Use of Higher-than-Recommended Doses of Antipsychotics in Children and Adolescents

Section 1. Basic Measure Information

1.A. Measure Name

Use of Higher-than-Recommended Doses of Antipsychotics in Children and Adolescents

1.B. Measure Number

0177

1.C. Measure Description

Please provide a non-technical description of the measure that conveys what it measures to a broad audience.

Measures the percentage of children and adolescents 1-17 years of age on an antipsychotic medication during the measurement year who received two or more antipsychotic medication prescriptions with higher-than-recommended doses.

1.D. Measure Owner

National Committee for Quality Assurance (NCQA).

1.E. National Quality Forum (NQF) ID (if applicable)

Not applicable.

1.F. Measure Hierarchy

Please note here if the measure is part of a measure hierarchy or is part of a measure group or composite measure. The following definitions are used by AHRQ:

1. **Please identify the name of the collection of measures to which the measure belongs (if applicable). A collection is the highest possible level of the measure hierarchy. A collection may contain one or more sets, subsets, composites, and/or individual measures.**

   Not applicable.

2. **Please identify the name of the measure set to which the measure belongs (if applicable). A set is the second level of the hierarchy. A set may include one or more subsets, composites, and/or individual measures.**

   Safe and Judicious Use of Antipsychotics in Children and Adolescents.

3. **Please identify the name of the subset to which the measure belongs (if applicable). A subset is the third level of the hierarchy. A subset may include one or more composites, and/or individual measures.**

   Not applicable.

4. **Please identify the name of the composite measure to which the measure belongs (if applicable). A composite is a measure with a score that is an aggregate of scores from other measures. A composite may include one or more other composites and/or individual measures. Composites may comprise component measures that can or cannot be used on their own.**

   Not applicable.

1.G. Numerator Statement

Received two or more antipsychotic medication prescriptions (for the same or different drugs) with higher-than-recommended doses.

1.H. Numerator Exclusions

None.

1.I. Denominator Statement

Children ages 1-17 years on an antipsychotic medication during the measurement year with at least two antipsychotic medication dispensing events.

- Age stratification: 1-5 years; 6-11 years; 12-17 years.
- Continuous eligibility: at least 3 months.
- Benefit: medical and pharmacy.

1.J. Denominator Exclusions

None.

1.K. Data Sources

Check all the data sources for which the measure is specified and tested.

Administrative data (e.g., claims data).

If other, please list all other data sources in the field below.

Not applicable.

Section 2: Detailed Measure Specifications

Provide sufficient detail to describe how a measure would be calculated from the recommended data sources, uploading a separate document (+ Upload attachment) or a link to a URL. Examples of detailed measure specifications can be found in the CHIPRA Initial Core Set Technical Specifications Manual 2011 published by the Centers for Medicare & Medicaid Services. Although submission of formal programming code or algorithms that demonstrate how a measure would be calculated from a query of an appropriate electronic data source are not requested at this time, the availability of these resources may be a factor in determining whether a measure can be recommended for use.

See Supporting Documents for measure specifications.

Section 3. Importance of the Measure

In the following sections, provide brief descriptions of how the measure meets one or more of the following criteria for measure importance (general importance, importance to Medicaid and/or CHIP, complements or enhances an existing measure). Include references related to specific points made in your narrative (not a free-form listing of citations).

3.A. Evidence for General Importance of the Measure

Provide evidence for all applicable aspects of general importance:

- **Addresses a known or suspected quality gap and/or disparity in quality (e.g., addresses a socioeconomic disparity, a racial/ethnic disparity, a disparity for Children with Special Health Care Needs (CSHCN), a disparity for limited English proficient (LEP) populations).**
- **Potential for quality improvement (i.e., there are effective approaches to reducing the quality gap or disparity in quality).**
- **Prevalence of condition among children under age 21 and/or among pregnant women.**
- **Severity of condition and burden of condition on children, family, and society (unrelated to cost).**
- **Fiscal burden of measure focus (e.g., clinical condition) on patients, families, public and private payers, or society more generally, currently and over the life span of the child.**
- **Association of measure topic with children's future health – for example, a measure addressing childhood obesity may have implications for the subsequent development of cardiovascular diseases.**
- **The extent to which the measure is applicable to changes across developmental stages (e.g., infancy, early childhood, middle childhood, adolescence, young adulthood).**

Antipsychotic medications offer the potential for effective treatment of psychiatric disorders in children; however, they also can increase a child's risk for developing serious health concerns, such as metabolic and physical health complications. Antipsychotic use is an important area of interest for measures development given the increased use of these medications in children and adolescents. This measure was developed as part of a set of measures to assess the use of antipsychotic medications in a general population of children, as well as those in the foster care system. This measure in particular assesses the proportion of children who are prescribed higher-than-recommended doses of antipsychotic medications.

Importance

Antipsychotic prescribing for children has increased rapidly in recent decades, driven both by new prescriptions as well as longer duration of use (Patten, Waheed, Breese, 2012). While some evidence supports the efficacy of antipsychotic use in youth for certain narrowly defined conditions, less is known about the safety and effectiveness of antipsychotic prescribing patterns in community use (e.g., combinations of medications, off-label prescribing, or dosing outside of recommended ranges).

Increasing Use of Antipsychotics, Particularly Costly Atypical Antipsychotics

The frequency of prescribing antipsychotics among youth increased almost five-fold from 1996 to 2002, from 8.6 per 1,000 children to 39.4 per 1,000 (Seida, Schouten, Boylan, et al., 2011). The increase in antipsychotic prescribing among youth is associated with the availability of atypical antipsychotic medications (or second-generation antipsychotics), which have different yet equally concerning side effect profiles from conventional antipsychotics (Olfson, Blanco, Liu, et al., 2006). Although the atypical antipsychotic agents are less likely than conventional antipsychotic agents to cause extrapyramidal side effects, a risk for disfiguring movement disorders remains, and atypical agents are more likely to cause metabolic disturbance including elevated blood glucose and cholesterol levels, weight gain, and diabetes. Atypical antipsychotics doubled their share of all psychotropic medication prescriptions among privately insured youth between 1997 and 2000, from 2.4 percent of all psychotropic prescriptions to 5.1 percent (Martin, Leslie, 2003). A national study of Medicaid-enrolled children found that prescribing of atypical antipsychotics increased 62 percent from 2002 to 2007 (Matone, Localio, Huang, et al., 2012). Atypical antipsychotics have the greatest mean prescription cost ($132) of any psychotropic medication (Martin, Leslie, 2003) and are the most costly drug class within the Medicaid program (Crystal, Olfson, Huang, 2009).

Analysis of the National Ambulatory Medical Care Survey found that predictors of antipsychotic use among youth included male sex, public insurance, and a diagnosis of psychosis, tic disorder, or pervasive development disorder or mental retardation (Olfson, et al., 2006). However, approximately half of the children receiving antipsychotics have attention deficit disorder or other conditions that do not have a first-line indication for antipsychotics.

Risks of Antipsychotics, Particularly for Subgroups

Children and adolescents prescribed antipsychotics are more at risk for serious health concerns, including weight gain, extrapyramidal side effects, hyperprolactinemia, and some metabolic

effects (Correll, Kratochvil, March, 2011). The field in general lacks high-quality research on outcomes and side effects associated with the use of higher-than-recommended doses of antipsychotics. Worrisome adverse effects of atypical antipsychotics have, however, been documented even at low doses, including excessive weight gain resulting in obesity, large increases in prolactin, and higher risk of extrapyramidal side effects including tardive dyskinesia. Studies of atypical antipsychotics in youth have demonstrated equal or worsening response when higher doses are compared to lower doses (Haas, Unis, Armenteros, et al., 2009; Schooler, Rabinowitz, Davidson, et al, 2005; Seida, et al., 2012). A review of 55 studies found no evidence that higher doses of antipsychotics were associated with better response (Davis, Chen, 2004). More recent systematic reviews of risperidone (Li, Xia, Wang, 2009) and quetiapine (Sparshatt, Jones, Taylor, 2008) doses for schizophrenia found that high doses were not associated with better outcomes but were associated with more adverse effects.

There is no research on the long-term effects of higher-than-recommended dosing of antipsychotics on children's health. However, the increased side effect burden of certain antipsychotic medications for youth, such as weight gain and metabolic disturbances, has implications for future physical health concerns including obesity and diabetes. Girls treated with certain antipsychotics may also be at increased risk for gynecological problems (Talib, Alderman, 2013) and osteoporosis (Cohen, Bonnot, Bodeau, et al., 2012. Research has demonstrated that the pharmacokinetics of antipsychotics may vary by developmental stage (Correll, et al., 2011). This suggests that higher-than-recommended dosing of antipsychotics may pose differing risks for children and adolescents compared to adults.

Opportunity for Improvement

Data on Frequency of Higher-than-Recommended Doses of Antipsychotics

As of March 1, 2012, 6.91 percent of youth under age 18 years in the New York State Medicaid behavioral health population (defined as at least one behavioral health service, diagnosis, or medication in the index year) on an antipsychotic were prescribed a higher-than-recommended dose.

There have been several approaches to improving the quality of psychotropic prescribing practices have been documented in the literature, including use of treatment algorithms (Moore, Buchanan, Buckley, et al., 2007), supervisory review of performance measures with individual psychiatrists (Patrick, Schleifer, Nurenberg, et al., 2006), and audit and feedback to hospital leadership on performance (Finnerty, Kealey, Leckman-westin, et al., 2011). Certain States have implemented prior authorization or second opinion programs to manage pharmacy benefits for Medicaid (Crystal et al., 2009), but the impact of these initiatives on the quality of prescribing is unclear (Constantine, Bengtson, Murphy, et al., 2012).

Health Disparities

Disparities Based on Race and Ethnicity

Overall, there is evidence to suggest that there may be racial disparities in antipsychotic medication practices for adults with schizophrenia, although these may not generalize to all ages or diagnoses (Busch, Lehman, Goldman, et al., 2009; Kuno, Rothbard, 2002; Rost, Hsieh, Xu, et

al., 2011). Studies of antipsychotic dosing in adults with schizophrenia have yielded mixed results, with some finding African Americans more likely to receive higher doses (e.g., dos Reis, Zito, Buchanan, et al., 2002; Walkup, McApine, Olfson, et al., 2000) and some showing no effect of race/ethnicity on dose (e.g. Busch, et al. 2009; Leslie, Rosenheck, 2001). There are no studies examining potential ethnic/racial disparities in higher-than-recommended dosing of antipsychotics in children and adolescents.

Disparities for Children in Foster Care

Over the last decade, the use of psychoactive medication among children and adolescents has increased, especially among those in foster care. A study of children placed into foster care in New York found that black children were more likely to be prescribed second-generation antipsychotics than children identified as Latino or other race (white and Asian) (Linares, Martinez-Martine, Castellanos, 2013). A study using data from the National Survey of Child and Adolescent Wellbeing (NSCAW II) found that use of psychotropic medication among children with a maltreatment report was significantly higher in rural areas compared to urban areas (Walsh, Mattingly, 2013).

3.B. Evidence for Importance of the Measure to Medicaid and/or CHIP

Comment on any specific features of this measure important to Medicaid and/or CHIP that are in addition to the evidence of importance described above, including the following:

- **The extent to which the measure is understood to be sensitive to changes in Medicaid or CHIP (e.g., policy changes, quality improvement strategies).**
- **Relevance to the Early and Periodic Screening, Diagnostic and Treatment benefit in Medicaid (EPSDT).**
- **Any other specific relevance to Medicaid/CHIP (please specify).**

A study of 16 State Medicaid programs found that the percentage of enrollees under age 19 on an antipsychotic varied greatly according to eligibility category, ranging from 0.6 percent for State Children's Health Insurance Program (CHIP) enrollees to 13.4 percent for those eligible under Aged, Blind and Disabled provisions; the rate for foster care youth was 12.4 percent. Among those on an antipsychotic, the proportion of youth on higher-than-recommended doses in 2007 in each reporting State ranged from 1.3 to 17.9 percent with an average across States of 8.9 percent (Medicaid Medical Directors Learning Network; Rutgers Center for Education and Research on Mental Health Therapeutics, 2010).

3.C. Relationship to Other Measures (if any)

Describe, if known, how this measure complements or improves on an existing measure in this topic area for the child or adult population, or if it is intended to fill a specific gap in an existing measure category or topic. For example, the proposed measure may enhance an existing measure in the initial core set, it may lower the age range for an existing adult-focused measure, or it may fill a gap in measurement (e.g., for asthma care quality, inpatient care measures).

Not applicable.

Section 4. Measure Categories

CHIPRA legislation requires that measures in the initial and improved core set, taken together, cover all settings, services, and topics of health care relevant to children. Moreover, the legislation requires the core set to address the needs of children across all ages, including services to promote healthy birth. Regardless of the eventual use of the measure, we are interested in knowing all settings, services, measure topics, and populations that this measure addresses. These categories are not exclusive of one another, so please indicate "Yes" to all that apply.

Does the measure address this category?

a. **Care Setting – ambulatory:** Yes.
b. **Care Setting – inpatient:** No.
c. **Care Setting – other – please specify:** No.
d. **Service – preventive health, including services to promote healthy birth:** No.
e. **Service – care for acute conditions:** No.
f. **Service – care for children with acute conditions:** Yes.
g. **Service – other (please specify):** No.
h. **Measure Topic – duration of enrollment:** No.
i. **Measure Topic – clinical quality:** No.
j. **Measure Topic – patient safety:** Yes.
k. **Measure Topic – family experience with care:** Yes.
l. **Measure Topic – care in the most integrated setting:** No.
m. **Measure Topic other (please specify):** No.
n. **Population – pregnant women:** No.
o. **Population – neonates (28 days after birth) (specify age range):** No.
p. **Population – infants (29 days to 1 year) (specify age range):** No.
q. **Population – pre-school age children (1 year through 5 years) (specify age range):** Yes; 1-5 years.
r. **Population – school-aged children (6 years through 10 years) (specify age range):** Yes; 6-11 years.
s. **Population – adolescents (11 years through 20 years) (specify age range):** Yes; 12-17 years.
t. **Population – other (specify age range):** No.
u. **Other category (please specify):** Not applicable.

Section 5. Evidence or Other Justification for the Focus of the Measure

The evidence base for the focus of the measures will be made explicit and transparent as part of the public release of CHIPRA deliberations; thus, it is critical for submitters to

specify the scientific evidence or other basis for the focus of the measure in the following sections.

5.A. Research Evidence

Research evidence should include a brief description of the evidence base for valid relationship(s) among the structure, process, and/or outcome of health care that is the focus of the measure. For example, evidence exists for the relationship between immunizing a child or adolescent (process of care) and improved outcomes for the child and the public. If sufficient evidence existed for the use of immunization registries in practice or at the State level and the provision of immunizations to children and adolescents, such evidence would support the focus of a measure on immunization registries (a structural measure).

Describe the nature of the evidence, including study design, and provide relevant citations for statements made. Evidence may include rigorous systematic reviews of research literature and high-quality research studies.

Most guidelines that address dosing of antipsychotics endorse the use of the lowest effective dose. American Academy of Child and Adolescent Psychiatry (AACAP) Practice Parameters for the Use of Atypical Antipsychotic Medications in Children and Adolescents recommend that "dosing of AAAs [atypical antipsychotic agents] should follow the 'start low and go slow' approach and seek to find the lowest effective dose." The AACAP Practice Parameter for the Assessment and Treatment of Children and Adolescents with Schizophrenia calls for "adequate dosages" of antipsychotic medications and states that "instituting large dosages during the early part of treatment generally does not hasten recovery … the medication dosage should be periodically reassessed to ensure that the lowest effective dose is being used." The Texas Psychotropic Medication Utilization Parameters for Foster Children notes "psychotropic medication dose exceeds usual recommended doses" as a situation that "suggests the need for additional review of a patient's clinical status" and specifies recommended doses. See Appendix 1 in the Supporting Documents for Clinical Guideline Tables.

5.B. Clinical or Other Rationale Supporting the Focus of the Measure (optional)

Provide documentation of the clinical or other rationale for the focus of this measure, including citations as appropriate and available.

The proposed measure identifies children and adolescents ages 1 to 17 years who received higher-than- recommended doses of antipsychotic medications, which is a safety concern. Risks associated with antipsychotic medications in children include delirium, serious behavioral changes, cardiac arrhythmias, and death. These risks are in addition to side effects such as metabolic disturbance, which may have a serious impact on children and adolescents who are still developing. This measure is intended for use by States and plans to target potentially inappropriate prescribing practices.

Section 6. Scientific Soundness of the Measure

Explain the methods used to determine the scientific soundness of the measure itself. Include results of all tests of validity and reliability, including description(s) of the study sample(s) and methods used to arrive at the results. Note how characteristics of other data systems, data sources, or eligible populations may affect reliability and validity.

6.A. Reliability

Reliability of the measure is the extent to which the measure results are reproducible when conditions remain the same. The method for establishing the reliability of a measure will depend on the type of measure, data source, and other factors.

Explain your rationale for selecting the methods you have chosen, show how you used the methods chosen, and provide information on the results (e.g., the Kappa statistic). Provide appropriate citations to justify methods.

Our results showed that this measure had high State-level reliability; the average State-level reliability was 0.98 (range 0.85 to 0.99). Plan-level reliability was lower, with an average of 0.87 (range 0.51 to 0.96). Higher reliability at the State level is due in part to the larger denominator sizes. See Testing Summary (Appendix 1 in the Supporting Documents) for full reliability findings.

6.B. Validity

Validity of the measure is the extent to which the measure meaningfully represents the concept being evaluated. The method for establishing the validity of a measure will depend on the type of measure, data source, and other factors.

Explain your rationale for selecting the methods you have chosen, show how you used the methods chosen, and provide information on the results (e.g., R2 for concurrent validity).

Face validity refers to whether the measure plausibly represents the concept being evaluated in the judgment of likely users of the measure. To assess different perspectives on the measure's validity, the National Collaborative for Innovation in Quality Measurement (NCINQ) reviewed the specifications and field test results with our NCINQ advisory panels and other stakeholders. NCINQ's stakeholders include patients and families, clinicians, and State Medicaid officials, as well as experts in the field of child health, foster care and measure development (i.e., individuals well positioned to speak to this measure's face validity). This process ensures measures are reasonable and important to those using them. Our advisory panels concluded this measure is a valid way to assess whether higher-than-recommended doses of antipsychotics were prescribed for children and adolescents. Stakeholder reviews of the specifications and field test results indicate the measure has face validity.

For construct validity, we examined the relationship between performance on this measure and the other two overuse measures in the Safe and Judicious Use of Antipsychotics in Children and Adolescents set: (1) Use of Multiple Concurrent Antipsychotics in Children and (2) Use of Antipsychotic Medications in Very Young Children. We anticipated that entities that have better

management of antipsychotic dosing (i.e., lower rates of higher-than-recommended doses) would also have better management of antipsychotic medication in general (i.e., lower rates of multiple concurrent antipsychotic use and less use among very young children). We found weak positive correlations (0.10 and 0.19) between the measures within the general population of children and moderate positive correlations (0.30 and 0.46) within the foster care population. This finding may be due to the homogeneity across States for foster care populations and the heterogeneity across States for the general Medicaid population. However, results were not significant. We also examined correlation with the medication management (higher-is-better) measures and found a moderate negative correlation (-0.56) between the Higher-than-Recommended Doses measure and the Metabolic Screening measure.

In rankings analysis, we found that plans and States can be approximately ranked based on profiles of performance across multiple measures. The consistency of performance across measures suggests the measures are assessing a dimension of quality.

See the Testing Summary (Appendix 1 in the Supporting Documents) for full validity findings.

Section 7. Identification of Disparities

CHIPRA requires that quality measures be able to identify disparities by race, ethnicity, socioeconomic status, and special health care needs. Thus, we strongly encourage nominators to have tested measures in diverse populations. Such testing provides evidence for assessing measure's performance for disparities identification. In the sections below, describe the results of efforts to demonstrate the capacity of this measure to produce results that can be stratified by the characteristics noted and retain the scientific soundness (reliability and validity) within and across the relevant subgroups.

7.A. Race/Ethnicity

Using the MAX data files, NCINQ was able to collect race and ethnicity data using these categories: white non-Hispanic, black non-Hispanic, Hispanic, and other race/ethnicity.

For both the general population and children in foster care, black non-Hispanic children had worse (i.e., higher) rates of higher-than-recommended doses of antipsychotics compared to white non-Hispanic and Hispanic children. Hispanic children had the lowest (i.e., better) overall rates for both populations. These findings are consistent with some studies (Table 3 in Appendix 1; see Supporting Documents).

7.B. Special Health Care Needs

NCINQ explored the relationship between the general population of children and children in the foster care system, defined as children who had spent any period of time in the foster care system. As expected, we saw a higher (i.e., worse) average rate of children on higher-than-recommended doses of antipsychotic medications among the foster care population compared with the general population of children (Table 4 in Appendix 1; see Supporting Documents).

7.C. Socioeconomic Status

We used Medicaid data only and were unable to assess socioeconomic status information.

7.D. Rurality/Urbanicity

We assessed rurality/urbanicity using 2003 Rural-Urban Continuum Codes from the Area Resource File, which provides a wide range of county-level data collected from a number of sources (United States Department of Agriculture [USDA], 2013). We merged these codes with the MAX data. Metropolitan is defined as counties in metropolitan areas. Non-Metropolitan is defined as urban populations of at least 2,500 population, adjacent or not adjacent to a metro area; and Rural is defined as completely rural or less than 2,500 urban population, either adjacent or not adjacent to a metro area.

For the general population of children, rates of higher-than-recommended doses of antipsychotic medications were higher (i.e., worse) in metropolitan areas (8.4 percent). In the foster care population, rates were worse in rural areas (12.9 percent). These findings are broadly consistent with research showing higher use of psychotropic medication among rural youth (Table 5 in Appendix 1; see Supporting Documents).

7.E. Limited English Proficiency (LEP) Populations

We were unable to assess information on limited English proficiency.

Section 8. Feasibility

Feasibility is the extent to which the data required for the measure are readily available, retrievable without undue burden, and can be implemented for performance measurement. Using the following sections, explain the methods used to determine the feasibility of implementing the measure.

8.A. Data Availability

1. What is the availability of data in existing data systems? How readily are the data available?

As specified, all data needed to calculate the Use of Higher-than-Recommended Doses of Antipsychotics in Children and Adolescents measure are present in administrative claims data.

2. If data are not available in existing data systems or would be better collected from future data systems, what is the potential for modifying current data systems or creating new data systems to enhance the feasibility of the measure and facilitate implementation?

Although this measure has been developed and tested for claims data, it is likely highly feasible to implement it in an electronic health record (EHR) or e-prescribing program. The value of this approach would be to increase opportunities for interventions at the point of service through decision support.

8.B. Lessons from Use of the Measure

1. Describe the extent to which the measure has been used or is in use, including the types of settings in which it has been used, and purposes for which it has been used.

A similar measure is used by New York State and is implemented in a Web-based application to support clinical decision-making and quality improvement. Several multi-State quality collaboratives have used a related measure, and a number of States have incorporated these measures into their pharmacy oversight systems.

2. If the measure has been used or is in use, what methods, if any, have already been used to collect data for this measure?

Not applicable.

3. What lessons are available from the current or prior use of the measure?

Not applicable.

Section 9. Levels of Aggregation

CHIPRA states that data used in quality measures must be collected and reported in a standard format that permits comparison (at minimum) at State, health plan, and provider levels. Use the following table to provide information about this measure's use for reporting at the levels of aggregation in the table.

For the purpose of this section, please refer to the definitions for provider, practice site, medical group, and network in the Glossary of Terms.

If there is no information about whether the measure could be meaningfully reported at a specific level of aggregation, please write "Not available" in the text field before progressing to the next section.

Level of aggregation (Unit) for reporting on the quality of care for children covered by Medicaid/ CHIP†:

State level* Can compare States

Intended use: **Is measure intended to support meaningful comparisons at this level? (Yes/No)**
Yes.

Data Sources: **Are data sources available to support reporting at this level?**
Yes.

Sample Size: **What is the typical sample size available for each unit at this level? What proportion of units at this level of aggregation can achieve an acceptable minimum sample size?**

871 individuals.

In Use: **Have measure results been reported at this level previously?**
No.

Reliability & Validity: **Is there published evidence about the reliability and validity of the measure when reported at this level of aggregation?**
No.

Unintended consequences: **What are the potential unintended consequences of reporting at this level of aggregation?**
None.

Other geographic level: Can compare other geographic regions (e.g., MSA, HRR)

Intended use: **Is measure intended to support meaningful comparisons at this level? (Yes/No)**
Yes.

Data Sources: **Are data sources available to support reporting at this level?**
Yes.

Sample Size: **What is the typical sample size available for each unit at this level? What proportion of units at this level of aggregation can achieve an acceptable minimum sample size?**
Did not calculate.

In Use: **Have measure results been reported at this level previously?**
No.

Reliability & Validity: **Is there published evidence about the reliability and validity of the measure when reported at this level of aggregation?**
No.

Unintended consequences: **What are the potential unintended consequences of reporting at this level of aggregation?**
None.

Medicaid or CHIP Payment model: Can compare payment models (e.g., managed care, primary care case management, FFS, and other models)

Intended use: **Is measure intended to support meaningful comparisons at this level? (Yes/No)**
Yes.

Data Sources: **Are data sources available to support reporting at this level?**
Yes.

Sample Size: **What is the typical sample size available for each unit at this level? What proportion of units at this level of aggregation can achieve an acceptable minimum sample size?**
Did not calculate

In Use: **Have measure results been reported at this level previously?**
No.

Reliability & Validity: **Is there published evidence about the reliability and validity of the measure when reported at this level of aggregation?**
No.

Unintended consequences: **What are the potential unintended consequences of reporting at this level of aggregation?**
None.

Health plan*: Can compare quality of care among health plans.

Intended use: **Is measure intended to support meaningful comparisons at this level? (Yes/No)**
Yes.

Data Sources: **Are data sources available to support reporting at this level?**
Yes.

Sample Size: **What is the typical sample size available for each unit at this level? What proportion of units at this level of aggregation can achieve an acceptable minimum sample size?**
613 individuals.

In Use: **Have measure results been reported at this level previously?**
No.

Reliability & Validity: **Is there published evidence about the reliability and validity of the measure when reported at this level of aggregation?**
No.

Unintended consequences: **What are the potential unintended consequences of reporting at this level of aggregation?**
Selection bias to plans.

Provider Level
Individual practitioner: Can compare individual health care professionals

Intended use: **Is measure intended to support meaningful comparisons at this level? (Yes/No)**
No.

Data Sources: **Are data sources available to support reporting at this level?**
No.

Sample Size: **What is the typical sample size available for each unit at this level? What proportion of units at this level of aggregation can achieve an acceptable minimum sample size?**
Not applicable.

In Use: **Have measure results been reported at this level previously?**
No.

Reliability & Validity: **Is there published evidence about the reliability and validity of the measure when reported at this level of aggregation?**
No.

Unintended consequences: **What are the potential unintended consequences of reporting at this level of aggregation?**
Not applicable.

Provider Level
Hospital: Can compare hospitals

Intended use: **Is measure intended to support meaningful comparisons at this level? (Yes/No)**
No.

Data Sources: **Are data sources available to support reporting at this level?**
No.

Sample Size: **What is the typical sample size available for each unit at this level? What proportion of units at this level of aggregation can achieve an acceptable minimum sample size?**
Not applicable.

In Use: **Have measure results been reported at this level previously?**
No.

Reliability & Validity: **Is there published evidence about the reliability and validity of the measure when reported at this level of aggregation?**
No.

Unintended consequences: **What are the potential unintended consequences of reporting at this level of aggregation?**
Not applicable.

Provider Level

Practice, group, or facility:** Can compare: (i) practice sites; (ii) medical or other professional groups; or (iii) integrated or other delivery networks

Intended use: **Is measure intended to support meaningful comparisons at this level? (Yes/No)**
No.

Data Sources: **Are data sources available to support reporting at this level?**
No.

Sample Size: **What is the typical sample size available for each unit at this level? What proportion of units at this level of aggregation can achieve an acceptable minimum sample size?**
Not applicable.

In Use: **Have measure results been reported at this level previously?**
No.

Reliability & Validity: **Is there published evidence about the reliability and validity of the measure when reported at this level of aggregation?**
No.

Unintended consequences: **What are the potential unintended consequences of reporting at this level of aggregation?**
Not applicable.

Section 10. Understandability

CHIPRA states that the core set should allow purchasers, families, and health care providers to understand the quality of care for children. Please describe the usefulness of this measure toward achieving this goal. Describe efforts to assess the understandability of this measure (e.g., focus group testing with stakeholders).

NCINQ specifically sought to assess the understandability of the measure from a wide range of stakeholders, including purchasers, families and providers. We convened an overall, multi-stakeholder advisory panel to assess all measures developed by our Center. This panel included representation from consumers, pediatricians, family physicians, adolescent medicine physicians, health plans, State Medicaid agencies, and researchers. In addition to our multi-stakeholder panel, we convened the following targeted panels:

- State advisory panel.
- Consumer advisory panel.
- Mental health technical subgroup.

We also convened two panels with particular relevance to antipsychotic measures: (1) a Foster Care Panel with representatives from State child welfare and behavioral health services, Medicaid officials, the Administration on Children, Youth and Families, and foster care alumni and (2) the Center for Health Care Strategies Improving the Use of Psychotropic Medications Among Children in Foster Care (PMQIC) Workgroup, a six-State collaborative working with cross-agency teams to improve issues around the use of psychotropic medications among youth. Input from these groups, in particular our targeted panels, were instrumental in ensuring these measures addressed needs of children in Medicaid and the foster care system. Throughout the measure development process, we presented the measures to these panels and solicited feedback on importance, understandability, and usability.

In addition, we posted the measure for public comment to obtain feedback from an even wider audience of stakeholders. In addition to our usual questions around importance of the topic, usability, and feasibility of implementation, we specifically sought feedback on the appropriateness of our continuous eligibility definitions, how we defined antipsychotic "use," and appropriateness of the specifications for foster care populations. The majority of comments received for the Use of Higher-than-Recommended Doses of Antipsychotics in Children and Adolescents either supported the measure as specified or supported with suggested modifications (28 of the 32 total measure comments).

This measure was prioritized as an important measure, both through public comment and by NCINQ advisory panels. Stakeholders noted the measure topic is of particular importance for the child and adolescent population. Final measure specifications were informed by commenters' and advisory panel feedback. Stakeholders expressed that the measure as specified is an understandable and sensible approach to assessing the use of high doses of antipsychotic medications for children and adolescents.

Section 11. Health Information Technology

Please respond to the following questions in terms of any health information technology (health IT) that has been or could be incorporated into the measure calculation.

11.A. Health IT Enhancement

Please describe how health IT may enhance the use of this measure.

This measure has been specified and tested in administrative claims data only. The measure could benefit from incorporation in health IT because it would allow determining whether the dose exceeds recommended levels for medications that base dose levels on weight (rather than age). Also, this measure could be incorporated into clinical decision support tools with alerts to clinicians where doses exceed recommendations.

11.B. Health IT Testing

Has the measure been tested as part of an electronic health record (EHR) or other health IT system?

No.

If so, in what health IT system was it tested and what were the results of testing?

A similar measure has been implemented in a Web-based application designed to improve clinical decision-making and quality improvement. The Psychiatric Services and Clinical Knowledge Enhancement System (PSYCKES) has been implemented in over 400 sites in New York State and is used as a tool to support quality improvement efforts.

11.C. Health IT Workflow

Please describe how the information needed to calculate the measure may be captured as part of routine clinical or administrative workflow.

As currently specified, measure elements are derived from claims/encounter data, and necessary data elements are generated when a prescription is filled at a pharmacy. For an EHR or e-prescribing-based measure, data elements are generated automatically when a prescription is written; no change in clinician workflow would be required. E-prescribing platforms can be designed to feed databases that can be used for performance reporting, but they also can be used to provide decision support to the prescriber.

11.D. Health IT Standards

Are the data elements in this measure supported explicitly by the Office of the National Coordinator for Health IT Standards and Certification criteria (see healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov__standards_ifr/1195)?

Yes.

If yes, please describe.

Both Stage 2 of Meaningful Use and the 2014 edition of ONC Certification of EHR Technology require the electronic capture of patient demographics and medication order/prescription data in ambulatory settings that are necessary to calculate this measure.

11.E. Health IT Calculation

Please assess the likelihood that missing or ambiguous information will lead to calculation errors.

Dose recommendations for some antipsychotics are based on weight, and if this field was missing or outdated in the EHR, it would create an error in the recommended dose for that youth. To mitigate this challenge, specification could place a time limit on the most recent weight (e.g., past 6 months), and if that was missing, default to a proxy for weight by age. In contrast to claims-based measures which are generally centralized at the State level, a second challenge for the EHR-based measure is prescribing that occurs outside of the provider's network for data sharing. A patient could have received prescriptions from different prescribers. As States move to expand regional health information networks and develop all-payer databases, provider-generated data will be increasingly complete.

11.F. Health IT Other Functions

If the measure is implemented in an EHR or other health IT system, how might implementation of other health IT functions (e.g., computerized decision support systems in an EHR) enhance performance characteristics on the measure?

Implementing this measure within an EHR or e-prescribing system could create opportunities for real-time, point-of-service clinical decision support and interventions to improve measure performance.

Section 12. Limitations of the Measure

Describe any limitations of the measure related to the attributes included in this CPCF (i.e., availability of measure specifications, importance of the measure, evidence for the focus of the measure, scientific soundness of the measure, identification of disparities, feasibility, levels of aggregation, understandability, health information technology).

Our measures development process, including feedback from advisory panels, public comment and field testing, helps us to identify potential limitations of proposed measures. For the Use of Higher-than-Recommended Doses of Antipsychotics in Children and Adolescents measure, some concerns were raised about the burden of maintaining and updating the measure tables when new medications are released or when existing medications obtain new Food and Drug Administration (FDA) dosing indications. However, measures that specify a list of medications that must be regularly updated do exist. Another concern was raised about using age as a proxy for weight when determining dosages. Although dose recommendations commonly are based on age, in the case of some antipsychotics, such as haloperidol, the dose recommendation is based on weight. Finally, FDA dose recommendations for youth only exist for nine antipsychotics, and other sources had to be used for recommendations. Despite these considerations, this measure was deemed a high-priority measure, both through public comment and by NCINQ advisory panels. On balance, our advisory panels concluded the benefits of such a measure outweigh the concerns.

Section 13. Summary Statement

Provide a summary rationale for why the measure should be selected for use, taking into account a balance among desirable attributes and limitations of the measure. Highlight specific advantages that this measure has over alternative measures on the same topic that were considered by the measure developer or specific advantages that this measure has over existing measures. If there is any information about this measure that is important for the review process but has not been addressed above, include it here.

The Use of Higher-than-Recommended Doses of Antipsychotics in Children and Adolescents measure addresses an important health concern, particularly among Medicaid and foster care youth. While high-quality research is limited around the outcomes and side effects associated with the use of higher-than-recommended doses in these populations, adverse effects of atypical antipsychotics have been documented even at low doses, including excessive weight gain

resulting in obesity, large increases in prolactin, and higher risk of extrapyramidal side effects such as tardive dyskinesia. Studies of atypical antipsychotics in children and adolescents have demonstrated equal or worsening response when higher doses are compared to lower doses. Testing showed that, among States, the average percentage of children prescribed at least two higher-than-recommended doses of an antipsychotic was 7.9 percent among the general population and 9.2 percent among children in foster care (a lower rate represents better performance). Among Medicaid plans, the average performance rate was 5.7 percent. We found that the measure is reliable at both the State and health plan levels. Stakeholder input indicated the measure has face validity.

The wide array of stakeholders who provided input for this measure, both through our development process and public comment, included State Medicaid and child welfare officials, as well as clinicians, consumers, and foster care alumni. Our stakeholders concluded the measure is feasible and a high priority for these populations, and they recommended its finalization and consideration for use in quality improvement and accountability programs.

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Section 14: Identifying Information for the Measure Submitter

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The CHIPRA Pediatric Quality Measures Program (PQMP) Candidate Measure Submission Form (CPCF) was approved by the Office of Management and Budget (OMB) in accordance with the Paperwork Reduction Act.

The OMB Control Number is 0935-0205 and the Expiration Date is December 31, 2015.

Public Disclosure Requirements

Each submission must include a written statement agreeing that, should U.S. Department of Health and Human Services accept the measure for the 2014 and/or 2015 Improved Core Measure Sets, full measure specifications for the accepted measure will be subject to public disclosure (e.g., on the Agency for Healthcare Research and Quality [AHRQ] and/or Centers for Medicare & Medicaid Services [CMS] websites), except that potential measure users will not be permitted to use the measure for commercial use. In addition, AHRQ expects that measures and full measure specifications will be made reasonably available to all interested parties. "Full measure specifications" is defined as all information that any potential measure implementer will need to use and analyze the measure, including use and analysis within an electronic health record or other health information technology. As used herein, "commercial use" refers to any sale, license or distribution of a measure for commercial gain, or incorporation of a measure into any product or service that is sold, licensed or distributed for commercial gain, even if there is no actual charge for inclusion of the measure. This statement must be signed by an individual authorized to act for any holder of copyright on each submitted measure or instrument. The authority of the signatory to provide such authorization should be described in the letter.

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