NATIONAL QUALITY FORUM

Measure Evaluation 4.1
January 2010

This form contains the measure information submitted by stewards. Blank fields indicate no information was provided. Attachments also may have been submitted and are provided to reviewers. The sub-criteria and most of the footnotes from the evaluation criteria are provided in Word comments and will appear if your cursor is over the highlighted area (or in the margin if your Word program is set to show revisions in balloons). Hyperlinks to the evaluation criteria and ratings are provided in each section.

TAP/Workgroup (if utilized)**:** Complete all yellow highlighted areas of the form. Evaluate the extent to which each sub-criterion is met. Based on your evaluation, summarize the strengths and weaknesses in each section.

Note: *If there is no TAP or workgroup, the SC also evaluates the* sub-criteria *(yellow highlighted areas)*.

Steering Committee: Complete all pink highlighted areas of the form. Review the workgroup/TAP assessment of the sub-criterion, noting any areas of disagreement; then evaluate the extent to which each major criterion is met; and finally, indicate your recommendation for the endorsement. Provide the rationale for your ratings.

Evaluation ratings of the extent to which the criteria are met
C = Completely (unquestionably demonstrated to meet the criterion)
P = Partially (demonstrated to partially meet the criterion)
M = Minimally (addressed BUT demonstrated to only minimally meet the criterion)
N = Not at all (NOT addressed; OR incorrectly addressed; OR demonstrated to NOT meet the criterion)
NA = Not applicable (only an option for a few sub-criteria as indicated)

(for NQF staff use) **NQF Review** #: OT1-028-09 **NQF Project:** Patient Outcomes Measure Submissions
MEASURE DESCRIPTIVE INFORMATION
De.1 **Measure Title:** HbA1c control for a selected population
De.2 **Brief description of measure***:* Comprehensive diabetes care: The percentage of patients 18-65 years of age with either type I or type Ii diabetes who had a HbA1c level of less than or equal to 7.0%.
1.1-2 **Type of Measure:** outcome De.3 **If included in a composite or paired with another measure, please identify composite or paired measure** Measure is component of NCQA Comprehensive Diabetes Care composite measure
De.4 **National Priority Partners Priority Area:** population health De.5 **IOM Quality Domain**: effectiveness, patient-centered De.6 **Consumer Care Need:** Living With Illness

CONDITIONS FOR CONSIDERATION BY NQF	
Four conditions must be met before proposed measures may be considered and evaluated for suitability as voluntary consensus standards:	**NQF Staff**
A. The measure is in the public domain or an intellectual property (measure steward agreement) is signed. *Public domain only applies to governmental organizations. All non-government organizations must sign a measure steward agreement even if measures are made publicly and freely available.* A.1 **Do you attest that the measure steward holds intellectual property rights to the measure and the right to use aspects of the measure owned by another entity (e.g., risk model, code set)?** Yes A.2 **Indicate if Proprietary Measure** (*as defined in measure steward agreement*)**:** proprietary measure A.3 **Measure Steward Agreement:** agreement signed and submitted A.4 **Measure Steward Agreement attached:**	**A** **Y**☐ **N**☐

B. The measure owner/steward verifies there is an identified responsible entity and process to maintain and update the measure on a schedule that is commensurate with the rate of clinical innovation, but at least every 3 years. Yes, information provided in contact section	**B** Y☐ N☐
C. The intended use of the measure includes both public reporting and quality improvement. ►**Purpose:** public reporting, quality improvement Accreditation, Accountability	**C** Y☐ N☐
D. The requested measure submission information is complete. Generally, measures should be fully developed and tested so that all the evaluation criteria have been addressed and information needed to evaluate the measure is provided. Measures that have not been tested are only potentially eligible for a time-limited endorsement and in that case, measure owners must verify that testing will be completed within 12 months of endorsement. D.1**Testing:** Yes, fully developed and tested D.2 **Have NQF-endorsed measures been reviewed to identify if there are similar or related measures?** Yes	**D** Y☐ N☐
(for NQF staff use**)** **Have all conditions for consideration been met?** **Staff Notes to Steward** (*if submission returned*)**:**	**Met** Y☐ N☐
Staff Notes to Reviewers (*issues or questions regarding any criteria*)**:**	
Staff Reviewer Name(s):	

TAP/Workgroup Reviewer Name:	
Steering Committee Reviewer Name:	
1. IMPORTANCE TO MEASURE AND REPORT	
Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance. *Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria.* (evaluation criteria) **1a. High Impact**	Eval Rating
(for NQF staff use) **Specific NPP goal**:	
1a.1 **Demonstrated High Impact Aspect of Healthcare:** affects large numbers, a leading cause of morbidity/mortality, severity of illness, patient/societal consequences of poor quality 1a.2 1a.3 **Summary of Evidence of High Impact:** Diabetes refers to a group of diseases that present high levels of blood sugar arising from defect in the secretion or action of the sugar-lowering hormone called insulin (NIDDK, 2007). The National Diabetes Statistics estimates at least twenty three million people (7.8%) of the people in the U.S have diabetes. Out of this total, 17.9 million have diagnosed diabetes while 5.7 million have undiagnosed diabetes (NDS, 2007) About 90% - 95% of patients with diabetes are Type 2 diabetics, with the remainder being Type 1 (NDS, 2007). Diabetes of either type may cause life-threatening or life-ending complications. Complications of diabetes include metabolic abnormalities, micro- and macrovascular disorders, blindness, neuropathy and renal insufficiency. Diabetic morbidity produces significantly increased health utilization and disability the total annual economic burden of diabetes has increased from $100 billion in 2003 to close to $174 billion in 2007believed to approach $100 billion in the United States (CDC Fact Sheet, 2007). Randomized clinical trials have demonstrated that improved glycemic control, as evidenced by reduced levels of glycohemoglobin, correlates with a reduction in the development of microvascular complications in both Type 1 and Type 2 diabetes (DCCT, 1993; Ohkubo, 1995; UKPDS, 1997). Recent literature further states that for patients with type 2 diabetes, improving glycemic control is more important than treating	**1a** C☐ P☐ M☐ N☐

dyslipidemia and hypertension for the reduction of macrovascular and microvascular complications (Vaag, 2006).

Direct and indirect costs of diabetes have a significant impact on society, especially when lost productivity due to diabetes-related morbidity and mortality is included. Cost of illnesses studies have shown the cost of diabetes in the United States to be over $100 billion (Ettaro, 2004). In 2002, the total cost of diabetes was $132 billion. This includes $116 billion for direct medical costs and $58 billion for indirect costs (disability, work loss, premature mortality) (CDC, 2008).

In a study done at Kaiser Permanente, expenditures overall for diabetics were 2.4 times those of non-diabetic controls. Excess annual costs for diabetics in this study were calculated to be $3,494 per patient. Of this total, 15.5% of the excess cost was attributable to outcomes which might be reduced by better glycemic control (exclusive of any potential benefit in cardiovascular disease) (Selby, 1997).

Nationwide, the long-term outcomes of blindness, amputation, and ESRD account for a considerable expenditure of health care dollars. Experts estimate annual costs for these complications in diabetics to be about $500 million for blindness and $2 billion for ESRD (Klien, 1995; Nelson, 1995). Diabetes is currently the leading cause of all new cases of blindness for adults, nontraumatic lower extremity amputations, and kidney failure (CDC, 2008). Cumulative costs for amputation total ~ $40,000 per case, including follow-up treatment (Reiber, 1995). Diabetes can lead to stroke, pregnancy complications, heart disease, and deaths associated with the flu and pneumonia. A reduction in any outcome would have significant financial implications and research has shown that adults with diabetes are 2-4 times higher than for non-diabetes people. In sum, over 200,000 people die from diabetes-related issues (CDC, 2008 and CDC Factsheet, 2007).

For every 1% reduction in HbA1c, the risks of eye, nerve, and kidney disease are lowered by almost 40%. The control of blood sugar levels is fundamental to reducing the burden that diabetes causes (CDC, 2008).

The intensive control of HbA1c as compared to conventional therapy has shown positive correlation with resting heart rates (RHR) which is a risk factor for cardiovascular disease. Evidence has shown through clinical case-control studies that patients with type 1 diabetes have lower RHR though the intense glycemic control (Paterson, 2007).

Studies show an association between the level of blood sugar and the probability of cardiovascular disease (CVD) among diabetic patients (Cefalu, NJEM 2008), however, an intensive approach may result in more harm in high-risk patients. In the Action to Control Cardiovascular Risk in Diabetes (ACCORD) study group, an intensive HbA1c control targeted at normal levels for 3.5 years did not reduce major cardiovascular events among high-risk patients. This excessively intensive approach instead led to an unforeseen increased risk for mortality among high-risk diabetic patients (NJEM, 2008).

Unlike the ACCORD study, findings from the Action in Diabetes and Vascular Disease (ADVANCE) study did not show increased mortality among those patients receiving aggressive treatment to lower blood glucose. The ADVANCE additionally underscores that safely controlled HbA1c levels to near normal significantly reduces serious complications from diabetes especially reduction in kidney disease. Although the study reports reduced mortality from CVD, the results are not statistically significant. (ADVANCE, 2008)

In another study, the Veterans Administration Diabetes Trial (VADT), even though blood sugar control resulted in minimal CVD risk reduction, holistically, aggressive blood sugar control therapy demonstrated profound long-term benefits. On the contrary, for high-risk older diabetic patients an overly intensive approach exhibited some risk (Diabetes, 2008).

1a.4 Citations for Evidence of High Impact: ADVANCE. "ADVANCE results go beyond existing evidence" San Francisco, USA, 6 June 2008:
http://www.advance- trial.com/static/html/virtual/contents.asp?P=41 (last accessed July 7, 2008)

American Diabetes Association. Tests of glycemia in diabetes. Diabetes Care 20(Suppl. 1):S18, 1997.

CDC (2008): Diabetes Disabling Disease to Double by 2050.
http://www.cdc.gov/nccdphp/publications/aag/ddt.htm.

DCCT Group . Intensive Diabetes Treatment and Cardiovascular Disease in Patients with Type 1 Diabetes. NEJM . 2005; 353:2643-2653.

Fowles JB, Rosheim K, Fowler EJ, Craft C, Arrichiello L. The validity of self-reported diabetes quality of care measures. Int J Qual Health Care. 1999 Oct;11(5):407-12.

Harris MI. "Summary", in Diabetes in America, 2nd ed. Bethesda: National Institutes of Health -National Institute of Diabetes and Digestive and Kidney Diseases, NIH Publication No. 95-1468, 1995.

Dluhy RG, McMahon GT. "Intensive Glycemic Control in the ACCORD and ADVANCE Trials" NJEM, 2008

Moss SE, Klein R, Klein BE, Meuer SM. The association of glycemia and cause-specific mortality in a diabetic population. Arch Intern Med 154(21):2473-9, 1994.

Moss SE, Klein R, Klein BE. The prevalence and incidence of lower extremity amputation in a diabetic population. Arch Intern Med 152(3):610-6, 1992.

National Committee for Quality Assurance: The State of Health Care Quality 2007:
http://www.ncqa.org/tabid/543/default.aspx.

National Diabetes Statistics (NDS), 2007 (National Diabetes Information Clearing House)
http://diabetes.niddk.nih.gov/dm/pubs/statistics/index.htm#what (Accessed July 14, 2008)

National Diabetes Information Clearinghouse. Diabetes statistics. Bethesda: National Institute of Diabetes and Digestive and Kidney Diseases, 1994. (NIH Publication no. 94-3822)

Nelson RG, Knowler WC, Pettitt DJ, Bennett PH. "Kidney diseases in diabetics", in Diabetes in America, 2nd ed. Bethesda: National Institutes of Health –National
Institute of Diabetes and Digestive and Kidney Diseases, NIH Publication No. 95-1468, 1995.

Ohkubo T, Kishikawa H, Araki E, et al. Intensive insulin therapy prevents the progression of diabetic microvascular complications in Japanese patients with non-insulin-dependent diabetes mellitus: a randomized prospective 6-year study. Diabetes Res Clin Pract 28(2):103-17, 1995.

Paterson AD, Rutledge BN, Cleary PA, Lachin JM, Crow RS. (2007) The effect of intensive diabetes treatment on resting heart rate in type 1 diabetes. Diabetes Care 30(8):2107-2112.

Ray NF, Wills S, Thamer M, and Medical Technology and Practice Patterns Institute: Direct and indirect costs of diabetes in the United States in 1992. American Diabetes Association, Alexandria, VA, 1993.

Reiber GE, Boyko EJ, Smith DG. "Lower extremity foot ulcers and amputations in diabetes", in Diabetes in America, 2nd ed. Bethesda: National Institutes of Health -National Institute of Diabetes and Digestive and Kidney Diseases, NIH Publication No. 95-1468, 1995.

Selby JV, Ray GT, Zhang D, Colby CJ. Excess costs of medical care for patients with diabetes in a managed care population, Diabetes Care 20(9):1396-1402, 1997.

Tisnado DM, Adams JL, Liu H, Damberg CL, Hu A, Chen WP, Kahn KL. What is the concordance between the medical record and patient self-report as data sources for ambulatory care? Med Care. 2006 Feb; 44(2):132-40.

UKPDS. BMJ 1998;317:703-13.
UKPDS. Lancet 1998;352:837-53

Vaag AA. (2006). Glycemic control and prevention of microvascular and macrovascular disease in the steno study. Endocrine Practice 12(1):89-92.

Cefalu WC. "Glycemic Targets and Cardiovascular Disease" NJEM June, 2008

68th Annual Scientific Sessions of the American Diabetes Association _ San Francisco, CA: Diabetes, 2008

1b. Opportunity for Improvement

1b.1 Benefits (improvements in quality) envisioned by use of this measure:

1b.2 Summary of data demonstrating performance gap (variation or overall poor performance) across providers:

HEDIS 2009: The median (50th percentile) eligible population size for Commercial plans for the HbA1c <7.0% w/Exclusions measure was 3,245 members. The median denominator prevalence for eligible members for Commercial plans was 32 (per 1000 member-years). The median (50th percentile) eligible population size for Medicaid plans for the HbA1c <7.0% w/Exclusions measure was 1,025 members. The median denominator prevalence for eligible members for Medicaid plans was 18 (per 1000 member-years).

Table 3a. Commercial – HbA1c <7.0% w/exclusions

Region	Mean	Std Dev	Percentiles				
			10th	25th	50th	75th	90th
National	28.68	17.85	4.2127	10.18	31.50	43.77	50.10
New England	29	21.27	5.72	6.52	28.81	47.20	56.92
East North Central	32.6	19.45	6.48	13.06	42.42	46.80	51.89
Middle Atlantic	35.82	16.52	2.19	24.15	43.86	48.79	54.26
Mountain	26.14	17.11	4.21	13.16	26.22	36.15	43.30
Pacific	26.63	14.8	3.9	12.15	32.01	38.35	43.55
South Atlantic	29.33	19.65	3.74	6.94	31.43	42.69	54.26
South Central	15.64	14.12	1.82	6.03	10.23	24.11	35.43
West North Central	40.99	13.93	16.11	43.19	44.28	48.17	53.84

Table 3b. Medicaid – HbA1c <7.0% w/exclusions

Region	Mean	Std Dev	Percentiles				
			10th	25th	50th	75th	90th
National	32.87	11.38	19.21	25.54	34.83	40.58	44.69
New England† --	--	--	--	--	--	--	--
East North Central	33.9	13.72	4.58	31	38.67	44.69	48.04
Middle Atlantic	35.86	10.96	16.39	38.82	40.42	41.49	42.18
Mountain	38.01	8.06	31.90	31.90	34.98	47.14	47.14
Pacific	30.34	10.25	21.02	25.50	30.71	37.26	42.03
South Atlantic	31.29	7.1	22.14	25.47	30.54	38.07	39.90
South Central	39.64	14.31	23.85	28.52	38.87	50.75	56.95
West North Central	28.21	14.07	9.19	17.75	31.33	38.66	40.96

† There were no Medicaid plans from New England that reported rates for the HbA1c < 7.0% measure.

There was considerable variability in rates across the regions. For commercial plans, the highest performing region was West North Central (mean 40.9%) and the lowest performing region was South Central (mean 15.6%). For Medicaid plans, the highest performing region was South Central (mean 39.6%) and the lowest was West North Central (mean 28.2%). For Medicare plans, the highest performing region was East North Central (mean 44.9%) and the lowest was South Atlantic (mean 27.7%).

1b.3 Citations for data on performance gap:

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1b.4 Summary of Data on disparities by population group:

1b.5 Citations for data on Disparities:

1c. Outcome or Evidence to Support Measure Focus

1c.1 Relationship to Outcomes (*For non-outcome measures, briefly describe the relationship to desired outcome. For outcomes, describe why it is relevant to the target population*)**:** To prevent microvascular complications of diabetes, the goal for glycemic control should be as low as is feasible without undue risk for adverse events or an unacceptable burden on patients. Treatment goals should be based on a discussion of the benefits and harms of specific levels of glycemic control with the patient. A hemoglobin A1c level less than 7% based on individualized assessment is a reasonable goal for many but not all patients.

1c.2-3. Type of Evidence: evidence based guideline

1c.4 Summary of Evidence (*as described in the criteria; for outcomes, summarize any evidence that healthcare services/care processes influence the outcome*)**:**

1c.5 Rating of strength/quality of evidence (*also provide narrative description of the rating and by whom***):**

1c.6 Method for rating evidence:

1c.7 Summary of Controversy/Contradictory Evidence: Study results from the ACCORD and ADVANCE randomized clinical trials and results for a large VA study, on the intensive treatment of patients with diabetes, have raised questions about the value of aggressive A1c control

1c.8 Citations for Evidence (*other than guidelines***):** ADVANCE. "ADVANCE results go beyond existing evidence" San Francisco, USA, 6 June 2008:
http://www.advance- trial.com/static/html/virtual/contents.asp?P=41 (last accessed July 7, 2008)

1c.9 Quote the Specific guideline recommendation (*including guideline number and/or page number***):**
ACP
To prevent microvascular complications of diabetes, the goal for glycemic control should be as low as is feasible without undue risk for adverse events or an unacceptable burden on patients. Treatment goals should be based on a discussion of the benefits and harms of specific levels of glycemic control with the patient. A hemoglobin A1c level less than 7% based on individualized assessment is a reasonable goal for many but not all patients.

The goal for hemoglobin A1c level should be based on individualized assessment of risk for complications from diabetes, comorbidity, life expectancy, and patient preferences.
Glycemic control and type 2 diabetes mellitus: the optimal hemoglobin A1c targets. A guidance statement from the American College of Physicians (ACP September, 2007).
ADA
Perform the A1C test at least two times a year in patients who are meeting treatment goals (and who have stable glycemic control).

Perform the A1C test quarterly in patients whose therapy has changed or who are not meeting glycemic goals.

Lowering A1C to an average of ~7% has clearly been shown to reduce microvascular and neuropathic complications of diabetes and, possibly, macrovascular disease. Therefore, the A1C goal for nonpregnant adults in general is <7%.

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American Diabetes Association (ADA). Standards of medical care in diabetes. V. Diabetes care. Diabetes Care 2008 Jan;31(Suppl 1):S16-24.

AACE
Encourage patients to achieve glycemic levels as near normal as possible without inducing clinically significant hypoglycemia. Glycemic targets include:
- HbA1c =6.5%
- Fasting plasma glucose concentration <110 mg/dL
- 2-hour postprandial glucose concentration <140 mg/dL

AACE Diabetes Mellitus Clinical Practice Guidelines Task Force. AACE diabetes mellitus guidelines. Glycemic management. Endocr Pract 2007 May-Jun;13 (Suppl 1):16-34. [178 references]

ICSI
Diabetes patients should have HbA1c levels less than 7% (ICSI, 2007).

Institute for Clinical Systems Improvement (ICSI). Management of type 2 diabetes mellitus. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2006 Nov. 82).

AGS
American Geriatrics Society (AGS): Monitor and treat hyperglycemia, with a target A1C of 7%, but less stringent goals for therapy may be appropriate once patient preferences, diabetes severity, life expectancy and functional status have been considered (AGS, 2004).

California Healthcare Foundation/American Geriatrics Society (AGS) Improving Care of Elders with Diabetes. Guidelines for Improving the Care of the Older Person with Diabetes Mellitus. J Am Geriatr Soc 2003;51:S265-S280.

Rationale for using these guidelines: It is NCQA's policy to use guidelines which are evidence-based, applicable to physicians and other healthcare providers, and developed by a national specialty organization or government agency.

1c.10 Clinical Practice Guideline Citation: See above
1c.11 National Guideline Clearinghouse or other URL:

1c.12 Rating of strength of recommendation (*also provide narrative description of the rating and by whom***):**

1c.13 Method for rating strength of recommendation (*If different from* USPSTF system*, also describe rating and how it relates to USPSTF)***:**

1c.14 Rationale for using this guideline over others:
The guidelines included are evidence-based, applicable to relevant health care providers, and developed by national specialty organizations or government agencies.

TAP/Workgroup: What are the strengths and weaknesses in relation to the sub-criteria **for** *Importance to Measure and Report?*	**1**
Steering Committee: Was the threshold criterion, *Importance to Measure and Report***, met?** **Rationale:**	**1** **Y☐** **N☐**
2. SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES	
Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about	Eval

the quality of care when implemented. (evaluation criteria)	Rating
2a. MEASURE SPECIFICATIONS	
S.1 Do you have a web page where current detailed measure specifications can be obtained? **S.2 If yes, provide web page URL:** **2a. Precisely Specified**	
2a.1 Numerator Statement (*Brief, text description of the numerator - what is being measured about the target population, e.g. target condition, event, or outcome***):** The most recent HbA1c level performed during the measurement year is <7.0% as identified by automated laboratory data or medical record review. **2a.2 Numerator Time Window (***The time period in which cases are eligible for inclusion in the numerator***):** the measurement year **2a.3 Numerator Details (***All information required to collect/calculate the numerator, including all codes, logic, and definitions***):** HbA1c <7.0% from automated laboratory data or medical record review. At a minimum, the note in the medical record must indicate the date on which the HbA1c test was performed and the result.	
2a.4 Denominator Statement (*Brief, text description of the denominator - target population being measured***):** All patients aged 18-65 years as of December 31 of the measurement year **2a.5 Target population gender:** Male, Female **2a.6 Target population age range:** 18-65 years **2a.7 Denominator Time Window (***The time period in which cases are eligible for inclusion in the denominator***):** a twelve month measurement period based in the calendar year **2a.8 Denominator Details (***All information required to collect/calculate the denominator - the target population being measured - including all codes, logic, and definitions***):** All patients with either Type I or Type II diabetes with any enrollment, claim or encounter during the measurement year.	
2a.9 Denominator Exclusions (*Brief text description of exclusions from the target population***):** Gestational diabetes, polycystic ovaries, Steroid induced diabetes,CABG or PTCA, Ischemic Vascular Disease (IVD), CHF, Prior MI, CRF/ESRD, Dementia, Blindness, Amputation of lower extremity **2a.10 Denominator Exclusion Details (***All information required to collect exclusions to the denominator, including all codes, logic, and definitions***):** Gestational Diabetes: ICD-9 Dx: 648.8,polycyctic ovaries: ICD-9 Dx: 256.4, Steroid induced: ICD-(Dx: 249, 251.8, 962.0, CABG: CPT-33510-33514, 33516-33519, 33521-33523, 33533-33536, HCPCS-S2205-S2209, ICD-9 Procedure - 36.1, 36.2; PTCA: CPT-33140, 92980, 92982, 92995, ICD-9 Procedure- 00.66, 36.06, 36.07, 36.09; AMI: ICD-9 Diagnosis-410.x1; CHF: ICD-9 - 428; Myocardial Infarction:ICD-9 410,412; CRF/ESRD: CPT-36145, 36800-36821, 36831-36833, 90919-90921, 90923-90925, 90935, 90937, 90940, 90945, 90947, 90957-90962, 90965, 90966, 90969, 90970, 90989, 90993, 90997, 90999, 99512, HCPCS-G0257, G0311-G0319, G0321-G0323, G0325-G0327, G0392, G0393, S9339, ICD-9 Diagnosis-585.4, 585.5, 585.6, V42.0, V45.1, V56; ICD-9 Procedure-38.95, 39.27, 39.42, 39.43, 39.53, 39.93, 39.94, 39.95, 54.98; UB Revenue-080x, 082x-085x, 088x; Blindness: ICD-9 Diagnosis-369.0, 369.1, 369.2, 369.4, 369.6, 369.7; Amputation (lower extremity): CPT-27290, 27295, 27590-27592, 27594, 27596, 27598, 27880, 27881, 27882, 27884, 27886, 27888, 27889, 28800, 28805, 28810, 28820, 28825; Dementia: ICD-9 Diagnosis-290, 291.2, 292.82, 294.0, 294.1, 294.8, 331.0, 331.1, 331.82; IVD: ICD-9 Diagnosis-411, 413, 414.0, 414.8, 414.9, 429.2, 433, 434, 440.1, 440.2, 440.4, 444, 445	**2a-specs** **C☐** **P☐** **M☐** **N☐**
2a.11 Stratification Details/Variables (*All information required to stratify the measure including the*	

stratification variables, all codes, logic, and definitions):
N/A

2a.12-13 **Risk Adjustment Type:** no risk adjustment necessary

2a.14 **Risk Adjustment Methodology/Variables (***List risk adjustment variables and describe conceptual models, statistical models, or other aspects of model or method***):**

2a.15-17 **Detailed risk model available Web page URL or attachment:**

2a.18-19 **Type of Score:** rate/proportion
2a.20 **Interpretation of Score:** better quality = higher score
2a.21 **Calculation Algorithm (***Describe the calculation of the measure as a flowchart or series of steps***):**
Step 1- Population selection - Patients aged 18-65 as of December 31 of the MY
Step 2 - Diagnosis of Diabetes using ambulatory prescriptions for anti-diabetic agents or two face to face encounters with a diagnosis of diabetes in the MY or the year prior to the MY
Step 3 - Exclude patients with comorbid conditions
Step 4 - look for HbA1c test value in MR
Step 5 - If value is <7% then numerator compliant. If result is missing or >7% then non-numerator compliant

2a.22 **Describe the method for discriminating performance** *(e.g., significance testing)*:
This measure has been collected as part of the Comprehensive Diabetes Care composite measure set for the HEDIS population for two years. the data collected indicates that there is significant variation among organizations and that there is room for improvement in the management of this select population. It has also been introduced as a requirement of the Diabetes Provider Recognition (DRP) program and the provider-level data submitted supports the variability across providers and that there is still much room for improvement.

2a.23 **Sampling (Survey) Methodology** *If measure is based on a sample (or survey), provide instructions for obtaining the sample, conducting the survey and guidance on minimum sample size (response rate)*:
Hybrid Method Requires the organization to look for numerator compliance in both administrative and medical record data. The denominator consists of a systematic sample of members drawn from the measure's eligible population. The organization reports a rate based on members in the sample who are found through either administrative or medical record data to have received the service required for the numerator.

2a.24 **Data Source (***Check the source(s) for which the measure is specified and tested)*
Electronic adminstrative data/claims, Electronic clinical data, electronic Health/Medical Record, external audit, lab data, pharmacy data

2a.25 **Data source/data collection instrument (***Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.***):**
administrative claims and electronic laboratory data

2a.26-28 **Data source/data collection instrument reference web page URL or attachment:** URL
www.ncqa.org

2a.29-31 **Data dictionary/code table web page URL or attachment:** Attachment DIA_LVL1_HbA1c_7.xlsx

2a.32-35 **Level of Measurement/Analysis** (*Check the level(s) for which the measure is specified and tested)*
Clinicians: Individual, Clinicians: Group, Health Plan, Integrated delivery system, Multi-site/corporate chain, Population: national, Population: regional/network, Can be measured at all levels, Program: Disease management

2a.36-37 **Care Settings (***Check the setting(s) for which the measure is specified and tested)*
Ambulatory Care: Office, Ambulatory Care: Clinic

2a.38-41 **Clinical Services** (*Healthcare services being measured, check all that apply*)
Clinicians: Physicians (MD/DO), Clinicians: PA/NP/Advanced Practice Nurse

TESTING/ANALYSIS	
2b. Reliability testing 2b.1 **Data/sample** *(description of data/sample and size)*: 2b.2 **Analytic Method** *(type of reliability & rationale, method for testing)*: 2b.3 **Testing Results** *(reliability statistics, assessment of adequacy in the context of norms for the test conducted)*:	**2b** C☐ P☐ M☐ N☐
2c. Validity testing 2c.1 **Data/sample** *(description of data/sample and size)*: 2c.2 **Analytic Method** *(type of validity & rationale, method for testing)*: 2c.3 **Testing Results** *(statistical results, assessment of adequacy in the context of norms for the test conducted)*:	**2c** C☐ P☐ M☐ N☐
2d. Exclusions Justified 2d.1 **Summary of Evidence supporting exclusion(s):** Restricting the 7% measure to those with a sufficient lifespan (10-20 years) would provide the opportunity for the patients to live long enough to have some tangible benefit from the tight control. o The further restrictions (outlined within the ADA guidelines) if feasible would reduce the likelihood of overtreatment of the sub population of patients that had excess CV death in the Accord study (associated with risk of complications). o This approach accomplishes a balance of retaining a "good control" target for those likely to experience a benefit of tight control, and excludes those where evidence indicates a higher risk of harm (the ACCORD population). 2d.2 **Citations for Evidence:** DA Perform the A1C test at least two times a year in patients who are meeting treatment goals (and who have stable glycemic control). Perform the A1C test quarterly in patients whose therapy has changed or who are not meeting glycemic goals. Lowering A1C to an average of ~7% has clearly been shown to reduce microvascular and neuropathic complications of diabetes and, possibly, macrovascular disease. Therefore, the A1C goal for nonpregnant adults in general is <7%. American Diabetes Association (ADA). Standards of medical care in diabetes. V. Diabetes care. Diabetes Care 2008 Jan;31(Suppl 1):S16-24. 2d.3 **Data/sample** *(description of data/sample and size)*: Hybrid Method Requires the organization to look for numerator compliance in both administrative and medical record data. The denominator consists of a systematic sample of members drawn from the measure's eligible population. The organization reports a rate based on members in the sample who are found through either administrative or medical record data to have received the service required for the numerator.	**2d** C☐ P☐ M☐ N☐ NA☐

2d.4 Analytic Method *(type analysis & rationale)*: Sample size is calculated assuming a two-tailed test of significance between two proportions (? = .05, 80 percent power, two-tailed test of significance). A normal approximation to the binomial with a continuity correction was employed in the sample size calculation. The worst-case assumption of a 50 percent expected value was assumed. In some cases, the size of the eligible population for the measure may be smaller than the required sample size of 548. In this case, the organization must use its entire eligible population and report the data with a 95 percent confidence interval. Why should a 95 percent confidence interval be used when the entire eligible population is included? When these data are used for decision-making, an inference is made to expected future performance or to a group of potential members. In either case, the user is interested in the "process of care," which goes beyond organization performance in a single year for a static product line. It is therefore appropriate to consider the organization's entire eligible population for a measure as a sample from the universe of "all years" or "all populations." **2d.5 Testing Results** *(e.g., frequency, variability, sensitivity analyses)*:	
2e. Risk Adjustment for Outcomes/ Resource Use Measures **2e.1 Data/sample** *(description of data/sample and size)*: **2e.2 Analytic Method** *(type of risk adjustment, analysis, & rationale)*: **2e.3 Testing Results** *(risk model performance metrics)*: **2e.4 If outcome or resource use measure is not risk adjusted, provide rationale:**	**2e** C☐ P☐ M☐ N☐ NA☐
2f. Identification of Meaningful Differences in Performance **2f.1 Data/sample from Testing or Current Use** *(description of data/sample and size)*: **2f.2 Methods to identify statistically significant and practically/meaningfully differences in performance** *(type of analysis & rationale)*: **2f.3 Provide Measure Scores from Testing or Current Use** *(description of scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance)*:	**2f** C☐ P☐ M☐ N☐
2g. Comparability of Multiple Data Sources/Methods **2g.1 Data/sample** *(description of data/sample and size)*: HEDIS 2009: The median (50th percentile) eligible population size for Commercial plans for the HbA1c <7.0% w/Exclusions measure was 3,245 members. The median denominator prevalence for eligible members for Commercial plans was 32 (per 1000 member-years). The median (50th percentile) eligible population size for Medicaid plans for the HbA1c <7.0% w/Exclusions measure was 1,025 members. The median denominator prevalence for eligible members for Medicaid plans was 18 (per 1000 member-years). **2g.2 Analytic Method** *(type of analysis & rationale)*: **2g.3 Testing Results** *(e.g., correlation statistics, comparison of rankings)*:	**2g** C☐ P☐ M☐ N☐ NA☐
2h. Disparities in Care	**2h** C☐

2h.1 If measure is stratified, provide stratified results *(scores by stratified categories/cohorts)***:** **2h.2 If disparities have been reported/identified, but measure is not specified to detect disparities, provide follow-up plans:**	**P☐ M☐ N☐ NA☐**
TAP/Workgroup: What are the strengths and weaknesses in relation to the sub-criteria **for** *Scientific Acceptability of Measure Properties?*	**2**
Steering Committee: Overall, to what extent was the criterion, *Scientific Acceptability of Measure Properties***, met?** **Rationale:**	*2* **C☐ P☐ M☐ N☐**
3. USABILITY	
Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (evaluation criteria)	Eval Rating
3a. Meaningful, Understandable, and Useful Information **3a.1 Current Use:** in use **3a.2 Use in a public reporting initiative (disclosure of performance results to the public at large)** *(If used in a public reporting initiative, provide name of initiative(s), locations, Web page URL(s). If not publicly reported, state the plans to achieve public reporting within 3 years)***:** Health plan, physician recognition, disease management **3a.3 If used in other programs/initiatives (***If used in quality improvement or other programs/initiatives, name of initiative(s), locations, Web page URL(s). If not used for QI, state the plans to achieve use for QI within 3 years***):** **Testing of Interpretability** (*Testing that demonstrates the results are understood by the potential users for public reporting and quality improvement*) **3a.4 Data/sample** *(description of data/sample and size)***:** **3a.5 Methods** *(e.g., focus group, survey, QI project)***:** **3a.6 Results** *(qualitative and/or quantitative results and conclusions)***:**	**3a** **C☐ P☐ M☐ N☐**
3b/3c. Relation to other NQF-endorsed measures **3b.1 NQF # and Title of similar or related measures:**	
(for NQF staff use) **Notes on similar/related** endorsed **or submitted measures:**	
3b. Harmonization If this measure is related to measure(s) already endorsed by NQF (e.g., same topic, but different target population/setting/data source or different topic but same target population): **3b.2 Are the measure specifications harmonized? If not, why?**	**3b** **C☐ P☐ M☐ N☐ NA☐**
3c. Distinctive or Additive Value **3c.1 Describe the distinctive, improved, or additive value this measure provides to existing NQF-endorsed measures:**	**3c** **C☐ P☐ M☐ N☐**

5.1 **Competing Measures If this measure is similar to measure(s) already endorsed by NQF (i.e., on the same topic and the same target population), describe why it is a more valid or efficient way to measure quality:**	
TAP/Workgroup: What are the strengths and weaknesses in relation to the sub-criteria **for** *Usability?*	**3**
Steering Committee: Overall, to what extent was the criterion, *Usability*, **met?** **Rationale:**	**3** **C☐** **P☐** **M☐** **N☐**
4. FEASIBILITY	
Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (evaluation criteria)	Eval Rating
4a. Data Generated as a Byproduct of Care Processes 4a.1-2 **How are the data elements that are needed to compute measure scores generated?** coding/abstraction performed by someone other than person obtaining original information,	**4a** **C☐** **P☐** **M☐** **N☐**
4b. Electronic Sources 4b.1 **Are all the data elements available electronically?** (*elements that are needed to compute measure scores are in defined, computer-readable fields, e.g., electronic health record, electronic claims*) Yes 4b.2 **If not, specify the near-term path to achieve electronic capture by most providers.**	**4b** **C☐** **P☐** **M☐** **N☐**
4c. Exclusions 4c.1 **Do the specified exclusions require additional data sources beyond what is required for the numerator and denominator specifications?** 4c.2 **If yes, provide justification.**	**4c** **C☐** **P☐** **M☐** **N☐** **NA☐**
4d. Susceptibility to Inaccuracies, Errors, or Unintended Consequences 4d.1 **Identify susceptibility to inaccuracies, errors, or unintended consequences of the measure and describe how these potential problems could be audited. If audited, provide results.**	**4d** **C☐** **P☐** **M☐** **N☐**
4e. Data Collection Strategy/Implementation 4e.1 **Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data/missing data, timing/frequency of data collection, patient confidentiality, time/cost of data collection, other feasibility/ implementation issues:** 4e.2 **Costs to implement the measure** (*costs of data collection, fees associated with proprietary measures*)**:** 4e.3 **Evidence for costs:**	**4e** **C☐** **P☐** **M☐** **N☐**

4e.4 **Business case documentation:**	
TAP/Workgroup: What are the strengths and weaknesses in relation to the sub-criteria **for** *Feasibility*?	**4**
Steering Committee: Overall, to what extent was the criterion, *Feasibility*, **met?** **Rationale:**	**4** **C☐** **P☐** **M☐** **N☐**
RECOMMENDATION	
(for NQF staff use) **Check if measure is untested and only eligible for time-limited endorsement.**	**Time-limited ☐**
Steering Committee: Do you recommend for endorsement? **Comments:**	**Y☐** **N☐** **A☐**

CONTACT INFORMATION

Co.1 **Measure Steward (Intellectual Property Owner)**
Co.1 **Organization**
National Committee for Quality Assurance (NCQA) | 1100 13th Street NW | Washington | District Of Columbia | 20001

Co.2 **Point of Contact**
Ben | Hamlin, MPH | hamlin@ncqa.org | 202-955-1716

Measure Developer If different from Measure Steward
Co.3 **Organization**
National Committee for Quality Assurance (NCQA) | 1100 13th Street NW | Washington | District Of Columbia | 20001

Co.4 **Point of Contact**
Ben | Hamlin, MPH | hamlin@ncqa.org | 202-955-1716

Co.5 **Submitter If different from Measure Steward POC**
Ben | Hamlin, MPH | hamlin@ncqa.org | --1716- |National Committee for Quality Assurance (NCQA)

Co.6 **Additional organizations that sponsored/participated in measure development**

ADDITIONAL INFORMATION

Workgroup/Expert Panel involved in measure development
Ad.1 **Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.**

Name	Affiliation
Harlan Krumholz, MD, SM (Chair)	Yale University School of Medicine
Tom Lee, MD	Partners Healthcare System
Sheldon Greenfield, MD	University of California
James Rosenzweig, MD	Boston University School of Medicine
John Buse, MD, PhD	University of North Carolina School of Medicine
Richard Hellman, MD	
Joe Selby, MD	Kaiser Permanente
Denise Simons- Morton, MD	Division of Prevention and Population Sciences National Heart, Lung, and Blood Institute
Ted Ganiats, MD	
Judith Fradkin, MD	Division of Diabetes, Endocrinology, & Metabolic Diseases

	NIDDK, National Institutes of Health
Rodney Hayward, MD	VA HSR&D Center of Excellence
David Nathan	Partners Healthcare System
M. Sue Kirkman, MD	American Diabetes Association

Ad.2 If adapted, provide name of original measure:
Ad.3-5 If adapted, provide original specifications URL or attachment

Measure Developer/Steward Updates and Ongoing Maintenance
Ad.6 Year the measure was first released: 2008
Ad.7 Month and Year of most recent revision: 2009-12
Ad.8 What is your frequency for review/update of this measure? 3 years
Ad.9 When is the next scheduled review/update for this measure? 2012-0

Ad.10 Copyright statement/disclaimers:

Ad.11 -13 Additional Information web page URL or attachment:

Date of Submission (*MM/DD/YY*)**:**