NATIONAL QUALITY FORUM

Measure Submission and Evaluation Worksheet 5.0

This form contains the information submitted by measure developers/stewards, organized according to NQF's measure evaluation criteria and process. The evaluation criteria, evaluation guidance documents, and a blank online submission form are available on the submitting standards web page.

NQF #: 0548 NQF Project: Pulmonary Project

(for Endorsement Maintenance Review)
Original Endorsement Date: Aug 05, 2009 Most Recent Endorsement Date: Aug 05, 2009 Last Updated Date: Apr 03, 2012

BRIEF MEASURE INFORMATION

De.1 Measure Title: Suboptimal Asthma Control (SAC) and Absence of Controller Therapy (ACT)

Co.1.1 Measure Steward: Pharmacy Quality Alliance, Inc.

De.2 Brief Description of Measure: Rate 1: The percentage of patients with persistent asthma who were dispensed more than 3 canisters of a short-acting beta2 agonist inhaler during the same 90-day period.

Rate 2: The percentage of patients with persistent asthma during the measurement year who were dispensed more than three canisters of short acting beta2 agonist inhalers over a 90-day period and who did not receive controller therapy during the same 90-day period.

The full detailed measure specifications have also been submitted as a separate attachment.

2a1.1 Numerator Statement: Rate1: From the date of each prescription fill, count all of the canisters of short acting Beta2 Agonist Inhalers dispensed at that fill and dispensed within 90 days of that fill. If the patient receives 3 or more canisters in at least one 90 day period, then the patient is compliant for the numerator.

Short-Acting Inhaled Beta Agonists: albuterol MDI, albuterol HFA, pirbuterol, levalbuterol HFA

Rate 2: Patients who were not dispensed a controller therapy medication during the same 90-day period where they received more than three canisters of short-acting beta-agonist medication.

2a1.4 Denominator Statement: Rate 1: Step 1: Identify patients 5 - 50 years of age as of the last day of the measurement year.
Step 2: Identify patients who were dispensed at least two consecutive fills for any asthma medication during the measurement year.
Step 3: Exclude patients identified in step 1 who meet any of the following criteria:
• Any patient who filled one or more COPD medications during the measurement year.
• Any patient who filled one or more prescriptions for pulmozyme during the measurement year.
• Any patient who filled one or more nasal steroid medications during the measurement year.
Short-Acting Inhaled Beta Agonists: albuterol MDI, albuterol HFA, pirbuterol, levalbuterol HFA
Long-Acting Beta Agonists: salmeterol, formoterol
Inhaled Corticosteroids: beclomethasone, budesonide, flunisolide, fluticasone, fluticasone/salmeterol, mometasone, triamcinolone
Leukotriene Inhibitors: zafirlukast, montelukast, zileuton
Xanthines: long acting theophylline
Mast Cell Stabilizers: nedocromil, cromolyn
COPD Medications: tiotropium, ipratropium/albuterol MDI, ipratropium MDI
Nasal Steroids: beclomethasone, budesonide, flunisolide, fluticasone, mometasone, triamcinolone

Rate 2: Step 1: Identify patients 5 - 50 years of age as of the last day of the measurement year.

Step 2: Identify patients who were dispensed at least two consecutive fills for any asthma medication (Table ACT-A: Asthma

Medications) during the measurement year.

Step 3: Exclude patients identified in step 1 who meet any of the following criteria

• Any patient who filled one or more COPD medications during the measurement year.

• Any patient who filled one or more prescriptions for pulmozyme during the measurement year.

• Any patient who filled one or more nasal steroid medications during the measurement year.

Step 4: For the remaining patients, identify those who were dispensed more than five canisters of a short-acting beta-agonist medication during the same 90-day period in the measurement year. It is those patients who, from the date of each prescription fill, had at least 3 canisters of short acting Beta2 Agonist Inhalers dispensed at that fill or dispensed within 90 days of that fill.

Note: This is a count of canisters dispensed, not prescriptions filled. If a patient received 2 canisters at one fill, it counts as 2 canisters.

2a1.8 Denominator Exclusions:

1.1 Measure Type: Process
2a1. 25-26 Data Source: Electronic Clinical Data : Pharmacy
2a1.33 Level of Analysis: Health Plan

1.2-1.4 Is this measure paired with another measure? No

De.3 If included in a composite, please identify the composite measure (*title and NQF number if endorsed*):

STAFF NOTES (*issues or questions regarding any criteria*)

Comments on Conditions for Consideration:

Is the measure untested? Yes☐ No☐ If untested, explain how it meets criteria for consideration for time-limited endorsement:

1a. Specific national health goal/priority identified by DHHS or NPP addressed by the measure (*check De.5*):
5. Similar/related endorsed or submitted measures (*check 5.1*):
Other Criteria:

Staff Reviewer Name(s):

1. IMPACT, OPPORTUITY, EVIDENCE - IMPORTANCE TO MEASURE AND REPORT

Importance to Measure and Report is a threshold criterion that must be met in order to recommend a measure for endorsement. All three subcriteria must be met to pass this criterion. See guidance on evidence.
Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria. (evaluation criteria)

1a. High Impact: H☐ M☐ L☐ I ☐
(*The measure directly addresses a specific national health goal/priority identified by DHHS or NPP, or some other high impact aspect of healthcare.*)

De.4 Subject/Topic Areas *(Check all the areas that apply)*: Pulmonary/Critical Care : Asthma
De.5 Cross Cutting Areas (*Check all the areas that apply)*:

1a.1 Demonstrated High Impact Aspect of Healthcare: Affects large numbers, A leading cause of morbidity/mortality, Patient/societal consequences of poor quality

1a.2 If "Other," please describe:

1a.3 Summary of Evidence of High Impact *(Provide epidemiologic or resource use data)*:
Asthma is one of the most prevalent chronic diseases; becoming increasingly more commonplace over the past twenty years. In 2009, an estimated 12.8 million Americans (including 4.1 million children under 18) had an asthma attack. This represents 48% of the 24.6 million people who currently have asthma. (ALA 2011) In 2006, 13.3 million clinical visits (hospital, outpatient, emergency department, and physician offices) were attributed to asthma. Low-income populations, minorities, and children living in inner cities experience have higher prevalence of asthma and more emergency department visits, hospitalizations, and deaths due to asthma. The burden of asthma falls disproportionately on non-Hispanic black, American Indian/Alaskan Native, and Puerto Rican populations (CDC, 2008). The incidence rate, and subsequently the number of asthma-related health visits, is expected to increase by an additional 100 million globally by 2025 (World Health Organization, 2007).
Pharmacologic therapy is used to prevent and control asthma symptoms, improve quality of life, reduce the frequency and severity of asthma exacerbations, and reverse airflow obstruction (NHLBI/NAEPP). Medications for asthma are usually categorized into long-term controller medications used to achieve and maintain control of persistent asthma and quick-reliever medications used to treat acute symptoms and exacerbations. Regularly scheduled, daily, chronic use of SABA is not recommended. (NHLBI/NAEPP 2007).
The National Heart, Lung, and Blood Institute, National Asthma Education and Prevention Program, Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma states the frequency of SABA use can be clinically useful as a barometer of disease activity, because increasing use of SABA has been associated with increased risk for death or near death in patients who have asthma. Use of more than one SABA canister every 1–2 months is also associated with an increased risk of an acute exacerbation that requires an ED visit or hospitalization. Thus, the use of more than one SABA canister (e.g., albuterol, 200 puffs per canister), predominantly for quick-relief treatment during a 1-month period, most likely indicates overreliance on this drug and suggests inadequate control of asthma. (NHLBI/NAEPP 2007)

1a.4 Citations for Evidence of High Impact cited in 1a.3: American Lung Association. Epidemiology & Statistics Unit, Research and Program Services. 2010. Asthma. Available from: http://www.lungusa.org/lung- disease/asthma/. (January 2012)
American Lung Association. Trends in Asthma Morbidity and Mortality Epidemiology and Statistics Unit Research and Program Services Division July 2011 (January 2012)
Centers for Disease Control and Prevention. Asthma: A Presentation of Asthma Management and Prevention. 2009. Available from: http://www.cdc.gov/asthma/speakit/default.htm . (January 2012)
World Health Organization. 2007. Global surveillance, prevention and control of chronic respiratory diseases: a comprehensive approach.

National Heart Lung and Blood Institute/National Asthma Education and Prevention Program. Expert panel report 3: guidelines for the diagnosis and management of asthma. Washington (DC) (January 2012)

1b. Opportunity for Improvement: H☐ M☐ L☐ I ☐
(*There is a demonstrated performance gap - variability or overall less than optimal performance*)

1b.1 Briefly explain the benefits (improvements in quality) envisioned by use of this measure:
This measure will help clinicians, health plans, prescription drug plans and pharmacists identify patients who are exhibiting medication-use patterns that indicate poorly controlled asthma, and to determine if those patients are receiving preventive/controller medications.

1b.2 Summary of Data Demonstrating Performance Gap *(Variation or overall less than optimal performance across providers)*:
[*For Maintenance – Descriptive statistics for performance results for this measure - distribution of scores for measured entities by quartile/decile, mean, median, SD, min, max, etc.*]
PQA collaborated with Advanced Pharmacy Concepts to conduct additional testing of the PQA asthma measures in 2010. The testing used data from 3 health plans with members in the commercial (employer-based) segment. The results reveal a significant performance gap in both the excessive use of short-acting beta agonists (suboptimal control) as well as the underuse of controller medications. The results of the analysis are shown below.

Table 1. Health Plan Performance- Suboptimal Control

	Denominator	Numerator	Performance Rate
Plan A	28,284	4,166	14.7%
Plan B	2,867	509	17.8%
Plan C	1,713	145	8.5%
Total:	32,864	4,820	14.7%

Table 2 - Use of Controller Medications

	Denominator	Numerator	Performance Rate
Plan A	4,166	1,904	45.7%
Plan B	509	299	58.7%
Plan C	145	73	50.3%

The data were also analyzed at the pharmacy level using the data from the 3 health plans. There were 804 pharmacies that had at least 10 asthma patients that met the eligibility criteria. The rate of suboptimal control ranged from 0% to 23.3% across the 804 pharmacies. The rate of controller medication utilization ranged from 33.3% to 75% across the evaluated pharmacies. Thus, there was significant variation and significant room for improvement in both rates.

Further testing is underway within the Mississippi Medicaid population and will be completed in 2012.

1b.3 Citations for Data on Performance Gap: [*For Maintenance – Description of the data or sample for measure results reported in 1b.2 including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included*]
The testing results were not published, but the full report is available from PQA.

1b.4 Summary of Data on Disparities by Population Group: [*For Maintenance –Descriptive statistics for performance results for this measure by population group*]
Since prescription drug claims data do not contain data on race or ethnicity, no analyses of racial/ethnic disparities have yet been conducted with this measure. However, our current analyses with the Mississippi Medicaid population will provide us with estimates that could be compared to the results in the commercially-insured population that we conducted in 2010. This will help us identify how scores may differ by insurance status.

1b.5 Citations for Data on Disparities Cited in 1b.4: [*For Maintenance – Description of the data or sample for measure results reported in 1b.4 including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included*]
N/A

1c. Evidence (*Measure focus is a health outcome OR meets the criteria for quantity, quality, consistency of the body of evidence.*)
Is the measure focus a health outcome? Yes☐ No☐ If not a health outcome, rate the body of evidence.

Quantity: H☐ M☐ L☐ I☐ Quality: H☐ M☐ L☐ I☐ Consistency: H☐ M☐ L☐ I☐

Quantity	Quality	Consistency	Does the measure pass subcriterion1c?
M-H	M-H	M-H	Yes☐
L	M-H	M	Yes☐ IF additional research unlikely to change conclusion that benefits to patients outweigh harms: otherwise No☐
M-H	L	M-H	Yes☐ IF potential benefits to patients clearly outweigh potential harms: otherwise No☐
L-M-H	L-M-H	L	No ☐

Health outcome – rationale supports relationship to at least one healthcare structure, process, intervention, or service	Does the measure pass subcriterion1c? Yes☐ IF rationale supports relationship

1c.1 Structure-Process-Outcome Relationship *(Briefly state the measure focus, e.g., health outcome, intermediate clinical*

outcome, process, structure; then identify the appropriate links, e.g., structure-process-health outcome; process- health outcome; intermediate clinical outcome-health outcome):
The focus of the measure is to (1) determine the percentage of the population regularly using short acting beta agonist inhalers. Regular use of short acting beta agonists is linked in inadequately controlled asthma. (2) determine the percentage of patients regularly using SABAs that are not prescribed an inhaled corticosteroid. Inhaled corticosteroids are indicated when asthma is not controlled with first line therapy.

1c.2-3 Type of Evidence *(Check all that apply)*:
Clinical Practice Guideline, Systematic review of body of evidence (other than within guideline development)

1c.4 Directness of Evidence to the Specified Measure *(State the central topic, population, and outcomes addressed in the body of evidence and identify any differences from the measure focus and measure target population)*:

1c.5 Quantity of Studies in the Body of Evidence *(Total number of studies, not articles)*: NHLBI guidelines for asthma management (v. 2007) were based on over 400 studies.

1c.6 Quality of Body of Evidence (*Summarize the certainty or confidence in the estimates of benefits and harms to patients across studies in the body of evidence resulting from study factors. Please address: a) study design/flaws; b) directness/indirectness of the evidence to this measure (e.g., interventions, comparisons, outcomes assessed, population included in the evidence); and c) imprecision/wide confidence intervals due to few patients or events*): The evidence for NHLBI guidelines for asthma management with medications was graded as "A" which is the highest rating for evidence.

1c.7 Consistency of Results across Studies *(Summarize the consistency of the magnitude and direction of the effect):*

1c.8 Net Benefit *(Provide estimates of effect for benefit/outcome; identify harms addressed and estimates of effect; and net benefit - benefit over harms)*:

1c.9 Grading of Strength/Quality of the Body of Evidence. Has the body of evidence been graded? Yes

1c.10 If body of evidence graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias: According to the National Guideline Clearinghouse, the NHLBI guidelines for medication use in asthma was graded as "A" by the NHBLI panel.

1c.11 System Used for Grading the Body of Evidence: Other

1c.12 If other, identify and describe the grading scale with definitions: Expert consensus by NHLBI.

1c.13 Grade Assigned to the Body of Evidence: A

1c.14 Summary of Controversy/Contradictory Evidence:

1c.15 Citations for Evidence other than Guidelines*(Guidelines addressed below)*:

1c.16 Quote verbatim, the specific guideline recommendation *(Including guideline # and/or page #)*:
Pages 236- 237
Safety of Inhaled Short-Acting Beta2-Agonists
Key Points: Safety of Inhaled Short-Acting Beta2-Agonists
- SABAs are the most effective medication for relieving acute bronchospasm (Evidence A).
- Increasing use of SABA treatment or using SABA >2 days a week for symptom relief (not prevention of EIB) generally indicates inadequate control of asthma and the need for initiating or intensifying anti-inflammatory therapy (Evidence C).

- Regularly scheduled, daily, chronic use of SABA is not recommended (Evidence A).

The Expert Panel recommends the use of SABA as the most effective medication for relieving acute bronchoconstriction; SABAs have few negative cardiovascular effects (Evidence A).
The Expert Panel does not recommend regularly scheduled, daily, long-term use of SABA (Evidence A).

1c.17 Clinical Practice Guideline Citation: National Heart Lung and Blood Institute/National Asthma Education and Prevention Program. 2007. Measures of asthma assessment and monitoring:
Expert panel report 3: guidelines for the diagnosis and management of asthma. Washington (DC): National Heart Lung and Blood Institute (NHLBI);

1c.18 National Guideline Clearinghouse or other URL: http://www.guideline.gov/content.aspx?id=111332&search=asthma

1c.19 Grading of Strength of Guideline Recommendation. Has the recommendation been graded? Yes

1c.20 If guideline recommendation graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias: NHLBI

1c.21 System Used for Grading the Strength of Guideline Recommendation: Other

1c.22 If other, identify and describe the grading scale with definitions: NHLBI panel

1c.23 Grade Assigned to the Recommendation: A

1c.24 Rationale for Using this Guideline Over Others:

Based on the NQF descriptions for rating the evidence, what was the developer's assessment of the quantity, quality, and consistency of the body of evidence?
1c.25 Quantity: High 1c.26 Quality: High1c.27 Consistency: High

Was the threshold criterion, *Importance to Measure and Report*, met?
(*1a & 1b must be rated moderate or high and 1c yes*) Yes☐ No☐
Provide rationale based on specific subcriteria:

For a new measure if the Committee votes NO, then STOP.
For a measure undergoing endorsement maintenance, if the Committee votes NO because of 1b. (no opportunity for improvement), it may be considered for continued endorsement and all criteria need to be evaluated.

2. RELIABILITY & VALIDITY - SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES

Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. (evaluation criteria)
Measure testing must demonstrate adequate reliability and validity in order to be recommended for endorsement. Testing may be conducted for data elements and/or the computed measure score. Testing information and results should be entered in the appropriate field. Supplemental materials may be referenced or attached in item 2.1. See guidance on measure testing.

S.1 Measure Web Page *(In the future, NQF will require measure stewards to provide a URL link to a web page where current detailed specifications can be obtained*). Do you have a web page where current detailed specifications for this measure can be obtained? Yes

S.2 If yes, provide web page URL: www.pqaalliance.org

2a. RELIABILITY. Precise Specifications and Reliability Testing: H☐ M☐ L☐ I☐

2a1. Precise Measure Specifications. (*The measure specifications precise and unambiguous.*)

2a1.1 Numerator Statement *(Brief, narrative description of the measure focus or what is being measured about the target*

population, e.g., cases from the target population with the target process, condition, event, or outcome):
Rate1: From the date of each prescription fill, count all of the canisters of short acting Beta2 Agonist Inhalers dispensed at that fill and dispensed within 90 days of that fill. If the patient receives 3 or more canisters in at least one 90 day period, then the patient is compliant for the numerator.

Short-Acting Inhaled Beta Agonists: albuterol MDI, albuterol HFA, pirbuterol, levalbuterol HFA

Rate 2: Patients who were not dispensed a controller therapy medication during the same 90-day period where they received more than three canisters of short-acting beta-agonist medication.

2a1.2 Numerator Time Window *(The time period in which the target process, condition, event, or outcome is eligible for inclusion)*:

2a1.3 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, codes with descriptors, and/or specific data collection items/responses*:
Long-Acting Beta Agonists: salmeterol, formoterol
Inhaled Corticosteroids: beclomethasone, budesonide, flunisolide, fluticasone, fluticasone/salmeterol, mometasone, triamcinolone
Leukotriene Inhibitors: zafirlukast, montelukast, zileuton
Xanthines: long acting theophylline
Mast Cell Stabilizers: nedocromil, cromolyn

Short-Acting Inhaled Beta Agonists: albuterol MDI, albuterol HFA, pirbuterol, levalbuterol HFA

2a1.4 Denominator Statement *(Brief, narrative description of the target population being measured)*:
Rate 1: Step 1: Identify patients 5 - 50 years of age as of the last day of the measurement year.
Step 2: Identify patients who were dispensed at least two consecutive fills for any asthma medication during the measurement year.
Step 3: Exclude patients identified in step 1 who meet any of the following criteria:
• Any patient who filled one or more COPD medications during the measurement year.
• Any patient who filled one or more prescriptions for pulmozyme during the measurement year.
• Any patient who filled one or more nasal steroid medications during the measurement year.
Short-Acting Inhaled Beta Agonists: albuterol MDI, albuterol HFA, pirbuterol, levalbuterol HFA
Long-Acting Beta Agonists: salmeterol, formoterol
Inhaled Corticosteroids: beclomethasone, budesonide, flunisolide, fluticasone, fluticasone/salmeterol, mometasone, triamcinolone
Leukotriene Inhibitors: zafirlukast, montelukast, zileuton
Xanthines: long acting theophylline
Mast Cell Stabilizers: nedocromil, cromolyn
COPD Medications: tiotropium, ipratropium/albuterol MDI, ipratropium MDI
Nasal Steroids: beclomethasone, budesonide, flunisolide, fluticasone, mometasone, triamcinolone

Rate 2: Step 1: Identify patients 5 - 50 years of age as of the last day of the measurement year.

Step 2: Identify patients who were dispensed at least two consecutive fills for any asthma medication (Table ACT-A: Asthma Medications) during the measurement year.

Step 3: Exclude patients identified in step 1 who meet any of the following criteria

• Any patient who filled one or more COPD medications during the measurement year.

• Any patient who filled one or more prescriptions for pulmozyme during the measurement year.

• Any patient who filled one or more nasal steroid medications during the measurement year.

Step 4: For the remaining patients, identify those who were dispensed more than five canisters of a short-acting beta-agonist

medication during the same 90-day period in the measurement year. It is those patients who, from the date of each prescription fill, had at least 3 canisters of short acting Beta2 Agonist Inhalers dispensed at that fill or dispensed within 90 days of that fill.

Note: This is a count of canisters dispensed, not prescriptions filled. If a patient received 2 canisters at one fill, it counts as 2 canisters.

2a1.5 Target Population Category *(Check all the populations for which the measure is specified and tested if any)*: Adult/Elderly Care, Children's Health

2a1.6 Denominator Time Window *(The time period in which cases are eligible for inclusion)*:

2a1.7 Denominator Details (*All information required to identify and calculate the target population/denominator such as definitions, codes with descriptors, and/or specific data collection items/responses)*:
Short-Acting Inhaled Beta Agonists: albuterol MDI, albuterol HFA, pirbuterol, levalbuterol HFA
Long-Acting Beta Agonists: salmeterol, formoterol
Inhaled Corticosteroids: beclomethasone, budesonide, flunisolide, fluticasone, fluticasone/salmeterol, mometasone, triamcinolone
Leukotriene Inhibitors: zafirlukast, montelukast, zileuton
Xanthines: long acting theophylline
Mast Cell Stabilizers: nedocromil, cromolyn
COPD Medications: tiotropium, ipratropium/albuterol MDI, ipratropium MDI
Nasal Steroids: beclomethasone, budesonide, flunisolide, fluticasone, mometasone, triamcinolone

2a1.8 Denominator Exclusions *(Brief narrative description of exclusions from the target population)*:

2a1.9 Denominator Exclusion Details *(All information required to identify and calculate exclusions from the denominator such as definitions, codes with descriptors, and/or specific data collection items/responses)*:

2a1.10 Stratification Details/Variables *(All information required to stratify the measure results including the stratification variables, codes with descriptors, definitions, and/or specific data collection items/responses)*:

2a1.11 Risk Adjustment Type *(Select type. Provide specifications for risk stratification in 2a1.10 and for statistical model in 2a1.13)*: No risk adjustment or risk stratification 2a1.12 If "Other," please describe:

2a1.13 Statistical Risk Model and Variables *(Name the statistical method - e.g., logistic regression and list all the risk factor variables. Note - risk model development should be addressed in 2b4.)*:

2a1.14-16 Detailed Risk Model Available at Web page URL (or attachment). Include coefficients, equations, codes with descriptors, definitions, and/or specific data collection items/responses. Attach documents only if they are not available on a webpage and keep attached file to 5 MB or less. NQF strongly prefers you make documents available at a Web page URL. Please supply login/password if needed:

2a1.17-18. Type of Score:

2a1.19 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)*:

2a1.20 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.)*:

2a1.21-23 Calculation Algorithm/Measure Logic Diagram URL or attachment:

2a1.24 Sampling (Survey) Methodology. If measure is based on a sample (or survey), provide instructions for obtaining the sample, conducting the survey and guidance on minimum sample size (response rate):

2a1.25 Data Source *(Check all the sources for which the measure is specified and tested*). If other, please describe:
Electronic Clinical Data : Pharmacy

2a1.26 Data Source/Data Collection Instrument (*Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.*):

2a1.27-29 Data Source/data Collection Instrument Reference Web Page URL or Attachment:

2a1.30-32 Data Dictionary/Code Table Web Page URL or Attachment:
URL
www.PQAalliance.org

2a1.33 Level of Analysis (*Check the levels of analysis for which the measure is specified and tested)*: Health Plan

2a1.34-35 Care Setting *(Check all the settings for which the measure is specified and tested)*: Ambulatory Care : Ambulatory Surgery Center (ASC), Ambulatory Care : Clinician Office/Clinic, Pharmacy

2a2. Reliability Testing. (*Reliability testing was conducted with appropriate method, scope, and adequate demonstration of reliability*.)

2a2.1 Data/Sample *(Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:
Initial testing was conducted in 2007-08 using prescription claims data from multiple health plans. The testing was conducted by NCQA and Advance Pharmacy Concepts. Details were provided in the initial submission. The results from this 2008 testing are listed in 2a2.2 and 2a2.3

2a2.2 Analytic Method *(Describe method of reliability testing & rationale)*:
NCQA testing of the Suboptimal Asthma Control (SAC) and Absence of Controller Therapy (ACT) Measures from August 2008

NOTE: These measures had denominator criteria of more than 5 canisters of a short acting beta agonist used during the 3-month period rather than the current measures that use criteria of more than 3 SABA canisters.

Measure Testing Summary – 2008
Suboptimal Asthma Control and Absence of Controller Therapy

In order to provide varying perspectives of pharmacy services and the measures, the field-test was structured to include a cross-section of health plans and pharmacies. Pharmaceutical claims data for prescriptions filled at both retail and mail-order pharmacies

were analyzed from three plans and one national prescription drug plan. Plan enrollment ranged from approximately 3,330 to nearly 1.7 million members, and included commercial, Medicaid and Medicare populations

Plans participated in the field-test by providing pharmacy claims data under the terms of a formal data-sharing agreement. The field-test research protocol for this research was reviewed and approved by the Chesapeake Research Review Institutional Review Board (IRB). All claims information was blinded; plan names were stripped from associated data. Data were analyzed and reported at the aggregate pharmacy level and at the plan level for each health plan or prescription drug plan.

ELIGIBLE POPULATION
The unit of analysis for each measure was the plan and pharmacies, at an aggregate level. Enrollment information was not available in the pharmacy claims database so an algorithm was developed to serve as a proxy: all enrolled health plan members that filled any two prescriptions, with 150 days between the first fill and the last fill over a 12-month period, were eligible for the measures.

The algorithm ensured that the members included in the measures had adequate claims information for calculating the full measure specification. Since the algorithm used only prescriptions as the basis for inclusion in the eligible population and did not use diagnosis codes to identify specific clinical conditions, there is a potential for members who do not suffer from the clinical condition of interest (e.g., asthma, diabetes, heart failure) to be included in the measure. However, some measures examined conditions for which coding has not been accurately defined, making the prescription algorithm a more accurate method for identification.

AGGREGATE PHARMACY PERFORMANCE RATE CALCULATION
Generally, a denominator of 30 or more results in enough observations (or opportunities to serve patients) to achieve a normal distribution and calculate a valid rate; therefore, performance rates for each measure were calculated only for pharmacies that had a minimum sample size of 30 patients who met the eligible population criterion. In addition, performance rates were not calculated for plans with 10 or fewer pharmacies meeting the minimum sample size criterion. This additional requirement was added because an accurate reflection of pharmacy performance cannot be determined with 10 or fewer pharmacies.

HEALTH PLAN PERFORMANCE RATE CALCULATION
In addition to the aggregate pharmacy performance rate, an overall health plan performance rate was calculated for each plan. The health plan rate provides a benchmark for comparison to the aggregate pharmacy rates and also acts as an additional data quality check. Because all of the participating plans had large enrollment, there was no minimum sample size criterion for calculating the heath plan rate.

ATTRIBUTION METHODOLOGY
In most cases, an ongoing relationship between a pharmacy and a patient must be established before the pharmacy can be considered accountable for the ongoing management of services that patients receive. The exception to this is a “never-never” situation—a dispensation that should never occur: two contraindicated medications being dispensed at the same time. Specific rules were established to define how the pharmacy- patient link should be applied in order to determine which pharmacy will be considered accountable for pharmacy services rendered to a patient. These rules were applied in addition to the continuous enrollment criterion previously discussed.

It is necessary to accurately attribute patients to a particular pharmacy and to provide pharmacies with a reasonable number of opportunities to render services. To achieve this, a balance must be sought between providing a sufficient number of opportunities with patients and holding pharmacies accountable for services provided to patients. The more rigorous the methodology (i.e., requiring more fills or a higher percentage of fills before a patient is attributed to a pharmacy), the more restrictive the attribution is, leading to a reduced number of attributable patients/events. It is equally likely that pharmacy performance can benefit from prior services that patients received elsewhere, as it can suffer from patients for whom there was inadequate time to affect health services.

For this project, the following attribution methods were applied across all measures.
1. For measures where a performance event (i.e., prescription fill) qualifies for the denominator of the measure, the pharmacy that fills the prescription is assumed to be accountable (for safety or efficiency measures).
2. For measures where patients who quality for the denominator of a measure receive prescriptions from only one pharmacy during

the measurement period, patients are attributed to that pharmacy.
3. For measures where patients who qualify for the denominator use more than one pharmacy during the measurement year for medications within an identified drug class, patients are attributed to the pharmacy that filled the majority of the prescriptions in that drug class or drug classes.

Some issues that arose in determining the appropriate attribution method for each measure included the impact of patients utilizing more than one pharmacy; patients who travel frequently or live in different geographic locations for a portion of the year; and patients who use both mail order and retail pharmacies. Attribution issues also arose when initial data analysis revealed high utilization of mail order pharmacies in the two plans that offered mail order as an option to members. Given the high utilization in the two plans and PQA's mission to report meaningful information to help consumers, employers, plans and other health care decision makers make informed choices; the TEP recommended that mail order pharmacies be held to same standard of care as retail or community pharmacies. Accordingly, mail order pharmacy claims were included in the analysis and patients were attributed to the mail order pharmacies in the same way as they were attributed to retail or community pharmacies.

2a2.3 Testing Results *(Reliability statistics, assessment of adequacy in the context of norms for the test conducted)*:
2008 TESTING RESULTS
Suboptimal Asthma Control assesses the percentage of patients with persistent asthma who were dispensed more than five canisters of a short-acting beta2 agonist inhaler over any three-month period.

Measure Considerations
Overall, denominators sizes for measure were quite small.

Suboptimal Asthma Control
The number of eligible patients with at least one prescription during the measurement period ranged from 1–18,991. The overall health plan performance rate ranged from 0.0 percent–6.9 percent, which demonstrates minimal variation and room for improvement. While the rates among health plans show small percentages of suboptimal care, an opportunity exists to identify those patients who are using a high quantity of the targeted medications.

Table SAC-A Health Plan Performance - Suboptimal Asthma Control

Plans	Denominator/Eligible patients	Numerator	Performance Rate
Plan 1	1	0	0.0%
Plan 2	820	16	2.0%
Plan 3	18,991	1,302	6.9%
Plan 4	7,598	444	5.8%

At the pharmacy level, the number of pharmacies with each plan that had any eligible patients ranged from 1–5,707. Only one plan had any pharmacies that met the minimum sample size criterion of 30 or more eligible patients: Plan 3, with 99 pharmacies. The performance rates for their retail and mail order pharmacies were 3.7 percent and 26.3 percent, respectively, demonstrating variation between the two types of pharmacies and room for improvement.

The Suboptimal Asthma Control measure presented challenges related to attribution. Attribution for this measure is dependent not only where the patient fills their asthma medications, but also on how many canisters of short- acting beta2 agonists inhalers they fill and where they fill them. Concerns were raised about how best to attribute these patients given that they may be filling the medications that qualify them for the numerator at a different pharmacy than the medications that made them eligible for the measure. Additional testing was performed to investigate how many patients filled the prescription for their canisters at a different pharmacy than their other asthma medications. The overwhelming majority filled the prescriptions at the same pharmacy; however, up to 8 percent filled their short-acting beta2 agonist medication at a different pharmacy, then where they filled their other asthma medications meaning that those patients would be misattributed.

Absence of Controller Therapy

TESTING RESULTS
Absence of Controller Therapy assesses the percentage of patients with persistent asthma who should be receiving controller therapy. Specifically, those patients who were dispensed more than five canisters of a short- acting beta-agonist medication during any consecutive three-month period who were not dispensed a controller therapy.

Absence of Controller Therapy
The number of eligible patients with at least one prescription during the measurement period ranged from 0–1,302. The overall health plan performance rate ranged from 0.0 percent–48.4 percent, which demonstrates substantial variation and room for improvement. At the pharmacy level, the number of pharmacies with each plan that had any eligible patients ranged from 0–450. None of the plans had pharmacies that met the minimum sample size criterion of 30 or more eligible patients, therefore, performance rates could not be calculated. Given the relatively small numbers of pharmacies with any eligible patients, this measure has little utility at the pharmacy level but is useful at the health plan level.

Table ACT-A: Health Plan Performance-Absence of Controller Therapy

Plans	Denominator/Eligible Patients	Numerator	Performance Rate
Plan 1	0	0	0.0%
Plan 2	16	2	12.5%
Plan 3	1,302	590	45.3%
Plan 4	444	215	48.4%

2b. VALIDITY. Validity, Testing, including all Threats to Validity: H☐ M☐ L☐ I ☐

2b1.1 Describe how the measure specifications *(measure focus, target population, and exclusions)* are consistent with the evidence cited in support of the measure focus (*criterion 1c)* and identify any differences from the evidence:
original testing information was provided within original submission. Additional evidence in support of this measure comes from a study of the relationship of beta-agonist use and hospitalization risk:
Schatz et al. Validation of a ß-agonist long-term asthma control scale derived from computerized pharmacy data. Journal of Allergy and Clinical Immunology. 2006;117:995-1000. This study showed that asthma patients who used greater than 1 SABA per month (>12 per year) had a hospitalization rate that was nearly double that of patients who used 0.5 to 1 SABA per month (hospitalization rate of 13.1% vs 7.0%).

2b2. Validity Testing. (*Validity testing was conducted with appropriate method, scope, and adequate demonstration of validity.)*

2b2.1 Data/Sample *(Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:
Initial testing was conducted in 2007-08 using prescription claims data from multiple health plans. The testing was conducted by NCQA and Advance Pharmacy Concepts. Details were provided in the initial submission.

2b2.2 Analytic Method *(Describe method of validity testing and rationale; if face validity, describe systematic assessment)*:
Please see information provided in section 2a2.2

2b2.3 Testing Results *(Statistical results, assessment of adequacy in the context of norms for the test conducted; if face validity, describe results of systematic assessment)*:
Please see information provided in section 2a2.3

POTENTIAL THREATS TO VALIDITY. (*All potential threats to validity were appropriately tested with adequate results.*)

2b3. Measure Exclusions. (*Exclusions were supported by the clinical evidence in 1c or appropriately tested with results demonstrating the need to specify them.*)

2b3.1 Data/Sample for analysis of exclusions *(Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:
Initial testing was conducted in 2007-08 using prescription claims data from multiple health plans. The testing was conducted by NCQA and Advance Pharmacy Concepts. Details were provided in the initial submission and in section 2a2.2 and 2a2.3

2b3.2 Analytic Method (*Describe type of analysis and rationale for examining exclusions, including exclusion related to patient preference)*:
Please see information provided in section 2a2.2

2b3.3 Results *(Provide statistical results for analysis of exclusions, e.g., frequency, variability, sensitivity analyses):*
Please see information provided in section 2a2.3

2b4. Risk Adjustment Strategy. (*For outcome measures, adjustment for differences in case mix (severity) across measured entities was appropriately tested with adequate results.*)

2b4.1 Data/Sample *(Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:
no risk adjustment strategy is used.

2b4.2 Analytic Method (*Describe methods and rationale for development and testing of risk model or risk stratification including selection of factors/variables)*:
.

2b4.3 Testing Results *(Statistical risk model: Provide quantitative assessment of relative contribution of model risk factors; risk model performance metrics including cross-validation discrimination and calibration statistics, calibration curve and risk decile plot, and assessment of adequacy in the context of norms for risk models. Risk stratification: Provide quantitative assessment of relationship of risk factors to the outcome and differences in outcomes among the strata)*:
.

2b4.4 If outcome or resource use measure is not risk adjusted, provide rationale and analyses to justify lack of adjustment: .

2b5. Identification of Meaningful Differences in Performance. (*The performance measure scores were appropriately analyzed and discriminated meaningful differences in quality.*)

2b5.1 Data/Sample *(Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:
ongoing assessment with multiple health plans.

2b5.2 Analytic Method *(Describe methods and rationale to identify statistically significant and practically/meaningfully differences in performance)*:
Please see information provided in section 2a2.2

2b5.3 Results *(Provide measure performance results/scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance)*:
Please see information provided in section 2a2.3

2b6. Comparability of Multiple Data Sources/Methods. (*If specified for more than one data source, the various approaches result in comparable scores.*)

2b6.1 Data/Sample *(Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:
.

2b6.2 Analytic Method *(Describe methods and rationale for testing comparability of scores produced by the different data sources specified in the measure)*:
.

2b6.3 Testing Results *(Provide statistical results, e.g., correlation statistics, comparison of rankings; assessment of adequacy in the context of norms for the test conducted)*:
.

2c. Disparities in Care: H☐ M☐ L☐ I ☐ NA☐ (*If applicable, the measure specifications allow identification of disparities.*)

2c.1 If measure is stratified for disparities, provide stratified results *(Scores by stratified categories/cohorts)*: no stratification is used other than by insurance line-of-business (Medicare, Medicaid, Commercial)

2c.2 If disparities have been reported/identified (e.g., in 1b), but measure is not specified to detect disparities, please explain:
.

2.1-2.3 Supplemental Testing Methodology Information:

Steering Committee: Overall, was the criterion, *Scientific Acceptability of Measure Properties*, met?
(*Reliability and Validity must be rated moderate or high*) Yes☐ No☐
Provide rationale based on specific subcriteria:

If the Committee votes No, STOP

3. USABILITY

Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (evaluation criteria)

C.1 Intended Purpose/ Use *(Check all the purposes and/or uses for which the measure is intended)*: Public Reporting, Quality Improvement (Internal to the specific organization), Quality Improvement with Benchmarking (external benchmarking to multiple organizations)

3.1 Current Use *(Check all that apply; for any that are checked, provide the specific program information in the following questions)*: Regulatory and Accreditation Programs, Quality Improvement with Benchmarking (external benchmarking to multiple organizations), Quality Improvement (Internal to the specific organization)

3a. Usefulness for Public Reporting: H☐ M☐ L☐ I ☐
(*The measure is meaningful, understandable and useful for public reporting.*)

3a.1. Use in Public Reporting - disclosure of performance results to the public at large *(If used in a public reporting program, provide name of program(s), locations, Web page URL(s)).* If not publicly reported in a national or community program, state the reason AND plans to achieve public reporting, potential reporting programs or commitments, and timeline, e.g., within 3 years of endorsement: [*For Maintenance – If not publicly reported, describe progress made toward achieving disclosure of performance results to the public at large and expected date for public reporting; provide rationale why continued endorsement should be considered.*]
The measure is available for public reporting. URAC recently adopted this measure as part of its accreditation programs for health plans and pharmacy benefit managers (PBMs). In 2013, URAC will begin public reports on this measure and others in their accreditation programs. The National Business Coalition on Health uses this measure within their eValue8 program which evaluates health plan performance and publicly shares the results. We are also encouraging Medicaid programs to use the asthma measure and have recommended it through the AHRQ-coordinated effort to select pediatric measures for Medicaid.

3a.2.Provide a rationale for why the measure performance results are meaningful, understandable, and useful for public reporting. If usefulness was demonstrated (e.g., focus group, cognitive testing), describe the data, method, and results: The measure is important because it identifies patients with poorly controlled asthma as evidenced by their excessive use of short-acting reliever medications, and it then assesses whether those patients with poorly-controlled asthma had received any controller/preventive medication.

3.2 Use for other Accountability Functions (payment, certification, accreditation). If used in a public accountability program, provide name of program(s), locations, Web page URL(s):

3b. Usefulness for Quality Improvement: H☐ M☐ L☐ I ☐
(*The measure is meaningful, understandable and useful for quality improvement.*)

3b.1. Use in QI. If used in quality improvement program, provide name of program(s), locations, Web page URL(s):
[*For Maintenance – If not used for QI, indicate the reasons and describe progress toward using performance results for improvement*].
The measure is being used by the Indian Health Service for QI within their clinics and pharmacies. Several PBMs are using the measures for QI for their commercially-insured patients. We can provide contact information upon request.

3b.2. Provide rationale for why the measure performance results are meaningful, understandable, and useful for quality improvement. If usefulness was demonstrated *(e.g., QI initiative),* describe the data, method and results:
The measure is important because it identifies patients with poorly controlled asthma as evidenced by their excessive use of short-acting reliever medications, and it then assesses whether those patients with poorly-controlled asthma had received any controller/preventive medication. The measure is easily calculated from prescription drug claims and is highly actionable.

Overall, to what extent was the criterion, *Usability*, met? H☐ M☐ L☐ I ☐
Provide rationale based on specific subcriteria:

4. FEASIBILITY

Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (evaluation criteria)

4a. Data Generated as a Byproduct of Care Processes: H☐ M☐ L☐ I ☐

4a.1-2 How are the data elements needed to compute measure scores generated? *(Check all that apply).*
Data used in the measure are:
generated by and used by healthcare personnel during the provision of care, e.g., blood pressure, lab value, medical condition

4b. Electronic Sources: H☐ M☐ L☐ I ☐

4b.1 Are the data elements needed for the measure as specified available electronically *(Elements that are needed to compute measure scores are in defined, computer-readable fields)*: ALL data elements in electronic claims

4b.2 If ALL data elements are not from electronic sources, specify a credible, near-term path to electronic capture, OR provide a rationale for using other than electronic sources:

4c. Susceptibility to Inaccuracies, Errors, or Unintended Consequences: H☐ M☐ L☐ I ☐

4c.1 Identify susceptibility to inaccuracies, errors, or unintended consequences of the measurement identified during testing and/or operational use and strategies to prevent, minimize, or detect. If audited, provide results:
Studies of prescription claims accuracy indicate that 99% of claims contain accurate data elements that are necessary for calculation of this measure.

4d. Data Collection Strategy/Implementation: H☐ M☐ L☐ I ☐

A.2 Please check if either of the following apply (*regarding proprietary measures*):
4d.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 *(e.g., fees for use of proprietary measures)*:
The users of this measure have indicated that it is easy to use.

Overall, to what extent was the criterion, *Feasibility*, met? H☐ M☐ L☐ I ☐
Provide rationale based on specific subcriteria:

OVERALL SUITABILITY FOR ENDORSEMENT

Does the measure meet all the NQF criteria for endorsement? Yes☐ No☐
Rationale:

If the Committee votes No, STOP.
If the Committee votes Yes, the final recommendation is contingent on comparison to related and competing measures.

5. COMPARISON TO RELATED AND COMPETING MEASURES

If a measure meets the above criteria and 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 before a final recommendation is made.

5.1 If there are related measures *(either same measure focus or target population)* or competing measures *(both the same measure focus and same target population*), list the NQF # and title of all related and/or competing measures:
0620 : Asthma - Short-Acting Beta Agonist Inhaler for Rescue Therapy

5a. Harmonization

5a.1 If this measure has 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:
PQA has considered whether our measure NQF 0548, Suboptimal Asthma Control (SAC) and Absence of Controlled Therapy (ACT) should be harmonized with NQF 0620 Use of Short-Acting Beta Agonist Inhaler for Rescue Therapy. While both measures measure the use of short-acting beta agonists in asthmatic patients, the measures are distinctly different. NQF 0548 measures two rates of poor asthma control- 1. frequent use of short-acting beta agonists in a short time period (3 months) and 2. the population identified in rate one that also have no controller medication in the same period. Both rates indicate over utilization of a rescue medication and need for additional therapeutic intervention. Measure 0620 also uses patients with asthma as the denominator, but measures those patients that have received a refill of a short-acting beta agonist in a 24 month period. This rate may be useful to identify those that have not refilled this medication. The measure does not provide information about over utilization or poor asthma control. Since these two measures, NQF 0548 and 0620, measure very different aspects of use of short-acting beta agonists in an asthmatic population, they should not be harmonized.

5b. Competing Measure(s)

5b.1 If this measure has 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)*:

CONTACT INFORMATION

Co.1 Measure Steward (Intellectual Property Owner): Pharmacy Quality Alliance, Inc., 9687 South Run Oaks Dr., Fairfax Station, Virginia, 22039

Co.2 Point of Contact: Dave, Nau, dnau@pqaalliance.org, 859-537-8462-

Co.3 Measure Developer if different from Measure Steward: Pharmacy Quality Alliance, Inc., 9687 South Run Oaks Dr., Fairfax Station, Virginia, 22039

Co.4 Point of Contact: David, Nau, Senior Director, dnau@pqaalliance.org, 859-537-8462-

Co.5 Submitter: David, Nau, Senior Director, dnau@pqaalliance.org, 859-537-8462-, Pharmacy Quality Alliance (PQA)

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

Co.7 Public Contact: Dave, Nau, dnau@pqaalliance.org, 859-537-8462-, Pharmacy Quality Alliance, Inc.

ADDITIONAL INFORMATION
Workgroup/Expert Panel involved in measure development Ad.1 Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.
Ad.2 If adapted, provide title of original measure, NQF # if endorsed, and measure steward. Briefly describe the reasons for adapting the original measure and any work with the original measure steward:
Measure Developer/Steward Updates and Ongoing Maintenance Ad.3 Year the measure was first released: 2009 Ad.4 Month and Year of most recent revision: 06, 2011 Ad.5 What is your frequency for review/update of this measure? every year Ad.6 When is the next scheduled review/update for this measure? 06, 2012
Ad.7 Copyright statement:
Ad.8 Disclaimers:
Ad.9 Additional Information/Comments:
Date of Submission (*MM/DD/YY*): 10/18/2011