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 sub criterion 1b).

Brief Measure Information

NQF #: 2337
Corresponding Measures:
De.2. Measure Title: Antipsychotic Use in Children Under 5 Years Old
Co.1.1. Measure Steward: Pharmacy Quality Alliance
De.3. Brief Description of Measure: The percentage of children under age 5 who were dispensed antipsychotic medications during the measurement period.
1b.1. Developer Rationale: In general, adverse effects from receipt of antipsychotic medication by adults and children include an increased risk of metabolic syndrome, hyperprolactemia, thyroid dysfunction, diabetes, depression, agranulocytosis, and extrapyramidal syndromes; though, many of these adverse effects have been shown to occur at a higher rate or to a greater degree in children than in the adult population. More specifically, studies have demonstrated that children who receive antipsychotic medications have a greater risk of diabetes, metabolic, and cardiovascular issues, and adverse effects such as increases in weight, BMI, total cholesterol, triglycerides, QTc interval, heart rate, and liver function abnormalities. These adverse effects have been demonstrated not only in immediate complications but also in long-term complications and ill effects on health. In particular, cardiometabolic adverse effects have been shown to be particularly problematic during childhood development because they predict poor outcomes such as adult obesity, the metabolic syndrome, cardiovascular morbidity, and cancer.

This measure examines the rate in which antipsychotic medications are dispensed to patients under the age of 5 years, where usage is especially concerning, and where an increase in prescribing has been noted. Usage in this population is being increasingly scrutinized by academic studies, Medicaid directors and recently through an investigation launched by the United States Inspector General's Office. Also, of note are the disparities in the rate of usage between Medicaid patients and the privately insured, along with higher prevalence rates in foster children. Because the risk of childhood obesity is related to poverty, those children at high risk for obesity and related metabolic disorders may be more vulnerable to the adverse effects of weight gain from antipsychotics.

Of the long list of antipsychotic medications available, only two – chlorpromazine and haloperidol – have indications for use in patients less than 5 years of age; however, these indications were granted in 1954 and 1986, respectively. The increased numbers of studies, meta-analysis, and systematic reviews that have been completed since that time have demonstrated that these medications have the same adverse effects as other antipsychotics, which would caution against their use. Additionally, the data used in the testing of this measure demonstrate very limited, small numbers of prescriptions filled of these medications, with only 2 prescriptions filled for chlorpromazine and 14 prescriptions filled for haloperidol (nationally).

As stated, although in general antipsychotics are not indicated for use in children under age 5 and have been determined to be unsafe, their usage is increasing. Our testing has shown that prescribing rates in children under 5 in the Medicaid population differ significantly from state to state. In addition, testing shows that there is a statistically significant difference in prescribing rates between the top and bottom quartile of the population, as well as between all four quartile groups. If all 44 states and the District of Columbia were to achieve the average prescribing rate of the 75th percentile, harm could be reduced in 7,432 children. Shining a light on this area helps to address both medication safety and disparities issues.

S.4. Numerator Statement: The number of patients under 5 years of age with one or more prescription claims for an antipsychotic medication with days supply that total greater than or equal to 30 days.
S.6. Denominator Statement: Children who are less than 5 years old at any point during the measurement period, and also enrolled in a health plan for one month or longer during the measurement period.
S.8. Denominator Exclusions: None.

De.1. Measure Type: Process
S.17. Data Source: Claims
S.20. Level of Analysis: Health Plan, Population : Regional and State

IF Endorsement Maintenance – Original Endorsement Date: Nov 10, 2014 **Most Recent Endorsement Date:** Nov 10, 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? The measure is not paired/grouped.

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 sub criteria to pass this criterion and be evaluated against the remaining criteria.***

1a. Evidence to Support the Measure Focus – See attached Evidence Submission Form
MeasSub_Evidence_PQA_AP_5_FINAL_011614.pdf
1a.1 For Maintenance of Endorsement: Is there new evidence about the measure since the last update/submission?
Please update any changes in the evidence attachment in red. Do not remove any existing information. If there have been any changes to evidence, the Committee will consider the new evidence. If there is no new evidence, no updating of the evidence information is needed.

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., how the measure will improve the quality of care, the benefits or improvements in quality envisioned by use of this measure)*
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.)
IF a COMPOSITE (e.g., combination of component measure scores, all-or-none, any-or-none), SKIP this question and provide rationale for composite in question 1c.3 on the composite tab.
In general, adverse effects from receipt of antipsychotic medication by adults and children include an increased risk of metabolic syndrome, hyperprolactemia, thyroid dysfunction, diabetes, depression, agranulocytosis, and extrapyramidal syndromes; though, many of these adverse effects have been shown to occur at a higher rate or to a greater degree in children than in the adult population. More specifically, studies have demonstrated that children who receive antipsychotic medications have a greater risk of diabetes, metabolic, and cardiovascular issues, and adverse effects such as increases in weight, BMI, total cholesterol, triglycerides, QTc interval, heart rate, and liver function abnormalities. These adverse effects have been demonstrated not only in immediate complications but also in long-term complications and ill effects on health. In particular, cardiometabolic adverse effects have been shown to be particularly problematic during childhood development because they predict poor outcomes such as adult obesity, the metabolic syndrome, cardiovascular morbidity, and cancer.

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Of the long list of antipsychotic medications available, only two – chlorpromazine and haloperidol – have indications for use in patients less than 5 years of age; however, these indications were granted in 1954 and 1986, respectively. The increased numbers of studies, meta-analysis, and systematic reviews that have been completed since that time have demonstrated that these medications have the same adverse effects as other antipsychotics, which would caution against their use. Additionally, the data used in the testing of this measure demonstrate very limited, small numbers of prescriptions filled of these medications, with only 2 prescriptions filled for chlorpromazine and 14 prescriptions filled for haloperidol (nationally).

As stated, although in general antipsychotics are not indicated for use in children under age 5 and have been determined to be unsafe, their usage is increasing. Our testing has shown that prescribing rates in children under 5 in the Medicaid population differ significantly from state to state. In addition, testing shows that there is a statistically significant difference in prescribing rates between the top and bottom quartile of the population, as well as between all four quartile groups. If all 44 states and the District of Columbia were to achieve the average prescribing rate of the 75th percentile, harm could be reduced in 7,432 children. Shining a light on this area helps to address both medication safety and disparities issues.

1b.2. **Provide performance scores on the measure as specified (<u>current and over time</u>) at the specified level of analysis**. *(<u>This is required for maintenance of endorsement</u>. 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 include.) This information also will be used to address the sub-criterion on improvement (4b) under Usability and Use.*
Based upon 2007 testing data, there were 12,767 of 11,302,233 (0.11%) children under the age of 5 in state Medicaid programs across 44 states and the District of Columbia who received one or more prescriptions for an antipsychotic medication, with a days supply that totaled greater than 30 days. 2,283 of the 12,767 children who received antipsychotics were foster children. The mean rate of antipsychotic use in beneficiaries aged 3 & 4 was 0.32% (n=10,497). The minimum state rate seen in patients less than 5 years of age was 0% (n=0) with the maximum being 0.35% (n=537). In foster children on Medicaid, the mean rate of antipsychotic use under the age of 5 was 0.99% (n=2,238) and specifically in 3 & 4 year olds was 2.25% (n=1,918). In beneficiaries in foster care, the minimum rate seen in patients less than 5 years of age was 0% (n=0) with the maximum being 2.80% (n=579). In beneficiaries in foster care, the minimum rate seen in patients who were 3 & 4 years of age was 0% (n=0) with the maximum being 6.51% (n=477).

Two data sources were used in the analysis. The first data set from 44 states and DC was obtained through the utilization of the 2007 Medicaid Max File. The second data set examined the state of Mississippi in 2012 and included the Medicaid data from that state in 2012. The data obtained in the study can be broken down by state in terms of patient demographics, age, managed care status, race, and percentage of foster care patients.

The characteristics of the total population include: 48.8% of the patients were female with 51.2% being male; 56.2% of the population were less than 2 years of age, 15.9% were 3 years of age, 15.2% were 4 years of age, and 12.7% were 5 years of age at the end of the observation period; 36.5% were Caucasian, 22.4% were African American, 29.5% were Hispanic, and 11.5% were classified as other; 8.9% of the patients were enrolled in a fee-for-service plan only, 64.6% were enrolled in a managed care plan only, and 26.5% were enrolled in mixed plans; and 2% of the patients were in the foster care system.

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.**
Data from testing for this measure has been provided in 1b.2. In addition, there is data from the literature that also indicates opportunity for improvement.

• The Inspector General's office at the Department of Health and Human Services (HHS) announced a probe into pediatric antipsychotic usage in the Medicaid population. In addition to the probe, HHS agencies are requiring state officials in every state to examine and tighten the oversight of antipsychotic medication use in Medicaid pediatric patients. The Wall Street Journal (WSJ) cited a Mathematica analysis that found a three-fold increase in Medicaid prescriptions from 1999 to 2008 for antipsychotic medications in patients under 20 years of age. CMS´ chief medical officer reported that the government wants to reduce the "unnecessarily high utilization of antipsychotics." The WSJ cited Medicaid representatives who reported that in 2008, 19,045 children under the age of 5 were prescribed antipsychotics through Medicaid, up from 7,759 in 1999.

Lagnado L. U.S. Probes Use of Antipsychotic Drugs on Children: Federal health officials are reviewing antipsychotic drug use on children in the Medicaid system. Wall Street Journal. 2013 Aug 11 [accessed 2013 Aug 11]. Available from: http://online.wsj.com/news/articles/SB10001424127887323477604578654130865747470

• Zito et al. is a cross-sectional study examining the increased antipsychotic medication usage in youth in various Medicaid-eligibility categories. In examining computerized administrative claims data, the prevalence of antipsychotic use in pediatric patients increased from 1.2% in 1997 to 3.2% in 2006. The greatest increase of odds of antipsychotic usage was in youths enrolled in SCHIP (AOR=5.9), foster children (AOR=4.1), Temporary Assistance for Needy Families (AOR=3.6), and supplemental security income (AOR=2.8). Additionally, the proportion of antipsychotic usage increase was significantly higher in African Americans and Hispanics as compared to Caucasians.

Zito JM, Burcu M, Ibe A, Safer DJ, Magder LS. Antipsychotic use by medicaid-insured youths: impact of eligibility and psychiatric diagnosis across a decade. Psychiatr Serv. 2013 Mar 1;64(3):223-9. doi: 10.1176/appi.ps.201200081. Available from: http://ps.psychiatryonline.org/article.aspx?articleid=1486122

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 maintenance of endorsement. Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included.) For measures that show high levels of performance, i.e., "topped out", disparities data may demonstrate an opportunity for improvement/gap in care for certain sub-populations. This information also will be used to address the sub-criterion on improvement (4b) under Usability and Use.*

During measure testing, the rate of antipsychotic use in children under 5 was determined for the entire Medicaid population. In addition, the subgroups that the measure was broken down into for additional analysis included foster children (275,451) and non-foster children (11,026,782). Results showed that 2,283 foster children met the numerator criteria for antipsychotic usage in children under the age of 5, which resulted in a rate of 0.99% as compared with 10,484 non-foster children who met the numerator criteria for antipsychotic usage in children under the age of 5, which resulted in a rate of 0.09%.

1b.5. **If no or limited data on disparities from the measure as specified is reported in 1b.4, then provide a summary of data from the literature that addresses disparities in care on the specific focus of measurement. Include citations. Not necessary if performance data provided in 1b.4**

Disparities data from testing for this measure has been provided in 1b.4. In addition, there is data from the literature that addresses disparities in care related to this measure.

•In a Medicaid report examining antipsychotic usage across 16 states, the rate of antipsychotic use in Medicaid beneficiaries under 18 was examined based on demographics. The study found a considerable increased rate of usage in the foster care population as compared to non-foster care (12.37% vs 1.40%). Additionally, male beneficiaries had a greater likelihood of receiving antipsychotics (2.23% vs 1.05%). The rate for patients who were aged, blind, or disabled was also greater than the average at 13.44%.

Antipsychotic medication use in Medicaid children and adolescents: report and resource guide from 16-page study. June 2010. Available from: http://chsr.rutgers.edu/MMDLNAPKIDS/Antipsychotic_Use_in_Medicaid_Children_Report_and_Resource_Guide_Final.pdf

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Zito JM, Safer DJ, Sai D, et al. Psychotropic medication patterns among youth in foster care. Pediatrics. 2008 Jan;121(1):e157-63. doi: 10.1542/peds.2007-0212. Available from: http://pediatrics.aappublications.org/content/121/1/e157.long

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children under the age of 5 were prescribed antipsychotics through Medicaid, up from 7,759 in 1999.

Lagnado L. U.S. Probes Use of Antipsychotic Drugs on Children: Federal health officials are reviewing antipsychotic drug use on children in the Medicaid system. Wall Street Journal. 2013 Aug 11 [accessed 2013 Aug 11]. Available from: http://online.wsj.com/news/articles/SB10001424127887323477604578654130865747470

•Shrewsbury et al. noted that because the risk of childhood obesity is related to poverty, those children at high risk for obesity and related metabolic disorders may be more vulnerable to the adverse effects of weight gain from antipsychotics.

Shrewsbury V, Wardle J. Socioeconomic status and adiposity in childhood: A systematic review of cross-sectional studies, 1990-2005. Obesity. 2008;16:275-284.

2. Reliability and 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. *Measures must be judged to meet the sub criteria 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):*
Behavioral Health

De.6. Non-Condition Specific*(check all the areas that apply):*
Disparities Sensitive, Safety, Safety : Medication, Safety : Overuse

De.7. Target Population Category *(Check all the populations for which the measure is specified and tested if any):*
Children, Populations at Risk

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.)*

S.2a. If this is an eMeasure, HQMF specifications must be attached. Attach the zipped 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)
This is not an eMeasure **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)*
No data dictionary **Attachment:**

S.3.1. For maintenance of endorsement: Are there changes to the specifications since the last updates/submission. If yes, update the specifications for S1-2 and S4-22 and explain reasons for the changes in S3.2.

S.3.2. For maintenance of endorsement, please briefly describe any important changes to the measure specifications since last measure update and explain the reasons.
N/A

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) DO NOT include the rationale for the*

measure.
IF an OUTCOME MEASURE, state the outcome being measured. Calculation of the risk-adjusted outcome should be described in the calculation algorithm (S.14).
The number of patients under 5 years of age with one or more prescription claims for an antipsychotic medication with days supply that total greater than or equal to 30 days.

S.5. 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, time period for data collection, 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 (S.14).
Numerator
Step 1: Of those included in the denominator, count the number of patients with one or more prescription claims for an antipsychotic medication with days supply that total greater than or equal to 30 days.
Step 2: Of those identified in Step 1, include only those patients for whom a prescription claim for an antipsychotic medication was generated when the patient was under the age of 5.
The number of patients remaining after completing Step 2 represents the numerator for this measure.

Antipsychotic Medications for this measure include: aripiprazole, asenapine, chlorpromazine, clozapine, fluphenazine, haloperidol, iloperidone, loxapine, lurasidone, olanzapine, paliperidone, perphenazine, pimozide, quetiapine, risperidone, thioridazine, thiothixene, trifluoperazine, and ziprasidone.
(Note: Includes combination products that contain any of the above-listed medications.The active ingredients are limited to oral, sublingual, injectable, and intramuscular formulations only.)

S.6. Denominator Statement *(Brief, narrative description of the target population being measured)*
Children who are less than 5 years old at any point during the measurement period, and also enrolled in a health plan for one month or longer during the measurement period.

S.7. Denominator Details *(All information required to identify and calculate the target population/denominator such as definitions, time period for data collection, 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 target population is identified. Calculation of the risk-adjusted outcome should be described in the calculation algorithm (S.14).
The denominator includes all patients who were under 5 years of age at any time during the measurement period, and also enrolled in a health plan for one month or longer during the measurement period.

Denominator Calculation:
Step 1: Identify patients that are less than 5 years of age at any point during the measurement period.
Step 2: Of those patients identified in Step 1, only include those patients that were enrolled in a health plan for one month or longer during the measurement period.

The number of patients identified in Step 2 is the denominator for the measure.

S.8. Denominator Exclusions *(Brief narrative description of exclusions from the target population)*
None.

S.9. Denominator Exclusion Details *(All information required to identify and calculate exclusions from the denominator such as definitions, time period for data collection, 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.)*
None.

S.10. Stratification Information *(Provide all information required to stratify the measure results, if necessary, including the stratification variables, definitions, specific data collection items/responses, code/value sets, and the risk-model covariates and coefficients for the clinically-adjusted version of the measure when appropriate – 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.)
None.

S.11. **Risk Adjustment Type** (Select type. Provide specifications for risk stratification in measure testing attachment)
No risk adjustment or risk stratification
If other:

S.12. **Type of score:**
Rate/proportion
If other:

S.13. **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 = Lower score

S.14. **Calculation Algorithm/Measure Logic** (*Diagram or 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; time period for data, aggregating data; risk adjustment; etc.)*
Denominator Calculation:
Step 1: Identify patients that are less than 5 years of age at any point during the measurement period.
Step 2: Of those patients identified in Step 1, only include those patients that were enrolled in a health plan for one month or longer during the measurement period.

The number of patients identified in Step 2 is the denominator for the measure.

Numerator Calculation:
Step 3: Of those patients identified in Step 2, count the number of patients with one or more prescription claims for an antipsychotic medication with days supply that total greater than or equal to 30 days.
Step 4: Of those patients identified in Step 3, include only those patients for whom a prescription claim for an antipsychotic medication was generated when the patient was under the age of 5.

The number of patients identified by completing Step 4 represents the numerator for this measure.

Step 5: Divide the numerator by the denominator and then multiply by 100 to obtain the rate (as a percentage) for the measure.

Antipsychotic Medications for this measure include: aripiprazole, asenapine, chlorpromazine, clozapine, fluphenazine, haloperidol, iloperidone, loxapine, lurasidone, olanzapine, paliperidone, perphenazine, pimozide, quetiapine, risperidone, thioridazine, thiothixene, trifluoperazine, and ziprasidone.
(Note: Includes combination products that contain any of the above-listed medications.The active ingredients are limited to oral, sublingual, injectable, and intramuscular formulations only.)

S.15. **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.
N/A

S.16. **Survey/Patient-reported data** *(If measure is based on a survey or instrument, provide instructions for data collection and guidance on minimum response rate.)*
IF a PRO-PM, specify calculation of response rates to be reported with performance measure results.
N/A

S.17. **Data Source** *(Check ONLY the sources for which the measure is SPECIFIED AND TESTED).*
If other, please describe in S.18.
 Claims

S.18. **Data Source or Collection Instrument** *(Identify the specific data source/data collection instrument (e.g. name of database,*

clinical registry, collection instrument, etc., and describe how data is collected.)
<u>IF a PRO-PM</u>, identify the specific PROM(s); and standard methods, modes, and languages of administration.
Health plan (e.g., Medicaid, other) enrollment data
Health plan (e.g., Medicaid, other) prescription claims data

S.19. 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.20. Level of Analysis *(Check ONLY the levels of analysis for which the measure is SPECIFIED AND TESTED)*
Health Plan, Population : Regional and State

S.21. Care Setting *(Check ONLY the settings for which the measure is SPECIFIED AND TESTED)*
Other
If other: Health plan

<u>S.22.</u> **<u>COMPOSITE Performance Measure</u>** - Additional Specifications *(Use this section as needed for aggregation and weighting rules, or calculation of individual performance measures if not individually endorsed.)*
N/A

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2. Validity – See attached Measure Testing Submission Form
Measure_Testing_PQA_AP_5_FINAL_011614.pdf

2.1 <u>For maintenance of endorsement</u>
Reliability testing: If testing of reliability of the measure score was not presented in prior submission(s), has reliability testing of the measure score been conducted? If yes, please provide results in the Testing attachment. (Do not remove prior testing information – include date of new information in red.)

2.2 <u>For maintenance of endorsement</u>
Has additional empirical validity testing of the measure score been conducted? If yes, please provide results in the Testing attachment. (Do not remove prior testing information – include date of new information in red.)

2.3 <u>For maintenance of endorsement</u>
Risk adjustment: For outcome, resource use, cost, and some process measures, risk-adjustment that includes SDS factors is no longer prohibited during the SDS Trial Period (2015-2016). Please update sections 1.8, 2a2, 2b2, 2b4, and 2b6 in the Testing attachment and S.14 and S.15 in the online submission form in accordance with the requirements for the SDS Trial Period. NOTE: These sections must be updated even if SDS factors are not included in the risk-adjustment strategy.   If yes, and your testing attachment does not have the additional questions for the SDS Trial please add these questions to your testing attachment:

What were the patient-level sociodemographic (SDS) variables that were available and analyzed in the data or sample used? For example, patient-reported data (e.g., income, education, language), proxy variables when SDS data are not collected from each patient (e.g. census tract), or patient community characteristics (e.g. percent vacant housing, crime rate).

Describe the conceptual/clinical and statistical methods and criteria used to select patient factors (clinical factors or sociodemographic factors) used in the statistical risk model or for stratification by risk (e.g., potential factors identified in the literature and/or expert panel; regression analysis; statistical significance of $p<0.10$; correlation of x or higher; patient factors should be present at the start of care)

What were the statistical results of the analyses used to select risk factors?

Describe the analyses and interpretation resulting in the decision to select SDS factors (e.g. prevalence of the factor across measured entities, empirical association with the outcome, contribution of unique variation in the outcome, assessment of between-unit effects and within-unit effects)

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*) Update this field for **maintenance of endorsement**.
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.** For **maintenance of endorsement**, if this measure is not an eMeasure (eCQM), please describe any efforts to develop an eMeasure (eCQM).

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. Please also complete and attach the NQF Feasibility Score Card.**
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. **Required for maintenance of endorsement.** **Describe difficulties (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 PRO data (patients, service recipients, respondents) and those whose performance is being measured.**
No feasibility issues were found as a result of testing the measure.

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*).
PQA develops and maintains numerous performance measures related to the medication use system. The Measures are the proprietary property of PQA, and it is in the interest of PQA to protect and promote the appropriate use of the Measures. PQA may approve an organization's use of the Measures; however, no organization may use the Measures without first obtaining permission from PQA prior to using the Measures. Certain uses of the Measures are only approved with a licensing agreement from PQA that specifies the terms of use and the licensing fee. PQA reserves the right to determine the conditions under which it will approve and/or license the Measures.

Licenses are granted on a year-to-year basis. PQA reserves the right to audit the licensee's use of the Measures and may revoke a license if it is determined that the licensee has used the Measures in a manner that is outside the scope of permitted use that was

specified in the licensing agreement.

Certain licensees will be required to pay a fee to PQA for the use of the Measures. The licensing fee may be structured as a fixed annual amount or as a variable amount that is dependent on the volume of utilization of the Measures. As a benefit of membership, PQA members who use the Measures only for internal quality improvement initiatives (i.e., self-assessment) will not be assessed a licensing fee.

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.

Specific Plan for Use	Current Use (for current use provide URL)
Public Reporting	Quality Improvement (Internal to the specific organization) http://www.medicaid.ms.gov/ Mississippi Medicaid

4a.1. For each CURRENT use, checked above (update for maintenance of endorsement), provide:
- Name of program and sponsor
- Purpose
- Geographic area and number and percentage of accountable entities and patients included
- Level of measurement and setting

Mississippi Medicaid - State Medicaid Drug Utilization Review (DUR) Program

MS Medicaid has utilized this measure and reported the results to their DUR Board. They are planning to track the measure and develop additional edits, etc. to try and further reduce the rate. They currently do not have a specific intervention program but are evaluating all of the clinical edits performed in the prior authorization process.

In 2012, they had 167,482 children in the denominator and 184 children in the numerator, for a rate of 0.11%.

The project lead will be reporting on the national numbers for this measure at the American Drug Utilization Review Society (ADURS) meeting in February 2014.

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?*)
Measure development and PQA membership approval of this measure recently was completed (May 2013). The measure specifications are publicly available and are provided upon request to the Measure Steward point of contact, or other PQA staff. Ongoing strategies to support measure adoption and implementation include outreach to: pharmacy directors of State Medicaid programs through the American Drug Utilization Review Society (ADURS); Medicaid Health Plans of America; CMS; and others. We anticipate use of this measure beginning in 2014 (in addition to the use described above, in 4a.1).

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.*)

Ongoing strategies to support measure adoption and implementation include outreach to: pharmacy directors of State Medicaid programs through the American Drug Utilization Review Society (ADURS); Medicaid Health Plans of America; CMS; and others. PQA also is advocating for this measure to be included in the core set of measures for children in Medicaid programs. As a result of our multi-faceted outreach strategy, we anticipate use of this measure beginning in 2014 (in addition to the use described above, in 4a.1).

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. **Refer to data provided in 1b but do not repeat here. Discuss any progress on improvement (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.)**
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.
N/A

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. **Please explain any unexpected findings (positive or negative) during implementation of this measure including unintended impacts on patients.**
No negative consequences were incurred by individuals or populations during the testing nor has any evidence of unintended negative consequences to individuals or populations been demonstrated since implementation. The testing for this measure was purely an examination and extrapolation from the data to obtain the percentage of children receiving antipsychotics.

4c.2. **Please explain any unexpected benefits from implementation of this measure.**

4d1.1. **Describe how performance results, data, and assistance with interpretation have been provided to those being measured or other users during development or implementation.**
How many and which types of measured entities and/or others were included? If only a sample of measured entities were included, describe the full population and how the sample was selected.

4d1.2. **Describe the process(es) involved, including when/how often results were provided, what data were provided, what educational/explanatory efforts were made, etc.**

4d2.1. **Summarize the feedback on measure performance and implementation from the measured entities and others described in 4d.1.**
Describe how feedback was obtained.

4d2.2. **Summarize the feedback obtained from those being measured.**

4d2.3. **Summarize the feedback obtained from other users**

4d.3. Describe how the feedback described in 4d.2 has been considered when developing or revising the measure specifications or implementation, including whether the measure was modified and why or why not.

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)

5.1b. If related or competing measures are not NQF endorsed please indicate measure title and steward.

5a. Harmonization of Related Measures
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 harmonized to the extent possible?

5a.2. If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden.
N/A - there are no related or competing NQF-endorsed measures.

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.)
N/A. There are no related or competing NQF-endorsed measures.

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.
No appendix **Attachment:**

Contact Information

Co.1 **Measure Steward (Intellectual Property Owner):** Pharmacy Quality Alliance
Co.2 **Point of Contact:** Lynn, Pezzullo, lpezzullo@pqaalliance.org, 515-554-6685-
Co.3 **Measure Developer if different from Measure Steward:** Pharmacy Quality Alliance
Co.4 **Point of Contact:** Lynn, Pezzullo, lpezzullo@pqaalliance.org, 703-347-7963-

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.

PQA Mental Health Workgroup Members and Organizations:
Nancy England (Academy of Managed Care Pharmacy)
Mary von Vital (Aetna)
Raymond Love (American Pharmacists Association)
Terry   O´Shea (American Society of Consultant Pharmacists)
Eric Kutscher (American Society of Health-System Pharmacists)
Laura Parker (Amerigroup)
Steve Blackwell (Centers for Medicare & Medicaid Services)
Tori Booth (CVS/Caremark)
Laurence Samet (CVS/Caremark)
Keith   Widmer (Express Scripts, Inc.)
Brandon Suehs (Humana)
Jaren   Howard (Humana)
Mike   Durkin (Johnson & Johnson)
Nina   Escasa (Kaiser Permanente)
Meghan Kelly (Medication Management Systems)
Jane Howard (MedImpact Healthcare Systems, Inc.)
Grant H. Brown (National Alliance of State Pharmacy Associations)
Dale   Masten (National Association of Chain Drug Stores)
Barbara Zarowitz (Omnicare)
Richard McLeod (Pfizer, Inc.)
Ly Tran (PharmMD)
Kevin Masci (Target)
Carol Pamer (U.S. Food & Drug Administration)
Benjamin Banahan, III (University of Mississippi Center for Pharmaceutical Marketing & Management)
John   Marakas (Walmart)
Angel Wolf (Wellcare)

PQA Mental Health Workgroup Members´ role: Being a consensus-based membership organization, PQA workgroup members identify measure concepts that may be appropriate for development into performance measures. Workgroups focus on specific aspects of the medication-use system and/or specific therapeutic areas. Measure concepts developed in workgroups can be recommended to the PQA Quality Metrics Expert Panel (QMEP) for evaluation and refinement.

PQA Quality Metrics Expert Panel (QMEP) Members and Organizations:
Steven Burch, RPh, PhD (Population Analytics & Center for Economic Affairs (PACE) Field Director, National Accounts, GlaxoSmithKline)
Catherine Coast, PharmD (Clinical Pharmacy Specialist, Highmark BCBS)
Chris Dezii RN, MBA, CPHQ (Director, Healthcare Quality and Performance Measures Health Services, Bristol-Myers Squibb Company)
Chris DuPaul (Vice President, Enterprise Product Development, CVS Caremark)
Pat Gleason, PharmD, FCCP, BCPS (Director of Health Outcomes, Prime Therapeutics Adjunct Associate Professor, Univ. MN, College of Pharmacy)
Mary Ann Kliethermes, BS, PharmD (Vice Chair of Ambulatory Care & Associate Professor Chicago College of Pharmacy, Midwestern University)

Terri Moore, PhD, RPh, MBA (Senior Manager, Product Development, URAC)
Bimal Patel (Director, Health Outcomes Research, MedImpact Healthcare Systems)
Christopher Powers, PharmD (Acting Director, Information Products Group Centers for Medicare & Medicaid Services)
Marissa Schlaifer, MS, RPh (Head of Policy, CVS Caremark)
Elliott Sogol, PhD, RPh, FAPhA (Consultant)
Kent Summers, RPh, PhD (Vice President, Health Economics & Outcomes Research, Endo)
Brad Tice, PharmD, MBA, FAPhA (Adverse Drug Event Clinical Pharmacist, Humana, Inc.)
Gary Young, JD, PhD (Director, Northeastern University Center for Health Policy and Healthcare Research, Professor of Strategic Management and Healthcare Systems, Northeastern University)

PQA QMEP members´ role: The PQA Quality Metrics Expert Panel (QMEP) is charged with evaluating the measure concepts proposed by the PQA workgroups and prioritizing the measure concepts for specification and testing. The Panel reviews comments from PQA members on draft measures to determine whether modifications should be made or what variations should be considered during testing. The QMEP reviews the results of the pilot-testing of the draft measures and makes final recommendations to the PQA membership regarding endorsement of the draft measures. The Panel is comprised of persons who have clinical or other technical expertise related to quality measurement. The members are invited to serve on the QMEP by PQA's senior measurement development team. The composition of the QMEP reflects PQA's membership.

Measure Developer/Steward Updates and Ongoing Maintenance
Ad.2 Year the measure was first released: 2013
Ad.3 Month and Year of most recent revision: 05, 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? 2014

Ad.6 Copyright statement: Rights retained by PQA, INC. 2014
Ad.7 Disclaimers: N/A

Ad.8 Additional Information/Comments: NOTE: UNABLE TO ATTACH THE EVIDENCE FORM AND MEASURE TESTING FORM DUE TO TECHNICAL CHALLENGES, WHICH WERE REPORTED TO ANDREW LYZENGA. I HAVE EMAILED THE DOCUMENTS TO ANDREW, PER HIS GUIDANCE, AND THEY WILL BE INCLUDED WITH THIS SUBMISSION.