Use of Antipsychotics in Very Young Children

Section 1. Basic Measure Information

1.A. Measure Name

Use of Antipsychotics in Very Young Children

1.B. Measure Number

0178

1.C. Measure Description

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

The percentage of children 1-5 years of age who are on one or more antipsychotic medications during the measurement year.

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

Any antipsychotic medication use during the measurement year.

1.H. Numerator Exclusions

None.

1.I. Denominator Statement

- Children ages 1-5 years during the measurement year.
- Age stratification: less than 2 years; 2-3 years; 4-5 years.
- Continuous eligibility: at least 1 month.
- 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.

Please see Supporting Documents for detailed 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 can also 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 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 children in the foster care system. This measure in particular assesses the proportion of very young children (under age 6) who are prescribed antipsychotic medication.

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, Bresse, 2012). While some evidence supports the efficacy of antipsychotics 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), particularly for children under age 6.

Increasing Use of Antipsychotics, Particularly Costly Atypical Antipsychotics

The frequency of prescribing antipsychotics among youth in general 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, et al., 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 hyperactivity disorder or other conditions that do not have a first-line indication for antipsychotics.

Risks of Antipsychotics for Very Young Children

The Preschool Psychopharmacology Working Group noted that, although there is no systematic evaluation of the impact of early exposure to psychotropic medications, neurological research highlights the importance of central nervous system development in very young children (Gleason, Egger, Emslie, et al., 2007).

Both the efficacy and side effects of antipsychotic medications may vary according to age, with very young children who are prescribed antipsychotics being more at risk for serious health

concerns, including weight gain and hyperprolactinemia (Bartelink, Rademaker, Schobben, et al., 2006; Correll, Kratochvil, March, 2011; Luby, Mrakotsky, Stalets, et al., 2006). Appropriate doses of medications may also be more difficult to determine for young children due to developmental changes in metabolism and other biological functions (Bartelink, et al., 2006; Correll, et al., 2011).

There is no research on the long-term effects of antipsychotic use among very young children. However, the increased side effect burden of certain antipsychotic medications for children, 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 demonstrating that the pharmacokinetics of antipsychotics may vary by developmental stage (Correll, et al., 2011) suggests that use of antipsychotics among young children may pose differing risks compared to older children.

Opportunity for Improvement

Data on Frequency of Antipsychotic Use in Very Young Children

Rates of prescription of psychotropic medications to preschool children have risen for both Medicaid and privately insured groups in recent decades. The rate of antipsychotic use in privately insured children ages 2 to 5 years more than doubled from 1999 to 2007 (Olfson, Marcus, 2010) and use of antipsychotics among Medicaid-enrolled children ages 2 to 4 years in one State increased from 0.1 percent in 1997 to 0.5 percent in 2006 (Zito, Burcu, Ibe, et al., 2013). Zito and colleagues also found that the rate of increase for antipsychotic use among children ages 2 to 4 years was similar to that of children ages 10 to 17 years (Zito, et al., 2013). Earlier research on children ages 2 to 4 years insured through Medicaid found that 17 percent of those on any psychotropic medication were on an antipsychotic, with 96 percent of those on an atypical antipsychotic (Zito, Safer, Valluri, et al., 2007). A study of 16 State Medicaid programs found that the proportion of children under the age of 6 prescribed an antipsychotic ranged from 0.02 to 0.67 percent (MMDLN/Rutgers CERTs, 2010).

A study of national Medicaid data found that 14 percent of children 5 years and younger with a diagnosis of autism were prescribed neuroleptic medication, most likely due to risperidone's FDA indication for treatment of irritability in autism (Mandell, Morales, Marcus, et al., 2008). Medicaid-enrolled children younger than 6 years who were started on an antipsychotic medication were, on average, exposed to antipsychotics for over half of the days in the following 4-year period after first starting the antipsychotic (Constantine, Bengtson, Murphy, et al., 2012). The study by Olfson and Marcus (2010) also found that fewer than half of very young children on an antipsychotic received specialty mental health services. Although the prevalence of this quality concern is low in absolute terms, the rapid increase over time, pattern of long-term use, and risks of adverse events are of concern.

Options for Improving Care

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 (Finnerty, Kealey, Leckman-Westin, et al., 2011). Florida's preauthorization program for use of antipsychotics in youth younger than age 6 yielded an overall decline in requests, but applications from child psychiatrists fell compared to other prescribers (Constantine, Jentz, 2012).

Health Disparities

Disparities based on race/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). Some studies have found that Latino and African-American children are less likely to be prescribed psychotropic medication than white children (e.g., Leslie, Weckerly, Landsverk, et al., 2003; Zito, Safer, dosReis, et al., 1998). No data specific to disparities based on race and ethnicity in antipsychotic prescribing for very young children were identified.

Disparities for children in foster care

Although data are lacking on antipsychotic medication use in very young foster care children, in general the use of antipsychotics in foster care has increased rapidly. For example, a study of Medicaid-insured children in one State found that antipsychotic use among children in foster care increased from 4.4 percent in 1997 to 16.4 percent in 2006 (Zito, et al., 2013). In a sample of foster care Medicaid children in another state, 53.2 percent of those on any psychotropic medication were prescribed an antipsychotic medication (Zito, Safer, Sai, et al., 2008).

Another study of children placed into foster care in New York State 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 older than age 4 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 according to eligibility category, ranging from 0.6 percent for 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 (Medicaid Medical Directors Learning Network and Rutgers Center for Education and Research on Mental Health Therapeutics [MMDLN-Rutgers CERTs], 2010). This study also showed the percentage of children under the age of 6 prescribed an antipsychotic ranged from 0.02 to 0.67. A study of preschoolers insured through Medicaid found that 17 percent of those on any psychotropic medication were on an antipsychotic, with 96 percent of those on an atypical antipsychotic (Zito, et al., 2007). A study of national Medicaid data found that 14 percent of children aged 5 years and younger with a diagnosis of autism were prescribed neuroleptic medication, most likely due to risperidone's FDA indication for treatment of irritability in autism (Mandell, et al., 2008).

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).

During development of this measure, the Pharmacy Quality Alliance (2018) developed a similar measure, Antipsychotic Use in Children under Five Years Old, that assesses use of antipsychotics in children younger than age 5. The developers note that the 5-year age cut-off was chosen based on one risperidone indication for irritability from autism in age 5 and older and because none of the antipsychotics have any FDA-approved indications for children under age 5.

The measure includes 5-year olds based on expert feedback that any use for age 5 and under should be flagged as potentially problematic.

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 special health care needs/chronic 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; ages 1-5 years.
r. **Population – school-aged children (6 years through 10 years) (specify age range):** No.
s. **Population – adolescents (11 years through 20 years) (specify age range):** No.
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.

The Preschool Psychopharmacology Working Group identifies certain antipsychotics as appropriate psychopharmacological interventions for specific disorders, including disruptive behaviors, bipolar disorder, and pervasive developmental disorders (Gleason, et al., 2007). However, the group stated that psychopharmacological intervention for behavior problems without psychotherapy is not recommended in this younger age group. The Texas Psychotropic Medication Utilization Parameters for Foster Children includes use of antipsychotics among children younger than 4 years of age" as a situation that "suggests the need for additional review

of a patient's clinical status" (see Appendix 1 for Guidelines Table in the Supporting Documents).

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.

This measure identifies very young children (5 years and younger) who are on antipsychotic medications. These children are at risk of problems related to the early use of antipsychotic medications, including excessive weight gain and hyperprolactinemia. The measure is intended for use by States and plans to target potentially inappropriate prescribing practices in a vulnerable age group of children.

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 reliability at the State level, with an average reliability of 0.99. This high reliability statistic is due in part to the large denominator sizes for this measure. Details are presented in the Testing Summary (see Supporting Documents).

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, we reviewed the specifications and field test results with our advisory panels and other

stakeholders. Our 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 the use of antipsychotic medications in very young children. Stakeholder reviews of the specifications and field test results indicate the measure has face validity.

We assessed the correlation between the three antipsychotic appropriateness/overuse measures in the set: Use of Multiple Concurrent Antipsychotics in Children, Use of Antipsychotics in Very Young Children, and Children on Higher than Recommended Doses of Antipsychotics. We found weak positive correlations (0.10 and 0.19) between the measures within the general population of children and moderate correlation (0.30 and 0.46) within the foster care population. Details are presented in the Testing Summary (see Supporting Documents).

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

Very limited data are available around the effectiveness, safety, and appropriate dosing of antipsychotics in very young children. Two consensus-based recommendations are available. Using the MAX data files, we were able to collect race and ethnicity data using these categories: white non-Hispanic, black non-Hispanic, Hispanic, and other.

In both the general and foster care population of children, antipsychotic medication use among the very young was higher (i.e., worse) among white non-Hispanic children compared to other racial/ethnic groups. This finding is consistent with literature that has suggested that white children are more likely to receive the broader category of psychotropic medications. Full results are presented in Table 1 in Appendix 1 (see Supporting Documents).

7.B. Special Health Care Needs

We 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 based on the literature, we saw a higher rate of antipsychotic medication use in very young children in foster care compared with the general population of children (full results are presented in Table 2 in Appendix 1 (see Supporting Documents).

7.C. Socioeconomic Status

We used Medicaid data only; thus, we were unable to assess socioeconomic status.

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. We merged these codes with the MAX data. Metropolitan is defined as counties in metro areas. Non-Metropolitan is defined as urban with populations of at least 2,500, adjacent or not adjacent to a metro area. Rural is defined as completely rural or less than 2,500 population, either adjacent or not adjacent to a metro area.

For both the general and foster care populations, higher (i.e., worse) rates of antipsychotic use among very young children were seen in rural areas (0.30 and 2.61 percent, respectively) with lowest rates seen in metropolitan areas (0.11 and 1.15 percent, respectively). This finding is consistent with the literature, which has shown that rural children are more likely to receive the broader category of psychotropic medications (see the Supporting Documents for Table 3 in Appendix 1).

7.E. Limited English Proficiency (LEP) Populations

We were unable to assess LEP.

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?

All data needed to calculate the Use of Antipsychotics in Very Young Children measure are available 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 medical record 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 claims- and encounter-based measure was implemented by New York State in a Web-based application to support clinical decision making and quality improvement, the Psychiatric Services and Clinical Knowledge Enhancement System (PSYCKES). 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?**
822.

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?**
A small number of events may affect reliability.

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?**
A small number of events may affect reliability.

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?**
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?**
A small number of events may affect reliability.

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

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
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).

We convened multi-stakeholder advisory panels with representation from a wide range of stakeholders, including consumers, pediatricians, family physicians, adolescent medicine physicians, health plans, State Medicaid agencies, and researchers. We also convened two targeted panels of stakeholders with particular relevance to antipsychotics 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 use of psychotropic medications among youth. Input from these groups, in particular our targeted panels, were instrumental in ensuring these

measures address the needs of children in Medicaid and the foster care system who may be exposed to antipsychotic medications. Throughout the measure development process, we presented the measures to these panels and solicited feedback on importance, understandability, and usability.

We also posted the measures 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 this measure, Use of Antipsychotics in Very Young Children, were supportive (all but one of the 25 comments received either supported the measure as specified or supported it with suggested modifications), and the measure was identified as a priority by our advisory panels. Stakeholders noted the measure topic is of particular importance for the child population. Commenters provided feedback on the appropriate age range and continuous eligibility definition, which informed our final specifications. There were concerns about small numerator events. Thus, stakeholders recommended the measure be used for quality improvement and decision support rather than accountability. Thus, we recommend the measure for quality improvement efforts at the State level.

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.

Not applicable.

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 was used in the Psychiatric Services and Clinical Knowledge Enhancement Systems (PSYCKES), a Web-based application used in more than 400 sites in New York State 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 electronic health record (EHR) or e-prescribing-based high dose 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 and also 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 (ONC) 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.

Calculation errors are unlikely.

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 the opportunity for real-time, point-of-service clinical decision support that could flag potentially inappropriate prescribing in this age group.

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. The extremely low rate of use of antipsychotic medications in very young children makes reliable comparisons

difficult. Thus, we propose this measure for quality improvement and decision support rather than for accountability and public reporting.

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 Antipsychotics in Very Young Children measure addresses an important health concern, particularly among Medicaid and foster care youth. Little is currently known about the effectiveness, safety, and appropriate dosing of antipsychotics in very young children. Although the prevalence is low, the rate of prescribing antipsychotics in this population has doubled in recent years. In general, there are a number of serious health concerns associated with the use of antipsychotic medications in youths, especially among very young children, including weight gain, hyperprolactinemia, and other metabolic disturbances, which could also have implications for a child's future physical health, leading to obesity and diabetes.

Based on 2008 MAX data for 11 States, the average percentage of very young children 5 years of age and younger in the general Medicaid population who were on an antipsychotic medication was 0.13 percent. Among foster care children, the average rate was 1.23 percent (a lower rate represents better performance). While the measure does provide reliable estimates of use at the State level, the variability is low and differences may not be meaningful.

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 indicated the measure is a high priority for these populations and recommended specifications be finalized. However, because the extremely low rates of use of antipsychotic medications in very young children will make meaningful comparisons difficult, we propose this measure for quality improvement and decision support rather than for accountability and public reporting. This measure may enable States or other entities to compare rates with like entities and decide whether to do further, drill-down analyses around use of antipsychotics in this age group.

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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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