March CMS eHealth Vendor Workgroup

March 24, 2016
12:00 PM EDT

Agenda Item	Speaker
Update on Bonnie, the eCQM Testing Tool	Peter Krautscheid *Lead Software Systems Engineer, MITRE*
Overview of Enhanced Transparency Requirements for Developers Under the ONC Health IT Certification Program	Karson Mahler *Senior Policy Advisor, Office of the National Coordinator for Health Information Technology (ONC)*
2016 CMS Quality Reporting Document Architecture Implementation Guide Appendix and Updated Schematrons	Shanna Hartman *Nurse Consultant, Division of Electronic and Clinician Quality (DECQ), QMVIG, CCSQ, CMS*
Hospital Inpatient Quality Reporting (HIQR) Update	Artrina Sturges *Project Lead, Hospital Inpatient VIQR Outreach and Education Support Contractor, Health Services Advisory Group (HSAG)*
The Office of the National Coordinator of Health Information Technology's (ONC) Oversight Rule Update	Michael Lipinski *Policy Analyst, Office of the National Coordinator for Health Information Technology (ONC)*
Questions	

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Peter Krautscheid

UPDATE ON BONNIE, THE ECQM TESTING TOOL

Bonnie Testing Tool

Peter Krautscheid

https://bonnie.healthit.gov

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What is Bonnie?

- **Bonnie is a clinical quality measure testing tool that allows:**
  - Loading clinical quality measures from the HQMF format
  - Exploring the behavior and complexity characteristics of clinical quality measures
  - Rapidly building synthetic patients using data elements defined as part of the measure definition
  - Testing synthetic patients against existing and updated versions of a clinical quality measure
  - Creating synthetic patients for use in certification with Cypress
  - Sharing synthetic patient records with other Bonnie users using the patient bank

History

- **First released April 2014**
- **Used extensively for testing 2015 annual update measures**
  - 5,000 synthetic test patient records
  - Most measures have tests covering at least 80% of the logic
- **Currently being used for testing 2016 annual update measures**
  - Over 10,000 synthetic test patient records
  - Most measures have tests covering 100% of the logic

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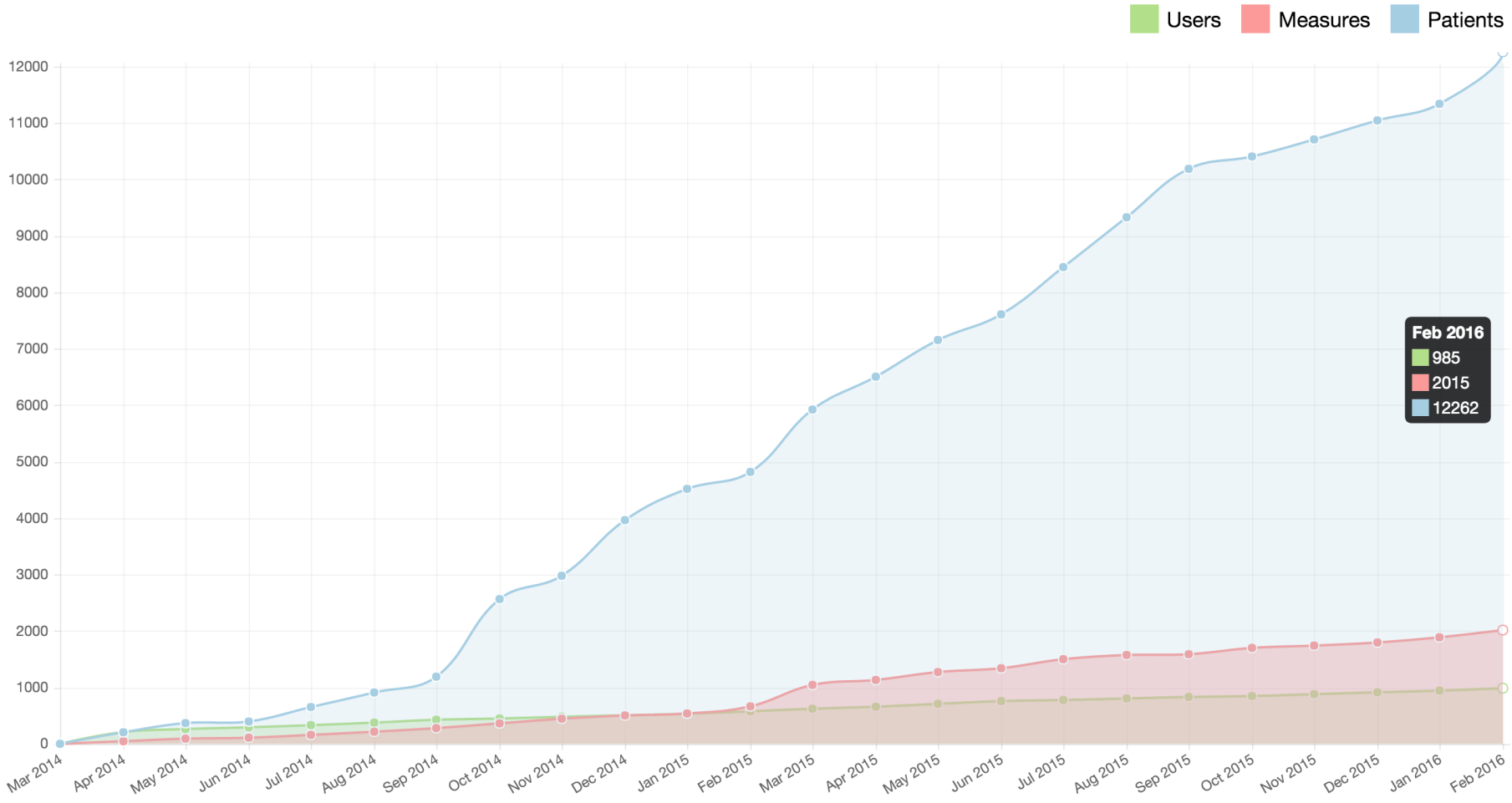
Bonnie Usage Over Time



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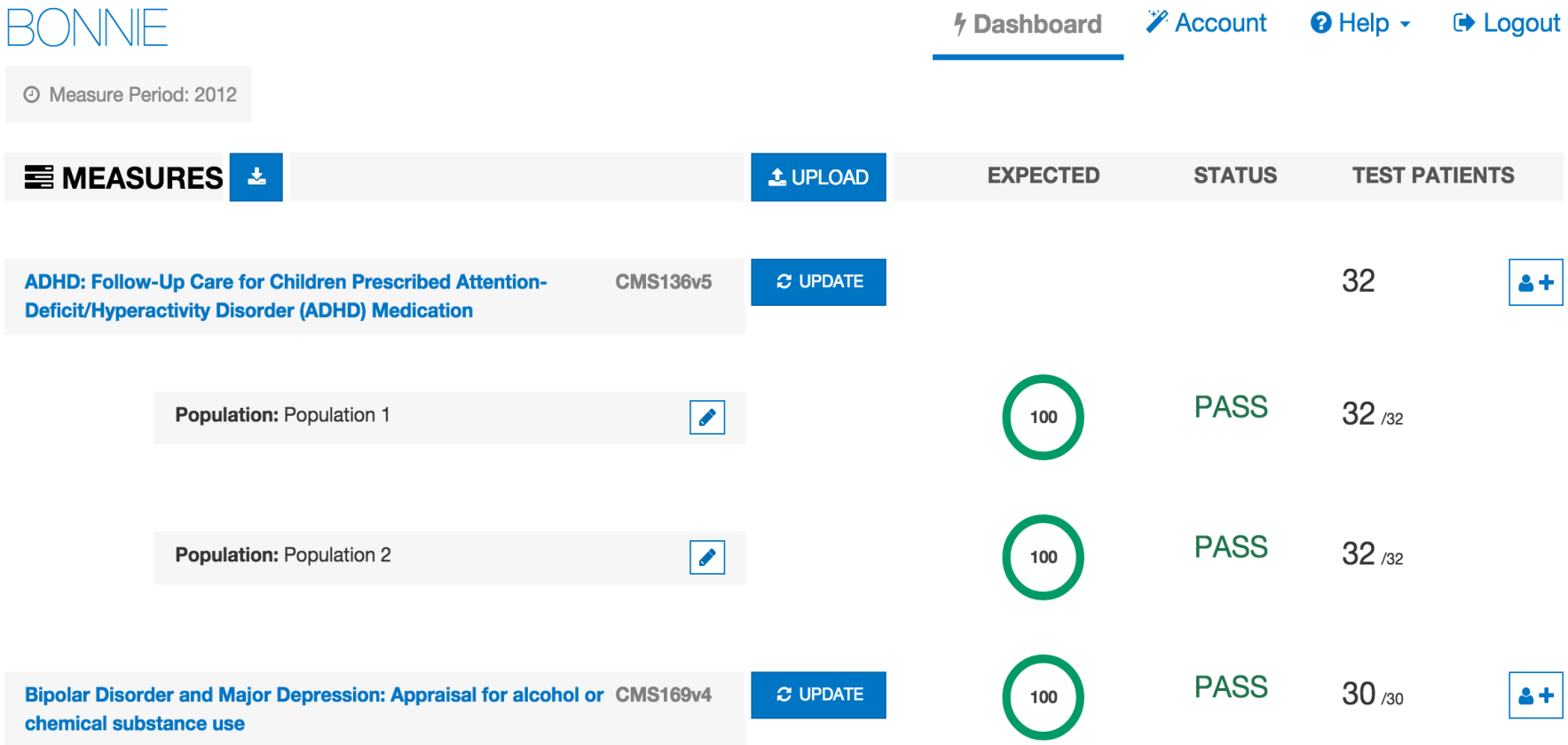
Bonnie Screenshot



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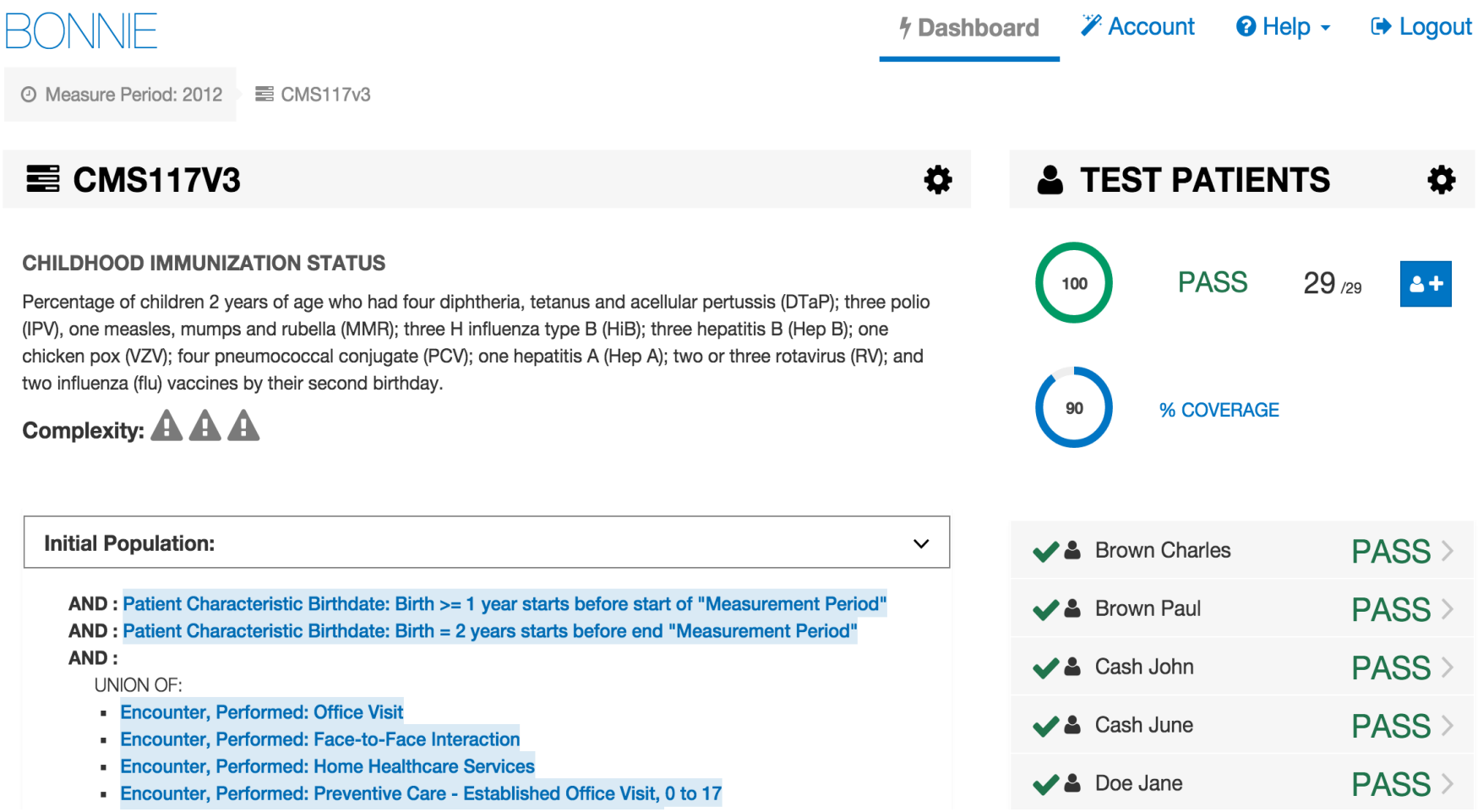
Bonnie Screenshot (continued)



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Bonnie is under active development

- **Current development work includes**
  - Measure debugging tools
  - Test planning tools
  - Measure analysis tools
  - Application Programming Interface (API) support
  - Support for new standards

New Feature: Value set debugging

- **A large proportion of measure debugging challenges are due to issues with value sets**
- **New value set debugging features include**
  - Listing the value sets used by each measure
  - Listing value sets that have overlapping codes within a measure
  - Noting codes referenced by test patient records that are no longer contained in value sets used by the measure
- **This feature is currently in production**

Value set debugging (continued)

DATA CRITERIA

1.3.6.1.4.1.33895.1.3.0.45	Intervention, Order: Comfort Measures	Draft
1.3.6.1.4.1.33895.1.3.0.45	Intervention, Performed: Comfort Measures	Draft
2.16.840.1.113762.1.4.1021.7	Medication, Discharge not done: Statin ingredient specific	Draft
2.16.840.1.113762.1.4.1021.7	Medication, Discharge not done: Statin ingredient specific	Draft
2.16.840.1.113762.1.4.1021.7	Medication, Discharge: Statin ingredient specific	Draft
2.16.840.1.113883.3.117.1.7.1.212	Diagnosis, Active: Hemorrhagic Stroke	Grouping
2.16.840.1.113883.3.117.1.7.1.215	Laboratory Test, Performed: LDL-c	Draft
2.16.840.1.113883.3.117.1.7.1.215	Laboratory Test, Result: LDL-c	Draft
2.16.840.1.113883.3.117.1.7.1.215	Laboratory Test: LDL-c	Draft

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Value set debugging (continued)

OVERLAPPING VALUE SETS

2.16.840.1.113762.1.4.1045.39 Low Dose Unfractionated Heparin For Vte Prophylaxis	**2.16.840.1.113883.3.117.1.7.1.218** Unfractionated Heparin	1 overlapping code
2.16.840.1.113883.3.117.1.7.1.218 Unfractionated Heparin	**2.16.840.1.113762.1.4.1045.39** Low Dose Unfractionated Heparin For Vte Prophylaxis	1 overlapping code
2.16.840.1.113883.3.117.1.7.1.255 General Surgery	**2.16.840.1.113883.3.117.1.7.1.272** Urological Surgery	7 overlapping codes
2.16.840.1.113883.3.117.1.7.1.263 Obstetrics	**2.16.840.1.113883.3.117.1.7.1.264** Obstetrics Vte	10 overlapping codes
2.16.840.1.113883.3.117.1.7.1.264 Obstetrics Vte	**2.16.840.1.113883.3.117.1.7.1.263** Obstetrics	10 overlapping codes
2.16.840.1.113883.3.117.1.7.1.272 Urological Surgery	**2.16.840.1.113883.3.117.1.7.1.255** General Surgery	7 overlapping codes

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Value set debugging (continued)

2.16.840.1.113883.3.117.1.7.1.255
General Surgery

2.16.840.1.113883.3.117.1.7.1.272
Urological Surgery

7 overlapping codes

Code System	Code	Name
ICD-10-PCS	0WQFXZZ	Repair Abdominal Wall, External Approach
ICD-10-PCS	0WQF0ZZ	Repair Abdominal Wall, Open Approach
ICD-10-PCS	0WQFXZ2	Repair Abdominal Wall, Stoma, External Approach
ICD-10-PCS	0TRB07Z	Replacement of Bladder with Autologous Tissue Substitute, Open Approach
SNOMED-CT	68960009	Closure of enterovesical fistula with bowel and bladder resection (procedure)
SNOMED-CT	21482000	Closure of enterovesical fistula with bowel resection (procedure)
SNOMED-CT	56614001	Repair of fistula involving bladder and intestine (procedure)

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New Feature: Excel patient record export

- **Excel is commonly used as a planning tool for test case development**
- **Generating Excel documents for planning is time consuming**
- **Bonnie synthetic patient records can be exported as Excel test case reports**
- **Reports include**
  - Patient record demographic data
  - Patient record expected calculation results vs actual calculation results
  - Calculation results for each measure logic clause
- **This feature is currently in production**

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Excel patient record export

Expected								Actual												
IPP	DENOM	NUMER	DENEXCEP	IPP	DENOM	NUMER	DENEXCEP	notes	first	last	birthdate	expired	deathdate	ethnicity	race	gender	Patient Characteristic Birthdate: Birth Date >= 18 years starts before start of "Measurement Period"	Diagnosis: Primary Open-Angle Glaucoma overlaps Occurrence A: $EyeCareEncounters	Occurrence A: $EyeCareEncounters
0	0	0	0	0	0	0	0		Zelda	TESTArnold	12/31/1994			Not Hispanic c	American Indi	F	FALSE	TRUE	TRUE
0	0	0	0	0	0	0	0		Xander	TESTClay	04/13/1986			Not Hispanic c	American Indi	F	TRUE	FALSE	FALSE
0	0	0	0	0	0	0	0		Veronica	TESTEldridge	04/13/1976			Not Hispanic c	American Indi	F	TRUE	FALSE	FALSE
0	0	0	0	0	0	0	0		Udi	TESTFranklin	05/14/1971			Not Hispanic c	American Indi	M	TRUE	FALSE	TRUE
0	0	0	0	0	0	0	0		Trudie	TESTGermain	06/14/1966			Not Hispanic c	American Indi	F	TRUE	FALSE	TRUE
1	1	0	0	1	1	0	0		Penelope	TESTKessingt	09/18/1946			Not Hispanic c	American Indi	F	TRUE	TRUE	TRUE
1	1	0	0	1	1	0	0		Hilda	TESTSalinger	03/11/1981			Not Hispanic c	American Indi	F	TRUE	TRUE	TRUE
1	1	0	0	1	1	0	0		George	TESTTrotsky	04/12/1976			Not Hispanic c	American Indi	M	TRUE	TRUE	TRUE
0	0	0	0	0	0	0	0		Quin	TESTJackson	09/18/1951			Not Hispanic c	American Indi	M	TRUE	FALSE	TRUE
1	1	0	0	1	1	0	0		Otis	TESTLightner	09/17/1941			Not Hispanic c	American Indi	M	TRUE	TRUE	TRUE
1	1	1	0	1	1	1	0		Manny	TESTNolan	10/17/1937			Not Hispanic c	American Indi	M	TRUE	TRUE	TRUE
1	1	0	1	1	1	0	1		Jane	TESTQuasay	01/10/1992			Not Hispanic c	American Indi	F	TRUE	TRUE	TRUE
1	1	0	0	1	1	0	0		Fergie	TESTUnderhil	05/13/1971			Not Hispanic c	American Indi	F	TRUE	TRUE	TRUE
1	1	0	1	1	1	0	1		Edward	TESTVance	06/14/1966			Not Hispanic c	American Indi	M	TRUE	TRUE	TRUE
1	1	0	1	1	1	0	1		Denise	TESTWest	08/16/1956			Not Hispanic c	American Indi	F	TRUE	TRUE	TRUE
1	1	0	1	1	1	0	1		Keith	TESTPaulson	11/18/1927			Not Hispanic c	American Indi	M	TRUE	TRUE	TRUE
1	1	0	0	1	1	0	0		Ian	TESTRutenbe	04/13/1986			Not Hispanic c	American Indi	M	TRUE	TRUE	TRUE
1	1	1	0	1	1	1	0		Curtis	TESTXiao	08/16/1951			Not Hispanic c	American Indi	M	TRUE	TRUE	TRUE

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New Feature: Patient overview dashboard

- **Allow more measure planning to take place directly within Bonnie**
- **Measure developers will be able to**
  - View all synthetic patient records on one page
  - Examine detailed calculation results
  - Identify areas of missing test coverage
  - Edit patient records directly on dashboard
- **This feature is currently under development**

Patient overview dashboard

Status	Name	Description		Initial Patient Population: Patient Characteristic Birthdate: Birth Date >= 18 years starts before start of Occurrence A: $EncounterInpatient NonElective +16	Denominator: Intersection of: Occurrence A: $EncounterInpatientNonElective Encounter, Performed: Non-Elective Inpatient Encounter (Principal Diagnosis: Ischemic Stroke) +5	Denominator Exclusion: Intersection of: Occurrence A: $EncounterInpatientNonElective Encounter, Performed: Non-Elective Inpatient Encounter SATISFIES ANY (Discharge Status: Discharge To Acute Care Facility) (Discharge Status: Left Against Medical Advice) (Discharge Status: Patient Expired) (Discharge Status: Discharged To Home For Hospice Care) (Discharge Status: Discharged To Health Care Facility For Hospice Care) +27	Numerator: Medication, Discharge: Antithrombotic Therapy starts during Occurrence A: $EncounterInpatient NonElective +4
NO POPULATION							
PASS	1 IPFail	Patient is 17 with Non-Elective Inpatient Encounter (LOS 120 days) with principal diagnosis of ischemic stroke ends during MP.		✗	✓		
PASS	2 IPFail	Patient is 19 with no Encounter Inpatient		✗	✗		
PASS	3 IPFail	Patient is 18 with Non-Elective Inpatient Encounter (LOS 121 days) ends during MP with principal diagnosis of ischemic stroke		✗	✗		
INITIAL PATIENT POPULATION							
PASS	1 IPPass	Patient is 18 with Non-Elective Inpatient Encounter (LOS 120 days) with principal diagnosis of ischemic stroke ends during MP		✓	✓	✗	✗
PASS	2 turn 18 day of admission IPPass	Patient turns 18 day of admission with Non-Elective Inpatient Encounter ends during MP with principal diagnosis of stroke		✓	✓	✗	✗
PASS	3 turn 18 day before admission (1) IPPass	Patient turns 18 day before admission with Non-Elective Inpatient Encounter ends during MP with principal diagnosis of stroke		✓	✓	✗	✗
PASS	4 LOS 119 days (1) IPPass	Patient is 18 with Non-Elective Inpatient Encounter (LOS 119 days) with principal diagnosis of ischemic stroke ends during MP		✓	✓	✗	✗
DENOMINATOR							
PASS	1 DenexFail	Patient receives comfort measures performed before ED visit that ends <= 1 hour before IP Encounter		✓	✓	✗	✗
PASS	2 DenexFail	Patient receives comfort measures performed during ED visit that ends greater than 1 hour before IP Encounter		✓	✓	✗	✗
PASS	3 DenexFail	Patient receives comfort measures performed after IP encounter		✓	✓	✗	✗
PASS	4 DenexFail	Patient receives comfort measures performed before IP encounter		✓	✓	✗	✗
PASS	1 NumFail	Patient received anti thrombotic during encounter		✓	✓	✗	✗
PASS	1 NumFail	Patient is 18 with Non-Elective Inpatient Encounter (LOS 120 days) with principal diagnosis of ischemic stroke ends during MP received antithrombotic before IP encounter		✓	✓	✗	✗

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New Feature: Measure history analysis

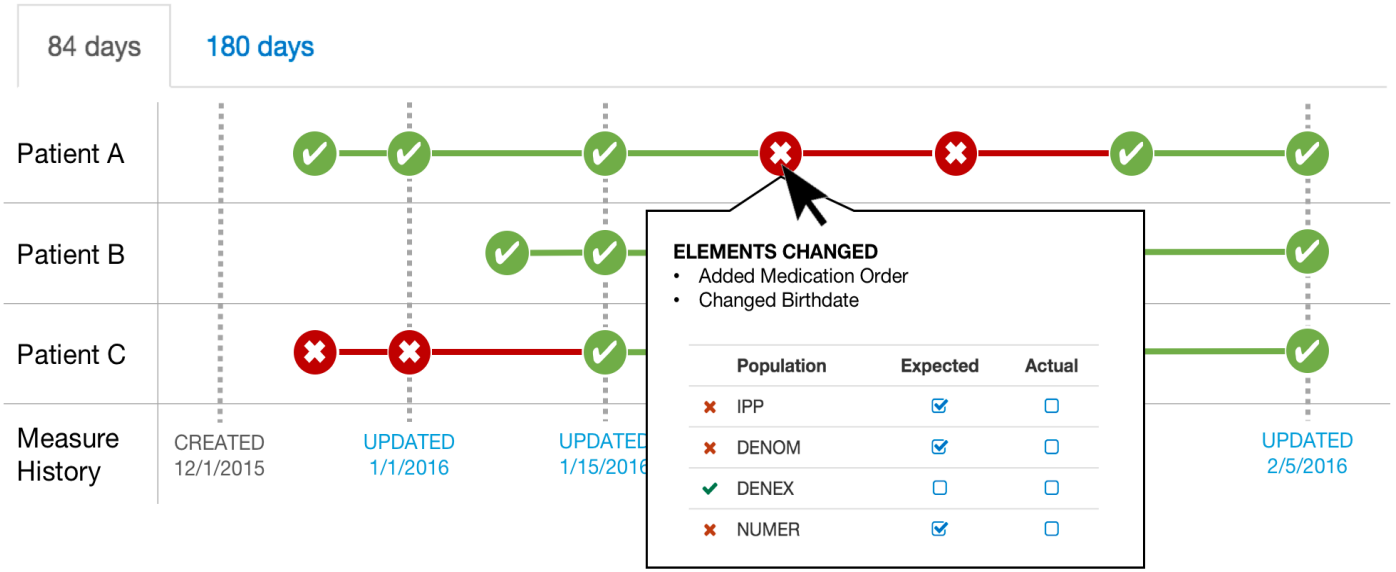
- **View detailed information on changes in a measure over time**
  - Store information on multiple versions of a measure
  - Display the differences between the different versions
  - Store information on test patient changes over time
  - Connect changes in test results to specific changes in measures or test patients
- **This feature is currently under development**

Measure history analysis

CMS00V1

SOME MEASURE

Measure description lorem ipsum dolor sit amet, nisl utamur no nec, odio utamur iudicabit mea ea, sea ad sale quidam fuisset. Ius viris salutatus sadipscing ne, omnes offendit ei eum. In mea hendrerit consetetur, nam inermis scriptorem ut. Per id stet esse, mei partem alienum ad.



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New Feature: Application Programming Interface

- **Intended to allow Bonnie to integrate with other tools**
- **Will support functionality such as**
  - Uploading measures
  - Downloading test results
- **The initial driving goal is eventual closer integration with the Measure Authoring Tool (MAT)**
- **Other uses are certainly possible and welcome**
- **This feature is currently under development**

Support For Upcoming Standards

- The Clinical Quality Language (CQL) is a new standard for describing Clinical Quality Measures
- CQL logic is expected to eventually replace existing QDM logic
- Regression testing during the transition will be vital to ensure that measures continue to convey the same clinical intent
- Bonnie will support testing of both CQL-based and QDM-based measures during the transition
- The functionality that Bonnie implements will leverage the extensive existing open source CQL implementation
- Initial support for testing and learning purposes will be available in Bonnie towards the end of 2016, well in advance of the transition
- Development is beginning now

Support For Upcoming Standards

CQL Evaluation (Alpha)

SNIPPET 1 → SNIPPET 2 → SNIPPET 3 → SNIPPET 4 → SNIPPET 5

```
define OverEighteen: AgeInYearsAt(start of MeasurementPeriod) >= 18

// Inpatient encounters during the Measurement Period
define Encounters:
 ["Encounter, Performed": "Inpatient Encounter"] E where E."admission datetime" during MeasurementPeriod

define IschemicStroke: ["Diagnosis": "Ischemic Stroke"]

// Inpatient encounters where an ischemic stroke was diagnosed
define EncountersWithIschemicStroke:
  Encounters E with IschemicStroke D such that Interval[E."admission datetime", E."discharge datetime"] includes D."onset datetime"

define Denominator: OverEighteen and Count(EncountersWithIschemicStroke) > 0

// Discharged on antithrombotic therapy during an encounter with a stroke diagnosis
```

EVALUATE

Statement	Ischemic, No Meds	Ischemic, With Meds	Ischemic, Patient Left
OverEighteen	✔	✔	✔
Encounters	Encounter, Performed: Inpatient Encounter	Encounter, Performed: Inpatient Encounter	Encounter, Performed: Inpatient Encounter
IschemicStroke	Diagnosis: Ischemic Stroke	Diagnosis: Ischemic Stroke	Diagnosis: Ischemic Stroke
EncountersWithIschemicStroke	Encounter, Performed: Inpatient Encounter	Encounter, Performed: Inpatient Encounter	Encounter, Performed: Inpatient Encounter

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Bonnie User Group

- **Interaction with our user community is vital as we**
  - Seek feedback for new features under development
  - Determine the future direction of the application
  - Share news about updates and changes
- **The users group uses an online forum**
  - https://groups.google.com/forum/#!forum/bonnie

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Where To Look For Info

- **Main Bonnie site**
  - https://bonnie.healthit.gov/
- **JIRA for tracking issues**
  - https://jira.oncprojectracking.org/browse/BONNIE
- **Contact development team**
  - bonnie-feedback-list@lists.mitre.org
- **Open Source on GitHub**
  - https://github.com/projecttacoma/bonnie

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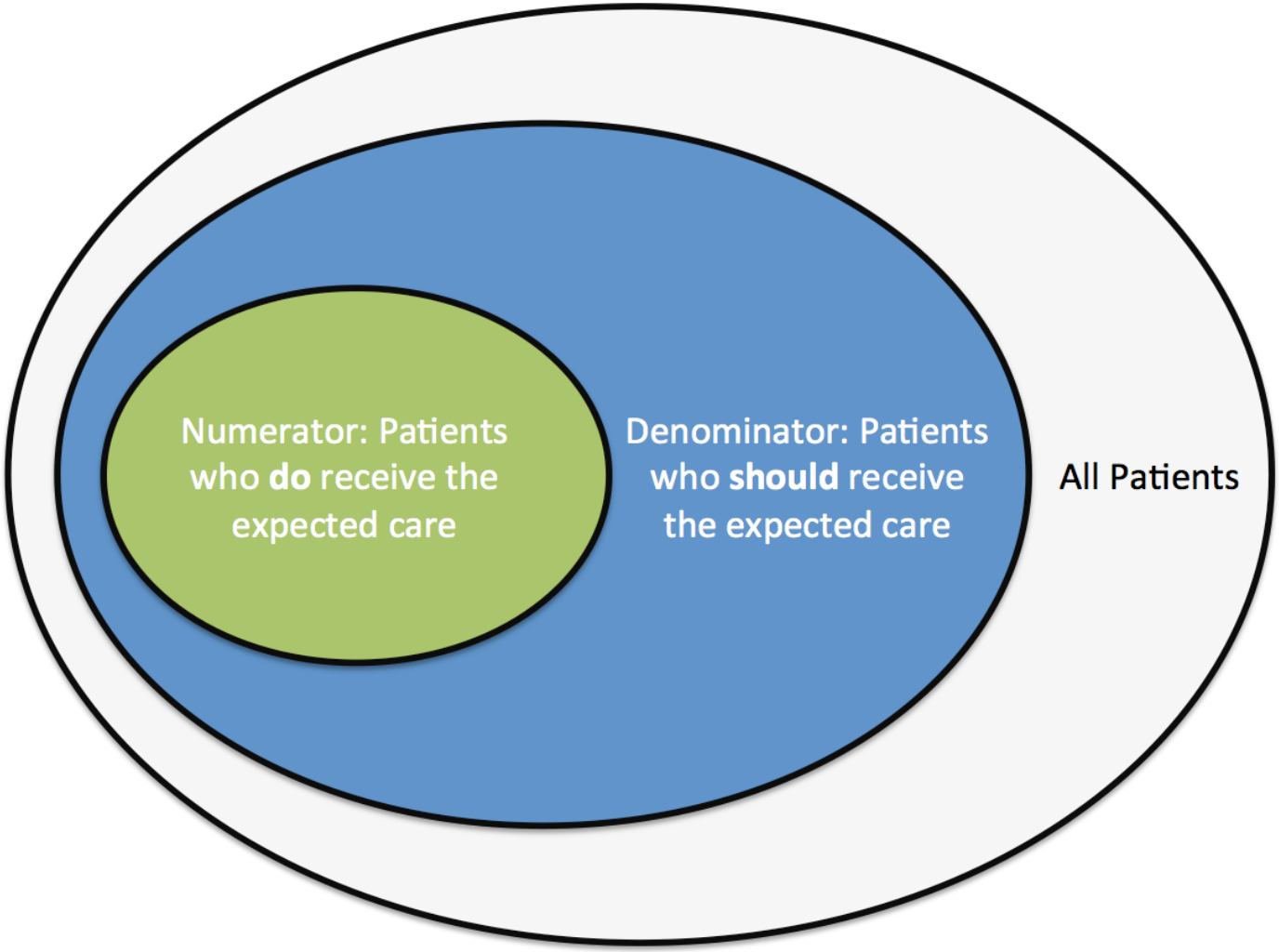
Backup Slides

Clinical Quality Measures

- **Health Care Reports**
- **Measure provider delivery of standard of care to patients**
- **Electronic specification: eCQM**
- **Combine logical statements with clinical concepts**

Patient Populations



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History

- **The process of Measure Development has been grueling:**
  - Does the measure logic capture clinical intent?
  - Lots of subtleties: timing, operator precedence, etc.
  - Hundreds or thousands of lines of logic
  - Every release is manually reviewed

Tooling

- **Better tooling is needed**
  - Understand what you're building
  - Don't test and review entirely by hand
- **Bonnie helps with both**

Delivery

- **Went live April 1st, 2014**
  - 778 users, about 210 actually testing measures
  - Over 1,500 measures loaded
  - Over 8,500 test patient records created
  - OFMQ, The Joint Commission, Mathematica, HHS, etc.

Final Notes

- **Open source**
- **http://bonnie.healthit.gov/**

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Questions?

krautscheid@mitre.org

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Karson Mahler

OVERVIEW OF ENHANCED TRANSPARENCY REQUIREMENTS FOR HEALTH IT DEVELOPERS UNDER THE ONC HEALTH IT CERTIFICATION PROGRAM

The Office of the National Coordinator for Health Information Technology

Enhanced Transparency Requirements for Developers Under the ONC Health IT Certification Program

Karson F. Mahler, JD
Senior Policy Advisor
Office of the National Coordinator for Health Information Technology

March 24, 2016

The Office of the National Coordinator for Health Information Technology

Background

2015 Edition Certification Final Rule (80 FR 62601)

- The 2015 Edition Certification Final Rule was published in October 2015. In addition to establishing new certification criteria, the rule made significant changes to strengthen and improve the ONC Health IT Certification Program.
- A major focus of these changes is to **increase transparency and accountability** of certified health IT products, developers, and business practices. Key provisions include:
  - Enhanced **transparency and disclosure requirements** for health IT developers.
  - **Certified Health IT Product List (CHPL) — open data and APIs.**
  - More extensive and more rigorous **post-market surveillance** of certified products/developers.
  - Strict requirements and processes for **corrective action** and for publicly reporting this action to the CHPL.

Certified Health IT Product List (CHPL) — open data and APIs

- **Open data CHPL** launched in February 2016.
- Additional data and functionality to be rolled out over the Spring.
- APIs and granular data will enable comparisons/research.
- New types of information will increase transparency of certified products and developer business practices. For example:
  - **Links to product disclosures (limitations, restrictions, types of costs)**
  - **Transparency attestations**
  - **Corrective action information (from surveillance of products/developers)**
  - **API documentation and terms of use**
  - **Standards used to meet quality management, safety-enhanced design, and accessibility requirements.**

Post-market Surveillance and Corrective Action

- The 2015 Final Rule significantly expands **post-market surveillance of certified health IT products (and developer business practices)**.
- ONC-Authorized Certification Bodies (ONC-ACBs) will conduct more frequent and extensive surveillance of certified products and developers, including:
  - **In-the-field surveillance.** Surveillance of capabilities as deployed and used by clinicians in production environments.
  - **Reactive surveillance.** Based on specific complaints and other information that suggest potential non-compliance with any Program requirements.
    - Non-compliance includes **developer business practices that impair the use of certified capabilities** as deployed/used (regardless of performance in the testing lab).
    - **A developer's failure to disclose known material information about its certified products or capabilities is a per se violation of its certification.**
  - **Randomized surveillance.** To identify problems not easily detected through complaints and other mechanisms.
- ONC-ACBs must follow defined processes for **corrective action** and must **report such action to the publicly-accessible CHPL on a weekly basis**.

The Office of the National Coordinator for Health Information Technology

Enhanced Transparency Requirements for Developers Under the ONC Health IT Certification Program

Overview

- The 2015 Final Rule requires an **unprecedented level of disclosure** from health IT developers about certified health IT products.
- Two separate (complementary) requirements:
  - **Mandatory Disclosures** - 45 CFR §170.523(k)(1)
  - **Transparency Attestation** - 45 CFR §170.523(k)(2)
- Compliance is required by **April 13, 2016**.
  - ONC has directed ONC-ACBs to **prioritize and vigorously enforce surveillance of these requirements**.
  - Non-compliance will result in **corrective action** and, if not corrected, **decertification**.

Overview (cont'd)

Transparency Policy Rationale:

- For health IT purchasers and users:
  - **Avoid unexpected costs and limitations** when implementing and using certified health IT.
  - **Enable better-informed purchasing and implementation decisions**.
  - **Enable comparisons** across products and vendors.
- For health IT developers:
  - **Increase accountability** and responsiveness to the needs of customers and users.
  - **Encourage competition** to improve products.
  - **Discourage information blocking and opportunistic business practices**.

Mandatory Disclosure Requirements - 45 CFR 170.523(k)(1)

Key Features of the Disclosure Requirements:

- Health IT developers must publicly disclose **all known material information** about:
  - **Additional types of costs** that a user may incur to successfully implement or use capabilities of certified health IT.
  - **Limitations** (including contractual terms, policies, business practices, and technical/practical considerations) that may interfere with a user's ability to successfully implement or use certified health IT capabilities.
- Disclosures are not limited to meaningful use objectives or measures.
  - Developers must disclose all limitations and additional types of costs that a provider may encounter **to successfully implement or use the health IT for any purpose reasonably related to the use of the certified capabilities.**
- Developers must disclose this information **in plain language** and **with particularity**, including the **nature, magnitude, and extent** of the disclosed limitations or types of costs.
- Disclosures must be posted on developers' websites and included in any marketing or other materials that refer to the certified health IT.

Mandatory Disclosure Requirements (cont.)

Form of Disclosures:

- **Public Disclosure Statement ("Blanket Disclosure")**
  - Health IT developers must provide a **hyperlink to a single webpage** that provides **all** of the required information and for all of products.
- **Targeted Disclosures**
  - In addition to publishing a blanket disclosure, developers must disclose all relevant known material information in marketing and other materials that mention certified health IT products or capabilities (whether or not the certification is referenced).
  - This information must be disclosed in a way that is **obvious** and **contextually relevant**.

Mandatory Disclosure Requirements (cont.)

Plain Language:

- Limitations and types of costs must be disclosed in plain language.
- The disclosure must be **understandable, without special effort**, to a reasonable customer or user, such as a clinician or practice manager with minimal technical knowledge or familiarity with certification requirements.
  - » Rule of thumb: The disclosure should be no less plain or understandable than the approach and language used by the developer in its general sales and marketing materials.

Mandatory Disclosure Requirements (cont.)

Particularity

- A developer's disclosure possesses the requisite particularity if it contains sufficient information and detail from which a reasonable person under the circumstances would, without special effort, be able to reasonably identify the specific limitations he may encounter and reasonably understand the potential costs he may incur in the course of implementing and using capabilities for any purpose within the scope of the health IT's certification.
- Examples of information that **must be disclosed**:
  - nature of the limitation or type of cost
  - to whom and under what circumstances it applies
  - potential impact of the limitation or type of costs for the customer/user (e.g., on practice and patient needs)
  - factors that may affect the extent of the limitation or amount of the cost (e.g., user, geographical, volume, usage etc.)
  - potential impact on use of the health IT, including other related capabilities

Mandatory Disclosure Requirements (cont.)

Example: Transitions of Care Capability

Assume that a Health IT Module is certified to the 2014 Edition transitions of care (ToC) capability and that the following limitations and types of costs apply:

- The developer charges an **"annual subscription fee"** to use the ToC capability.
- The developer **bundles the ToC capability with its own HISP**.
- The developer is not a member of any trust network but negotiates some **one-off trust agreements** with third-party HISPs.
- The developer **charges a "transaction fee"** for each ToC summary sent or received via a third-party HISP.

See 80 FR 62723.

Mandatory Disclosure Requirements (cont.)

Example: Transitions of Care Capability (cont.):

The developer must disclose these limitations and types of costs in **plain language** and with **particularity**, including:

- The **annual subscription fee** for ToC, including:
  - The factors used to determine the amount of the subscription fee (e.g., number of licenses, volume of transactions or usage).
- The **developer's HISP policy**, including:
  - How the developer's limited network of supported HISPs and lack of participation in trust networks could impact a customer's ability to exchange ToC summaries (and other Direct messages) with providers and persons with whom it may need or wish to share information.
  - Which third-party HISPs the developer does and does not support.
  - That the developer is willing to negotiate trust agreements with additional HISPs.
  - Any HISPs with whom the developer will not negotiate an agreement or who the developer knows will not agree to a one-off trust agreement (e.g., because the developer is not a member of a particular trust network).
  - How a customer would request such an agreement, how long it could take to fulfill, what costs will be passed through to the customer, etc.
- The **transaction fee** for sending/receiving ToC summaries to third-party HISPs, including:
  - That it charges a fee for every ToC summary sent/received.
  - The factors on which the transaction fee is based (e.g., volume, geography, exchange partner technology).
  - Additional information to assist the customer in realistically understanding his costs.
- The **potential impact** of these fees and limitations on a reasonable person's implementation and use of the ToC capability and related features/functionality of the health IT.

Transparency Attestation - 45 CFR 170.523(k)(2)

- In addition to the mandatory disclosure requirements, the 2015 Final Rule includes a **Transparency Attestation** designed to complement the disclosure requirements.
- Developers must attest whether (**"yes" or "no"**) they will take additional, voluntary actions to support transparency, such as:
  - » Engaging in an **open and public dialogue** about their business practices.
  - » Making information available in ways that are most impactful to purchasers and users (e.g., proactive, targeted disclosures tailored to individual customers/recipients)
  - » Assisting professional associations and product researchers to obtain **comparative information** about developers' products, services, and business practices.
- Developers attestations will be published on the CHPL and a central ONC webpage, along with other transparency-related information, including:
  - » **Hyperlinks to developers' mandatory disclosures**
  - » **Corrective action information** for developers who do not comply with the disclosure requirements

The Office of the National Coordinator for Health Information Technology

@ONC_HealthIT

@HHSONC

HealthIT.gov

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Questions?

karson.mahler@hhs.gov

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Shanna Hartman

2016 CMS QUALITY REPORTING DOCUMENT ARCHITECTURE IMPLEMENTATION GUIDE APPENDIX AND UPDATED SCHEMATRONS

CMS Publishes 2016 CMS Quality Reporting Document Architecture Implementation Guide Appendix and Updated Schematrons

Review New Information for Guidance on Submitting Quality Reporting Document Architecture Files in the 2016 Reporting Period

The Centers for Medicare & Medicaid Services (CMS) has published the 2016 CMS Quality Reporting Document Architecture (QRDA) Implementation Guide (IG) for Eligible Professional (EP) Programs and Hospital Quality Reporting (HQR) Appendix *(Version 1.0, February 26, 2016)*.

The 2016 CMS QRDA IG provides implementation guidance for the 2016 reporting period for submitting QRDA Category I (QRDA-I) and/or QRDA Category III (QRDA-III) files to the CMS EP and HQR programs.

This Appendix lists important updates and clarifications to the 2016 CMS QRDA IG, which include:

- Technical corrections to some of the templates of the 2016 CMS QRDA IG.
- Clarifications and additional guidance for QRDA-I file submission to HQR.
- Clarifications on elements used for eligible hospital eCQM calculations when specifications are not clear.
- Clarifications and additional guidance for specific validations to the Physician Quality Reporting System (PQRS) programs.
- Patient Data Section entry templates constraints for PQRS.
- A complete list of the Universally Unique Identifiers (UUIDs) referenced by the eCQM Specifications for EP Update June 2015 (total 64 eCQMs), which include the Version Specific Measure Identifier for each EP eCQM and the population identifiers for all population criteria within each of the eCQMs. It also includes the identifiers for reporting strata, if applicable.

For More Information

You can find the 2016 CMS QRDA IG Appendix and Schematrons on the CMS eCQM Library and the eCQI Resource Center.

Questions?

https://jira.oncprojectracking.org/browse/QRDA

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Artrina Sturges

HOSPITAL INPATIENT QUALITY REPORTING (HIQR) UPDATE

Hospital Inpatient Quality Reporting (IQR) Program Update

Artrina Sturges, EdD
Project Lead
Inpatient Value, Incentives, and Quality Reporting (VIQR)
Outreach and Education Support Contractor (SC)

March 24, 2016

eCQM Receiving System Update

The electronic Clinical Quality Measure (eCQM) Receiving System through the *QualityNet Secure Portal:*

- Test File Submission is expected to re-open later this year (CMS will distribute notification when the system is available)
- Production File Submission will be available in October 2016
- Receiving System will remain open until the submission deadline of February 28, 2017

2016 CMS QRDA IG Appendix and Updated Schematrons

CMS notified data submitters on March 11, 2016, that the Appendix and Updated Schematrons are available on the eCQM Library. The Appendix lists updates and clarifications to the 2016 Quality Reporting Data Architecture (QRDA) Implementation Guide (IG):

- Technical corrections to some templates on the 2016 CMS QRDA IG
- Clarifications and additional guidance for QRDA-I file submission for Hospital Quality Reporting (HQR)
- Clarifications on elements used for Eligible Hospital (EH) eCQM calculations when specifications are not clear
- Clarifications and additional guidance for specific validations to the Physician Quality Reporting System (PQRS) programs
- A complete list of the Universally Unique Identifiers (UUIDs) referenced by the eCQM Specifications for Eligible Professional (EP) Update June 2015 (total 64 eCQMs), including:
  - Version Specific Measure Identifier for each EP eCQM
  - Population identifiers for all population criteria within each eCQM
  - Identifiers for reporting strata, if applicable

PSVA
Access and Acquisition Update

- The Pre-Submission Validation Application (PSVA) is currently available for download in the Secure File Transfer (SFT) section of qualitynet.org.
- The 1.1.1 Version of the User Guide and Tool is available
- Users must have the Electronic Health Record (EHR) Data Upload role assigned to their *QualityNet* Account in order to access the PSVA.

CMS webinars for PSVA

- *PSVA Demonstration and eCQM Q&A Session,* March 10, 2016
- *Pre-Submission Validation Application (PSVA) for 2016,* January 20, 2016.

The recordings and transcripts are available for review at http://www.qualityreportingcenter.com/inpatient/ecqm-archived-events/.

Upcoming Training

CMS will be hosting an eCQM related webinar on Wednesday, April 14, 2016.

- Visit the http://www.qualityreportingcenter.com website for more details as they become available.
- A ListServe message with registration information will be sent to all ListServe participants.

How to Get Involved

CMS strongly encourages vendors and hospitals to continue working toward the successful submission of eCQM data by:

- Testing QRDA Category I file structure utilizing the PSVA
- Submitting test files through the CMS eCQM Receiving System (*QualityNet Secure Portal*) once the system re-opens this year
- Signing-up for the Hospital Reporting EHR ListServe and participating in training opportunities at www.qualitynet.org/dcs/ContentServer?pagename=QnetPublic/ListServe/Register

Resources

QualityNet HelpDesk

- Qnetsupport@hcqis.org
- 1.866.288.8912, 7 a.m.–7 p.m. CT, Monday through Friday

eCQM General Program Questions

https://cms-ip.custhelp.com

866.800.8765 or 844.472.4477, 7 a.m.–7 p.m. CT Monday through Friday (except holidays)

The JIRA – ONC Project Tracking Website

http://oncprojectracking.org resource to submit questions and comments regarding:

- Issues identified with eCQM logic
- Clarification on specifications
- The Combined QRDA IG for 2016
- The EHR Incentive Program

Questions?

artrina.sturges@area-m.hcqis.org

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Michael Lipinski

THE OFFICE OF THE NATIONAL COORDINATOR OF HEALTH INFORMATION TECHNOLOGY'S (ONC) OVERSIGHT RULE UPDATE

The Office of the National Coordinator for Health Information Technology

"ONC Health IT Certification Program: Enhanced Oversight and Accountability" Proposed Rule

March 24, 2016

Elise Sweeney Anthony, J.D., Acting Director, Office of Policy

Agenda

- ONC Direct Review of Certified Health IT
- ONC-Authorized Testing Laboratories (ONC-ATLs)
- Public Availability of Identifiable Surveillance Results
- Public Comment
- Additional Information and Resources

The Proposal Rule…

- **Would not** create new certification requirements for health IT developers
- **Would not** create new certification/health IT requirements for providers participating in HHS programs
- **Would not** establish a means for ONC to directly test and certify health IT (ONC-ACBs will continue to test and certify)
- **Would not** establish regular or routine auditing of certified health IT by ONC

- **Would enable** ONC to directly review already certified health IT products
- **Would enable** increased ONC oversight of health IT testing bodies
- **Would enable** increased transparency and accountability by making identifiable surveillance results of certified health IT publicly available

ONC Direct Review of Certified Health IT

- Proposal: Expand ONC's role in the Program to encompass the ability to directly review health IT certified under the Program and when necessary, take corrective action, including the suspension and termination of certified health IT

- ONC Direct review would:
  - Be independent of, and may be in addition to, reviews conducted by ONC-ACBs
  - Extend beyond the continued conformance of the certified health IT's capabilities w/the specific certification criteria, test procedures, and specific certification requirements
  - Extend to the interaction of all capabilities within the certified health IT w/certified capabilities and the interaction of all capabilities w/ other products
  - Focus on situations that pose a **risk to public health or safety** and other exigencies

ONC Direct Review of Certified Health IT

Goals include:

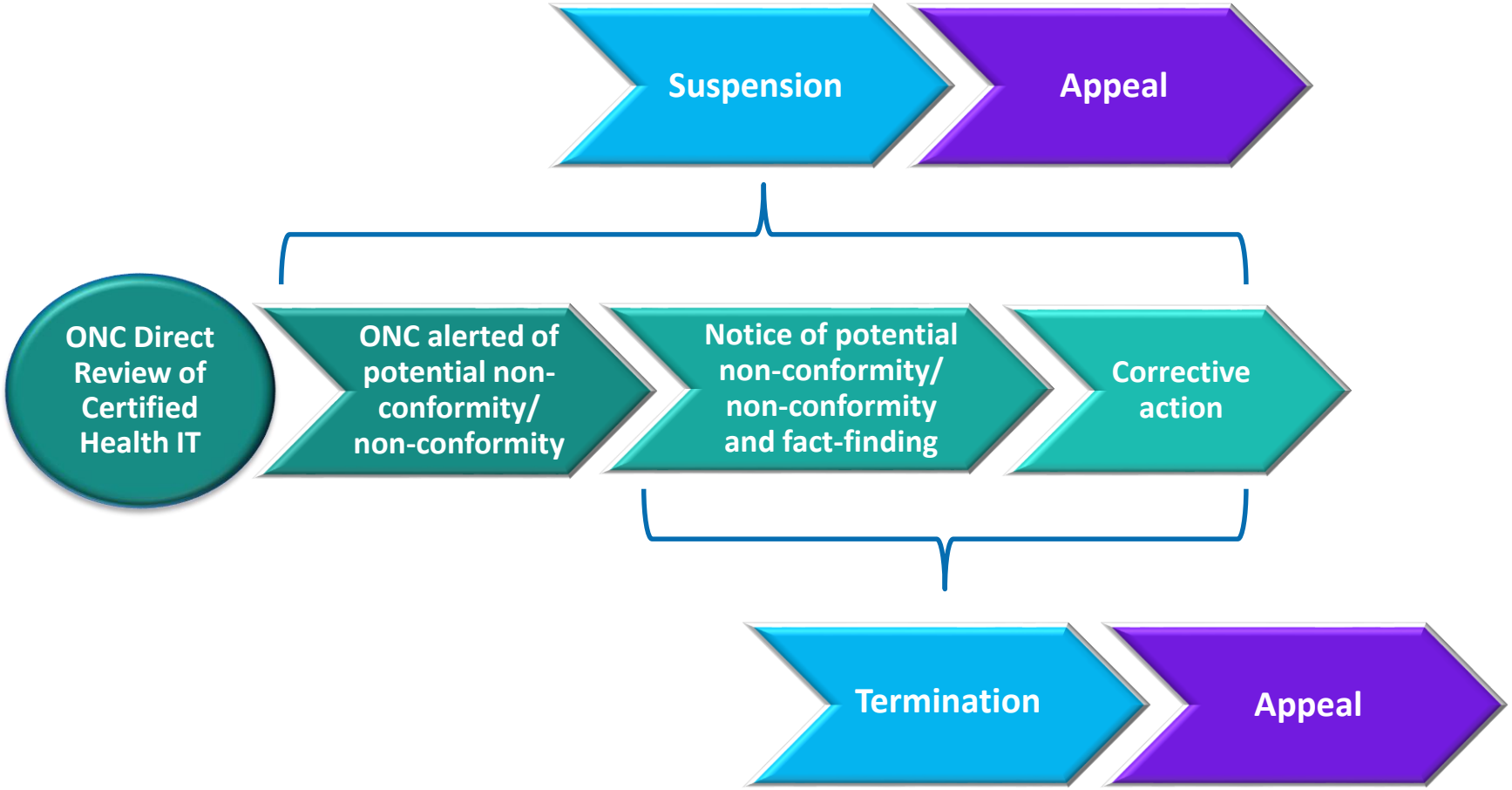
- Supporting greater accountability for health IT developers under the Program
- Providing greater confidence that health IT conforms to Program requirements
- Permitting ONC to work with health IT developers to remedy any identified non-conformities of certified health IT in a timely manner

Examples of Non-Conformities That Could Warrant ONC Direct Review

- Developer has **products certified by 2 different ONC-ACBs** and a potential non-conformity w/certified capability may extend across all developers' certified health IT
- **Systemic, widespread, or complex issues** (e.g., certain fraudulent activities) that could be difficult for an ONC-ACB to investigate or address in a timely, effective manner
- **Risk to public health or safety**, including, for example, capabilities (certified or uncertified) of health IT directly contributing to or causing medical errors
- **Other exigencies** such as a non-conformity that could compromise the security or protection of patients' health information in accordance w/applicable law or that could lead to inaccurate or incomplete documentation and resulting inappropriate or duplicative care under federal health care programs
- **Issues w/confidential information** or information that cannot be shared w/ONC-ACB

ONC Direct Review of Certified Health IT

ONC Direct Review Processes and Actions



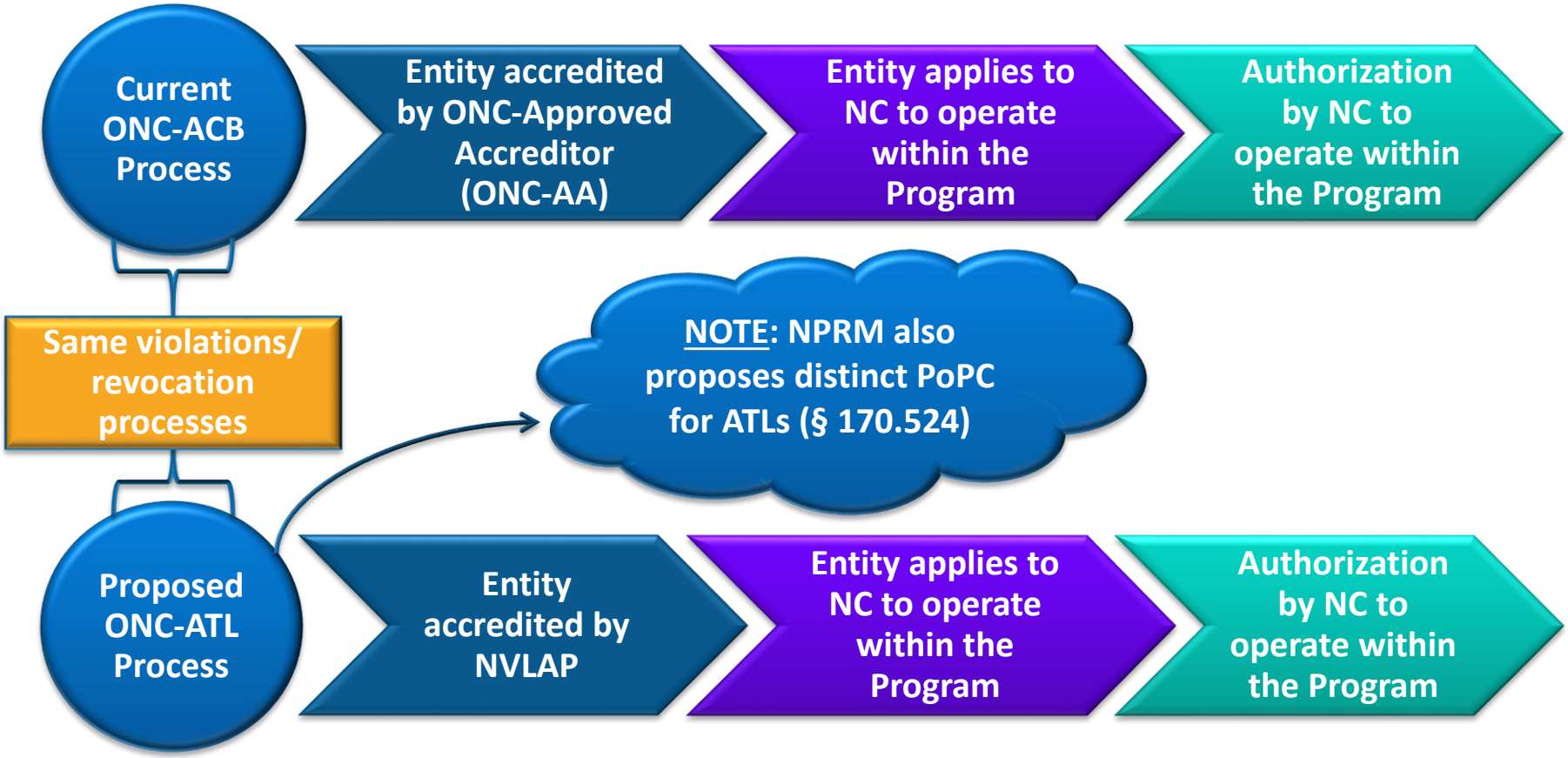
ONC-Authorized Testing Laboratories (ONC-ATLs)

- Proposal:
  - Means for ONC to have direct oversight of National Voluntary Laboratory Accreditation Program (NVLAP)-accrediting testing labs by having them apply to become ONC-ATLs
  - Means for **authorizing, retaining, suspending, and revoking ONC-ATL status** under the Program, which are similar to current ONC-ACB processes

- Goal: Enable ONC to oversee and address testing and certification performance issues throughout the entire continuum of the Program in an immediate, direct, and precise manner

ONC-ATLs

Comparison of Current ONC-ACB and Proposed ONC-ATL Processes



Public Availability of Identifiable Surveillance Results

- Proposal: Require ONC-ACBs to make identifiable surveillance results publicly available on their websites on a quarterly basis
- Goals:
  - Enhance transparency and provides valuable, balanced information about the **continued performance** of certified health IT and surveillance efforts
  - We expect that the prospect of publicly identifiable surveillance results would motivate some health IT developers to improve their maintenance efforts, but also believe that most published surveillance results would reassure customers and users of certified health IT

Public Comment

- The "ONC Health IT Certification Program: Enhanced Oversight and Accountability" Proposed Rule was published in the Federal Register on **March 2, 2016**
- The comment period is open until **5 p.m. on May 2, 2016**
- You can review the proposed rule and comment here: https://federalregister.gov/a/2016-04531
- To assist in commenting on the proposed rule, ONC provides a **Microsoft Word version** of the proposed rule and a **Public Comment Template**. These documents are available at: https://www.healthit.gov/policy-researchers-implementers/standards-and-certification-regulations

Additional Information and Resources

- **Press Release and Fact Sheet:** https://www.healthit.gov/policy-researchers-implementers/standards-and-certification-regulations
- **ONC Regulations:** http://www.healthit.gov/policy-researchers-implementers/standards-and-certification-regulations

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Questions?

michael.lipinski@hhs.gov

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For general questions related to the Medicare & Medicaid EHR Incentive Programs,
e-mail: **EHRINQUIRIES@CMS.HHS.GOV**