Overuse of Imaging: Policy for ALARA Specific to Imaging Children

Section 1. Basic Measure Information

1.A. Measure Name

Overuse of Imaging: Policy for ALARA Specific to Imaging Children

1.B. Measure Number

0243

1.C. Measure Description

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

This measure assesses the percentage of facilities with a policy for “as low as reasonably achievable” (ALARA) dosing of radiation, specific to the imaging of children. This measure was tested using information obtained from (1) self-reported use of a written policy to implement ALARA principles or specific protocols to reduce radiation exposure for computed tomography (CT) imaging of children and (2) published pediatric CT imaging accreditation information from the American College of Radiology (ACR).

Over the past two decades, significant advancements in multi-detector computed tomography (MDCT) technology have contributed to a substantial increase in the diagnostic applications and accuracy of CT imaging studies. Correspondingly, CT imaging can figure prominently in characterizing and facilitating treatment of a myriad of neurologic and oncologic-based childhood diseases. However, a major disadvantage of MDCT is the use of ionizing radiation and the prospect of increased risk for latent malignancies. Children who have multiple CTs in early childhood tend to be at greater risk for developing leukemia and related malignancies (Pearce, Salotti, Little, et al., 2012). Although the available evidence on the risks of low-dose radiation still remains a matter of discussion, it is generally believed that there is a “linear-no threshold” risk relationship (Nievelstein, van Dam, van der Molen, 2010). In other words, no dose of radiation is safe. Consequently, there is an overwhelming need to consider that any radiation used in the course of imaging has the capacity to cause secondary cancer.

Within this context, reducing the medical radiation dose and exposure to children as much as possible by performing imaging studies with radiation doses “as low as reasonably achievable” (that is, ALARA) continues to gain attention and prominence for pediatric imaging best practice (American College of Radiology [ACR], 2009). In particular, professional practice and patient advocacy groups, as well as international scientific organizations, have focused on MDCT radiation dose reduction and optimization strategies. These groups include the ACR, the American Academy of Neurology (AAN), and the American Academy of Pediatrics (AAP). The

ACR accredits facilities for different imaging modalities, CT being one of them. As part of achieving ACR accreditation, facilities should have a policy and imaging protocols in place stating that radiation exposure to patients will be as low as reasonably achievable and therefore is consistent with ALARA principles (ACR, 2014).

An even higher level of care is specified by the Image Gently campaign, in which facilities are accredited by the ACR in pediatric CT imaging and commit to imaging pediatric patients with appropriate radiation dose. Having ALARA policies with age and/or size-specific radiation doses programmed into CT scanners is the essential first step for following this best practice. Although imaging guidelines have been developed, published, and advocated by numerous professional organizations, many hospitals and imaging entities still do not apply ALARA-based dose reduction techniques for all varieties of pediatric imaging. With that in mind, the feasibility and validity of this measure was tested: The percentage of eligible facilities with a policy for "as low as reasonably achievable" (ALARA), specific to the imaging of children (numerator divided by denominator).

A higher percentage indicates better performance, as reflected by use of minimal radiation when imaging. This measure is intended to be used for assessing ALARA policies among CT imaging sites in a specific geographic jurisdiction; we tested this measure in a statewide setting (Michigan).

This measure was tested using an in-person telephone survey of lead CT technologists or medical directors at facilities indicating that they provide CT services to children. The provision of CT services to children was determined from State Certificate of Need (CoN) reports (Michigan CoN, 2012). ALARA protocol responses were validated through accreditation information published by the ACR (ACR CT Accreditation, 2014).

1.D. Measure Owner

The Quality Measurement, Evaluation, Testing, Review, and Implementation Consortium (Q-METRIC).

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

Not applicable.

1.F. Measure Hierarchy

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

1. **Please identify the name of the collection of measures to which the measure belongs (if applicable). A collection is the highest possible level of the measure hierarchy. A**

collection may contain one or more sets, subsets, composites, and/or individual measures.

This measure is part of the Q-METRIC Overuse of Imaging measures collection.

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

   Not applicable.

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

The numerator is the number of facilities that perform imaging of children with a policy for ALARA specific to the imaging of children in Michigan. Others may wish to test this measure at many different levels, including geographic units, hospital groups, hospital associations, and health plans that contract with specific hospitals

ALARA refers to the “as low as reasonably achievable” amount of radiation exposure for a given imaging study for a patient based on age and size. Facilities include all those that perform imaging of children, defined as a CT scan of any part of the body.

1.H. Numerator Exclusions

Facilities that do not image children younger than 18 years of age are excluded.

1.I. Denominator Statement

The denominator is the number of facilities that perform imaging of children younger than 18 years of age in Michigan. Others may wish to test this measure at many different levels, including geographic units, hospital groups, hospital associations, and health plans that contract with specific hospitals

1.J. Denominator Exclusions

Facilities that do not image children younger than 18 years of age are excluded.

1.K. Data Sources

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

Survey, healthcare professional report. In-person telephone survey.

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

Denominator: Michigan Certificate of Need Annual Survey Report: Computed Tomography (CT) Services Provided by Hospitals, Freestanding Facilities, and Host Sites (2012). Michigan CoN, 2012.

Numerator: American College of Radiology (ACR) Accreditation for Computed Tomography and Image Gently Supporters (ACR CT Accreditation, 2014).

Section 2: Detailed Measure Specifications

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

Please see the Supporting Documents for detailed measure specifications.

Section 3. Importance of the Measure

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

3.A. Evidence for General Importance of the Measure

Provide evidence for all applicable aspects of general importance:

- **Addresses a known or suspected quality gap and/or disparity in quality (e.g., addresses a socioeconomic disparity, a racial/ethnic disparity, a disparity for Children with Special Health Care Needs (CSHCN), a disparity for limited English proficient (LEP) populations).**

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

Importance

ALARA applications to pediatric imaging policies have gained importance as ionizing radiation has become increasingly relied upon for the diagnosis and characterization of a variety of diseases (Broder, Fordham, Warshauer, 2007; Dorfman, Fazel, Einstein, 2011). For both adult and pediatric patients, imaging has gained primacy and is in the vanguard of tools that clinicians use to understand a variety of pathologies.

With regard to ionizing radiation, there continues to be the prevailing notion of a "linear-no threshold" risk relationship in terms of radiation dose (Nievelstein, et al., 2010). This theory holds that any radiation dose is deemed incrementally harmful; excess cancer risks related to low-dose radiation are directly proportional to the dose (Lin, 2010). This model is used to extrapolate excess cancer risk at low doses from the known risk at higher doses (Lin, 2010). In general, this has meant that any radiation used in the course of imaging has the capacity to cause secondary cancer. This is especially concerning for children, who have more rapidly dividing cells and have a baseline increased risk compared with their adult counterparts. Within this context, there is a recurring need to be judicious with radiation dose and to consider the benefits of information obtained from imaging vis-à-vis risks of malignancy.

Baseline Considerations for ALARA: Prevalence and Incidence of Malignancy in Children

ALARA and its related application to pediatric imaging policies require an assessment of the prevalence and incidence of malignancy in the pediatric population. A review of the literature reveals that childhood malignancies have been increasing slightly for the past few decades but still account for less than 1 percent of all malignancies diagnosed each year (American Cancer Society [ACS], 2014). For 2014, this correlates to nearly 10,450 children in the United States under the age of 15 years receiving a diagnosis of malignancy (ACS, 2014). Despite a

malignancy rate of less than 1 percent, such cancers are the second leading cause of death in children in the United States (after injuries) (ACS, 2014). The ACS estimated that approximately 1,350 children younger than 15 years of age were expected to die from malignancy in 2014 (ACS, 2014).

To date, there is no definitive study or literature that reveals, in an absolute sense, the additional malignancy burden created by ionizing radiation used in the course of imaging children. However, it is widely understood that any reduction in radiation dose is beneficial and reduces harm to children (Lin, 2010). In a 2009 study, it was estimated that compared with a patient aged 40 years, the risk of cancer from a radiation imaging test is doubled for a patient aged 20 years and 50 percent lower for a patient aged 60 years (Smith-Bindman, Lipson, Marcus, et al., 2009).

Considering that malignancy is the second leading cause of death in children in the United States, ALARA policies should be incorporated as the standard-of-care for all pediatric imaging that makes use of ionizing radiation. This measure will reveal the percentage of facilities that have implemented ALARA policies for pediatric imaging, as well as the percentage that have gone the extra step to support the Image Gently campaign.

Overuse of Radiation Exposure in Imaging Related to Lack of ALARA Policies: Radiation Dose Pathology and Severity

Use of ionizing radiation-based imaging has increased substantially in recent years. The use of CT on older children nearly tripled from 1996 to 2005 to a peak of 27 CT scans per 1,000 children (Miglioretti, Johnson, Williams, et al., 2013). Radiation dose associated with CT-imaging introduces the possibility of chronic health risks related to malignancies sustained from radiation effects (ACR, 2009). CT-based radiation dose for pediatric patients is problematic because the developing cellular structures and tissues of children are significantly more radiosensitive than those of adults; children, therefore, will be at substantially elevated risk for malignancy (ACR Expert Panel on Pediatric Imaging, 2012).

Radiosensitive organs—including the brain, bone marrow, lens of the eye, and thyroid gland—can be exposed to radiation during CT of the head (Papadakis, Perisinakis, Oikonomou, et al., 2011). In children under 5 years of age, about 20 percent of the active bone marrow is in the cranium, compared with 8 percent in adults (Christy, 1981). Children who have multiple CT scans in early childhood tend to be at greater risk for developing leukemia (Pearce, et al., 2012).

While radiation reduction strategies are important, the emphasis should continue to be on avoiding unnecessary imaging altogether for maximal mitigation of harm. Some studies suggest that as many as a third of pediatric CT scans are unnecessary, and that eliminating them could potentially reduce the number of CT-attributable cancers by a third (Miglioretti, et al., 2013). Combining the two strategies — reducing the highest 25 percent of doses and reducing unnecessary scans — could potentially prevent 62 percent of the projected radiation-related cancers (Miglioretti, et al., 2013).

Performance Gap

Despite the availability of evidence-based guidelines for using ALARA policies while imaging children to reduce radiation dose, there is room for improvement in minimizing the radiation dose received (Shah, Platt, 2008). A universal means of tracking a patient's cumulative radiation dose would be ideal, especially if the patient has undergone exams that use ionizing radiation at more than one facility. Minimizing excess radiation dose via instituting ALARA policies consistently is the crucial gap to fill.

To promote safer imaging, the ACR and related organizations have undertaken concerted and specific efforts targeted at reducing the dose of radiation that children receive during CT imaging. These efforts have culminated in the Image Gently Campaign (https://www.imagegently.org/) launched in 2008. The goals of this campaign continue to include increasing understanding of the harms of excessive radiation dose, as well as promoting an ongoing initiative to reduce radiation dose and maintain image quality. These efforts continue via specific imaging policy and protocol-based maneuvers in radiology departments throughout the United States, as well as globally.

Facilities that complete the ACR pediatric CT imaging accreditation process incorporate the Image Gently criteria successfully and routinely into pediatric imaging practice. Incorporating and implementing ACR-specific dose reduction policies to receive accreditation certainly involves additional preparation and effort on the part of facilities seeking accreditation. However, these efforts accrue value in the form of quantifiable dose reduction to children. Facilities may meet the standards put forth by the ACR for CT accreditation and Image Gently without going through the additional time/cost of seeking formal accreditation.

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).**

CT Imaging and Medicaid/CHIP

This measure is relevant to Medicaid/CHIP because children with Medicaid/CHIP undergo CT imaging for a variety of indications. Likewise, facilities that image children are likely to encounter patients with Medicaid/CHIP coverage.

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).

We are unaware of any existing quality measures specific to minimizing radiation exposure for children undergoing imaging using CT. Facilities have been able to seek accreditation for CT through the ACR since 1987. Facilities are also able to obtain pediatric CT imaging accreditation by demonstrating their support for the ACR's Image Gently campaign.

Section 4. Measure Categories

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

Does the measure address this category?

a. **Care Setting – ambulatory:** Yes.
b. **Care Setting – inpatient:** Yes.
c. **Care Setting – other – please specify:** No.
d. **Service – preventive health, including services to promote healthy birth:** No.
e. **Service – care for acute conditions:** Yes.
f. **Service – care for children with special health care needs/chronic conditions:** Yes.
g. **Service – other (please specify):** No.
h. **Measure Topic – duration of enrollment:** No.
i. **Measure Topic – clinical quality:** Yes.
j. **Measure Topic – patient safety:** Yes.
k. **Measure Topic – family experience with care:** No.
l. **Measure Topic – care in the most integrated setting:** No.
m. **Measure Topic other (please specify):** No.
n. **Population – pregnant women:** No.
o. **Population – neonates (28 days after birth) (specify age range):** Yes; all ages in this range.
p. **Population – infants (29 days to 1 year) (specify age range):** Yes; all ages in this range.
q. **Population – pre-school age children (1 year through 5 years) (specify age range):** Yes; all ages in this range.
r. **Population – school-aged children (6 years through 10 years) (specify age range):** Yes; all ages in this range.
s. **Population – adolescents (11 years through 20 years) (specify age range):** Yes; adolescents 11 through 17 years of age.

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.

This measure assesses the percentage of facilities with a policy for "as low as reasonably achievable" (ALARA) dosing of radiation specific to the imaging of children. A higher percentage indicates better performance, as reflected by use of minimal radiation for CT imaging. Table 1 (see Supporting Documents) summarizes several key sources of evidence for this measure using the U.S. Preventive Services Task Force (USPSTF) rankings (criteria denoted in Table 1).

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.

Not applicable.

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.

The reliability of this measure was not separately tested; NQF guidance indicates that separate reliability testing of data elements is not necessary if data element validity testing is conducted as described in the next section (National Quality Forum [NQF], 2011).

6.B. Validity

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

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

The validity of this measure was determined from two perspectives: face validity and validity of the facility survey data in relation to accreditation information published online.

Face Validity

The face validity of this measure was established by a national panel of experts and parent representatives for families of children with headaches and seizures convened by Q-METRIC. The Q-METRIC panel included nationally recognized experts in the area of imaging children, representing general pediatrics, pediatric radiology, pediatric neurology, pediatric neurosurgery, pediatric emergency medicine, general emergency medicine, and family medicine. In addition, face validity of this measure was considered by experts in State Medicaid program operations, health plan quality measurement, health informatics, and healthcare quality measurement. In total, the Q-METRIC imaging panel included 15 experts, providing a comprehensive perspective on imaging children and the measurement of quality metrics for States and health plans.

The Q-METRIC expert panel concluded that this measure has a high degree of face validity through a detailed review of concepts and metrics considered to be essential to the appropriate imaging of children. Concepts and draft measures were rated by this group for their relative importance. This measure was very highly rated, receiving an average score of 9.0 (with 9 as the highest possible score).

Data and Methods

This measure was tested using an in-person telephone survey of staff members at facilities in Michigan indicating that they provide CT services to children. Indication of pediatric CT service capabilities was confirmed with State Certificate of Need (CoN) reports; ALARA protocol responses were validated through accreditation information published by the ACR.

We obtained the statewide universe of CT imaging facilities from the Michigan Department of Community Health (MDCH) Certificate of Need Annual Survey Report for CT Services Provided by Hospitals, Freestanding Facilities, and Host Sites (Michigan CoN, 2012). Facilities eligible to be surveyed were restricted to those that reported at least one pediatric head or body scan for children less than 18 years of age (Appendix; see Supporting Documents). CoN programs are designed to ensure that health facilities, services, and equipment match the needs of the population. In Michigan, facilities with CT scanners submit survey data in order to document sufficient utilization of the service to justify the location. Please note, at the time of measure testing, the 2012 annual survey was the most current report available.

The telephone survey was conducted among a convenience sample of facilities to determine if information could feasibly and accurately be obtained from facility staff. Respondents consisted of lead CT technologists or medical directors at each facility; the brief telephone survey asked whether their facility performed CT scans on pediatric patients younger than 18 years of age. Those responding 'yes' to this question were then asked: "Does your facility have a written policy to implement ALARA principles or specific protocols to reduce radiation exposure for CT imaging of children?" This question was followed by a brief set of questions to determine the number of different protocols to reduce radiation exposure during CT imaging in use at the facility for three body regions (head, chest, and abdomen/pelvis).

We employed a convenience sample of 65 facilities providing CT imaging, of which 40 facilities were affiliated with other sites within a larger healthcare organization. From this sample, we obtained completed surveys from 21 individual sites representing a total of 58 (30 percent) of the 194 facilities reported to conduct CT scans of children in Michigan. Among the surveyed staff at these facilities, 100 percent reported the presence of policies to implement ALARA specific to children who undergo a CT scan. Seven staff members provided answers to questions regarding the number of protocols, two of whom responded they were unsure. The range of the number of protocols by body region was 2 to 12 among respondents who provided a number.

Validity of Survey Data

Telephone survey responses were validated using data acquired from the ACR Accreditation website (ACR CT Accreditation, 2014).

Of the 194 Michigan facilities that performed CT scans of children in 2012, 49 percent were ACR accredited in 2014 for CT imaging, indicating that they had policies for ALARA. Additionally, 39 percent of the facilities were noted to support Image Gently, indicating a commitment to imaging pediatric patients with an appropriate radiation dose (Table 2; see Supporting Documents). It should be noted that all facilities (100 percent) supporting Image Gently were also ACR-accredited. Among the 58 facilities that reported ALARA policy

compliance via the telephone survey, 33 (57 percent) were verified as having ACR accreditation (which includes having an ALARA policy).

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 data obtained did not contain information related to the race/ethnicity of individuals undergoing imaging at the facilities evaluated.

7.B. Special Health Care Needs

The data obtained did not contain information related to the special healthcare needs of individuals undergoing imaging at the facilities evaluated.

7.C. Socioeconomic Status

The data obtained did not contain information related to the socioeconomic status of individuals undergoing imaging at the facilities evaluated.

7.D. Rurality/Urbanicity

Based on research conducted by Borders and colleagues, there is evidence that ALARA policies for pediatric CT imaging vary corresponding to the setting for the CT examination (Borders, Barnes, Parks, et al., 2012). In particular, there has been a documented statistically significant decrease in the estimated effective dose for CT studies performed in pediatric radiology departments compared with combined pediatric and adult radiology departments (Borders, et al., 2012). Facilities that have specialized pediatric radiology departments tend to be located almost exclusively in urban areas. This suggests that a child receiving care in an urban setting may have a higher likelihood of having access to pediatric-based ALARA CT practices compared with a child receiving care in a rural setting.

We did not have access to information regarding home addresses for pediatric patients undergoing imaging. However, we were able to consider the location of imaging facilities in terms of health service areas (HSA) in Michigan. We found that facilities in predominantly rural HSAs had lower proportions of ACR-accredited facilities and facilities that support the Image Gently campaign (Table 3; see Supporting Documents). Similarly, the proportions of pediatric

CT scans performed at ACR-accredited facilities and facilities that support the Image Gently campaign were lower in predominantly rural HSAs.

7.E. Limited English Proficiency (LEP) Populations

The data obtained did not contain information related to the primary language of individuals undergoing imaging at the facilities evaluated.

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?

This measure was tested at the statewide level using an in-person telephone survey of lead CT technologists or medical directors at facilities indicating that they provide CT services to children. Facilities to target for the survey were determined from Certificate of Need reports for the State of Michigan (2012), which indicated that 194 imaging facilities reported CT imaging of children (Michigan CoN, 2012). It should be noted that other States may not include CT imaging in their CoN reports or may not specifically indicate whether facilities conduct CT imaging for children.

The survey-based ALARA protocol responses were validated through accreditation information routinely published by the ACR (ACR CT Accreditation, 2014). Facilities were identified as having ALARA policies/protocols based on accreditation status as indicated on the ACR accreditation website.

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?

This measure was determined to be feasible by Q-METRIC using publicly available data for facilities with CT scanners used to image children in the State of Michigan. Based on testing of the telephone survey, it is recommended that future data collection efforts consider use of the web-based data sources employed in the Q-METRIC validation process as the primary data collection source. To minimize the potential for bias, future implementations may augment ACR accreditation data with telephone-based surveys targeting sites not represented in accreditation data.

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.

To our knowledge, this measure is not currently in use anywhere in the United States.

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

Not applicable.

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

Not applicable.

Section 9. Levels of Aggregation

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

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

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

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

State level* Can compare States

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

Data Sources: **Are data sources available to support reporting at this level?**
Survey data at the State Health Department level.

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

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

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

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

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?**
Survey data at the hospital service level.

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

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

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

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

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)**
No.

Data Sources: **Are data sources available to support reporting at this level?**
Not applicable.

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

Not applicable.

In Use: **Have measure results been reported at this level previously?**
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.

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?**
Survey data at the health plan level.

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

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

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

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

Provider Level
Individual practitioner: Can compare individual health care professionals

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

Data Sources: **Are data sources available to support reporting at this level?**
Not applicable.

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

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

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

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

Provider Level
Hospital: Can compare hospitals

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

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

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

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

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

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

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?**
Survey data at the health system or facility level.

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

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

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

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

Section 10. Understandability

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

This measure provides a straightforward means to assess if imaging facilities consider radiation reduction strategies for children who require CT imaging. Lack of attention to ALARA is easily understood to be unsatisfactory. The simplicity of the measure likewise makes it a straightforward guide for providers and purchasers to assess at which facilities children will be more likely to receive radiation doses during CT imaging that are as low as reasonably achievable. This measure has not been assessed for comprehension, although respondents did not indicate that the survey questions were unclear.

Section 11. Health Information Technology

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

11.A. Health IT Enhancement

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

Health IT provides a platform that can support three new uses of the measure. First, health IT can begin by showing radiation dose levels. Health IT also can provide education about alternatives to higher dose imaging. Alerts and reminders, given to patients as well as providers, might also enhance use.

11.B. Health IT Testing

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

No.

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

Not applicable.

11.C. Health IT Workflow

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

This information will be captured through order entry systems, as well as noted in structural fields in radiology notes. Structured information of this sort could then be totaled for each patient over a period of time.

11.D. Health IT Standards

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

Yes.

If yes, please describe.

The ONC's health IT standards explicitly address the receipt of CT imaging results and other diagnostic tests into EHRs, which may be relevant to determining ALARA policies in hospitals providing imaging services to children. The ONC standards include the following specific requirements in the Certification criteria (ONC, 2010) pertaining to Stage 2 Meaningful Use requirements:

Stage 2 (beginning in 2013): CMS has proposed that its goals for the Stage 2 meaningful use criteria expand upon the Stage 1 criteria to encourage the use of health IT for continuous quality improvement at the point of care. In addition, the exchange of information in the most structured format possible is encouraged. This can be accomplished through mechanisms such as the electronic transmission of orders entered using computerized provider order entry (CPOE) and the electronic transmission of diagnostic test results. Electronic transmission of diagnostic test

results includes a broad array of data important to quality measurement, and for this measure, specifically includes radiology studies such as CT imaging and the radiation dose delivered.

11.E. Health IT Calculation

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

Missing or ambiguous information in the following areas could lead to missing cases or calculation errors:

1. Lack of consistent radiation dose moderation strategy.
2. Possibly a scanned or electronic clinical document in the medical record.

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?

Health IT may enhance the use of this measure by providing real-time alerts for patients whose clinician has ordered a radiologic imaging test that may subject the patient to more or unnecessary radiation dose when a similarly effective alternative might exist. Health IT could display a warning about age and/or size-appropriate radiation dose policy at the point of care and use alerts and reminders to alert the clinicians that a child has had prior radiation exposure through CT imaging and at what dose. Health IT may also enhance the use of this measure by providing real-time alerts for patients with one or more chief complaints likely to trigger use of CT imaging. For example, a physician, nurse, or CT technologist seeing a patient with a chief complaint likely to prompt CT imaging can be alerted that the patient should receive imaging that makes use of ALARA policy.

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).

This measure assesses the percentage of facilities with a policy for “as low as reasonably achievable” (ALARA), specific to the imaging of children. The measure was tested by conducting a telephone survey of staff at facilities in Michigan that image children. The survey responses were validated by searching the ACR accreditation website, which represents a source of verified information. State-level data regarding pediatric CT procedures provided the denominator pool of facilities that image children.

Q-METRIC testing determined that this measure is feasible. However, several limitations were identified during our testing process:

Telephone Survey

- Validity testing was limited by not knowing the content of the ALARA policies based on survey responses. We were unable to determine if radiation exposure was actually reduced through the use of ALARA policies in facilities that did not seek ACR accreditation.
- Because many facilities enter their ALARA policies directly into their CT scanners and hold this information as proprietary, we were not able to directly assess the content of these policies.
- Some facility contacts did not know if they were ACR-accredited.
- Few staff provided a number of protocols for three common body regions imaged by CT – the head, chest, and abdomen/pelvis.
- While there were a small number of individuals completing the survey, many indicated they were able to provide responses for multiple facilities within the same health system. The accuracy of the information provided for these other facilities within the same health system was not assessed.
- Participation in the telephone survey was sometimes difficult for imaging facility staff members, as the phone calls often interrupted their day and conflicted with their workload.
- The telephone survey was subject to response bias.

Online Accreditation Information

- Some facilities that were not ACR-accredited reported following ALARA policies in the telephone survey. Thus, relying solely on the ACR website may underestimate the extent to which facilities follow ALARA policies, as this approach excludes sites that use ALARA policies without completing the ACR accreditation process.
- Occasionally, facilities would be ACR-accredited and/or have pediatric-specific accreditation/Image Gently certification and/or identify themselves in the phone survey as seeing children, yet be shown in State data as conducting only adult imaging studies. Reasons for this discrepancy may include (1) a time lag between the data published by the ACR and state website and (2) the possibility that facilities were more comprehensively accredited than their patient roster indicated for insurance or public relations purposes.
- The degree of detail provided by State Certificate of Need data may vary; in some cases, only aggregate data characterizing multiple facilities may be reported for some health systems. Consequently, distinguishing all distinct physical locations within a health system that furnish CT imaging services for children may not be possible.
- All data sources were as current as possible. However, information on the ACR website was presumed to be more current (2014) than the Michigan State Certificate of Need survey (2012).

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.

This measure, Overuse of Imaging: Policy for ALARA Specific to Imaging Children, assesses the percentage of facilities with a policy for "as low as reasonably achievable" (ALARA) dosing of radiation, specific to the imaging of children. This measure assesses the number of facilities that adhere to the computed tomography accreditation standards of the American College of Radiology and the number of facilities that support the pediatric Image Gently campaign.

Significant advancements in multi-detector CT technology have increased the diagnostic applications and accuracy of CT imaging studies for neurologic and oncologic-based childhood diseases. However, ionizing radiation is associated with an increased risk for latent malignancies. There is an overwhelming need to consider that any radiation used in the course of imaging has the capacity to cause secondary cancer. Within this context, reducing the medical radiation exposure to children to the extent possible by performing imaging studies with radiation doses "as low as reasonably achievable" (ALARA) is considered a pediatric imaging best practice. Facilities with ALARA policies with age and/or size-specific radiation doses programmed into CT scanners are taking an essential step to reduce the risk of latent malignancies in children. An even higher level of care is specified by the Image Gently campaign, in which facilities are accredited by the ACR in pediatric CT imaging and commit to imaging pediatric patients with appropriate radiation dose. Although imaging guidelines have been promoted widely, many hospitals and imaging entities still do not apply ALARA-based dose reduction techniques for all varieties of pediatric imaging.

Q-METRIC tested this measure among a total of 194 facilities that image children using primary data collected through in-person telephone surveys and published accreditation data. All of the sites (100 percent) responding to the telephone survey indicated the presence of an ALARA policy; 57 percent of these were confirmed with ACR accreditation data. Overall, 49 percent of the 194 facilities were accredited by the ACR, indicating that they have a policy and protocols in place stating that the radiation dose to patients will be as low as reasonably achievable. Additionally, 39 percent of the ACR-accredited facilities also had pediatric-specific CT imaging accreditation indicating a commitment to the Image Gently campaign by imaging pediatric patients with an appropriate radiation dose.

This measure provides a straightforward means of assessing if imaging facilities consider radiation reduction strategies for children who require CT imaging. The primary information needed for this measure comes from accredited facility search data from the American College of

Radiology and from State-level survey data on CT use in hospitals and freestanding facilities, both of which may be accessed through publicly available websites.

Continuing advances in the development and implementation of health IT may further support the aims of this measure by flagging imaging tests likely to subject patients to excessive or unnecessary radiation doses or by tracking cumulative radiation levels across procedures and facilities.

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Section 14: Identifying Information for the Measure Submitter

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

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

Public Disclosure Requirements

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

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