TO: Consensus Standards Approval Committee (CSAC)

FR: Karen Johnson, Katie Streeter, and Kaitlynn Robinson-Ector

RE: Endocrine Cycle 3 Member Voting Results

DA: May 12, 2015

The CSAC will review recommendations from the *Endocrine* (Cycle 3) project during its May 12, 2015 conference call.

This memo includes a summary of the project, recommended measures, public and member comments submitted, and responses to each comment.

Member voting on these recommended measures ends on May 7, 2015.

Accompanying this memo are the following documents:

1. **Endocrine (Cycle 3) 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**. This is a complete table of comments submitted, along with the responses to each comment and the actions taken by the Standing Committee.

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

Endocrine Cycle 3 Measures Recommended for Endorsement:

- 0061: Comprehensive Diabetes Care: Blood Pressure Control (<140/90 mm Hg)
- 0729: Optimal Diabetes Care

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 process. This 22-month project includes three full endorsement "cycles," allowing for the submission and review of both new and previously-endorsed measures every six months. The background and description of the project, review of NQF's Endocrine portfolio, and the results of the cycle 1 and cycle 2 evaluations are

available on NQF's project web page. In cycle 3 of this project, the Standing Committee evaluated two measures undergoing maintenance review against NQF's standard measure evaluation criteria.

DRAFT REPORT

The Endocrine (Cycle 3) Draft Report presents the results of the evaluation of two measures considered under the CDP. Both measures were recommended by the Standing Committee for endorsement as voluntary consensus standards suitable for accountability and quality improvement. The measures were evaluated against the 2013 version of the measure evaluation criteria.

	MAINTENANCE	NEW	TOTAL
Measures considered	2	0	2
Withdrawn from consideration	0	0	0
Recommended	2	0	2
Not recommended	0	0	0

COMMENTS AND THEIR DISPOSITION

NQF received six comments from five member organizations and individuals pertaining to the measures under consideration.

A table of comments submitted during the comment period, with the responses to each comment and the actions taken by the Standing Committee and measure developers, is posted to the Endocrine project page.

Comments Received and Committee Responses

Measure 0061: Comprehensive Diabetes Care: Blood Pressure Control (<140/90 mm Hg)

NQF received one comment in support of the Committee's recommendation for endorsement of this measure.

NQF response: NQF has reviewed your comment and appreciates your input. Your comment has been forwarded to the Standing Committee for consideration.

Measure 0729: Optimal Diabetes Care

NQF received five comments regarding this measure, each of which was critical of the measure, for various reasons. Commenters questioned the blood glucose threshold of less than eight percent, criticized the composite approach, suggested a need for inclusion of sociodemographic factors in the risk-adjustment approach, and advised including additional detail regarding moderate or high intensity dosing of statin therapy for the measure. The Committee discussed each of the comments but did not change their recommendation for continued endorsement.

Comment: The glucose control component of the composite measure

Two comments (ID #4687 and #4794) specifically related to the glucose control component of the composite measure. The comments referenced the National Action Plan for Adverse Event Prevention,

(released in August, 2014), which states that the blood glucose threshold of <8% for patients <75 years of age does not conform to current clinical practice guidelines for glycemic control.

Developer Response #1: Thank you for your comments. According to the Institute for Clinical Systems Improvement (ICSI) 2014 Guidelines for Diabetes there is high quality evidence and a strong recommendation in support of an A1c target of less than 8.0. Excerpt from the guideline is as follows: Algorithm Annotation #4- Glycemic Control and A1c Goals. Recommendation: A clinician should personalize goals with patients diagnosed with T2DM to achieve glycemic control with a hemoglobin A1c < 7% to < 8% depending on individual patient factors. Benefits: Achieving near-normal glycemic control lowers risk of diabetes microvascular complications such as retinopathy, nephropathy and amputations. Achieving A1c of 6.9 to 7.9% may also significantly reduce macrovascular complications based on Steno-2 and UKPDS data. Quality of Evidence: High Strength of Recommendation: Strong. www.icsi.org/guidelines__more/catalog_guidelines_and_more/catalog_guidelines/catalog_endocrine_guidelines/diabetes/ Measurement does not and should not preclude good clinical judgement; however the measure development work group believes that a target of < 8.0 is reasonable and supported by guidelines. Our measure does have an upper age limit cut-off of 75 years and we allow exclusions for death, permanent nursing home resident or patients who are receiving hospice or palliative care services.

Committee Response*:* Thank you for your comment. During its review of the individual measure assessing HbA1c<8% in the spring of 2014 (#0575), the Committee considered 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). During their discussion of measure #0575, members specifically noted that for some patients (e.g., frail elderly patients, those with limited life expectancy,) HbAc1 values slightly above 8% might be reasonable and that target HbA1c values for such patients should be individualized. In their more recent evaluation of this composite measure (#0729) in January 2015, the Committee considered the 2014 clinical practice guideline recommendations from the Institute for Clinical Systems Improvement, which suggest a target threshold of <7% - <8%, depending on patient factors. The Committee acknowledged that the <8% threshold may not be appropriate for all patients, but agreed that the 8.0% cutoff was a reasonable target for a national healthcare performance measure and that 100% performance on the measure is not expected. The Committee also noted that measure #0729 includes an the upper age limit of 75 and excludes patients who died, are permanent nursing home residents, or are receiving hospice or palliative care services, which addresses at least some of the concerns voiced by the commenters. Finally, the Committee strongly recommended development of performance measures that assess occurrence and severity of hypoglycemia in the outpatient setting.

Comment: Composite Measure

Two comments (ID #4717 and #4720) were critical of the composite measure itself, citing concern that use of the composite measure could mask the individual care processes that most need improvement.

Developer Response #1: Thank you for your comment. While it is true that the measure is reported at the composite level, the individual components and the associated rates are available to the medical groups for better understanding their rates and for use in quality improvement to know which areas have opportunity for improvement. MNCM and the measure development work group firmly believe

that achieving the intermediate physiological outcome targets related to blood pressure and glycemic control in addition being tobacco free and use of daily aspirin and statins where appropriate are the diabetic patient's best mechanisms of avoiding or postponing long term complications associated with this chronic condition which affects millions of Americans. Measuring providers separately on individual targets is not as patient centric as a measure that seeks to reduce multiple risk factors for each patient. Diabetic patients are more likely to reduce their overall risk and maximize health outcomes by achieving several intermediate physiological targets. *(remainder of response refers to other issues)*

Developer Response #2: Thank you for your comment and support of the components of this patient level all-or-none composite measure. (*remainder of response same as above and/or refers to other issues)*.

Committee Response: Thank you for your comment. Use of an all-or-not scoring approach does not hinder providers from tracking performance of the individual components of the composite and instituting appropriate improvement initiatives. Moreover, use of such composite measures is a patient-centric approach that allows providers to assess their success in reducing multiple patient risk factors across a variety of clinical areas.

Comment: documenting HbA1c levels between 8-9 percent cannot be done using CPT-II coding

Two comments (ID #4717 and #4720) noted the inability to document HbA1c levels between 8-9 percent using CPT-II codes.

Developer Response #1: A point of clarification, these measure do not rely on CPTII codes for numerator compliance, nor are they indicated anywhere in our measure specification. Measure specifications focus on the electronic health record as a source of clinical information for calculating numerator compliance; actual A1c values are utilized in the case of the A1c target. Additionally, 80 to 90% of all the clinics in MN are reporting this information from their electronic health records without the need for additional chart abstraction.

Developer Response #2: *Almost identical to above.*

Comment: Risk adjustment for sociodemographic factors

One comment (ID #4720) also suggested a need for including sociodemographic factors in the risk-adjustment approach.

Developer Response: Additionally, our risk adjustment model does include insurance product which is a proxy for socioeconomic status. During the process of measure development, the expert panel discusses potential variables for risk adjustment that are important to consider for the measured population. For this measure, variables that are available for evaluation include gender, age, zip, race/ethnicity, country of origin, primary language, insurance product, diabetes type, depression and ischemic vascular disease. The potential risk adjustment variables are then evaluated for appropriate inclusion in the model based on a t value outside the range of -2.0 and +2.0. Currently, the variables that have demonstrated acceptable properties are insurance product, age bands (18-25, 26-50, 51-65 and 65 to 75) and diabetes type (1 or 2). Race/ethnicity has been collected for this measure in MN for the past few years, but has

now reached a level of reliability in which it can be evaluated for its impact. MNCM continues to review variables and their impact on the measure and part of its measure risk adjustment strategy.

Committee Response: Thank you for your comment. The Committee acknowledged NQF's recent policy change that has lifted the prohibition against including sociodemographic factors in risk-adjustment for outcome, resource use, and other quality measures. The Committee agreed that insurance type, which is included in the risk-adjustment model for this measure, can be considered a proxy for sociodemographic status. The Committee also accepted the developer's explanation that other potential sociodemographic factors were considered for inclusion in the measure's risk-adjustment approach but ultimately were not included because they were not statistically significant.

Comment: Need for more details regarding moderate or high intensity statin dosing

One comment suggested the need for additional detail regarding moderate or high intensity statin dosing in the description of statin use for the measure.

Developer Response: Thank you for your comment and suggestion for the inclusion of a dose of statin (moderate or high intensity statin). The measure development work group thoroughly discussed the pros and cons of specifying a certain dose of the statin medication and based on the following factors ultimately decided to not specify a dose of moderate or high intensity for numerator compliance: 1) data burden for practices, 2) controversy and burden surrounding the CV risk calculator, 3) ICSI 2014 Diabetes Guideline recommendations for measurement and 4) cardiology work group member's believe that there is some benefit for some patients who can only tolerate a lower intensity dose.

NQF MEMBER VOTING RESULTS

Endocrine (Cycle 3) Member Voting Results will be available to both the public and the CSAC in an addendum shortly after the Member Voting Period ends on May 7, 2015 6pm ET.

Appendix A-Measure Evaluation Summary Tables

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

0061 Comprehensive Diabetes Care: Blood Pressure Control (<140/90 mm Hg)

Submission |

Description: The percentage of patients 18-75 years of age with diabetes (type 1 and type 2) whose most recent blood pressure level taken during the measurement year is <140/90 mm Hg.

Numerator Statement: Patients whose most recent blood pressure level was <140/90 mm Hg during the measurement year. The outcome being measured is a blood pressure reading of <140/90 mm Hg, which indicates adequately controlled blood pressure. Adequately controlled blood pressure in patients with diabetes reduces cardiovascular risks and microvascular diabetic complications.

Denominator Statement: Patients 18-75 years of age by the end of the measurement year who had a diagnosis of diabetes (type 1 and type 2) during the measurement year or the year prior to the measurement year. See question S.9 Denominator Details for methods to identify patients with diabetes.

Exclusions: Exclusions

-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. e

AND either:

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

-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: No risk adjustment or risk stratification

Level of Analysis: Clinician : Group/Practice, Clinician : Individual, Health Plan, 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 : Electronic Health Record, Electronic Clinical Data : Laboratory, Electronic Clinical Data : Pharmacy, Paper Medical Records

Measure Steward: National Committee for Quality Assurance

STANDING COMMITTEE MEETING [01/22/2015]

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

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: H-2; M-11; L-1; I-3; 1b. Performance Gap: H-15; M-2; L-0; I-0

Rationale:

- Evidence provided by the developer included a reference to five clinical practice guideline recommendations published in a February 2014 article in the *Journal of the American Medical Association* by the panel members appointed to the Eighth Joint National Committee (JNC8). Three randomized controlled trials (RCTs) were presented as evidence to support a blood pressure goal of <150/90 mm Hg for patients with diabetes. The goal of <140/90 mmHg is based on expert opinion of the JNC8 panel members and is consistent with the blood pressure goals articulated by the panel for the general population younger than 60 years.
- Both Committee members and the developers acknowledged there are no studies that directly support a blood pressure goal of <140/90 mm Hg for patients with diabetes. However, the Committee agreed that there is strong evidence that moderate lowering of blood pressure in patients with diabetes is associated with a reduction of cardiovascular risks and microvascular diabetic complications.
- Some Committee members suggested that there is no clinical or evidentiary support to distinguish between a threshold of **<**140/90 mm Hg vs. **≤**140/90 mm Hg, noting that, operationally, clinicians tend to round up to 140/90 when not using digital cuffs if the reading is just slightly below that value. The developer explained that they based the measure threshold on the JNC8 panel members' guideline recommendation of <140/90 mm Hg for diabetic patients.
- HEDIS data presented by the developer for commercial, Medicaid, and Medicare health plans indicate average performance rates from 59% to 65% between 2012-2014. Data presented by the developer for clinicians and practices participating in the NCQA Diabetes Recognition Program (DRP) indicate performance rates ranging from 80% to 81% for 2011-2013 The Committee agreed that there remains opportunity for improvement.

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-3; M-14; L-0; I-0 2b. Validity: H-6; M-8; L-0; I-3

Rationale:

- Developers provided results of reliability testing of the performance measure score from signal-to-noise analysis of HEDIS and DRP data for the health plans and clinician levels of analysis, respectively. For health plans, the median reliability was 0.98 for commercial health plans, 0.97 for Medicaid health plans, and 0.95 for Medicare health plans; for clinicians, the median reliability was 0.6. The Committee agreed that the testing results demonstrate sufficient reliability.
- To demonstrate validity of the performance measure score, developers correlated the scores for this measure to scores from several other diabetes measures. For health plans, the correlations were moderate to high, statistically significant, and in the expected directions; for clinicians, the correlations were low but for most part in the expected directions. The developer also noted that face validity of the measure was assessed by three internal groups.
- The Committee agreed that the exclusions to the measure were appropriate. However, members raised concerns about the reliability and validity of the measure due to the potential for rounding (discussed more fully under evidence). The Committee also noted that often the intake blood pressure reading is what is entered into EHRs, but if a lower blood pressure is observed later in the visit, this value may not be recorded in the EHR (or perhaps only in the physician's notes). The developer explained that the most recent reading in the measurement year is used, and if there are multiple readings in one day or visit, the lowest systolic and the lowest diastolic readings can be reported by the provider. However, the Committee noted that this level of selection would be difficult to implement in EHRs.

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

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

Rationale:

- The Committee agreed that given the measure is in use, it is feasible to collect the data. Members also agreed that the data elements are generated as part of the care delivery process.

4. Usability and Use: H-12; M-5; L-0; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

- The Committee agreed that the measure is in use in several accountability programs, including public reporting of health plan data.
- One member mentioned the lack in improvement in health plan performance over time; however, another member noted that physicians in the DNR have substantially higher rates than the health plans, suggesting that further improvement should be possible.
- The Committee voiced no concerns about potential unintended consequences of the measure.

5. Related and Competing Measures

- This measure is a competing measure to measure 0729: Optimal Diabetes Care, a composite measure that includes blood pressure control as one of its components.
- NQF staff asked the Committee to discuss whether there is justification for continued endorsement of this individual measure if the composite retains endorsement. The Committee discussed the pros and cons of endorsing both the individual measure and the composite measure. The Committee ultimately agreed that, while the composite measure is useful to assess patient-centric performance across a variety of clinical areas, endorsement of this individual measure also can be beneficial, particularly for users who want to focus on the blood pressure control components specifically or for those who have data collection constraints and cannot use the composite. The Committee therefore recommended continued endorsement of both the individual measure and the composite measure.

Standing Committee Recommendation for Endorsement: Y-14; N-3

6. Public and Member Comment

Comments received:

- One commenter supported the Committee's recommendation for endorsement of this measure.

0729 Optimal Diabetes Care

Submission |

Description: The percentage of adult diabetes patients who have optimally managed modifiable risk factors (A1c, blood pressure, statin use, tobacco non-use and daily aspirin or anti-platelet use for patients with diagnosis of ischemic vascular disease) with the intent of preventing or reducing future complications associated with poorly managed diabetes.

Patients ages 18 - 75 with a diagnosis of diabetes, who meet all the numerator targets of this composite measure: A1c less than 8.0, Blood Pressure less than 140 systolic and less than 90 diastolic, Statin use unless contraindications or exceptions, Tobacco-free (non-user) and for patients with diagnosis of ischemic vascular disease daily aspirin or antiplatelet use unless contraindicated.

Please note that while the all-or-none composite measure is considered to be the gold standard, reflecting best patient outcomes, the individual components may be measured as well. This is particularly helpful in quality improvement efforts to better understand where opportunities exist in moving the patients toward achieving all of the desired outcomes. Please refer to the additional numerator logic provided for each component.

Numerator Statement: Patients ages 18 to 75 with diabetes who meet all of the following targets from the most recent visit during the measurement year:

A1c less than 8.0, Blood Pressure less than 140/90, Statin Use if no contraindications/ exceptions, Tobacco non-user and Daily aspirin or anti-platelets for patients with diagnosis of ischemic vascular disease use unless contraindicated.

Denominator Statement: Patients ages 18 to 75 with diabetes who have at least two visits for this diagnosis in the last two years (established patient) with at least one visit in the last 12 months.

Exclusions: Valid exclusions include patients who only had one visit to the clinic with diabetes codes during the last two years, patients who were pregnant, died or were in hospice or palliative care, or a permanent resident of a nursing home during the measurement year.

Adjustment/Stratification:

Level of Analysis: Clinician : Group/Practice

Setting of Care: Ambulatory Care : Clinician Office/Clinic

Type of Measure: Composite

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

Measure Steward: MN Community Measurement

STANDING COMMITTEE MEETING [01/22/2015] / [01/28/2015]

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

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: H-5; M-11; L-0; I-1; 1b. Performance Gap: H-15;

1d. Composite – Quality Construct and Rationale: H-4; M-7; L-4; I-1

Rationale:

- For all but one of the components included in this composite (tobacco-free), the developer presented recommendations from the 2014 clinical practice guidelines developed by the Institute for Clinical Systems Improvement (ICSI), which were based on a systematic review of evidence that was graded either high or moderate. Additional evidence-based recommendations from the American College of Cardiology and U.S. Preventive Services Task Force also were presented. Committee members agreed that the evidence supports the relationship between each component and desired health outcomes.
- Data provided by the developer indicate that for 2014, only 38.9% of diabetic patients in Minnesota met all five component targets from the composite measure. Committee members agreed that although

performance on some of the components is quite high, overall performance indicates opportunity for improvement.

- Although some Committee members voiced concern over the "all-or-none" structure of the measure others agreed that a more comprehensive measure that focuses on management of multiple risk factors is needed. The Committee agreed that the developer description of the quality construct, rationale, and aggregation and weighting approach is explicitly articulated and logical.

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-9; M-7; L-0; I-0; 2b. Validity: H-1; M-10; L-4; I-1; 2d. Composite: H-1; M-10; L-4; I-1

<u>Rationale</u>:

- Committee members noted that the specifications of the statin component of this measure have changed since the most recent endorsement of the measure due to changes in the ACC/AHA clinical practice guidelines cholesterol management released in November, 2013 In the earlier version of the measure, the statin component assessed reaching a target LDL < 100; the revised version of this component assesses statin use.
- Committee members questioned whether the measure assesses if a patient is on the appropriate statin dose. Developers clarified that the measure does not consider the statin dose but assesses only if a patient is on a statin.
- Members also questioned the age range of 18-75 for the statin component of the measure. The developer clarified that for patients 21-39 years of age, this component is applicable only if the patient has ischemic vascular disease or a very high LDL, in accordance with the ACC/AHA guidelines.
- The developer clarified that the level of analysis for the measure is clinician groups (not individual clinicians), and also noted that multiple clinics may form a clinician group. They also clarified that the measure does not require having a minimum of 30 patients.
- Developers presented results of signal-to-noise reliability testing of the performance measure score. They clarified that the beta-binomial method was used for the reliability testing because the composite score itself is a binary (yes/no) measure. Members agreed that the reliability was high in general, although they noted that it was lower than 0.7 for some clinician groups.
- To demonstrate validity of the performance measure score, developers examined the association between the scores for this measure with the scores from the Optimal Vascular Care measure (NQF #0076), hypothesizing that clinician groups likely provide similar quality of care to different patients who also require management of multiple risk factors. The R^2 value from this analysis was 0.64. The developers also described several steps occurring during the data submission process as demonstration of empiric validity testing at the data level element.
- Developers also clarified that the measure is risk-adjusted for three factors (insurance type, age group, and diabetes type) and noted that the risk-adjustment strategy was developed using data from all clinicians in Minnesota. However, one member expressed some concern that the only adjustment for sociodemograhic status is insurance type. Developers clarified that other potential risk factors that were considered were not statistically significant and thus were not included in the risk-adjustment model.
- Several Committee members voiced concern about holding physicians accountable for the patient's tobacco use, as some see actual tobacco use (as opposed to efforts for tobacco cessation) as out of the control of the clinician. However, another member referred to data showing that physicians can influence their patients to stop tobacco use. Developers also noted that statewide, they have seen an approximate 2.5% increase in tobacco-free patients in MN.
- One Committee member noted the need for clarity about potential adverse effects related to statin use. Another member referenced the flow diagram provided by the developer that details several contraindications for statin use, while another member echoed the importance of the potential for adverse reactions when making treatment decisions.

- After developers clarified the performance rates for each of the components, Committee members questioned whether the aspirin component (performance rate =99.5% in MN) is needed in the composite. Developers noted that while this component may be "topped out" in MN, this happened over a four-year period of focus on this component. They also referenced a *New England Journal of Medicine* article that found a 34.8% performance rate nationally in the primary care setting. Finally, they noted that performance on this component across ACOs nationally is, on average, 75.3%.

3. Feasibility: H-7; M-4; L-4; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

Rationale:

- The measure data can be collected through electronic clinical data and paper records.
- One Committee member noted that the data collection effort for this composite measure may be intensive, due to the number of components included in the composite. Developers noted that submission of this measure by all clinician groups in MN is mandated by the state. While they acknowledged that MN has many large practices that use EHRs, small practices—even those who still use paper medical records—are able to submit data on this measure. They did, however, acknowledge the data collection burden for the new statin component if a patient has not been prescribed a statin (i.e., identifying exceptions due to contraindications).

4. Usability and Use: H-5; M-7; L-4; I-0

((Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

- Committee members noted that the measure is publicly reported and is used in pay-for-performance and accreditation programs. Performance is slowly increasing across the state of Minnesota, suggesting quality of care may be improving.
- Data submitted by the developer demonstrate relatively consistent improvement of performance in MN from the years 2006-2014.
- Committee members agreed that this composite measure is patient-centric and acknowledged the importance of using a comprehensive measure that assess performance of reduce multiple risk factors.
- Some committee members expressed concern that the measure could incent some providers to "cherry-pick" patients or make their practices less hospitable to certain patients or certain subgroups of patients (the tobacco-free component of the measure was a particular concern).

5. Related and Competing Measures

- This measure is a competing measure to the following measures
  - 0061: Comprehensive Diabetes Care: Blood Pressure Control (<140/90 mm Hg).
  - 0575: Comprehensive Diabetes Care: Hemoglobin A1c (HbA1c) control (<8%)
- NQF staff asked the Committee to discuss whether there is justification for continued endorsement of the individual measures if the composite retains endorsement. The Committee discussed the pros and cons of endorsing both individual measures and the composite measure. The Committee ultimately agreed that while the composite measure is useful to assess patient-centric performance across a variety of clinical areas, endorsement of individual measures also can be beneficial, particularly for users who want to focus on certain components of the composite or those who have data collection constraints and cannot use the composite. The Committee therefore recommended continued endorsement of both the individual measures and the composite measure.

Standing Committee Recommendation for Endorsement: Y-13; N-4

6. Public and Member Comment

Comments received:

- Two commenters raised concern over the glucose control component of the composite, referencing the National Action Plan for Adverse Event Prevention, which was released in August, 2014. The National Action Plan states that the blood glucose threshold of <8% for patients <75 years of age does not conform to glycemic control guidelines from the American Diabetes Association, Department of Veterans Affairs, Department of Defense, and American Geriatrics Society (i.e., by excluding certain patients such as those with limited life expectancy or with certain co-morbid conditions, or by stratifying according to medication type).

  Developer response: According to the Institute for Clinical Systems Improvement (ICSI) 2014 Guidelines for Diabetes there is high quality evidence and a strong recommendation in support of an A1c target of less than 8.0. Excerpt from the guideline is as follows: Algorithm Annotation #4- Glycemic Control and A1c Goals. Recommendation: A clinician should personalize goals with patients diagnosed with T2DM to achieve glycemic control with a hemoglobin A1c < 7% to < 8% depending on individual patient factors. Benefits: Achieving near-normal glycemic control lowers risk of diabetes microvascular complications such as retinopathy, nephropathy and amputations. Achieving A1c of 6.9 to 7.9% may also significantly reduce macrovascular complications based on Steno-2 and UKPDS data. Quality of Evidence: High Strength of Recommendation: Strong. Measurement does not and should not preclude good clinical judgement; however the measure development work group believes that a target of < 8.0 is reasonable and supported by guidelines. Our measure does have an upper age limit cut-off of 75 years and we allow exclusions for death, permanent nursing home resident or patients who are receiving hospice or palliative care services.
- Two commenters were critical of the composite measure itself, citing concern that use of the composite measure could mask the individual care processes that most need improvement.

  Developer response: While it is true that the measure is reported at the composite level, the individual components and the associated rates are available to the medical groups for better understanding their rates and for use in quality improvement to know which areas have opportunity for improvement. MNCM and the measure development work group firmly believe that achieving the intermediate physiological outcome targets related to blood pressure and glycemic control in addition being tobacco free and use of daily aspirin and statins where appropriate are the diabetic patient's best mechanisms of avoiding or postponing long term complications associated with this chronic condition which affects millions of Americans. Measuring providers separately on individual targets is not as patient centric as a measure that seeks to reduce multiple risk factors for each patient. Diabetic patients are more likely to reduce their overall risk and maximize health outcomes by achieving several intermediate physiological targets.
- Two commenters noted that documenting HbA1c levels >8% but less than 9% cannot be done using CPT-II coding, necessitating need for medical chart review.

  Developer response: A point of clarification, these measure do not rely on CPTII codes for numerator compliance, nor are they indicated anywhere in our measure specification. Measure specifications focus on the electronic health record as a source of clinical information for calculating numerator compliance; actual A1c values are utilized in the case of the A1c target. Additionally, 80 to 90% of all the clinics in MN are reporting this information from their electronic health records without the need for additional chart abstraction.
- One commenter suggested a need for including sociodemographic factors in the risk-adjustment approach.

  Developer response: Our risk adjustment model does include insurance product which is a proxy for socioeconomic status. During the process of measure development, the expert panel discusses potential variables for risk adjustment that are important to consider for the measured population. For this measure, variables that are available for evaluation include gender, age, zip, race/ethnicity, country of origin, primary language, insurance product, diabetes type, depression and ischemic vascular disease. The potential risk adjustment variables are then evaluated for appropriate inclusion in the model based on a t value outside the range of -2.0 and +2.0. Currently, the variables that have demonstrated acceptable properties are insurance product, age bands (18-25, 26-50, 51-65 and 65 to 75) and diabetes type (1 or 2).

Race/ethnicity has been collected for this measure in MN for the past few years, but has now reached a level of reliability in which it can be evaluated for its impact. MNCM continues to review variables and their impact on the measure and part of its measure risk adjustment strategy.

One commenter suggested the need for additional detail regarding moderate or high intensity in the description of statin use for the measure.

Developer response: The measure development work group thoroughly discussed the pros and cons of specifying a certain dose of the statin medication and based on the following factors ultimately decided to not specify a dose of moderate or high intensity for numerator compliance: 1) data burden for practices, 2) controversy and burden surrounding the CV risk calculator, 3) ICSI 2014 Diabetes Guideline recommendations for measurement and 4) cardiology work group member's believe that there is some benefit for some patients who can only tolerate a lower intensity dose.

Committee response: During its review of the individual measure assessing HbA1c<8% in the spring of 2014 (#0575), the Committee considered 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). During their discussion of this measure, members specifically noted that for some patients (e.g., frail elderly patients, those with limited life expectancy,) HbAc1 values slightly above 8% might be reasonable and that target HbA1c values for such patients should be individualized. In their more recent evaluation of the composite measure (#0729) in January 2015, the Committee considered the 2014 clinical practice guideline recommendations from the Institute for Clinical Systems Improvement, which suggest a target threshold of <7% - <8%, depending on patient factors. The Committee acknowledged that the <8% threshold may not be appropriate for all patients but they agreed that the 8.0% cutoff was a reasonable target for a national healthcare performance measure and that 100% performance on the measure is not expected. The Committee also noted that measure #0729 includes an the upper age limit of 75 and excludes patients who died, are permanent nursing home residents, or are receiving hospice or palliative care services, which addresses at least some of the concerns voiced by the commenters. Finally, the Committee strongly recommended development of performance measures that assess occurrence and severity of hypoglycemia in the outpatient setting.

Committee response: Use of an all-or-none scoring approach does not hinder providers from tracking performance of the individual components of the composite and instituting appropriate improvement initiatives. Moreover, use of such composite measures is a patient-centric approach that allows providers to assess their success in reducing multiple patient risk factors across a variety of clinical areas.

Committee response: The Committee acknowledged NQF's recent policy change that has lifted the prohibition against including sociodemographic factors in risk-adjustment for outcome, resource use, and other quality measures. The Committee agreed that insurance type, which is included in the risk-adjustment model for this measure, can be considered a proxy for sociodemographic status. The Committee also accepted the developer's explanation that other potential sociodemographic factors were considered for inclusion in the measure's risk-adjustment approach but ultimately were not included because they were not statistically significant.