NATIONAL QUALITY FORUM

Memo

TO: Consensus Standards Approval Committee (CSAC)

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

RE: Appeal on Endocrine Measure

DA: September 1, 2015

In accordance with the NQF Consensus Development Process (CDP), the measures recommended by the NQF Endocrine Standing Committee for cycle 3 of the project were released for a 30-day appeals period, which closed on July 30, 2015. NQF received one letter of appeal on behalf of the Veterans Health Administration; the appeal is pertinent to measure #0729 (Optimal Diabetes Care). Measure #0729 is an all-or-none composite that assesses the percentage diabetes patients ages 18 to 75 who have optimally-managed modifiable risk factors (HbA1c <8%; blood pressure <140/90; statin use, tobacco non-use, and daily aspirin or anti-platelet use for patients with diagnosis of ischemic vascular disease).

The following documents are appended to this memo:

1. **Appendix A** - Appeal Letter: 0729 Optimal Diabetes Care
2. **Appendix B** - Response from measure developer
3. **Appendix C** - Measure evaluation summary table

CSAC ACTION REQUIRED

The CSAC will review the letter of appeal, the response submitted by the developer, and this memo in consideration of the appeal. The CSAC will determine whether to uphold the endorsement decision or uphold the appeal for the measure.

Summary of Issues Raised in the Appeal

The appellants submitted an appeal specific to the HbA1c component of the measure. The issues raised in the appeal include:

- Application of the <8% threshold will expose patients 65-75 years of age to the risk of adverse drug events, especially, but not limited to, hypoglycemia, without significant health benefits.
- Reliance upon the Institute for Clinical Systems Improvement (ICSI) guidelines has resulted in a compromised evidence review that is not consistent with the position of the DHHS National Action Plan for Prevention of Adverse Drug Events. The appellants argue that the ICSI guidelines presented by the developers are not as explicit in addressing older, more vulnerable populations and in identifying risk factors that justify A1c values greater than 8%.
- The exclusions specified in the measure (death, permanent nursing home placement, receipt of hospice or palliative care services) are not consistent with American Diabetes Association, American Geriatric Society, and VA/DoD guidelines, which recommend multiple exclusion criteria for a <8% target, including life expectancy less than 5 years, risk factors for

hypoglycemia, prior hypoglycemia, food insufficiency, issues of health literacy and numeracy, etc.

- Use of insurance type as one of the factors included in the risk-adjustment approach cannot adequately address research findings indicating that low health literacy and low socio-economic status is associated with risk of hypoglycemia among those who have insurance. The appellant also noted that food insufficiency is an increasingly recognized issue.
- Concerns about the accuracy of A1c testing results
- Lack of a balancing measure for high-risk patients

Summary of the Developer Response:
The developer addressed each of the issues raised by the appellant. They specifically included information about the blood glucose control guidelines from the American Diabetes Association, the American Geriatrics Society, and the Veterans Administration/Department of Defense. They also provided a brief discussion of the evolution of the measure as clinical practice guidelines changed, as well as information about their experience with the measure in Minnesota over the last decade.

Summary of the Evaluation:
Both the VHA and CMS raised concern over the glucose control component of the composite during the public and member commenting period, and both referenced the National Action Plan for Adverse Event Prevention. In their discussion of the comments during the post-comment call, the Endocrine Standing 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 briefly discussed the exclusions to the measure and recommended development of measures to assess occurrence and severity of hypoglycemia in the outpatient setting. The Committee did not discuss testing accuracy during the post-comment call, nor did they have additional discussion of the risk-adjustment approach.

Only six NQF members voted on the measure, but all six were in favor of the measure. The <8% threshold issue for older patients was specifically discussed by the CSAC during its review of the measure. The CSAC voted unamiously to approve the measure.

Additional details of the measure evaluation are included in Appendix C.

Appendix A – Veterans Health Administration Appeal Letter

1. **APPELLANT INTERESTS:**

The Veterans Health Administration (VHA) is submitting an appeal of the <8% A1c component of the National Quality Forum-endorsed (NQF) composite measure 0729, directly applicable to patients 65-75 years of age and older (although not included in the measure). We note that the VHA is the largest integrated health care system in the United States, and applying the NQF measure to the Veteran population is not consistent with other national guidelines, including our own evidence-based guidelines, and will result in potential overtreatment in a substantial number of patients, placing several hundred thousand Veterans at risk for adverse drug events. There were about 1,500,000 Veterans with diabetes, or about 25% of nearly 6,000,000 Veterans receiving care in the VHA in 2013. About 40% were 60-69 years of age, and about 10% 70-74 years of age. Of this group, 50% had moderate or severe disability, 60% had at least one serious co-morbid condition, and 60% had one or more serious co-morbid conditions such as cognitive impairment, chronic kidney disease, advanced diabetes complications, and other significant medical illnesses. Many of these co-morbid conditions and/or complications will limit life expectancy to <5 years. Although the percent with food insufficiency is not known, about 25% are considered "poor" based upon VHA priority enrollment status. Thus, our great interest in this measure is that the VHA is directly responsible for the care of hundreds of thousands of Veterans with diabetes who are, or shortly will be, impacted by the <8% measure. Our sole interest is in providing the highest quality care to these Veterans. In doing so, we want to apply the strongest evidence, such that treatment goals are risk-stratified, patient-centered, and appropriately balance risks and benefits.

VHA previously submitted public comment as to why a <8% measure without additional clinical exclusion criteria and stratification for medications was inappropriate and inconsistent with the Department of Health and Human Services (DHHS) National Action Plan for Prevention of Adverse Drug Events (Diabetes Agents), which was co-led by the VHA and the Center for Medicare and Medicaid Services (CMS). CMS has also submitted a public comment arguing against the <8% measure.

The VHA, upon review of the Consensus Standards Approval Committee (CSAC) of the NQF, is filing an appeal because the agency position is that neither the measurement Developers (Minnesota) nor the Committee were responsive to our previously submitted public comments. The VHA reiterates that applying the <8% measure will expose many Veterans to the risk of adverse drug events, especially but not limited to hypoglycemia, without significant health benefits. We ask the NQF leadership to specifically address the VHA concerns that the reliance upon the Institute for Clinical Systems Improvement (ICSI) guidelines has resulted in a compromised evidence review that is not consistent with the position of the DHHS National Action Plan for Prevention of Adverse Drug Events (Diabetes Agents), and to also address the Department of Veterans Affairs (VA) and CMS public comments. Additionally, we ask NQF leadership to specifically address the fact that the Clinical Advisory Committee National Glycosylated Standardization Program, which oversees A1c proficiency in the United States, have repeatedly raised the issue of A1c testing accuracy, even from most higher-quality clinical laboratories. The Program focuses particularly on the fact that a single laboratory result of 8% can be within 0.5% of the reported result (that is, 7.5% to 8.5%). Point of care cannot be evaluated. This fact is included in the National Institutes of Health (NIH) Clearing House materials for patients as well as the DHHS National Action Plan, but is not widely communicated to the public.

With these considerations in mind, we note the following comments from the Developer and the Committee (from the CSAC minutes), and their respective VHA responses.

2. **EVIDENCE:**

Developer Comment: Thank you for your comments. According to the 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.

Committee Comment: In their more recent evaluation of this composite measure (0729) in January 2015, the Committee considered the 2014 clinical practice guideline recommendations from the ICSI, which suggest a target threshold of <7% to <8%, depending on patient factors.

VHA Comment: The ICSI guideline is not as explicit as other major national guidelines in addressing older, vulnerable populations and in identifying risk factors that justify A1c target values greater than 8%. We also note the American Geriatric Society recommendation to "avoid using medications other than metformin to achieve hemoglobin A1c <7.5% in most older adults; moderate control is generally better" for most persons with diabetes over 65 (http://www.choosingwisely.org/clinician-lists/american-geriatrics-society-medication-to-control-type-2-diabetes/).

The Developers appear to generalize the benefit of A1c lowering from 7.9% to 6.9% based upon UKPDS (patients with new onset diabetes, average age 51) and the Steno 2 Study, which had a small number of patients with a multi-factorial risk approach that addressed cardiovascular mortality as the primary outcome. These studies cannot be generalized to an older population with frequent co-morbid conditions, most of whom were not eligible for ACCORD, ADVANCE, or VADT. Indeed, the absolute benefit of significant progression of significant microvascular complications over 5 years in VADT, ACCORD, and ADVANCE is minimal for tighter control compared to A1c values of 7.5% to 8.4%, supporting the American Geriatric Society recommendations. While the individual decision should be a matter of patient preference guided by professional advice, the VADT, ACCORD and ADVANCE support moderate control for older patients with co-morbid conditions who are already on medications, especially insulin. Also, and this is a key point given the accuracy of the A1c test (see below), a target value is the average achieved over a long period time—years. In other words, A1c is expected to vary around the target given the accuracy of the A1c test as well as patient factors.

The ICSI guideline also does not explicitly address patient preferences, prior hypoglycemic events, and socio-demographic factors such as low socio-economic status, food insufficiency and low health literacy. The VHA therefore contends that the review of the evidence presented by the Developers to support the <8% measure for all patients with diabetes 65-75 years of age is inaccurate and potentially harmful.

3. **PATIENT-CENTERED CARE/PATIENT PREFERENCE:**

Developer Comment: 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 cutoff of 75 years and we allow exclusions for death, permanent nursing home residents or patients who are receiving hospice or palliative care services.

Committee Comment: The Committee acknowledged that the <8% threshold may not be appropriate for all patients, but agreed that the 8% cutoff was a reasonable target for a national health care performance measure and that 100% performance on the measure is not expected. The Committee also noted that measure 0729 includes an 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.

VHA Comment: Both VHA data (Tseng et al., JAMA-Internal Medicine, 2014) and National Population Weighted Data (Lipska et al., JAMA-Internal Medicine, 2015) indicate that about 60% of the respective populations have serious co-morbid conditions. Many of these individuals could reasonably have a target value above 8% based upon American Geriatric Society, American Diabetes Association, and VA/Department of Defense (DoD) guidelines, especially if they are already taking agents that may predispose to hypoglycemia, such as insulin or sulfonylurea therapy. This represents a large proportion of both populations.

The argument that 100% performance is not expected provides us with little solace. The issue is whether or not the <8% measure, as applied to the 65-75-year-old population, should have appropriate exclusions, as recommended by the DHHS National Action Plan, the VA and CMS, to avoid incentivizing inappropriate care for individual patients that can result in harm. If exclusions are included, then the NQF notes that the "exclusions are supported by the clinical evidence; otherwise, they are supported by evidence of sufficient frequency of occurrence to the point that results are distorted without the exclusion (http://www.qualityforum.org/docs/measure_evaluation_criteria.aspx).

The current measure exclusion criteria of death, hospice or palliative care, is so restrictive that it cannot be considered concordant with other major guidelines. Professional guidelines, including the American Diabetes Association, American Geriatric Society, VA/DoD, all recommend multiple exclusion criteria for a <8% target, including life expectancy less than 5 years, risk factors for hypoglycemia, prior hypoglycemia, food insufficiency, issues of health literacy and numeracy, etc. They note that values can be slightly above 8% to less than 9%. We strongly disagree with the Committee that this highly limited set of exclusion criteria addresses our concerns. Therefore, the measure has the unintended consequence of incentivizing intensification of therapy in circumstances when it is of minimal benefit and exposes patients to potential risk.

4. **SOCIO-DEMOGRAPHIC FACTORS:**

Additionally, neither the Developers nor the Committee addressed socio-demographic factors.

Committee Comment: The Committee acknowledged NQF's recent policy change that has lifted the prohibition against including socio-demographic 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 socio-demographic status. The Committee also accepted the Developer's explanation that other potential socio-demographic factors were considered for inclusion in the measure's risk adjustment approach, but ultimately were not included because they were not statistically significant.

VHA Comment: Several papers from the Diabetes Study of Northern California (DISTANCE) indicate that despite having insurance, low health literacy was common and associated with risk of hypoglycemia (Sakar UJ, Gen Med, 2010), as was having low socio-economic status (Berkowitz SA et al., J Health Care Poor Underserved, 2014). Clearly, insurance type cannot address these patient factors. We note that universal health literacy is a cornerstone of prevention of hypoglycemic events.
Additionally, food insufficiency is an increasingly recognized issue (Seligman HK et al., Health Aff [Millwood], 2014; Berkowitz SA et al., Health Serv Res., 2013).
Failure to address these issues places many high-risk older Veterans at risk for hypoglycemia from intensification of therapy, especially with insulin.

5. **A1c TEST ACCURACY:**

The CMS public comment noted concerns over the accuracy of A1c Point of Care testing that are not addressed by the Committee.

VHA Comment: The Committee did not address this concern. The Developer did not address the inaccuracy of the A1c test in everyday practice, especially the use of Point of Care testing. According to the National Glycosylated Standardization Program (NGSP), 60% of all clinical laboratories use an assay with coefficient of variation (CV) of <3% at all levels of A1c tested. At that level of CV, a reported A1c level of 8% would fall between 7.5% to 8.5% with 95% confidence (19 out of 20 times), and 7.76% to 8.24% with 67% confidence (13 out of 20 times). Point of Care A1c tests, which are CLIA waived, are even more inaccurate. Therefore, using a single A1c value that is within the range of laboratory variation, especially if marginally elevated, as a high-stakes measure of clinical performance will not be of benefit to most patients.

This issue has been discussed for many years by the Clinical Advisory Committee of the NGSP, chaired by the Centers for Disease Control. However, while the NIH Diabetes Clearing House has publicized this issue, clinical laboratories have not. In contrast, the VHA recently issued a memorandum that would eliminate "target levels" from A1c laboratory reports and require VHA clinical laboratories to publicize the CV of their tests. The objective is to educate all clinicians, as well as Veterans, on the interpretation of the A1c test, consistent with a national health numeracy and literacy approach.

6. **LACK OF A BALANCING MEASURE:**

Committee Comment: Finally, the Committee strongly recommended development of performance measures that assess occurrence and severity of hypoglycemia in the outpatient setting.

VHA Comment: The failure to have an over-treatment measure that balances the under-treatment measure allows vulnerable patients to be over-treated yet still meet the <8% measure. This assertion is also supported by DHHS. In a recent VA Health Research-funded VA study presented at the 2015 American Diabetes Association (Pogach et al.), about 63% of Veterans who were 65-75 years of age and on insulin or sulfonylurea treatment and with dementia or chronic kidney disease had A1c <8%; 49.5% of those had A1c <7%. Thus, meeting the <8% measure includes a substantial number of patients who are at increased risk of serious hypoglycemia from potential over-treatment. This underscores the position of DHHS that without a balancing measure for high-risk patients, a high level of achievement of less than <8% measure may be masking potentially harmful care. The VHA has initiated a national Hypoglycemic Safety Initiative to address over-treatment (http://www.va.gov/opa/pressrel/pressrelease.cfm?id=2666).

Date: Thursday, August 27, 2015

To: National Quality Forum
Consensus Standards Advisory Committee (CSAC)

From: MN Community Measurement
Measure Steward for # 0729 Optimal Diabetes Care
Collette Pitzen, RN BSN CPHQ, Clinical Measure Developer
Jasmine Larson, MBA CPHQ, Manager Healthcare Measure Development

Re: Appeal Process/ Response to Comments Measure #0729 Optimal Diabetes Care

Greetings,

Thank you for the opportunity to respond to and participate in the continued discussion of the A1c component of Optimal Diabetes Care, a patient level all-or-none composite measure. MN Community Measurement (MNCM), received notice of the appeal submitted by the Veterans Health Administration (VHA) on August 18, 2015, the full text of which can be found at www.qualityforum.org.

We understand and appreciate the concerns expressed by the commenter and would like to respond to several points related to the A1c target of less than 8.0%, as well as provide some additional information about our experience with this measure in Minnesota over the last decade.

MNCM is a non-profit organization whose mission is to accelerate the improvement of health through public reporting, with community stakeholder involvement in all levels of our organization, including our consensus based measure development processes.

MNCM and the Diabetes Measure Development Work Group firmly believe that patients with diabetes are more likely to reduce their overall risk and maximize health outcomes by simultaneously achieving several intermediate physiological outcomes (blood pressure, glycemic control, tobacco free) in addition to the appropriate use of aspirin/ antiplatelets and statins. Achieving all of these goals represents the patient's best chance of avoiding or postponing long term complications associated with this chronic condition that affects millions of Americans. A recent study concluded that patients, whose diabetes was optimally controlled, as defined by the MNCM Optimal Diabetes Care measure, were associated with decreased morbidity and mortality. Patients whose diabetes was not optimally managed had increased risks of adverse health outcomes, including hospitalization [Hazard Ratio (HR) 1.11], ED visits [HR 1.15] and mortality [HR 1.29]. *[Health outcomes in diabetics measured with Minnesota Community Measurement Quality Metrics. Takahashi, Paul Y et al Diabetes, Metabolic Syndrome and Obesity: Targets and Therapy 2015:8 1–8]*

History

This measure was originally developed by HealthPartners in 2003, and MNCM accepted the stewardship of this measure in 2007. Since that time, we have responded in a nimble fashion to changing guidelines over the years; redesigning measure components related to A1c (ACCORD), blood pressure (JNC) and cholesterol management (ACC/AHA).

In 2007, the A1c target was less than 7.0%, in accordance with the current guidelines at that time. With the publication of ACCORD study results (2008/2009) that demonstrated a potential increased risk of mortality with very intense glucose control (A1c < 6.0%), MNCM convened a team of experts for redesign of the A1c component. The work group recognized that many patients could benefit from and safely manage a target A1c of less than 7.0%; however there are patients who are at higher risk who cannot tolerate a target of less than 7.0% and should be managed to less than 8.0%.

The work group explored redesigning the A1c component by tiering the target; less than 7.0% for most patients or, if high risk conditions are present, a target of less than 8.0%. The work group concluded that many of the high risk conditions, particularly those related to hypoglycemia and limited life expectancy, do not have clear cut, objective definitions that can be translated to measure specifications for the purpose of exclusion or alternate targets. In fact, the Department of Health and Human Services (DHHS) National Action Plan for Prevention of Adverse Drug Events specifically addresses the lack of agreed upon definitions and supporting coding structures to identify and classify hypoglycemia (Figure 13, page 105). Ultimately, the work group recommended a measurement target of A1c less than 8.0% for all patients.

Of additional importance, providers in Minnesota, who have been held accountable for this measure since its design and implementation, have a number of opportunities to provide feedback and criticism. MNCM serves as a sub-contractor to the Minnesota Department of Health (MDH) in the implementation of Minnesota's Health Care Reform legislation. As part of this work, MNCM participates in the annual rule making process for mandated state-wide quality reporting by physician based practices. As part of rule-making, there are multiple opportunities annually for stakeholders to provide public comment. Additionally, MNCM and MDH hold public forums where the community can ask questions and voice concerns regarding the draft and final rule. In the seven year history of rule-making that has included mandated reporting of the Optimal Diabetes Care measure, not a single organization or individual has expressed concern regarding the A1c target of less than 8.0%. Minnesota providers continue to agree that a target of less than 8.0% is reasonable for performance measurement purposes.

Measurement does not and should not preclude good clinical judgement. This is a measure of optimal management of the modifiable risk factors that have the greatest potential impact to reduce long term complications for patients with diabetes. It is understood that individual patient factors are going to influence personalized goals for glycemic control for individual patients, and as such, risk adjustment is applied to the measure results using age categories (ages 18-25, 26-50, 51-65 and 66-75) and type of diabetes. The measure is constructed with a target of less than 8.0% to acknowledge the balance between benefits and harms and is supported by a number of guidelines, as described in the following paragraphs.

Guidelines

Institute for Clinical Systems Improvement (ICSI)

ICSI champions the use of evidence-based medicine. The cornerstone of its work is enlisting clinicians from its membership to perform rigorous reviews of current scientific literature and develop evidence-based guidelines and protocols on a number of health conditions. These guidelines and protocols enable clinicians in 180 countries to practice best medicine. www.icsi.org.

The complete ICSI guideline for diabetes, its references and the evidence table of the literature reviewed and included in the creation of the guideline can be accessed on ICSI's website via the links provided.

Specific recommendations for glycemic Control are as follows:

> *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. [Quality of evidence: High, Strength of Recommendation: Strong]*
>
> *For patients with T2DM, an A1c goal of less than 8% may be more appropriate than an A1c goal of less than 7%, when including the following factors:*
>
> - *Known cardiovascular disease or high cardiovascular risk, and may be determined by the Framingham or ACC/AHA Cardiovascular Risk Calculator, or alternatively as having two or more cardiovascular risks (BMI > 30, hypertension, dyslipidemia, smoking and microalbuminuria)*
> - *Inability to recognize and treat hypoglycemia, including a history of severe hypoglycemia requiring assistance*
> - *Inability to comply with standard goals, such as polypharmacy issues*
> - *Limited life expectancy or estimated survival of less than 10 years.*
> - *Cognitive impairment*
> - *Extensive comorbid conditions such as renal failure, liver failure and end-stage disease complications*

Glycemic Control and A1c Goals

Recommendation	Quality of Evidence and Strength of 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.	Quality of Evidence: High Strength of Recommendation: Strong
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. **Harms:** Near-normal glycemic control (A1c around 6.4 to 6.5%) achieved through intensive pharmacotherapy appears to have less benefit for major CV events (ACCORD ADVANCE VADT) and in one large trial significantly increased mortality 20% (ACCORD). In some patients, aggressive pharmacotherapy with insulin, sulfonylureas or certain other agents may lead to weight gain and severe hypoglycemia. The long-term cardiovascular safety of agents other than metformin and human insulins has yet to be established. **Benefits-Harms Assessment:** Therefore, to optimize the balance between benefits and harms for a given patient, personalization of glycated hemoglobin (A1c) goals in the range of < 7% to < 8% is recommended.	
Relevant Resources: *Hemmingsen, 2013; Callaghan, 2012; Action to Control Cardiovascular Risk in Diabetes Study Group 2008, 2011; ACCORD, 2010b; Ismail-Beigi, 2010; Duckworth, 2009; NICE – Sugar Study Investigators, The, 2009; Ray, 2009; Turnbull, 2009; ADVANCE, 2008; Gaede, 2008; Holman 2008a; Vadt, 2008*	

MNCM disagrees with the commenter's assertion that reliance on the ICSI guidelines in the development of the Optimal Diabetes Care measure has resulted in a compromised evidence review. MNCM does not rely solely on the ICSI guidelines in the construction of its measures. As part of MNCM's stewardship role, we routinely review national guidelines and, when necessary, convene the measure development work group to respond to significant changes in evidence that may impact the reliability and validity of an existing measure.

Further guideline support for the measure construct is included below.

American Diabetes Association

The American Diabetes Association (ADA) recommends an A1c target of less than 7.0% for non-pregnant adults with diabetes. [B] Furthermore, the ADA goes on to provide additional guidance for individualized goal setting:

> *More [C] or less [B] stringent glycemic goals than 7.0% may be appropriate for individual patients. Goals should be individualized based on duration of diabetes, age/life expectancy, comorbid conditions, known CVD or advanced microvascular complications, hypoglycemia unawareness, and individual patient considerations.* (pg. S37, Table 6.2, 2015 ADA Standards of Care)

Older Adults

The table provided below includes ADA's recommendations for glycemic control in older adults and the relationship to the MNCM diabetes measure construct for the A1c component. (pg. S67 – S68 2015 ADA Standards of Care)

Patient Characteristics/ Health Status	Rationale	Reasonable A1c Goal ‡	MNCM Comments regarding A1c Target less than 8.0%
Healthy (few coexisting chronic illnesses, intact cognitive and functional status)	Longer remaining life expectancy	less than 7.5%	A1c goal aligns with measure component construct
Complex/intermediate (multiple coexisting chronic illnesses* or 2+ instrumental ADL impairments or mild-to moderate cognitive impairment)	Intermediate remaining life expectancy, high treatment burden, hypoglycemia vulnerability, fall risk	less than 8.0%	A1c goal aligns with measure component construct
Very complex/poor health (long-term care or end stage chronic illnesses** or moderate-to-severe cognitive impairment or 2+ ADL dependencies)	Limited remaining life expectancy makes benefit uncertain	less than 8.5%†	Allowable exclusions for permanent nursing home resident (long term care), hospice or palliative care services

This represents a consensus framework for considering treatment goals for glycemia, blood pressure, and dyslipidemia in older adults with diabetes. The patient characteristic categories are general concepts. Not every patient will clearly fall into a particular category. Consideration of patient and caregiver preferences is an important aspect of treatment individualization. Additionally, a patient's health status and preferences may change over time. ADL, activities of daily living.

‡A lower A1C goal may be set for an individual if achievable without recurrent or severe hypoglycemia or undue treatment burden.

*Coexisting chronic illnesses are conditions serious enough to require medications or lifestyle management and may include arthritis, cancer, congestive heart failure, depression, emphysema, falls, hypertension, incontinence, stage 3 or worse chronic kidney disease, myocardial infarction, and stroke. By "multiple," we mean at least three, but many patients may have five or more (6).

**The presence of a single end-stage chronic illness, such as stage 3–4 congestive heart failure or oxygen-dependent lung disease, chronic kidney disease requiring dialysis, or uncontrolled metastatic cancer, may cause significant symptoms or impairment of functional status and significantly reduce life expectancy.

†A1C of 8.5% equates to an estimated average glucose of 200 mg/dL. Looser glycemic targets than this may expose patients to acute risks from glycosuria, dehydration, hyperglycemic hyperosmolar syndrome, and poor wound healing.

Older adults who are functional and cognitively intact and have significant life expectancy should receive diabetes care with goals similar to those developed for younger adults. E

Glycemic goals for some older adults might reasonably be relaxed, using individual criteria, but hyperglycemia leading to symptoms or risk of acute hyperglycemic complications should be avoided in all patients. E

The ADA further addresses hypoglycemia with the following strong recommendation:

> *Insulin treated patients with hypo-glycemia unawareness or an episode of severe hypoglycemia should be advised to raise their glycemic targets to strictly avoid further hypoglycemia for at least several weeks in order to partially reverse hypoglycemia unawareness and reduce risk of future episodes.[A]* (pg. S38)

Of significant note, this adjustment in treatment and goals is recommended for several weeks, and not a recommendation for a permanent adjustment of the glycemic target. Hypoglycemia has the potential to impact a patient's control of their diabetes and their quality of life, but the appropriate clinical approach to managing hypoglycemia is not a long-term relaxation of glycemic control, but is personalized education that teaches the patient to recognize situations that increase their risk of hypoglycemia, e.g. fasting for tests or procedures, during or after intense exercise, and during sleep.

American Geriatrics Society (AGS)

"Diabetes in Older Adults," a consensus report published jointly by the American Diabetes Association (ADA) and the American Geriatrics Society (AGS), was written by a panel of diabetes experts and is based on information from the ADA Consensus Development Conference on Diabetes and Older Adults, held in February 2012. http://www.ndei.org/ADA-AGS-diabetes-older-adults-2012.aspx

This report further supports ADA's recommendations for glycemic control for older adults as outlined in the above table.

Veterans Administration/Department of Defense (DoD)

Additionally, the Veterans Administration/Department of Defense (DoD) 2010 Diabetes guidelines have the following recommendations:

> *The patient with either none or very mild microvascular complications of diabetes, who is free of major concurrent illnesses, and who has a life expectancy of at least 10-15 years, should have an HbA1c target of <7 percent, if it can be achieved without risk. [A]*

> *The patient with longer duration diabetes (more than10 years) or with comorbid conditions, and who require combination medication regimen including insulin, should have an HbA1c target of < 8 percent. [A]*

Of note, the recommendation for an A1c target of less than 8.0% includes patients with co-morbid conditions and patients who require insulin. The VA/DoD guideline also includes a recommendation that "patients with advanced microvascular complications and/or major comorbid illness, and or a life expectancy of less than 5 years…should have a HbA1c target of 8-9 percent;" however, MNCM asserts that the existing exclusions for hospice, palliative care and permanent nursing home residence provide balance and are the most feasible methods for identifying the population in this category. The value of adding additional exclusions to the measure is uncertain in light of the imperfect methods we have to reliably define and identify them.

Socio-demographic Factors

We acknowledge that universal health literacy and food insufficiency are recognized issues for the prevention of hypoglycemic events; however, the data currently available does not allow for direct capture of these elements on the patient level. MNCM is continuously exploring additional data sources and critical elements for data collection in order to address meaningful socio-demographic factors that impact outcomes. While it is imperfect, payer type is the most broadly available proxy for use at this time.

A1c Test Accuracy

We acknowledge that point of care testing results may inherently have a margin of error; however, this margin of error is expected to have comparable impact across measured entities, thus preserving the measure's ability to detect variation and demonstrate improvements in care. This is not unlike the expected margin of error in any measurement of physiologic variables and outcomes, e.g. blood pressure, functional status, weight.

Lack of a Balancing Measure

We agree that a measure for high-risk patients, particularly the previously considered measure of the percentage of patients on sulfonylurea/insulin therapy with an out-of-range HbA1c < 7% from the DHHS National Action Plan for Prevention of Adverse Drug Events would be valuable. We encourage the continued development of such measures.

Conclusion

We would like to reiterate that, while MNCM is not a guideline development organization, we routinely review relevant guidelines and current evidence to ensure that the measures we steward reflect current best practice. We have a strong history of timely revision of our measures in response to changes in evidence and guideline recommendations, and we will continue to do so in the future. MNCM's mission and vision are steeped in the philosophy of accelerating change and improving the health of patients with patient centric measures and a strong preference for reporting outcomes over process measures. A key difference between outcome and process measures is that while process measures have the capacity to reach reported rates of 100%, outcome measures and intermediate outcome measures, do not have that expectation. Clinically, one could not expect every single patient to achieve the measured outcome, however, it is the measure's ability to identify variation and highlight opportunities for improvement that enable it to drive systemic improvements in the delivery of care and in the health of our nation.

Appendix C - Measure Evaluation Summary Tables

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

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: <u>The measure meets the Importance criteria</u>

(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**

<u>Rationale</u>:

- 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 the2014 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.
- 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.
- 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 sociodemogrpahic status. The Committee also accepted the developer's explanation that other potential sociodemogrpahic were considered for inclusion in the measure's risk-adjustment approach but ultimately were not included because they were not statistically significant.

7. Consensus Standards Approval Committee (CSAC) Review (May 12, 2015): Y-15; N-0; A-0

CSAC Decision: Approved for continued endorsement

8. Board of Directors Review: Yes (June 15, 2015)

Board Decision: Ratified for continued endorsement