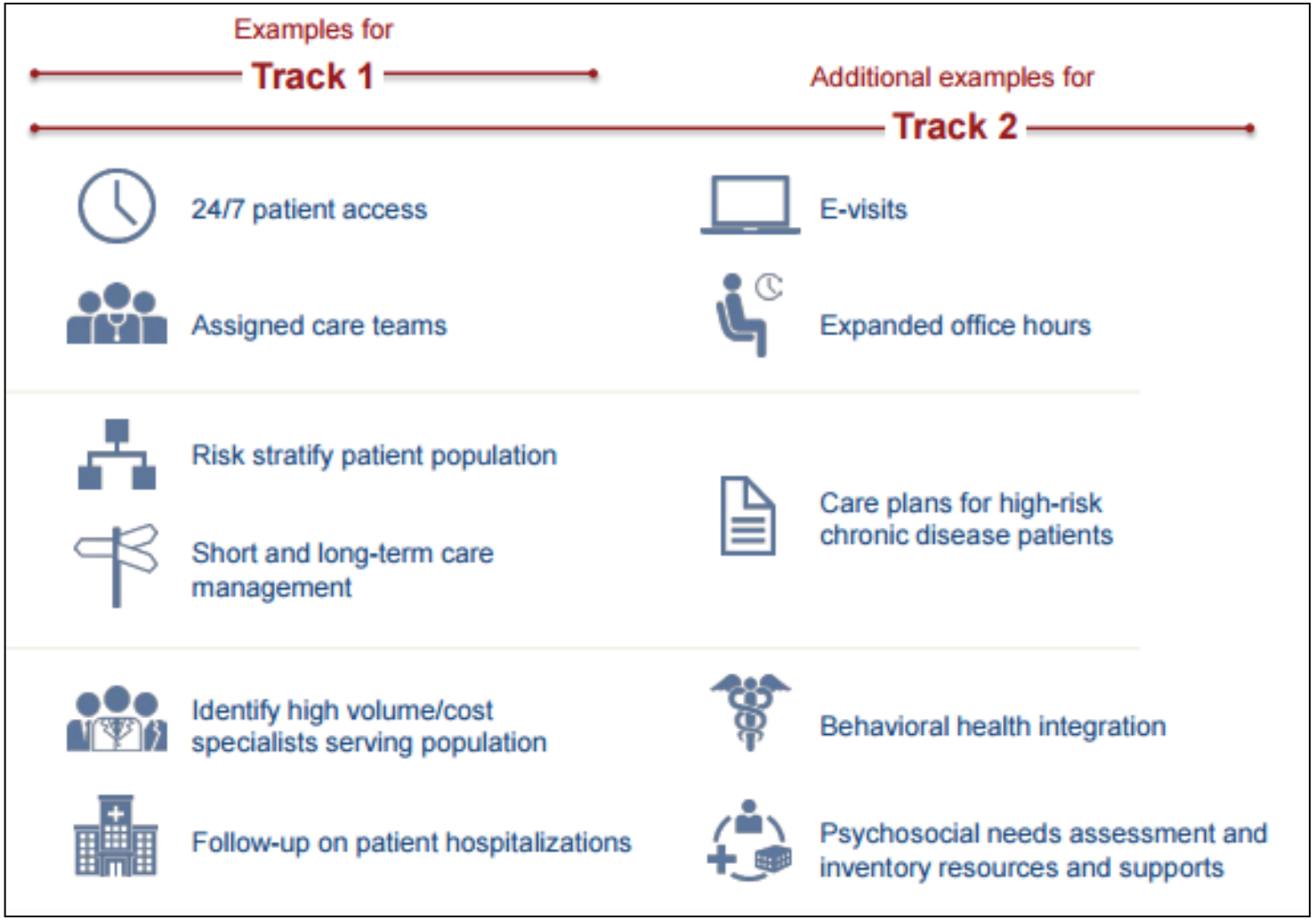
Pathway for practices ready to build the capabilities to deliver comprehensive primary care.

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)



Comprehensive Primary Care (+/- Plus)

	Care Management Fee (PBPM)	Performance-Based Incentive Payment	Underlying Payment Structure
Track 1	$15 average	$2.50 opportunity	Standard FFS
Track 2	$28 average; including $100 to support patients with complex needs	$4.00 opportunity	Reduced FFS with prospective "Comprehensive Primary Care Payment" (CPCP)

MACRA: Medicare Access and CHIP Reauthorization Act of 2015

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

APMs & MIPS

Paying for Performance

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Alternative Payment Model (APM)

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

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

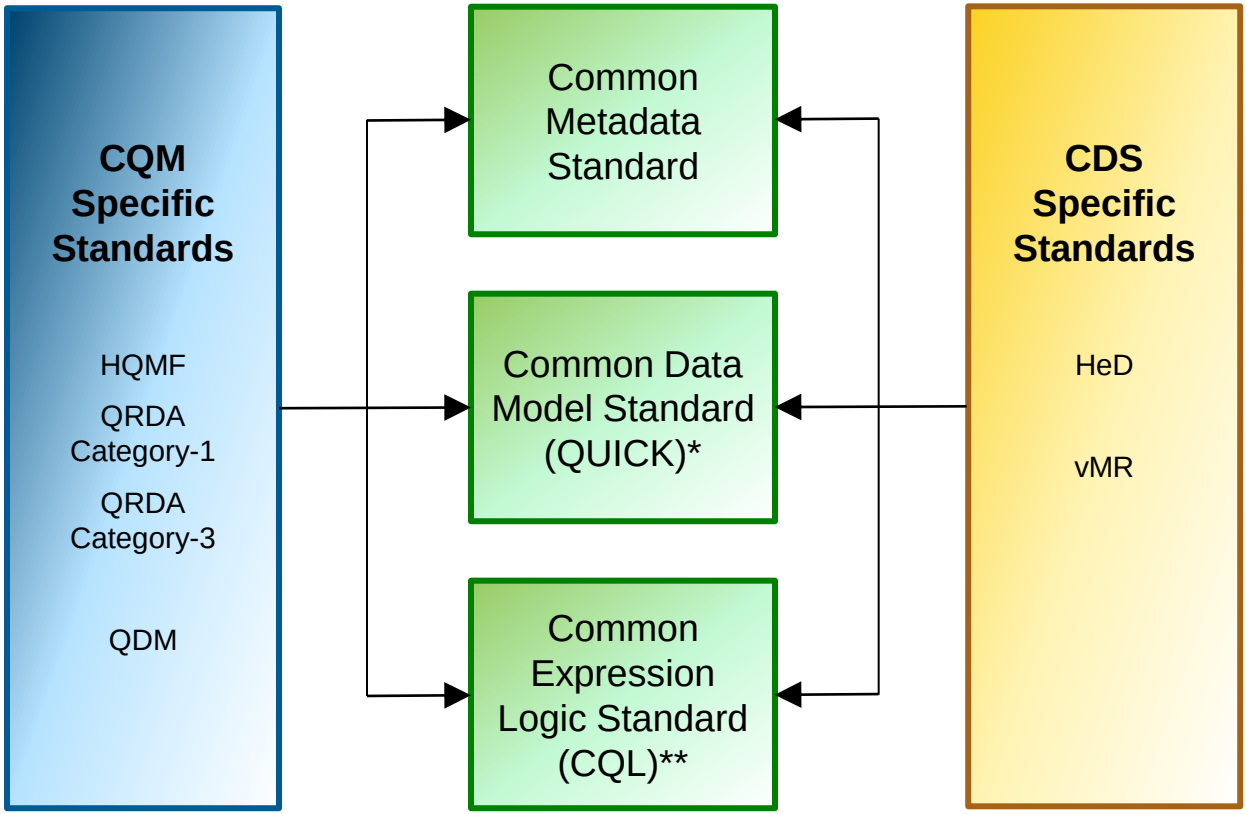
Current State

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

Future Vision

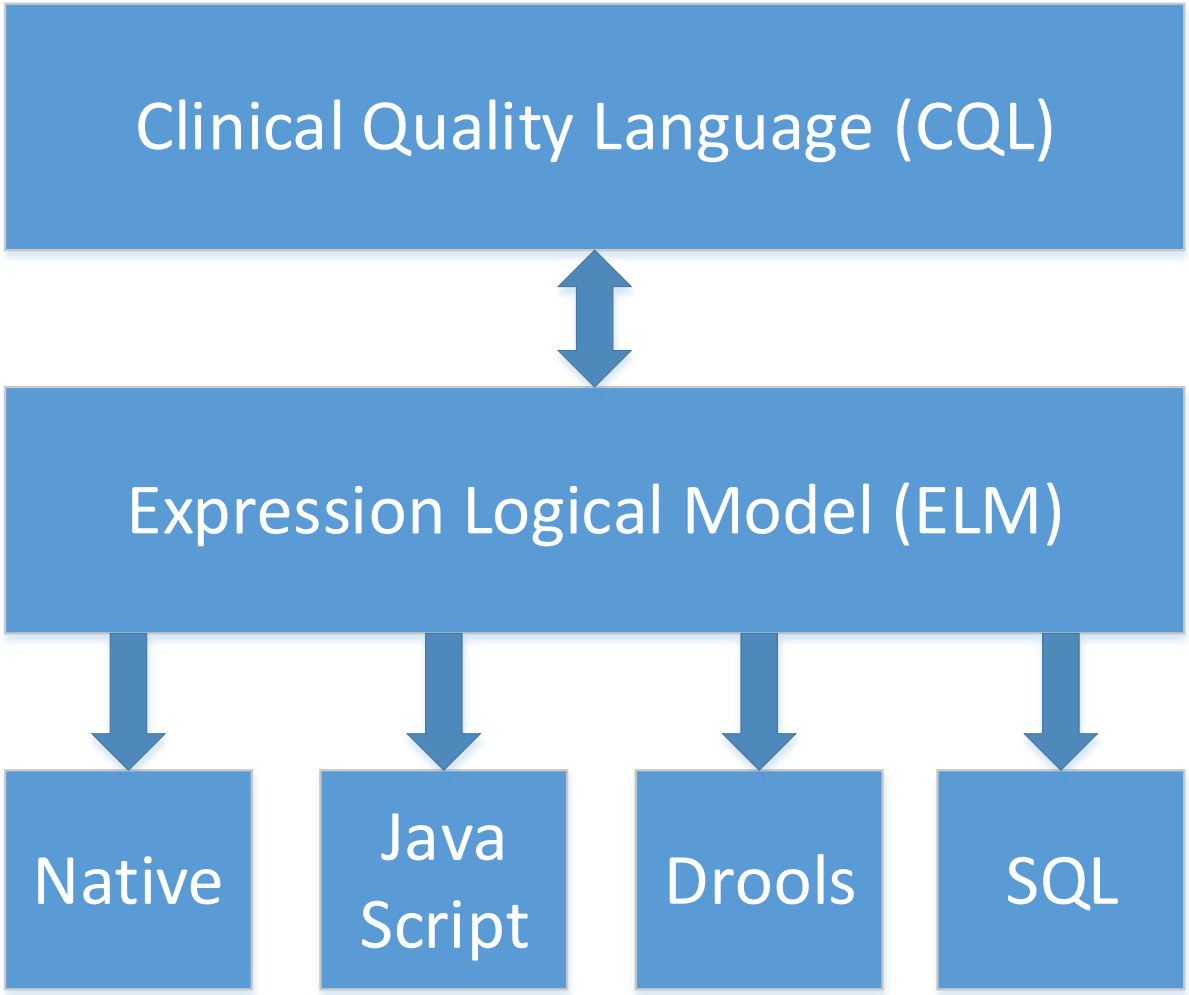
- CDS drives care activities
- Performance is consistently improved through CDS
- CQM data capture is automatic
- CQMs are available with paired optional CDS artifacts

Standards improvement and harmonization:
Clinical Quality Measurement and Clinical Decision Support



** Quality Improvement and Clinical Knowledge*
*** Clinical Quality Language*

Future Standards Need to be Interoperable to Each Other to Allow Flexibility



Authors use CQL to produce libraries containing human-readable yet precise logic.

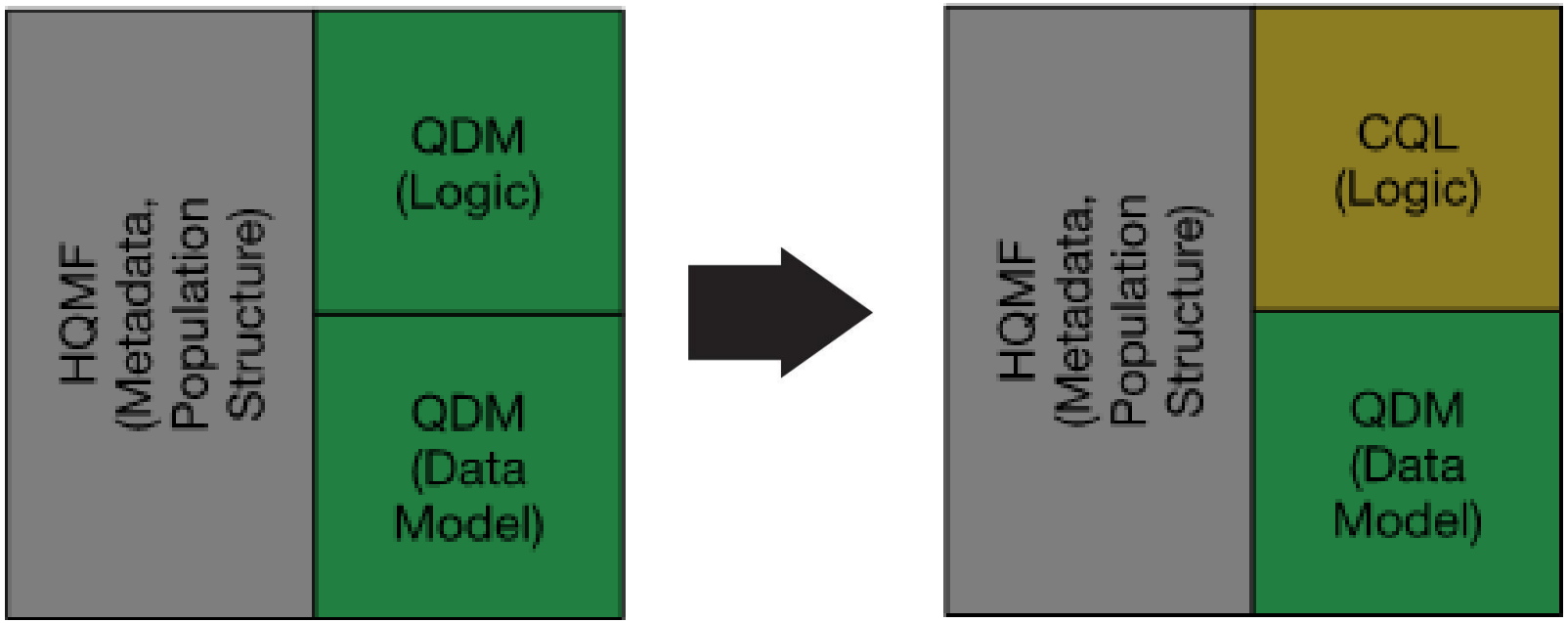
ELM XML documents contain machine-friendly rendering of the CQL logic. This is the intended mechanism for distribution of libraries.

Implementation environments will either directly execute the ELM, or perform translation from ELM to their target environment language.

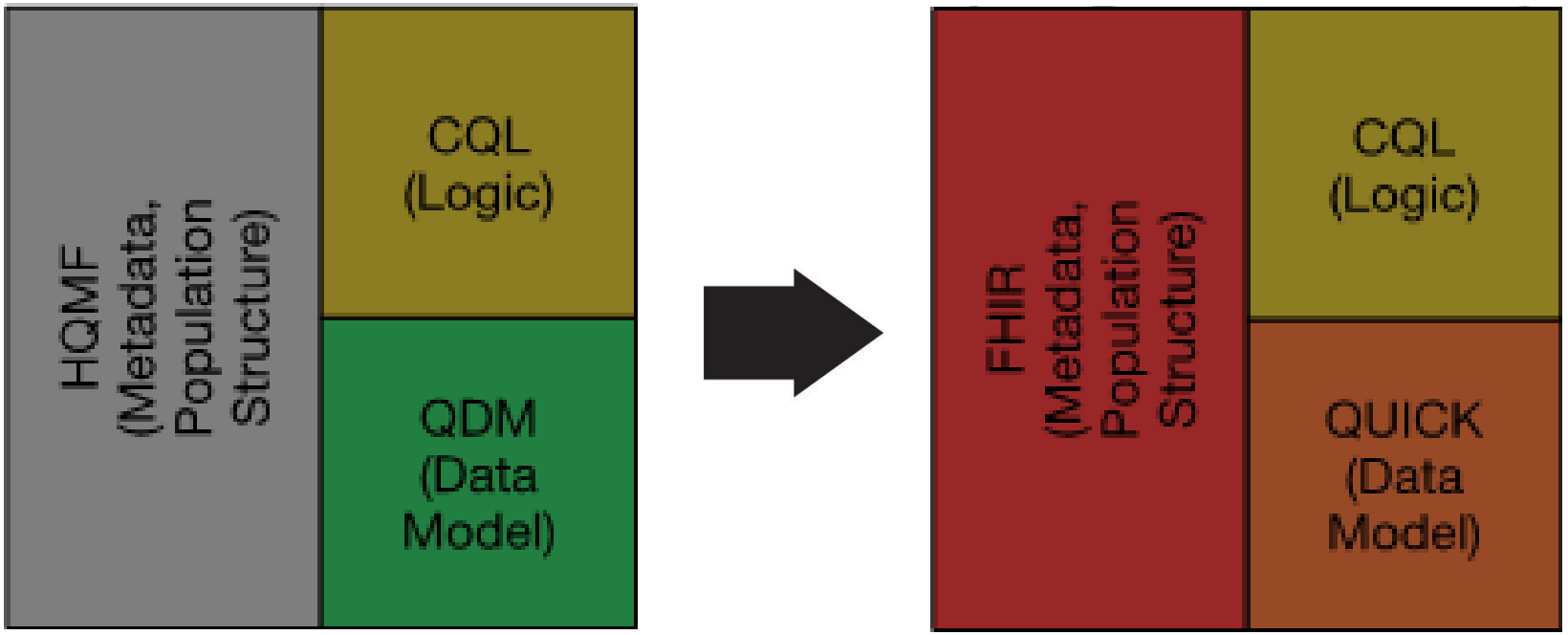
Moving Towards Next Generation Standards

- 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

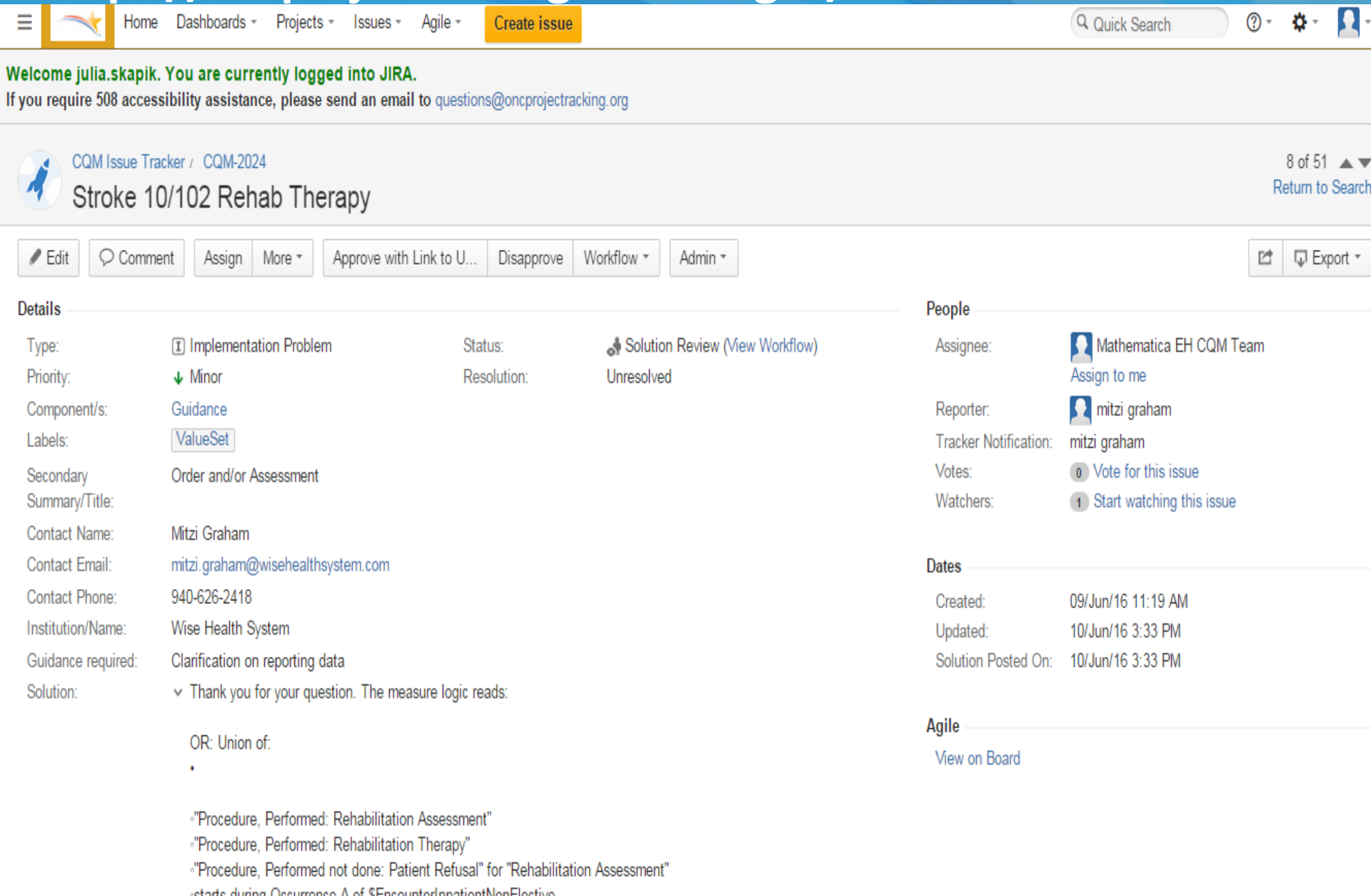
Proposed 2018 Standards Evolution for CMS eCQM Specifications



Proposed Next Generation Standard?



ONC Issue Tracking System
https://oncprojectracking.healthit.gov/



The Electronic Clinical Quality Improvement (eCQI) Resource Center

ecqi.healthit.gov

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!

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

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ONC TechLab: https://www.healthit.gov/techlab/

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HealthIT.gov Interoperability Proving Ground

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 occuring in the United States (and around the world).

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

Active

Complete

Click the map to see where interoperability projects are taking place

Active Projects

Add a Project | Show 25 entries | Showing 1 to 25 of 237 entries | Previous 1 2 3 4 5 ... 10 Next | Export

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Questions? Contact ONC.techlab@hhs.gov

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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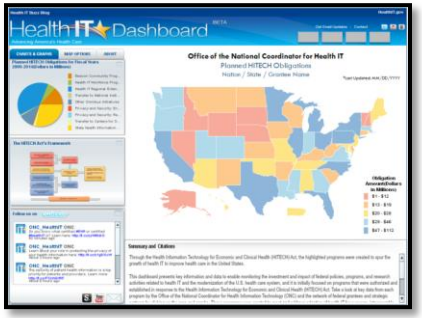

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- **Visit the ONC Newsroom for news and announcements**