**TO:** Consensus Standards Approval Committee (CSAC)

**FR:** Karen Johnson, Katie Streeter, Lindsey Tighe, and Poonam Bal

**RE:** Endocrine Member Voting Results

**DA:** July 9, 2014

The CSAC will review recommendations from the *Endocrine* (Cycle 1) project at its July 9-10 in-person meeting.

This memo includes a summary of the project, recommended measures, and themes identified from—and responses to—the public and member comments.

This project followed the National Quality Forum's (NQF) version 1.9 of the Consensus Development Process (CDP). Member voting on these recommended measures ended on June 20.

Accompanying this memo are the following documents:

1. **Endocrine Cycle 1 Draft Report.** The draft report has been updated to reflect the changes made following Standing Committee discussion of public and member comments. The complete draft report and supplemental materials are available on the project page.
2. **Comment table.** Staff has identified themes within the comments received during the 30-day post-evaluation comment period. This table lists the 83 post-evaluation comments received and the corresponding NQF, Standing Committee, and/or developer responses. Also included in this table are the 76 comments that were received prior to the evaluation of the measures.

**CSAC ACTION REQUIRED**
Pursuant to the CDP, the CSAC may consider approval of 14 candidate consensus standards.

Endocrine Measures Recommended for Endorsement:

- 0055: Comprehensive Diabetes Care: Eye Exam (retinal) performed
- 0056: Diabetes: Foot Exam
- 0057: Comprehensive Diabetes Care: Hemoglobin A1c (HbA1c) testing
- 0059: Comprehensive Diabetes Care: Hemoglobin A1c (HbA1c) Poor Control (>9.0%)
- 0062: Comprehensive Diabetes Care: Medical Attention for Nephropathy
- 0519: Diabetic Foot Care and Patient Education Implemented
- 0545: Adherence to Statins for Individuals with Diabetes Mellitus
- 0575: Comprehensive Diabetes Care: Hemoglobin A1c (HbA1c) Control (<8.0%)
- 2362: Glycemic Control - Hyperglycemia
- 2363: Glycemic Control - Hypoglycemia
- 2416: Laboratory Investigation for Secondary Causes of Fracture
- 2417: Risk Assessment/Treatment After Fracture
- 2467: Adherence to ACEIs/ARBs for Individuals with Diabetes Mellitus

- 2468 (Adherence to Oral Diabetes Agents for Individuals with Diabetes Mellitus)

Endocrine Measures Not Recommended

- 2418 Discharge Instructions – Emergency Department

**BACKGROUND**

This project seeks to identify and endorse performance measures for accountability and quality improvement that address endocrine-specific conditions. The endocrine topic area includes measures for diabetes, thyroid disease, osteoporosis, and metabolic syndrome.

NQF currently has more than thirty endorsed measures in the areas of diabetes and osteoporosis. The diabetes measures in NQF's portfolio are some of the longest-standing NQF endorsed measures. Because diabetes and osteoporosis are high-volume, high-morbidity, high-cost conditions, endorsement of strong measures for these conditions is critical for continued improvements in care quality.

NQF selected the Endocrine measure evaluation project to pilot more frequent submission and evaluation of measures than what is possible in our current 3-year measure maintenance cycle. This 22-month project will include three full endorsement "cycles," allowing for the submission and review of both new and previously-endorsed measures every six months. In addition, this project is one of the first to transition to the use of Standing Committees. The 20 Standing Committee members recommended 14 out of 17 measures initially submitted for endorsement in Cycle 1 of the project.

**DRAFT REPORT**

The Endocrine Cycle 1 Draft Report presents the results of the evaluation of 17 measures considered under the CDP. Fourteen of these measures have been recommended for endorsement as voluntary consensus standards suitable for accountability and quality improvement, one measure was not recommended, and two were withdrawn from consideration. The measures were evaluated against the 2013 version of the measure evaluation criteria.

| | MAINTENANCE | NEW | TOTAL |
|---|---|---|---|
| **Measures considered** | 12 | 5 | 17 |
| **Withdrawn from Consideration*** | 2 | 0 | 2 |
| **Recommended** | 10 | 4 | 14 |
| **Not recommended** | 0 | 1 | 1 |
| **Reasons not Recommended** | Importance- 0<br>Scientific Acceptability- 0<br>Overall- 0<br>Competing Measure- 0 | Importance- 0<br>Scientific Acceptability- 1<br>Overall- 0<br>Competing Measure- 0 | |

*These two measures have been brought back in Cycle 2 (beginning June 2014)

**COMMENTS AND THEIR DISPOSITION**

NQF received a total of 76 pre-evaluation comments, the majority of which pertained to, and were supportive of, three newly-submitted osteoporosis measures. All of these pre-evaluation comments were provided to the Committee prior to their initial deliberations held during the workgroups calls.

NQF also received 83 post-evaluation comments from 10 member organizations and individuals pertaining to the general draft report and to the measures under consideration.

A complete table of comments submitted pre- and post-evaluation, along with the responses to each comment and the actions taken by the Standing Committee, is posted to the Endocrine project page.

**Comment Themes and Committee Responses**

Only one overall theme was identified in the post-evaluation comments: that of support for the recommended measures. Specifically, a total of 48 of the comments received expressed support for (but no additional questions or concerns regarding) the Committee's initial decisions to recommend 13 of the evaluated measures for endorsement. Several additional comments also expressed support of the Committee's decisions, but also requested clarification regarding measure specifications (these were forwarded to the appropriate developer for response).

While there were several comments that were not supportive of the Committee's recommendations, most simply explained the reasoning but did not offer additional data or information to promote further discussion of the measure.

At its review of the post-evaluation comments, the Standing Committee had the benefit of developer responses. Committee members focused their discussion on measures with the most significant issues.

**Measure Specific Comments**

***2468: Adherence to Oral Diabetes Agents for Individuals with Diabetes Mellitus***

*Description:* NQF received 3 post-evaluation comments regarding this measure, each of which concurred with the Committee's ***initial decision not to recommend*** the measure for endorsement because members questioned the validity of the measure. Specifically, the measure as initially evaluated by the Committee did not exclude patients who switched from oral agents to insulin during the measurement period. The Committee noted that in older adults, transition to insulin (and associated discontinuation of oral medications) is common and that the measure as specified would incorrectly categorize such patients as non-adherent; members also expressed concern that the measure as specified might incentivize physicians to leave patients on oral diabetes agents rather than switch them to insulin when appropriate. The Committee encouraged the developer to quantify the number of patients who transitioned to insulin and, if possible, revise the measure to exclude those patients.

As requested by the Committee, the measure developer—during the 30-day post-evaluation comment period—conducted additional analysis, finding that 13.1% of patients in their 10-state sample switched from oral diabetes agents to an insulin-only therapy. Based on these results, the developer re-specified the measure to 1) limit the number of days in the denominator for those who switched from oral diabetes agents to insulin-only therapy and 2) compute an overall percentage-of-days-covered value for those who switched between oral drug classes; they also re-tested the newly specified measure for reliability and validity.

*Committee response*: After discussion of the change in specifications and the additional reliability and validity testing results, the committee agreed to re-vote on the measure. Upon re-vote, the Committee agreed that the analysis and re-specification of the measure addressed their initial concerns with the

validity of the measure. After additional discussion, the Committee voted on the Feasbility and Usability and Use criteria, and ultimately recommended the re-specified measure for endorsement.

***2418: Discharge Instructions – Emergency Department***

*Description:* NQF received 4 post-evaluation comments regarding this measure, each of which reflected disagreement with the Committee's decision not to recommend the measure for endorsement. During the evaluation of this measure at the in-person meeting, the Committee agreed that this measure did not meet the Evidence subcriterion under Importance to Measure and Report. Specifically, the Committee noted that there is minimal evidence indicating that provision of written discharge instructions improves care for osteoporosis patients or has any impact on outcomes such as prevention of future fractures. None of the submitted comments referenced additional evidence to show that provision of discharge instructions would help to prevent future fractures.

*Committee response:* Committee members agreed that no additional information was presented to change their evaluation of the measure and therefore declined to re-vote on the measure.

***0055: Comprehensive Diabetes Care: Eye Exam (retinal) performed***

*Description:* NQF received 7 post-evaluation comments regarding this measure. Four of these comments were supportive of the measure and the Committee's decision to recommend the measure for endorsement. Two of the comments requested clarification as to why women with polycystic ovarian syndrome are excluded from the measure. One commenter noted that the measure can be met through use of remote imaging, contrary to medical guidelines. Finally, one commenter suggested that this measure be aligned with the new age specifications agreed to by the developer for measure #0056 (i.e., NCQA removed the upper age restriction so that the measure now applies to diabetes patients ages 18 and older).

*Committee response:* Committee members noted that the ADA guidelines, as well as other evidence, indicate that retinal photographs are acceptable; therefore, they did not recommend a change to the specifications of the measure. The Committee agreed that because complications of diabetes disproportionately affects older patients, the measure developer should consider changing the specifications to include those aged 18 and older rather than including only those aged 18-75.

***2362: Glycemic Control – Hyperglycemia and 2363: Glycemic Control – Hypoglycemia***

***Description:*** NQF received 6 post-evaluation comments regarding this measure. One commenter submitted 2 comments, noting low reliability scores for one of the hospitals included in the testing of one measure and questioning the reliability of the other measure for smaller facilities. The commenter also expressed the desire that the measures be made consistent. In addition, one commenter questioned the need for these measures while another expressed support for the measures.

*Committee response:* After review and discussion of the comments and the response from the developer, the Committee supported the construction of the measures and accepted the explanation of the developer regarding reliability. The Committee agreed that these measures meet the three

subcriteria under Importance to Measure and Report (i.e., evidence, opportunity for improvement, and high priority).

**NQF MEMBER VOTING RESULTS**
All measures recommended by the Standing Committee received unanimous support.

**Voting Comments:**

- **Measure #0056 Diabetes: Foot Exam**
  American College of Emergency Physicians: The ACEP Quality and Performance Committee greatly appreciate the opportunity to provide comments to the measure developer. ACEP is concerned regarding the inclusion of CPT codes 99281-99285 and 99291 in the denominator of this measure. This measure states that at a minimum documentation in the medical record must include a note indicating the date when the exam was performed and the result. The patient is numerator compliant if a foot exam during the measurement year and result are documented." This is an impossible measure to meet in the Emergency Department as any measures pertaining to emergency care must be visit level measures rather than "measurement year." Emergency physicians have little to no opportunity for follow-up with a majority of their patients. We assume that this is a mistake because the care setting states: "Ambulatory Care: Clinician Office/Clinic" so it does not appear to be the intention of the measure developers to include emergency department visits. Of note neither these codes nor the emergency department setting appears to be included for any of the other measures in this set. If the measure developer were to address this error we would wholeheartedly support this measure.

- **Measure #2468 Adherence to Oral Diabetes Agents for Individuals with Diabetes Mellitus**
  GlaxoSmithKline: GSK supports adherence to diabetes agents and recommends that the word oral" be taken out of #2468 and strongly recommends including other non-insulin diabetic agents in this adherence measure. Rather than suggesting development of a new measure for non-oral diabetic agents we recommend a single adherence measure for both. Adherence to these agents improves patient outcomes and is consistent with the intent of this measure."

**REMOVE ENDORSEMENT OF MEASURES**

Two measures previously endorsed by NQF have not been re-submitted, or not recommended for continued endorsement:

| Measure | Description | Reason for removal of endorsement |
|---|---|---|
| 0060: HbA1c testing for pediatric patients | The percentage of children aged 5 to 17 years of age with diabetes (type 1 and type 2) that had a Hemoglobin A1c (HbA1c) test during the measurement year. | Retired due to removal from CHIP Child Core set and NCQA DRP program. |
| 0731: Comprehensive Diabetes Care | The percentage of patients 18–75 years of age with diabetes (type 1 and type 2) who had each of the following:<br>- Hemoglobin A1c (HbA1c) testing (NQF#0057)<br>- HbA1c poor control (>9.0%) (NQF#0059) | Retired due to the measure no longer being in use. |

| Measure | Description | Reason for removal of endorsement |
|---|---|---|
| | - HbA1c control (<8.0%) (NQF#0575)<br>- HbA1c control (<7.0%) for a selected population*<br>- Eye exam (retinal) performed (NQF#0055)<br>- LDL-C screening (NQF#0063)<br>- LDL-C control (<100 mg/dL) (NQF#0064)<br>- Medical attention for nephropathy (NQF#0062)<br>- BP control (<140/90 mm Hg) (NQF#0061)<br>- Smoking status and cessation advice or treatment | |

**Measure Evaluation Summary Tables**

**LEGEND: Y = Yes; N = No; H = High; M = Moderate; L = Low; I = Insufficient I= Insufficient with Exception**

### 0056 Diabetes: Foot Exam

Submission | Specifications

**Description**: The percentage of patients 18-75 years of age with diabetes (type 1 and type 2) who received a foot exam (visual inspection and sensory exam with mono filament and a pulse exam) during the measurement year.

**Numerator Statement**: Patients who received a foot exam (visual inspection and sensory exam with monofilament and pulse exam) during the measurement period.

**Denominator Statement**: Patients 18-75 years of age by the end of the measurement year who had a diagnosis of diabetes (type 1 or type 2) during the measurement year or the year prior to the measurement year.

**Exclusions**: A diagnosis of gestational or steroid-induced diabetes

**Adjustment/Stratification**: None

**Level of Analysis:** Clinician : Group/Practice, Clinician : Individual

**Setting of Care:** Ambulatory Care : Clinician Office/Clinic

**Type of Measure**: Process

**Data Source**: Administrative claims, Paper Medical Records, Electronic Clinical Data : Pharmacy

**Measure Steward**: National Committee for Quality Assurance

**STANDING COMMITTEE MEETING [02/26/2014-02/27/2015]**

**1. Importance to Measure and Report: The measure meets the Importance criteria**

(1a. Evidence: 1b. Performance Gap, 1c. High Priority)

1a. Evidence: **H-4**; **M-13**; **L-3**; **I- 0; IE-0**; 1b. Performance Gap: **H-14**; **M-5**; **L-1**; **I-0** 1c. High Priority: **H-17**; **M-3; L-0**; **I-0**

Rationale:

- The Committee acknowledged that evidence exists indicating the benefit of a foot exam in conjunction with other interventions such as performing risk assessment and creating treatment plans for high risk patients; however, the Committee found it difficult to apply the evidence to performing a foot exam alone.
- While the evidence for foot exams may not exist, the Committee felt the evidence provided did indicate foot exam interventions for patients who are high risk can lead to improved outcomes.
- The measure specifies that a foot exam include a visual inspection and sensory exam with monofilament and a pulse exam. While there was agreement that the monofilament foot exam is an acceptable method for reducing diabetes complications and improving quality of life, the Committee questioned if the evidence was strong enough to classify this exam as the gold standard intervention. Some Committee members felt that the monofilament exam is cumbersome, difficult to use, and not that useful, while others felt it was better than the alternatives. Data presented by the developer indicated that monofilament, vibratory, and other similar interventions have equal predictive value for lower limb complications.

| 0056 Diabetes: Foot Exam |
|---|
| • Data presented by the developer showed relatively high performance, with most percentiles reaching 100%. Though performance data was high, the Committee stated that during the time-period that the measure has been used, there is evidence of decreased lower limb complications. The Committee stated that it is difficult to ascertain whether the measure itself or another unknown intervention led to this improvement; as such, the Committee concluded maintaining endorsement of the measure was necessary.<br>• Diabetes is the 7th leading cause of death in the US and when unmanaged can cause serious health complications, including heart disease and stroke, hypertension, blindness, kidney disease, nervous system disease, amputations, dental disease, and pregnancy complications. |
| **2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>**<br>(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)<br>2a. Reliability: **H-3**; **M-13**; **L-4**; **I-0** 2b. Validity: **H-8**; **M-9**; **L-2**; **I-0**<br><u>Rationale</u>:<br>• The Committee found the signal-to-noise reliability testing results using the beta binomial method to be strong with most of the reliability results being above .7 and the majority above .9.<br>• Face validity was assessed with several panels of experts from diverse backgrounds. The Committee stated concern that the upper age limit of 75 specified in the denominator was not justified by the evidence, as patients over 75 are at a higher risk for lower limb complications and thus would benefit the most from this measure intervention. The developer agreed to remove the upper age limit. |
| **3. Feasibility: H-1; M-15; L-3; I-0**<br>*(3a. Data generated during care; 3b. Electronic sources; and 3c. Data collection can be implemented (eMeasure feasibility assessment of data elements and logic)*<br><u>Rationale</u>:<br>• The Committee agreed that the measure was feasible to implement, as the measure has already been in use and the data elements necessary to compute the measure score are generated during care and easily captured.<br>• The Committee expressed concern that the measure requires three actions to occur in order to meet the requirements of the measure, which may create confusion regarding proper documentation as there is not currently a common data element that collects this information. The Committee felt this may result in difficulties in extracting data correctly. Ultimately the Committee agreed that the endorsement of the measure would drive EMR developers to create a distinct field to collect the data. |
| **4. Use and Usability: H-7; M-9; L-2; I-0**<br>*(4a. Accountability/transparency; and 4b. Improvement – progress demonstrated; and 4c. Benefits outweigh evidence of unintended negative consequences)*<br><u>Rationale</u>:<br>• The measure is currently used in NCQA's accountability programs, Diabetes Physician Recognition Program (DPRP) and Physician Quality Reporting System (PQRS).<br>• The Committee acknowledged that there has been little improvement in performance of the measure over time; however, mean performance of 78% at the physician level in 2012 indicates a significant opportunity for more improvement.<br>• Continued use of this measure maintains pressure and a priority on performing (and measuring) annual foot exams. Foot exams are a low-burden procedure with minimal risks to patient, with significant potential benefits for patients including decreased wounds and amputations. |

## 0056 Diabetes: Foot Exam

**5. Related and Competing Measures**

- No related or competing measures noted.

**Standing Committee Recommendation for Endorsement: Y-16; N-3**

**6. Public and Member Comment:**

Comments received:

- Commenters generally expressed support for the measure and the Committee's recommendation for endorsement.

**7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X; A-X**

**8. Board of Directors Vote: Y-X; N-X**

**9. Appeals**

## 0519 Diabetic Foot Care and Patient Education Implemented

Submission | Specifications

**Description**: Percentage of home health episodes of care in which diabetic foot care and patient/caregiver education were included in the physician-ordered plan of care and implemented for diabetic patientssince the previous OASIS assessment.

**Numerator Statement**: Number of home health episodes where at end of episode, diabetic foot care and education specified in the care plan had been implemented.

**Denominator Statement**: Number of home health episodes of care ending with a discharge or transfer to inpatient facility during the reporting period, other than those covered by generic or measure-specific exclusions.

**Exclusions**: Episodes in which the patient was not diabetic and/or had bilateral foot/lower leg amputations. Episodes ending in patient death.

**Adjustment/Stratification**: None

**Level of Analysis:** Facility

**Setting of Care:** Home Health

**Type of Measure**: Process

**Data Source**: Electronic Clinical Data

**Measure Steward**: Centers for Medicare & Medicaid

**STANDING COMMITTEE MEETING [02/26/2014-02/27/2014]**

**1. Importance to Measure and Report: The measure meets the Importance criteria**

(1a. Evidence: 1b. Performance Gap, 1c. High Priority)

1a. Evidence: **H-0**; **M-1**; **L-4**; **I-1; IE-13;** 1b. Performance Gap: **H-0**; **M-11**; **L-8**; **I-0** 1c. High Priority: **H-9**; **M-8**; **L-1**; **I-1**

Rationale:

- Evidence provided by the developer included the 2013 ADA guideline recommendation to provide foot care education to all patients with diabetes and a systematic review of 12 RCTs related to patient education for preventing diabetic foot ulceration. However, the review concluded that there is insufficient evidence showing that patient education alone is effective in reducing diabetic foot ulcers.

The studies included in the review were conducted in an ambulatory setting rather than in the home health setting. The developer did not provide evidence that foot care leads to improved outcomes, although the Committee noted that there is evidence that an assessment and referral for comprehensive care—which would include foot care and patient education—has been shown to improve outcomes. The Committee recommended invoking the evidence exception due to a desire to maintain accountability in home health agencies for performing this intervention, particularly given the overall declines in amputation rates.

- The average performance on the measure was 93.4%, with a 7.7% performance gap between the 75th and 25th percentiles. Some Committee members interpreted these results as demonstration of a performance gap, while others viewed them as an indication that there is not an opportunity for improvement. Members noted that this measure is derived from an item from the mandatory CMS OASIS assessment form and that high performance on the measure would be expected
- Developers noted that the prevalence of diabetes among older people is 6-10, that more than 5% of diabetic patients have foot ulcers, the lifetime prevalence of foot ulcer development is estimated to be 15-25%, and more than 80% of non-traumatic amputations for persons with diabetes are due to foot ulcers.

**2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>**

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-17**; **M-1**; **L-1**; **I-0** 2b. Validity: **H-15**; **M-4**; **L-0**; **I-0**

<u>Rationale</u>:

- The developers verified that the measure includes all patients with diabetes (except those with bilateral amputation), includes all home health episodes, regardless of length, and allows for education to be provided to either the patient or the caregiver. They also explained that the measure specifications do not require performance of a particular type of educational or foot care intervention; instead, the measure incents the home health agency to collaborate with the physician include specific interventions in the patient plan of care and requires documentation in the patient chart that the intervention(s) has occurred.
- Signal-to-noise testing using the beta binomial method resulted in an average reliability statistic of 0.92. Developers also examined variation within and between agencies; the resulting Interclass correlation (ICC) coefficient value 0.89 for agencies with at least 40 valid episodes, indicating that most of the total variation is due to between-agency variation.
- To demonstrate validity of the measure, developers correlated the scores from this measure with several other publicly-reported home health measures; results indicated slight to moderate positive correlations with most of the other measures and a slight negative correlation with ED visits. Developers also described a face validity assessment of the measure score by a technical expert panel, where 8 of the 9 panel members agreed that the measure partially or completely reflects the quality of care...

**3. Feasibility: H-19; M-0; L-0; I-0**

*(3a. Data generated during care; 3b. Electronic sources; and 3c. Data collection can be implemented (eMeasure feasibility assessment of data elements and logic)*

<u>Rationale</u>:

- The data elements are included in the OASIS assessment and are thus s routinely collected in the course

| 0519 Diabetic Foot Care and Patient Education Implemented |
|---|
| of care. |
| **4. Use and Usability: H-12; M-7; L-0; I-0**<br>*(4a. Accountability/transparency; and 4b. Improvement – progress demonstrated; and 4c. Benefits outweigh evidence of unintended negative consequences)*<br>Rationale:<br>• The Committee noted that the measure is publicly reported and also used for internal quality improvement.<br>• The Committee concluded that performance on the measure has improved performance in the three years since it was implemented (from 87% to 92%.<br>• The Committee noted that a potential unintended consequence with this measure might be that the time and attention spent on patient education on foot care might be better spent on something else. |
| **5. Related and Competing Measures**<br>• No related or competing measures noted. |
| **Standing Committee Recommendation for Endorsement: Y-17; N-2** |
| **6. Public and Member Comment**<br>Comments included:<br>• Comments were received in support of this measure and the Committee's recommendation for endorsement.<br>• One commenter expressed concern that the evidence that foot care leads to improved outcome exception was not provided and that the evidence exception was invoked.<br><br>Developer response:<br>• The developer responded that there is sufficient evidence that the care processes being measured are valid and important ones and the literature supports the use of these care processes in other settings. The evidence exception for Diabetic Foot Care and Education was related to the lack of evidence in the literature specific to the home health setting, where there is frequently a shortage of evidence available. |
| **7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X; A-X** |
| **8. Board of Directors Vote: Y-X; N-X** |
| **9. Appeals** |

| 0055 Comprehensive Diabetes Care: Eye Exam (retinal) performed |
|---|
| Submission \| Specifications |
| **Description**: The percentage of patients 18-75 years of age with diabetes (type 1 and type 2) who had an eye exam (retinal) performed.<br>**Numerator Statement**: Patients who received an eye screening for diabetic retinal disease. This includes people with diabetes who had the following: -a retinal or dilated eye exam by an eye care professional (optometrists or ophthalmologist) in the measurement year OR –a negative retinal exam or dilated eye exam (negative for retinopathy) by an eye care professional in the year prior to the measurement year. For exams performed in the year prior to the measurement year, a result must be available.<br>**Denominator Statement**: Patients 18-75 years of age by the end of the measurement year who had a |

diagnosis of diabetes (type 1 or type 2) during the measurement year or the year prior to the measurement year.

**Exclusions**: Exclusions (optional):

-Exclude patients who did not have a diagnosis of diabetes, in any setting, during the measurement year or the year prior to the measurement year.

AND

-Exclude patients who meet either of the following criteria:

-A diagnosis of polycystic ovaries, in any setting, any time in the patient's history through December 31 of the measurement year.

-A diagnosis of gestational or steroid-induced diabetes, in any setting, during the measurement year or the year prior to the measurement year

**Adjustment/Stratification**: None

**Level of Analysis:** Clinician : Group/Practice, Health Plan, Clinician : Individual, Integrated Delivery System

**Setting of Care:** Ambulatory Care : Clinician Office/Clinic

**Type of Measure**: Process

**Data Source**: Administrative claims, Electronic Clinical Data, Paper Medical Records, Electronic Clinical Data : Pharmacy

**Measure Steward**: National Committee for Quality Assurance

**STANDING COMMITTEE MEETING [02/26/2014-02/27/2014]**

**1. Importance to Measure and Report: <u>The measure meets the Importance criteria</u>**

(1a. Evidence: 1b. Performance Gap, 1c. High Priority)

1a. Evidence: **H-4**; **M-12**; **L-4**; **I-0; IE-0;** 1b. Performance Gap: **H-18**; **M-2**; **L-0**; **I-0** 1c. High Priority: **H-15**; **M-3**; **L-0**; **I-1**

<u>Rationale</u>:

- The Committee agreed that the evidence presented from clinical practice guidelines from the American Diabetes Association (2013) and the American Academy of Ophthalmology (2008) supported the measure intervention, as the performance of retinal exams leads to maintenance of diabetic retinopathy and improvement in quality of life.
- Data submitted by the developer suggests that a majority of adults with diabetes do not receive annual eye exams and performance levels for this measure are low with performance for the years 2011-2013 as follows: commercial HMO mean rate - 57.74 – 56.82%; commercial PPO mean rate- 45 – 48%; Medicaid HMO rate – 53%; Medicare HMO rate -64-66%; Medicare PPO – 62-64%.
- Diabetes is the 7th leading cause of death in the US and is the leading cause of blindness in adults aged 20-74 years. The impact of a loss in vision - either partial or full - is substantial. Not only does it impact quality of life, but it greatly impacts functionality, the ability to work, and the quality of care for one's diabetes. Slowing the progression of retinal disease through annual screening would be a huge benefit for patients and forestall increases in cost per patient.

**2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>**

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-7**; **M-13**; **L-0**; **I-0** 2b. Validity: **H-6**; **M-13**; **L-1**; **I-0**

<u>Rationale</u>:

| 0055 Comprehensive Diabetes Care: Eye Exam (retinal) performed |
|---|
| • The Committee determined that the measure specifications were precise, noting that all codes necessary to calculate the measure were present and the specifications were consistent with the evidence presented.<br>• The measure was tested for reliability at the level of the measure score using the beta binomial method. The Committee concluded the measure was reliable due to a majority of reliability ratings for the different health plans and physicians being greater than .8.<br>• The Committee expressed concern the measure specifications require the exam to be performed too frequently, as the evidence indicated that eye exams are only necessary every 3 years; however, the Committee concluded that the benefits from having the exam outweighed the consequences of potential extra screenings.<br>• Reliability testing results presented by the developer demonstrated strong reliability at the level of the health plan, and weaker reliability at the level of the clinician. The Committee found the weaker reliability at the clinician level acceptable because the data comes from the Diabetes Recognition Program, which captures data from voluntary high performers with little variation. The developer explained that because there is little variation amongst the high performers, and no data from low performers, that a signal to noise analysis does not indicate strong reliability. A more robust data sample would perform better in a signal to noise analysis. |
| **3. Feasibility: H-2; M-13; L-5; I-0**<br>*(3a. Data generated during care; 3b. Electronic sources; and 3c. Data collection can be implemented (eMeasure feasibility assessment of data elements and logic)*<br>Rationale:<br>• The Committee noted it may be difficult to capture this data in electronic sources, as this information is not all currently captured electronically.<br>• Overall they agreed the measure was feasible to implement at the plan level but may be difficult at the provider level, as the data may not exist due to many patients using a different doctor and often using eye insurance instead of their regular health plan to perform the eye exam. |
| **4. Use and Usability: H-7; M-11; L-2; I-0**<br>*(4a. Accountability/transparency; and 4b. Improvement – progress demonstrated; and 4c. Benefits outweigh evidence of unintended negative consequences)*<br>Rationale:<br>• The developer describes at least five current accountability uses of the measure including public reporting of health plan data.<br>• The Committee acknowledged that there has been little improvement in performance of the measure over time; however, mean performance ranging from 45-66% at the health plan level in particular and to some degree at the physician level ranging indicates a significant opportunity for more improvement.<br>• There is little burden of measurement or unintended consequences and substantial benefits to continuing the measure. |
| **5. Related and Competing Measures** |

### 0055 Comprehensive Diabetes Care: Eye Exam (retinal) performed

- No related or competing measures noted.

**Standing Committee Recommendation for Endorsement: Y-18; N-2**

**6. Public and Member Comment**

Comments included:

- Comments were received in support of the measure and the Committee's decision to recommend the measure for endorsement.
- Commenters requested clarification as to why women with polycystic ovarian syndrome are excluded from the measure.
- A commenter noted that using the remote imaging CPT codes in the specifications for the measure causes quality concerns and is contrary to the American Diabetes Association and the AOA's clinical guidelines for patients with diabetes. Including the remote retinal imaging codes in the measure specifications could indicate that remote retinal imaging is sufficient eye care for a patient with diabetes.
- One commenter suggested that this measure be aligned with the new age specifications agreed to by the developer for measure #0056 (i.e., NCQA removed the upper age restriction so that the measure now applies to diabetes patients ages 18 and older).

Developer response:

- NCQA responded that polycystic ovarian syndrome is a long-standing exclusion which was recommended by their first joint NCQA-AMA-PCPI expert panel when the diabetes measures were first developed. NCQA will take this comment into consideration during the next re-evaluation of the diabetes care measures.
- NCQA responded they will review the use of the CPT codes with expert panels and if appropriate, update the Diabetic Retinal Screening value set.
- NCQA responded that they will evaluate appropriate age thresholds during the next re-evaluation of the diabetes care measures.

Committee response:

- Committee members noted that the ADA guidelines, as well as other evidence, indicate that retinal photographs are acceptable and therefore did not recommend a change to the specifications of the measure.
- The Committee also agreed that because complications of diabetes disproportionately affects older patients, the measure developer should consider changing the specifications to include those aged 18 and older rather than including only those aged 18-75.

**7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X; A-X**

**8. Board of Directors Vote: Y-X; N-X**

**9. Appeals**

### 0062 Comprehensive Diabetes Care: Medical Attention for Nephropathy

Submission | Specifications

## 0062 Comprehensive Diabetes Care: Medical Attention for Nephropathy

**Description**: The percentage of patients 18-75 years of age with diabetes (type 1 and type 2) who received a nephropathy screening test or had evidence of nephropathy during the measurement year.

**Numerator Statement**: Patients who received a nephropathy screening test or had evidence of nephropathy during the measurement year.

**Denominator Statement**: Patients 18-75 years of age by the end of the measurement year who had a diagnosis of diabetes (type 1 or type 2) during the measurement year or the year prior to the measurement year.

**Exclusions**:

**Adjustment/Stratification**: None

**Level of Analysis:** Clinician : Group/Practice, Health Plan, Clinician : Individual, Integrated Delivery System

**Setting of Care:** Ambulatory Care : Clinician Office/Clinic

**Type of Measure**: Process

**Data Source**: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Laboratory, Paper Medical Records, Electronic Clinical Data : Pharmacy

**Measure Steward**: National Committee for Quality Assurance

**STANDING COMMITTEE MEETING [02/26/2014-02/27/2014]**

**1. Importance to Measure and Report: <u>The measure meets the Importance criteria</u>**

(1a. Evidence: 1b. Performance Gap, 1c. High Priority)

1a. Evidence: **H-13**; **M-7**; **L-0**; **I-0; IE-0;** 1b. Performance Gap: **H-11**; **M-7**; **L-2**; **I-0** 1c. High Priority: **H-16**; **M-4**; **L-0**; **I-0**

<u>Rationale</u>:

- The Committee agreed that the evidence presented from clinical practice guidelines from the American Diabetes Association (2013), American Geriatrics Society (2003), and American Association of Clinical Endocrinologists (AACE) (2011) supported the link between nephropathy screening and improvement in diabetes complications and quality of life.
- Some Committee members mentioned a glomerular filtration rate (GFR) count may be able to capture nephropathy sooner than a microalbumin test. The developer stated the test was meant to detect a urinary protein burden and the GFR would not fulfill that. The Committee accepted this explanation.
- The Committee concluded the data presented by the developer, which included HEDIS health plan data from 2011-2013 with mean rates as follows: Commercial HMO – 83-84%; Commercial PPO – 74-78%; Medicaid HMO – 77-78%; Medicare HOM – 89%; Medicare PPO – 87-88%, showcased the substantial number of physicians and practices that still fail to meet minimum nephropathy screening recommendations.
- Kidney disease is a major concern for diabetes patients, causing high levels of mostly preventable morbidity, mortality and costs. This issue has been and continues to be documented by many clinical studies and retrospective analyses. Early diagnosis through screening can help slow the progression of CKD and possibly prevent ESRD.

## 0062 Comprehensive Diabetes Care: Medical Attention for Nephropathy

**2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>**

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-10**; **M-8**; **L-2**; **I-0** 2b. Validity: **H-10**; **M-9**; **L-1**; **I-0**

<u>Rationale</u>:

- The Committee agreed the measure was reliable with most reliability results from the signal-to-noise testing using the beta binomial method being above the generally acceptable threshold of 0.7.
- Pearson Correlation Test results indicated a positive association between nephropathy screening and HbA1c testing and an inverse association between nephropathy screening and poor diabetes. The Committee stated that these associations would be expected, as high performers on a measure of nephropathy screening would likely also perform well for HbA1c testing; likewise, high performers on nephropathy screening would likely not have many patients with poorly controlled diabetes.

**3. Feasibility: H-13; M-7; L-0; I-0**

*(3a. Data generated during care; 3b. Electronic sources; and 3c. Data collection can be implemented (eMeasure feasibility assessment of data elements and logic)*

<u>Rationale</u>:

- The Committee expressed concern that data can be collected from different databases, such as billing, pharmacy, and lab, which might create burden on those reporting the measure. However, the Committee acknowledged that the measure is currently in use and the data is routinely generated through care delivery and captured in electronic sources so this may not create a major issue.

**4. Use and Usability: H-13; M-6; L-0; I-0**

*(4a. Accountability/transparency; and 4b. Improvement – progress demonstrated; and 4c. Benefits outweigh evidence of unintended negative consequences)*

<u>Rationale</u>:

- The developer described at least five current accountability uses of the measure including public reporting of health plan data.
- The Committee acknowledged that there has been little improvement in performance of the measure over time, as the measure has been relatively stable over the past 3 years; however, mean performance at the health plan level, and to some degree at the physician level indicates an opportunity for more improvement exists.

**5. Related and Competing Measures**

- No related or competing measures noted.

**Standing Committee Recommendation for Endorsement**: **Y-19**; **N-0**

**6. Public and Member Comment:**

Comments received:

- Commenters generally expressed support for the measure and the Committee's recommendation for endorsement.

**7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X; A-X**

**8. Board of Directors Vote: Y-X; N-X**

**9. Appeals**

## 0057 Comprehensive Diabetes Care: Hemoglobin A1c (HbA1c) testing

Submission | Specifications

## 0057 Comprehensive Diabetes Care: Hemoglobin A1c (HbA1c) testing

**Description**: The percentage of patients 18-75 years of age with diabetes (type 1 and type 2) who received an HbA1c test during the measurement year.

**Numerator Statement**: Patients who had an HbA1c test performed during the measurement year.

**Denominator Statement**: Patients 18-75 years of age by the end of the measurement year who had a diagnosis of diabetes (type 1 or type 2) during the measurement year or the year prior to the measurement year.

**Exclusions**: Exclusions (optional):

-Exclude patients who did not have a diagnosis of diabetes, in any setting, during the measurement year or the year prior to the measurement year.

AND

-Exclude patients who meet either of the following criteria:

-A diagnosis of polycystic ovaries, in any setting, any time in the patient's history through December 31 of the measurement year.

-A diagnosis of gestational or steroid-induced diabetes, in any setting, during the measurement year or the year prior to the measurement year.

**Adjustment/Stratification**: None

**Level of Analysis:** Health Plan, Integrated Delivery System

**Setting of Care:** Ambulatory Care : Clinician Office/Clinic

**Type of Measure**: Process

**Data Source**: Administrative claims, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Laboratory, Paper Medical Records

**Measure Steward**: National Committee for Quality Assurance

**STANDING COMMITTEE MEETING [02/26/2014-02/27/2014]**

**1. Importance to Measure and Report: <u>The measure meets the Importance criteria</u>**

(1a. Evidence: 1b. Performance Gap, 1c. High Priority)

1a. Evidence: **H-10**; **M-6**; **L-1**; **I-0; IE-3;** 1b. Performance Gap: **H-3**; **M-13**; **L-4**; **I-0** 1c. High Priority: **H-8**; **M-7**; **L-5**; **I-0**

<u>Rationale</u>:

- The Committee stated that the evidence, which included clinical guideline recommendations from the American Diabetes Association (2013) and the VA (2010), supporting HbA1c testing for diabetes patients was strong, as HbA1c is the only laboratory test measure validated in randomized controlled trials as a predictor of risk for microvascular complications.
- While testing for HbA1c is relatively high, with the mean performance ranging from 82-91%, the data presented suggest a startlingly low level of testing within some facilities and settings. Further, the variation seen within certain ethnic patient populations suggests that emphasizing HbA1c as a critical outcome measure is an important action for this committee.
- Information presented by the developer indicates that diabetes is the 7th leading cause of death in the US, costing approximately $245 billion in 2012.

**2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>**

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

## 0057 Comprehensive Diabetes Care: Hemoglobin A1c (HbA1c) testing

2a. Reliability: **H-16**; **M-4**; **L-0**; **I-0** 2b. Validity: **H-11**; **M-9**; **L-0**; **I-0**

Rationale:

- The Committee agreed the measure was reliable, with most signal-to-noise reliability testing results using the beta binomial method being above the generally acceptable threshold of 0.7.
- Pearson correlation test indicated a positive association between HbA1c testing and measures of eye exams and good control of HbA1C; it also demonstrated an inverse association between HbA1c testing and poor diabetes control (HbA1c >9). The Committee stated that these associations would be expected, as high performers on a measure of HbA1c testing would likely also perform well for eye exams and good control of diabetes; likewise, high performers on HbA1c testing would likely not have many patients with poorly controlled diabetes.
- Additionally, the developer indicated that face validity was assessed by three groups within NCQA for the health plan level. The Committee found this assessment to be acceptable.
- Concern was raised that the evidence indicated HbA1c testing should be performed more frequently than the measure specifies; however, the Committee acknowledged that though one HbA1c test per year may be low bar, the importance of performing this exam necessitated recommending the measure for endorsement.

**3. Feasibility: H-18; M-2; L-0; I-0**

*(3a. Data generated during care; 3b. Electronic sources; and 3c. Data collection can be implemented (eMeasure feasibility assessment of data elements and logic)*

Rationale:

- The Committee agreed that the data is routinely generated through care delivery and captured in electronic sources.

**4. Use and Usability: H-14; M-4; L-2; I-0**

*(4a. Accountability/transparency; and 4b. Improvement – progress demonstrated; and 4c. Benefits outweigh evidence of unintended negative consequences)*

Rationale:

- The developer describes at least five current accountability uses of the measure including public reporting of health plan data.
- While performance for HbA1c testing is relatively high and has shown little improvement in the past three years, the variation seen within certain ethnic patient populations suggests further improvements are needed.
- The Committee found the benefit of performing HbA1c testing to outweigh any potential unintended consequences or burden of measurement of requiring HbA1c testing be performed more frequently than the evidence provided suggested.

**5. Related and Competing Measures**

- This measure directly competes with:
    - 0059 Comprehensive Diabetes Care: Hemoglobin A1c (HbA1c) Poor Control (>9.0%)
        - The percentage of patients 18-75 years of age with diabetes (type 1 and type 2) whose most recent HbA1c level during the measurement year was greater than 9.0% (poor control) or was missing a result, or if an HbA1c test was not done during the measurement year]
    - 0575 Comprehensive Diabetes Care: Hemoglobin A1c (HbA1c) Control (<8.0%)
        - The percentage of patients 18-75 years of age with diabetes (type 1 and type 2) whose

## 0057 Comprehensive Diabetes Care: Hemoglobin A1c (HbA1c) testing

most recent HbA1c level is <8.0% during the measurement year.

- Not having an HbA1c test is captured in the numerators of #0059 and #0575, in that that if the test is not performed for a particular patient, the provider "fails" the measure for that patient. Some members thought that the testing measure (#0057) isn't needed since that information is captured in #0059 and #0575. However, other members use #0057 as a way to identify those patients who have not been tested, noting that this information would be hard for certain practices (e.g., small private practices that may not use EHRS) to obtain if the testing measure is not endorsed. Members also agreed that the data collection burden for the testing measure is not high and that performance rates still indicate opportunity for improvement. The Committee concluded that there is justification to continue endorsement of the testing measure at this time.

**Standing Committee Recommendation for Endorsement: Y-18; N-2**

**6. Public and Member Comment:**

Comments received:

- Commenters generally expressed support for the measure and the Committee's recommendation for endorsement.

**7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X; A-X**

**8. Board of Directors Vote: Y-X; N-X**

**9. Appeals**

## 0059 Comprehensive Diabetes Care: Hemoglobin A1c (HbA1c) Poor Control (>9.0%)

Submission | Specifications

**Description**: The percentage of patients 18-75 years of age with diabetes (type 1 and type 2) whose most recent HbA1c level during the measurement year was greater than 9.0% (poor control) or was missing a result, or if an HbA1c test was not done during the measurement year.

**Numerator Statement**: Patients whose most recent HbA1c level is greater than 9.0% or is missing a result, or for whom an HbA1c test was not done during the measurement year. The outcome is an out of range result of an HbA1c test, indicating poor control of diabetes. Poor control puts the individual at risk for complications including renal failure, blindness, and neurologic damage. There is no need for risk adjustment for this intermediate outcome measure.

**Denominator Statement**: Patients 18-75 years of age by the end of the measurement year who had a diagnosis of diabetes (type 1 or type 2) during the measurement year or the year prior to the measurement year.

**Exclusions**: Exclusions (optional):

-Exclude patients who did not have a diagnosis of diabetes, in any setting, during the measurement year or the year prior to the measurement year.

AND

-Exclude patients who meet either of the following criteria:

-A diagnosis of polycystic ovaries, in any setting, any time in the patient's history through December 31 of the measurement year.

-A diagnosis of gestational or steroid-induced diabetes, in any setting, during the measurement year or the year prior to the measurement year.

**Adjustment/Stratification**: None

**Level of Analysis:** Clinician : Group/Practice, Health Plan, Clinician : Individual, Integrated Delivery System,

## 0059 Comprehensive Diabetes Care: Hemoglobin A1c (HbA1c) Poor Control (>9.0%)

Population : National, Population : Regional, Population : State

**Setting of Care:** Ambulatory Care : Clinician Office/Clinic

**Type of Measure**: Outcome

**Data Source**: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Laboratory, Paper Medical Records, Electronic Clinical Data : Pharmacy

**Measure Steward**: National Committee for Quality Assurance

**STANDING COMMITTEE MEETING [02/26/2014-02/27/2014]**

**1. Importance to Measure and Report: <u>The measure meets the Importance criteria</u>**

(1a. Evidence: 1b. Performance Gap, 1c. High Priority)

1a. Evidence: **H-3**; **M-16**; **L-1**; **I-0; IE-0;** 1b. Performance Gap: **H-17**; **M-3**; **L-0**; **I-0** 1c. High Priority: **H-20**; **M-0**; **L-0**; **I-0**

<u>Rationale</u>:

- Evidence presented by the developer included information from systematic reviews associated with clinical practice guideline recommendations from four entities, each of which indicate that HbA1c targets should be 9.0% or less, depending on individual patient characteristics.
- Data presented by the developer showed a gap in care from HEDIS for years 2011-2013 for health plans and the Diabetes Recognition Program and 2012 PQRS program for individual physicians with performance as follows: commercial HMO mean rate – 71.5- 72.7%; commercial PPO mean rate- 53.4 – 64.8%; Medicaid HMO rate – 55.6-57%; Medicare HMO rate -73.6-74.1%; Medicare PPO – 65.3-71.3%; Diabetes Recognition Program- 12%. There was also evidence of disparities in certain high-risk groups, such as African Americans, Asians, and Latinos.
- Data presented by the developer demonstrates that the measure affects large numbers, as it is estimated that 1 in 3 US adults could have diabetes by 2050. The measure targets a condition that is a leading cause of morbidity/mortality, as diabetes is the seventh leading cause of death in the US. The measure targets a high cost condition, as diabetes costs the US an estimated $245 billion in 2012.

**2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>**

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-5**; **M-13**; **L-2**; **I-0** 2b. Validity: **H-7**; **M-13**; **L-0**; **I-0**

<u>Rationale</u>:

- The Committee noted that the evidence did not specifically support 9.0% as the cutoff value for poor glucose control but found that threshold to be acceptable given that evidence is clear that patients with poor diabetes control have poorer outcomes.
- The Committee agreed that the measure was reliable at the health plan level, given that the majority of the reliability statistics from the signal-to-noise analysis of the measure were >0.9. However, the Committee expressed concern over the low reliability values at the physician level, many of which were below the generally accepted threshold of 0.7. The developer explained that the clinician-level reliability results were obtained using data from the NCQA Diabetes Recognition Program. They noted that providers who participate in this program are a self-selected group of high performers with little variation in performance on this measure, and that the lack of variation was the reason for the low reliability

statistics. The Committee accepted this explanation.

- A Pearson correlation test for health plans and physicians, and face validity of the performance measure score were presented by the developer. For health plans, Pearson correlation test indicated a strong inverse relationship between the HbA1c poor control measure (>9.0%) and the HbA1c good control measure (<8.0%) and for physicians, the Pearson correlation results indicated a moderate inverse relationship between the HbA1c poor control measure (>9.0%) and the HbA1c good control measure (<8.0%) as assessed by three NCQA expert panels.
- The Committee expressed some concern about whether this clinical outcome measure truly represents quality of care, given that HbA1c results can be influenced by patient factors that cannot be completely controlled by the clinician. Members also noted that the measure is not risk-adjusted and queried the developers about whether they had considered risk adjustment, particularly for socioeconomic status. The developer explained their policy of not risk-adjusting for socioeconomic status, noting that excellent care can be provided to challenging populations. Committee members noted that stratifying results for various subgroups or comparing results to "like" peers can be used to illuminate quality problems.
- Committee members also expressed concern about the validity of the measure and its ability to reflect quality of clinician care, particularly in a fee-for-service environment where the clinician may not know definitively if a particular patient is really a part of the practice (or if, for example, he/she has moved away). The developer acknowledged this difficulty and reminded the committee about how the denominator is specified (i.e., multiple office visits, at least one hospital/ED encounter, and/or anti-diabetic prescriptions dispensed).

**3. Feasibility: H-14; M-5; L-1; I-0**

*(3a. Data generated during care; 3b. Electronic sources; and 3c. Data collection can be implemented (eMeasure feasibility assessment of data elements and logic)*

Rationale:

- The Committee agreed that the data used in the measure are routinely generated during care delivery and captured in electronic sources; they also noted that the measure is currently in use, thus demonstrating its feasibility

**4. Use and Usability: H-9; M-11; L-0; I-0**

*(4a. Accountability/transparency; and 4b. Improvement – progress demonstrated; and 4c. Benefits outweigh evidence of unintended negative consequences)*

Rationale:

- The Committee noted the measure is currently in use in at least eight public reporting and accountability programs, including the Physician Quality Reporting System, the Healthcare Effectiveness Data and Information Set (HEDIS), and the Diabetes Recognition Program.
- The Committee agreed that while there has been improvement nationally in lowering HbA1c rates over time, in the past three years the improvement trend has remained fairly stable; nonetheless, members agreed that the potential for improvement has not been exhausted
- The Committee questioned whether this measure might result in the unintended negative consequence of disincentivizing providers from caring for more complex or difficult-to-treat patients (i.e., "cherry-picking"); however, they agreed that there is no concrete evidence that this is happening (and some evidence from the UK that it is actually not happening).

| 0059 Comprehensive Diabetes Care: Hemoglobin A1c (HbA1c) Poor Control (>9.0%) |
|---|
| **5. Related and Competing Measures**<br>• This measure directly competes with:<br>  ○ 0057: Comprehensive Diabetes Care: Hemoglobin A1c (HbA1c) testing<br>  ▪ The percentage of patients 18-75 years of age with diabetes (type 1 and type 2) who received an HbA1c test during the measurement year.<br>  ○ 0575: Comprehensive Diabetes Care: Hemoglobin A1c (HbA1c) Control (<8.0%)<br>  ▪ The percentage of patients 18-75 years of age with diabetes (type 1 and type 2) whose most recent HbA1c level is <8.0% during the measurement year.<br>• Not having an HbA1c test is captured in the numerators of #0059 and #0575, in that that if the test is not performed for a particular patient, the provider "fails" the measure for that patient. Some members thought that the testing measure (#0057) isn't needed since that information is captured in #0059 and #0575. However, other members use #0057 as a way to identify those patients who have not been tested, noting that this information would be hard for certain practices (e.g., small private practices that may not use EHRS) to obtain if the testing measure is not endorsed. Members also agreed that the data collection burden for the testing measure is not high and that performance rates still indicate opportunity for improvement.<br>• Taking into consideration the above discussion points, the Committee voted 15-2 that there was justification for recommending measure 0059 for endorsement. |
| **Standing Committee Recommendation for Endorsement: Y-20; N-0** |
| **6. Public and Member Comment:**<br>Comments received:<br>• Commenters generally expressed support for the measure and the Committee's recommendation for endorsement. |
| **7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X; A-X** |
| **8. Board of Directors Vote: Y-X; N-X** |
| **9. Appeals** |

NATIONAL QUALITY FORUM

# Memo

## 0575 Comprehensive Diabetes Care: Hemoglobin A1c (HbA1c) Control (<8.0%)

Submission | Specifications

**Description**: The percentage of patients 18-75 years of age with diabetes (type 1 and type 2) whose most recent HbA1c level is <8.0% during the measurement year.

**Numerator Statement**: Patients whose most recent HbA1c level is less than 8.0% during the measurement year. The outcome is a result of an HbA1c test, indicating desirable control of diabetes. Poor control puts the individual at risk for complications including renal failure, blindness, and neurologic damage. There is no need for risk adjustment for this intermediate outcome.

**Denominator Statement**: Patients 18-75 years of age by the end of the measurement year who had a diagnosis of diabetes (type 1 or type 2) during the measurement year or the year prior to the measurement year.

**Exclusions**: Exclusions (optional):

-Exclude patients who did not have a diagnosis of diabetes, in any setting, during the measurement year or the year prior to the measurement year.

AND

-Exclude patients who meet either of the following criteria:

-A diagnosis of polycystic ovaries, in any setting, any time in the patient's history through December 31 of the measurement year.

-A diagnosis of gestational or steroid-induced diabetes, in any setting, during the measurement year or the year prior to the measurement year.

**Adjustment/Stratification**: None

**Level of Analysis:** Clinician : Group/Practice, Health Plan, Clinician : Individual, Integrated Delivery System

**Setting of Care:** Ambulatory Care : Clinician Office/Clinic

**Type of Measure**: Outcome

**Data Source**: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Laboratory, Paper Medical Records, Electronic Clinical Data : Pharmacy

**Measure Steward**: National Committee for Quality Assurance

**STANDING COMMITTEE MEETING [02/26/2014-02/27/2014]**

**1. Importance to Measure and Report: <u>The measure meets the Importance criteria</u>**

(1a. Evidence: 1b. Performance Gap, 1c. High Priority)

1a. Evidence: **H-9**; **M-8**; **L-3**; **I-0; IE-0;** 1b. Performance Gap: **H-16**; **M-4**; **L-0**; **I-0** 1c. High Priority: **H-16**; **M-3**; **L-1**; **I-0**

<u>Rationale</u>:

- The Committee found the evidence underpinning the clinical practice guideline recommendations from American Diabetes Association (2013), American Geriatric Society (2003), VA/DOD (2010), and American Association of Clinical Endocrinologists (AACE) (2011) to be sufficient to support this measure. The evidence showed significant reductions in risk of microvascular complications, retinopathy, and MI for patients with HbA1c levels less than 8.0%.
- The Committee agreed that there is a large gap in performance based on Health plan level data for years 2011-2013 (commercial HMO mean rate – 62-61%; commercial PPO mean rate- 50-54%; Medicaid HMO rate – 47-46%; Medicare HMO rate -65-64%; Medicare PPO – 57-62%), and self-reported physician level

## 0575 Comprehensive Diabetes Care: Hemoglobin A1c (HbA1c) Control (<8.0%)

results from PQRS 2010 -2012 (mean -75.2 – 76.7%; 10th percentile – 63-64%).

- Data presented by the developer notes that diabetes is the 7th leading cause of death in the U.S., costing an estimated $245 billion annually, and that reducing HbA1c level results by one percentage point (e.g., from 8.0 percent to 7.0 percent) helps reduce the risk of microvascular complications (eye, kidney and nerve diseases) by as much as 40 percent..

**2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>**
(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)
2a. Reliability: **H-3**; **M-14**; **L-3**; **I-0** 2b. Validity: **H-4**; **M-12**; **L-4**; **I-0**
<u>Rationale</u>:

- The Committee members agreed that 8.0% is a realistic, evidence-based threshold for good control of diabetes. The Committee stated concerns that prior attempts to target HbA1c levels lower than 7.0% were shown to produce a high level of a risk relative to the benefit, when compared to target levels below 8.0%.
- The Committee determined that the measure specifications were precise, noting that all codes necessary to calculate the measure were present and the specifications were consistent with the evidence presented.
- There was some confusion about whether the denominator is calculated differently for clinicians versus for health plans. The developer clarified that the denominator is consistent across the levels of analysis (i.e., diabetic patients are identified in the same way), although when implemented in the NCQA Diabetes Recognition Program, only a sampling of patients is used to compute the clinician-level rate.
- The Committee agreed that the measure was reliable at the health plan level, given that the majority of the reliability statistics from the signal-to-noise analysis of the measure were >0.9. However, the Committee expressed concern over the low reliability values at the physician level, many of which were below the generally accepted threshold of 0.7. The developer explained that the clinician-level reliability results were obtained using data from the NCQA Diabetes Recognition Program. They noted that providers who participate in this program are a self-selected group of high performers with little variation in performance on this measure, and that the lack of variation was the reason for the low reliability statistics. The Committee accepted this explanation.
- Empiric validity testing results indicate a strong inverse correlation of this measure with poor glucose control (HbA1c >9) and good correlation with HbA1c testing and provision of eye exams for health plans; for physicians, testing results indicate an inverse correlation with poor glucose control but no correlation with HbA1c testing or provision of eye exams. Face validity also was assessed by three groups within NCQA for both the plan and physician–level measure.
- Committee members noted the role of the patient in glucose control and the need for individualized care; however, they agreed that these factors do not impact the validity of the measure.

**3. Feasibility: H-17; M-3; L-0; I-0**
*(3a. Data generated during care; 3b. Electronic sources; and 3c. Data collection can be implemented (eMeasure feasibility assessment of data elements and logic)*
<u>Rationale</u>:

- The Committee agreed that the data used in the measure are routinely generated during care delivery

**0575 Comprehensive Diabetes Care: Hemoglobin A1c (HbA1c) Control (<8.0%)**

and captured in electronic sources.

**4. Use and Usability: H-7; M-8; L-4; I-0**

*(4a. Accountability/transparency; and 4b. Improvement – progress demonstrated; and 4c. Benefits outweigh evidence of unintended negative consequences)*

Rationale:

- The Committee noted that the developer listed five current uses of the measure, including public reporting.
- The Committee agreed there has been improvement in HbA1c rates over time(e.g., from 67.4% between 1999-2010 to 79.1% between 2007-2010 between, as noted in a 2013 CDC report
- As in their discussion of measure #0059, the Committee questioned whether this measure might result in the unintended negative consequence of disincentivizing providers from caring for more complex or difficult-to-treat patients. They also suggested that some providers may inappropriately consider this measure to encourage tight control, even though evidence suggests that very tight control may be harmful. Finally, members noted that for some patients (e.g., the frail elderly patients, those limited life expectancy) HbAc1 values slightly above 8% might be reasonable and that target HbA1c values for such patients should be individualized.

**5. Related and Competing Measures**

- This measure directly competes with:
  - 0057 Comprehensive Diabetes Care: Hemoglobin A1c (HbA1c) testing
    - The percentage of patients 18-75 years of age with diabetes (type 1 and type 2) who received an HbA1c test during the measurement year.
  - 0059 Comprehensive Diabetes Care: Hemoglobin A1c (HbA1c) Poor Control (>9.0%)
    - The percentage of patients 18-75 years of age with diabetes (type 1 and type 2) whose most recent HbA1c level during the measurement year was greater than 9.0% (poor control) or was missing a result, or if an HbA1c test was not done during the measurement year]
- Not having an HbA1c test is captured in the numerators of #0059 and #0575, in that that if the test is not performed for a particular patient, the provider "fails" the measure for that patient. Some members thought that the testing measure (#0057) isn't needed since that information is captured in #0059 and #0575. However, other members use #0057 as a way to identify those patients who have not been tested, noting that this information would be hard for certain practices (e.g., small private practices that may not use EHRS) to obtain if the testing measure is not endorsed. Members also agreed that the data collection burden for the testing measure is not high and that performance rates still indicate opportunity for improvement.
- Taking into consideration the above discussion points, the Committee voted 15-2 that there was justification for recommending measure #0059 for endorsement.

**Standing Committee Recommendation for Endorsement: Y-17; N-2**

**6. Public and Member Comment:**

Comments received:

- Commenters generally expressed support for the measure and the Committee's recommendation for endorsement.

**7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X; A-X**

**8. Board of Directors Vote: Y-X; N-X**

**9. Appeals**

## 2362 Glycemic Control – Hyperglycemia

Submission | Specifications

**Description**: Average percentage of hyperglycemic hospital days for individuals with a diagnosis of diabetes mellitus, anti-diabetic drugs (except metformin) administered, or at least one elevated glucose level during the hospital stay

**Numerator Statement**: Sum of the percentage of hospital days in hyperglycemia for each admission in the denominator

**Denominator Statement**: Total number of admissions with a diagnosis of diabetes mellitus, at least one administration of insulin or any anti-diabetic medication except metformin, or at least one elevated blood glucose value (>200 mg/dL [11.1 mmol/L]) at any time during the entir

**Exclusions**: The following admissions are excluded from the denominator:

• Admissions with diagnosis of diabetic ketoacidosis (DKA) or hyperglycemic hyperosmolar syndrome (HHS)

• Admissions without any hospital days included in analysis

• Admissions with lengths of stay greater than 120 days

**Adjustment/Stratification**: None

**Level of Analysis:** Facility

**Setting of Care:** Hospital/Acute Care Facility

**Type of Measure**: Outcome

**Data Source**: Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Laboratory, Electronic Clinical Data : Pharmacy

**Measure Steward**: Centers for Medicare & Medicaid Services

## 2362 Glycemic Control – Hyperglycemia

**STANDING COMMITTEE MEETING [02/26/2014-02/27/2014]**

**1. Importance to Measure and Report: The measure meets the Importance criteria**

(1a. Evidence: 1b. Performance Gap, 1c. High Priority)

1a. Evidence: **H-5**; **M-8**; **L-1**; **IE-5; I-0;** 1b. Performance Gap: **H-16**; **M-3**; **L-0**; **I-0** 1c. High Priority: **H-16**; **M-2**; **L-0**; **I-1**

Rationale:

- Evidence presented by the developer included nine studies that considered the relationship between hyperglycemia and mortality, infection rates, and length of stay among hospitalized adults; these studies found that patients with hyperglycemia (defined differently across each study) had a higher risk of mortality, higher rates of urinary tract infection, postoperative infection, and pneumonia, and longer lengths of inpatient stays. Members noted that interventional studies showing benefit have been in ICU settings, although some data have shown an association between interventions and benefit in non-ICU settings. Although Committee members acknowledged that there isn't evidence that better control of hyperglycemia in the inpatient setting leads to better outcomes, members did agree that there is strong evidence supporting the relationship of hyperglycemia with poor outcomes and that keeping HbA1c levels below 200mg/dL is beneficial.
- Data presented by the developer indicate that average performance scores range from 22-33% and that half of the tested facilities had measure results higher 28.24
- The Committee agreed that the measure addressed a significant health problem, as hyperglycemia is associated with higher mortality, higher infection rates, increased hospital length of stay, and higher costs.

## 2362 Glycemic Control – Hyperglycemia

**2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>**
(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)
2a. Reliability: **H-1**; **M-17**; **L-1**; **I-0**; 2b. Validity: **H-4**; **M-14**; **L-1**; **I-0**
<u>Rationale</u>:

- The Committee had several questions about how the measure was specified, particularly about the timing of the glucose measurement, why only one day with one measurement > 200mg/dL would be considered a hyperglycemic day, why measurement is truncated after the 10th day of admission, whether very high values are treated the same as values just over 200mg/dL, and why non-diabetics are included in the measure. The developer explained the following:
  - The measure requires at least two hyperglycemic events that occur at least 6 hours apart
  - The 1st admission day not is included
  - ER values are not included,
  - Only one day of testing >200mg/dL is included to incent additional testing
  - A maximum of 10 days is used to ensure that one patient doesn't dominate the results
  - The measure focuses on sustained hyperglycemia rather than peak values, and
  - The measure also incents blood glucose monitoring because many non-diabetic patients have sustained hyperglycemia while in the hospital.
- Committee members asked about how the patients are attributed to the various stratification groupings; the developer explained that the stratification was suggested for reporting purposes (not as part of the measure calculation) but that if done, assignment to the various reporting strata could be based on where a patient spent the majority of time in a particular day.
- One Committee member questioned whether meter variation would decrease the reliability of this measure; another member noted that such variation would likely be random (i.e., as many readings just above the 200mg/dL level as below) and that this variation also likely be would uniform across hospitals. .
- The developer presented reliability testing results at the level of the performance measure score All hospitals tested except one (which had only 225 patients and 74 qualifying admissions) had signal-to-noise reliability statistics >= .92.
- Committee members agreed that while the definition of hyperglycemia was different across the various studies included in the evidence, there is evidence that keeping HbA1c levels below 200mg/dL is beneficial; they therefore agreed that the specifications are consistent with the evidence.
- Developers presented empirical validity testing results with high percent agreement (>90%) for all critical data elements except for the ICU date/time. They also described a systematic assessment of face validity by an 18-member expert panel.
- Committee members asked whether the measure might make unfairly penalize tertiary care hospitals who often have higher-acuity patients. The developer noted that, in testing, tertiary hospitals actually had better performance on this measure than did others, possibly due to better insulin infusion protocols.
- There was some concern that there is currently no benchmark value for inpatient hyperglycemic rate; however, NQF staff clarified that lack of a benchmark value should not be considered a threat to validity.

## 2362 Glycemic Control – Hyperglycemia

**3. Feasibility: H-9; M-8; L-1; I-0**

*(3a. Data generated during care; 3b. Electronic sources; and 3c. Data collection can be implemented (eMeasure feasibility assessment of data elements and logic)*

Rationale:

- Because this is an eMeasure, one Committee member raised concern about the programming burden required to implement the measure. The developer noted that the difficulty for the testing facilities was the up-front work to identify which lab tests/values should be included in the measure (e.g., metabolic panel, normal daily draws, etc.) and that the subsequent retrieval of the data was not burdensome..
- The Committee agreed that data element scores from the feasibility scorecard that was submitted by the developer (had average scores of 2.5 or higher on a 3-point scale) supported the feasibility of the measure.

**4. Use and Usability: H-11; M-7; L-1; I-0**

*(4a. Accountability/transparency; and 4b. Improvement – progress demonstrated; and 4c. Benefits outweigh evidence of unintended negative consequences)*

Rationale:

- This de novo eMeasure is not currently in use but has been submitted for consideration in the CMS Hospital Inpatient Quality Reporting Program (IQR) and for Meaningful Use (MU) Stage 3.
- The Committee noted that a possible unintended negative consequence of the measure might be a tendency for tight glucose control, which could lead to hypoglycemia. However, members noted that this measure is paired with a hypoglycemia measure (#2363).

**5. Related and Competing Measures**

- No related or competing measures noted.

**Standing Committee Recommendation for Endorsement: Y-18; N-1**

**6. Public and Member Comment**

Comments received:

- One commenter noted low reliability scores for one of the hospitals included in the testing of the measure and questioning the reliability of the measure for smaller facilities. The commenter also expressed the desire that the measure be made consistent with NQF # 2363.
- Comments were also received questioning the need for this measure, as well as in support of this the Committee's recommendation for endorsement

Developer response:

- The developer noted that it is correct the smallest facility tested had inadequate reliability; however, the other facility had a score of 0.67, which would indicate the measure is closely approaching the reliability threshold of 0.7. The developer will monitor reliability carefully for small facilities if implemented.
- Regarding measure consistency, the measures are designed to measure two very different events clinically. Hyperglycemia is usually sustained and can occur in patients that do not have a current diagnosis of diabetes; whereas, severe hypoglycemia is a relatively rare event that typically occurs after the administration of an anti-diabetic agent.

Committee response:

- The Committee supported the construction of the measure and accepted the explanation of the developer regarding reliability.

**7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X; A-X**

**8. Board of Directors Vote: Y-X; N-X**

## 2362 Glycemic Control – Hyperglycemia

**9. Appeals**

## 2363 Glycemic Control - Hypoglycemia

Submission | Specifications

**Description**: The rate of hypoglycemic events following the administration of an anti-diabetic agent

**Numerator Statement**: Total number of hypoglycemic events (<40 mg/dL) that were preceded by administration of rapid/short-acting insulin within 12 hours or an anti-diabetic agent other than short-acting insulin within 24 hours, were not followed by another glucose value greater than 80 mg/dL within five minutes, and were at least 20 hours apart

Optional numerator: Total number of hypoglycemic events (<70 mg/dL) that were preceded by administration of rapid/short-acting insulin within 12 hours or an anti-diabetic agent other than short-acting insulin within 24 hours, were not followed by another glucose value greater than 80 mg/dL within five minutes, and were at least 20 hours apart

**Denominator Statement**: Total number of hospital days with at least one anti-diabetic agent administered

**Exclusions**: Admissions with lengths of stay greater than 120 days are excluded.

**Adjustment/Stratification**: None

**Level of Analysis:** Facility

**Setting of Care:** Hospital/Acute Care Facility

**Type of Measure**: Outcome

**Data Source**: Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Laboratory, Electronic Clinical Data : Pharmacy

**Measure Steward**: Centers for Medicare & Medicaid Services

**STANDING COMMITTEE MEETING [02/26/2014-02/27/2014]**

**1. Importance to Measure and Report: The measure meets the Importance criteria**

(1a. Evidence: 1b. Performance Gap, 1c. High Priority)

1a. Evidence: **H-13**; **M-6**; **L-0**; **IE-0; I-0;** 1b. Performance Gap: **H-12**; **M-6**; **L-1**; **I-0** 1c. High Priority: **H-17**; **M-2**; **L-0**; **I-0**

Rationale:

- The developer identified, reviewed, and reported on 5 studies regarding the relationship between hypoglycemia and outcomes of mortality and length of stay. The Committee agreed that the evidence that poor outcomes and mortality are associated with hypoglycemia is very strong
- Data presented by the developer indicate that average performance scores range from 36-89%. Although a low incidence outcome, the best performance score was less than half of the poorest performance score.
- The Committee agreed that the measure addressed a significant health problem, as hypoglycemia has been associated with higher mortality, increased length of stay, and discharge to a nursing home.

**2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria**

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-11**; **M-7**; **L-1**; **I-0;** 2b. Validity: **H-10**; **M-8**; **L-0**; **I-0**

Rationale:

- The Committee discussed whether blood glucose <40mg/dL was an appropriate cutoff for hypoglycemia, noting that some patients can experience poor outcomes with blood glucose of <70mg/dL. However, the

## 2363 Glycemic Control - Hypoglycemia

Committee agreed that blood glucose <40mg/dL should be preventable, but blood glucose <70 may not be preventable in some patients. The Committee agreed that for public reporting and accountability purposes, <40mg/dL was an appropriate cutoff for identifying hypoglycemia.

- The developer clarified that the optional <70mg/dL threshold measurement was intended for internal quality improvement uses only However, because NQF endorsement implies suitability for use in both accountability applications and internal quality improvement efforts, the Committee requested that the developer remove the optional numerator of <70mg/dL. The developer agreed to this change.
- 
- A signal-to-noise analysis was used to test the reliability testing of the performance measure scores . Although there were only 8 testing sites, 6 of the 8 had reliability of 0.7 or greater (which is typically considered the minimum acceptable value). The one test site with a very low reliability statistic (0.08) was a small provider with only 340 patient days in denominator and 3 hypoglycemic events.
- The developer tested data element validity by comparing electronic data used in the measure to data abstracted from the full electron medical record; the percent agreement was high (>95%) for all critical data elements.

**3. Feasibility: H-15; M-4; L-0; I-0**

*(3a. Data generated during care; 3b. Electronic sources; and 3c. Data collection can be implemented (eMeasure feasibility assessment of data elements and logic)*

Rationale:

- The Committee agreed that data element scores from the feasibility scorecard submitted by the developer supported the feasibility of the measure (all critical data elements had average scores of 2.5 or higher on a 3-point scale).

**4. Use and Usability: H-16; M-2; L-1; I-0**

*(4a. Accountability/transparency; and 4b. Improvement – progress demonstrated; and 4c. Benefits outweigh evidence of unintended negative consequences)*

Rationale:

- This de novo eMeasure is not currently in use but has been submitted for consideration in the CMS Hospital Inpatient Quality Reporting Program (IQR) and for Meaningful Use (MU) Stage 3.

**5. Related and Competing Measures**

- No related or competing measures noted.

**Standing Committee Recommendation for Endorsement: Y-19; N-0**

Rationale

- The Committee noted that this measure will serve as a companion measure to balance the Glycemic Control – Hyperglycemia (2362) measure.
- The Committee also recommended that the developer change the name of the measure to "Glycemic Control – Severe Hypoglycemia".
- The Committee also noted that use of this measure to assess severe hypoglycemia should not be

## 2363 Glycemic Control - Hypoglycemia

construed to mean that hospitals can ignore blood glucose levels that are between 40-70mg/dL.

**6. Public and Member Comment**

Comments received:

- One commenter noted low reliability scores for one of the hospitals included in the testing of the measure and questioning the reliability of the measure for smaller facilities. The commenter also expressed the desire that the measure be made consistent with NQF # 2362.
- One commenter questioned the need for these measures while another expressed support for the measures.

Developer response:

- The developer noted that it is correct the smallest facility tested had inadequate reliability; however, the other facility had a score of 0.67, which would indicate the measure is closely approaching the reliability threshold of 0.7. The developer will monitor reliability carefully for small facilities if implemented.
- Regarding measure consistency, the measures are designed to measure two very different events clinically. Hyperglycemia is usually sustained and can occur in patients that do not have a current diagnosis of diabetes; whereas, severe hypoglycemia is a relatively rare event that typically occurs after the administration of an anti-diabetic agent.

Committee response:

- The Committee supported the construction of the measure and accepted the explanation of the developer regarding reliability.

**7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X; A-X**

**8. Board of Directors Vote: Y-X; N-X**

**9. Appeals**

## 0545 Adherence to Statins for Individuals with Diabetes Mellitus

Submission | Specifications

**Description**: The measure addresses adherence to statins. The measure is reported as the percentage of eligible individuals with diabetes mellitus who had at least two prescriptions for statins and who have a Proportion of Days Covered (PDC) of at least 0.8 during the measurement period (12 consecutive months).

**Numerator Statement**: Individuals in the denominator with at least two prescriptions for statins with a PDC of at least 0.8 for statins.

**Denominator Statement**: Individuals at least 18 years of age as of the beginning of the measurement period with diabetes mellitus and at least two prescriptions for statins during the measurement period (12 consecutive months).

**Exclusions**: We excluded the following individuals from the denominator:

Individuals with polycystic ovaries, gestational diabetes, or steroid-induced diabetes who do not have a face-to-face visit with a diagnosis of diabetes in any setting during the measurement period.

Exclusion 1

Individuals with a diagnosis of polycystic ovaries who do not have a visit with a diagnosis of diabetes in any setting during the measurement period*; and,

Exclusion 2

Individuals with a diagnosis of gestational diabetes or steroid-induced diabetes who do not have a visit with a diagnosis of diabetes mellitus in any setting during the measurement period.

*Adapted from NCQA HEDIS 2013 (2013). Note: HEDIS uses a look-back period of one year prior to the measurement period for both the prescription data and diagnosis.

## 0545 Adherence to Statins for Individuals with Diabetes Mellitus

**Adjustment/Stratification**: None
**Level of Analysis:** Clinician : Group/Practice, Health Plan, Integrated Delivery System, Population : State
**Setting of Care:** Ambulatory Care : Clinician Office/Clinic
**Type of Measure**: Process
**Data Source**: Administrative claims, Other, Electronic Clinical Data : Pharmacy

**Measure Steward**: Centers for Medicare & Medicaid

**STANDING COMMITTEE MEETING [02/26/2014-02/27/2014]**

**1. Importance to Measure and Report: The measure meets the Importance criteria**

(1a. Evidence: 1b. Performance Gap, 1c. High Priority)

1a. Evidence: **H-10**; **M-8**; **L-1**; **I-0; IE-0;** 1b. Performance Gap: **H-15**; **M-4**; **L-0**; **I-0** 1c. High Priority: **H-14**; **M-4**; **L-1**; **I-0**

Rationale:

- Evidence submitted by the developer included clinical practice guideline recommendations from three organizations and a 2010 systematic review of the efficacy of statin use. The Committee agreed that there is strong evidence supporting the use of statins to reduce cardiovascular risk in diabetic patients. Members acknowledged that adherence to statins is not directly addressed in the guidelines, but noted that studies referenced by the developer and an observational study identified by a Committee member showed there was a difference in outcomes between patients who were high-adherent versus. patients who were low-adherent.
- Results from measure testing using 2012 Medicare data indicate average performance rates of 71.8% for states (n=10), 72.2% for drug plans (n=72), and 70.8% for physicians (n= 7,393).
- The Committee noted the high burden of both diabetes and of cardiovascular disease in diabetic patients, and agreed that these conditions affects high numbers, are a leading cause of morbidity and mortality, and require high resource use.

**2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria**

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-14**; **M-4**; **L-0**; **I-0** 2b. Validity: **H-3**; **M-13**; **L-1**; **I-2**

Rationale:

- The Committee questioned why the measure is specified for those aged 18 or older, given that the American Diabetes Association guideline recommendations are for diabetics aged 40 and older and that the measure is computed using Part D Medicare claims. The developer reminded the Committee that the measure focus is adherence among those patients whose physicians have prescribed statin medications at least twice in the measurement year and that it is not meant to address whether the prescriptions were or were not appropriate. The developer agreed to change the title to Adherence to Statins for Medicare Eligible Individuals with Diabetes Mellitus as a way to emphasize that the measure was specified for those enrolled in Medicare Part D.
- The Committee also asked for clarification about what would happen if a physician stops statin therapy (e.g., because of adverse reactions); the developer again noted the denominator requirement for at least two prescriptions but acknowledged that if therapy were discontinued for a particular patient during the measurement year, that patient could be considered non-adherent. However, the developer clarified

## 0545 Adherence to Statins for Individuals with Diabetes Mellitus

that change from one brand of statins to another would not result in a finding of non-adherence.

- There was some discussion among the Committee about whether there should be an exclusion for women who become pregnant (because statins are not indicated for women who are pregnant). The developer noted that an analysis of Medicare data from 10 states for the population covered by this measure, the occurrence of pregnancy was "exceedingly rare".
- The developer conducted a signal to noise analysis to test the reliability of the measure; all values of the reliability statistics were > 0.98 for states and >0.82 for ACOs; the average value of the reliability statistics was 0.72 for drug plans and 0.70 for physician groups. The Committee agreed that these results demonstrated high reliability for states and ACOs and moderate reliability for physician groups and drug plans.
- The Committee accepted the systematic assessment of face validity conducted by the developers; in this assessment, a technical expert panel rated the measure on whether the measure results are a valid representation of quality; 77.8% of the panelists responded that they either agreed or strongly agreed with that statement.
- The Committee discussed the effect of missing data for those patients who do not use their Part D benefit to pay for their medications (e.g., by paying cash getting it for free). The developers noted that they had performed some sensitivity analysis to try to understand the effect of cash purchases on the performance rates and did not see an appreciable difference; they did acknowledge, however, that this analysis was limited because of data limitations. The developer also suggested that cash prescriptions might not be problematic if patients generally fill the statin prescriptions in a consistent place and manner (e.g., those who always pay with cash would not be included in the denominator anyway).

**3. Feasibility: H-14; M-4; L-1; I-0**

*(3a. Data generated during care; 3b. Electronic sources; and 3c. Data collection can be implemented (eMeasure feasibility assessment of data elements and logic)*

Rationale:

- The Committee agreed that the data used in this measure is routinely generated during care delivery and is electronically available.

## 0545 Adherence to Statins for Individuals with Diabetes Mellitus

**4. Use and Usability: H-5; M-10; L-4; I-0**

*(4a. Accountability/transparency; and 4b. Improvement – progress demonstrated; and 4c. Benefits outweigh evidence of unintended negative consequences)*

Rationale:

- The measure is not currently in use but has been submitted through the Measures under Consideration process for the CMS ACO Shared Savings program.
- Some Committee members expressed concern that because the measure includes young women and there is no exclusion for pregnancy, it might unintentionally lead to inappropriate adherence to statins among pregnant women if the measure is applied to a non-Medicare population.
- Some Committee members were concerned with the potential use of this measure in accountability applications because of the possibility of the unintended negative consequence of adverse patient selection (since adherence is not solely under the control of the physician). However, other members noted anecdotal and published accounts indicating that adherence can be influenced substantially by the physician/health system.

**5. Related and Competing Measures**

- No related or competing measures noted.

**Standing Committee Recommendation for Endorsement: Y-15; N-4**

Rationale

- The developer has requested that the three adherence measures that were initially endorsed as one measure (#0545, #2467, and #2468) be paired.
- At the Committee's request, the developer agreed to change the title to Adherence to Statins for Medicare-Eligible Individuals with Diabetes Mellitus.

**6. Public and Member Comment:**

Comments received:

- Commenters generally expressed support for the measure and the Committee's recommendation for endorsement.

**7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X; A-X**

**8. Board of Directors Vote: Y-X; N-X**

**9. Appeals**

## 2467 Adherence to ACEIs/ARBs for Individuals with Diabetes Mellitus

Submission | Specifications

## 2467 Adherence to ACEIs/ARBs for Individuals with Diabetes Mellitus

**Description**: The measure addresses adherence to angiotensin converting enzyme inhibitors (ACEIs)/angiotensin receptor blockers (ARBs). The measure is reported as the percentage of eligible individuals with diabetes mellitus who had at least two prescriptions for ACEIs/ARBs and who have a Proportion of Days Covered (PDC) of at least 0.8 during the measurement period (12 consecutive months).

**Numerator Statement**: Individuals in the denominator with at least two prescriptions for ACEIs/ARBs with a PDC of at least 0.8 for ACEIs/ARBs.

**Denominator Statement**: Individuals at least 18 years of age as of the beginning of the measurement period with diabetes mellitus and at least two prescriptions for ACEIs/ARBs during the measurement period (12 consecutive months).

**Exclusions**: We excluded the following individuals from the denominator:

Individuals with polycystic ovaries, gestational diabetes, or steroid-induced diabetes who do not have a face-to-face visit with a diagnosis of diabetes in any setting during the measurement period.

Exclusion 1

Individuals with a diagnosis of polycystic ovaries who do not have a visit with a diagnosis of diabetes in any setting during the measurement period*; and,

Exclusion 2

Individuals with a diagnosis of gestational diabetes or steroid-induced diabetes who do not have a visit with a diagnosis of diabetes mellitus in any setting during the measurement period.

*Adapted from NCQA HEDIS 2013 (2013). Note: HEDIS uses a look-back period of one year prior to the measurement period for both the prescription data and diagnosis.

**Adjustment/Stratification**: None

**Level of Analysis:** Clinician : Group/Practice, Health Plan, Integrated Delivery System, Population : State

**Setting of Care:** Ambulatory Care : Clinician Office/Clinic

**Type of Measure**: Process

**Data Source**: Administrative claims, Other, Electronic Clinical Data : Pharmacy

**Measure Steward**: Centers for Medicare & Medicaid

**STANDING COMMITTEE MEETING [02/26/2014-02/27/2014]**

**1. Importance to Measure and Report: <u>The measure meets the Importance criteria</u>**

(1a. Evidence: 1b. Performance Gap, 1c. High Priority)

1a. Evidence: **H-6**; **M-12**; **L-1**; **IE-0; I-0;** 1b. Performance Gap: **H-15**; **M-3**; **L-1**; **I-0** 1c. High Priority: **H-14**; **M-3**; **L-0**; **I-0**

<u>Rationale</u>:

- The developer presented clinical practice guideline recommendations from three organizations and a review that addresses the effects of blood pressure-lowering medications on cardiovascular events in patients with and without diabetes. In addition, one Committee member noted additional studies that linked adherence to ARBs in diabetics to desired outcomes. The Committee as agreed that the benefits of ACEIs/ARBs use assume medication adherence.
- Results from measure testing using 2012 Medicare data indicate average performance rates of 75.7% for states (n=10), 76.1% for drug plans (n=72), and 74.1% for physicians (n= 7,393).
- The Committee noted the high prevalence, severity, and cost of diabetes and of cardiovascular disease in diabetic patients

## 2467 Adherence to ACEIs/ARBs for Individuals with Diabetes Mellitus

**2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>**
(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)
2a. Reliability: **H-10**; **M-9**; **L-0**; **I-0;** 2b. Validity: **H-5**; **M-13**; **L-1**; **I-0**
<u>Rationale</u>:

- As with measure #0545, this measure is computed using Part D Medicare claims; the developer agreed to change the title to Adherence to ACEIs/ARBs for Medicare-Eligible Individuals with Diabetes Mellitus as a way to emphasize that the measure was specified for those enrolled in Medicare Part D.
- The developer conducted a signal to noise analysis to test the reliability of the measure; all values of the reliability statistics were > 0.82 for states and >0.81 for ACOs; the average value of the reliability statistics was 0.76 for drug plans and 0.74 for physician groups. The Committee agreed that these results demonstrated high reliability for states and ACOs and moderate reliability for physician groups and drug plans.
- The Committee accepted the systematic assessment of face validity conducted by the developers; in this assessment, a technical expert panel rated the measure on whether the measure results are a valid representation of quality; 77.8% of the panelists responded that they either agreed or strongly agreed with that statement.
- The Committee's discussion of missing data for measure #0575 also applies to this measure, although members did not revisit the concern in their discussion of this measure.

**3. Feasibility: H-16; M-3; L-0; I-0**
*(3a. Data generated during care; 3b. Electronic sources; and 3c. Data collection can be implemented (eMeasure feasibility assessment of data elements and logic)*
<u>Rationale</u>:

- The Committee agreed that the data used in this measure is routinely generated during care delivery and is electronically available.

**4. Use and Usability: H-10; M-8; L-1; I-0**
*(4a. Accountability/transparency; and 4b. Improvement – progress demonstrated; and 4c. Benefits outweigh evidence of unintended negative consequences)*
<u>Rationale</u>:

- The measure is not currently in use but has been submitted through the Measures under Consideration process for the CMS ACO Shared Savings program.
- The Committee's discussion (for measure #0575) of possible adverse patient selection also applies to this measure, although members did not revisit the concern in their discussion of this measure.

**5. Related and Competing Measures**

- No related or competing measures noted.

## 2467 Adherence to ACEIs/ARBs for Individuals with Diabetes Mellitus

**Standing Committee Recommendation for Endorsement: Y-18**; **N-1**

Rationale

- At the Committee's request, the developer agreed to change the title to Adherence to ACEI/ARBs for Medicare-Eligible Individuals with Diabetes Mellitus.
- The developer has requested that the three adherence measures that were initially endorsed as one measure (#0545, #2467, and #2468) be paired.

**6. Public and Member Comment:**

Comments received:

- Commenters generally expressed support for the measure and the Committee's recommendation for endorsement.

**7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X; A-X**

**8. Board of Directors Vote: Y-X; N-X**

**9. Appeals**

## 2468 Adherence to Oral Diabetes Agents for Individuals with Diabetes Mellitus

Submission | Specifications

**Description**: The measure addresses adherence to oral diabetes agents (ODA). The measure is reported as the percentage of eligible individuals with diabetes mellitus who had at least two prescriptions for a single oral diabetes agent or at least two prescriptions for multiple agents within a diabetes drug class and who have a Proportion of Days Covered (PDC) of at least 0.8 for at least one diabetes drug class during the measurement period (12 consecutive months)

**Numerator Statement**: Individuals in the denominator with at least two prescriptions for oral diabetes agents, in any diabetes drug class, with a PDC of at least 0.8 for at least one diabetes drug class.

**Denominator Statement**: Individuals at least 18 years of age as of the beginning of the measurement period with diabetes mellitus and at least two prescriptions for a single oral diabetes agent or at least two prescriptions for multiple agents within a diabetes drug class during the measurement period (12 consecutive months).

**Exclusions**: We excluded the following individuals from the denominator:

Individuals with polycystic ovaries, gestational diabetes, or steroid-induced diabetes who do not have a face-to-face visit with a diagnosis of diabetes in any setting during the measurement period.

Exclusion 1

Individuals with a diagnosis of polycystic ovaries who do not have a visit with a diagnosis of diabetes in any setting during the measurement period*; and,

Exclusion 2

Individuals with a diagnosis of gestational diabetes or steroid-induced diabetes who do not have a visit with a diagnosis of diabetes mellitus in any setting during the measurement period.

*Adapted from NCQA HEDIS 2013 (2013). Note: HEDIS uses a look-back period of one year prior to the measurement period for both the prescription data and diagnosis.

**Adjustment/Stratification**: None

**Level of Analysis:** Clinician : Group/Practice, Health Plan, Integrated Delivery System, Population : State

**Setting of Care:** Ambulatory Care : Clinician Office/Clinic

**Type of Measure**: Process

**Data Source**: Administrative claims, Other, Electronic Clinical Data : Pharmacy

## 2468 Adherence to Oral Diabetes Agents for Individuals with Diabetes Mellitus

**Measure Steward**:Centers for Medicare & Medicaid

**STANDING COMMITTEE MEETING [02/26/2014-02/27/2014]**

**1. Importance to Measure and Report: The measure meets the Importance criteria**

(1a. Evidence: 1b. Performance Gap, 1c. High Priority)

1a. Evidence: **H-4**; **M-15**; **L-0**; **IE-0; I-0;** 1b. Performance Gap: **H-14**; **M-5**; **L-0**; **I-0** 1c. High Priority: **H-13**; **M-6**; **L-0**; **I-0**

Rationale:

- Evidence presented by the developer included a summary of the quality, quantity, and consistency of six studies that relate good adherence to medications in patients with diabetes with a variety of desired health outcomes; the developer also presented 2013 clinical practice guideline from the American Diabetes Association recommending use of oral hypoglycemic agents, but these recommendations did not specially address adherence to medication. The Committee agreed that there is evidence for use of oral hypoglycemic agents and that the benefits described in the evidence presented assume adherence to the medications.
- Results from measure testing using Medicare data indicate average performance rates of 73.9% for states (n=10), 74.2% for drug plans (n=72), and 72.6% for physicians (n= 7,393).
- The Committee agreed that diabetes affects high numbers, is a leading cause of morbidity and mortality, and consumes high resources.

**2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria**

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-8**; **M-11**; **L-0**; **I-0**; 2b. Validity: **H-1**; **M-4**; **L-9**; **I-5; 2b. Validity (post-comment): H-1**; **M-13**; **L-I**; **I-0**

Rationale:

- The Committee verified that patients who switch from one form of oral hypoglycemic agent to another would not be counted as non-adherent, assuming they were adherent to at least one of the medications.
- Average reliability statistics obtained from signal-to-noise analyses varied based on level of analysis, but were at or above the generally considered the minimum threshold of 0.7.
- The Committee questioned the validity of the measure because it does not exclude patients who switch from oral agents to insulin during the measurement period. The Committee noted that in older adults, transition to insulin (and associated discontinuation of oral medications) is common and that the measure as currently specified would incorrectly categorize such patients as non-adherent. They also expressed concern that the measure as specified might incentivize physicians to leave patients on oral diabetes agents rather than switch them to insulin when appropriate. The Committee encouraged the developer to quantify the number of patients who transitioned to insulin and, if possible, revise the measure to exclude those patients.
- Although not the deciding factor in their initial recommendation not to endorse the measure, Committee members also noted that some Medicaid programs limit the number of prescriptions that beneficiaries can fill per month. These members cautioned that the validity of the measure might be affected if dually-eligible beneficiaries are unable to maintain medication adherence due to this policy.
- As requested by the Committee, the measure developer conducted additional analysis and found that

## 2468 Adherence to Oral Diabetes Agents for Individuals with Diabetes Mellitus

13.1% of patients in their 10-state sample switched from oral diabetes agents to an insulin-only therapy. Based on these results, the developer re-specified the measure to 1) limit the number of days in the denominator for those with a switch from oral diabetes agents to insulin-only therapy and 2) compute an overall percentage of days covered value for those who switched between oral drug classes; they also re-tested the newly specified measure for reliability and validity. After discussion, the committee agreed to re-vote on the measure. Upon re-vote, the Committee agreed that the analysis and re-specification of the measure addressed their initial concerns with the validity of the measure.

**3. Feasibility (post-comment): H-8; M-8; L-0; I-0**

*(3a. Data generated during care; 3b. Electronic sources; and 3c. Data collection can be implemented (eMeasure feasibility assessment of data elements and logic)*

Rationale:

- The Committee agreed that the data used in this measure is routinely generated during care delivery and is electronically available.

**4. Use and Usability (post-comment): H-2; M-13; L-1; I-0**

*(4a. Accountability/transparency; and 4b. Improvement – progress demonstrated; and 4c. Benefits outweigh evidence of unintended negative consequences)*

Rationale:

- The measure is not currently in use but has been submitted through the Measures under Consideration process for the CMS ACO Shared Savings program.
- The Committee's discussion (for measure #0575) of possible adverse patient selection also applies to this measure, although members did not revisit the concern in their discussion of this measure.

**5. Related and Competing Measures**

- No related or competing measures noted.

**Standing Committee Recommendation for Endorsement (post-comment): Y-15; N-1**

**6. Public and Member Comment**

Comments received:

- Comments were received supporting the Committee's decision not to recommend the measure for endorsement because of concern over excluding patients who switch from oral agents to insulin during the measurement period.

Developer response:

- FMQAI, on behalf of CMS, conducted additional analysis to ascertain how many patients switched from oral diabetes agents to an insulin-only therapy. Results from analyses of a 10-state sample indicated that 13.1% of patients made this switch. Based on these results, the developer re-specified the measure to 1) limit the number of days in the denominator for those with a switch from oral diabetes agents to insulin-only therapy and 2) compute an overall percentage of days covered value for those who switched between oral drug classes; they also re-tested the newly specified measure for reliability and validity.

Committee response:

- The Committee agreed that the analysis and re-specification of the measure addressed their initial concerns with the validity of the measure. After additional discussion, the Committee also voted on the Feasibility and Usability and Use criteria, and ultimately recommended the re-specified measure for endorsement.

## 2416 Laboratory Investigation for Secondary Causes of Fracture

Submission | Specifications

**Description**: Percentage of patients age 50 and over with fragility fracture who have had appropriate laboratory investigation for secondary causes of fracture ordered or performed prior to discharge from inpatient status.

**Numerator Statement**: Patients who have all the specified laboratory tests ordered or performed prior to discharge:

1. Complete blood cell count (CBC)
2. Kidney function test
3. Liver function test
4. Serum calcium
5. 25(OH) Vitamin D level OR Oral Administration of Vitamin D

**Denominator Statement**: Patients age 50 and over discharged from inpatient status with an ICD-9-CM Principal or Other Diagnosis Code of selected fractures as defined in Table 3.1 Vertebral Fracture, Table 4.1 Hip Fracture, or Table 5.1 Other Fracture

**Exclusions**: Exclusions are those patients with:

- Age less than 50 years
- "Comfort Measures Only" documented
- Enrollment in a clinical trial pertaining to osteoporosis
- Laboratory testing performed in the prior 12 months
- Expired

**Adjustment/Stratification**: None

**Level of Analysis:** Facility

**Setting of Care:** Hospital/Acute Care Facility

**Type of Measure**: Process

**Data Source**: Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Paper Medical Records

**Measure Steward**: The Joint Commission

**STANDING COMMITTEE MEETING [02/26/2014-02/27/2014]**

**1. Importance to Measure and Report: <u>The measure meets the Importance criteria</u>**

(1a. Evidence: 1b. Performance Gap, 1c. High Priority)

1a. Evidence: **H-1**; **M-12**; **L-6**; **IE-0; I-0**; 1b. Performance Gap: **H-11**; **M-7**; **L-0**; **I-0;** 1c. High Priority: **H-6**; **M-11**; **L-2**; **I-0**

<u>Rationale</u>:

- The evidence presented for this measure included the 2010 clinical practice guideline recommendations from American Association of Clinical Endocrinologists as well as additional articles discussing a variety of laboratory tests for secondary causes of osteoporosis. The Committee agreed that the evidence , was supportive of evaluating patients with fractures for secondary causes, as this allows for treatment of the underlying causes and potentially prevention of future fractures, readmissions, mortality, and unnecessary associated costs.
- The developer submitted data from pilot studies conducted in in testing hospitals that reflected an average performance rate of only16.6%..
- The measure developer presented data indicating that about half of women and one-fourth of men over

## 2416 Laboratory Investigation for Secondary Causes of Fracture

the age of 50 will sustain a fracture due to osteoporosis. Among these patients, osteoporosis that is secondary to other diseases or conditions occurs in almost two-thirds of men, more than half of premenopausal and perimenopausal women, and in about one-fifth of postmenopausal women.

**2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>**
(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)
2a. Reliability: **H-6**; **M-10**; **L-3**; **I-0;** 2b. Validity: **H-3**; **M-13**; **L-3**; **I-0**
<u>Rationale</u>:

- The Committee expressed concern that the evidence provided, while supportive of investigating for secondary causes of fracture, did not support the need for the specific tests required by the numerator. The developer clarified that the five tests specified would allow the provider to determine whether there was an underlying cause for the fracture, such as osteoporosis, osteopenia, low bone mass, Vitamin D deficiency, glucocorticoid administration, etc. The Committee found this explanation to be sufficient.
- The developer presented results from reliability testing that was conducted on 133 patient charts from 6 hospitals that are diverse by geography, type and size. Inter-rater reliability testing was performed comparing the results of two different abstractors; five data elements of the numerator were tested. The results demonstrate a high degree of agreement (>94%) for the all data elements except "laboratory tests ordered or performed prior to discharge" where the percent agreement was 78%. The
- Face validity was assessed by hospital test sites for all data elements, and the only data element scoring below 75% was "laboratory test performed in 12 months prior to fracture". However, face validity of the computed measure score was not assessed by the developer.

**3. Feasibility: H-1; M-16; L-2; I-0**
*(3a. Data generated during care; 3b. Electronic sources; and 3c. Data collection can be implemented (eMeasure feasibility assessment of data elements and logic)*
<u>Rationale</u>:

- Committee members expressed concern that Vitamin D levels may not be available when the measure is calculated; however, the developers noted that administration of Vitamin D meets the measure requirements and also that medical charts are abstracted at least 30 days post-discharge, which would allow sufficient time for the test results to be recorded prior to measure score calculation.
- The Committee acknowledged that the measure is specified for chart abstraction and is coded by someone other than the person obtaining the original information.

## 2416 Laboratory Investigation for Secondary Causes of Fracture

**4. Use and Usability: H-4; M-14; L-1; I-0**

*(4a. Accountability/transparency; and 4b. Improvement – progress demonstrated; and 4c. Benefits outweigh evidence of unintended negative consequences)*

Rationale:

- Although the measure is not currently in use, the Joint Commission plans to use the measure for accreditation purposes and public reporting on its web site by 2017.
- There was some discussion by the Committee that Vitamin D therapy might be started prior to definitive documentation of deficiency (given that it usually takes several days to get the results of the Vitamin D test). The Committee also noted that this measure might encourage hospitals to perform unnecessary or duplicative testing.

**5. Related and Competing Measures**

- No related or competing measures noted.

**Standing Committee Recommendation for Endorsement: Y-16; N-6**

**6. Public and Member Comment:**

Comments received:

- Commenters generally expressed support for the measure and the Committee's recommendation for endorsement.

**7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X; A-X**

**8. Board of Directors Vote: Y-X; N-X**

**9. Appeals**

## 2417 Risk Assessment/Treatment After Fracture

Submission | Specifications

**Description**: Patients age 50 or over with a fragility fracture who have either a dual-energy X-Ray absorptiometry (DXA) scan ordered or performed, or a prescription for FDA-approved pharmacotherapy for osteoporosis, or who are seen by or linked to a fracture liaison service prior to discharge from inpatient status,. If DXA is not available and documented as such, then any other specified fracture risk assessment method may be ordered or performed.

**Numerator Statement**: Patients who had either a DXA scan ordered or performed, OR a prescription for FDA-approved pharmacotherapy for osteoporosis treatment, OR those who were seen by, contacted by, or linked to a fracture liaison service prior to discharge OR had other fracture risk assessment method ordered or performed if DXA is not available.

**Denominator Statement**: Patients age 50 and over discharged from inpatient status with an ICD-9-CM Principal or Other Diagnosis Code of selected fractures as defined in Table 3.1 Vertebral Fracture, Table 4.1 Hip Fracture, or Table 5.1 Other Fracture,

**Exclusions**: • Age less than 50 years

- "Comfort Measures Only" documented
- Enrollment in a clinical trial pertaining to osteoporosis
- On FDA-Approved pharmacotherapy for osteoporosis treatment as defined in Table 1.1 prior to the fracture date
- Bone Mineral density test documented in the 12 months prior to the fracture
- Expired

## 2417 Risk Assessment/Treatment After Fracture

See attached Excel file for definitions

**Adjustment/Stratification**: None

**Level of Analysis:** Facility

**Setting of Care:** Hospital/Acute Care Facility

**Type of Measure**: Process

**Data Source**: Electronic Clinical Data : Electronic Health Record, Paper Medical Records

**Measure Steward**: The Joint Commission

**STANDING COMMITTEE MEETING [02/26/2014-02/27/2014]**

**1. Importance to Measure and Report: The measure meets the Importance criteria**

(1a. Evidence: 1b. Performance Gap, 1c. High Priority)

1a. Evidence: **H-9**; **M-10**; **L-0**; **IE-0; I-0**; 1b. Performance Gap: **H-17**; **M-2**; **L-0**; **I-0;** 1c. High Priority: **H-18**; **M-1**; **L-**; **I-0**

Rationale:

- The developer presented evidence based on a Cochrane review, clinical practice guidelines, and meta-analysis supporting measuring bone density by DXA and use of a fracture liaison service to diagnose osteoporosis for fragility fracture patients. Committee members agreed that there is strong evidence that detecting and treating osteoporosis prevents additional fracture. However, some Committee members noted that the evidence submitted did not fully support linkage between other risk assessment methods and fracture prevention; members also questioned the efficacy of ordering a DXA in preventing future fractures.
- According to the developer, the rate of osteoporosis testing or treatment after fracture is approximately 20%
- The developer presented information indicating that about half of women and one-fourth of men over the age of 50 will sustain a fracture due to osteoporosis. Of those who sustain a fragility fracture, the risk of additional fractures in the future increases by 1.5-2.0 times.

**2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria**

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-8**; **M-11**; **L-0**; **I-0;** 2b. Validity: **H-9**; **M-11**; **L-0**; **I-0**

Rationale:

- The Committee asked what other risk assessments might be performed (other than DXA of the hip/spine). The developers named several, including, the QCT of the spine, the QUS of the heel, DXA of the forearm, SXA/DXA of the heel, and the FRAX assessment; however, they noted that DXA of the hip/spine is the most commonly used method.
- The developer presented results from reliability testing that was conducted on 133 patient charts from 6 hospitals that are diverse by geography, type and size. Inter-rater reliability testing was performed comparing the results of two different abstractors; five data elements of the numerator were tested. The results demonstrate a high degree of agreement (>97%) for the all data elements tested; however,
- One numerator data element, “Fracture liaison service,” and two exclusion data elements (“Bone Mineral Density Test Performed in the 12 Months Prior to the Fracture” and “On FDA-approved Pharmacotherapy for Treatment of Osteoporosis Prior to Fracture.”) were not tested. The Committee found these results to be acceptable.

## 2417 Risk Assessment/Treatment After Fracture

- The developer assessed the face validity for all data elements on their clarity, collectability, and correctness of data sources, finding that the only data element scoring below 75% was "BMD test performed in 12 months prior to fracture"; however, face validity of the computed measure score was not assessed by the developer. Informally, however, the Committee agreed that provision of the care processes specified in the measure after a fragility fracture would be a valid assessment of quality.
- The Committee noted that DXA scans generally are not performed in hospitals and that documentation of previous DXA testing is not easily available to hospitals. The Committee agreed that the various other methods specified in the measure should allow any hospital to meet the measure.
- The Committee also questioned what "other fracture risk assessments" could be used if DXA was not available; the developer clarified that these were provided in the appendix of the measure submission.
- The Committee expressed concerns about exclusions; the developer clarified that the measure excludes patients that had a recent bone mineral density scan or were on prescription medication for osteoporosis at the time of the fracture. Data from testing indicate that the occurrence of exclusions is low (1.6% on prescription medication and 0.3% with prior bone mineral density test). The Committee also verified that non-fragility fractures are excluded from the measure.

**3. Feasibility: H-2; M-11; L-6; I-0**

*(3a. Data generated during care; 3b. Electronic sources; and 3c. Data collection can be implemented (eMeasure feasibility assessment of data elements and logic)*

Rationale:

- Committee members had concerns that documentation of previous DXA scans may not be easily available for hospitals; however the majority of the Committee rated feasibility as moderate.
- The Committee acknowledged that the measure is specified for chart abstraction and is coded by someone other than the person obtaining the original information.

**4. Use and Usability: H-7; M-10; L-2; I-0**

*(4a. Accountability/transparency; and 4b. Improvement – progress demonstrated; and 4c. Benefits outweigh evidence of unintended negative consequences)*

Rationale:

- Although the measure is not currently in use, the Joint Commission plans to use the measure for accreditation purposes and public reporting on its web site by 2017.
- The Committee noted that a possible unintended negative consequence is duplication of tests; however, members suggested that the risk of duplication likely would be low.

**5. Related and Competing Measures**

- No related or competing measures noted.

**Standing Committee Recommendation for Endorsement: Y-19; N-0**

**6. Public and Member Comment:**

Comments received:

- Commenters generally expressed support for the measure and the Committee's recommendation for endorsement.

**7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X; A-X**

**8. Board of Directors Vote: Y-X; N-X**

| 2417 Risk Assessment/Treatment After Fracture |
| --- |
| **9. Appeals** |