NATIONAL QUALITY FORUM

Measure Information

This document contains the information submitted by measure developers/stewards, but is organized according to NQF's measure evaluation criteria and process. The item numbers refer to those in the submission form but may be in a slightly different order here. In general, the item numbers also reference the related criteria (e.g., item 1b.1 relates to subcriterion 1b).

Brief Measure Information

NQF #: 0545

De.2. Measure Title: Adherence to Statins for Individuals with Diabetes Mellitus

Co.1.1. Measure Steward: Centers for Medicare & Medicaid Services

De.3. Brief Description of Measure: The measure addresses adherence to statins. The measure is reported as the percentage of eligible individuals with diabetes mellitus who had at least two prescriptions for statins and who have a Proportion of Days Covered (PDC) of at least 0.8 during the measurement period (12 consecutive months).

1b.1. Developer Rationale: Several important benefits related to quality improvement are envisioned with the implementation of this measure. Specifically, the measure will help providers to identify individuals with diabetes mellitus who are not adherent (at a critical threshold of a PDC of 0.8 or greater) to statins. Furthermore, this measure will encourage providers to develop communication and education tools and processes to improve adherence in their patients with diabetes mellitus. Higher medication adherence rates are expected to result in lower rates of hyperlipidemia, cardiovascular events, and mortality. Adoption of this performance measure has the potential to improve quality of care for individuals with diabetes mellitus and, therefore, advance quality of care by engaging patients as partners in their care, a priority area identified in the National Quality Strategy.

S.4. Numerator Statement: Individuals in the denominator with at least two prescriptions for statins with a PDC of at least 0.8 for statins.

S.7. Denominator Statement: Individuals at least 18 years of age as of the beginning of the measurement period with diabetes mellitus and at least two prescriptions for statins during the measurement period (12 consecutive months).

S.10. Denominator Exclusions: We excluded the following individuals from the denominator:

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

Exclusion 1
Individuals with a diagnosis of polycystic ovaries who do not have a visit with a diagnosis of diabetes in any setting during the measurement period*; and,

Exclusion 2
Individuals with a diagnosis of gestational diabetes or steroid-induced diabetes who do not have a visit with a diagnosis of diabetes mellitus in any setting during the measurement period.

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

De.1. Measure Type: Process

S.23. Data Source: Administrative claims, Electronic Clinical Data : Pharmacy, Other

S.26. Level of Analysis: Clinician : Group/Practice, Health Plan, Integrated Delivery System, Population : State

IF Endorsement Maintenance – Original Endorsement Date: Aug 05, 2009 **Most Recent Endorsement Date:** Sep 02, 2014

IF this measure is included in a composite, NQF Composite#/title:

IF this measure is paired/grouped, NQF#/title:

De.4. IF PAIRED/GROUPED, what is the reason this measure must be reported with other measures to appropriately interpret results? IF this measure is paired/grouped, NQF#/title:

NQF 2467 – Adherence to ACEIs/ARBs for Individuals with Diabetes Mellitus
NQF 2468 – Adherence to Oral Diabetes Agents for Individuals with Diabetes Mellitus

Diabetic patients often require chronic treatment with oral diabetes agents, statins, and/or ACEIs/ARBs to lower their risk of diabetic complications, adverse cardiovascular disease outcomes, and mortality. Adherence to chronic medication regimens has been documented in the literature to be less than optimal. In addition, the testing result from the 2011 and 2012 10-state Medicare claim data demonstrated substantial room for improvement. Poor adherence can reduce the effectiveness of treatment, and interventions to improve adherence can provide an opportunity for quality improvement.

1. Evidence, Performance Gap, Priority – Importance to Measure and Report

Extent to which the specific measure focus is evidence-based, important to making significant gains in healthcare quality, and improving health outcomes for a specific high-priority (high-impact) aspect of healthcare where there is variation in or overall less-than-optimal performance. ***Measures must be judged to meet all subcriteria to pass this criterion and be evaluated against the remaining criteria.***

1a. Evidence to Support the Measure Focus – See attached Evidence Submission Form
NQF0545_Evidence_Form_statins.docx

1b. Performance Gap
     Demonstration of quality problems and opportunity for improvement, i.e., data demonstrating:
- considerable variation, or overall less-than-optimal performance, in the quality of care across providers; and/or
- disparities in care across population groups.

1b.1. **Briefly explain the rationale for this measure** *(e.g., the benefits or improvements in quality envisioned by use of this measure)*
Several important benefits related to quality improvement are envisioned with the implementation of this measure. Specifically, the measure will help providers to identify individuals with diabetes mellitus who are not adherent (at a critical threshold of a PDC of 0.8 or greater) to statins. Furthermore, this measure will encourage providers to develop communication and education tools and processes to improve adherence in their patients with diabetes mellitus. Higher medication adherence rates are expected to result in lower rates of hyperlipidemia, cardiovascular events, and mortality. Adoption of this performance measure has the potential to improve quality of care for individuals with diabetes mellitus and, therefore, advance quality of care by engaging patients as partners in their care, a priority area identified in the National Quality Strategy.

1b.2. **Provide performance scores on the measure as specified (current and over time) at the specified level of analysis.** *(This is required for endorsement maintenance. Include mean, std dev, min, max, interquartile range, scores by decile. Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included). This information also will be used to address the subcriterion on improvement (4b.1) under Usability and Use.*
Following is an overview of the testing results based on Medicare data.

State, Plan, and Physician Group Analysis
Sample Characteristics: 2007-2008 all Medicare Parts A, B, and D claims data during calendar years 2007 and 2008 from eight states (Arizona, Delaware, Florida, Iowa, Indiana, Mississippi, Rhode Island, and Washington); the sample consisted of 4,789,034 Medicare beneficiaries, 13,023 Physician Groups, and 93 Part D plans.

2011-2012 all Medicare Parts A, B, and D claims data during calendar years 2011 and 2012 from ten states (Arizona, Delaware, Florida, Iowa, Indiana, Mississippi, Missouri, Rhode Island, Texas, and Washington); the sample consisted of 14,162,440 Medicare beneficiaries, 26,181 Physician Groups, and 83 Part D plans.

State
Year/ n / Mean / Median / Min / Max / STD / IQR / P10 / P25 / P50 / P75 / P90
2008/ 8 / 66.4% / 67.1% / 60.7% / 73.5% / 5.1% / 9.1% / 60.7% / 61.1% / 67.1% / 70.2% / 73.5%
2012/ 10 / 71.8% / 73.2% / 65.5% / 78.9% / 4.1% / 5.0% / 66.2% / 68.8% / 73.2% / 73.9% / 77.1%

Prescription Drug Plans
Year/ n / Mean / Median / Min / Max / STD / IQR / P10 / P25 / P50 / P75 / P90

Plans with at least 260 eligible individuals (minimum denominator for reliability > 0.7):
2008/ 32 / 66.0% / 65.2% / 57.6% / 78.9% / 5.0% / 5.1% / 59.6% / 62.9% / 65.2% / 68.0% / 72.5%

Plans with at least 200 eligible individuals (minimum denominator for reliability > 0.7):
2012/ 40 / 72.2% / 72.9% / 59.1% / 81.2% / 5.4% / 6.3% / 65.2% / 69.5% / 72.9% / 75.8% / 78.5%

Physician Groups
Year/ n / Mean / Median / Min / Max / STD / IQR / P10 / P25 / P50 / P75 / P90

Physician groups with at least 155 eligible individuals (minimum denominator for reliability > 0.7):
2008/ 217 / 67.3% / 67.6% / 47.4% / 82.0% / 6.5% / 8.8% / 58.9% / 63.0% / 67.6% / 71.8% / 76.4%

Physician groups with at least 175 eligible individuals (minimum denominator for reliability > 0.7):
2012/ 491 / 70.8% / 71.2% / 44.6% / 85.7% / 5.9% / 7.6% / 62.9% / 67.2% / 71.2% / 74.8% / 78.3%

ACO
Sample Characteristics: Parts A, B, and D data for 682,036 beneficiaries (204,075 who met the denominator criteria) attributed to 31 ACOs from calendar year 2011

Year/ n / Mean / Median / Min / Max / STD / IQR / P10 / P25 / P50 / P75 / P90
2011/ 31 / 72.3% / 72.9% / 61.8% / 81.8% / 4.8% / 7.3% / 66.9% / 68.2% / 72.9% / 75.5% / 78.2%

1b.3. If no or limited performance data on the measure as specified is reported in 1b2, then provide a summary of data from the literature that indicates opportunity for improvement or overall less than optimal performance on the specific focus of measurement.
Following is an overview of the data from published studies demonstrating the performance gap/variation related to this measure on adherence to chronic medications for diabetes mellitus:

Overview of the Performance Gap and Details on Variation
Five recent studies (Pladevall et al., 2004; Ratanawongsa et al., 2013; Vink et al., 2009; Yang et al., 2009; Zhang et al., 2011) report a substantial percentage of patients with diabetes mellitus have adherence <80% for statins.

Three of the studies (Pladevall et al., 2004; Yang et al., 2009; Zhang et al., 2011) reported rates of adherence >=80% for statins to be 64%, 54%, and 52%, respectively. Another two studies (Ratanawongsa et al., 2013; Vink et al., 2009) reported adherence >=80% for all lipid-lowering medications (i.e., not restricted to statins) to be 79% and 77%, respectively.

Summary of Published Studies on Variation in Adherence Rates to Statins among Patients with Diabetes Mellitus

Pladevall et al. (2004): In this retrospective study of 677 patients with diabetes and 18 years of age and older (mean age of 64 years), the association between rates of medication adherence and clinical outcomes were measured. Patients with a diagnosis of diabetes, hypertension, and dyslipidemia during the period of 1999 to 2001 and at least one prescription drug claim for an anti-diabetic, lipid-lowering, or antihypertensive drug in each of those years were included. Health plan, administrative, and clinical data were used to identify patients. Non-adherence was measured for three classes of drugs: metformin, statins, and ACE inhibitors. Patients were classified as non-adherent when the percentage of the continuous measure of medication gaps (CMG) was 20% or higher. The rate of non-adherence for statins was 36%.

Ratanawongsa et al. (2013): In this study, poor communication between patients and healthcare providers was associated with inadequate refill adherence for cardiometabolic medications. Patients were chosen from the Diabetes Study of Northern California (DISTANCE) survey collected from May 2005 to December 2006. Patients were between the ages of 30 to 75 (mean age of 60 years), had diabetes, indicated having a primary care provider, and were dispensed one or more oral hypoglycemic agents, antihypertensive, or lipid-lowering medication (i.e., ezetimibe, fibrates, niacin, bile acid resins, statins, or fish oil) in the 12 months before the survey. Patients were considered to be poorly adherent if they had no medication supply for more than 20% of the

observation time (CMG >20%) and were considered adherent when medications were available for 80% or more of the time. There were a total of 9,377 eligible respondents, of which 7,052 were prescribed lipid-lowering medications. Poor adherence for lipid-lowering medication was 21%.

Vink et al. (2009): In this observational study of 3,877 patients with type 2 diabetes (mean age of 66 years), differences in medication adherence were observed based on drug class. Patients who were participating in the Groningen Initiative to Analyze Type 2 Diabetes Treatment study and were diagnosed and managed for diabetes in January 2005 were selected for inclusion in this study. Refill adherence was assessed for the year 2004 for oral glucose-lowering medications (including biguanides, SU-derivates, acarbose, glitazones, and glinides), antihypertensives (including diuretics, beta-blocking agents, calcium-antagonists, and RAS-inhibitors), and lipid-lowering medications (including statins, fibrates, bile acid sequestrants, nicotinic acid derivates, and other lipid modifying drugs). Defining poor adherence as medication possession ratio (MPR) <80%, the overall rate of poor adherence was 23% for lipid-lowering medications.

Yang et al. (2009): In this retrospective study of 1,888,682 Medicare Part D enrollees with diabetes (mean age of 71.6 years), adherence to medications varied across subgroups. Data from this study were obtained from administrative claims from October 2005 to June 2006. Patients were included if they had at least one diabetes diagnosis in inpatient or outpatient data during the time period, at least one claim for insulin in the first six months of 2006, at least two claims for an oral hypoglycemic agent, or at least one claim for more than a >30 day supply of any oral hypoglycemic agent from January 2006 to June 2006. Medication adherence was calculated as the proportion of days covered (PDC), defined as the proportion of the actual number of days with medication available divided by the maximum possible number of days of therapy for those with at least one claim within the class. Non-adherence was defined as a PDC of less than 80%. The estimated rate of non-adherence was 46.4% for statins.

Zhang et al. (2011): In this retrospective study of 52,414 patients with type 2 diabetes (mean age of 62 years), persistence with statin therapy lagged behind persistence with anti-hyperglycemic therapy in patients treated concomitantly. Commercial claims data for patients ages 18 and older with type 2 diabetes who were dispensed both a statin and any oral anti-hyperglycemic agent on the same date in 2006 were included in the study. Compliance with medication was estimated as the MPR over two years. After two years of follow-up, the proportion with an MPR >=80% for statin medications was significantly lower compared to oral anti-hyperglycemic agents (51.9% vs. 63.5%, p<0.0001). Among patients who initiated statin and oral anti-hyperglycemic therapy on the same date, the percentage with an MPR >=80% was also lower for the statin when compared to the oral anti-hyperglycemic agent at two-year follow-up (42.5% vs. 56.2%, p<0.0001).

Conclusion
Estimates of adherence rates for statins in individuals with diabetes mellitus from recently published studies suggest a clear performance gap. Among those with diabetes, adherence of 0.8 or higher ranged from 52% to 64% for statins. These rates represent performance gaps and opportunities for improvement in the management of statins in individuals with diabetes mellitus.

Citations for Data on Performance Gap
Pladevall, M., Wiliams, L., Potts, L., Divine, G., Xi, H., & Lafata, J. (2004). Clinical outcomes and adherence to medications measured by claims data in patients with diabetes. Diabetes Care, 27(12), 2800-2906.
Ratanawongsa, N., Karter, A., Parker, M., Lyles, C., Heisler, M., Moffet, H. H., . . . Schillinger, D. (2013). Communication and medication refill adherence: The Diabetes Study of Northern California. JAMA Internal Medicine, 173(3), 210-218.
Vink, N., Klungel, O., Stolk, R., & Denig, P. (2009). Comparison of various measures for assessing medication refill adherence using prescription data. Pharmacoepidemiology and Drug Safety, 18, 159-165.
Yang, Y., Thumula, V., Pace, P., Banahan, B., Wilkin, N., & Lobb, W. (2009). Predictors of medication nonadherence among patients with diabetes in Medicare Part D programs: A retrospective cohort study. Clinical Therapeutics, 31(10), 2178-2188.
Zhang, Q., Zhao, C., Davies, M., Radican, L., & Seck, T. (2011). Compliance and persistence with concomitant statin and oral antihyperglycemic therapy. American Journal of Managed Care, 17(11), 746-752.

1b.4. Provide disparities data from the measure as specified (current and over time) by population group, e.g., by race/ethnicity, gender, age, insurance status, socioeconomic status, and/or disability. *(This is required for endorsement maintenance. Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities include.) This information also will be used to address the subcriterion on improvement (4b.1) under Usability and Use.*
The summary of data on disparities by population group is discussed in the overview of disparities by population group, summary of published studies on disparities by population group, and testing results based on Medicare data.

This measure was stratified for disparities by age, race/ethnicity, and dual-eligibility (beneficiaries covered by both Medicare and Medicaid). The results/scores are presented for these categories/cohorts.

Rates by age and race/ethnicity for the entire 10-state sample:
Category or Cohort / Denominator / Numerator / Measure Rate

All Ages/ 617,726 / 434,284 / 70.3%
White / 476,889 / 346,628 / 72.7%
African American / 78,688 / 47,492 / 60.4%
Hispanic / 36,599 / 22,715 / 62.1%
Other /   25,550 / 17,449 / 68.3%

18 – 24   / 166 / 92 / 55.4%
White / 86 / 54 / 62.8%
African American / 39 / 14 / 35.9%
Hispanic / 31 / 18 / 58.1%
Other /   10 / 6 / 60.0%

25 – 44 / 13,793 / 8,110 / 58.8%
White / 8,863 / 5,569 / 62.8%
African American / 3,113 / 1,541 / 49.5%
Hispanic / 1,258 / 677 / 53.8%
Other / 559 / 323 / 57.8%

45 – 64   / 115,368 / 75,136 / 65.1%
White / 77,835 / 53,533 / 68.8%
African American / 25,908 / 14,599 / 56.3%
Hispanic / 7,449 / 4,408 / 59.2%
Other / 4,176 / 2,596 / 62.2%

65 – 74   / 275,652 / 196,503 / 71.3%
White / 221,771 / 162,538 / 73.3%
African American / 28,909 / 17,834 / 61.7%
Hispanic / 13,041 / 7,973 / 61.1%
Other /   11,931 / 8,158 / 68.4%

75 – 84   / 167,167 / 121,029 / 72.4%
White   / 132,757 / 98,341 / 74.1%
African American / 16,344 / 10,585 / 64.8%
Hispanic / 10,758 / 6,908 / 64.2%
Other /   7,308 / 5,195 / 71.1%

85 + / 45,580 / 33,414 / 73.3%
White / 35,577 / 26,593 / 74.7%
African American / 4,375 / 2,919 / 66.7%
Hispanic / 4,062 / 2,731 / 67.2%
Other /   1,566 / 1,171 / 74.8%

Rates by age and dual-eligible status for the entire 10-state sample:
Category or Cohort / Denominator / Numerator / Measure Rate

Dual-Eligible / 234,194 / 158,080 / 67.5%
18 – 24   / 156 / 87 / 55.8%
25 – 44   / 11,162 / 6,652 / 59.6%
45 – 64   / 74,230 / 48,720 / 65.6

65 – 74 / 78,856 / 53,687 / 68.1%
75 – 84 / 54,280 / 37,820 / 69.7%
85 + / 15,510 / 11,114 / 71.7%

Not Dual-Eligible / 383,532 / 276,204 / 72.0%
18 – 24 / 10 / 5 / 50.0%
25 – 44 / 2,631 / 1,458 / 55.4%
45 – 64 / 41,138 / 26,416 / 64.2%
65 – 74 / 196,796 / 142,816 / 72.6%
75 – 84 / 112,887 / 83,209 / 73.7%
85 + / 30,070 / 22,300 / 74.2%

In general, younger individuals had lower rates of adherence. Measure rates did not differ among age groups older than 75 years of age or younger than 64 years of age. Comparisons were statistically significant (p-value<0.0001) across all other age groups. For race-ethnicity, rates were statistically different between all race groups (p-value<0.0001). Of note, in the younger age groups (18-64), African Americans had noticeably lower adherence. In age groups >=65 years of age, non-dual-eligible individuals had higher rates of adherence than those who are dual-eligible.

These results indicate considerable variation by race-ethnicity and dual-eligible status, which presents opportunities for quality improvement within these subgroups. In particular, younger (<65 years of age) African Americans and older (>=65 years of age) dually eligible individuals had rates lower than other groups.

1b.5. **If no or limited data on disparities from the measure as specified is reported in 1b4, then provide a summary of data from the literature that addresses disparities in care on the specific focus of measurement. Include citations.**
Overview of Disparities by Population Group
Disparities in rates of adherence to statins have been observed by age, gender, and race/ethnicity among patients with diabetes in published studies.

Summary of Published Studies on Disparities by Population Group
In regard to disparities related to age, gender, and race/ethnicity in patients with diabetes, one study is included that reports lower adherence to statins among younger patients (<65 years of age) compared to older patients (65-74), female patients compared to male patients, and black and Hispanic patients compared to white and "other" patients.

Yang et al. (2009): In this retrospective cohort study of 1,888,682 Medicare Part D enrollees with diabetes, enrollees younger than age 65, females, and those who were black or Hispanic were more likely to be non-adherent to statins. Non-adherence was defined as a PDC of less than 80%. Patients under 65 years were 29% (OR 1.29; 95% CI 1.28-1.31, p<0.001) more likely to be non-adherent to statins when compared to patients aged 65-74 years. Female patients were 11% (OR 1.11; 95% CI 1.10-1.12, p<0.001) more likely to be non-adherent to statins when compared to male patients. Black patients were 24% (OR 1.24; 95% CI 1.22-1.25; p<0.001) more likely than whites to be non-adherent to statins. Hispanic patients were also 41% (OR 1.41; 95% CI 1.39-1.43; p<0.001) more likely to be non-adherent to statins, compared to white patients.

Conclusion
Among patients with diabetes, lower adherence to statins was observed among female patients compared to male patients; among those less than 65 years compared to those over 65 years, and among Hispanics and African-Americans compared to Whites and "other" patients.

Citations for Data on Disparities
Yang, Y., Thumula, V., Pace, P., Banahan, B., Wilkin, N., & Lobb, W. (2009). Predictors of medication nonadherence among patients with diabetes in Medicare Part D programs: A retrospective cohort study. Clinical Therapeutics, 31(10), 2178-2188.

1c. High Priority (previously referred to as High Impact)
    The measure addresses:
- a specific national health goal/priority identified by DHHS or the National Priorities Partnership convened by NQF; OR
- a demonstrated high-priority (high-impact) aspect of healthcare (e.g., affects large numbers of patients and/or has a substantial impact for a smaller population; leading cause of morbidity/mortality; high resource use (current and/or

future); severity of illness; and severity of patient/societal consequences of poor quality).

1c.1. Demonstrated high priority aspect of healthcare
Affects large numbers, A leading cause of morbidity/mortality, High resource use, Other
1c.2. If Other: Related to national priorities

1c.3. Provide epidemiologic or resource use data that demonstrates the measure addresses a high priority aspect of healthcare. List citations in 1c.4.
Regarding the summary of evidence of high impact, an overview is presented below, together with information from the literature on the number of individuals affected, the relationship between diabetes, morbidity, and mortality, efficacy of statins in preventing adverse outcomes, and the resource use associated with diabetes and its adverse outcomes:

Overview
More than 11% of individuals 20 years of age and older in the United States, which is approximately 25.6 million people, have diagnosed or undiagnosed diabetes (Centers for Disease Control and Prevention, 2011c). Patients with diabetes are at higher risk of developing hyperlipidemia, and often require long-term treatment with statins to lower their risk of adverse cardiovascular disease outcomes and mortality.

Efficacy of Statins for Individuals with Diabetes
Substantial evidence exists to support the positive effect of statin therapy on cardiovascular disease outcomes in individuals with diabetes, as described in the "Standards of Medical Care in Diabetes—2013" guidelines (American Diabetes Association, 2013b) and reports from multiple clinical trials cited in the guidelines (Cholesterol Treatment Trialists´ (CTT) Collaborators, 2005, 2012; Goldberg et al., 1998; Heart Protection Study Collaborative Group, 2003; Pyorala et al., 1997; Sever et al., 2005; Shepherd et al., 2006; Colhoun et al., 2004; Knopp, d´Emden, Smilde, Pocock, & ASPEN Study Group, 2006; Rajpathak et al., 2009; Sattar et al., 2010; Ridker, Pradhan, MacFayden, Libby, & Glynn, 2012).

Affects Large Numbers
In 2010, an estimated 11.3% of individuals 20 years of age and older in the United States had diagnosed or undiagnosed diabetes (Centers for Disease Control and Prevention, 2011c). Among those 65 years of age and older, the rate was more than twice as high – 26.9% or 10.9 million people (Centers for Disease Control and Prevention, 2011c). According to the Centers for Disease Control and Prevention National Diabetes Surveillance System, the prevalence of diagnosed diabetes in 2011 among people ages 65-74 (21.8%) was nearly 14 times that of people less than 45 years of age (1.6%) (Centers for Disease Control and Prevention, 2013). The incidence of new cases of diabetes among those 18-44 years, 45-64 years, and 65-79 years of age were 4.6, 13.5, and 12.4 per 1,000 population in 2010 (Centers for Disease Control and Prevention, 2012a). Age-adjusted incidence of diabetes was similar among men and women in 2010 (9.7 vs. 7.3 per 1,000 population respectively) (Centers for Disease Control and Prevention, 2011b). Incidence of newly diagnosed diabetes in adults ages 18 to 79 years is higher among blacks (13.0 per 1,000) and Hispanics (12.9 per 1,000) when compared to whites (7.7 per 1,000 population) (Centers for Disease Control and Prevention, 2011a).

A Leading Cause of Morbidity and Mortality
In 2007, diabetes was the seventh leading cause of death in the U.S. based on death certificates, and the overall risk of mortality among persons with diabetes is about twice that of similarly aged persons without diabetes (Centers for Disease Control and Prevention, 2011c). Among adults with diabetes mellitus, high blood cholesterol was a common comorbidity in 2009, with a prevalence of 52%, 67%, 66%, and 60% among those 18-44, 45-64, 65-74, and >=75 years of age, respectively (Centers for Disease Control and Prevention, 2012b). Among adults with diabetes, heart disease mortality rates and stroke rates are two to four times higher than among those without diabetes (Centers for Disease Control and Prevention, 2011c).

High Resource Use
The total costs (direct and indirect) of diabetes were $174 billion in 2007 according to the CDC (Centers for Disease Control and Prevention, 2011c). Direct medical costs accounted for $116 billion and after adjusting for age and sex differences, medical expenditures for those with diabetes were 2.3 times higher than estimated expenditures in the absence of diabetes (Centers for Disease Control and Prevention, 2011c). The remaining $58 billion in costs were indirect and associated with disability, work loss, and premature mortality (Centers for Disease Control and Prevention, 2011c). The estimated economic costs of undiagnosed diabetes in 2007 were $18 billion which included $11 billion in direct medical costs and $7 billion in indirect costs (Zhang et al., 2009). In 2008, there were over 7.7 million hospital stays for which diabetes was listed as a principal or secondary diagnosis or co-existing condition (Fraze et al., 2010). Of those, 540,000 stays (7.0%) had diabetes listed as the primary diagnosis. In that year, the

mean cost for hospitalization was $10,937 for patients with diabetes compared to $8,746 in patients without diabetes (Fraze et al., 2010). Average length of stay for patients with diabetes was longer than for patients without diabetes (5.3 vs. 4.4 days). Hospital stays involving diabetes (primary or secondary diagnosis) accounted for 23% ($83 billion) of total U.S. hospital costs (Fraze et al., 2010). According to the American Diabetes Association, the estimated cost of diabetes in the U. S. in 2012 was $245 billion which was a 41% increase from the previous estimate of $174 billion (2007 dollars) (American Diabetes Association, 2013a). Of that estimated amount, $176 billion were due to direct medical costs ($76 billion or 43% attributed to inpatient hospital care and $15 billion or 9% attributed to physician office visits) and $69 billion attributed to reduced work-related productivity ($5 million or 7% attributed to absenteeism and $20.8 million or 30% attributed to reduced productivity while at work) (American Diabetes Association, 2013a).

Related to National Priorities
This measure (NQF 0545) relates to adherence to statins among individuals with diabetes mellitus. The National Quality Forum's Measure Prioritization Advisory Committee ranked diabetes fourth in a list of the top 20 high-impact Medicare conditions identified on the basis of cost, prevalence, variability, improvability, and disparities (National Quality Forum, 2010). In addition, a recent study of gaps in diabetes measures identified "Access to care and medications" as a high priority for measure development. In fact, this report suggested that it would be important to understand why a measure of chronic medication adherence for individuals with diabetes was not already in use (National Quality Forum, 2013). Furthermore, the National Quality Strategy has identified engaging patients as partners in their care as one of six major priorities for quality improvement in the nation's healthcare system (U.S. Department of Health and Human Services, 2013). Therefore, national priorities support the potential high impact of this measure.

1c.4. Citations for data demonstrating high priority provided in 1a.3
American Diabetes Association. (2013a, March 13). Economic costs of diabetes in the U.S. in 2012. Diabetes Care, online, 1-14. doi: 10.2337/dc12-2625
American Diabetes Association. (2013b). Standards of Medical Care in Diabetes. IX. Diabetes care in specific settings. Diabetes Care, 36(Supplement 1), S11-S66.
Centers for Disease Control and Prevention. (2011a, January 5). Age-Adjusted Incidence of Diagnosed Diabetes per 1,000 Population Aged 18–79 Years, by Race/Ethnicity, United States, 1997–2010. Retrieved June 18, 2013, from
http://www.cdc.gov/diabetes/statistics/incidence/fig6.htm
Centers for Disease Control and Prevention. (2011b, January 5). Age-Adjusted Incidence of Diagnosed Diabetes per 1,000 Population Aged 18–79 Years, by Sex, United States, 1980–2011. Retrieved June 18, 2013, from
http://www.cdc.gov/diabetes/statistics/incidence/fig4.htm
Centers for Disease Control and Prevention. (2011c). National diabetes fact sheet: National estimates and general information on diabetes and prediabetes in the United States, 2011. (C. f. D. C. a. Prevention, Trans.). Atlanta, GA: U.S. Department of Health and Human Services.
Centers for Disease Control and Prevention. (2012a, February 14). Incidence of Diagnosed Diabetes per 1,000 Population Aged 18–79 Years, by Age, United States, 1980–2010. Retrieved June 18, 2013, from
http://www.cdc.gov/diabetes/statistics/incidence/fig3.htm
Centers for Disease Control and Prevention. (2012b). Percentages of Adults with Diagnosed Diabetes Who Have High Cholesterol, by Age, United States, 1995–2009. Retrieved June 18, 2013, from http://www.cdc.gov/diabetes/statistics/comp/table8_2a.htm
Centers for Disease Control and Prevention. (2013, March 28). Percentage of Civilian, Non-institutionalized Population with diagnosed Diabetes, by Age, United States, 1980-2011. Retrieved June 18, 2013, from
http://www.cdc.gov/diabetes/statistics/prev/national/figbyage.htm
Cholesterol Treatment Trialists´ (CTT) Collaborators. (2005). Efficacy and safety of cholesterol-lowering treatment: Prospective meta-analysis of data from 90,056 participants in 14 randomised trials of statins. The Lancet, 366, 1267-1278.
Cholesterol Treatment Trialists´ (CTT) Collaborators. (2012). The effects of lowering LDL cholesterol with statin therapy in people at low risk of vascular disease: Meta-analysis of individual data from 27 randomised trials. The Lancet, 380, 581-590.
Colhoun, H., Betteridge, D., Durrington, P., Hitman, G., Neil, H., Livingstonne, S., . . . Fuller, J. (2004). Primary prevention of cardiovascular disease with atorvastatin in type 2 diabetes in the Collaborative Atorvastatin Diabetes Study (CARDS): Multicentre randomised placebo-controlled trial. The Lancet, 364, 684-696.
Fraze, T., Jiang, J., & Burgess, J. (2010). Hospital Stays for Patients with Diabetes, 2008 (h. C. a. U. Project, Trans.) Statistical Brief. Rockville, MD: Agency for Healthcare Research and Quality.
Goldberg, R., Mellies, M., Sacks, F., Moye, L., Howard, B., Howard, W., . . . Braunwald, E. (1998). Cardiovascular events and their reduction with pravastatin in diabetic and glucose-intolerant myocardial infarction survivors with average cholesterol levels: Subgroup analyses in the cholesterol and recurrent events (CARE) trial. Circulation, 98, 2513-2519.
Heart Protection Study Collaborative Group. (2003). MRC/BHF Heart Protection Study of cholesterol-lowering with simvastatin in

5963 people with diabetes: A randomised placebo controlled trial. The Lancet, 361, 2005-2016.

Knopp, R., d´Emden, M., Smilde, J., Pocock, S., & ASPEN Study Group. (2006). Efficacy and safety of atorvastatin in the prevention of cardiovascular end points in subjects with type 2 diabetes: The Atorvastatin Study for Prevention of Coronary Heart Disease Endpoints in non-insulin-dependent diabetes mellitus (ASPEN). Diabetes Care, 29, 1478-1485.

National Quality Forum. (2010). Prioritization of high-impact Medicare conditions and measure gaps. Measure Prioritization Advisory Committee Report. Washington, DC: National Quality Forum.

National Quality Forum. (2013, March 31). Report from National Quality Forum: 2012 NQF measure gap analysis. Washington, DC: National Quality Forum.

Pyorala, K., Pedersen, T., Kjekshus, J., Faergeman, O., Olsson, A., Thorgeirsson, G., & The Scandinavian Simvastatin Survival Study Group. (1997). Cholesterol lowering with simvastatin improves prognosis of diabetic patients with coronary heart disease. Diabetes Care, 20(4), 614-620.

Rajpathak, S., Kumbhani, D., Crandall, J., Barzilai, N., Alderman, M., & Ridker, P. (2009). Statin therapy and risk of developing type 2 diabetes: A meta-analysis. Diabetes Care, 32(10), 1924-1929.

Ridker, P., Pradhan, A., MacFayden, J., Libby, P., & Glynn, R. (2012). Cardiovascular benefits and diabetes risks of statin therapy in primary prevention: An analysis from the JUPITER trial. The Lancet, 380(9841), 565-571.

Sattar, N., Preiss, D., Murray, H. W., P., Buckley, B., de Craen, A., Seshasai, S., . . . Ford, I. (2010). Statins and risk of incident diabetes: A collaborative meta-analysis of randomised statin trials. The Lancet, 375(9716), 735-742.

Sever, P., Poulter, N., Dahlof, B., Wedel, H., Collins, R., Beevers, G., . . . Ostergren, J. (2005). Reduction in cardiovascular events with atorvastatin in 2,532 patients with type 2 diabetes. Diabetes Care, 28, 1151-1157.

Shepherd, J., Barter, P., Carmena, R., Deedwania, P., Fruchart, J., Haffner, S., . . . Waters, D. (2006). Effect of lowering LDL cholesterol substantially below currently recommended levels in patients with coronary heart disease and diabetes: The Treating to New Targets (TNT) study. Diabetes Care, 29, 1220-1226.

U.S. Department of Health and Human Services. (2013). National strategy for quality improvement in healthcare: 2013 Annual Report to Congress. Washington, DC: U.S. Department of Health and Human Services.

Zhang, Y., Dall, T., Mann, S., Chen, Y., Martin, J., Moore, V., . . . Quick, W. (2009). The economic costs of undiagnosed diabetes. Population Health Management, 12(2), 95-101.

1c.5. **If a PRO-PM (e.g. HRQoL/functional status, symptom/burden, experience with care, health-related behaviors), provide evidence that the target population values the measured PRO and finds it meaningful.** *(Describe how and from whom their input was obtained.)*
Not applicable

2. Reliability and Validity—Scientific Acceptability of Measure Properties

Extent to which the measure, <u>as specified</u>, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. ***Measures must be judged to meet the subcriteria for both reliability and validity to pass this criterion and be evaluated against the remaining criteria.***

2a.1. Specifications The measure is well defined and precisely specified so it can be implemented consistently within and across organizations and allows for comparability. eMeasures should be specified in the Health Quality Measures Format (HQMF) and the Quality Data Model (QDM).

De.5. **Subject/Topic Area** *(check all the areas that apply):*
Endocrine, Endocrine : Diabetes

De.6. **Cross Cutting Areas** *(check all the areas that apply):*
Disparities, Safety : Medication Safety

S.1. **Measure-specific Web Page** *(Provide a URL link to a web page specific for this measure that contains current detailed specifications including code lists, risk model details, and supplemental materials. Do not enter a URL linking to a home page or to general information.)*
Not applicable

S.2a. **If this is an eMeasure**, HQMF specifications must be attached. Attach the output from the eMeasure authoring tool (MAT) - if the MAT was not used, contact staff. (Use the specification fields in this online form for the plain-language description of the specifications)

No HQMF specs **Attachment:**

S.2b. **Data Dictionary, Code Table, or Value Sets** *(and risk model codes and coefficients when applicable) must be attached. (Excel or csv file in the suggested format preferred - if not, contact staff)*
Attachment **Attachment:** NQF0545_-_Codes_Table_-_statins.xls

S.3. **For endorsement maintenance**, please briefly describe any changes to the measure specifications since last endorsement date and explain the reasons.
The age requirement for the target population was changed from 18 years or older at the end of the measurement period to 18 years or older at the beginning of the measurement period to harmonize with other measures in the portfolio. ICD-9-CM, ICD-10-CM, and National Drug Codes have been updated annually. Optional criteria to stratify the measure between new and continuous users were removed to harmonize with other NQF-endorsed measures. The new drugs on the market that are applicable to the measure have been added to the medication list, and agents that have been discontinued for more than three years have been removed.

S.4. **Numerator Statement** *(Brief, narrative description of the measure focus or what is being measured about the target population, i.e., cases from the target population with the target process, condition, event, or outcome)*
IF an OUTCOME MEASURE, state the outcome being measured. Calculation of the risk-adjusted outcome should be described in the calculation algorithm.
Individuals in the denominator with at least two prescriptions for statins with a PDC of at least 0.8 for statins.

S.5. **Time Period for Data** *(What is the time period in which data will be aggregated for the measure, e.g., 12 mo, 3 years, look back to August for flu vaccination? Note if there are different time periods for the numerator and denominator.)*
The time period for data is defined as any time during the measurement period (12 consecutive months).

S.6. **Numerator Details** *(All information required to identify and calculate the cases from the target population with the target process, condition, event, or outcome such as definitions, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b)*
IF an OUTCOME MEASURE, describe how the observed outcome is identified/counted. Calculation of the risk-adjusted outcome should be described in the calculation algorithm.
The numerator is defined as individuals with a PDC of 0.8 or greater.

The PDC is calculated as follows:
• PDC Numerator: The PDC numerator is the sum of the days covered by the days' supply of all drug claims in each respective drug class. The period covered by the PDC starts on the day the first prescription is filled (index date) and lasts through the end of the measurement period, or death, whichever comes first. For prescriptions with a days' supply that extends beyond the end of the measurement period, count only the days for which the drug was available to the individual during the measurement period. If there are prescriptions for the same drug (generic name) on the same date of service, keep the prescription with the largest days' supply. If prescriptions for the same drug (generic name) overlap, then adjust the prescription start date to be the day after the previous fill has ended.
• PDC Denominator: The PDC denominator is the number of days from the first prescription date through the end of the measurement period, or death date, whichever comes first.

S.7. **Denominator Statement** *(Brief, narrative description of the target population being measured)*
Individuals at least 18 years of age as of the beginning of the measurement period with diabetes mellitus and at least two prescriptions for statins during the measurement period (12 consecutive months).

S.8. **Target Population Category** *(Check all the populations for which the measure is specified and tested if any):*
Populations at Risk, Populations at Risk : Dual eligible beneficiaries, Senior Care

S.9. **Denominator Details** *(All information required to identify and calculate the target population/denominator such as definitions, specific data collection items/responses , code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b)*
Target population meets the following conditions:
1. Continuously enrolled in Part D with no more than a one-month gap in enrollment during the measurement year;

2. Continuously enrolled in Part A and Part B with no more than a one-month gap in Part A enrollment and no more than a one-month gap in Part B enrollment during the measurement year; and,
3. No more than one month of HMO enrollment during the measurement year.

IDENTIFICATION OF DIABETES MELLITUS
Individuals with diabetes mellitus are identified using diagnosis codes and/or drug proxy to identify diabetes mellitus within the inpatient or outpatient claims data.*

Individuals must have:
At least two encounters with a principal or secondary diagnosis of diabetes with different dates of service in an outpatient setting or non-acute inpatient setting during the measurement period;

OR

At least one encounter with a principal or secondary diagnosis of diabetes in an acute inpatient or emergency department setting during the measurement period;

OR

At least one ambulatory prescription claim for insulin or other oral diabetes medication dispensed during the measurement period.

*Adapted from NCQA HEDIS 2012 (2012). Note: HEDIS uses a look-back period of one year for both the prescription data and diagnosis.

Table 1. Codes Used to Identify Diabetes Mellitus Diagnosis
ICD-9-CM: 250.xx, 357.2, 362.01, 362.02, 362.03, 362.04, 362.05, 362.06, 362.07, 366.41, 648.00, 648.01, 648.02, 648.03, 648.04
ICD-10-CM: E08.311, E08.319, E08.321, E08.329, E08.331, E08.339, E08.341, E08.349, E08.351, E08.359, E08.40, E08.42, E09.311, E09.319, E09.321, E09.329, E09.331, E09.339, E09.341, E09.349, E09.351, E09.359, E09.36, E09.40, E09.42, E10.10, E10.11, E10.21, E10.22, E10.29, E10.311, E10.319, E10.321, E10.329, E10.331, E10.339, E10.341, E10.349, E10.351, E10.359, E10.36, E10.39, E10.40, E10.41, E10.42, E10.43, E10.44, E10.49, E10.51, E10.52, E10.59, E10.610, E10.618, E10.620, E10.621, E10.622, E10.628, E10.630, E10.638, E10.641, E10.649, E10.65, E10.69, E10.8, E10.9, E11.00, E11.01, E11.21, E11.22, E11.29, E11.311, E11.319, E11.321, E11.329, E11.331, E11.339, E11.341, E11.349, E11.351, E11.359, E11.36, E11.39, E11.40, E11.41, E11.42, E11.43, E11.44, E11.49, E11.51, E11.52, E11.59, E11.610, E11.618, E11.620, E11.621, E11.622, E11.628, E11.630, E11.638, E11.641, E11.649, E11.65, E11.69, E11.8, E11.9, E13.00, E13.01, E13.10, E13.11, E13.21, E13.22, E13.29, E13.311, E13.319, E13.321, E13.329, E13.331, E13.339, E13.341, E13.349, E13.351, E13.359, E13.36, E13.39, E13.40, E13.41, E13.42, E13.43, E13.44, E13.49, E13.51, E13.52, E13.59, E13.610, E13.618, E13.620, E13.621, E13.622, E13.628, E13.630, E13.638, E13.641, E13.649, E13.65, E13.69, E13.8, E13.9, O24.011, O24.012, O24.013, O24.019, O24.02, O24.03, O24.111, O24.112, O24.113, O24.119, O24.12, O24.13, O24.311, O24.312, O24.313, O24.319, O24.32, O24.33, O24.811, O24.812, O24.813, O24.819, O24.82, O24.83, O24.911, O24.912, O24.913, O24.919, O24.92, O24.93
DRG: 637,638

Codes Used to Identify Encounter Type
Table 2.1. Outpatient Setting
CPT: 92002, 92004, 92012, 92014, 99201-99205, 99211-99215, 99217-99220, 99241-99245, 99341-99345, 99347-99350, 99384-99387, 99394-99397, 99401-99404, 99411, 99412, 99420, 99429, 99455, 99456
UB-92 revenue: 051x, 0520-0523, 0526-0529, 057x-059x, 077x, 082x-085x, 088x, 0982, 0983

Table 2.2 Non-Acute Inpatient
CPT: 99304-99310, 99315, 99316, 99318, 99324-99328, 99334-99337
UB-92 revenue: 0118, 0128, 0138, 0148, 0158, 019x, 0524, 0525, 055x, 066x

Table 2.3 Acute Inpatient
CPT: 99221-99223, 99224-99226, 99231-99233, 99238, 99239, 99251-99255, 99291
UB-92 revenue: 010x, 0110-0114, 0119, 0120-0124, 0129, 0130-0134, 0139, 0140-0144, 0149, 0150-0154, 0159, 016x, 020x-022x, 072x, 080x, 0987

Table 2.4 Emergency Department
CPT: 99281-99285
UB-92 revenue: 045x, 0981

The following are the diabetic medications by class for the denominator. The route of administration includes all oral and injectable formulations of the medications listed below.

Table 3. Codes Used to Identify Diabetic Individuals
Alpha-glucosidase inhibitors:
acarbose
miglitol

Anti-diabetic amylin analogs:
pramlintide

Anti-diabetic combinations:
alogliptin-metformin
alogliptin-pioglitazone
glipizide-metformin
glyburide-metformin
pioglitazone-glimepiride
pioglitazone-metformin
rosiglitazone-glimepiride
rosiglitazone-metformin
saxagliptin-metformin
sitagliptin-metformin
repaglinide-metformin
sitagliptin-simvastatin
linagliptin- metformin

Dipeptidyl peptidase-4 (dpp-4) inhibitors:
alogliptin
sitagliptin,
saxagliptin,
linagliptin

Incretin mimetics:
exenatide
liraglutide

Insulin:
insulin aspart
insulin aspart
protamine & aspart (human)
insulin detemir
insulin glargine
insulin glulisine
insulin isophane & reg (human)
insulin isophane (human)
insulin lispro (human)
insulin lispro protamine & lispro (human)
insulin regular (human)

Meglitinides:

nateglinide
repaglinide

Sodium-glucose cotransporter 2 Inhibitors:
canagliflozin

Sulfonylureas:
chlorpropamide
glimepiride
glipizide
glyburide
tolazamide
tolbutamide
glyburide micronized

Thiazolidinediones:
pioglitazone
rosiglitazone

The following are the statin medications by class for the denominator. The route of administration includes all oral formulations of the medications listed below.

Table 4. Statin Medications
HMG-COA reductase inhibitors (statins):
atorvastatin
fluvastatin
lovastatin
pitavastatin
pravastatin
rosuvastatin
simvastatin

HMG-COA reductase inhibitors (statins) combinations:
amlodipine-atorvastatin
ezetimibe-atorvastatin
ezetimibe-simvastatin
niacin-lovastatin
niacin-simvastatin
sitagliptin-simvastatin

S.10. **Denominator Exclusions** *(Brief narrative description of exclusions from the target population)*
We excluded the following individuals from the denominator:
Individuals with polycystic ovaries, gestational diabetes, or steroid-induced diabetes who do not have a face-to-face visit with a diagnosis of diabetes in any setting during the measurement period.
Exclusion 1
Individuals with a diagnosis of polycystic ovaries who do not have a visit with a diagnosis of diabetes in any setting during the measurement period*; and,

Exclusion 2
Individuals with a diagnosis of gestational diabetes or steroid-induced diabetes who do not have a visit with a diagnosis of diabetes mellitus in any setting during the measurement period.

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

S.11. **Denominator Exclusion Details** *(All information required to identify and calculate exclusions from the denominator such as definitions, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b)*
Table 5. Diagnostic Exclusions for Diabetes Denominator
Exclusion 1
Polycystic Ovaries
ICD-9-CM: 256.4
ICD-10-CM: E28.2

Exclusion 2
Steroid-Induced Diabetes
ICD-9-CM: 249.xx, 251.8, 962.0
ICD-10-CM: E08.00, E08.01, E08.10, E08.11, E08.21, E08.22, E08.29, E08.311, E08.319, E08.321, E08.329, E08.331, E08.339, E08.341, E08.349, E08.351, E08.359, E08.36, E08.39, E08.40, E08.41, E08.42, E08.43, E08.44, E08.49, E08.51, E08.52, E08.59, E08.610, E08.618, E08.620, E08.621, E08.622, E08.628, E08.630, E08.638, E08.641, E08.649, E08.65, E08.69, E08.8, E08.9, E09.00, E09.01, E09.10, E09.11, E09.21, E09.22, E09.29, E09.311, E09.319, E09.321, E09.329, E09.331, E09.339, E09.341, E09.349, E09.351, E09.359, E09.36, E09.39, E09.40, E09.41, E09.42, E09.43, E09.44, E09.49, E09.51, E09.52, E09.59, E09.610, E09.618, E09.620, E09.621, E09.622, E09.628, E09.630, E09.638, E09.641, E09.649, E09.65, E09.69, E09.8, E09.9, E16.8, T38.0X1A, T38.0X2A, T38.0X3A, T38.0X4A, T50.0X1A, T50.0X2A, T50.0X3A, T50.0X4A

Gestational Diabetes
ICD-9-CM: 648.80, 648.81, 648.82, 648.83, 648.84
ICD-10-CM: O24.410, O24.414, O24.419, O24.420, O24.424, O24.429, O24.430, O24.434, O24.439, O99.810, O99.814, O99.815

S.12. **Stratification Details/Variables** *(All information required to stratify the measure results including the stratification variables, definitions, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format with at S.2b)*
Depending on the operational use of the measure, measure results may be stratified by:
• State
• Accountable Care Organizations (ACOs)*
• Plan
• Physician Group
• Age - Divided into 6 categories: 18-24, 25-44, 45-64, 65-74, 75-84, and 85+ years
• Race/Ethnicity
• Dual Eligibility
*ACO attribution methodology is based on where the beneficiary is receiving the plurality of his/her primary care services and subsequently assigned to the participating providers.

S.13. **Risk Adjustment Type** (Select type. Provide specifications for risk stratification in S.12 and for statistical model in S.14-15)
No risk adjustment or risk stratification
If other:

S.14. **Identify the statistical risk model method and variables** *(Name the statistical method - e.g., logistic regression and list all the risk factor variables. Note - risk model development and testing should be addressed with measure testing under Scientific Acceptability)*
Not applicable

S.15. **Detailed risk model specifications** *(must be in attached data dictionary/code list Excel or csv file. Also indicate if available at measure-specific URL identified in S.1.)*
Note: Risk model details (including coefficients, equations, codes with descriptors, definitions), should be provided on a separate worksheet in the suggested format in the Excel or csv file with data dictionary/code lists at S.2b.

S.15a. **Detailed risk model specifications** (*if not provided in excel or csv file at S.2b*)
Not applicable

S.16. **Type of score:**
Rate/proportion
If other:

S.17. **Interpretation of Score** *(Classifies interpretation of score according to whether better quality is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score)*
Better quality = Higher score

S.18. **Calculation Algorithm/Measure Logic** *(Describe the calculation of the measure score as an ordered sequence of steps including identifying the target population; exclusions; cases meeting the target process, condition, event, or outcome; aggregating data; risk adjustment; etc.)*
To calculate Adherence to Statins for Individuals with Diabetes Mellitus, Medicare administrative claims data and related files, as described in detail in Section S.24, will be required.

Denominator: Individuals at least 18 years of age as of the beginning of the measurement period with diabetes mellitus and at least two prescriptions for statins during the measurement period (12 consecutive months).
Create Denominator
1. Pull individuals who are 18 years of age or older as of the beginning of the measurement period.
2. Include individuals who were continuously enrolled in Part D coverage during the measurement year, with no more than a one-month gap in enrollment during the measurement year, or up until their death date if they died during the measurement period.
3. Include individuals who had no more than a one-month gap in Part A enrollment, no more than a one-month gap in Part B enrollment, and no more than one month of HMO enrollment during the current measurement period (FFS individuals only).
4. Of those individuals identified in Step 3, keep those who had:
At least two face-to-face encounters with a principal or secondary diagnosis of diabetes with different dates of service in an outpatient setting or non-acute inpatient setting during the measurement period;
OR
At least one face-to-face encounter with a principal or secondary diagnosis of diabetes in an acute inpatient setting or emergency department setting during the measurement period;
OR
At least one ambulatory prescription claim for insulin or other oral diabetes medication dispensed during the measurement period.
5. Of the individuals identified in Step 4, exclude those with a diagnosis of polycystic ovaries, gestational diabetes, or steroid-induced diabetes who do not have at least one face-to-face visit with a diagnosis of diabetes in any setting during the measurement period.
6. Pull all Part D claims for statins. Attach generic name and drug ID to the dataset.
7a. Keep individuals with at least two claims for a drug in the statin class on different dates of service during the measurement period.
7b. Of the individuals not excluded in Step 5, keep those that are also in the statins class dataset created in Step 7a. This is the denominator.
7c. For each individual in the dataset created in Step 7b, identify the date of the first prescription in the measurement period as the index event.

Numerator: Individuals in the denominator with at least two prescriptions for statins with a PDC of at least 0.8 for statins.
Create Numerator
For the individuals in the denominator, calculate the PDC for each individual according to the following methods:
1. Determine the individual's measurement period, defined as the number of days from the index prescription date through the end of the measurement year, or death, whichever comes first. Index date is the date of the first statin prescription in the measurement period.
2. Within the measurement period, count the days the individual was covered by at least one drug in the statin class based on the prescription fill date and days of supply.
a. Pull Part D claims for drugs in the respective drug class for individuals in the denominators. Attach drug ID and generic name to the datasets.
b. Sort and de-duplicate claims by beneficiary ID, service date, generic name, and descending days' supply. If prescriptions for the same drug (generic name) are dispensed on the same date of service for an individual, keep the dispensing with the largest days' supply.
c. Calculate the number of days covered per individual for each drug class.

i. For prescriptions with a days' supply that extends beyond the end of the measurement period, count only the days for which the drug was available to the individual during the measurement period.
ii. If prescriptions for the same drug (generic name) overlap, then adjust the prescription start date to be the day after the previous fill has ended.
iii. If prescriptions for different drugs (different generic names) overlap, do not adjust the prescription start date.
3. Calculate the PDC for each individual. Divide the number of covered days found in Step 2 by the number of days in the individual's measurement period found in Step 1.

An example of SAS code for Steps 1-3 was adapted from PQA and is also available at the URL:
http://www2.sas.com/proceedings/forum2007/043-2007.pdf.

4. Of the individuals identified in Numerator Step 3, count the number of individuals with a calculated PDC of at least 0.8 for the statins class. This is the numerator.

S.19. Calculation Algorithm/Measure Logic Diagram URL or Attachment *(You also may provide a diagram of the Calculation Algorithm/Measure Logic described above at measure-specific Web page URL identified in S.1 OR in attached appendix at A.1)*
Available in attached appendix at A.1

S.20. Sampling *(If measure is based on a sample, provide instructions for obtaining the sample and guidance on minimum sample size.)*
IF a PRO-PM, identify whether (and how) proxy responses are allowed.
Not applicable

S.21. Survey/Patient-reported data *(If measure is based on a survey, provide instructions for conducting the survey and guidance on minimum response rate.)*
IF a PRO-PM, specify calculation of response rates to be reported with performance measure results.
Not applicable

S.22. Missing data (specify how missing data are handled, e.g., imputation, delete case.)
Required for Composites and PRO-PMs.
We have identified two potential scenarios where measure results could be biased by missing data:
1. Missing days' supply within the prescription drug event data, which is a required data element to calculate medication adherence; and,
2. Missing drug claims due to individuals using alternative payment sources for prescription drugs (e.g., $4 commercial discount prescription programs), and other alternative drug benefits, such as the Veterans Administration (VA).

Days' Supply
For missing days' supply, the number (%) of beneficiaries in the measure denominator with one or more claims that had missing days' supply was analyzed. Beneficiaries missing days' supply are excluded from the analysis.

Cash Prescriptions
For bias from cash prescriptions or alternative sources, we conducted a limited sensitivity analysis using a two-state sample (FL and RI) to estimate the potential impact of a commercial cash discount program on measure rates. Specifically, we created a National Drug Code (NDC) list from the formulary of a leading cash discount program to identify those individuals with at least one claim for a statin and no claims for any other Part D drugs on the formulary as a proxy to potentially indicate the individual was filling medications through the cash discount program. We then simulated the effect on measure rates, if each of these individuals' statin medication use extended from the last consecutive claim to the end of the measurement period, assuming that individuals had switched to the cash program. We simulated two scenarios: including complete coverage of all remaining days until the end of the measurement period was 100% or extrapolating the average proportion of days covered from the first prescription in the measurement period to the last prescription in the measurement period.

Results from the analyses were discussed in Section 2b2.4 of the Measure Testing Submission Form. The findings suggest that very little impact on measure rates would be expected from missing days' supply and utilization of the cash discount program. In addition, CMS issued a memo in May 2012 to incentivize network pharmacies to submit claims directly to the plan for drugs dispensed outside the Part D benefit unless the member refuses; we anticipate that this would result in additional claims being captured from cash discount programs.

S.23. Data Source *(Check ONLY the sources for which the measure is SPECIFIED AND TESTED).*
If other, please describe in S.24.
 Administrative claims, Electronic Clinical Data : Pharmacy, Other

S.24. Data Source or Collection Instrument *(Identify the specific data source/data collection instrument e.g. name of database, clinical registry, collection instrument, etc.)*
IF a PRO-PM, identify the specific PROM(s); and standard methods, modes, and languages of administration.
For measure calculation, the following Medicare files were required:
• Denominator tables
• Prescription drug benefit (Part D) coverage tables
• Beneficiary file
• Institutional claims (Part A)
• Non-institutional claims (Part B)—physician carrier/non-DME
• Prescription drug benefit (Part D) claims

For ACO attribution, the following were required:
• Denominator tables for Parts A and B enrollment
• Prescription drug benefit (Part D) coverage tables
• Beneficiary file
• Institutional claims (Part A)
• Non-institutional claims (Part B)—physician carrier/non-DME
• Prescription drug benefit (Part D) claims

For physician group attribution, the following were required:
• Non-institutional claims (Part B)—physician carrier/non-DME
• Denominator tables to determine individual enrollment
• Beneficiary file or coverage table to determine hospice benefit and Medicare as secondary payor status
• CMS physician and physician specialty tables
• National Plan & Provider Enumeration System (NPPES) database

S.25. Data Source or Collection Instrument *(available at measure-specific Web page URL identified in S.1 OR in attached appendix at A.1)*
No data collection instrument provided

S.26. Level of Analysis *(Check ONLY the levels of analysis for which the measure is SPECIFIED AND TESTED)*
 Clinician : Group/Practice, Health Plan, Integrated Delivery System, Population : State

S.27. Care Setting *(Check ONLY the settings for which the measure is SPECIFIED AND TESTED)*
 Ambulatory Care : Clinician Office/Clinic
If other:

S.28. COMPOSITE Performance Measure - Additional Specifications *(Use this section as needed for aggregation and weighting rules, or calculation of individual performance measures if not individually endorsed.)*
Not applicable

2a. Reliability – See attached Measure Testing Submission Form
2b. Validity – See attached Measure Testing Submission Form
NQF0545_Measure_Testing_Form_statins-635267742111041248.docx

3. Feasibility

Extent to which the specifications including measure logic, require data that are readily available or could be captured without undue burden and can be implemented for performance measurement.

3a. Byproduct of Care Processes

For clinical measures, the required data elements are routinely generated and used during care delivery (e.g., blood pressure, lab test, diagnosis, medication order).

3a.1. Data Elements Generated as Byproduct of Care Processes.
Coded by someone other than person obtaining original information (e.g., DRG, ICD-9 codes on claims)
If other:

3b. Electronic Sources
The required data elements are available in electronic health records or other electronic sources. If the required data are not in electronic health records or existing electronic sources, a credible, near-term path to electronic collection is specified.

3b.1. To what extent are the specified data elements available electronically in defined fields? *(i.e., data elements that are needed to compute the performance measure score are in defined, computer-readable fields)*
ALL data elements are in defined fields in electronic claims

3b.2. If ALL the data elements needed to compute the performance measure score are not from electronic sources, specify a credible, near-term path to electronic capture, OR provide a rationale for using other than electronic sources.

3b.3. If this is an eMeasure, provide a summary of the feasibility assessment in an attached file or make available at a measure-specific URL.
No feasibility assessment **Attachment:**

3c. Data Collection Strategy
Demonstration that the data collection strategy (e.g., source, timing, frequency, sampling, patient confidentiality, costs associated with fees/licensing of proprietary measures) can be implemented (e.g., already in operational use, or testing demonstrates that it is ready to put into operational use). For eMeasures, a feasibility assessment addresses the data elements and measure logic and demonstrates the eMeasure can be implemented or feasibility concerns can be adequately addressed.

3c.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 and frequency of data collection, sampling, patient confidentiality, time and cost of data collection, other feasibility/implementation issues.
IF a PRO-PM, consider implications for both individuals providing PROM data (patients, service recipients, respondents) and those whose performance is being measured.**
Testing demonstrated that the measure was feasible to specify and calculate using CMS administrative claims data. Data sources needed to implement the measure are readily available, accessible, and timely. No threats to the validity of this measure were identified using a limited analysis designed to address missing data.

3c.2. Describe any fees, licensing, or other requirements to use any aspect of the measure as specified *(e.g., value/code set, risk model, programming code, algorithm).*
The administrative data (collected by CMS primarily for billing purposes) are used as the data source for this measure. Therefore, the cost of data collection is negligible.

4. Usability and Use

Extent to which potential audiences (e.g., consumers, purchasers, providers, policy makers) are using or could use performance results for both accountability and performance improvement to achieve the goal of high-quality, efficient healthcare for individuals or populations.

4a. Accountability and Transparency
Performance results are used in at least one accountability application within three years after initial endorsement and are publicly reported within six years after initial endorsement (or the data on performance results are available). If not in use at the time of initial endorsement, then a credible plan for implementation within the specified timeframes is provided.

4.1. Current and Planned Use

NQF-endorsed measures are expected to be used in at least one accountability application within 3 years and publicly reported within 6 years of initial endorsement in addition to performance improvement.

Planned	Current Use (for current use provide URL)
Public Reporting Quality Improvement with Benchmarking (external benchmarking to multiple organizations) Quality Improvement (Internal to the specific organization) Not in use	

4a.1. **For each CURRENT use, checked above, provide:**
- Name of program and sponsor
- Purpose
- Geographic area and number and percentage of accountable entities and patients included

Not applicable

4a.2. **If not currently publicly reported OR used in at least one other accountability application (e.g., payment program, certification, licensing) what are the reasons?** (*e.g., Do policies or actions of the developer/steward or accountable entities restrict access to performance results or impede implementation?*)
The measure was not previously submitted to the MAP list for inclusion in a reporting program.

4a.3. **If not currently publicly reported OR used in at least one other accountability application, provide a credible plan for implementation within the expected timeframes -- any accountability application within 3 years and publicly reported within 6 years of initial endorsement.** (*Credible plan includes the specific program, purpose, intended audience, and timeline for implementing the measure within the specified timeframes. A plan for accountability applications addresses mechanisms for data aggregation and reporting.*)
The measure has been submitted through the Measures Under Consideration process for the CMS ACO Shared Savings program.

4b. Improvement
Progress toward achieving the goal of high-quality, efficient healthcare for individuals or populations is demonstrated. If not in use for performance improvement at the time of initial endorsement, then a credible rationale describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.

4b.1. **Progress on Improvement. (Not required for initial endorsement unless available.)**
Performance results on this measure (current and over time) should be provided in 1b.2 and 1b.4. Discuss:
- **Progress (trends in performance results, number and percentage of people receiving high-quality healthcare)**
- **Geographic area and number and percentage of accountable entities and patients included**

Not applicable; the measure has not been used in a public reporting or quality improvement program.

4b.2. **If no improvement was demonstrated, what are the reasons? If not in use for performance improvement at the time of initial endorsement, provide a credible rationale that describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.**
Diabetic patients often require chronic treatment with oral diabetes agents, statins, and/or ACEIs/ARBs to lower their risk of diabetic complications, adverse cardiovascular disease outcomes, and mortality. Adherence to chronic medication regimens has been documented in the literature to be less than optimal. In addition, the testing result from the 2011 and 2012 10-state Medicare claim data demonstrated substantial room for improvement. Poor adherence can reduce the effectiveness of treatment, and interventions to improve adherence can provide an opportunity for quality improvement.

Although this measure is not currently in use in any reporting programs, related measures assessing medication adherence with the PDC methodology have been used in multiple demonstration projects coordinated by PQA, Inc. These projects involved multiple

health plans and community pharmacies across five states (in PA, IA, IN, WI and NC). As part of the first phase of the demonstration, health plans provided data for calculation of the PDC and other performance measures related to medications. The performance results were made available to the plans and to hundreds of community pharmacies in the demonstration states. Two evaluations of the first phase were conducted. One of the evaluations involved academic investigators from multiple universities as well as PQA staff, while the second evaluation was conducted by an AHRQ-selected contractor (CNA in partnership with Thomas Jefferson University). Both evaluations gathered feedback on the feasibility and usability of the PDC and other performance metrics. The report funded by AHRQ was presented at the 2010 AHRQ Conference (http://www.ahrq.gov/about/annualconf10/conf10trackb.htm).

The PQA-funded evaluation by academic investigators has recently been accepted for publication by a scientific journal and is also available from PQA upon request. The evaluations determined that the health plan leadership and the community pharmacists found the PDC measure to be easy to understand and potentially helpful for performance improvement. PQA is currently engaged in the second phase of the demonstrations wherein performance improvement interventions have been implemented to spur improvements in PDC scores. A new initiative is about to begin in the state of California wherein the Integrated Healthcare Association (IHA) is pilot-testing the PDC measures for a physician pay-for-performance (P4P) program. The technical advisory panel for IHA felt that physicians and plans would likely be able to understand the PDC metric, but are conducting a pilot test to assess the usefulness of this metric in public reporting and P4P for physicians.

4c. Unintended Consequences
The benefits of the performance measure in facilitating progress toward achieving high-quality, efficient healthcare for individuals or populations outweigh evidence of unintended negative consequences to individuals or populations (if such evidence exists).

4c.1. **Were any unintended negative consequences to individuals or populations identified during testing; OR has evidence of unintended negative consequences to individuals or populations been reported since implementation? If so, identify the negative unintended consequences and describe how benefits outweigh them or actions taken to mitigate them.**
The measure has not been implemented in any reporting programs, and no unintended negative consequences were identified during testing.

5. Comparison to Related or Competing Measures

If a measure meets the above criteria <u>and</u> there are endorsed or new related measures (either the same measure focus or the same target population) or competing measures (both the same measure focus and the same target population), the measures are compared to address harmonization and/or selection of the best measure.

5. Relation to Other NQF-endorsed Measures
Are there related measures (conceptually, either same measure focus or target population) or competing measures (conceptually both the same measure focus and same target population)? If yes, list the NQF # and title of all related and/or competing measures.
Yes

5.1a. **List of related or competing measures (selected from NQF-endorsed measures)**
0055 : Comprehensive Diabetes Care: Eye Exam (retinal) performed
0056 : Diabetes: Foot Exam
0057 : Comprehensive Diabetes Care: Hemoglobin A1c (HbA1c) testing
0059 : Comprehensive Diabetes Care: Hemoglobin A1c (HbA1c) Poor Control (>9.0%)
0061 : Comprehensive Diabetes Care: Blood Pressure Control (<140/90 mm Hg)
0062 : Comprehensive Diabetes Care: Medical Attention for Nephropathy
0063 : Comprehensive Diabetes Care: LDL-C Screening
0064 : Comprehensive Diabetes Care: LDL-C Control <100 mg/dL
0416 : Diabetic Foot & Ankle Care, Ulcer Prevention – Evaluation of Footwear
0417 : Diabetic Foot & Ankle Care, Peripheral Neuropathy – Neurological Evaluation
0541 : Proportion of Days Covered (PDC): 3 Rates by Therapeutic Category
0542 : Adherence to Chronic Medications
0543 : Adherence to Statin Therapy for Individuals with Cardiovascular Disease
0569 : ADHERENCE TO STATINS
0575 : Comprehensive Diabetes Care: Hemoglobin A1c (HbA1c) Control (<8.0%)

0604 : Adult(s) with diabetes mellitus that had a serum creatinine in last 12 reported months.
0619 : Diabetes with Hypertension or Proteinuria - Use of an ACE Inhibitor or ARB
0630 : Diabetes and Elevated HbA1C – Use of Diabetes Medications
1879 : Adherence to Antipsychotic Medications for Individuals with Schizophrenia

5.1b. If related or competing measures are not NQF endorsed please indicate measure title and steward.
None identified

5a. Harmonization
    The measure specifications are harmonized with related measures;
    OR
    The differences in specifications are justified

5a.1. If this measure conceptually addresses EITHER the same measure focus OR the same target population as NQF-endorsed measure(s):
Are the measure specifications completely harmonized?
No

5a.2. If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden.
NQF 0545 is related to and completely harmonized with the four NQF-endorsed measure that use the Proportion of Days Covered (PDC) method of calculating adherence. These four measures include one NQF-endorsed measure by PQA (NQF 0541) and three NQF-endorsed measures by CMS (NQF 0542, 0543, and 1879). For the related measures that are not completely harmonized with NQF 0545, the following sections identify differences between these measures and NQF 0545, rationale, and impact on interpretability, and data collection burden. Diabetes Measures by National Committee for Quality Assurance (NCQA) and Optum - NQF 0545 has the same target population (i.e., individuals with diabetes mellitus) as the nine Diabetes Measures developed by the National Committee for Quality Assurance (NCQA) and one measure developed by Optum. The nine NCQA measures (NQF 0055, 0056, 0057, 0059, 0061, 0062, 0063, 0064, and 0075) and the Optum measure (NQF 0604) are related to, but are not completely harmonized with, NQF 0545. Differences Between NQF 0545 and NCQA and Optum Diabetes Measures - Identification of Individuals with Diabetes Mellitus: NQF 0545 uses the same algorithm for identifying individuals with diabetes as the NCQA and Optum Diabetes Measures, which entails using diagnosis codes and/or drug proxy to identify diabetes mellitus within the inpatient or outpatient claims data. However, NQF 0545 uses only claims for the 12-month measurement period, whereas the NCQA and Optum Diabetes Measures use a look-back period of one year for both the prescription data and diagnosis data. In addition, the Optum measure (NQF 0604) also uses a Disease Registry Input File, if available, to identify patients with diabetes mellitus. Age of Individuals Included in the Measure: NQF 0545 includes individuals who are at least 18 years of age and older as of the beginning of the measurement year, whereas the NCQA and Optum Diabetes Measures include individuals who are 18-75 years as of December 31st of the measurement year. Rationale - NQF 0545 uses a one-year time frame, rather than two years for the NCQA Diabetes measures, which allows more individuals (i.e., those with one year of data) to be included. NQF 0545 includes individuals 18 years and older, rather than 18-75 years for the NCQA and Optum measures, because many Medicare beneficiaries are over 75 years of age, and the guideline recommendations for the medication therapies do not restrict to the 18-75 age group. Impact on interpretability - NQF 0545 is easier to interpret than the NCQA and Optum Diabetes measures because it focuses on a single year and includes all adults 18 years and older. Data collection burden - The target populations of NQF 0545 and the NCQA Diabetes measures are identified using administrative claims or encounter data, so the data collection burden should be similar. The Optum Diabetes measure uses a Disease Registry Input File, if available, and therefore, may require more time and resources than administrative data to identify patients with diabetes mellitus. Diabetes Measures by American Podiatric Medical Association (APMA) - NQF 0545 has the same target population (i.e., individuals with diabetes mellitus) as the two Diabetes Measures by the APMA (NQF 416 and 417). These two APMA measures are related to, but are not completely harmonized with NQF 0545. Differences Between NQF 0545 and APMA Diabetes Measures - Identification of Individuals with Diabetes Mellitus: NQF 0545 uses a different algorithm for identifying individuals with diabetes than the APMA Diabetes Measures. NQF 0545 requires two outpatient or nonacute inpatient visits or one acute inpatient or emergency department visit or a prescription claim for insulin or other anti-diabetic medication. However, the APMA Diabetes Measures require only one claim for an outpatient visit or a nonacute inpatient visit or a selected procedure with a diagnosis of diabetes mellitus, but they do not use acute inpatient data or pharmacy data for identifying individuals with diabetes. Rationale - NQF 0545 requires two claims so the coded outpatient or nonacute inpatient diagnosis is confirmed. Using only one outpatient diagnosis could lead to including individuals who do not actually have diabetes. NQF 0545 uses acute inpatient and pharmacy data in the definition of diabetes, in addition to outpatient and nonacute inpatient data, to capture as many individuals with a diagnosis of diabetes as possible. Impact on interpretability - Requiring two claims for an

outpatient or nonacute inpatient diagnosis of diabetes will eliminate individuals who received a diagnosis of diabetes in error, or if it was coded as a rule-out diagnosis. If the additional data sources (i.e., acute inpatient data and pharmacy data) are not used, only individuals who have an outpatient or nonacute inpatient diagnosis of diabetes would be included in the denominator; those with only an inpatient admission or a prescription for diabetes would not be included. This might result in missing individuals with diabetes. Data collection burden - The target populations of NQF 0545 and the APMA Diabetes measures both are identified using administrative claims or encounter data, so the data collection burden should be similar. Diabetes Measures by ActiveHealth Management - NQF 0545 has the same target population (i.e., individuals with diabetes mellitus) as two Diabetes Measures by ActiveHealth Management, NQF 0619 and 0630. These two ActiveHealth Management measures are related to, but are not completely harmonized with, NQF 0545. Differences Between NQF 0545 and ActiveHealth Management Diabetes Measures - Identification of Individuals with Diabetes Mellitus: NQF 0545 uses an algorithm for identifying individuals with diabetes, which entails using diagnosis codes and/or drug proxy to identify diabetes mellitus within the inpatient or outpatient claims data during the 12-month measurement period. The two ActiveHealth Management Diabetes Measures require four diabetes mellitus diagnoses from administrative claims in the past 12 months, one diabetes mellitus diagnosis from electronic clinical data anytime in the past, one diabetes mellitus diagnosis in the electronic personal health record, or one diabetes mellitus diagnosis from administrative claims in the past five years plus filled prescriptions for diabetes medications, insulin, or a HbA1C value in the past 12 months. In addition, the target populations in the two ActiveHealth Management Diabetes Measures are further restricted either to those with diabetes mellitus and hypertension or proteinuria (NQF 0619), or to those with diabetes mellitus and at least one elevated HbA1C in the past six months (NQF 0630). Age of Individuals Included in the Measure: NQF 0545 includes individuals who are at least 18 years of age as of the beginning of the measurement year, whereas the ActiveHealth Management Diabetes Measures include individuals who are 18-75 years of age. Rationale - The target population of NQF 0545 is defined on the basis of a diagnosis of diabetes mellitus and either at least two prescriptions of statins. This denominator definition of NQF 0545 limits the measure to those individuals who have been on the medication long enough for the prescribing provider to determine that statin therapy is appropriate for the patient and is tolerated. NQF 0545 includes individuals 18 years and older, rather than 18-75 years for the ActiveHealth Management Diabetes measures, because many Medicare beneficiaries are over 75 years of age, and the guideline recommendations do not restrict to the 18-75 age group. Impact on interpretability - NQF 0545 is easier to interpret than the ActiveHealth Management Diabetes measures because it estimates adherence to medications among individuals with diabetes mellitus who have had at least two prescriptions, and it includes all adults 18 years and older. Data collection burden - NQF 0545 is based on administrative claims data. The ActiveHealth Management Diabetes measures are based on multiple data sources (e.g., administrative claims, electronic clinical data, patient data from electronic personal health records and feedback, provider survey). Therefore, NQF 0545 presents less of a data collection burden. NQF 0569 Adherence to Statins (Health Benchmark-IMS Health) - NQF 0545 and 0569 address the same measure focus (i.e., adherence to statin therapy), but NQF 0569 has a different target population (i.e., diabetes, hyperlipidemia, and CAD). Differences Between NQF 0545 and NQF 569 - NQF 0545 uses the PDC methodology rather than MPR. The PDC used in NQF 0545 provides a more conservative estimate of adherence when a patient might be switching among several medications for the same indication or using multiple medications within a single class (Nau, undated) than the MPR used by NQF 0569. The PDC provides a better estimate of adherence under these circumstances. NQF 0569 excludes "new users of a statin that started after the first three months of the measurement year." NQF 0545 covers the entire 12-month measurement period. The impact of the exclusion used in NQF 0569 would be to limit the measure to those who have at least 9 months of data. Rationale - NQF 0545 is intended as a statin adherence measure for all patients with diabetes. Impact on interpretability - NQF 0545 is easier to interpret than NQF 569 because it calculates adherence for all patients with diabetes, rather than those with diabetes and other indications. Data collection burden - There are no differences in data collection burden. Citation for 5a.2 - Nau, D. P. (undated). Proportion of Days Covered (PDC) as a Preferred Method of Measuring Medication Adherence. Pharmacy Quality Alliance. Retrieved November 12, 2013 from http://www.pqaalliance.org/images/uploads/files/PQA%20PDC%20vs%20%20MPR.pdf

5b. Competing Measures

The measure is superior to competing measures (e.g., is a more valid or efficient way to measure);
OR
Multiple measures are justified.

5b.1. **If this measure conceptually addresses both the same measure focus and the same target population as NQF-endorsed measure(s):**
Describe why this measure is superior to competing measures (e.g., a more valid or efficient way to measure quality); OR provide a rationale for the additive value of endorsing an additional measure. (Provide analyses when possible.)
Not applicable

Appendix

A.1 Supplemental materials may be provided in an appendix. All supplemental materials (such as data collection instrument or methodology reports) should be organized in one file with a table of contents or bookmarks. If material pertains to a specific submission form number, that should be indicated. Requested information should be provided in the submission form and required attachments. There is no guarantee that supplemental materials will be reviewed.
Attachment **Attachment:** NQF_0545_Measure_Logic_Diagram.pdf

Contact Information

Co.1 Measure Steward (Intellectual Property Owner): Centers for Medicare & Medicaid Services
Co.2 Point of Contact: Corette, Byrd, MMSSupport@Battelle.org, 202-786-1158-
Co.3 Measure Developer if different from Measure Steward: Centers for Medicare & Medicaid Services
Co.4 Point of Contact: Elizabeth, Ricksecker, Elizabeth.Ricksecker@cms.hhs.gov, 410-786-6723-

Additional Information

Ad.1 Workgroup/Expert Panel involved in measure development
Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.
Original Technical Expert Panel (TEP) Members
Douglas Bell, MD, PHD, Associate Professor in Residence, UCLA Department of Medicine, Division of General Internal Medicine and Health Services Research
Jill S. Borchert, PharmD, BCPS, FCCD, Professor, Pharmacy Practice & PGY1 Residency Program Director, Midwestern University, Chicago College of Pharmacy
Anne Burns, RPH, Vice President, Professional Affairs, American Pharmacists Association
Jannet Carmichael, PharmD, BCPS, FCCP, FAPHA, VISN 21 Pharmacy Executive, VA Sierra Pacific Network
Marshall H. Chin, MD, MPH, Professor of Medicine, University of Chicago
Edward S. Eisenberg, MD, Vice President and Chief Medical Officer, Medicare, Medco Health Solutions
Jay A. Gold, MD, JD, MPH, Senior Vice President and Medicare Chief Medical Officer, MetaStar, Inc.
David Nau, PHD, MS, Senior Director of Research & Performance Measurement, PQA, Inc.
N. Lee Rucker, PHD, MS, Senior Strategic Policy Advisor, AARP - Public Policy Institute
Marissa Schlaifer, RPH, MS, Director of Pharmacy Affairs Academy of Managed Care Pharmacy
Brad Tice, PharmD, Chief Clinical Officer, PharmMD Solutions, LLC
Jennifer K. Thomas, PharmD, Manager, Pharmacy Services, Delmarva Foundation for Medical Care/Delmarva Foundation of the District of Columbia
Darren M. Triller, PharmD, Director, Pharmacy Services, IPRO
Neil Wenger, MD, MPH, Professor of Medicine, UCLA Department of Medicine, Division of General Internal Medicine and Health Services Research

The TEP evaluated proposed medication measures drafted by FMQAI in regard to the four primary measure evaluation criteria used in the NQF consensus endorsement process (importance, scientific acceptability, feasibility, and usability). The TEP discussed the strengths and weaknesses of the proposed measures and make recommendations regarding measure specifications, inclusion and exclusion criteria, and appropriate risk adjustment as applicable.

Current Technical Expert Panel (TEP) Members
Dale W. Bratzler DO, MPH, TEP Chair, Professor and Associate Dean, College of Public Health, University of Oklahoma Health Sciences Center
Mary Brennan-Taylor, Adjunct Research Instructor of Family Medicine, School of Medicine and Biomedical Sciences, University of Buffalo
Frank E. Briggs III, PharmD, MPH, Vice President, Quality and Patient Safety, West Virginia University Healthcare
Daniel Castillo, MD, MBA, Medical Director, Healthcare Quality Evaluation, The Joint Commission
Joan Ching, RN, MN, CPHQ, Administrative Director, Hospital Quality & Safety, Virginia Mason Medical Center
Edward S. Eisenberg, MD, FACP, Senior Vice President, Performance Measurement and Strategic Alliances, Pharmacy Quality Alliance
Floyd Eisenberg, MD, MPH, FACP, President, iParsimony, LLC
Marybeth Farquhar, PhD, MSN, RN, Vice President of Research & Measurement, URAC
Frank Federico, BS, RPH, Executive Director for Strategic Partners, Institute for Heallthcare Improvement

Robert Feroli, PharmD, FASHP, Medication Safety Officer, Johns Hopkins Hospital

Tejal Gandhi, MD, MPH, President, National Patient Safety Foundation

P. Michael Ho, MD, PhD, FACC, Staff Cardiologist, VA Eastern Colorado Health Care System

Mark L. Holtsman, PharmD, Co-Director, Inpatient Pain Service and Pain Management Service Pharmacist, UC Davis Medical Center

Clifford Ko, MD, MS, MSHS, FACS, Director, ACS Division of Research and Optimal Patient Care

Janet Maurer, MD, MBA, FCCP, Operations Medical Director, National Imaging Associates, Health Dialog

Michael N. Neuss, MD, Chief Medical Officer, Vanderbilt-Ingram Cancer Center

N. Lee Rucker, MSPH, Senior Advisor, National Council on Patient Information and Education

Edward Septimus, MD, FACP, FIDSA, FSHEA, Medical Director, Infection Prevention and Epidemiology Clinical Service Group, HCA Healthcare System

Nathan Spell, MD, FACP, Chief Quality Officer, Emory University Hospital

Stephen J. Traub, MD, FACEP, Chair, Department of Emergency Medicine, Mayo Clinic

Darren M. Triller, PharmD, TEP Co-Chair, Senior Director, Quality Improvement, IPRO QIO

Federal Guests on TEP

Mary Andrawis, PharmD, MPH, Contract Officer Representative & Medication Safety Co-Lead, Centers for Medicare & Medicaid Services, Center for Medicare & Medicaid Innovation

Andrew Geller, MD, LCDR, USPHS, Epidemic Intelligence Service Officer, Medication Safety Program, Division of Healthcare Quality Promotion, Centers for Disease Control and Prevention

Sherriann Moore, MS, Deputy Director, U.S. Department of Health and Human Services, Indian Health Service, Office of Urban Indian Health Programs

Nadine Shehab, PharmD, MPH, Senior Service Fellow, Division of Healthcare Quality Promotion, Centers for Disease Control and Prevention

The current TEP evaluated the updated measure testing results and evaluated face validity of the measure.

Measure Developer/Steward Updates and Ongoing Maintenance
Ad.2 Year the measure was first released: 2009
Ad.3 Month and Year of most recent revision: 01, 2013
Ad.4 What is your frequency for review/update of this measure? Annually
Ad.5 When is the next scheduled review/update for this measure? 12, 2014

Ad.6 Copyright statement: Limited proprietary coding is contained in the measure specifications for user convenience. Use of these codes may require permission from the code owner or agreement to a license.

ICD-10 codes are copyright © World Health Organization (WHO), Fourth Edition, 2010. CPT® 2010 American Medical Association; CPT is a registered trademark of the American Medical Association. All rights reserved.

Ad.7 Disclaimers: This performance measure does not establish a standard of medical care and has not been tested for all potential applications.

Ad.8 Additional Information/Comments: Not applicable