November 2, 2011

Carol A. Bean, PhD
Director, Division of Certification and Testing
Office of Interoperability and Standards
Office of the National Coordinator for Health IT

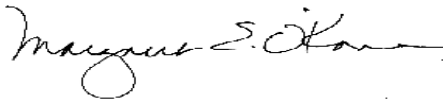
Dear Dr. Bean:

NCQA seeks consideration of its testing program for Clinical Quality Measures (CQM) software for use in the ONC Certified EHR Technology Program. The attached document describes NCQA's process for certifying software that produces CQMs and how that process can serve the needs of the ONC EHR certification program as an approved testing system.

The NCQA Software Certification process has evolved over the past 15 years into a well-established program that ensures the integrity of commercial software products to produce clinical quality measures. We have certified over 20 vendors and their products in the collection and reporting on various quality measurement programs, including the NCQA Healthcare Effectiveness Data and Information Set (HEDIS), the California Pay-4-Performance program, and measures collected by EHR vendors in NCQA's Physician Recognition Program. We certify the processes that vendors use to develop and implement reporting software to ensure the software accurately collects the specified data (correct patients) and accurately calculates clinical quality measures (accounting for inclusion/exclusion criteria) using EHR (clinical) and claims (administrative) data.

NCQA proposes that by authorizing the use of our proven software certification program in ONC's Certified EHR Technology Program, EHR modules can produce nationally comparative measures and the ONC can benefit from an established record of success. If you have questions about this request, please contact Mary Braman, Director of NCQA Software Certification Program at braman@ncqa.org, or (202) 955-3599. Thank you for your consideration of this request and we look forward to working with you on this program.

Sincerely,



Margaret O'Kane
President, NCQA

Attachment: NCQA Software Certification Program Description

NCQA Software Certification Program
Description

The following sections address ONC's request for information.

Test tool or test procedure developer

NCQA HEDIS Software Certification[SM] is a service mark of NCQA. The test tool and all test procedures are owned, developed, and maintained by NCQA.

For 15 years, NCQA has worked with industry leaders to develop our test deck algorithms and ensure the validity and reliability of the programming. The result is a test method that ensures the software producing the results for each measure is tested against thousands of parameters of data input. In addition to our software certification process, NCQA also has a **data validation audit** for CQM measure reporting; however, that portion of our data collection program **is not addressed** in this test program submission consideration. Although not discussed in this consideration memo, we would encourage ONC to consider how a data validation audit could enhance the comparability of the CQMs collected for Meaningful Use.

Explain how the test procedure would evaluate a Complete EHR's or EHR Module's compliance with the applicable Certification criteria

NCQA's certification program tests any CQM that is accurately and thoroughly specified with these components:

1. A denominator – eligible population of members, patients, or events
2. Exclusions/exceptions – any service, cause, or reason that a person or event is removed from the denominator
3. A numerator – the number of members, patients, or events after exclusions/exceptions who received the care or service specified

Any such "measure specification" can be the criteria on which a test is based.

Describe the process used to develop the test tool process and tool

NCQA's completely automated testing process is based on Boris Beizer's "black-box" testing theory, which takes an external perspective of the test object to derive test cases (test decks). The test designer uses valid and invalid input data and determines the correct output. There is no need for the tester to have any knowledge of the test subject's structure.

Generic black-box testing

The generic diagram shows input, run through a program, with output achieved.

Software Certification Black Box Testing Model

In NCQA's certification program, the vendor uses the input data, our test decks, runs it through their software to calculate the CQM results as the output, which we match to predetermined output.

Defining Input & Output Standards

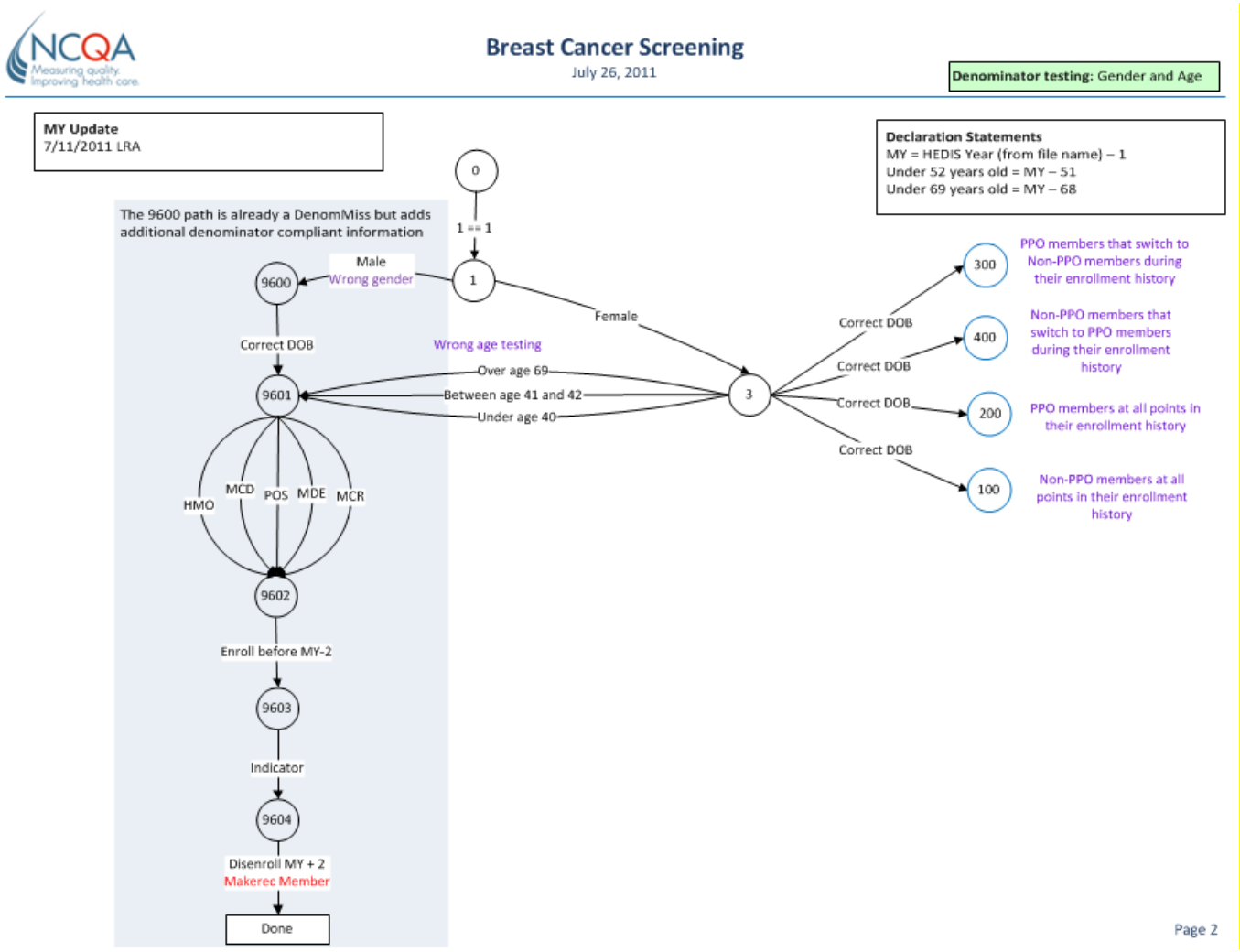
In Black Box testing theory, if we agree on the input (Input Standard), and we agree on the output (Output Standard), the tester should produce the same answers.

The input standard is a data file map for the test data, which mimics data an EHR module would receive; e.g., information about patients (name, DOB, address, gender, etc.) and actual services (ICD-9 or 10 diagnosis codes, CPT codes, RX Norm, SNOMED codes). The output file is a defined specification for the information the vendors return. For each measure, it contains details for the patient in the test deck.

If the CQM specification looks for patients with hypertension, and the test deck has an entry for a compliant patient, the software must determine if that person is in the denominator, eligible for an exclusion, and in the numerator. We collect data at this level to ensure that we agree who in the test deck is compliant for the measure.

We create test decks to test each decision point in the specification, as well as common or known issues: e.g., typos in numbers, not checking age ranges correctly, including a range of codes instead of an individual code.

To visualize the decision points and their results, we use an automated Microsoft Visio™ program to create a flow diagram. The example below is a flow diagram for Breast Cancer Screening.



The first decision point is gender. Males are excluded; females continue because they might be eligible. The next decision point might be age; patients between 42 and 69 continue, but patients younger than 42 or older than 69 do not. The diagram processes every decision point throughout the denominator, exclusions, and numerator.

The Microsoft Visio™ flow diagrams are automatically translated into programming language called Specifications Analysis Language (SAL) that was developed for NCQA. With SAL, every arrow coming out of a node in the diagram is assigned a piece of data, which is marked as a hit or a miss. When all paths are created and marked, we create the decks.

A program called BlackPath, written in PERL, creates a set of test data using the SAL data. It calculates every possible path from the beginning to the end of the program. The output is a list of each patient to be generated and all the paths that the program will go down to generate that person. For example, it may calculate that one path it will go down creates a woman between 42 and 69 with 2 lines for office visits, one of which will be a mammogram.

At the same time, it also creates the scoring file. Because it is tracing the path for every patient, it knows if the patient is a hit or a miss. It records the hits and misses in a file used to score the vendor's file.

NCQA uses public input, via beta-testing vendors, to ensure the "testability" of the test decks. Beta-testers must test and pass every measure in the measure set. Problems found during beta testing are reviewed, recoded, and retested until NCQA and the beta testers agree on the process and results.

After the beta-testing vendors are finished, each remaining vendor practices with a "sample" deck and answer key (answer keys are produced by our test tool). The vendors work with the sample deck until their answer completely matches our answer.

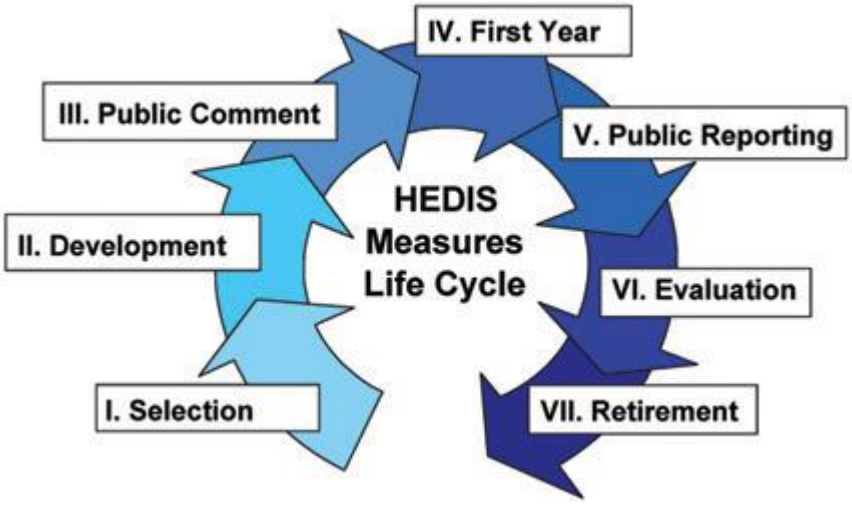
During live testing, the vendors receive completely new production test decks. When they produce an answer, they upload it to our online scoring program. There are two possible test-deck submission responses:

- Pass – the vendor completed the measure by calculating the same answers as are in the answer key.
- Review – the deck is scored, but with errors (an Adobe report indicates which cases are wrong).

When "Review" is the status for a measure, the vendor receives an additional explanation from NCQA staff, makes the necessary software adjustments, receives a new test deck, and submits a retest. Each failed attempt requires a new test deck and answer key. This test method ensures the vendor cannot just correct the test case answer set; they must pass new data through their software each time.

Describe the public comment process used during the development of the test procedure.

NCQA's current test procedure produces a reliable set of test decks in accordance with publicly available CQM specifications (e.g., HEDIS, PQRI, eMeasures, etc.). NCQA has established an industry best practice and a well-documented measure specification life cycle that includes a public-comment process.



Each year, NCQA posts a request-for-comment period on our Web site: (http://www.ncqa.org/tabid/621/default.aspx).

The site is open to the public for any input. NCQA's multi-specialty and cross-organizational subject-matter experts (Measurement Advisory and Technical Panels) consider all comments and advise NCQA

staff on appropriate recommendations that are reviewed and approved by the Committee on Performance Measurement (CPM), a committee, with representatives from purchasers, consumers, health plans, health care providers and policy makers, that oversees the evolution of the CQM.

After this extensive public comment period, input by technical expert panels, and approval by the CPM, NCQA develops applicable test decks. Beta testing, conducted with two long-standing vendors, provides a vetting process for the test decks. In the current program, every measure is beta tested every year, and the beta vendors provide a means of ensuring that all logic and data sources are considered.

Explain how the test tool would evaluate a Complete EHR or EHR Module's compliance with the applicable certification criteria and be sufficiently comprehensive to assess all required capabilities.

The Certification Criterion for §170.304 (j) Calculate and submit CQMs is:

(1) Calculate.
    (i) Electronically calculate all of the core clinical measures specified by CMS for eligible professionals.
    (ii) Electronically calculate, at a minimum, three clinical quality measures specified by CMS for eligible professionals, in addition to those clinical quality measures specified in paragraph (1)(i).
(2) Submission. Enable a user to electronically submit calculated clinical quality measures in accordance with the standard and implementation specifications specified in §170.205(f).

The Test Procedure document further states:

"This test procedure evaluates conformance to the Physician Quality Reporting Initiative (PQRI) standard and implementation specifications identified in the Federal Register; however, the test procedure does not fully evaluate the correctness of the implemented algorithms or calculation of the quality measures based on Vendor test data. An automated test tool to determine the correct calculation of measures is currently under development through an HHS/ONC effort."

NCQA's software certification process is specifically designed to test the following requirement: "Calculate and Submit Clinical Quality Measures Modules." In addition, the process can create test decks for any clinical quality measure logic, and fully evaluate the correctness of the implemented algorithms or calculation of the quality measures for any vendor. The test decks would be used to meet criteria (i), and the output files would be tested to meet criteria (ii).

Note: The test format for submitting the PQRI XML schema is defined by CMS and a tool is available; however, NCQA could incorporate that test format into its program if required.

Demonstrate that the test tool is clearly traceable to the certification adopted by the Secretary (traceability)

The design, output, and testing processes used in NCQA's software certification are transparent and verifiable with reference to each test deck creation, application, and result. All input and output files are available to the public, and the scoring files can be provided on request.

As stated above, the NCQA test-deck process will enable the ONC to trace all elements of the test specification.

- Calculate: show that correct data are collected and all algorithms for inclusion and exclusion are applied
- Submit: ensure that each vendor's EHR CQM program produces a set of nationally comparative (standardized) measures.

Our multi-case process would ensure traceability and accuracy of all vendor's results, allowing reliable comparison among all participating submitters.

Guarantee provision of training, as required by ONC, for the ONC-Authorized Testing and Certification Bodies (ATCBs) and/or Accredited Test Labs (ATLs).

NCQA provides complete training and support to all applicants for the test certification process.

Although the current testing process is administered by NCQA and managed by NCQA staff, we envision several potential adaptations for use by ONC. We look forward to working with ONC to determine an optimum program for use by all ATCBs or ATLs.