Medication Reconciliation in Pediatric Mental Health Care Settings: Attributes of Medication Reconciliation by Organizational Self-Report

Section 1. Basic Measure Information

1.A. Measure Name

Medication Reconciliation in Pediatric Mental Health Care Settings: Set 1, Attributes of Medication Reconciliation by Organizational Self-Report

1.B. Measure Number

0179

1.C. Measure Description

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

This measure assesses a variety of key attributes of hospitals, systems, and clinical practices that serve children with mental health conditions to promote an effective and patient-centered medication reconciliation process as part of child healthcare.

1.D. Measure Owner

Collaboration for Advancing Pediatric Quality Measures (CAPQuaM).

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.**

This measure belongs to the PQMP Mental Health Medication Reconciliation Measures Collection.

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.**

   This measure belongs to the PQMP Mental Health Medication Reconciliation Measure Set.

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.**

   Please see technical specifications (see Supporting Documents).

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

This measure relies on a scoring algorithm applied to data collected using the data collection instruments described in this report (see technical specifications in the Supporting Documents) or their functional equivalents.

1.H. Numerator Exclusions

Not applicable.

1.I. Denominator Statement

There is no true denominator for this measure. It is better described via two sampling frames:

1. Hospitals that have at least 30 discharges of children ages 0-18 during the reporting year whose primary discharge diagnosis is a mental health condition or an E- or V-code indicating suicidality. Also eligible are all hospitals that discharge at least one child or adolescent between 0-21 years of age using a place of service code 51, 55, or 56.

2. Clinical practices that have any mental health clinician, defined for this purpose as a psychologist, psychiatrist (including child psychiatrist), clinical social worker, behavioral-developmental pediatrician, or child neurologist.

1.J. Denominator Exclusions

Clinical practices as described above that saw less than five children ages 0-21 years attributable to the accountable organization in the reporting year.

1.K. Data Sources

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

Administrative data (for eligibility only); healthcare professional report.

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 the 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).**

CAPQuaM was assigned the topics of Medication Reconciliation, General (Med Rec) and Medication Reconciliation, Mental Health, as a PQMP priority by the Agency for Healthcare Research and Quality (AHRQ) and the Centers for Medicare & Medicaid Services (CMS). Following the development of an extensive literature review of medication reconciliation and in close consultation with an expert panel convened around the topic, measure sets were developed.

Background. In 2005, the Joint Commission brought the concept of medication reconciliation into the national conversation about patient safety and medication error reduction through the addition of medication reconciliation to the list of National Patient Safety Goals (The Joint Commission, 2006). The Institute for Healthcare Improvement (IHI), the Institute for Safe Medication Practices, and the Institute of Medicine (IOM), as well as government agencies, joined the Joint Commission as leaders in the effort to improve medication safety in inpatient and ambulatory settings through enhanced communication and the development of new systems and technologies. To date, there has been very little focus on pediatric medication reconciliation and the issues and concerns that may be specific to a pediatric population. In addition, medication reconciliation as it relates to mental health is not particularly well documented or researched; this is especially true for the pediatric mental health population (Bates, Cullen, Laird, et al., 1995). The mental health population poses the additional complexity of receiving care across more healthcare settings (primary care, hospital, community-based services, etc.) and needing to address various confidentiality components of behavioral health, which vary according to individual State laws (Bates, et al., 1995).

Literature. In the past, med rec implementation and improvement efforts focused on increasing interactions between patients and pharmacists, and health information technology (IT)-related interventions, without adequate attention paid to prescribing clinicians and their interactions with other treating providers.

Review of the literature shows that research still has not determined conclusively if IT and pharmacy improvements positively impact practices within the field (Berlan, Bravender, 2009; Bourgeois, Taylor, Emans, 2008; CMS, 2010). Coupled with reliance on IT and pharmacy, the field concentrates on inpatient care and largely ignores clinical handoffs between inpatient and outpatient clinicians, practices, and facilities. This is an inherent failing of current efforts to

improve medication reconciliation and reveals a disconnect between continuity of care and clinical handoffs with respect to med rec. Literature suggests that the risk of polypharmacy increases in a pediatric population, which can lead to adverse drug events, unnecessary hospital admissions due to incorrect medication use, and other unplanned medical visits (Chen, Patel, Sherer, et al., 2011; Classen, Bates, Denham, 2010).

Pediatrics: There are many fewer studies on med rec in pediatric populations as compared to adult populations. Rappaport and colleagues describe the implementation of an electronic medical record-based intervention targeting med rec in an outpatient pediatric setting (Rappaport, Collins, Koster, 2011). The 5-year study found that a comprehensive intervention to increase medication reconciliation showed an improved performance from 0 percent to 71 percent (Coffey, Mack, Streitenberger, et al., 2009). In a study reviewing inpatient med rec in a pediatric population, at least one medication discrepancy was found in 76 percent of the patients. In the analysis, the patient-related factor most related to inaccurate medication reconciliation was to have four or more prescription medications (Coffey, Mack, Streitenberer, et al., 2009). Stone and colleagues evaluated medication reconciliation in children with medically complex conditions and found admitting order errors in half of the patients. The most common type of error was omission of medications (Stone, Boehme, Mundorff, et al., 2010).

Not conducting a reconciliation of medications can be especially dangerous in pediatric populations, where large numbers of over-the-counter medications are often taken in conjunction with prescription medicines. Several studies have documented the risks and negative outcomes associated with polypharmacy, accidental overdosing of medications, and parental misunderstanding of appropriate medication administration (Chen, et al., 2011; Coffey, et al., 2009). Smith and colleagues have shown that since 2003, 200,000 out-of-hospital medication errors have been reported to U.S. poison control centers annually, and ~30 percent of these involve children, 6 years of age and younger (Smith, Spiller, Casavant, et al., 2014). Many over-the-counter drugs were implicated in these adverse events, led by analgesics and cough and cold medications. Smith posits that increased efforts to prevent medication errors can only help to alleviate the problems of adverse drug events, especially those leading to hospitalization and potentially death (Smith, et al., 2014).

Mental Health: Despite the increase in the use of antipsychotic drugs in pediatric populations, nearly doubling over a 10-year period (Walsh, Stille, Mazor, et al., 2008), there remains a lack of research on medication reconciliation and medication errors in pediatric populations in mental health literature. This topic is of particular importance given the ever-increasing number of mental health medications being prescribed to children for on- or off-label indications. A 2006 review article came to the conclusion that "medicine management in mental health settings should be a priority for future research" (Maidment, Lelliott, Paton, 2006). Rothschild and colleagues found rates of adverse drug events to be about one-third higher in psychiatric inpatients when compared to general hospital inpatients, though a lower proportion of the adverse drug events were preventable (Rothschild, Mann, Keohane, et al., 2007). In patients with mental health diagnoses, there is the added concern of medical co-morbidities and the question of who is responsible for which elements of the care. Mental health patients are often under the care of multiple providers, and there is a strong need for coordination and communication

between the patient and those involved in their care (Institute for Healthcare Improvement [IHI], 2011). Of relevance for the mental health population, sometimes it is more challenging to get a complete medication history for these patients; therefore, including the patient as a key source of information for medication reconciliation may prove challenging, especially at an inpatient psychiatric admission (IHI, 2011). In 2015, the National Committee for Quality Assurance (NCQA) issued new HEDIS measures that provide guidance for the safe and judicious use of antipsychotics in pediatric populations and also address the appropriate use of such drugs in this population.

Information Technology: Pediatric populations may be especially vulnerable to medication management errors and therefore stand to benefit from the use of information systems.

Pediatric-specific information technology should include standards (such as pediatric dosing data and adjustments for weight and height) in order to best manage clinical care (Kim, Lehmann, 2008). While there are technical considerations related to the use and sharing of electronic information, there are also policy implications, particularly for pediatrics. Policy implications include such issues as who has access to the information—parent, child (dependent on age), or both—and how to monitor access to the information. Also, the privacy needs of adolescent patients may change over time or with clinical circumstances, and there would have to be built-in safeguards for their protection. Improvements in med rec and the need for privacy may lead to positive changes in electronic health records (EHRs) and patient portals and may increase their use in outpatient care, leading to improved coordination of care.

Patient-centered Med Rec. There is very little in the existing literature about how to involve patients and their families in the med rec process, though there appears to be agreement in the belief that patient engagement is needed (Kim, Lehmann, 2008). A strong med rec process must include a comprehensive medication history that engages the patient and their family in the process (Gleason, McDaniel, Feinglass, et al., 2010; Lisby, Thomsen, Nielsen, et al., 2010). Patient and family involvement is especially critical in pediatrics where patients are often seen by different providers in different settings of care, and there is a lack of communication between systems and providers.

This measure set addresses issues with current medication reconciliation practices at both hospital system and practice levels, as noted by clinicians, and may help to improve an understanding of outcomes in pediatric populations. The proposed med rec measure set reviews the issue in a pediatric population, from many angles and at various levels of service provision, in an effort to improve outcomes and prevent catastrophic drug interactions. Utilizing lessons learned in adult populations and developing innovative methods to apply those learned lessons has informed this work. Both surveys aim to optimize collected information for desired outcomes in pediatric populations.

Existing Measures. There are no current measures of medication reconciliation that focus on pediatric populations. The National Quality Forum (NQF) has endorsed a med rec measure that focuses on patients over 65 years of age who are seen in outpatient settings within 60 days of an inpatient facility discharge (NQF, 2009). While The Joint Commission has not endorsed this

specific measure, it does include a similar measure in its National Patient Safety Goals, and CMS has included med rec as part of their Meaningful Use measure set. Existing measures of medication reconciliation require a checkbox "yes/no" in response to the question of "if med rec was completed." However, the literature suggests that this "yes/no" check-off is not adequate, does not provide an accurate picture of what med rec entails at an institution, and does not mitigate the potential for adverse drug interactions and harm to patients. The current method of med rec does not aid in improving care or coordination of care between providers, both in inpatient and in outpatient settings. We posit that by allowing clinicians, practices, and health systems to query their providers about current practice, they can identify areas for improvement, and implement strategies to address the shifting landscape of med rec in an increasingly electronic (and fast-paced) environment. Identifying these areas for improvement may also aid in cutting costs while boosting the quality of patient care, which is of utmost importance in the current CMS fiscal climate. Current efforts in the MATCH and MARQUIS studies are working to identify cost- effective methods of improving medication reconciliation after hospital discharge and to decrease medication errors through better med rec practices (Gleason, et al., 2010; Schnipper, Kirwin, Cotugno, et al., 2006).

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).**

Focus groups have demonstrated the importance of this topic to a variety of families including those insured with Medicaid. Our analyses of New York State Medicaid data reveals large amounts of medication use, overuse of asthma rescue medications compared to preventive ones, the use of polypharmacy in many cases, and the use of medications whose side effects are consistent with mental health diagnoses that are being managed in practice.

Children with mental health conditions make up about 20 percent of the population managed by general pediatrics; the percentage is a bit higher in Medicaid. Much of the recent literature has focused specifically on mental health medications, including psychotropic medications, stimulant medications, and drug use in autism spectrum disorder children (see, for example, EXPRESS SCRIPTS 2014 statement at http://lab.express-scripts.com/lab/insights/government-programs/children-using-psychotropics-account-for-16-of-medicaid-drug-costs).

Racial disparities are noted in medication expenditures in Medicaid, including in the mental health area (Maidment, Lelliott, Paton, 2006). Optimal medication use and effective and

appropriate expenditures for childhood medication in both physical and mental health is a high priority for Medicaid programs across the country.

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).

This measure breaks new ground and is distinct from existing measures, including an NQF-approved measure regarding the use of pharmacists at hospital discharge. It derives from a Joint Commission National Safety Goal, conceptual work done by the Institute for Healthcare Improvement, CMS's work on attestation for meaningful use, and others, but it truly represents a new measure set.

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:** Yes.
   c. **Care Setting – other – please specify:** No.
   d. **Service – preventive health, including services to promote healthy birth:** Yes; avoiding complications.
   e. **Service – care for acute conditions:** Yes.
   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:** Yes.
   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):** Yes.
p. **Population – infants (29 days to 1 year) (specify age range):** Yes.
q. **Population – pre-school age children (1 year through 5 years) (specify age range):** Yes.
r. **Population – school-aged children (6 years through 10 years) (specify age range):** Yes.
s. **Population – adolescents (11 years through 20 years) (specify age range):** Yes.
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.

We conducted a two-stage literature review, begun with an ad hoc review by CAPQuaM staff to orient ourselves to the literature and the topic. For the Round 2 measure development, the original literature search conducted by a librarian at Columbia University resulted in 8,835 references that were not separated into mental health and medication reconciliation. The articles were first divided among pairs of reviewers (eight reviewers in total). Each pair of reviewers decided if each article was to be included or excluded and if it was appropriate for mental health, appropriate for medication reconciliation, or for both. Results were merged into Excel, and disagreements were discussed and resolved. Our final write-up on the medication reconciliation portion of the lit review includes 319 citations.

The team built upon a portion of this literature to develop an integrated model for coordination of care that incorporated our measure assignments from AHRQ and CMS (Figure 1; see Supporting Documents).

Medication reconciliation in adults is mainly focused on hospitalized populations. In 2010, the Society for Hospital Medicine published a consensus statement titled "Making Inpatient Medication Reconciliation Patient Centered, Clinically Relevant and Implementable: A Consensus Statement on Key Principles and Necessary First Steps" (Greenwald, Halasyamani, Greene, et al., 2010). One of the critical elements of the consensus statement is the declaration that medication reconciliation should be viewed with an eye toward patient safety, not only as an accreditation mandate.

During the past decade, there have been various interventions related to medication reconciliation as a means for addressing adverse drug events that have been described in the literature. Many of these have focused on pharmacist-related interventions (Gillespie, Alassaad, Henrohn, et al., 2009, Lisby, et al., 2010; Schnipper, et al., 2006), which have found varying degrees of effectiveness. In addition, there have been studies that examined the use of information technology as a means of implementing and improving medication reconciliation. Similarly, these studies have shown varying degrees of effectiveness in terms of medication reconciliation (Schnipper, Hamann, Ndumele, et al., 2009; Showalter, Rafferty, Swallow, et al., 2011).

Accurate and complete medication reconciliation has proven difficult to implement in inpatient settings. Vira and colleagues found 60 percent of patients had at least one unintended variance in their medications (Vira, Colquhoun, Etchells, 2006). Pronovost and colleagues studied medication reconciliation when surgical ICU patients were discharged and found that implementing a reconciliation process resulted in 21 percent of patients requiring a change to their medication orders (Pronovost, Hobson, Earsing, et al., 2004).

Pediatrics. There are many fewer studies on medication reconciliation in pediatric populations as compared with adult population. Rappaport and colleagues describe the implementation of an electronic medical record-based intervention targeting medication reconciliation in an outpatient pediatric setting. The 5-year study found that a comprehensive intervention to increase medication reconciliation showed an improved performance from 0 percent to 71 percent (Rappaport, et al., 2011). In a study reviewing inpatient medication reconciliation in a pediatric population, at least one medication discrepancy was found in 76 percent of the patients. In the analysis, the patient-related factor most related to inaccurate medication reconciliation was to have four or more prescription medications (Coffey, et al., 2009). Stone and colleagues evaluated medication reconciliation in children with medically complex conditions and found admitting order errors in half of the patients. The most common type of error was omission of medications (Stone, et al., 2010).

Not conducting a reconciliation of medications can be especially dangerous in pediatric populations, where large numbers of over-the-counter medications are often taken in conjunction with prescription medicines. Several studies have documented the risks and negative outcomes

associated with polypharmacy, accidental overdosing of medications, and parental misunderstanding of appropriate medication administration (Chen, et al., 2011; Walsh, et al., 2008).

Mental Health. There is a lack of research on medication reconciliation and medication errors in the mental health literature. A 2006 review article came to the conclusion that "medicine management in mental health settings should be a priority for future research" (Maidment, et al., 2006). Rothschild and colleagues found rates of adverse drug events to be about one-third higher in psychiatric inpatients when compared to general hospital inpatients, though a lower proportion of the adverse drug events were preventable (Rothschild, et al., 2007). In patients with mental health diagnoses, there is the added concern of medical co-morbidities and the question of who is responsible for which elements of the care. Mental health patients are often under the care of multiple providers, and there is a strong need for coordination and communication involving the patient and everyone involved in their care (Procyshyn, Barr, Brickell, et al., 2010).

Electronic prescribing has been endorsed by CMS as an efficient way to deliver accurate, error-free, and understandable prescriptions from point-of-care to the pharmacy. In addition, there are many commercially-available products (e.g., RxHub, Surescripts) that allow providers to make better clinical decisions about medication management.

Medication reconciliation is part of the measure set for hospitals eligible for Meaningful Use, defined as the number of transitions of care where medication reconciliation was performed. Pediatric populations may be especially vulnerable to medication management errors and therefore stand to benefit from the use of information systems. However, pediatric-specific information technology should include standards (such as pediatric dosing data and adjustments for weight and height) in order to best manage clinical care (Kim, Lehmann, 2008).

Ideally, anytime a patient is "touched" by the healthcare system, reconciliation should occur. Within the inpatient environment, patients undergo many transitions in care, including admission, discharge, and transfers within the institution. Information needs to follow patients until the transition to the destination occurs. A medication reconciliation process of prescription and over-the-counter medications at key transition points can effectively decrease medication errors. Some studies have shown a decrease in errors by as much as 70 percent (Vira, et al., 2006).

Ethics. Because of the amount and nature of information that is exchanged during medication reconciliation, it is critical to consider confidentiality, particularly for adolescents. When thinking about access to information, consent and confidentiality are intricately linked and need to be considered. Privacy as it relates to care of an adolescent has long been understood to be necessary in order to keep adolescents routinely engaged in healthcare (Berlan, et al., 2009).

Medical Information. Recent attention has been focused on the portability and flexibility of patient-specific medical information.

Involvement of the patient and family in medication reconciliation is critical for a number of reasons:

1. Patients and families need to be educated on the value of medication reconciliation in medication safety. Some hospitals have launched community service campaigns and have information available on their Websites.
2. Everyone involved in the process needs to understand their role and responsibility (not only providers). Patients need to be treated like valued partners.
3. Medication reconciliation crosses settings of care. Patients and their families participate in the communication between those different places.

We can use the existing evidence as the groundwork for creating medication reconciliation measures that are meaningful to patients and improve the quality of healthcare for pediatric and adolescent patients. Very little work has been done on medication reconciliation in the pediatric population, with even less focus on pediatric patients with mental health diagnoses. Pediatric and adolescent patients have unique needs, and any new measures we create must be sensitive to the specific concerns of the population. Issues around validity of information, confidentiality, and multiple settings of care are all relevant to new measure development. The gaps in the existing literature show the need for medication reconciliation that is truly patient-centered—that is, meaningful and relevant to patients. Attention needs to be paid to what patients and their families care about in terms of medication reconciliation and focus on what will be helpful to them as they manage medications.

The measurement opportunities that exist in this domain are truly exciting. Designing a medication reconciliation process for pediatric and adolescent populations that can cross settings (e.g., outpatient, inpatient, community-based organizations) and truly be patient-centered will fill an existing gap, as will the additional focus on pediatric mental health. There is an opportunity to add to the national dialogue on medication safety and medication reconciliation through the development of measures that reflect an accurate representation of medications taken that corresponds to what is actually taken by a patient, as opposed to a "yes/no" measure of whether medication reconciliation happens.

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.

Medication errors happen frequently, are costly, and often, are potentially preventable. Medication errors occur for a number of reasons, including discontinuity of care during transitions, insufficient patient and family education about medications, polypharmacy, and multiple providers involved in the care of a single patient. Clearly, improving the processes around medication history taking, medication management, education of parents and families, and information sharing among clinicians would decrease the number of adverse drug events that occur annually both in and out of hospitals. Children in particular are a vulnerable population

when it comes to medication errors. As noted elsewhere, with the dramatic rise in the use of mental health medications in children, there is an additional reason to focus on this topic.

Analyzing Medicaid data in New York State, we find that many children are on multiple drugs, and frequently they are on medications that are not expected to ameliorate the symptoms of their diagnoses or medications that are not recommended by CMS for their diagnosis. We also found prescription fills for asthma rescue medications far exceed those for preventive medications, beyond what would be recommended by guidelines. A large number of children are on medications for both physical and mental health indications that have common side effects that may be confused with the symptoms of their mental health diagnoses, suggesting suboptimal use of these medications.

CAPQuaM conceptualizes med rec as a framework of desirable attributes of effective, patient-centered processes to enable decreased medication-related adverse outcomes for children, as called for by the guidelines developed by our expert panel.

The validity of our work has benefited from the use of a formal methodology that included opportunities for input from stakeholders throughout the process. A detailed literature review grounded our work in the existing science. We reviewed literature on medication reconciliation and medication errors in both pediatric and adult populations, as well as literature focused on patient-centered care, health information technology, and privacy and confidentiality. We engaged diverse expert panels on the topics of med rec (general) and med rec mental health. Using a modified version of the Rand Appropriateness Method, we rated scenarios and develop Boundary Guidelines based on the panel's recommendation. In turn, these guidelines formed the data from which the survey instruments were created.

Our vision of a broader, more inclusive vision of medication reconciliation has been widely endorsed by the Senior Advisory Board, our multidisciplinary expert panels, and individuals unrelated to the development work with whom we have consulted and/or who participated in cognitive interviews. Our work is further informed by the results of two focus groups we conducted with a diverse group of family members in Chicago.

Parents generally felt that they were aware of their child's medications and managed them well. However, they also described that they were often responsible for updating the list or correcting clinicians. Parents reported sometimes changing their child's dosing based on their perceptions of their child's symptoms or needs, and they did not view it as central that they inform the clinician of this at the time they did it. Overall, they did not exhibit a detailed awareness of how information was communicated within the healthcare system, beyond what they could see from an EHR. Similar to the parents who participated in our other focus groups, these parents accepted as a necessary burden the idea that coordination and accurate information, record keeping, and so on would most likely fall on them, rather than on the clinicians or health systems. This was a struggle for a number of the parents in the groups. They understood the value of systems to assist with medication reconciliation.

To truly reduce the rates of medication-related adverse events in children and adolescents, med rec must move from a check box at transitions to a process that crosses settings (e.g., outpatient, inpatient, community-based organizations) and is patient-centered. There is an opportunity to add to the national dialogue on medication safety and medication reconciliation through the development of measures that reflect that an accurate representation of medications taken corresponds to what is actually taken by a patient, as opposed to a "yes/no" measure of whether medication reconciliation happens.

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.

Medication reconciliation (med rec) is challenging to achieve and consequential. Optimal med rec requires that many moving parts come together correctly. It may be supported by policies/guidelines and standards of practice (care); sharing of prescribed medication data between practice-based health systems, inpatient and outpatient hospital-based health systems (including both the mental health and primary care disciplines), pharmacists, and health information technology including e-prescribing; clinical decision support, and bi-directional communication/information-sharing, as well as an effective EHR. The current measure set provides an overview of the extent to which current policies and practices at eligible institutions are in place to achieve such desirable practices.

As a rapidly evolving (indeed emerging) construct, there is very little history of measurement regarding the nuanced ideas addressed by the current measure set. As a result we choose to follow CMS's lead for how to conceptualize and assess a similarly complex emerging construct, that of meaningful use of health information technology (IT). These measures depend upon a well-constructed survey to collect information, and they require attestation to enhance accountability, reliability, and validity.

To date, measurement regarding med rec has been quite limited. Measures have typically taken one of two forms. A review of whether a yes/no checkbox indicates that med rec was performed is the main type of measurement in practice. There is a recently approved NQF measure that

assesses the use of pharmacists at the time of discharge. Neither of these measure types truly assess effective med rec, and neither has been optimized to meet the needs of pediatric healthcare.

Two distinct expert panels with different composition, one optimized for mental health med rec and the other for general med rec converged in their findings. While there were a few expected differences in the specific details, there were none at all in the endorsement of principles or key constructs. This convergence demonstrates the reliability of the constructs that emerged from CAPQuaM's systematic exploration of the literature in the context of developing measures for med rec.

Questionnaires are a widely accepted approach to assess clinical practices. Despite the limitations of self-report, there is evidence in the literature that describes clinician report of practices and the level of adoption of various methods or tools (Blendon, Schoen, Donelan, et al., 2001; Boohaker, Ward, Uman, et al., 1996; DesRoches, Campbell, Rao, et al., 2008; DesRoches, Audet, Painter, et al., 2013; Golnik, Ireland, Borowsky, 2009). The level of analysis for these questionnaires may be the clinician, the practice, or the hospital/system.

Best practices in survey development include incorporating perspectives from experts in the field to identify important constructs, the iterative development of questions that includes cognitive interviews and pilot testing to receive feedback from both those who were and were not involved in developing the constructs. This is the approach that we have used. Results from our two distinct expert panels (general med rec and mental health med rec) converged into guidelines that are consistent and guided development of our questionnaire instrument.

To enhance reliability, the CAPQuaM team used well-accepted methods to design a questionnaire/survey instrument. The questions on the surveys are designed in a combination of yes/no boxes, checklists, and "Likert-type" formats to provide clarity, avoid ambiguity, and promote reliability. The responses can be analyzed using an electronic statistical spreadsheet software program that will be made available by the CAPQuaM team to accountability organizations upon request. The scoring algorithm that generates measures from the answers to the questionnaire is included in our specifications.

CAPQuaM partners, including patient and family advocates at the Institute for Family-Centered Care, provided critical feedback, as did survey experts at the Office of Health Insurance Programs at the New York State Department of Health, and two prominent pharmacists who had each participated in an expert panel: one is a lead developer of the AHRQ-funded Medication at Transition and Clinical Handoffs (MATCH) toolkit, and the other is an international expert at the Institute for Healthcare Quality, the organization that first articulated the phrase medication reconciliation. We conducted more than a dozen cognitive interviews and received feedback from a number of other respondents. Feedback from the interviewees resulted in refinement and clarification in the wording of several questions on the survey. Cognitive interviews were conducted with experts from various disciplines (psychiatry, family medicine, pediatrics, hospitalist, nursing, pharmacy, IT) and helped to enhance our instrument. Review with CAPQuaM stakeholders late in the cognitive interview process confirmed that we had resolved

the various wording issues identified during the review process. The consistency and uniformity of positive feedback from the beginning of our survey assessment process enhances our confidence in the reliability of our data collection instrument

There are two data collection instruments in the medication reconciliation measures, one targeted at the practice level that is completed by medical directors or equivalent clinical leaders and the other targeted at the hospital level to be completed by a senior quality/safety officer. We have developed the questionnaires in a paper format so that they can be reviewed in their entirety, and all necessary data can be obtained prior to completion, attestation, and submission. We intend for the individuals taking the survey to be able to confirm data with knowledgeable colleagues within their organization as needed prior to completion. Each of the instruments was subject to similar testing and development processes.

Our CAPQuaM approach is modeled after the CMS approach to assess meaningful use for high stakes decision-making: meaningful use status impacts reimbursement decisions. The CMS approach collects information using closed-ended questions across distinct aspects of the underlying constructs. The questionnaires are presented to professionals at the various healthcare organizations and require attestation to enhance accountability, validity, and reliability. That CAPQuaM follows a similar model further solidifies our confidence in the reliability of our survey instrument.

The measures themselves are probably best considered as indices, in contrast to scales. That is, there are underlying constructs that have been validated using an expert process as described. These constructs collectively represent an underlying latent variable of patient-centered pediatric medication reconciliation. However the constructs themselves can also be mapped to observable real world phenomena. These structures exist or they don't. These processes occur or they do not. We lay out the desirable attributes of patient-centered med rec and have developed a series of indices to quantify the extent to which they are present. This is a well-established approach to measurement. The lack of a gold standard for some type of outcomes can be viewed both as a limitation of these measures and as a motivation regarding why development and implementation of these innovative measures are critical to advance the field.

Our sampling strategies are well defined, clearly specified, and benefit from data analysis of data from the Healthcare Cost and Utilization Project (HCUP) from the previous year, for which the sampling strategy included 100 percent of hospital discharges for those hospitals included in the sample. We have identified that selecting a sample of all hospitals that have at least 100 pediatric discharges will allow us to survey hospitals that account for nearly 99.5 percent of hospital discharges for children and will include nearly two-thirds of hospitals that have any pediatric discharges.

Regarding the mental health med rec measures, we have found that including hospitals with 30 or more discharges of children 0-18 years of age with primary psychiatric diagnoses (as specified in the measure's technical specifications) achieves the dual goals of efficiency (including about 20 percent of hospitals) and inclusion (accounting for more than 91 percent of such discharges). In our actual specification, we include these hospitals as well as any facility classified with at

least one pediatric discharge (specified as under age 18 or under age 21 at the option of the accountability entity) and classified as either an Inpatient Psychiatric Facility (CMS' place of service code = 51), or Psychiatric Residential Treatment Center (CMS' place of service code = 56), or Residential Substance Abuse Treatment Facility (CMS' POS code = 55).

Our plan for practice sampling is likewise straightforward. We use a unit of analysis of a practice, as defined contractually by managed care, accountable-care, and other paying entities. The defining characteristic is not the corporate or organizational structure but its role as a contracting entity. Our partners at New York State Medicaid assure us that these data are well-maintained, up to date, and valid, as well as accessible to such organizations whose accountability may be assessed by the program.

Any practice that treats 50 or more children or that has 100 or more clinical encounters with children (0-18 or 0-21 years of age, as specified by the accountability entity) should be included in the general medication reconciliation practice measures.

For the mental health measure, any practice that includes at least one practicing psychiatrist, child psychologist or child psychiatrist, behavioral and developmental pediatrician, or licensed clinical social worker and that has had any clinical encounters with any children in the included age group should be included in the sample for the mental health practices measure.

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).

The reliability section also contains information related to validity. Validity of the constructs underlying our data collection instruments has been established by an extensive 360 degree method described here. The use of questionnaires for information collection in measure assessment is common practice. The questionnaires contain consistent elements of the constructs developed by a multidisciplinary team of experts, are accessible to a large number of practitioners and health safety and quality administrators, and are relatively inexpensive to implement. Such questionnaires are widely used, including with attestation for high stakes decisions and also by CMS (e.g., meaningful use) (Blendon, et al., 2001; Boohaker, et al., 1996; DesRoches, et al., 2008; DesRoches, et al., 2013; Golnik, et al., 2009).

CAPQuaM's 360 degree method is highly engaged with collaborators, partners, and the literature. It seeks to have measures emerge from a systematic process. In developing the medication reconciliation measures we incorporate:

- A high level of engagement with partnered institutions and senior advisors that bring into the process a wide diversity of stakeholders.

- A detailed literature review that is updated and supplemented as needed. In the current instance, an electronic database literature search resulted in 8,835 articles for the medication reconciliation and mental health measures. Using process of elimination by title, 6,394 articles were eliminated, and 1,521 articles were designated for the medication reconciliation measure. After two more article elimination rounds based on abstract review and prioritization respectively, we included 958 articles in the scoping literature review of which more than 300 were cited in the final write-up.

- A geographically diverse, multidisciplinary expert panel whose members participated in a two-round RAND/UCLA modified Delphi process, with enhanced follow-up.

- Development of clinical guidance in the form of a Boundary Guideline that simultaneously accounts for a variety of gradients, including gradients of importance, relevance, and certainty, as appropriate to the construct being represented.

- Specification and review of measures and approaches to measurement by stakeholders and experts.

- Testing and assessment of the data collection instrument and resulting constructs was limited by the rapidly emerging field and the lack of an existing gold (or even silver) standard for comparison. However, the consistency of findings across the two panels represents important evidence for consensual validation regarding the desirable attributes that we measure.

The use of expert panels has been demonstrated to be useful in measure development and healthcare evaluation, including for children (Fink, Kosecoff, Chassin, et al., 1984; Kleinman, Kosecoff, Dubois, et al., 1994). Practitioners have been identified as a resource for researchers in developing and revising measures, since they are on the frontlines working with the populations who often become research participants. Involving practitioners can assist researchers in the creation of measures that are important to medication reconciliation and assist in measure implementation.

Questions developed from the constructs for the medication reconciliation measures were generated from the expert panel process using a two-round RAND/UCLA modified Delphi method. The expert panel was first presented with a group of scenarios related to constructs within the med rec measure that were generated from a literature review conducted by the CAPQuaM team. The expert panel then individually rated each scenario on a 9-point rating scale, followed by a team discussion on the decisions behind their grading. Highly rated scenarios were used to develop specific measures within med rec that our survey questions reflect, along with feedback from CAPQuaM partners. Our nine-member expert panels were geographically diverse and multidisciplinary in composition and included professionals in pediatrics, psychiatry, family medicine, clinical pharmacy, discharge planning, medical IT and healthcare navigation. Upon review of the survey questions by the committee and an internal review with revisions, there is general consensus that the questions capture items recommended by our medication reconciliation panel that target the following key constructs underlying our measure: comprehensiveness, structural IT, structural policy, communications with family and

professionals, practices, frequency of reconciliation, types of medication included in med rec, and integration of the pharmacist.

Confidence in the validity of our constructs is supported by consensual validation – not only of the two expert panels with one another – but with external events. NQF recently approved a measure regarding pharmacist involvement in med rec, and in January, 2015, the Commonwealth of Massachusetts circulated to licensed physicians an Advisory regarding mec rec that emphasizes a number of the key constructs within our measures: the importance of transitions, dosage and allergy dangers, the importance of prescribers successfully sharing medication information in a timely fashion, the importance of a comprehensive medication history, the importance of having a pre-defined and comprehensive med rec process (i.e., policy), the role of pharmacists, and the importance of patient engagement among others (Commonwealth of Massachusetts, 2015). A publication by Smith and colleagues pointed out the importance of outpatient medication errors in children in recent years (Smith, Spiller, Casavant, et al., 2014), which is further motivation for this work.

Our internal development work supported the validity of these constructs and the capacity of the questionnaires to develop indices consistent with the constructs. A wide diversity of clinicians, technology experts, pharmacists, and patient advocates were consistent in their positive feedback.

Our testing process included developing a spreadsheet that allowed us to rapidly enter data and calculate measure scores. Entering data by simulating questionnaire responses with specific organizational characteristics (e.g., low IT and advanced med rec; good med rec practices and no policy; strong content with infrequent med rec, strong IT but no med rec practices, etc.) allowed us to validate that our scoring system captured the intended characteristics and was sensitive to changes in the expected direction. After many dozens of iterations using data generated by various team members, we are confident that we have achieved meaningful ranges, typically five per measure. While any categorical system emphasizes the importance of differences at the boundaries of those categories at the expense of differences in the middle of the range, our testing supports the use of such categories. Particularly at this stage in the evolution of the constructs, we believe that reporting performance via ordinal categories is justified and appropriate. The raw numbers can be made available for studying longitudinal follow-up and for benchmarking over time.

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

This measure is specified to assess racial disparities in the following ways. Practices may be stratified according to the racial composition of the county of record in which they practice. We specify two schemas for how to do this using either 5 or 10 strata. The accountability entity is to choose among the two schemas provided. For the basic analysis, we will use proportion of minorities to determine which stratum the County falls into. However, we provide data that allows for specific analysis based on the proportion of black, Hispanic, Asian, or American Indian in each county equivalent. The cutoffs for stratifications are developed from 2013 U.S. Census data for children age 0-18 years.

For the hospital-level questionnaire, the data are based upon a 100 percent sample of discharges in a representative sample of hospitals using HCUP data. For the general med rec measure, the cutoffs represent the distribution of all discharges for children 0 – 18 years old, while for the CAPQuaM mental health medication reconciliation measures, the specified cutoff points reflect the national distribution of the proportion of each hospitals' discharges considering only mental health diagnoses as specified for that measure set. Again, for the basic analysis, we will use proportion of minorities to determine which stratum the hospital falls into. However, we provide data that allow for specific analysis based on the proportion of black, Hispanic, Asian or American Indian patients discharged by each.

Research done by members of the CAPQuaM team suggests the relationship between outcomes and racial distribution of hospital patients, independent of individual level predictors (Howell, Hebert, Chatterjee, et al., 2008).

7.B. Special Health Care Needs

These measures are especially relevant for children on multiple medications, such as children with special health care needs (CSHCN). Children with mental health conditions are often CSHCN. We do not further specify to seek disparities within the population pertaining to special healthcare needs.

7.C. Socioeconomic Status

We have specified an approach to examining poverty in the county of each practice or hospital.

7.D. Rurality/Urbanicity

We have specified an approach to examining the rurality/urbanicity in the county of each practice or hospital.

7.E. Limited English Proficiency (LEP) Populations

We have not tested or specified this measure for this specific purpose. There are no barriers to stratifying on this variable should it be available elsewhere. We do inquire about the availability of information in other than the English language in our data collection instrument.

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?

Data for this measure should be readily available in administrative data sets. Eligibility may be determined by the accountability entity. Identification of practices and provider types within each practice is required.

Data collection for this measure requires the completion of one survey per institution for the measure. Information requested as part of the surveys should be readily available to quality managers in hospitals or hospital systems, and to medical directors or equivalent at the practice level.

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?

Not applicable.

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.

This measure is not currently in use.

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?

This measure is not currently in use.

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?**
Not currently.

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 determined.

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 anticipated.

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?**
Not currently.

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 determined.

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 anticipated.

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?**
Not currently.

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 determined.

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 determined.

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?**
Not currently.

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 determined.

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 anticipated.

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?**
Not applicable.

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?**
Not applicable.

Reliability & Validity: **Is there published evidence about the reliability and validity of the measure when reported at this level of aggregation?**
Not applicable.

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)**

Yes.

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

Not currently.

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 determined.

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 anticipated.

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)**

Yes.

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

Not currently.

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 determined.

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 anticipated.

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).

This measure set outlines a set of constructs that provide a framework of desirable attributes of effective, patient-centered medication reconciliation (Med Rec) processes for children cared for in practices or hospitals that provide the bulk of pediatric mental health services. The attributes were developed along the guidelines developed by two expert panels, including one focused specifically on pediatric mental healthcare. Medication reconciliation for children is seen as both a process and an outcome. By this we mean that not only are the activities of med rec a process of care, but children are either in a state of their medications being accurately reconciled or they are not. Structures may promote the processes.

Our vision of medication reconciliation is broad and includes aspects of care otherwise termed medication management. The guidelines suggest that efforts to reconcile medications at transitions of care are only a first step on the path to developing patient-centered med rec. Effective med rec results in common understanding of medication use by the family and clinical team and benefits from policies and systems that provide information to prescribers, including data regarding prescription fills and refills, key medication alerts, and reminders. The goal of med rec activities is to optimize health by avoiding preventable medication-related complications and improving the likelihood of medications achieving their intended purpose. These practices allow patients, families, and healthcare providers to better understand not only medication reconciliation, but how it can improve quality of care for children.

The desirable attributes of patient-centered med rec for children cared for within the children's mental healthcare system go beyond transitions of care to include regular, periodic med rec at least annually for all children, even those not seen by a healthcare provider in the past year. Additional desirable attributes include having pharmacists participating in med rec for complex patients and high utilizers; having medication histories obtained in a systematic way; having families involved in reviewing medications; and providing patients and families with a written list of medications, dosages, and descriptions of the medications at each change of medication.

Medication information should be freely communicated among clinicians caring for the child, and policies describing this should be readily available to parents. Privacy options should exist for adolescents. Medication reconciliation should go well beyond prescription drugs. All clinicians caring for the patient should have sufficient information regarding current medications. These attributes are captured by our distinct measures, which are briefly described as follows:

Med Rec IT Infrastructure: This structural measure captures the capacity of an organization's information technology to support med rec processes, including electronic prescribing capabilities and decision support systems.

Med Rec Policy Infrastructure: This structural measure aims to assess the extent to which policies are in place as a component of infrastructure to support and promote desirable attributes of med rec.

Medication-Related Communications with Families (self-reported): This process measure captures several key aspects of bi-directional communication related to med rec, including both information seeking from families and information sharing with families. This measure at the organizational level represents an organizational perspective of how families are integrated into the med rec process.

Medication-related Communications with Clinicians: This process measure integrates the reported content and quality of the information related to medications exchanged between clinicians with certain key elements of infrastructure. Information exchange between clinicians and potential prescribers is a key element of med rec.

Med Rec Procedures: This measure assesses the extent to which reported practices achieve a variety of desirable attributes of med rec, including integration of med rec practices, such as medication history, the sharing of information, such as with a medication list. It is the most inclusive of the various process measures.

Frequency of Med Rec: This process measure assesses the timing of med rec practices. Med rec may be triggered by clinical transitions or encounters, as well as by periodicity or clinical encounters that serve as triggers. The measure includes assessment of when medication histories are taken and when medication lists are provided to families. The measure incorporates some structural (policy) elements as well.

Content and Comprehensiveness of Med Rec: This measure aims to assess the content incorporated into med rec and the comprehensiveness of specific information that is included in the medication list. Accuracy of the medication list is a fundamental element of med rec. We consider both policies and practices for this measure, making it an integration of process and structural attributes.

Involvement of Pharmacists: This measure assesses the utilization of pharmacists in the process of med rec. Pharmacist involvement is evaluated for its role in optimizing medication

history, prescribing, and follow-up with clinicians and families. While this measure incorporates structural elements, we consider it to be fundamentally a process measure.

Use of Med Rec: This process measure assesses the extent to which med rec practices are audited and incorporated into organizational reporting and improvement activities. This is a measure that is only assessed for hospitals and hospital systems.

Privacy Score: Not available for all practices, this process measure when present documents the presence or absence of attentiveness to detail regarding practices that relate to taking issues of privacy into appropriate consideration (e.g., for adolescents and children with mental health conditions).

Medication Reconciliation Assessment Performance Score (MRAPS): An overall performance score that is algorithmically determined to incorporate multiple categories.

The MRAPS is specified in such a way that the measure can be assessed at the level of individual practices, and the percent in each category can be reported, and also so that the distribution of measure scores among contracted practices and affiliated hospitals for any healthcare plan can be compared.

Our primary specification is to report on the distribution of performance within an accountable organization, such as a healthcare plan. We specify the 25th percentile as the defining moment of the distribution for each individual measure when calculating MRAPS. We have chosen the 25th percentile as a means to capture the bulk of the distribution and still allow some leniency recognizing the early stage of development that medication reconciliation (the construct) is at. We anticipate changing this specification to the 10th percentile in the future as the measure and the construct mature.

As specified for accountable organizations, such as healthcare plans, this measure first assesses whether or not the 25th percentile for any specific measure's score is in the lowest defined category for performance. If so, we define the MRAPS as "Needs Improvement." This nomenclature recognizes that each of the desirable attributes that is measured is important to achieve patient-centered medication reconciliation, and that substandard performance on any measure represents evidence of failure.

If all measures suggest basic performance without higher scores, the nomenclature recognizes this as "Consistently Basic Performance."

Six measures were identified as more comprehensive and potentially influential than others: IT, Policy, Procedures, Family Communication, Pharmacists, and Clinician Communications. These were used to define three categories of MRAP that represent better than Basic performance. If the majority of these exceed a basic performance score at the 25th percentile, then the accountable organization is designated to have "Leadership performance." Better than basic in half of these categories is considered "Outstanding performance," and in one-third, "Distinguished performance." If a single category is above basic, the plan is acknowledged to

have "Consistently basic performance with distinction in" that category. Scores that are in the Advanced or Leader categories (category 4 or 5) are acknowledged as "with honors" or "with high honors," respectively, in those measures.

For all of these measures, higher scores are more desirable. The use of categorical descriptions for performance enhances understandability. The definitions that follow are derived from the scores that would be achieved by plans whose performance corresponds to the described attribute. We use as our benchmark standards the constructs developed by our expert panelists in our evidence-informed 360 degree process as described above, rather than the distribution of current performance.

Pre-Foundation (category 1) suggests performance is insufficient to meet current ideas regarding med rec in terms of the indicated attribute. Basic (category 2) suggests performance that is current and meets minimum standards for appropriate performance without distinction or favorable performance. Good performance (category 3) is an achievement that indicates performance that goes beyond the minimums required for Basic and that still has meaningful opportunities for improvement without leaving the mainstream. Advanced (category 4) represents excellent performance in typical systems or practices.

Leader (category 5) represents outstanding or distinguished performance that is consistent with early adopters and innovators in the area of med rec. For the privacy measures, insufficient attention suggests that policies and practices are not sufficient to demonstrate the system has a satisfactory solution to some key challenges of privacy regarding med rec. Advanced indicates better than minimum performance.

Assessment of medication reconciliation-related infrastructure, policies, and practices will allow insurers and other purchasers of healthcare to delineate the desirable and effective attributes of med rec in an effort to positively change existing practices and improve patient-centered safety. Throughout development of the measure set, CAPQuaM brought together diverse stakeholders—clinicians, scientists, payers, purchasers, consumer organizations, and families—to ensure their engagement in advancing quality measures that are understandable, salient, and actionable. CAPQuaM employed a 360 degree method designed to involve key stakeholders in meaningful ways. Our consortium partners, advisory board members, scientific team, and expert panel members guided our process and contributed broadly. We also had in-depth conversations regarding this measure and its understandability with our partners at the New York State Department of Health, including leadership of the Medicaid program. The development process for these measures was also guided by medical literature (both peer-reviewed and gray, including websites).

In-depth cognitive interviews with individuals from diverse backgrounds have ensured relevance and understandability of key constructs. Feedback from the in-depth cognitive interviews confirms the salience of the work. In addition, four focus groups (two on medication reconciliation and two regarding mental health, including follow-up and medication reconciliation) with parents and caregivers have grounded the work. Parents in these groups had

children with a variety of diagnoses, including asthma, an autoimmune disorder, ADHD, and other mental health disorders.

Parents generally felt that they were aware of their child's medications and managed them well. Those whose children were in a system of care with an EHR described having few problems with different providers having access to the medication list. However, they also described that they were often responsible for updating the list or correcting clinicians, suggesting that reconciliation processes were flawed even in such systems. Parents reported sometimes changing their child's dosing based on their perceptions of their child's symptoms or needs and did not view it as central that they inform the clinician of this when they did it. Overall, they did not describe confusion or difficulties in keeping track of their child's medications or dosing schedules, but they also did not exhibit a detailed awareness of how information was communicated within the healthcare system, beyond what they could see from an EHR. Similar to those parents who participated in our mental health focus groups, these parents accepted as a necessary burden the idea that coordination and accurate information, record keeping, and such was most likely to fall on them, rather than upon the clinicians or health systems. This was a struggle for a number of parents in the groups. They understood the value of systems to assist with medication reconciliation.

In aggregate, the feedback we have received validates the underlying constructs and approach. Our team has far exceeded the expected standards for incorporating expertise outside of the mainstream medical system, ensuring understandability at various levels and by a variety of audiences.

Since this is an emerging field, we expect that results will be clustered around the lower end (category 2, rather than categories 3-5) of performance initially. The measures were designed to remain relevant as the standard of care and performance improve.

This measure set, when assessed using the recommended specifications, describes medication reconciliation among the clinical organizations that provide the bulk of mental healthcare services to children.

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.

As noted earlier in this report (see Section 3.A), there are technical considerations related to the use and sharing of electronic information, and there also are policy implications, particularly for pediatric populations (e.g., who has access to the information – parent, child, or both; how to

monitor access to the information; and other considerations). Improvements in medication reconciliation and the need for privacy may lead to positive changes in EHRs that will facilitate the use of health IT in outpatient mental health care that will lead to improvements in care coordination.

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?

Not applicable.

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.

The technical specifications for this measure (see Supporting Documents) indicate how to use administrative data to identify samples for the measure.

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)?

No.

If yes, please describe.

Not applicable.

11.E. Health IT Calculation

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

Encounter data are needed for parts of the sample selection and stratification.

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?

Not applicable.

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).

These measures suffer from the usual limitations of self-reported data. Our careful and iterative processes have developed a questionnaire designed to mitigate these limitations to the extent possible. Our specification that the questionnaire is not intended to be filled out without the requisite data collection within the organization should also help to mitigate this and enhance reliability.

Since this is an emerging field, we expect that results will be clustered around the low end of performance initially. The measures were designed to remain relevant as the standard of care and performance improve.

There is no gold standard, but our inclusive and systematic processes allow the measures to stand on their own. As they have not been implemented widely, benchmarks are not currently available.

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.

These measures represent an assessment of desirable attributes and an overall performance score that emerged from a guideline developed by two expert panels after review of extensive literature and vigorous discussions. They are intended to support measurement in the context of a rapidly emerging field. Consensual validation internal and external to the team leaves us confident of their timeliness and their value. Although these were optimized for child health, the path to modifying them for use in adult healthcare is straightforward.

Interpretation and potentially the most desirable scoring strategies are likely to be enhanced with increased implementation and more widespread data collection.

1. **Med Rec IT Infrastructure:** This structural measure captures the capacity of an organization's information technology to support med rec processes, including electronic prescribing capabilities and decision support systems.

2. **Med Rec Policy Infrastructure:** This structural measure aims to assess the extent to which policies are in place as a component of infrastructure to support and promote desirable attributes of med rec.

3. **Medication-Related Communications with Families (self-reported):** This process measure captures several key aspects of bi-directional communication related to med rec, including both information-seeking from families and information sharing with families. This measure at the organizational level represents an organizational perspective of how families are integrated into the med rec process.

4. **Medication-Related Communications among Clinicians:** Information exchange between clinicians and especially potential prescribers is a key element of med rec. This process measure integrates the reported content and quality of the information related to medications exchanged between clinicians with certain key elements of the infrastructure.

5. **Med Rec Procedures:** This measure assesses the extent to which reported practices achieve a variety of desirable attributes of med rec, including integration of med rec practices, such as medication history and the sharing of information, such as with a medication list. It is the most inclusive of the various process measures.

6. **Frequency of Med Rec:** This process measure assesses the timing of med rec practices. Med rec may be triggered by clinical transitions or encounters, as well as by periodicity or clinical encounters that serve as triggers. The measure includes assessment of when medication histories are taken and when medication lists are provided to families. The measure incorporates some structural (policy) elements as well.

7. **Content and Comprehensiveness of Med Rec:** This measure aims to assess the content incorporated into med rec and the comprehensiveness of specific information that is included in the medication list. Accuracy of the medication list is a fundamental element of med rec. We consider both policies and practices for this measure.

8. **Involvement of Pharmacists:** This measure assesses the utilization of pharmacists in the process of med rec. Pharmacist involvement is evaluated for their role in optimizing medication history, prescribing, and follow-up with clinicians and families.

9. **Use of Med Rec:** This measure assesses the extent to which med rec practices are audited and incorporated into organizational reporting and improvement activities. This is a measure that is only assessed for hospitals and hospital systems.

10. **Privacy Score:** Not available for all practices, this score when present documents the presence or absence of attentiveness to issues of adolescent privacy in key medication reconciliation practices.

11. **Medication Reconciliation Assessment Performance Score-Mental Health:** An overall performance score that is algorithmically determined to incorporate multiple categories, such as IT infrastructure, policy, and practices.

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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.