March CMS eHealth Vendor Workgroup

March 24, 2016
12:00 PM EDT
<table>
<thead>
<tr>
<th>Agenda Item</th>
<th>Speaker</th>
</tr>
</thead>
</table>
| 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
Peter Krautscheid

UPDATE ON BONNIE, THE ECQM TESTING TOOL
Bonnie Testing Tool
Peter Krautscheid

https://bonnie.healthit.gov
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
## Bonnie Screenshot

### Bonnies Measures

<table>
<thead>
<tr>
<th>Measure Period: 2012</th>
</tr>
</thead>
</table>

#### MEASURES

<table>
<thead>
<tr>
<th>Measure</th>
<th>Description</th>
<th>Expected</th>
<th>Status</th>
<th>Test Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADHD: Follow-Up Care for Children Prescribed Attention-Deficit/Hyperactivity Disorder (ADHD) Medication</td>
<td>CMS136v5</td>
<td>32</td>
<td>PASS</td>
<td>32/32</td>
</tr>
<tr>
<td>Population: Population 1</td>
<td>100</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Population: Population 2</td>
<td>100</td>
<td></td>
<td></td>
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</table>

| Bipolar Disorder and Major Depression: Appraisal for alcohol or chemical substance use | CMS169v4 | PASS | 30/30 |

CHILDHOOD IMMUNIZATION STATUS

Percentage of children 2 years of age who had four diphtheria, tetanus and acellular pertussis (DTaP); three polio (IPV), one measles, mumps and rubella (MMR); three H influenza type B (HIB); three hepatitis B (Hep B); one chicken pox (VZV); four pneumococcal conjugate (PCV); one hepatitis A (Hep A); two or three rotavirus (RV); and two influenza (flu) vaccines by their second birthday.

Complexity: ⚠⚠⚠

Initial Population:

AND : Patient Characteristic Birthdate: Birth >= 1 year starts before start of "Measurement Period"
AND : Patient Characteristic Birthdate: Birth = 2 years starts before end "Measurement Period"
AND :

UNION OF:

• Encounter, Performed: Office Visit
• Encounter, Performed: Face-to-Face Interaction
• Encounter, Performed: Home Healthcare Services
• Encounter, Performed: Preventive Care - Established Office Visit, 0 to 17

PASS 29/29
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
## DATA CRITERIA

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Status</th>
</tr>
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<tbody>
<tr>
<td>1.3.6.1.4.1.33895.1.3.0.45</td>
<td>Intervention, Order: Comfort Measures</td>
<td>Draft</td>
</tr>
<tr>
<td>1.3.6.1.4.1.33895.1.3.0.45</td>
<td>Intervention, Performed: Comfort Measures</td>
<td>Draft</td>
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<tr>
<td>2.16.840.1.113762.1.4.1021.7</td>
<td>Medication, Discharge not done: Statin ingredient specific</td>
<td>Draft</td>
</tr>
<tr>
<td>2.16.840.1.113762.1.4.1021.7</td>
<td>Medication, Discharge not done: Statin ingredient specific</td>
<td>Draft</td>
</tr>
<tr>
<td>2.16.840.1.113762.1.4.1021.7</td>
<td>Medication, Discharge: Statin ingredient specific</td>
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<tr>
<td>2.16.840.1.113883.3.117.1.7.1.212</td>
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<td>Grouping</td>
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<tr>
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<td>Laboratory Test, Performed: LDL-c</td>
<td>Draft</td>
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<tr>
<td>2.16.840.1.113883.3.117.1.7.1.215</td>
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<td>Draft</td>
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<tr>
<td>2.16.840.1.113883.3.117.1.7.1.215</td>
<td>Laboratory Test: LDL-c</td>
<td>Draft</td>
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### Value set debugging (continued)

<table>
<thead>
<tr>
<th>OVERLAPPING VALUE SETS</th>
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<tr>
<td>2.16.840.1.113762.1.4.1045.39</td>
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<tr>
<td>Unfractionated Heparin</td>
<td></td>
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<tr>
<td>1 overlapping code</td>
<td></td>
<td></td>
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<td>2.16.840.1.113883.3.117.1.7.1.218</td>
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<tr>
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<td>2.16.840.1.113883.3.117.1.7.1.255</td>
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<tr>
<td>General Surgery</td>
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<tr>
<td>2.16.840.1.113883.3.117.1.7.1.272</td>
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<tr>
<td>Urological Surgery</td>
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<tr>
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<tr>
<td>Obstetrics</td>
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<td>2.16.840.1.113883.3.117.1.7.1.264</td>
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<td>Obstetrics Vte</td>
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<tr>
<td>10 overlapping codes</td>
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<td>2.16.840.1.113883.3.117.1.7.1.272</td>
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### Value set debugging (continued)

<table>
<thead>
<tr>
<th>Code System</th>
<th>Code</th>
<th>Name</th>
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<tbody>
<tr>
<td>ICD-10-PCS</td>
<td>0WQFXZZ</td>
<td>Repair Abdominal Wall, External Approach</td>
</tr>
<tr>
<td>ICD-10-PCS</td>
<td>0WQF0ZZ</td>
<td>Repair Abdominal Wall, Open Approach</td>
</tr>
<tr>
<td>ICD-10-PCS</td>
<td>0WQFXZ2</td>
<td>Repair Abdominal Wall, Stoma, External Approach</td>
</tr>
<tr>
<td>ICD-10-PCS</td>
<td>0TRB07Z</td>
<td>Replacement of Bladder with Autologous Tissue Substitute, Open Approach</td>
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<tr>
<td>SNOMED-CT</td>
<td>68960009</td>
<td>Closure of enterovesical fistula with bowel and bladder resection (procedure)</td>
</tr>
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<td>SNOMED-CT</td>
<td>21482000</td>
<td>Closure of enterovesical fistula with bowel resection (procedure)</td>
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<tr>
<td>SNOMED-CT</td>
<td>56614001</td>
<td>Repair of fistula involving bladder and intestine (procedure)</td>
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</table>
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
## Excel patient record export

<table>
<thead>
<tr>
<th>Expected</th>
<th>Actual</th>
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</table>

<table>
<thead>
<tr>
<th>notes</th>
<th>first</th>
<th>last</th>
<th>birthdate</th>
<th>expired</th>
<th>deathdate</th>
<th>ethnicity</th>
<th>race</th>
<th>gender</th>
<th>Patient Characteristic</th>
<th>Diagnosis: Primary Open-Angle Glaucoma overlaps Occurrence A: $EveCareEncounters</th>
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</thead>
<tbody>
<tr>
<td>Zelda</td>
<td>TESTArnold</td>
<td>12/31/1994</td>
<td>Not Hispanic c American Indi F</td>
<td>FALSE</td>
<td>TRUE</td>
<td>TRUE</td>
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</tr>
<tr>
<td>Xander</td>
<td>TESTClay</td>
<td>04/13/1986</td>
<td>Not Hispanic c American Indi F</td>
<td>TRUE</td>
<td>FALSE</td>
<td>FALSE</td>
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<td></td>
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<tr>
<td>Veronica</td>
<td>TESTEldridge</td>
<td>04/13/1976</td>
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<td>FALSE</td>
<td>FALSE</td>
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<td></td>
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<tr>
<td>Udi</td>
<td>TESTFranklin</td>
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<tr>
<td>Trudie</td>
<td>TESTGermain</td>
<td>06/14/1966</td>
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<tr>
<td>Penelope</td>
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<td>TRUE</td>
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<tr>
<td>Hilda</td>
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<td>TRUE</td>
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<tr>
<td>George</td>
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<tr>
<td>Quin</td>
<td>TESTJackson</td>
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<tr>
<td>Manny</td>
<td>TESTNolan</td>
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<tr>
<td>Jane</td>
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<td>TRUE</td>
<td>TRUE</td>
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<tr>
<td>Fergie</td>
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<tr>
<td>Edward</td>
<td>TESTVance</td>
<td>06/14/1986</td>
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<td>Denise</td>
<td>TESTWest</td>
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<tr>
<td>Keith</td>
<td>TESTPaulson</td>
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<td>TRUE</td>
<td>TRUE</td>
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<td></td>
<td></td>
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</tr>
<tr>
<td>Ian</td>
<td>TESTRutenbe</td>
<td>04/13/1986</td>
<td>Not Hispanic c American Indi M</td>
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<td>TRUE</td>
<td>TRUE</td>
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<tr>
<td>Curtis</td>
<td>TESTXiao</td>
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<td>TRUE</td>
<td>TRUE</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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

<table>
<thead>
<tr>
<th>Status</th>
<th>Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
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<tr>
<td>PASS</td>
<td>1</td>
<td>IFFail</td>
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<tr>
<td>PASS</td>
<td>2</td>
<td>IFFail</td>
</tr>
<tr>
<td>PASS</td>
<td>3</td>
<td>IFFail</td>
</tr>
</tbody>
</table>

| INITIAL PATIENT POPULATION | | |
| PASS | 1 | IFPass | Patient is 18 with Non-Elective inpatient Encounter (LOS 120 days) with principal diagnosis of ischemic stroke ends during MP |
| PASS | 2 | IFPass | Patient turns 18 day of admission with Non-Elective inpatient Encounter ends during MP with principal diagnosis of stroke |
| PASS | 3 | IFPass | Patient turns 18 day before admission with Non-Elective inpatient Encounter ends during MP with principal diagnosis of stroke |
| PASS | 4 | IFPass | Patient is 15 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 | 5 | NumFail | Patient received anti thrombotic during encounter |
| PASS | 6 | 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 |
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. Lus viris salutatus sadipscing ne, omnes offendit ei eum. In mea hendrerit consetetur, nam inermis scriptorem ut. Per id stet esse, mei partem alienum ad.

<table>
<thead>
<tr>
<th>84 days</th>
<th>180 days</th>
</tr>
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<tbody>
<tr>
<td>Patient A</td>
<td></td>
</tr>
<tr>
<td>Patient B</td>
<td></td>
</tr>
<tr>
<td>Patient C</td>
<td></td>
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</tbody>
</table>

**Measure History**

<table>
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<tr>
<th>Population</th>
<th>Expected</th>
<th>Actual</th>
</tr>
</thead>
<tbody>
<tr>
<td>IPP</td>
<td>✓</td>
<td>☐</td>
</tr>
<tr>
<td>DENOM</td>
<td>✓</td>
<td>☐</td>
</tr>
<tr>
<td>DENEX</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>NUMER</td>
<td>✓</td>
<td>☐</td>
</tr>
</tbody>
</table>

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
CQL Evaluation (Alpha)

```cql
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
```

<table>
<thead>
<tr>
<th>Statement</th>
<th>Ischemic, No Meds</th>
<th>Ischemic, With Meds</th>
<th>Ischemic, Patient Left</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>OverEighteen</strong></td>
<td>✅</td>
<td>✅</td>
<td>✅</td>
</tr>
<tr>
<td><strong>Encounters</strong></td>
<td>Encounter, Performed: Inpatient Encounter</td>
<td>Encounter, Performed: Inpatient Encounter</td>
<td>Encounter, Performed: Inpatient Encounter</td>
</tr>
<tr>
<td><strong>IschemicStroke</strong></td>
<td>Diagnosis: Ischemic Stroke</td>
<td>Diagnosis: Ischemic Stroke</td>
<td>Diagnosis: Ischemic Stroke</td>
</tr>
<tr>
<td><strong>EncountersWithIschemicStroke</strong></td>
<td>Encounter, Performed: Inpatient Encounter</td>
<td>Encounter, Performed: Inpatient Encounter</td>
<td>Encounter, Performed: Inpatient Encounter</td>
</tr>
</tbody>
</table>
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
Where To Look For Info

- **Main Bonnie site**
  - [https://bonnie.healthit.gov/](https://bonnie.healthit.gov/)

- **JIRA for tracking issues**
  - [https://jira.oncprojecttracking.org/browse/BONNIE](https://jira.oncprojecttracking.org/browse/BONNIE)

- **Contact development team**
  - bonnie-feedback-list@lists.mitre.org

- **Open Source on GitHub**
  - [https://github.com/projecttacoma/bonnie](https://github.com/projecttacoma/bonnie)
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

Numerator: Patients who do receive the expected care

Denominator: Patients who should receive the expected care

All Patients
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
Questions?

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OVERVIEW OF ENHANCED TRANSPARENCY REQUIREMENTS FOR HEALTH IT DEVELOPERS UNDER THE ONC HEALTH IT CERTIFICATION PROGRAM
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
Background
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.
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.
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.
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.
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.
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.
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
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.
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
Questions?

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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.oncprojecttracking.org/browse/QRDA
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
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
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
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.

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](http://www.qualitynet.org/dcs/ContentServer?pagename=QnetPublic/ListServe/Register)
Resources

**QualityNet HelpDesk**
- [Qnetsupport@hcqis.org](mailto: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](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://oncprojecttracking.org](http://oncprojecttracking.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?

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Michael Lipinski

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

- Suspension
- Appeal

ONC alerted of potential non-conformity/non-conformity
Notice of potential non-conformity/non-conformity and fact-finding
Corrective action

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

Current ONC-ACB Process
- Entity accredited by ONC-Approved Accreditor (ONC-AA)
- Entity applies to NC to operate within the Program
  - Authorization by NC to operate within the Program

Proposed ONC-ATL Process
- Entity accredited by NVLAP
- Entity applies to NC to operate within the Program
  - Authorization by NC to operate within the Program

Same violations/revocation processes

NOTE: NPRM also proposes distinct PoPC for ATLs (§ 170.524)
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.

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**Diagram:**

- **Balanced View of Surveillance Results**
  - Reassurance of Conformance
  - Non Conformities, CAPS (on CPHL)

**Overall Performance**
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
Questions?

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