Follow-up with Patient Family after Developmental Screening

Section 1. Basic Measure Information

1.A. Measure Name

Follow-up with Patient Family after Developmental Screening

1.B. Measure Number

0202

1.C. Measure Description

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

Percentage of patients aged 6 months to 36 months whose family received a follow-up discussion of developmental screening results on the same day of the screening visit.

1.D. Measure Owner

Agency for Healthcare Research and Quality (AHRQ), Pediatric Measurement Center of Excellence (PMCoE).

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.

Developmental Screening and Follow-up

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.

Developmental Screening and Follow-up

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

Not applicable.

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

Not applicable.

1.G. Numerator Statement

Patients whose family received a discussion of the developmental screen by a primary care clinician on the same day of the screening visit. Follow-up discussion is defined as a communication from clinician to patient family in which the clinician reports the screening scores, explains the screening results, and outlines next steps (which may include referrals) and expectations.

1.H. Numerator Exclusions

None.

1.I. Denominator Statement

All patients aged 6 months to 36 months who received a developmental screen using a standardized developmental screening tool that was administered either by the primary care clinician or if conducted elsewhere, appears in the patient's medical chart.

A standardized developmental screening instrument is defined as an instrument that meets the following criteria:

- *Developmental domains:* The following domains must be included in the standardized developmental screening tool: motor, language, cognitive, and social-emotional.
- *Reliability:* Reliability scores of approximately 0.70 or above.
- *Validity:* Validity scores for the tool must be approximately 0.70 or above. Measures of validity must be conducted on a significant number of children and using appropriate standardized developmental or social-emotional assessment instrument(s).
- Sensitivity/Specificity: Sensitivity and specificity scores of approximately 0.70 or above.

Some tools that might meet these criteria include:

Ages and Stages Questionnaire (ASQ), 2 months − 5 years.

- Battelle Developmental Inventory Screening Tool (BDI-ST), birth 95 months.
- Bayley Infant Neuro-developmental Screen (BINS), 3 months 2 years.
- Bigrance Screens-II, birth 90 months.
- Child Development Inventory (CDI), 18 months 6 years.
- Child Development Review-Parent Questionnaire (CDR-PQ), 18 months 5 years.
- Infant Development Inventory, birth 18 months.
- Parents' Evaluation of Developmental Status (PEDS), birth 8 years.

Non-recommended tools are those that do not meet the above criteria. It is important to note that standardized tools specifically focused on one domain of development [e.g., child's socioemotional development (ASQ-SE) or autism (M-CHAT)] are not included in the list above, as this measure is anchored to recommendations focused on global developmental screening using tools that focus on identifying risk for developmental, behavioral, and social delays.

1.J. Denominator Exclusions

This measure has no exceptions.

1.K. Data Sources

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

Paper Medical Record, Electronic Medical Record.

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

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 Attachment 2.1 for measure specifications.

Section 3. Importance of the Measure

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

3.A. Evidence for General Importance of the Measure

Provide evidence for all applicable aspects of general importance:

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

The discussion between the clinician and the patient family or guardian after a developmental screen is just as important as the screening itself. With high quality preventive care, which includes clear communication between the provider and the patient's family or guardian, early identification and follow-up of developmental delays can be improved. Approximately, one-half of parents nationwide report that their doctors ask about their developmental concerns, and one-third of children do not receive care that is family-centered at visits, with parents reporting that doctors do not spend enough time,)listen carefully, or provide them with needed information during visits (Coker, Shaikh, Chung, 2012). In a qualitative study focusing on barriers to evaluation for early intervention (EI) services, Jimenez et al. found that parents who reported that their child was not evaluated by EI were more likely to report that their pediatrician did not explain what EI was or how to obtain services (Jiminez, Barg, Guevara, et al., 2012). This

indicates that parents may be misinformed or uninformed about what to do in the case of a developmental delay.

A quality measure that evaluates whether a clinician discussed developmental screening results with the patient family or guardian will promote high quality preventive care by ensuring that the patient's family or guardians are aware of both the status of their child's developmental health and whether any further steps are needed. This knowledge may also lead to more timely and appropriate follow-up care, ultimately improving future health outcomes. Further, as described and documented in the American Academy of Pediatrics (2006) policy statement, Identifying Infants and Young Children with Developmental Disorders in the Medical Home: an Algorithm for Developmental Surveillance and Screening, early identification and treatment of children with neurodevelopmental and behavioral problems is critical to their well-being and development. This guidance provided the pediatric practitioner with a new paradigm and algorithm to direct screening within the medical home. This policy statement is being revised to "create a universal system of screening of all children in the primary care setting for the wide range of neurodevelopmental and behavioral conditions that affect the early and long-term development and achievement of affected children." Early identification of problems and referral for treatment are essential for children to achieve their full potential. The 2006 policy statement emphasizes the critical need to simultaneously pursue any indicated medical evaluation while also linking the family with early intervention or early childhood education.

This goal of universal surveillance and screening is encouraged and expected, not only in medical homes, but now with other health care professionals in numerous settings. For example, the Departments of Health and Human Services and Education have launched their developmental and behavioral screening initiative Birth to 5: Watch Me Thrive! This effort encourages all early childhood experts to work together to screen, identify developmental delays, and refer for more in-depth evaluation and treatment, as appropriate (Birth to 5, Website). The Federal partners that are participating in this initiative speak to the need and importance of screening and referral and include: the Administration for Children and Families; the Centers for Disease Control and Prevention; the National Institute of Child Health and Human Development; the Substance Abuse and Mental Health Services Administration; the Centers for Medicare & Medicaid Services (CMS); the Health Resources and Services Administration; and the Office of Special Education and Rehabilitative Services at the Department of Education. There are existing developmental screening measures (National Committee for Quality Assurance [NCQA], 2009a, 2009b; National Quality Measures Clearinghouse, 2007; Child and Adolescent Health Measurement Initiative, undated). However, these measures have not as yet been adopted nationally for use in quality assessment and improvement. Please see Attachment 3A.1 for additional information on the existing measures. The current proposed set of measures on developmental screening follow-up are recommended for use.

These, and other initiatives, are necessary because of the known quality gap in developmental screening and follow-up communication of the results to the patient's family or guardians. As noted by the Centers for Disease Control and Prevention (CDC), 13 percent of children in the United States have developmental or behavioral disabilities (Boulet, Boyle, Schieve, 2009). However, according to the U.S. Department of Education, fewer than half of the children with developmental delays are identified before they start school (U.S. Department of Education).

Obviously, when a delay in diagnosis and treatment occurs, critical and often time-sensitive opportunities are missed to for early intervention in brain and child development. Over the last few years, there has been an improvement in the number of primary care physicians who routinely perform developmental screening with a validated tool, but still only 50 percent do so (Radecki, Sand-Loud, O'Connor, et al., 2011), demonstrating the potential and need for quality improvement. Even for those who perform the evaluation, the issues of documenting the results, discussing the results with the families, referring when appropriate, and following up on referrals are daunting at best. The need for the measures becomes even more critical with the addition of numerous organizations involved in the screening. The link back to the medical homes will be crucial—in order to assure not only that the screening is done and that the families receive consistent messaging, but also to complete the evaluation and to confirm/document the referrals and track the outcomes with parents and other clinicians. These measures are applicable to changes across the developmental stages of infancy and early childhood. Their association with children's future health and education has been documented. The earlier the intervention, the less need for future, more extensive, intensive, and expensive interventions (Heckman Web site, undated). The number one recommendation of the Robert Wood Johnson Foundation's Commission to Build a Healthier America was to "make investing in America's youngest children a high priority" to "build a strong foundation in the early years for a lifetime of good health" (Robert Wood Johnson, 2014).

References

American Academy of Pediatrics. Identifying Infants and Young Children with Developmental Disorders in the Medical Home: An Algorithm for Developmental Surveillance and Screening. Pediatrics 2006; 118(1): 405-20.

Birth to 5: Watch Me Thrive! Early Childhood Development Web site. Available at http://www.acf.hhs.gov/programs/ecd/watch-me-thrive. Accessed August 13, 2014.

Boulet SL, Boyle CA, Schieve LA. Health Care Use and Health and Functional Impact of Developmental Disabilities Among U.S. Children, 1997-2005. Arch Pediatr Adolesc Med 2009; 163(1):19-26.

Child and Adolescent Health Measurement Initiative. Key measurement issues in screening, referral, and follow-up care for young children's social and emotional development. National Academy for State Health Policy; 2005. Available at http://www.nashp.org/sites/default/files/key_measurement_issues.pdf. Accessed July 20, 2016.

Coker TR, Shaikh Y, Chung PJ. Parent-reported quality of preventive care for children at-risk for developmental delay. Acad Pediatr 2012; 12(5):384-90.

Heckman Web site. The Case for Investing in Disadvantaged Young Children. Available at http://www.heckmanequation.org/content/resource/case-investing-disadvantaged-young-children. Accessed July 11, 2016.

Jimenez ME, Barg FK, Guevara JP, et al. Barriers to evaluation for early intervention services: parent and early intervention employee perspectives. Acad Pediatr 2012; 12(6): 551-7.

National Committee for Quality Assurance. Well-Child Visits in the First 15 Months of Life. Washington, DC: 2009a.

National Committee for Quality Assurance. Well-Child Visits in the Third, Fourth, Fifth and Sixth Years of Life. Washington, DC: 2009b.

National Quality Measures Clearing House. Measure Summary: Follow-up for children at risk for delays: proportion of children who were determined to be at significant risk for development, behavioral, or social delays who received some level of follow-up care. Rockville, MD: 2007.

Radecki L, Sand-Loud N, O'Connor KG, et al. Trends in the use of standardized tools for developmental screening in early childhood: 2002-2009. Pediatrics 2011; 128(1):14-9.

Robert Wood Johnson Foundation Commission to Build a Healthier America. Time to Act: Investing in the Health of Our Children and Communities. Investing in Early Childhood Development. Updated January 2014 Available at

http://www.rwjf.org/content/dam/farm/reports/reports/2014/rwjf409002#page=44. Accessed July 11, 2016.

U.S. Department of Education, Office of Special Education Programs [Internet], Data Analysis System (DANS), Part C Child Count, 1997–2006.

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).

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) was established to meet the child health component of Medicaid (EPSDT Web site). EPSDT specifically addresses the issues as described: Screening—developmental, hearing, vision, physical, mental and other tests to identify problems; Diagnostic—performing appropriate testing when a problem is identified; and Treatment—treating any problems found. The program was developed in 1967 to "discover, as early as possible, the ills that handicap our children" and to provide continuing follow-up and treatment "so that handicaps do not go neglected." This program is exactly what is being facilitated with the proposed measures as defined. It is clear to see why CMS is involved in the Help Me Thrive initiative.

In addition, the prevention guidelines for children (Bright Futures and the Periodicity Schedule) as included in the Affordable Care Act (ACA) clearly define the times for pediatric preventive care visits for the first 5 years of life, during which developmental surveillance and screening should take place (American Academy of Pediatrics, Periodicity Schedule). The screening evaluation, follow-up, and referral are the next necessary steps. Documentation and measurement

of the discussion with the patient's parents or guardian are critical for appropriate interventions and outcomes.

Federal law requires that Medicaid cover a comprehensive set of benefits and services specifically for children. Since one in three U.S. children under age 6 is eligible for Medicaid, EPSDT offers a very important way to ensure that young children receive appropriate health, mental health, and developmental services (Health Resources and Services Administration [HRSA], undated).

Both the Title V Maternal and Child Health Services Block Grant program and the **EPSDT** component of Medicaid recognize social and emotional development as an integral aspect of children's health care, and research demonstrates the value of early identification and intervention to address children's needs. In Title V, the definition of children with special health care needs (CSHCN) includes socialemotional needs (HRSA, Title V). From screening to diagnosis to treatment, Medicaid and EPSDT are critical to financing evidence-based services for children (Howell, Teich, 2008). Federal law requires comprehensive well-child examinations with screening services through EPSDT, including screening for potential developmental, mental, behavioral, and/or substance use disorders. EPSDT also finances diagnostic and treatment services, if medically necessary, for these conditions (HRSA, EPSDT Overview). However, studies have found that as low as 23 percent of low-income children enrolled in Medicaid receive the recommended preventive and developmental services considered a basic threshold for quality care (NCINQ, 2011). In addition, children insured by Medicaid had almost a two-fold higher prevalence of any developmental disorder compared to those with private insurance, and children from families below the Federal poverty level had a higher prevalence of developmental disabilities (CDC, 2011). Given the higher prevalence of developmental delay and the low percentage of children receiving adequate developmental services, quality measures that track developmental screening follow-up communication with the patient's parent or guardian could greatly improve the long-term health outcomes of children enrolled in Medicaid and CHIP.

References

American Academy of Pediatrics Web site. Periodicity Schedule. http://www.aap.org/enus/professional-resources/practice-support/Pages/PeriodicitySchedule.aspx Accessed August 13, 2014.

Centers for Disease Control and Prevention (CDC). Key findings: Trends in the prevalence of developmental disabilities in U.S. children: 1997-2008. 2011. Available at https://www.cdc.gov/ncbddd/developmentaldisabilities/features/birthdefects-dd-keyfindings.html. Accessed July 20, 2016.

Early and Periodic Screening, Diagnostic, and Treatment. Medicaid Web site. Available at http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Early-and-Periodic-Screening-Diagnostic-and-Treatment.html Accessed July 11, 2016.

Health Resources and Services Administration, Maternal and Child Health Bureau. EPSDT Overview. Available at http://mchb.hrsa.gov/maternal-child-health-initiatives/mchb-programs/early-periodic-screening-diagnosis-and-treatment. Accessed July 20, 2016.

Health Resources and Services Administration: Maternal and Child Health. Title V: Maternal and Child Health Services Block Grant Program. Available at http://mchb.hrsa.gov/programs/titlevgrants/. Accessed July 11, 2016.

Howell EM, Teich J. Variations in Medicaid mental health service use and cost for children. *Adm Policy Ment Health*. 2008;35(3):220-228.

National Collaborative for Innovation in Quality Measurement Center of Excellence (NCINQ). (2011). Developmental screening in children. Developed by NCINQ for use in the AHRQ PQMP Consortium. Unpublished.

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 enhances the developmental screening measure in the initial core set (CMS, 2011), filling the critically important referral/follow-up component of screening. This measure will complement other existing measures and others in this set through assessment of whether a screening took place and a discussion took place with the patient's parents or guardian regarding the results. Since screening and discussion about the developmental screen are equally important, this measure will give a better indication about the outcomes of the screening event and whether the screening event was successful in informing the patient's parents or guardian about the status of their child's developmental health through communication between the clinician and the patient's parent or guardian.

Reference

Centers for Medicare & Medicaid Services (CMS). Initial Core Set of Children's Health Care Quality Measures: Technical Specifications and Resource Manual for Federal Fiscal Year 2011 Reporting. Baltimore, MD; 2011.

Section 4. Measure Categories

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

Does the measure address this category?

- a. Care Setting ambulatory: Yes.
- **b.** Care Setting inpatient: No.
- c. Care Setting other please specify: Yes. Other community and public health settings.
- d. Service preventive health, including services to promote healthy birth: Yes.
- e. Service care for acute conditions: No.
- f. Service care for children with acute conditions: Yes.
- g. Service other (please specify): No.
- h. Measure Topic duration of enrollment: No.
- i. Measure Topic clinical quality: Yes.
- j. Measure Topic patient safety: Yes.
- k. Measure Topic family experience with care: No.
- **l.** Measure Topic care in the most integrated setting: Yes.
- m. Measure Topic other (please specify): No.
- n. Population pregnant women: No.
- o. Population neonates (28 days after birth) (specify age range): No.
- p. Population infants (29 days to 1 year) (specify age range): Yes; 6 to 36 months.
- q. Population pre-school age children (1 year through 5 years) (specify age range): N_0 .
- r. Population school-aged children (6 years through 10 years) (specify age range): $N_{\rm O}$.
- s. Population adolescents (11 years through 20 years) (specify age range): No.
- t. Population other (specify age range): No.
- u. Other category (please specify): Not applicable.

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

The evidence base for the focus of the measures will be made explicit and transparent as part of the public release of CHIPRA deliberations; thus, it is critical for submitters to specify the scientific evidence or other basis for the focus of the measure in the following sections.

5.A. Research Evidence

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

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

Early identification of developmental disorders and referral to services are critical to the well-being of children and their families. The rapid growth and development that occur during the first 5 years of life of a child's life have been well-documented. The important skills gained during this period become the foundation for all development that follows. Yet the rate of development and the age at which children display certain abilities vary greatly. Screening can determine whether a child is developing on track, and it is the first step in determining if a child has delays within a normal range or delays or disabilities that are outside the normal range (McCann, Yarbrough, 2006).

Screening tests can identify children with developmental delay with reasonable accuracy. General developmental screening tools enable providers to screen across several developmental domains: language, cognitive, physical, motor, sensory, and social-emotional. Children's healthy social-emotional development is a cornerstone of school readiness, academic success, health, and overall well-being (Meisels, Atkins-Burnett, 2005). This developmental domain includes several areas, such as personality, temperament, social problem solving, self-concept, and self-regulation. This capacity develops over time in the context of family, community, and cultural expectations for young children (Korfmacher, 2014). Research has shown that parental questioning is a valid means of screening for developmental delays, and that standardized instruments have sensitivity and specificity similar to that of screens that require direct elicitation of a child's skills (Hamilton, 2006).

A study of standardized developmental screening found that when providers were instructed to score and respond to survey results with the parent at the visit during which the screen was interpreted, providers' confidence in their ability to screen and identify developmental delays increased. Similarly, discussing screening results with parents allowed providers to better refer children to follow-up services, and it also provided an opportunity for parents to discuss general developmental concerns that might not have been identified with the screening tool (King, Tandon, Macias, et al., 2010). The reason for conducting screens is to determine if there are developmental concerns that require an intervention to diminish the impact of a delay and address the developmental concern. See Attachment 5A.1 for the Pediatric Developmental Screening Flowchart for appropriate evidence-based developmental screening follow-up. It is as important to discuss the results of a developmental screen as it is to discuss any other clinical finding or test result, but it may be even more important to discuss developmental screening

results because children develop in the context of relationships. Parents are the child's most important caregivers, and early relationships matter (Wahl, undated). Furthermore, in addressing developmental health, clear communication between the clinician and the patient's caregiver is one of the primary actions that will determine and impact the course and quality of a child's treatment plan (Coker, Shaikh, Chung, 2012). Providers must spend time with parents/guardians reviewing the results of developmental screens in order to better understand concerns and direct the caregivers to appropriate resources (Pizur-Barnekow, Erickson, Johnston, 2010).

Effective discussions with family members can provide essential information and make it more likely that they will follow up to get further recommended evaluation or treatment. Parental understanding leads to better referral follow up by the family.

Unfortunately, information or guidance is often absent in communication between screening providers and parents (Jennings, Hanline, 2013). Providers require proper training in systematic collection of developmental risk and protective factors, administration of screening tools, communication of results to parents, and skill in knowing what information is necessary to provide during referral for diagnostic evaluation (Pizur-Barnekow, et al., 2010). A study by Coker et al. (2012) found that non-white race/ethnicity, lower parental education level, poverty, non-English primary language households, male gender, special health care needs, older age child, and public insurance status were all associated with being at risk for developmental delay. Further, unadjusted and adjusted regression analyses indicated that parents of children at moderate and high risk for developmental delay were less likely to report that their doctor usually or always spends enough time with them, listens carefully, provides them with needed information, shows sensitivity to the family's values and customs, and helps the parent feel like a partner in care (Coker, et al., 2012). Similarly, a national survey confirmed that most parents of young children have one or more education- or guidance-related health need(s) that are unmet in one or more area(s) of care (Bethell, Reuland, Schor, 2011).

Results from the screening process need to be shared with parents in a clear, culturally sensitive, and timely manner. Parents should be told that while screening generally provides an accurate picture of a child's development, it is only a snapshot. Similarly, the results are not predictive of how their child will develop in the future. The screener may start the discussion with parents by asking them what they think about their child's growth and behavior and then continue the discussion by following up on any specific areas of concern that were identified during the screening process. If the screening and discussion with the parent raise no concerns, the screener should provide anticipatory guidance to the parents about what to expect next in their child's development and share the schedule for the next screening. If the screening does raise concerns, parents should be reminded that the results are not a diagnosis. The screener should discuss the parents' expectations for their child and compare those expectations with developmental norms and standardized screening results. When the results of a screen definitively indicate the need for further evaluation, the screener should provide a referral to the parents.

Regardless of the screener's recommendations, the parent or family should be supported in deciding what next steps make sense for the child and family's needs. It is better for a child to have an evaluation than miss the opportunity to prevent a more severe delay or disability.

References

Bethell C, Reuland C, Schor E, et al. Rates of parent-centered developmental screening: disparities and links to services access. Pediatrics 2011; 128(1):146-55.

Coker TR, Shaikh Y, Chung PJ. Parent-reported quality of preventive care for children at-risk for developmental delay. Acad Pediatr 2012; 12(5):384-90.

Hamilton S. Screening for developmental delay: reliable, easy-to-use tools. J Fam Pract 2006; 55(5):415-22.

Jennings DJ, Hanline MF. Developmental screening referrals: child and family factors that predict referral completion. Topics Early Child Spec Educ 2013; 33(2):102-11.

King TM, Tandon SD, Macias MM, et al. Implementing developmental screening and referrals: lessons learned from a national project. Pediatrics 2010: 125(2):350-60.

Korfmacher J. Infant, toddler, and early childhood mental health competencies: a comparison of systems. Washington, DC: Zero to Three; 2014. Available at http://www.zerotothree.org/public-policy/pdf/infant-mental-health-report.pdf. Accessed July 12, 2016.

McCann CE, Yarbrough K. Snapshots: Incorporating comprehensive developmental screening into programs and services for young children. Chicago, IL: Ounce of Prevention Fund; 2006.

Meisels S, Atkins-Burnett S. Developmental screening in early childhood, 5th Ed. Washington, DC: National Association for the Education of Young Children; 2005.

Pizur-Barnekow K, Erickson S, Johnston M, et al. Early identification of developmental delays through surveillance, screening, and diagnostic evaluation. Infants Young Child 2010; 23(4):323-30.

Wahl E. Sharing screening results with families. Wisconsin Medical Home Webcast Series. Madison, WI: University of Wisconsin, Madison, Waisman Center; undated. Available at http://www.waisman.wisc.edu/connections/pdfs/webcast/SharingScreeningResultsFamilies.pdf. Accessed July 12, 2016.

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.

Discussion of the results with the family of a positive developmental screen is critical to any other follow-up actions that may be necessary, as the child is dependent on the parents for accessing any follow-up appointments to address the developmental concerns. The communication with the family has to effectively establish for the parent an understanding of the concerns to increase the likelihood of parental follow through with the discussed follow-up actions. Furthermore, in a study by Jennings and Hanline they describe the breakdown in the link

between widespread screening and developmental delays in children as they report no impact from the screening if the family did not follow-up with the referrals provided and the child did not receive services (Jennings, Hanline, 2013).

Pizur-Barnekow et al. (2010) suggest that providers must communicate the screening results to the family in a supportive and direct manner. First, the provider should explain to the parents the benefits of screening. Parents need to be informed that if a screening result is positive that does not confirm a diagnosis. Parents should also be informed that if a delay is confirmed after a diagnostic evaluation, they can access early intervention services that will assist the child in developing to his or her fullest potential. Second, the provider needs to explain the potential risks linked with screening. For instance, even if the screening suggests a delay, the subsequent diagnostic evaluation may indicate no actual delay. Since scheduling and waiting for results of a diagnostic evaluation can be stressful for the family, the provider should reassure the family that they will be available for support and to address any concerns about the screening. Third, the provider should give a description of the processes of how the parents will be informed about the results. Specifically, parents need to know whether they will be notified irrespective of the screening results. Fourth, the provider must explain the importance of a diagnostic evaluation after a positive screen and subsequently connect the family to the proper medical providers. Finally, parents need to be informed if there is a fee associated with the screening (Pizur-Barnekow, Erickson, Johnston, 2010).

References

Jennings DJ, Hanline MF. Developmental screening referrals: child and family factors that predict referral completion. Topics Early Child Spec Educ 2013; 33(2):102-11.

Pizur-Barnekow K, Erickson S, Johnston M, et al. Early identification of developmental delays through surveillance, screening, and diagnostic evaluation. Infants Young Child 2010; 23(4):323-30.

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.

Manual Chart Abstraction of the Measure

Testing Sites

The testing sites for reliability testing through manual chart abstraction of this measure included the primary care networks of the Chicago Pediatric Quality and Safety Consortium (CPQSC): Ann and Robert H. Lurie Children's Hospital of Chicago, Advocate Children's Hospital—Park Ridge, Advocate Children's Hospital—Oak Lawn, and John H. Stroger, Jr. Hospital of Cook County. See description of the CPQSC in Attachment 6A.1.

Methods

Each site identified two research nurses with previous experience conducting pediatric chart abstraction, who then received additional project specific training on how to identify, select, and stratify the charts for inclusion and conduct the manual chart abstraction to test and construct each measure in the Developmental Follow-up measure set. A chart abstraction tool and algorithm were developed by the Developmental Screening Follow-up Leadership Team, and the research nurses were presented with a formal training and relevant materials on how to use these tools. The chart abstraction tool (Attachment 6A.2) was used at each site to complete the manual chart abstractions.

At each site, two research nurses were instructed to identify up to 70 charts to review retrospectively in August, 2014 that matched the denominator criteria. For this measure, chart abstractors abstracted demographic information, numerator elements, and denominator elements. This measure has no exclusions.

To complete the manual chart abstraction, the following algorithm was followed: (1) Select Charts: Patients with CPT code 96110; well-child visit codes 99381, 99382, 99391, and 99392; and were between 6-42 months of age during 2011 and 2013; charts meeting these criteria were randomized for inclusion in the testing; (2) Collect demographics and elements for equity assessment: Age, Gender, Race/Ethnicity, Language Preference, Insurance Status/Type; (3) Review and document measure elements in the chart abstraction tool; (4) Record summary of measure elements; and (5) Note relevant comments.

Analysis

Across all testing sites, medical charts were reviewed for 141 pediatric patients aged 6 – 42 months. See Patient Characteristics Tables Overall and By Site in Attachment 6A.3 Table 1. Performance and reliability results can be found in Attachment 6A.3 Tables 2-3. For reliability, we report the overall agreement and kappa statistics based on two independent reviews of the medical charts. Overall, agreement across the four testing sites (93.6 percent) and kappa (kappa=0.87) for the use of a validated tool was high, but the agreement and kappa for the measure Follow-up with Patient Family after Developmental Screening was somewhat lower (73 percent; kappa=0.42), primarily due to the drop-off in charts meeting the denominator criteria for this measure leading to a smaller N for analysis.

For overall measure performance, approximately 60 percent of the providers used a validated tool meeting the denominator criteria. In approximately 64 percent of these cases, it was noted in

the chart that the clinician discussed the results with the patient's family. Overall, 38 percent (60 percent x 64 percent) of charts indicated both that the provider used a validated tool and that the clinician discussed the results with the patient's family. Only approximately 39 percent of those children who had a positive developmental screen received a follow-up referral, and referral tracking was performed for only approximately 36 percent of the small proportion of those who received a referral. See Attachment 6A.3 Table 4.

There was considerable cross-site variability for this measure. Performance ranged from 83 percent to approximately 20 percent. See Attachment 6A.3 Table 4.

eMeasure Testing

Testing Sites

Based on feasibility testing (See Section 8 for more detail), Children's Hospital of Philadelphia (CHOP) and Ashe Pediatrics were the only two sites able to implement the measures in their EHR systems. CHOP performed feasibility testing in their fully electronic system by attempting to implement this measure, while Ashe Pediatrics participated in parallel forms reliability testing.

CHOP's EHR System

CHOP started using a customized electronic system for developmental screening in 2011, and use now extends across practices in 13 counties and early intervention programs in Pennsylvania and New Jersey with approximately 42,000 developmental screens completed each year. Screenings at well-visits are completed by the parent, and the clinician is presented with a summary score as well as full responses to each item in the chart. When relevant, tailored decision support tools will also appear.

In order to test whether the Electronic Health Record (EHR) contained documentation of a discussion between a clinician and parent about developmental screening results, CHOP randomly selected 20 records for patients who had completed developmental screening between July 2011 - April 2014. Results indicated that CHOP does not have a structured data field to capture discussion with the patient's family, specifically about the developmental screening results or whether a discussion with family/guardian occurred. CHOP also expressed concern that even a drop down menu or checkbox in the EHR would not indicate the quality of the discussion.

ASHE Pediatrics

Ashe Pediatrics is a small private practice in North Carolina with a highly customized EHR based on eClinicalWorks. Ashe Pediatrics is a Level III Medical Home and provides vaccines and hearing, vision, and developmental screenings for well child care check-ups. They also offer premier care for children and youth with special health care needs, attention deficit hyperactivity disorder, and other chronic illnesses.

As feasibility testing indicated that this measure was technically feasible in Ashe Pediatrics' EHR system, this site performed parallel forms reliability testing where a computed assessment of the measure was compared against manual chart reviews. Ashe Pediatrics implemented this

measure in their EHR using an electronic algorithm which computed the measure automatically and generated a performance report on a sample of patients. At the same time, a trained chart abstracter performed manual chart reviews on the same patients. Manual chart abstraction was then compared to the automated data abstraction to determine how reliably the overall measure and individual measure elements were calculated.

A total of 224 developmental screens (117 unique patients) were identified in the time period of January 2013 – December 2013 and were abstracted both manually and electronically. While this eMeasure was considered technically feasible after feasibility testing at this site, parallel forms reliability testing indicated that the while there is a queriable field in the EHR indicating whether a discussion with the patient's family has occurred, it is not routinely used. Thus, this eMeasure was deemed not feasible, and parallel forms reliability could not be assessed.

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).

Manual Chart Abstraction

The data collected through the manual chart abstraction in the primary care networks of the CPQSC were also used to assess the accuracy of the performance score and the validity of the measure. Direct inspection of the data was performed to determine that each of the elements of the measure could be abstracted from the charts. The data were reviewed to look for missing data or other irregularities in the data and to assess the accuracy of the data and the validity of the resulting overall performance score.

Results

The elements of the Follow-up with Patient Family after Developmental Screening measure are generally documented in the charts when done. Clinical performance on this measure is consistent with the literature reports of the results overall and across sites, given the sites' characteristics (American Academy of Pediatrics, 2006; Bethell, Reuland, Schor, et al., 2011; Coker, Shaikh, Chung, 2012; Jennings, Hanline, 2013; Jiminez, Barg, Guevara, et al., 2012; NCINQ, 2011). See Attachment 6A.3 Tables 1-4.

Public Comment

In fall of 2013, the three Developmental Screening Follow-up measures went through an online public comment process. Prior to the Public Comment Period, members of the PMCoE Developmental Screening Follow-up Expert Workgroup were asked to identify organizations and individuals who could provide valuable feedback on the measures. Materials were provided to these groups, and they were asked in turn to pass along the materials in order to elicit views and comments from a comprehensive and broad range of stakeholders. Stakeholders were notified

and requested to participate through an email that included a link to the measures and the online survey. Participants were provided with some background information on the AHRQ-CMS CHIPRA PMCoE and the Pediatric Quality Measurement Program and then were asked to review the descriptions of each of the measures. Comments were requested specifically on any or all of the following aspects of the measures: importance, feasibility, consistency with current organizations' practices, and additional evidence for consideration. A total of 185 stakeholders started the public comment survey, and 108 stakeholders reviewed and commented on the developmental screening follow-up measure set. Please see Attachment 6B.1 for a summary of participants.

Feedback received during public comment was then analyzed by the PMCoE Developmental Screening Follow-up Leadership Team. Results on a scale of 1 (not important) to 9 (extremely important) were aggregated for the domains of importance, feasibility, validity, and clinical relevance. Please see Attachment 6B.2 for histograms of the validity and clinical relevance domains.

Comments were initially sorted by measure and by domain. Then, comments were analyzed thematically and sorted according to the identified themes. For this measure, themes included: measure setting, feasibility, EHR configurations, validity- quality of discussion, timeframe concerns, definitional changes, and denominator exceptions. This allowed the Leadership Team and Expert Workgroup to identify key stakeholder concerns and then to address the concerns by updating and refining the measure as necessary.

Results

On a scale of 1 (not important) to 9 (extremely important), 55.37 percent of the stakeholders who commented on Developmental Screening Follow-up, Measure 1 - Follow-up with Patient's Family after Developmental Screening, responded that the measure was extremely important. Further, over 90 percent of the participants gave the measure a score of 7 or higher, indicating that this measure is viewed as important among stakeholders in this topic area. Nearly 77 percent of the participants provided a validity score of 7 or higher, and 89 percent provided a score of 7 or higher in the clinically relevant category, reconfirming that this measure does accurately capture the targeted concepts and is applicable to developmental screening and follow-up care.

Participants were also provided with a free text comment box in which they could express their comments on the measure and suggest any changes. Some excerpts that speak to the validity of the measure include:

"While we encourage our health care providers to acknowledge all developmental screening results with families and would hope that is carried out as part of the current CMS/AHRQ measure, we applaud this effort to ensure that all results are discussed with families."

"Considered a highly clinically relevant and important measure."

"I think this measure is a wonderful measure to emphasize the importance of this issue and to ensure the development of standardization about the measure."

"I feel that it is very important that families receive this information in real time – during the same visit."

"I think that the current developmental screening measure (whether screening is done or not) does not necessarily encourage that developmental screening be a component of developmental promotion... this measure helps to move toward appropriate integration of developmental screening into anticipatory guidance and developmental promotion – which is in line with the spirit of the AAP policy statement on developmental screening."

The primary concern regarding the validity of this measure is the quality of the discussion between parent/guardian and clinician and whether having a clinician check a box in an EHR that a discussion occurred actually indicates that a discussion occurred. The Leadership Team discussed this and concluded that while it may be nearly impossible to evaluate the quality of a discussion between a parent/guardian and a clinician, adding elements to the EHR, like a checkbox to indicate that a discussion occurred, will hopefully facilitate a change in workflow so that clinicians will have a conversation with the guardian at the same visit as a developmental screen. In this way, this measure could drive change in the way care is provided to children.

References

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Coker TR, Shaikh Y, Chung PJ. Parent-reported quality of preventive care for children at risk of developmental delay. Acad Pediatr 2012; 12(5):384-90.

Jennings DJ, Hanline MF. Developmental screening referrals: child and family factors that predict referral completion. Topics Early Child Spec Educ 2013; 33(2):102-11.

Jimenez ME, Barg FK, Guevara JP, et al. Barriers to evaluation for early intervention services: parent and early intervention employee perspectives. Acad Pediatr 2012; 12(6):551-7.

National Collaborative for Innovation in Quality Measurement Center of Excellence (NCINQ). Developmental screening in children. 2011. Developed by NCINQ for use in the AHRQ PQMP Consortium; unpublished.

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

The first developmental screening follow-up measure – Follow-up with Patient Family after a Developmental Screen – was tested in four of the Chicago Pediatric Quality and Safety Consortium Sites by manual chart review. Across all sites, 32.14 percent of the population was white, 30.71 percent was black, 14.29 percent was Hispanic, 7.86 percent was other, and 15.00 percent was unknown. Please see Attachment 7A.1 for Table 1 Demographic Information.

In order to meet the denominator criteria of this measure, a validated screening tool must be administered during a developmental screening. Across all sites, over 90 percent of white patients were screened with a validated screening tool. In stark contrast, only approximately 17 percent of black patients and 52 percent of Hispanic patients were screened using a validated tool. This disparity is further pronounced when looking across sites, as one site, Site D, has a predominantly black patient population and rarely uses a validated screening tool; it has reporting rates as low as 16.5 percent for white patients, 8.5 percent for black patients, and 20 percent for Hispanic patients. Please see Attachment 7A.1 for Table 2 Use of a Validated Tool by Race.

As for measure performance, across all sites, approximately 76.5 percent of white patients, 42 percent of black patients, and 55 percent of Hispanic patients met the measure. Please see Attachment 7A.1 for Table 3 Follow-up with Patient Family after Developmental Screening – by Race/Ethnicity. Our results are supported by AHRQ's National Health Care Disparities Report, 2013 that reports in 2011 and 2012, black children and Hispanic children had lower rates of well-child visits compared with their white counterparts (AHRQ, 2013). If children are unable to attend well-child visits, they are unlikely to receive a developmental screening administered with a validated screening tool. Further, even with access to care, developmental screening in the pediatric setting with a standardized tool is only close to 50 percent. The American Academy of Pediatrics in a Technical Report on racial and ethnic disparities concluded that racial/ethnic disparities in children's health and health care are extensive, pervasive, and persistent and occur across the spectrum of health and health care (Flores, 2010).

References

Agency for Healthcare Research and Quality. National Healthcare Disparities Report, 2013. Available at http://www.ahrq.gov/sites/default/files/publications/files/2013nhdr.pdf. Accessed July 12, 2016.

Flores G. Technical report: racial and ethnic disparities in the health and health care of children. Pediatrics 2010; 124(4):e979-e1020.

7.B. Special Health Care Needs

The performance of this measure was not assessed for children with special health care needs.

7.C. Socioeconomic Status

Across all testing sites, 64.29 percent of patients used Medicaid, 32.14 percent of patients used private insurance, and insurance data were missing for 3.57 percent of patients. Please see Attachment 7A.1 for Table 1 Demographic Information.

In order to meet the denominator criteria for this measure, a validated screening tool must be administered during a well-child visit. Across all testing sites, approximately, 41.76 percent of Medicaid users were screened using a validated tool, while nearly 98 percent of patients using private insurance were screened with a validated tool. The site-specific data are included in Attachment 7C.1, Table 1 Use of a Validated Tool by Insurance Status.

As for measure performance, approximately 45 percent of Medicaid users met this measure, indicating that they had both a developmental screen using a validated screening tool during a well-child visit and that their clinician discussed screening results with the patient's family and/or guardian. In contrast, approximately 86 percent of private insurance users met this measure. Please see Attachment 7C.1, Table 1 Follow-up with Patient Family after Developmental Screening – by Insurance Status.

7.D. Rurality/Urbanicity

All testing sites are located in the Chicagoland area; therefore, the measure performance was not tested by rurality/urbanicity.

7.E. Limited English Proficiency (LEP) Populations

Across all testing sites, the majority of patients were English-speaking (95.74 percent). Please see Attachment 7A.1, Table 1 Demographic Information.

In order to meet the denominator criteria for this measure, a validated screening tool must be administered during a well-child visit. Across all sites, approximately 59 percent of English-speaking patients and 67 percent of non-English-speaking patients received a developmental screen using a validated screening tool. While it may appear that non-English-speaking patients were more likely to be screened using a validated tool, this result is primarily driven by the low rates of validated tool use at Site D as in all other sites, non-English-speaking patients were as likely or less likely to receive a developmental screening using a validated screening tool. Please see Attachment 7E.1, Table 1 Use of a Validated Tool by Language.

As for measure performance, approximately 69 percent of patients whose primary language is English met the measure, while 62.5 percent of non-English-speakers met this measure. Please see Attachment 7E.1, Table 2 Follow-up with Patient Family after Developmental Screening – by Language. Our results are supported by an American Academy of Pediatrics (AAP) Periodic Survey of Fellows, which reported that while health literacy is not limited to immigrant families, developmental screening, referral, and follow-up can certainly be much more difficult in the context of language proficiency issues and health literacy fellows (American Academy of Pediatrics, undated).

Reference

American Academy of Pediatrics. Periodic survey of fellows #86. August 2013 – 2014. Available at http://www.aap.org/en-us/professional-resources/Research/pediatrician-surveys/Pages/Periodic-Survey-of-Fellows.aspx. Accessed July 12, 2016.

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?

eMeasure Feasibility Testing – Electronic Health Record Systems

The PMCoE Team conducted a national search through the networks and suggestions of the PMCoE Developmental Screening Follow-up (DSF) Expert Workgroup for practices with EHRs that would have the elements of this measure in structured fields to test this eMeasure for public use.

Twelve networks comprising 52 sites overall were recommended for assessment. Of these, seven networks could feasibly or nearly feasibly construct the measures in the Developmental Screening Follow-up measure set. Systems that had the necessary elements for the measures were either eClinicalWorks or individually customized EHR systems. Of the seven sites, two sites – the Children's Hospital of Philadelphia (CHOP) and Ashe Pediatrics – were capable of performing feasibility testing. We also performed feasibility testing in the Chicago Pediatric Quality and Safety Consortium.

eMeasure Testing - Chicago Pediatric Quality and Safety Consortium

The primary care networks in the Chicago Pediatric Quality and Safety Consortium (CPQSC) include: Mount Sinai Children's Hospital, Advocate Children's Hospital – Park Ridge, Advocate Children's Hospital- Oak Lawn, John H. Stroger Hospital, and Lurie Children's Hospital. The EHR vendor systems assessed were Epic, Cerner, and Allscripts TouchWorks. Some important data elements required to calculate this measure do not exist in structured data fields in CPQSC site EHRs at this time. It is therefore not possible to calculate this measure electronically using only structured data fields from the EHRs of these test sites.

eMeasure Testing - Children's Hospital of Philadelphia

CHOP started using an electronic system for developmental screening in 2011, and use now extends across practices in 13 counties and early intervention programs, with approximately 42,000 developmental screens completed each year. Screenings at well visits can be completed by the patient's family. The clinician is presented with a summary score as well as full responses to each item in the chart. To test the feasibility to construct this eMeasure in the CHOP EHR,

CHOP randomly selected 20 patient records with a developmental screening between July 2011 and April 2014. The CHOP EHR system was able to construct a measure of performance for this measure. They found that providers are allowed to choose from a discrete menu of options if a child does not pass a screening test, but any additional information about the screening or next steps to be taken are recorded as free text in the notes field.

eMeasure Testing - Ashe Pediatrics

Ashe Pediatrics, a private practice in North Carolina with a customized EHR system based on eClinicalWorks, also completed feasibility testing. See the Data Element Table (DET) tool used for data collection (Attachment 8A.1, DET example).

A discussion of test site capabilities to calculate the measure are summarized in Attachment 8A, Tables 8.1 and 8.2. Standard demographic data elements including race, gender, ethnicity, preferred language, and payer are currently captured in structured data fields at all sites. The denominator elements "birth date" and "encounter" are stored as structured variables. However, some important data elements required to calculate this measure do not exist in structured data fields in this site's EHRs at this time. It is therefore, not possible to calculate this measure electronically using only structured data fields from the EHRs of these test sites. These structured, queriable fields exist in the Ashe Pediatrics EHR and therefore, it is technically possible to calculate this measure electronically using only structured data fields.

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?

Important data elements required to calculate this measure do not exist in structured data fields in CPQSC site EHRs at this time. For example, the denominator element "positive developmental screening result" and the corresponding date are not captured as a structured variable at any of the test sites. While developmental screening can be identified with CPT code 96110 at each test site, none of the sites have structured fields to indicate administration of an acceptable developmental screening tool for this measure. If a developmental screening tool is administered at a site, the results are scanned into the EHR systems, but there is no structured data field indicating whether or not the screen was positive. In addition, the numerator element "discussion" of a screening result is documented using free text, generally in the notes field.

Recommendations for changes to future EHR systems include the following:

- 1. All sites should administer a developmental screening tool to patients, preferably electronically rather than paper-based so that the results could be more easily incorporated into the EHR.
- 2. Each site should have a structured data field within the EHR that stores a dichotomous variable (e.g., "positive" or "negative") indicating the results of the screen and the corresponding date.

- 3. Each site should have a structured data field within the EHR that stores a dichotomous variable (e.g., "true" or "false") indicating whether or not the provider discussed the results of a developmental screen with the patient's parents/caregiver.
- 4. A structured field for the date the discussion occurred.
- 5. Sites capable of free text searches using natural language processing (NLP), such as Lurie Children's Hospital, may be capable of extracting the necessary data elements with NLP. Sites for which NLP techniques cannot be implemented will require workflow modifications or changes to the EHRs. See the Recommendations to Vendors Table Attachment 8A.2.

While this measure was technically feasible in Ashe Pediatrics' EHR, through reliability testing, it became apparent that while a structured, queriable field exists for documentation of the occurrence of a discussion with a patient's family, it was not in use at the time of testing. To improve implementation feasibility at this site, workflow changes are necessary such that clinicians will use this structured field to document when a discussion with a patient's family occurs.

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.

The Developmental Screening Follow-up Measure - Follow-up with Patient Family after Developmental Screening, as specified by the PMCoE Developmental Screening Leadership Team and Expert Technical Panel, is in use in the American Board of Pediatrics (ABP) Maintenance of Certification (MOC) – Part 4, Performance Improvement Module (PIM) for use by physicians in the process of Re-Certification.

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?

Pediatric physicians must conduct a PIM in the process of Re-Certification and can elect to conduct 100 chart reviews using the Developmental Screening Follow-up with Patient Family after Developmental Screening measure specifications, assess their own performance, implement improvement, and conduct 100 post chart reviews to assess improvement. This is then entered into the ABP MOC PIM electronic system.

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

The ABP found this measure to be an effective and usable measure within the structure of the MOC PIM for physician Re-Certification.

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? No.

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

Not available at this time.

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?

There are no unintended consequences for reporting this measure if the data are accurate. For State programs that do not reimburse for CPT code 96110, which indicates that a validated developmental screening tool was used, it may be difficult to identify the accurate denominator population if physicians use this code in the medical record to indicate that an appropriate screening tool was used. Thus, eligible patients could be left out of the denominator.

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? No.

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

Not available at this time.

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 available.

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? No.

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

Not available at this time.

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?

There are no unintended consequences for reporting this measure if the data are accurate. For State programs that do not reimburse for CPT code 96110, which indicates that a validated developmental screening tool was used, it may be difficult to identify the accurate denominator

population if physicians use this code to indicate in the medical record that an appropriate screening tool was used. Thus, eligible patients could be left out of the denominator.

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? No.

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

Not available at this time.

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?

There are no unintended consequences for reporting this measure if the data are accurate.

Provider Level

Individual practitioner: Can compare individual health care professionals

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? No.

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

Not available at this time.

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?

There are no unintended consequences for reporting this measure if the data are accurate.

Provider Level

Hospital: Can compare hospitals

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

No.

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

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

Not available at this time.

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

Reliability & Validity: Is there published evidence about the reliability and validity of the measure when reported at this level of aggregation?

No.

Unintended consequences: What are the potential unintended consequences of reporting at this level of aggregation?

Not applicable.

Provider Level

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

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

Yes.

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

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

Not available at this time.

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?

There are no unintended consequences for reporting this measure if the data are accurate.

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).

Public Reporting

This measure is based on guideline-recommended practice (American Academy of Pediatrics, 2009; National Center for Medical Home Implementation, Web site) and modeled on elements of the well-respected American Academy of Pediatrics (AAP), Bright Futures national initiative and the Health Resources and Services Administration (HRSA), Maternal and Child Health Bureau (MCHB) Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) Program (American Academy of Pediatrics, Bright Futures; Health Resources and Services Administration, EPSDT). In addition, the measures in the Developmental Screening Follow-up measure set are being developed for implementation and use in two State Medicaid/CHIP Programs (North Carolina and Pennsylvania). Developmental Screening Follow-up and particularly the Follow-up with Patient's Family after a developmental screening is a fundamental aspect of pediatric practice. It is easy for both clinicians and the patient's family to understand the rationale and importance for the patient's clinician to inform the family of the screening results and provide standard anticipatory guidance based on the results or, in the case of a concerning result, discuss the next steps to address the concern.

This measure can be used to provide transparency regarding comparative best, evidence-based pediatric practice for the child and his or her family and provide a measure of accountability for payers, purchasers, and States. Because this measure and the two other measures in the Developmental Screening Follow-up measure set are focused on such a fundamental aspect of primary care pediatrics, these may represent a proxy for general pediatric primary care quality.

This measure is meant to be used to calculate performance and/or reporting at the practice, institution, health plan, State, regional, and national levels.

The results from a broad range of stakeholders (N=108) through Public Comment regarding this measure indicate that the measure is Important, Valid, and Clinically Relevant. See Attachment 6B.2.

Performance Improvement

Performance measurement serves as an important component of a quality improvement strategy. This measure can be used appropriately for performance measurement directed at improving the frequency of evidence-based follow-up with the patient's family after a developmental screening. These measures can provide critical information to direct improvement, as they are linked directly to specific guideline-recommended processes for developmental screening follow-up and operational steps that clinicians can apply in pediatric primary care practice to improve care.

References

American Academy of Pediatrics. Bright Futures: Practice Guides and Other Resources. Accessed on August 26, 2014. Available at http://brightfutures.aap.org/practice_guides_and_other_resources.html. Accessed July 20, 2016.

American Academy of Pediatrics. Developmental screening in early childhood systems: summary report. Oak Grove, II: American Academy of Pediatrics; 2009. Available at http://www.healthychildcare.org/pdf/DSECSreport.pdf. Accessed July 13, 2016.

Health Resources and Services Administration, Maternal and Child Health Bureau. EPSDT & Title V Collaboration to Improve Child Health. Available http://mchb.hrsa.gov/maternal-child-health-initiatives/mchb-programs/early-periodic-screening-diagnosis-and-treatment. Accessed July 20, 2016.

National Center for Medical Home Implementation. Website. Developmental/Behavioral Screening. Oak Grove, IL: American Academy of Pediatrics. Available at http://www.medicalhomeinfo.org/how/clinical_care/developmental_screening/. Accessed July 13, 2016.

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.

Health IT could be helpful in resolving challenges with assessment of performance for the measures of developmental screening follow-up. Because of the structure and uneven use of administrative claims codes related to developmental screening (CPT code 96110) and the absence of codes in administrative claims for other critical elements of developmental screening follow-up, we looked to the electronic health record (EHR) as a source to capture the necessary

elements to assess performance of evidence-based recommended follow-up across the Developmental Screening Follow-up quality measure set.

11.A. Health IT Enhancement

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

Health IT could be helpful in resolving three issues with construction of the measure in the EHR. The issues are related to the denominator element "developmental screening tool" and the numerator element "discussion" of the results of the screen. First, when a child receives a screen, four structured data elements could be captured by the EHR: (1) the screening tool name (perhaps from a drop-down list of approved screens), (2) the CPT code for a developmental screen (96110), and (3) a well-child visit code (CPT 99381, 99382, 99391, 99392, or 99432; ICD-9CM V20.2, V70.0, V70.3, V70.5, V70.6, V70.8, or V70.9). A fourth structured element with a standardized drop-down menu regarding the results of the screen would enable the stratification of the follow-up discussion by the results of the screen. Second, knowing the name of the administered screening tool would enable assessment of whether an appropriate validated tool was used and allow providers to make more informed decisions during future encounters should there be a developmental concern. Third, a discussion of the results of a developmental screen could be more effectively documented by capturing and structuring two pieces of information: (1) a simple dichotomous variable indicating whether a discussion with a parent/caregiver occurred, and (2) a drop-down list of topics discussed (e.g., strengths and concerns, specific domains, activities to promote development, and community resources). A summary of these issues appears in Attachment 8A.2.

11.B. Health IT Testing

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

Yes.

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

Feasibility testing for construction of this measure was conducted using three EHR vendor systems (Cerner, EPIC, Allscripts TouchWorks, and eClinicalWorks) and a self-developed system. It was determined that of these four systems, only eClinicalWorks has the necessary elements for the construction of Developmental Screening Follow-up Measure 1 - Follow-up with Patient Family after Developmental Screening. Further detail is given in Section 8 and Table 8.1.

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 Health IT workflow for this measure could be enhanced in several ways (see Attachment 8A.2 for a summary). One is to create a prompt function within the EHR that could notify providers if a child in a designated age range did not have a screen associated with their previous visit. This would help to correct oversights and keep the child on the proper care schedule.

Another way to improve workflow and prevent oversight involves the discussion. If a screen was performed at the current visit, a prompt could appear before the end of the visit urging the provider to discuss the screening results with the child's parent/caregiver. Another option would be for discussion options to appear in a prompt after the completion of the screen. In addition to including prompts to enhance workflow, it would be helpful to the providers to include reporting functions in the EHR for provider summary statistics related to this measure. Allowing providers to generate a report of children by age who have received a screen and those who have not would quickly identify potential workflow or care quality issues. Further, a report on the rate of discussions of screens and the date on which they occurred would remind providers to share information with parents/caregivers and listen to their concerns. Of course, to be effective these workflow modifications should fit well with current practices and not significantly increase the time the provider takes to enter information into the EHR, since complicating the information entry tends to decrease the amount of time the provider spends conversing with the patient, parent, or caregiver.

11.D. Health IT Standards

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

No.

If yes, please describe.

11.E. Health IT Calculation

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

Two of the elements for this measure ("birth date" and "encounter") were identifiable and encoded as structured data in the EHR systems of each of our test sites. We are confident that these two elements will exist as structured data in the majority of EHR systems. The biggest concern regarding the calculation of this measure is that the two remaining elements ("developmental screening tool" and "developmental screening tool, date") will not be captured in structured data fields.

There are two potential issues. The first is the ability to determine whether a screen was administered. This element may not exist in many EHR systems. The second issue is determining the type of screen administered. We have identified a group of acceptable screens (Ages and Stages Questionnaire (ASQ), 2 months – 5 years, Battelle Developmental Inventory Screening Tool (BDI-ST), birth – 95 months, Bayley Infant Neuro-developmental Screen (BINS), 3 months – 2 years, Brigance Screens-II, birth – 90 months, Child Development Inventory (CDI), 18 months – 6 years, Child Development Review-Parent Questionnaire (CDR-PQ), 18 months – 5 years, Infant Development Inventory, birth – 18 months, Parents' Evaluation of Developmental Status (PEDS), birth – 8 years) that are capable of measuring general development in our patient population. However, while Lurie Children's uses their own set of questions built into their EPIC EHR implementation, none of our test sites currently use any of these screening tests. Without

the use of standardized screening tests, the measure may produce inconsistent results. We would therefore recommend that sites adopt the use of one or more of these approved screens.

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).

eMeasure Limitations

The slow diffusion of the use of EHRs in pediatrics provides a limitation for the implementation of eMeasures. EHRs were not designed with pediatric patients in mind, as they were modified from records designed for billing in adult medicine and therefore were not designed to prioritize pediatric-focused care. As more pediatric practices are using EHRs, practices are beginning to customize their EHR systems in order to collect and report on fundamental aspects of pediatric care such as Developmental Screening and Developmental Screening Follow-up. Cerner and Epic, which have large proportions of the EHR market share do not have structured fields for discussion of the results of a developmental screen with the family. The EHR system used at CHOP which was customized for the purpose of collecting information about developmental screening and follow-up also does not have this structured field. This field was omitted because they were concerned that it would not reflect the quality of the discussion, which is also an important consideration ,as a clinician might check it whether or not a discussion took place if it was tracked as a quality metric. A limitation of this measure is that is does not reflect on the quality of the discussion with the family. This measure was not able to be constructed as an eMeasure in the CHOP EHR at this time.

This measure can technically be constructed in the eClinicalWorks EHR system and in several practices in Pennsylvania and North Carolina with EHR systems customized through a CHIPRA State demonstration grant. The construction of this measure was tested as an eMeasure in the EHR system of Ashe Pediatrics, a single practice in a statewide network of practices. While there is a structured, queriable field in the Ashe Pediatric EHR (technical feasibility), this field is not used by clinicians to document the discussion of the results of the developmental screen with the patient's family. Therefore, this eMeasure does not pass implementation feasibility and cannot be constructed at this time. Other large progressive practices with EHR systems are customizing their systems to make this measure implementable in their systems. We have also provided feedback to the Pediatric EHR developers on elements for inclusion needed to construct this critically important and fundamental aspect of pediatric practice quality measurement.

State Medicaid and CHIP programs do not have repositories built to receive and store this type of measure information; however, quality representatives at several State Medicaid and CHIP programs have told us that having eMeasures specified for important quality measures that cannot be assessed through administrative claims is very important in order to inform the development of such repositories.

Chart Review Measure Limitations

There is one primary limitation of this measure: most State Medicaid and CHIP programs find chart review as a method for quality assessment too challenging and burdensome and therefore do not use measures specified for manual chart abstraction. However, since all aspects of Developmental Screening Follow-up are such critical and fundamental aspects of pediatric care that lead to considerable morbidity and costs if not performed appropriately, there are no appropriate administrative codes by which to assess developmental screening follow-up, and only a few EHR systems can construct the measure as an eMeasure, manual chart review is the only current option for most practices. This will change quickly over the next few years, particularly if assessment of developmental screening follow-up becomes used for public reporting of pediatric care quality.

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.

Background

In 2009, Congress passed the Children's Health Insurance Program Reauthorization Act (CHIPRA, Public Law 111-3), which presented an unprecedented opportunity to measure and improve health care quality and outcomes for children. As part of this law, the CHIPRA Pediatric Quality Measures Program (PQMP) was developed to establish a set of measures to effectively assess the quality of pediatric care. An Initial Core Set of 25 pediatric measures was developed for recommended use. The Pediatric Measures Center of Excellence (PMCoE) was funded by AHRQ and assigned to develop and test Developmental Screening Follow-up (DSF) quality measures.

Importance

Universal surveillance and screening is expected to include a discussion of the screening results with the patient's family (Coker, Shaikh, Chung, 2012). Discussion between the clinician and the patient's family after a developmental screen is just as important as the screen itself. In fact, the billing for screening includes the discussion of the results with the family. With high quality preventive care, which includes clear communication between the provider and the patient's

family, early identification and follow-up on developmental delays can be improved. The prevention guidelines for children (Bright Futures and the Periodicity Schedule) as included in the Affordable Care Act (ACA) clearly define the elements for developmental surveillance and screening (Jiminez, Barg, Guevara, et al., 2012). After screening, follow-up and referral are the next necessary steps. Documentation and measurement of the discussion with the patient's parents/caregiver are critical for appropriate interventions and outcomes. Federal law requires that Medicaid cover a comprehensive set of benefits and services specifically for children. Since one in three U.S. children under age 6 is eligible for Medicaid, EPSDT offers a very important way to ensure that young children receive appropriate health and developmental services (American Academy of Pediatrics, 2006).

Measure Development

A framework for DSF quality measurement was proposed and was modeled on the work of Bright Futures and pediatric quality measurement in North Carolina and Pennsylvania. This framework included a measure set of three measures: (1) Follow-up with Patient's Family after Developmental Screen; (2) Follow-up Referral after Positive Developmental Screen; and (3) Follow-up Referral Tracking. This measure framework was reviewed, enhanced, and refined by a Developmental Screening Follow-up Expert Workgroup of a broad range of stakeholders. See Attachment 13.1 for Expert Workgroup materials.

Across a Public Comment period, a broad range of stakeholders (108) reviewed and commented on the measures. The measures were considered Important, Valid, and Clinically Relevant. Based on comments, the measures were refined by the Expert Workgroup and finalized for testing. See Attachment 13.2 for the finalized DSF Measures Worksheets.

Measure Testing

Feasibility. Feasibility testing for construction as an eMeasure was performed in the CPQSC, and it was determined that the measure was not able to be constructed as an eMeasure in any of the five sites. A national search was performed to identify sites that could test the measure as an eMeasure. It was determined feasible to construct the measure in the EHRs of the CHOP EHR and in Ashe Pediatrics, one practice in a statewide network of practices that had customized their eClinicalWorks system with an electronic Developmental Screening Follow-up module.

Reliability. Manual chart abstraction was applied to assess the reliability of the measure. Across four sites where reliability testing was performed, the agreement was 73.03 percent, Kappa was 0.4224. Agreement was reasonable, but the Kappa was low do to the challenge of identifying appropriate charts.

References

American Academy of Pediatrics. Identifying infants and young children with developmental disorders in the medical home: an algorithm for developmental surveillance and screening. Pediatrics 2006; 118(1):405-20.

Coker TR, Shaikh Y, Chung PJ. Parent-reported quality of preventive care for children at-risk for developmental delay. Acad Pediatr 2012; 12(5):384-90.

Jimenez ME, Barg FK, Guevara JP, et al. Barriers to evaluation for early intervention services: parent and early intervention employee perspectives. Acad Pediatr 2012; 12(6):551-7.

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.

The signed written statement was submitted.

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