# CHIPRA Pediatric Quality Measures Program (PQMP) Candidate Measure Submission Form (CPCF)

The **C**HIPRA **P**ediatric Quality Measures Program (PQMP) **C**andidate Measure Submission **F**orm (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.

# Contents

# INTRODUCTION

In 2009, the Children's Health Insurance Program Reauthorization Act (CHIPRA) reauthorized the Children's Health Insurance Program (CHIP) originally established in 1997.[1] Title IV of the law included a number of provisions aimed at improving health care quality and outcomes for children. Section 401(a) of CHIPRA called for the identification of an initial core set of health quality measures for children enrolled in Medicaid or CHIP based on measures available in 2009. The initial core set[2] was recommended by the Agency for Healthcare Research and Quality (AHRQ) National Advisory Subcommittee on Children's Health Quality Measures for Medicaid and CHIP (SNAC), posted for public comment by the Secretary of the U.S. Department of Health and Human Services (HHS) on December 29, 2009, and made available for voluntary use by State Medicaid and CHIP programs in February 2011, along with technical specifications.[3]

Section 401 (b) of CHIPRA created the Pediatric Quality Measures Program (PQMP) to improve the initial core set of pediatric quality measures and increase the portfolio of evidence-based measures available to public and private purchasers of children's health care services, providers, and consumers. Improved core measures are to be posted annually beginning January 1, 2013. The PQMP is a partnership between AHRQ and the Centers for Medicare & Medicaid Services (CMS). As part of the PQMP, there are seven Centers of Excellence (COEs)—a consortium of academic institutions, State partners, consumers, and others—that will develop and test measures over the course of the program for categories specified by CHIPRA and topics identified by CMS and AHRQ.[4] In addition to the measures submitted by the COEs, public nominations for quality measures will be solicited in the spring of each year. All submitted

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1 Children's Health Insurance Program Reauthorization Act of 2009. Public Law No. 111-3, 123 Stat. 8 (2009). Available at: http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_public_laws&docid=f:publ003.111.

2 CHIPRA Initial Core Set of Children's Health Care Quality Measures. Available at: http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Quality-of-Care/CHIPRA-Initial-Core-Set-of-Childrens-Health-Care-Quality-Measures.html.

3 CHIPRA Initial Core Set of Children's Health Care Quality Measures: Technical Specifications and Resource Manual for Federal Fiscal Year 2011 Reporting. Available at: http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Quality-of-Care/Downloads/InitialCoreSetResourceManual.pdf.

4 Pediatric Quality Measures Program Centers of Excellence Grant Awards. AHRQ Publication No. 12-P006, March 2012. AHRQ, Rockville, MD. http://www.ahrq.gov/policymakers/chipra/pubs/pqmpfact.html.

measures will be reviewed by a SNAC[5] of the AHRQ National Advisory Council on Research and Quality (NAC). The SNAC will make recommendations to the NAC, which advises the director of AHRQ, who in turn will make recommendations to CMS and the Secretary of HHS.

CHIPRA notes that measures in the improved core sets should be evidence based; cover a full range of services, conditions, and ages; be able to identify disparities by race, ethnicity, socioeconomic status, and special health care need; be risk adjusted as appropriate; and designed to ensure that data are collected and reported in a standard format that permits comparison of quality and data at a State, plan, and provider level.

This template, the **C**HIPRA **P**ediatric Quality Measures Program (PQMP) **C**andidate Measure Submission **F**orm (CPCF) was developed by the COEs, the SNAC, the CHIPRA Coordinating and Technical Assistance Center (CCTAC) at RTI International, and AHRQ as a standardized form to be used for all nominations for pediatric quality measures under the CHIPRA legislation. The first part of the CPCF template provides guidance on the submission process. The template then includes opportunities for all measure submitters to provide a basic description of their measure, and address a number of desirable measure attributes for pediatric quality measures. The desirable measure attributes include importance, evidence or other rationale for focus of the measure, scientific soundness of the measure itself, identification of disparities, feasibility, levels of aggregation, understandability, and health information technology. The form also requests identification of the limitations of the measure being submitted. It then provides an opportunity to summarize why the measure should be recommended by the SNAC, taking into account the measure's advantages and limitations in relation to the desirable measure attributes. The template requires measure submitter information, public disclosure requirement requiring signed written statement, and an opportunity to upload supplementary material including graphics, figures, tables, and any other information to facilitate review of the measure by the SNAC. Attachments may be in PDF format only. The final section of the template provides a glossary of terms. Many of the desirable attributes are similar to those called by other leading entities that solicit measures, but several are CHIPRA specific (e.g., more child focused, spotlight on disparities, and attention to specific levels of aggregation). The SNAC will interpret the extent to which the measure is suitable for voluntary use by Medicaid, CHIP, or other public and private programs, purchasers, plans, providers and consumers using the information provided in the template.

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5 AHRQ National Advisory Council on Research and Quality. Subcommittee on Quality Measures for Children's Health Care. Members List. 2012. Available at: http://www.ahrq.gov/policymakers/chipra/coreset/qmsnaclist12.html.

**NOTE**: If a section is not applicable to the measure, please write 'Not applicable' in the text field before progressing to the next section. If the information is not available, please write "Not available" in the text field before progressing to the next section.

<< >> indicates the name of a text field in the online version of CPCF.

+ indicates a field to upload attachment in the online version of CPCF.

# SECTION I.
# BASIC MEASURE INFORMATION

## I.A. Measure Name

Assessing the availability of the preconception component of High Risk Obstetrical Services by Estimating the Use of Teratogenic Medications Before and During Pregnancy

## I.B. Measure Number (auto-generated)

## I.C. Measure Description

The frequency with which teratogenic medications are dispensed to women before and during pregnancy.

## I.D. Measure Owner

CAPQuaM

## I.E. National Quality Forum (NQF) ID (if applicable)

Not applicable

## I.F. Measure Hierarchy

Please use this section to note 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's National Quality Measures Clearinghouse and are available at http://www.qualitymeasures.ahrq.gov/about/hierarchy.aspx:

**I.F.1.** Please identify the name of the **collection** of measures to which the measure belongs (if applicable). A Collection is the highest possible level of the measure hierarchy. A Collection may contain one or more Sets, Subsets, Composites, and/or Individual Measures.

This measure belongs to PQMP CAPQuaM's Availability of High-risk Obstetric (HROB) Services

**I.F.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.

Availability of Preconception High Risk Obstetrical Care

**I.F.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.

Teratogen subset

**I.F.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

## I.G. Numerator Statement

Various numerators are specified for the sub-measures in order to estimate the number of women who fill prescriptions for teratogenic medications in the specified circumstances, before and during pregnancy

Numerator Elements:
Dated ICD9 codes, DRGs, and prescription drug fill (or payment) data including NDC codes or compound names

## I.H. Numerator Exclusions (as appropriate)

None

## I.I. Denominator Statement

Various denominators are specified for a series of sub-measures and include: overall number of deliveries; eligible qualifying high risk pregnancies; and pregnancies with exposure to specified teratogenic (Class X) medications, using the indicated look back period.

Eligible high risk pregnancies look back period, and specified teratogenic (Class X) medications are all described in detail in Section 2 Detailed Measure Specifications.

Denominator Elements:

Maternal and infant ICD-9 codes,
Maternal DRG, CPT codes, and revenue codes
Infant ICD-9 codes when available
Pharmacy data, including NDC codes and/or compound names

## I.J. Denominator Exclusions (as appropriate)

Denominator exclusions are identified using maternal ICD-9 codes specified in Section 2 Detailed Measure Specifications.

## I.K. Data Sources

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

| Data Source | [Online form will have radio buttons here] |
|---|---|
| 1. Administrative Data (e.g., claims data) | YES |
| 2. Paper Medical Record | NO |
| 3. Survey – Health care professional report | NO |
| 4. Survey – Parent/caregiver report | NO |
| 5. Survey – Child report | NO |
| 6. Electronic Medical Record | NO |
| 7. Other (If other, please list all other data sources in the field below.) | |

# SECTION II.
# DETAILED MEASURE SPECIFICATIONS

Provide sufficient detail to describe how a measure would be calculated from the recommended data sources, either by uploading a separate document or by providing a link to a URL in the field below. 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.[6] 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.

## *A. Description*

This measure describes availability of the preconception component of high risk obstetrical care by estimating the use of specified teratogenic (i.e. "Class X") medications during potentially vulnerable periods before and during pregnancy as a marker for failures of availability. Optimal preconception care for high risk pregnancies includes a variety of services of which the failure to prevent or delay pregnancy until after stopping use of teratogenic medication is only one.

This measure contains 7 sub-measures that describe teratogen use among all pregnant women and among the subset of women classified as high risk because of comorbid illnesses or pregnancy complications. In defining high risk pregnancies, we consider the use of teratogenic medications around the time of conception or during pregnancy to constitute evidence of high risk. The use of teratogens in that subset of women who have preexisting illnesses or pregnancy complications is also of intrinsic interest and some sub-measures are reported distinctly for these women.

The 7 sub-measures can be divided into three groups of measures. The first two sub-measures describe the extent to which all women fill prescriptions that provide teratogenic (Class X) medications before and during pregnancy. These sub-measures estimate the maximum extent to which teratogen exposure may place pregnancy outcomes at risk in the assessed population.

A. The proportion of women who fill prescriptions for teratogenic medications within the 9 months prior to their delivery date.

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6 Initial Core Set of Children's Health Care Quality Measures: Technical Specifications and Resource Manual for Federal Fiscal Year 2011 Reporting. Available at http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Quality-of-Care/Downloads/InitialCoreSetResourceManual.pdf and http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Quality-of-Care/CHIPRA-Initial-Core-Set-of-Childrens-Health-Care-Quality-Measures.html.

B. The proportion of women who fill prescriptions for teratogenic medications within the 12 months prior to their delivery date.

The next set of 4-submeasures describes the extent to which the subset of high risk pregnant women fill prescriptions for teratogenic medications before and during pregnancy. We define high risk using two strategies. First, we use only pregnancy complications and/ or maternal comorbidities to designate high risk. Second, we employ an expanded definition for high risk pregnancies which includes exposure to teratogens.

C. The proportion of women with qualifying high risk pregnancies (defined as women with specified pregnancy complications and/or maternal comorbidities) who fill prescriptions for teratogenic medications within the 9 months prior to their delivery date.

D. The proportion of women with qualifying high risk pregnancies (defined as women with specified pregnancy complications and/or maternal comorbidities plus women who fill a prescription for teratogenic medications in the 12 months prior to delivery) who fill prescriptions for teratogenic medications within the 9 months prior to their delivery date.

E. The proportion of women with qualifying high risk pregnancies (defined as women with specified pregnancy complications and/or maternal comorbidities) who fill prescriptions for teratogenic medications within the 12 months prior to their delivery date.

F. The proportion of women with qualifying high risk pregnancies (defined as women with specified pregnancy complications and/or maternal comorbidities plus women who used teratogenic medications in the 12 months prior to delivery) who fill prescriptions for teratogenic medications within the 12 months prior to their delivery date.

The last sub-measure describes the extent to which women who fill at least two prescriptions for any teratogenic medication in the 15 months prior to pregnancy stop filling prescriptions for such medications prior to pregnancy.

G. The proportion of women who have at least one refill of a teratogenic medication in the 15 months prior to pregnancy who have no prescriptions filled for teratogenic medication in the 9 months prior to delivery.

## *B. Eligible Population*

Women age 10- 65 years who are pregnant and deliver an infant, whether living or dead. Delivery shall be identified using Table 1, with exclusions as noted regardless of how delivery was identified. The table was developed based on the work of CDC researchers.[1]

***Section 2 Table 1: Identify Qualifying Deliveries Using the Following Codes***

| Table 1 - Identification of Deliveries of Interest | |
|---|---|
| **Description** | **Code (s)** |
| **Revenue Code** | 722 Delivery |
| **Outcome of delivery ICD-9** | ICD-9-CM = V27 |
| **Normal delivery** | ICD-9-CM = 650 |
| **Diagnosis-related group (DRG) delivery codes** | 370(complicated cesarean section),<br>371 (uncomplicated cesarean section),<br>372 (complicated vaginal delivery),<br>373 (uncomplicated vaginal delivery)<br>374 (uncomplicated vaginal delivery with sterilization and/or dilatation & curettage)<br>375 (vaginal delivery with operation room procedure except sterilization and/or dilatation & curettage) |
| **Selected delivery related procedures** | ICD-9-CM =<br>720, 721, 7221, 7229,7231, 7239, 724, 726 (forceps)<br>7251, 7252, 7253, 7254 (breech extraction)<br>7271, 7279 (vacuum extraction)<br>728, 729 (other specified and unspecified delivery)<br>7322 (internal and combined version and extraction)<br>7359 (other manually assisted deliveries)<br>736 (episiotomy)740, 741, 742, 744, 7499 (cesarean section) |

| | |
|---|---|
| **Exclusions** | ICD-9 = CM 630 (hydatidiform mole)<br>631 (other abnormal product of conception) 633 (ectopic pregnancy)<br>632 (missed abortion)<br>634 (spontaneous abortion)<br>635 (legally induced abortion)<br>636 (illegal abortion)<br>637 (unspecified abortion)<br>638 (failed attempted abortion complication)<br>639 (complications following abortion and ectopic and molar pregnancies)<br>69.01, 69.51, 74.91, 75.0 (abortion) |

***Identify deliveries that include codes listed in Table 2, 3, or 4 below. These codes were identified using guidance from an expert panel using a modified RAND Delphi process. The CCS is the Clinical Classification Software developed by AHRQ.***

***Section 2 Table 2: Maternal Diagnoses and Comorbidities***

| *CCS Category* | *Look Back Period* | *Descriptor* | *Remove From Inclusion List** |
|---|---|---|---|
| **49** | 2y | DM without Cx | 7902 Abnormal Glucose<br>79021 Impaired fasting glucose<br>79022 Impaired glucose tolerance test (oral)<br>79029 Other abnormal glucose<br>7915 Glycosuria |
| **50** | 2y | DM with Cx | |

| | | | |
|---|---|---|---|
| **98** | 2y | Essential HTN | |
| **99** | 2y | HTN with CX and Secondary HTN | |
| **100** | 2y | Acute MI | |
| **101** | 2y | Coronary atherosclerosis and other heart disease | |
| **104** | 2y | Other and ill-defined heart disease | |
| **103** | 2y | Pulmonary heart disease | |
| **96** | 2y | Heart valve disorders | 4240 Mitral valve disorders<br>7852 Undiagnosed cardiac murmurs<br>7853 Other abnormal heart sounds |
| **97** | 2y | Peri, endo and myocarditis or cardiomyopathy | |
| **105** | 2y | Conduction disorders | |
| **106** | 2y | Cardiac Dysrhythmias | |
| **107** | 2y | Cardiac arrest and vfib | |
| **108** | 2y | CHF, non hypertensive | |

| | | | |
|---|---|---|---|
| **109** | 2y | Acute Cerebrovascular disease | |
| **110** | 2y | Occlusion or stenosis of pre cerebral arteries | |
| **111** | 2y | Other and ill defined cerebrovascular disease | |
| **112** | 2y | Transient cerebral ischemia | |
| **156** | 2y | Nephritis nephrosis, renal sclerosis | |
| **158** | 2y | Chronic kidney disease | |
| **157** | 2y | Acute and unspecified renal failure | |
| **161** | 2y | Other diseases of kidney and ureters | 5890 Unilateral small kidney<br>5891 Bilateral small kidneys<br>5899 Small kidney, unspecified |
| **128** | 10 m | Asthma | 49381 Exercise induced bronchospasm<br>49382 Cough variant asthma |
| **132** | 10 m | Lung disease due to external agents | |
| **133** | 2y | Other lower respiratory disease | 78600 Respiratory abnormality, unspecified<br>78601 Hyperventilation |

| | | | |
|---|---|---|---|
| | | | 78602 Orthopnea<br><br>78605 Shortness of breath<br><br>78606 Tachypnea<br><br>78607 Wheezing<br><br>78606 Tachypnea<br><br>78607 Wheezing<br><br>7862 Cough<br><br>7864 Abnormal sputum<br><br>78652 Painful respiration<br><br>7866 Swelling, mass, or lump in chest<br><br>7867 Abnormal chest sounds<br><br>7868 Hiccough<br><br>7931 Nonspecific (abnormal) findings on radiological and other examination of lung field<br><br>79311 Solitary pulmonary nodule<br><br>79319 Other nonspecific abnormal finding of lung field<br><br>7942 Nonspecific abnormal results of pulmonary function study<br><br>V126 Personal history of diseases of respiratory system<br><br>V1260 Personal history of unspecified disease of respiratory system<br><br>V1261 Personal history of pneumonia (recurrent)<br><br>V1269 Personal history of other diseases of respiratory system |
| **59, 61, 63, 64** | 2y | 59. Deficiency anemias<br><br>61. Sickle cell | 281xx 2820 2821 2822 2823 28246 2825 2859 2883 2885x 286x 2888 2889 289 2891 2892 2893 2894 2895 28950 28951 28953 28959 2896 2897 28983 2899 |

| | | | |
|---|---|---|---|
| | | 63. WBC disease<br><br>64. Other hematologic conditions | |
| **657** | 10m | Mood disorders | |
| **660** | 2y | Alcohol related | |
| **661** | 2y | Substance related | |
| **116** | 2y | Aortic and peripheral arterial embolic thrombotic | |
| **118** | 2y | Phlebitis, embolic, etc | 4510 45182 4536 4537 |
| **5** | 2y | HIV | |
| **182** | 2y | Hemorrhage during pregnancy, abruption, previa | 642.00 Threatened abortion unspecified as to episode of care<br><br>642.01 Threatened abortion delivered<br><br>642.03 Threatened abortion antepartum<br><br>640.80 Other specified hemorrhage in early pregnancy unspecified as to episode of care<br><br>640.81 Other specified hemorrhage in early pregnancy delivered<br><br>640.83 Other specified hemorrhage in early pregnancy antepartum<br><br>640.90 Unspecified hemorrhage in early pregnancy unspecified as to episode of care<br><br>640.91 Unspecified hemorrhage in early pregnancy delivered<br><br>640.93 Unspecified hemorrhage in early |

| | | | |
|---|---|---|---|
| | | | pregnancy antepartum |
| **183** | 10m | Hypertension complicating pregnancy | 642.30 Transient hypertension of pregnancy unspecified as to episode of care<br><br>642.31 Transient hypertension of pregnancy with delivery<br><br>642.32 Transient hypertension of pregnancy with delivery with postpartum complication<br><br>642.33 Antepartum transient hypertension<br><br>642.34 Postpartum transient hypertension |
| **83** | 2y | Epilepsy | |

***Section 2 Table 3: Pregnancy Complications***

| ***Table 3 ICD9 Code*** | ***Look Back Period*** | ***Descriptor*** |
|---|---|---|
| ***6565-65651, 65653*** | *10 m* | *Poor fetal growth* |
| ***679, 6790x, 641xx, 663, 66501-66511, 6560-65643, 666, 668, 670, 6713-67144, 673xx, 6740x, 6745x,*** | *10 m* | *Disorders of pregnancy and delivery: complications of in utero procedures, antepartum hemorrhage abruption placentae and previa, umbilical cord complications, uterine rupture, significant fetal complications affecting management of mother, postpartum bleed, complications of anesthesia, major puerperal infection, deep thrombo-embolus, OB Pulm Embolus, cerebrovascular disorders in the puerperium, peripartum cardiomyopathy, drug dependence* |
| ***648.4x*** | *10m* | *Mental disorders complicating pregnancy* |
| ***648.3x*** | *10m* | *Substance dependence during pregnancy* |
| ***648.5x*** | *10m* | *Congenital cardiac disorder, other CV disease, mother* |
| ***7620*** | *10m* | *Complete previa affecting the newborn* |
| ***694x***<br>***345xx*** | *10m* | *Epilepsy* |
| ***V23.49*** | *10m* | *Poor OB history* |

| | | |
|---|---|---|
| ***V23.41*** | *10m* | *History of preterm labor* |
| ***V27.1*** | | *Singleton stillborn* |
| ***V27.3 or V27.4*** | | *One twin stillborn; both twins stillborn* |
| ***V27.6*** | | *Other multiple birth with stillborn* |
| ***V27.7*** | | *Other multiple birth all stillborn* |
| ***768xx*** | | *Intrauterine hypoxia and birth asphyxia* |
| ***656.4x*** | | *Intrauterine death affecting management of mother* |

***These are ICD9 codes that are included in the CCS software for the indicated Group that need to be removed from the inclusion list. That is, they are not specific exclusions, but neither do they establish eligibility.**

## Section 2 Table 4: Prematurity or Small Infant Codes

| Table 4: Premature or small infant codes | | | |
|---|---|---|---|
| **WTNOS** | | **1250-1499 g** | |
| 76400 | LT-FOR-DATES | 76405 | LT-FOR-DATES |
| 76410 | LT-DATE W/MAL | 76415 | LT-DATE W/MAL |
| 76420 | FETAL MALNUTR | 76425 | FETAL MALNUTR |
| 76490 | FET GROWTH RET | 76495 | FET GROWTH RET |
| 76500 | EXTREME IMMATUR | 76505 | EXTREME IMMATUR |
| 76510 | PRETERM NEC | 76515 | PRETERM NEC |
| **< 500 g** | | **1500-1749 g** | |
| 76401 | LT-FOR-DATES | 76406 | LT-FOR-DATES |
| 76411 | LT-DATE W/MAL | 76416 | LT-DATE W/MAL |
| 76421 | FETAL MALNUTR | 76426 | FETAL MALNUTR |
| 76491 | FET GROWTH RET | 76496 | FET GROWTH RET |
| 76501 | EXTREME IMMATUR | 76506 | EXTREME IMMATUR |
| 76511 | PRETERM NEC | 76516 | PRETERM NEC |
| **500-749 g** | | **1750-1999 g** | |
| 76402 | LT-FOR-DATES | 76407 | LT-FOR-DATES |
| 76412 | LT-DATE W/MAL | 76417 | LT-DATE W/MAL |
| 76422 | FETAL MALNUTR | 76427 | FETAL MALNUTR |
| 76492 | FET GROWTH RET | 76497 | FET GROWTH RET |
| 76502 | EXTREME IMMATUR | 76507 | EXTREME IMMATUR |
| 76512 | PRETERM NEC | 76517 | PRETERM NEC |
| **750-999 g** | | **2000-2499 g** | |
| 76403 | LT-FOR-DATES | 76408 | LT-FOR-DATES |
| 76413 | LT-DATE W/MAL | 76418 | LT-DATE W/MAL |
| 76423 | FETAL MALNUTR | 76428 | FETAL MALNUTR |
| 76493 | FET GROWTH RET | 76498 | FET GROWTH RET |
| 76503 | EXTREME IMMATUR | 76508 | EXTREME IMMATUR |
| 76512 | PRETERM NEC | 76518 | PRETERM NEC |
| **1000-1249 g** | | | |
| 76404 | LT-FOR-DATES | 76494 | FET GROWTH RET |
| 76414 | LT-DATE W/MAL | 76504 | EXTREME IMMATUR |
| 76424 | FETAL MALNUTR | 76514 | PRETERM NEC |

## Section 2 Table 5: Class X Teratogens

| GP110 | Drug Name |
|---|---|
| 9652646363 | Fluorouracil (Bulk) |
| 2130003000 | Fluorouracil (IV) |
| 3004453000 | Denosumab |
| 1100003010 | Griseofulvin Microsize |
| 1100003020 | Griseofulvin Ultramicrosize |
| 1235307000 | Ribavirin (Hepatitis C) |
| 1260407500 | Ribavirin |
| 2130005000 | Methotrexate |
| 2130005010 | Methotrexate Sodium |
| 2140242000 | Bicalutamide |
| 2140243000 | Enzalutamide |
| 2140281000 | Anastrozole |
| 2140286000 | Letrozole |
| 2140401010 | Medroxyprogesterone Acetate (Antineoplastic) |
| 2140402010 | Megestrol Acetate |
| 2140500710 | Histrelin Acetate |
| 2140505020 | Triptorelin Pamoate |
| 2140552510 | Degarelix Acetate |
| 2140601020 | Abiraterone Acetate |
| 2145008000 | Pomalidomide |
| 2170822000 | Bexarotene |
| 2310000500 | Danazol |
| 2310001000 | Fluoxymesterone |
| 2310002000 | Methyltestosterone |
| 2310003000 | Testosterone |
| 2310003010 | Testosterone Cypionate |
| 2310003020 | Testosterone Enanthate |
| 2310003030 | Testosterone Propionate |
| 2320004000 | Oxandrolone |
| 2499100230 | Esterified Estrogens & Methyltestosterone |
| 2499300204 | Conjugated Estrogens-Medroxyprogesterone Acetate |
| 2600002020 | Medroxyprogesterone Acetate |
| 2600002320 | Megestrol Acetate (Appetite) |
| 2730405000 | Mifepristone (Hyperglycemia) |
| 2799300270 | Sitagliptin-Simvastatin |
| 3005305000 | Ospemifene |
| 3005306010 | Raloxifene HCl |
| 3008004510 | Histrelin Acetate (CPP) |
| 3008005510 | Nafarelin Acetate |
| 3015008510 | Tesamorelin Acetate |
| 3050206000 | Mifepristone |
| 3540002810 | Dronedarone HCl |
| 3940001010 | Atorvastatin Calcium |
| 3940003010 | Fluvastatin Sodium |
| 3940005000 | Lovastatin |
| 3940005810 | Pitavastatin Calcium |
| 3940006010 | Rosuvastatin Calcium |
| 3940007500 | Simvastatin |
| 3940990245 | Niacin-Lovastatin |
| 3940990270 | Niacin-Simvastatin |
| 3948005020 | Lomitapide Mesylate |
| 3999400230 | Ezetimibe-Simvastatin |
| 4016000700 | Ambrisentan |
| 4016001500 | Bosentan |
| 4099250215 | Amlodipine Besylate-Atorvastatin Calcium |
| 4925003000 | Misoprostol |
| 5210001000 | Chenodiol |
| 5660002000 | Acetohydroxamic Acid |
| 5685102000 | Dutasteride |
| 5685103000 | Finasteride |
| 5685990225 | Dutasteride-Tamsulosin HCl |
| 6020100500 | Estazolam |
| 6020103000 | Temazepam |
| 6020104000 | Triazolam |
| 6099800270 | Temazepam-Dietary Management Product |
| 6120001010 | Benzphetamine HCl |
| 6125356000 | Orlistat |
| 6610990220 | Diclofenac w/ Misoprostol |
| 6628005000 | Leflunomide |
| 6700003010 | Dihydroergotamine Mesylate |
| 6799100210 | Ergotamine w/ Caffeine |
| 8320003020 | Warfarin Sodium |
| 9005001300 | Isotretinoin |
| 9025007000 | Tazarotene |
| 9025051000 | Acitretin |
| 9025051030 | Acitretin w/ Moisturizer |
| 9037203000 | Fluorouracil (Topical) |
| 9037622000 | Bexarotene (Topical) |
| 9073603000 | Finasteride (Alopecia) |
| 9087990250 | Mequinol-Tretinoin |
| 9088606000 | Tazarotene (Facial Wrinkles) |
| 9642461570 | Acetohydroxamic Acid (Bulk) |
| 9642680260 | Anastrozole (Bulk) |
| 9646561542 | Chenodiol (Bulk) |
| 9652584300 | Finasteride (Bulk) |
| 9652646400 | Fluoxymesterone (Bulk) |
| 9654762710 | Griseofulvin Micronized |
| 9658784600 | Isotretinoin (Bulk) |
| 9664501010 | Leflunomide (Bulk) |
| 9664503250 | Letrozole (Bulk) |
| 9664708500 | Lovastatin (Bulk) |
| 9666501200 | Medroxyprogesterone Micronized |
| 9666501210 | Medroxyprogesterone Acetate Micronized (Bulk) |
| 9666585760 | Misoprostol (Bulk) |
| 9670870342 | Oxandrolone (Bulk) |
| 9676580603 | Ribavirin (Bulk) |
| 9680505052 | Testosterone Micronized (Bulk) |
| 9680505058 | Testosterone Decanoate (Bulk) |
| 9680505060 | Testosterone Enanthate (Bulk) |
| 9680505064 | Testosterone Isocaproate (Bulk) |
| 9680505070 | Testosterone Phenylpropionate (Bulk) |
| 9939207000 | Thalidomide |
| 9939405000 | Lenalidomide |

## C. Data Sources

### 1. Administrative Data: Billing data including diagnosis and procedure codes as well as pharmacy data

a. Identify eligible population
   i. Identify those eligible deliveries as described in Table 1.
   ii. Identify those deliveries associated with high risk conditions
      a. Maternal data record: High Risk Diagnoses
      b. Maternal data record: Delivery Complications
      c. Maternal data record: Stillbirth or Birth Asphyxia
      d. Maternal data record: (if available) Maternal race, ethnicity, county of residence (zip code or FIPS is acceptable alternative)
      e. Infant data record: Premature or Small Infant
   iii. Identify which drugs are classified as Class X as described above in Table 5.

### 2. Woman's medical record (only if needed for data in ii d above)

i. Maternal race, ethnicity, or data regarding place of residence.

## D. Calculations

The sub-measures are constructed as a suite of ratios of the number of women identified in the specified groups. In the calculation steps below, we describe how to identify each group and thus estimate the number of women who comprise each group.

Calculation of this measure includes:

a) collect appropriate data for stratification,
b) identify and count the women who comprise each group,
c) calculate the ratio required for each sub-measure, and
d) stratify as described for each sub-measure. Each sub-measure should be reported overall and by strata as specified.

The seven sub-measures are:

A. The proportion of all women who fill prescriptions for teratogenic medications within the 9 months prior to their delivery date

B. The proportion of women who fill prescriptions for teratogenic medications within the 12 months prior to their delivery date

C. The proportion of women with qualifying high risk pregnancies (defined considering only specified pregnancy complications and/or maternal comorbidities) who fill prescriptions for teratogenic medications within the 9 months prior to their delivery date.

D. The proportion of women with qualifying high risk pregnancies (considering both specified pregnancy complications and/or maternal comorbidities, plus women who fill prescriptions for teratogenic medications in the 12 months prior to delivery) who fill prescriptions for teratogenic medications within the 9 months prior to their delivery date

E. The proportion of women with qualifying high risk pregnancies (defined considering only specified pregnancy complications and/or maternal comorbidities) who fill prescriptions for teratogenic medications within the 12 months prior to their delivery date

F. The proportion of women with qualifying high risk pregnancies (considering both specified pregnancy complications and/or maternal comorbidities, plus women who used teratogenic medications in the 12 months prior to delivery) who fill prescriptions for teratogenic medications within the 12 months prior to their delivery date

G. The proportion of women who have at least one refill of a teratogenic medication (i.e., filled the prescription at least 2 times) in the 15 months prior to pregnancy who have not filled any prescriptions for specified teratogenic medication in the 9 months prior to delivery.

| Section 2 – Table 6<br><br>Eligible Time for Numerator Events –<br><br>Months Before Delivery<br>12 \| 11 \| 10 \| 9 \| 8 \| 7 \| 6 \| 5 \| 4 \| 3 \| 2 \| 1 \| 0 | Denominator (*D*) Description | *D* GROUP | MEASURE |
|---|---|---|---|
| Teratogen Use in 9 months | All women who deliver in Reporting Period | 1 | A |
| Teratogen Use in 12 months | All women who deliver in Reporting Period | 1 | B |
| Teratogen Use in 9 months | Women with high risk pregnancies – more narrow definition (Deliver in Reporting Period AND Comorbidities and /or pregnancy complications) | 5 | C |
| Teratogen Use in 9 months | Women with high risk pregnancies – broader definition (also includes women who filled RX for Teratogen in 12 months before delivery) | 6 | D |
| Teratogen Use in 12 months | Women with high risk pregnancies – more narrow definition (Deliver in Reporting Period AND Comorbidities and /or pregnancy complications) | 5 | E |
| Teratogen Use in 12 months | Women with high risk pregnancies – broader definition (also includes women who filled RX for Teratogen in 12 months before delivery) | 6 | F |
| Teratogen Free for 9 months | All women who deliver in Reporting Period & have more than one Rx for teratogens in the period of time from 24 months before delivery to conception | 7 | G |

**D1. Collection of Necessary Data Elements and Creation of Stratification Variables**

**Step 1**: Identify deliveries using the criteria above in Table 1.

**Step 2**: Collect the following data elements for all eligible women

i. Race
ii. Ethnicity
iii. Insurance type (Public, Commercial, Uninsured)
iv. Benefit type (if insured): HMO, PPO, Medicaid Primary Care Case Management (PCCM) Plan, Fee for Service (FFS), other
v. Zip code, state and county or equivalent area of mother's residence. Record FIPS if available

**Step 3**: Create stratification variables

i. Race/Ethnicity: Hispanic, Non-Hispanic Black, Non-Hispanic White; Non-Hispanic Asian/Pacific Islander, other Non-Hispanic

ii. Public vs Commercial (Private Insurance)
iii. HMO vs PPO vs FFS vs PCCM vs other
iv. Urban Influence Code. Identify the Urban Influence Code or UIC. (2013 urban influence codes available at: http://www.ers.usda.gov/data-products/urban-influence-codes.aspx#.UZUvG2cVoj8 ). Use mother's place of residence to determine UIC. State and county names can be linked or looked up directly or zip codes can be linked to county indirectly, using the Missouri Census Data Center (http://mcdc.missouri.edu/). These data will link to county or county equivalents as used in various states.
v. Identify the Level of Poverty in the mother's county of residence. The percent of all residents in poverty by county or county equivalent are available from the US Department of Agriculture at http://www.ers.usda.gov/data-products/county-level-data-sets/download-data.aspx. Our stratification standards are based on 2011 US population data that we have analyzed with SAS 9.3. Using mother's state and county of residence (or equivalent) or FIPS code, use the variable PCTPOVALL_2011 to categorize into one of 5 Strata:
    a. Lowest Quartile of Poverty if percent in poverty is <=12.5%
    b. Second Quartile of Poverty if percent in poverty is >12.5% and <=16.5%
    c. Third Quartile of poverty if percent in poverty is >16.5% and <=20.7%
    d. First Upper Quartile (75th-90th) if percent in poverty is >20.7% and <=25.7%
    e. Second Upper Quartile (>90th percentile)

    If needed, the Missouri Census Data Center linked in step iv may be used to link zip codes to county equivalents.

**D2. Calculate the Number of women in each group**

**Step 4**: Identify and count deliveries as described above in Table 1. This is **Group 1.**

**Step 5:** Identify and count all deliveries that had a class X drug prescriptions filled during the 9 months prior to delivery. This is **Group 2.**

a. Identify deliveries as specified above (Step 4).
b. Limit to deliveries that used any class X drug (Table 5) > or = 1 time during the 9 months prior to delivery.
c. The 9-month period is comprised of the 270 days prior to the date of delivery.

**Step 6:** Identify and count all deliveries that had a class X drug used during the 12 months prior to delivery. This is **Group 3.**

a. Identify deliveries as specified above (Step 4).
b. Limit to deliveries that used any class X drug (Table 5) > or = 1 time during the 12 months prior to delivery.

c. The 12-month period is comprised of the 360 days prior to the date of delivery.

**Step 7**: Identify and count all deliveries that had a class X drug used during the 24 months prior to delivery. This is **Group 4.**

a. Identify deliveries as specified above (Step 4).
b. Limit to deliveries that used any class X drug (Table 5) > or = 1 time during the 24 months prior to delivery.
c. The 24-month period is comprised of the 730 days prior to the date of delivery.

**Step 8**: Identify high risk pregnancies.

a) Use linked maternal and infant records.
Identify High Risk Pregnancies using Tables 2, 3, and 4.
Construct an unduplicated list of high risk pregnancies by merging the unduplicated results from Tables 2, 3, and 4.

OR

b) If only maternal records are available, use Tables 2 and 3 to identify high risk pregnancies.

These women are considered women in potential need of high risk services (have "high risk pregnancies").
Identify and count high risk pregnancies using the indicated look back period. This is **Group 5**.

To identify the look back period specified in Tables 2 and 3 do the following:

i. Identify date of delivery using codes from Table 1.
ii. The 2-year look back period is comprised 730 days prior to the delivery date.
iii. The 10-month look back period is comprised of the 300 days prior to the date of delivery.

**Step 9**: Identify and count women in **Group 6**, which is the union of the unique women included in Group 5 (high risk deliveries) and Group 3 (women who filled prescriptions for Class X drugs >or= 1 times during the 12 months prior to delivery).

**Group 6** combines women in Group 4 and Group 3 (without duplication).

**Step 10:** Identify and count all women in Group 4 who filled at least one refill for a teratogenic drug in the time period that is between 24 months and 9-months of delivery. This is **Group 7**.

**Step 11:** Identify and count all women who filled at least 2 prescriptions (i.e., had at least one refill) for specified teratogenic medications between 24 and 15 months prior to delivery WHO ALSO DID NOT FILL any prescriptions for specified teratogenic medications within 9 months of delivery. In other words, this group of

women will be that subset of women in Group 7 who are not also in Group 2. This is **Group 8**.

**D3. Calculation of the 7 Sub-measures**

**Step 12**: Calculate Sub-measures

- **a. Sub-measure A = Group 2 / Group 1**
- **b. Sub-measure B = Group 3 / Group 1**
- **c. Sub-measure C= Group 2 / Group 5**
- **d. Sub-measure D = Group 2 / Group 6**
- **e. Sub-measure E = Group 3 / Group 5**
- **f. Sub-measure F = Group 3 / Group 6**
- **g. Sub-measure G = Group 8 / Group 7**

**Step 13: Report results for sub-measures A-G.**

**D4. Guidance for Stratification of Sub-measures**

**Step 14**: For sub-measures A-G, repeat steps above for each stratification category listed below, using the following data elements. Report all strata with N of at least 50.

a. Race and ethnicity
b. Insurance type (Public/Medicaid, Private/Commercial, None, other)
c. Benefit type: HMO vs PPO vs FFS vs PCCM vs other
d. Urban Influence Code or UIC.
e. Level of Poverty in the county of residence.

**Step 15**: Calculate and report 95% confidence intervals (CI, using binomial distribution for each category).

a. Calculate the standard error as the square root of each proportion by 1-the same proportion divided by the number of deliveries.
b. Multiply the standard error by 1.96.
c. Subtract that value from the measured proportion. Report the greater of 0 and that number as the lower bound of the 95% confidence interval.

Add the product from b to the measured proportion. Use the lesser of that sum or 1 as the upper bound of the 95% confidence interval. Table 7 shows anticipated width of the confidence interval (CI) for various sample sizes, based on an assumed prevalence of 5 percent. CI width will be smaller if prevalence is lower and larger if higher.

**Section 2, Table 7**

| Width of 95% CI Based on Sample Size N and Assuming 5 % Prevalence | | | |
|---|---|---|---|
| N= | 50 | + / - | 6.0% |
| N= | 75 | + / - | 4.9% |
| N= | 100 | + / - | 4.3% |
| N= | 200 | + / - | 3.0% |

# SECTION III.
# 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).

## III.A. Evidence for General Importance of the Measure

Provide evidence for all applicable aspects of general importance, including but not limited to the following:

- Addresses a known or suspected quality gap or disparity in quality (e.g., addresses a socioeconomic disparity, a racial/ethnic disparity, a disparity for Children with Special Health Care Needs (CSHCN) and/or a disparity for limited English proficiency (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 Collaboration for Advancing Pediatric Quality Measures (CAPQuaM) was assigned the topic of availability of high-risk obstetrical services as a PQMP priority by the AHRQ and CMS. Our measures were developed in close collaboration with our Expert Panel and our partner stakeholders.

Availability of specific aspects of care for pregnant women, particularly those in need of high risk obstetric services, fosters healthy pregnancies and healthy deliveries.. This measure describes availability of the preconception component of high risk obstetrical care by estimating the use of teratogenic (i.e. "Class X") medications during potentially vulnerable periods before and during pregnancy as a marker for failures of availability. While preconception care for high risk pregnancies is a broad topic,

teratogen use in pregnancy offers a window that addresses a potential failure in the realm of patient safety.

This measure contains 6 sub-measures that describe how frequently a potentially dangerous circumstance occurs: pregnant women fill prescriptions for medications that have a very poor safety profile for pregnant women. The last (seventh) sub-measure describes the extent to which women who fill prescriptions for teratogenic medication in the 15 months prior to pregnancy (from 2 years before delivery to the estimated time of conception) stop filling prescriptions for such medications during pregnancy.

This measure addresses an important topic. Medication use during pregnancy is common with estimates ranging from <30% to >90% of women taking at least one prescription medication.[2, 3] In the United States, women of reproductive age (15-44 years) receive nearly 12 million prescriptions for potentially teratogenic medications each year.[4] A teratogen is a drug or substance capable of interfering with the development of a fetus causing birth defects. The FDA has a pregnancy category system (including categories A, B, C, D, and X) which describes the potential safety or risk of taking a medication during pregnancy. (Table 1) Due to limitations in the ability of the pregnancy categories to accurately and consistently convey the specific risk and benefit involved, the FDA has proposed new product labeling designed to improve risk versus benefit assessment of drugs used in pregnant and lactating women.[5]

Both FDA Category D and X medications are considered potentially teratogenic because category D medications have evidence of human risk with benefits of the drug typically outweighing risks and category X medications have evidence of human risk with risk clearly outweighing the benefit. It is estimated that 1 in 6 (16%) reproductive-aged women fill a prescription for a class D or X medication.[6] Unfortunately, only 20-50% of these women receive contraceptive counseling at the time that medication is prescribed.[4, 6] It has been estimated that 1/4 (27%) of U.S. pregnancies are exposed to potentially teratogenic medications which present potentially greater risk than benefit to the fetus.[6, 7] Pregnant women use an average of 4.2 medications (OTC and prescription) throughout their pregnancy, with 93.9% taking at least one medication.[3]

TABLE 1. Food and Drug Administration Pregnancy Category Rating

| Pregnancy Category | Explanation |
|---|---|
| **Category A** | Adequate and well-controlled studies have failed to demonstrate a risk to the fetus in the first trimester of pregnancy (and there is no evidence of risk in later trimesters). |
| **Category B** | Animal reproduction studies have failed to demonstrate a risk to the fetus and there are no adequate and well-controlled studies in pregnant women. |
| **Category C** | Animal reproduction studies have shown an adverse effect on the fetus and there are no adequate and well-controlled studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks. |
| **Category D** | There is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks. |
| **Category X** | Studies in animals or humans have demonstrated fetal abnormalities and/or there is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience, and the risks involved in use of the drug in pregnant women clearly outweigh potential benefits. |

Approximately half ( 51%) of the 6.6 million pregnancies each year in the United States are not planned.[8] Women may thus be exposed to potentially harmful teratogenic agents because they may not know they are pregnant or about to become pregnant; this is compounded because severe drug-induced malformations are more likely to occur within the first three months of pregnancy[8, 9]. Assuring that women on high risk drugs are off of those drugs *before* they get pregnant is a critical component of pre-conception care. Unplanned pregnancy rates are highest among young, poor, minority and low-income women.[8] Many women unknowingly expose their fetus to teratogens because they have not been counseled or managed sufficiently about teratogen use by their clinicians.

The most common teratogenic effects from medications include neural tube defects, congenital heart abnormalities, cleft lip or palate, and fetal stillbirth.[10] Additional adverse fetal effects that result in dysfunction of a formed organ or tissue include postnatal adaptation, withdrawal, electrolyte abnormalities, and altered glucose metabolism.[11] Examples of currently used prescription medications with known risks of teratogenicity include angiotensin-converting enzyme inhibitors, carbamazepine, warfarin, methotrexate, phenytoin, isotretinoin, lithium, misoprostol, tetracyclines, and valproate.[10, 12, 13]

Given the number and severity of fetal effects that can occur with many different medications, discussing medication use with women of reproductive age and child-bearing ability is critical. However, data suggests that only 20-50% of women receive contraceptive counseling when potentially teratogenic medications are prescribed.[6, 14-16] In a survey of over 800 women, 43% of reproductive-age women prescribed potential teratogens reported no counseling from their provider about teratogenic risks.[7] Another study demonstrated that among 146,758 women ages 18-44 years prescribed category X medications, only 26,136 (18%) also took oral contraceptives,[17] a rate which was similar to that of same-aged women not taking category X medications (17%). The fact that many women do not receive appropriate counseling is concerning as guidance from the internet and other sources can be incorrect. In an environmental scan of 25 different internet resources which included three medical and one professional organization, four pregnancy information resources, and 17 clinical practice resources, a total of 164 medication components were identified as “safe” for use by pregnant women.[18] When compared with the Teratogen Information System (TERIS), a database with expert assessments of the teratogenic risk of medication in human pregnancy after exposure, only 103 of those medications had existing evaluations with 49 (48%) rated as unlikely to pose a risk and 43 (42%) were of undetermined risk.

Prescription use during pregnancy is common. This measure considers the use of teratogenic medications during potentially vulnerable periods before and during pregnancy as a marker for that preconception and inter-conception high risk obstetrical care was not sufficiently available.

## III.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).[7]

- Any other specific relevance to Medicaid/CHIP (please specify).

The relevance of this measure for Medicaid and CHIP is demonstrated by a number of factors including: 1) the key Department of Health partnerships that played important roles in the development of the measure, 2) evidence demonstrating the high use of teratogen medications among pregnant women and the lack of appropriate counseling, and 3) the fact that unplanned pregnancies place women at higher risk for exposure to teratogens and that unplanned pregnancies are highest among young, minority and low-income women who are often covered by Medicaid.

Our expert panel strongly endorsed the importance of preconception care and the use of exposure to teratogens as a marker of failure of adequate preconception care. Our consortium partners at the New York State Department of Health, including the Office of Health Insurance Programs / New York State Medicaid, steering committee, and scientific team also played central roles in the development of these measures. Evidence for high level of interest in this work in particular was demonstrated by the fact that the CAPQuaM team was asked to present this work in development to the CMS Expert Panel on Improving Maternal and Infant Health Outcomes in Medicaid/CHIP Data, Measurement, and Reporting Workgroup. The New York State Office of Health Insurance Programs is an active CAPQuaM partner and has been engaged in the conceptualization and development of these measures. Our testing occurred in Medicaid data and is described below.

As described in Section IIIA above, the literature confirms the importance of this measure for all women.[4, 6, 19] Although the vast majority of studies on this topic have evaluated Health Maintenance Organizations and survey databases to describe potentially teratogenic medications dispensed, contraceptive counseling, and pregnancy testing in this reproductive age group.[4, 6, 19], a few studies have examined this topic among Medicaid enrollees. For example, one study evaluated a Medicaid program by analyzing category X prescriptions filled by 95,284 women enrolled in TennCare, Tennessee's program for Medicaid enrollees and individuals without health insurance. Using administrative data, it was found that 391 women (4.1/1000) filled a category X prescription during pregnancy.[20] The most common medications filled were non-contraceptive estrogens (n=118 women; 1.24/1000), sedatives (n=81 women; 0.85/1000), and statins (n=71; 0.75/1000) which represented 69% of all category X drug use. Most women (n=317; 81.1%) had a physician visit that was linked to the prescription. Furthermore, 239 (61.1%) of the 391 women filled a prescription for a category X drug >28 days after the last menstrual period when pregnancy would have occurred and 151 women (38.6%) filled a prescription for a category X drug after a physician visit in which pregnancy was diagnosed.

Certain subgroups of these women enrolled in TennCare had significantly increased risk of filling prescriptions for category X drugs during pregnancy: those above the age of 35 years (12.1/1000 for older than 35 years was nearly 10 times higher than

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[7] The EPSDT is a comprehensive set of benefits available to children and youth under age 21 who are enrolled in Medicaid. For more information, see http://www.healthlaw.org/images/stories/epsdt/3-ESDPT08.pdf.

1.5/1000 in women younger than 18 years; p<0.0001) and those enrolled in TennCare because of disability (nearly three times more likely to fill prescriptions for category X medications during pregnancy than women in other categories; p<0.0001). This study did not include reproductive age women of child-bearing ability that were not pregnant and exposed to potentially teratogenic medications or pregnant women exposed to category D medications. Therefore, highly vulnerable groups and additional fetal risks were not evaluated. The authors emphasized the need for monitoring of care delivery and communication to providers regarding exposure of women to category X medications. Specifically, communication should be focused on the highest risk populations including older reproductive age women and those with chronic health conditions.

Another study evaluated a small subset of women (n=105) enrolled in Michigan Medicaid who took loperamide in pregnancy; a drug with unknown effects at that time. It was found that the use of loperamide during pregnancy was not associated with an increased risk of major malformations. In a very recent study, a large national Medicaid database was used to examine rates of cardiac malformations with first-trimester antidepressant exposure in nearly 950,000 pregnant women.[21] Cardiac malformations were diagnosed in 90 per 10,000 antidepressant-exposed infants versus 72 per 10,000 unexposed infants, resulting in no significant difference between groups. While these studies had negative findings, they support the use of Medicaid databases for data analysis and the importance of evaluating this population for potential teratogenic risk.

Overall, although information evaluating pregnant women taking potentially teratogenic medications enrolled in Medicaid or Children's Health Insurance Program (CHIP) programs is inadequate, findings above confirm the importance of this measure for all women. There is widespread use of teratogens by reproductive age women and half of all pregnancies are not planned making this measure of high relevance. These issues are particularly acute for low-income women of color, a population disproportionately covered by Medicaid. High Risk pregnancies are common in general and more so in Medicaid populations.

## III.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).

Previously, we developed measures based on institutional self-report of whether there is 24 hour 7 day a week availability of structural characteristics at the facility in which the woman gave birth. We also developed two measures that focused on the availability of specialty physician services and multidisciplinary care for high risk pregnant women. The current measure focuses on teratogenic drug exposure as a marker of failure of availability of services. It will supplement the collection of measures focused on HROB services to further evaluate and enhance the safety and care for high risk women regardless of birth outcome. This measure represents a measure of safety for mother and infant. As appropriate, definitions and diagnoses used for this measure are harmonious with those of other CAPQuaM HROB measures.

The selection of these topics is valid and justified by evidence summarized above. All were prioritized during our formal expert process. Other priorities will guide future measure development.

*Key recommendations from international and national projects*

The importance of this measure is highlighted by two recent reports from the EUROCAT and EUROPLAN projects and the Centers for Disease Control and Prevention (CDC).[19, 22] The 2 European projects have joined together to provide policy recommendations for primary prevention of congenital anomalies. The recommendations include interdisciplinary expertise to encompass different actions aimed at reducing risk factors and increasing protective factors and behaviors. The scope of actions includes the field of medicinal drugs and specifically outlines goals of:

- advising women to seek medical advice before trying to get pregnant;
- ensuring guidelines will be made available for physicians regarding risk-benefit balance for use of medications in pregnancy (particularly those used for treating chronic diseases);
- providing a teratogen information service where specialized advice can be obtained by women and professionals; and
- conducting postmarketing pharmacovigilence to detect any risk of congenital anomalies associated with the use of medications

In addition, the CDC recently solicited expert input on an outline for a systematic approach to evaluating the quality and strength of evidence for associated risks of medication use in pregnancy. This strategy is known as “Treating for Two: Safer Medication Use in Pregnancy Initiative”.[23] It aims to identify birth defects prevention and optimize maternal health by improving clinical decisions about management of common conditions in pregnancy as well as the reproductive years. The proposed review will incorporate an evidence synthesis and review as well as guideline development via an independent panel of clinical, public health, and prevention experts. Primary outcomes that would be evaluated include preterm birth, fetal death, structural birth defects, poor fetal growth, neurocognitive and behavioral effects, and severe adverse maternal events. This multidisciplinary panel of experts proposed that this prioritization, synthesis, evaluation, and dissemination of safety information is of high clinical and public health relevance.

Our measure complements this focus. We suggest availability of care is essential for women who are at risk of adverse pregnancy outcomes due to teratogenic exposure. This measure has the potential to improve perinatal outcomes in the setting of high risk pregnancies. Thus, this measure strives to decrease the number of pregnancies exposed to teratogenic drugs. Further, our measure also assesses a critical component of safety for this population as high risk women with inadequate preconception and inter-conception care represent a critical failure of the system.

# SECTION IV.
# MEASURE CATEGORIES

CHIPRA legislation[8] 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,[9] 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.

| | | |
|---|---|---|
| a. Care Setting – ambulatory | Yes | |
| b. Care Setting – inpatient | No | |
| c. Care Setting – other—please specify | No | |
| d. Service – preventive health, including services to promote healthy birth | Yes | |
| e. Service – care for acute conditions | Yes | |
| f. Service - care for children with special health care needs/chronic conditions | No | |
| 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 | Yes | 10-65 |
| o. Population – neonates (28 days after birth) (specify age range) | No | |
| p. Population – infants (29 days to 1 year) (specify age range) | No | |
| q. Population – pre-school age children (1 year through 5 years) (specify age range) | No | |
| r. Population – school-age children (6 years through 10 years) (specify age range) | Yes | Pregnant >=10 |
| s. Population – adolescents (11 years through 20 years) (specify age range) | Yes | Pregnant |
| t. Population – other (specify) | Yes | Pregnant <=65 |
| u. Other category (please specify) | No | |

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8 Children's Health Insurance age range Program Reauthorization Act of 2009. Public Law No. 111-3, 123 Stat. 8 (2009). Available at: http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_public_laws&docid=f:publ003.111.

9 Under Section 214 of CHIPRA, States may elect to cover the following groups under Medicaid only or under both Medicaid and CHIP: pregnant women and children up to age 19 for CHIP or up to age 21 for Medicaid.

# SECTION V.
# 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.

## V.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.

Every 4.5 minutes a baby is born with a birth defect in the United States: 120,000 babies are affected by birth defects each year.[9] Certain medications increase the risk of having a birth defect. Negative outcomes can result from fetal exposure to potentially teratogenic medications. This risk can be minimized or avoided with reduced exposure to these potentially teratogenic medications. The use of highly effective contraception (i.e., intrauterine devices, implant, sterilization) can avoid the unplanned concurrence of pregnancy with teratogen use. The most effective structures and processes to provide information to clinicians and to patients about what medications have potential risk and how to communicate risk minimization strategies have not yet been fully elucidated.

Teratogenic risk counseling is not universal with the majority of patients reporting no counseling by their clinician despite being prescribed teratogenic medications. For example, only 40% of individuals prescribed carbamazepine and 22% prescribed valproate receiving this counseling.[24] Only 13-17% of women had documentation surrounding contraceptive issues. In general practice, less than 60% of physicians correctly identify category D or X medications and only 65% understand contraceptive failure rates for various contraceptive methods.[25] This is especially concerning when 1 in every 13 ambulatory care visits involves a prescription for a teratogenic medication.[4] Physicians agree they should be providing information about contraception and teratogenic medications, and patients want that information so it is critical to ensure that appropriate information and appropriate contraceptive counseling

methods are in place.[15, 25, 26] Counseling to avoid the concurrence of pregnancy and teratogen use is a fundamental aspect of pre-conception care.

While clinicians do feel responsible for counseling women about risks when they prescribe medications that may cause birth defects, they perceive many barriers that prevent them from doing so.[15, 27] Changes in alerts within electronic health records or clinical decision support systems have not been effective.[7, 28, 29] The transition within the FDA from pregnancy categories to labeling requirements which will describe in more detail human effects in pregnancy (and lactation) for individual medications may cause additional confusion and provide information that is difficult for clinicians to interpret. While documentation of contraception as a vital sign and quality improvement interventions in primary care have been suggested to address using contraception when potentially teratogenic medications are prescribed, there has been virtually no adoption of effective and sustainable methods that minimize risk of teratogenicity in reproductive age women taking teratogenic medications.[16, 30] This emphasizes a critical need to identify and develop effective and sustainable ways to reduce teratogenic risk.

For every reproductive age woman, the benefits and risks of medications must be weighed. For women with epilepsy or depression, the benefit of remaining on a potentially teratogenic medication may outweigh the medication risk. Preconception planning and counseling may minimize risk to the fetus and the mother. In other circumstances when pregnancy is not desired and these potentially teratogenic medications are used, providing a highly effective form of contraception may avoid teratogenic risk. Thus, while extenuating circumstances may favor use of teratogenic medications during pregnancy, this should be rare.

This measure represents a marker for the availability of the preconception component of high risk obstetrical care as it estimates the use of teratogenic medications during potentially vulnerable periods before and during pregnancy as a marker for failures of availability. This measure is of high relevance given the frequency of teratogenic medications among pregnant women before and during pregnancy.

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

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

This is discussed in detail in sections above. Birth defects and other adverse fetal effects due to medication use are preventable with proper identification and action. The ability to minimize and/or prevent adverse fetal effects due to potentially teratogenic medication use support the focus of this measure with identification of at-risk populations. Given that approximately half of pregnancies are unplanned, this measure will promote patient safety to both the mother and fetus and reduce the potential for adverse outcomes. Appropriate availability of specific aspects of care for women is necessary to achieve desired pregnancy outcomes – including delaying the onset of pregnancy until a time when it is safe for the woman to become pregnant. This measure describes availability of the preconception component of high risk obstetrical care by using the use of teratogenic medications during potentially vulnerable periods before and during pregnancy as evidence of a specific failure or preconception care. Since birth defects have financial as well as health costs, this measure relates to all 6 characteristics (Timely, Equitable, Safe, Efficient, Patient-Centered and Effective) of quality care described in the IOM's Crossing the Quality Chasm[31]. We have described

the importance of this measure in our review above. The proposed measure can provide a marker for the availability of preconception care.

The salience and validity of our work has benefited from our use of a formal method, a pragmatic adaptation of the CAPQuaM 360 degree method. The method, as adapted to availability of HROB services, described in the next paragraph was specifically designed to develop valid and reliable measures in the face of pragmatic epistemological uncertainty. That is, recognizing that practice extends well beyond the research base, we designed this method to allow us to develop reliable and valid state of the science measures, in part by explicitly modeling and accounting for uncertainties in the measure development, in part by the conceptualization and implementation of a Boundary Guideline. We have shared and refined this approach in a number of venues including within the PQMP, comprised of the various PQMP AHRQ-CMS CHIPRA Centers of Excellence, the state PQMP participants, and AHRQ and CMS participants. All presentations have invited dialogue and feedback. This work has been similarly presented at a number of Grand Rounds / weekly conferences in the New York-New Jersey area as well as to national/international audiences including the Bioethics and children's health services communities. These latter venues include:

- 2012 Pediatric Academic Societies State of the Science Plenary (Boston).
- 2012 Oxford-Mount Sinai Bioethics Consortium (Amsterdam)
- 2012 Child Health Services Research Interest Group at Academy Health (Orlando)

Feedback from these presentations has been extremely positive. The Boundary Guideline construct has generated particular enthusiasm. We asked the Bioethics Consortium to extrapolate the primum non nocere (First, do no harm) principle to apply regarding this aspect of performance measurement. We received strong feedback that not only is it ethical to measure using systematically developed measures (even in the context of some uncertainty), but that it is ethically preferable to use such measures compared with the alternative of providing care that is not assessed (and perhaps not assessable) because of residual uncertainty. Fortunately, in the case of this proposed measure we can present both a systematically developed measure and a variety of evidence to support its use.

# SECTION VI.
# 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.

## VI.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 strengths of this measure derive from its systematic development, its thoughtful specification, its careful conceptualization and articulation and its grounding in existing science and consensus.

Our specifications rely on the use of administrative data. These data are used to identify deliveries (our specifications are based on CDC methodologies described in Kuklina et al[32]). We initially tested these specifications in Medicaid MAX data. We added Revenue code 722 to Kuklina specified list as the Medicaid MAX data provided by CMS does not include DRGs, which are employed in the Kuklina method. We also tested a variation of the approach to identify deliveries employed by HEDIS in its Timing of PreNatal Care measure in the initial CHIPRA core set. We found that these approaches identified substantially the same population of deliveries in a sixteen state subset of the national MAX database. We chose the16 states to include in an attempt to manifest some standardization of approaches across the seven AHRQ-CMS CHIPRA Centers of Excellence—they were recommended to us as a diverse set of states with high data quality by the Children's Hospital of Pennsylvania Center which has used them extensively in a number of their validation activities. As the different approaches produced 90% or more overlap, we decided to specify the measure based upon the Kuklina/CDC approach as both widely used and relevant for the type of population-based approach to measurement proposed in this measure. We have used this method for all of CAPQuaM high risk obstetrical services availability measures.

In determining which women were to be considered potentially in need of HROB services, our specifications further rely upon administrative data. One study found that quality measures that could be calculated using administrative data showed higher rates of performance than indicated by a review of the medical record alone, and that claims data is more accurate for identifying services with a high likelihood of documentation due to reimbursement.[33] Further, at the current stage of EMR development and implementation, chart review is likely to prove infeasible for population-based measures of this scope. Since we identify all women for whom the prescription data indicates teratogen use during the year before delivery we are unlikely to miss very many women who were provided prescription teratogenic

medications within their insurance plan. We found that of ~119,000 Medicaid deliveries in New York State in 2010, 59,254 were at sufficiently elevated risk to qualify for this measure set (approximately 50%). Our team had predicted that 50 to 60% of all pregnancies would have elevated risk. Use of a mother-only algorithm in MAX data in 16 states indicates the proportion of high risk pregnancies ranges from 31.50% in NJ to 63.97% in KY. The NY MAX finding was 55,379 HROB pregnancies, almost identical to the 56,465 found using internal data bases on the maternal codes, indicating very high reliability across systems. In the New York State 2012 mother-baby linked dataset used for testing the final specifications, of 102,399 linked files 61,676 (60%) qualified as HROB. The vast majority of the sample qualified because of maternal comorbid illness as specified in Table 2, Section I (82%) or because of pregnancy complications as specified in Table 3, Section I (17%) This rate is consistent with our estimate that 50 to 60% of Medicaid pregnancies would be at elevated risk and within the range seen in our previous 16 state analysis.

As for the specification of teratogens, our scientific team, including an expert pharmacist generated a list of Class X teratogens for the testing of this measures (Table 5). Databases searched for classification included the FDA, Micromedix, and Reprotox databases. Our list was conservative including only Class X medications and omitting things such as Hydroxyzine HCL, an antihistamine suspected of causing birth defects and for which safer in class medications are available. Other medications might prove fertile for future testing for measurement. In our testing of the proportion of women who fill prescriptions for Class X medications before and during pregnancy, 323 deliveries (0.32%) filled prescriptions within the 9 months prior to delivery, 1,167 deliveries (1.14%) filled prescriptions within the 12 months prior to delivery, and 3,405 deliveries(3.33%) filled prescriptions within the 24 months prior to delivery.

In contrast to our hope that this would be a rare event, data analyses completed in 2012 New York State Medicaid linked mother baby records suggest that teratogen use within 12 months of pregnancy occurs with some frequency, more so among pregnancies identified using our HROB algorithm. Although a significant percentage of deliveries who filled two or more prescriptions within 24 months of delivery stopped using teratogens by 9 months prior to their delivery, there was still a considerable number who filled prescriptions for teratogenic medication during pregnancy. Table 2 describes results from testing this measure in New York State 2012 Medicaid data.

Table 2. Testing Results in New York State Medicaid

| Testing results for Teratogen Measures using New York State 2012 Medicaid Linked Mother Baby Records | | | |
|---|---|---|---|
| **Measures** | **Deliveries** | **Number** | **Percent** |
| A. Class X medications within the 9 months prior to delivery. (Lower is more safe) | 102,399 | 323 | 0.32% |
| B. Class X Medications within the 12 months prior to delivery. (Lower is more safe) | 102,399 | 1167 | 1.14% |

| | | | |
|---|---|---|---|
| C. Among High Risk pregnancies (pregnancy complications / maternal comorbidities) Class X Medications within 9 months prior delivery. (Lower is more safe) | 61,713 | 323 | 0.43% |
| D . Among High Risk pregnancies (pregnancy complications/ maternal comorbidities plus teratogen use within 12 months of delivery) Class X Medications within 9 months prior delivery (Lower is more safe) | 61,976 | 323 | 0.52% |
| E. Among High Risk pregnancies (pregnancy complications / maternal comorbidities) Class X Medications within 12 months prior to delivery. (Lower is more safe) | 61,713 | 904 | 1.46% |
| F. Among High Risk pregnancies (pregnancy complications/ maternal comorbidities plus teratogen use within 12 months of delivery) Class X Medications within 12 months prior delivery. (Lower is more safe) | 61,976 | 1167 | 1.88% |
| G. Women who have at least one refill of a teratogenic medication in the 15 months prior to pregnancy who have no prescriptions filled for teratogenic medication in the 9 months prior to delivery. (Higher is more safe) | 984 | 803 | 81.61% |

## VI.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., $R^2$ for concurrent validity). Provide appropriate citations to justify methods.

The reliability section above also contains information related to validity.

Our definition of high risk obstetrical services results from a formal RAND/UCLA modified Delphi process conducted with a multidisciplinary panel of national experts that included obstetricians, MFM specialists, and a nurse midwife, anesthesiologist and family physician. We carefully operationalized the panel's clinical recommendations by fine tuning AHRQ's Clinical Classification Software. We operationalized panel specifications using data elements that are available in typical administrative data sets.

Potential exceptions are elements such as race and ethnicity. Our feasibility work confirmed race/ethnicity are generally available in Medicaid datasets. The CHIPRA legislation (2009) which directs our measures to be capable of identifying disparities and we have specified it to be so, although we are aware of variability in the manner of assignment of race and ethnicity by health care facilities.

Use of administrative data in performance assessment is common. They contain consistent elements, are available, inform regarding large numbers of individuals, and are relatively inexpensive. Validity of many has been established, and their strengths and weaknesses relative to data abstracted from medical records and obtained via survey have been documented and their use encouraged by federal agencies.[34] The Centers for Medicare & Medicaid Services has made clear to the participating AHRQ-CMS CHIPRA Centers of Excellence funded to develop measures in the Pediatric Quality Measures Program that it places a premium on feasibility.

Expert Panels have been demonstrated to enhance measure development and health care evaluation, including for children.[35] Frontline practitioners can assist researchers to create useful measures.[36] CAPQuaM's 360 degree method is highly engaged with collaborators, partners, and the literature. It targets relevant information and perspective and measures emerge from the process. Potential measures are tested to the extent that time and resources permit. In developing the HROB availability measures we incorporate:

- Engagement with broadly diverse partnered institutions and senior advisors;
- Detailed literature review;
- Interviews with clinicians from around the country;
- The CAPQuaM scientific team;
- A geographically diverse, multidisciplinary expert panel who participated in a 2 Round RAND/UCLA modified Delphi process, with enhanced follow up;
- Development of a Boundary Guideline that incorporates simultaneously a variety of gradients, including gradients of importance, relevance, and certainty, as appropriate to the construct being represented;
- Specification and review of measures and approaches to measurement by stakeholders and experts;
- Testing and assessment of measure performance using Medicaid data.

**Availability**

The construct of availability is complex and can be muddied in the distinction or lack thereof between availability, access, and utilization.[1] For this PQMP measure set on availability of preconception HROB services, we use teratogen use as a marker of failure of availability of preconception (inter-conception) care among women needing HROB services. While these measures are challenging to validate definitively, evidence of systematic variation may suggest construct validity.

## High Risk

We have operationalized a systematic expert process informed by a detailed literature review and incorporating a well described and frequently utilized system developed by AHRQ. While we have modified this system, it has been done to be consistent with its use in this context and to remain consistent with the guidance of the expert panel. It is transparent and has high face validity. We validated its use in 16 states using MAX data and in two separate years of New York State Medicaid data. The rate of HROB ranges from 50 to 60% across these datasets, the results are consistent with the fact that

Medicaid pregnancies are higher risk because of higher rates of comorbid illness and pregnancy complications as demonstrated in the literature.

**Teratogen Use as a Marker for Availability of Preconception Care**
This measures describes availability of the preconception component of high risk obstetrical care by using the use of teratogenic (i.e. Class X) medications during potentially vulnerable periods before and during pregnancy as a marker for failures of availability. While only a small slice of what may be accomplished with preconception care, avoiding the use of teratogenic medications during pregnancy (or delaying pregnancy while such medications are in use) has face validity, was advocated by our expert panel, and may be a population marker for insufficient access to high quality preconception care for women at increased risk.

This construct was endorsed by our expert panel and our list of teratogenic medications was generated by our scientific team, including obstetricians and pharmacists. Our list of teratogenic medications includes FDA pregnancy category system (Class X) medications which are considered potentially teratogenic because they have evidence of human risk clearly outweighing the benefit. Pregnancy category classification was generated from the FDA, Micromedix, and Reprotox databases. Although Class D medications can be considered teratogenic our expert panel did not endorse the inclusion of these medications in this measure as Class D medications are more likely to be used appropriately in high risk pregnancies.

# SECTION VII.
# 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.

## VII.A. Race/Ethnicity

Data elements on race and ethnicity are often available in administrative data and typically available to Medicaid programs. The New York State Medicaid Program was able to identify race using their information systems. Forty five individuals out of nearly 60,000 pregnancies were missing data on race.

We examined race/ethnicity data in New York State Medicaid files for 2012. Of the over 102,399 deliveries included in our testing, 12803 (21%) were black, Non-Hispanic, 18,459 (30%) were Hispanic, 18,965 (31%) were white, and 11,486 (195) were other. We found that approximately 1% of all deliveries, and 1.8% percent of HROB deliveries filled prescriptions for teratogenic (Class X drugs) during the 12 months prior to their delivery date. Here are results describing the proportion of women who fill prescriptions for Class X medications within the 12 months prior to their delivery date by race.

**Table 3 Teratogen Use Stratified by Race/Ethnicity**

| Race/Ethnicity | Deliveries | Number Who Filled Class X Prescriptions within 12 Months of Delivery | Percent |
|---|---|---|---|
| **All Deliveries** | 102399 | 1167 | 1.14% |
| **Black, Non-Hispanic** | 18932 | 210 | 1.11% |
| **Hispanic** | 33039 | 262 | 0.79% |
| **Other** | 20139 | 386 | 1.92% |
| **White, Non-Hispanic** | 30289 | 309 | 1.02% |

Pairwise comparisons revealed significant differences by race for teratogen use within 12 months of delivery (whites versus all other races, p=.02; blacks versus all other races, NS, Hispanics versus all other races, p<.001; Others versus all other races, p=.001). These results suggest that variation in teratogen use can be identified with this measure. We recommend that reporting of results of this measure are stratified by race and ethnicity.

## VII.B. Special Health Care Needs

As a class, women with high risk pregnancy constitute a population with special health care needs, although they are not strictly “Children with special health care needs”

## VII.C. Socioeconomic Status

We used the national distribution of percent of individuals in poverty to establish five categories that reflect the counties level of poverty. We considered other data such as county median income or county unemployment, but felt that the percent of individuals in poverty was a more integrative measure. The use of a geographic rather than an individual measure is consistent with recent applications of hierarchical methods to study the impact of poverty and also with data that indicate that local disparities in income are an independent predictor of outcomes. It also allows this measure to consider issues of socioeconomic status while using publicly available data and requiring only the mother’s county of residence, a more reliable data point than self- reported income.

Our analysis of USDA data considering 3142 counties and related geographic units found a mean of 17.2 % of county residents living in poverty, a standard deviation of 6.5%, and an interquartile range of 8.2%. The distribution illustrated below, shows meaningful dispersion and supports our plan to build off quartiles of distribution with a finer focus in higher areas of poverty. See Table 4 below.

**Table 4**

| Quantile | Percent in Poverty |
|---|---|
| Maximum | 49.9% |
| 99 | 37.5% |
| 95 | 28.9% |
| 90 | 25.7% |
| 75 | 20.7% |
| 50 | 16.5% |
| 25 | 12.5% |
| 10 | 10.0% |
| 5 | 8.6% |
| 1 | 6.1% |
| Minimum | 2.9% |

All of New York State lies in the top three quartiles. We would expect to find the largest differences between poorer and other counties, than across the upper end of the spectrum. Plans can use county poverty levels to stratify measures by level of poverty.

## VII.D. Rurality/Urbanicity

As described in the specification, we used the Urban Influence Codes (UIC) below to describe the level of rurality or urbanicity.

Metropolitan

1. In large metro area of 1+ million residents
2. In small metro area of less than 1 million residents

Non-metropolitan

3. Micropolitan adjacent to large metro
4. Non-core adjacent to large metro
5. Micropolitan adjacent to small metro
6. Non-core adjacent to small metro with own town
7. Non-core adjacent to small metro no own town
8. Micropolitan not adjacent to a metro area
9. Non-core adjacent to micro with own town
10. Non-core adjacent to micro with no own town
11. Non-core not adjacent to metro or micro with own town
12. Non-core not adjacent to metro or micro with no own town

We analyzed 3143 county equivalents in the U.S, and the results are shown in Table 5 below.

**Table 5**

| UIC_2013 | | |
|---|---|---|
| **UIC_2013** | **Frequency** | **Percent** |
| **1** | 432 | 13.74 |
| **2** | 735 | 23.39 |
| **3** | 130 | 4.14 |
| **4** | 149 | 4.74 |
| **5** | 242 | 7.70 |
| **6** | 344 | 10.94 |
| **7** | 162 | 5.15 |
| **8** | 269 | 8.56 |
| **9** | 184 | 5.85 |
| **10** | 189 | 6.01 |
| **11** | 125 | 3.98 |
| **12** | 182 | 5.79 |

The population is heavily weighted to metropolitan areas as demonstrated in Table 6 below.

**Table 6**

| UIC_2013 | | | | |
|---|---|---|---|---|
| **UIC_2013** | **Frequency** | **Percent** | **Cumulative Frequency** | **Cumulative Percent** |
| **1** | 1.672E8 | 55.07 | 1.672E8 | 55.07 |
| **2** | 91886000 | 30.27 | 2.5909E8 | 85.34 |
| **3** | 6921700 | 2.28 | 2.6601E8 | 87.62 |
| **4** | 3094100 | 1.02 | 2.691E8 | 88.64 |
| **5** | 10760300 | 3.54 | 2.7986E8 | 92.18 |
| **6** | 7005400 | 2.31 | 2.8687E8 | 94.49 |
| **7** | 1511900 | 0.50 | 2.8838E8 | 94.99 |
| **8** | 8459500 | 2.79 | 2.9684E8 | 97.78 |
| **9** | 2684400 | 0.88 | 2.9952E8 | 98.66 |
| **10** | 1289100 | 0.42 | 3.0081E8 | 99.09 |
| **11** | 1887800 | 0.62 | 3.027E8 | 99.71 |
| **12** | 887700 | 0.29 | 3.0359E8 | 100.00 |

As noted, we use Urban Influence Codes (UIC), which have been developed by the USDA based on a number of criteria to describe the levels of urbanicity and rurality. This is intended not only to report within plan differences but to allow for aggregation as appropriate. While each UIC has its own meaningful definition, some researchers choose to aggregate various codes. We recommend consideration of the aggregation schema of Bennett and colleagues at the South Carolina Rural Research Center (44). Their aggregation scheme brings together Codes 1 & 2 as Urban; 3, 5, & 8 as micropolitan rural; 4, 6, & 7 as rural adjacent to a metro area; and 9, 10, 11, & 12 as remote rural. We observe that UIC 5 might also be aggregated with 4, 6, & 7 as an adjacent rural area. Further, this approach to rurality does not map exactly to the population density based definition of frontier (< 6 persons per square mile) as articulated in the Affordable Care Act. However, use of such categories is consistent with the ACA's intent that the Secretary ask that data collected for racial and ethnic disparities also look at underserved frontier counties. Frontier health care may be approximated by analysis of the remote rural categories (45). Our judgment was confirmed after CAPQuaM consulted with Gary Hart, Director of the Center for Rural Health at the University of North Dakota School of Medicine & Health Sciences, who is heading a HRSA-funded project to develop new methods to analyze frontier health. We clarified that his work suggests that UIC 9-12 is the best overall approach to using county level data to study frontier health. Those interested in care specific to large cities may wish to aggregate rural areas and analyze UIC 1 and 2 separately. Our testing suggests confirms that analyzing UIC 1 and 2 separately is necessary for certain settings and the findings considering overall teratogen use suggest this.

The New York State Medicaid data was less sensitive to the distinction between urban versus rural but was sensitive to the distinction between large versus smaller urban cities. Table7 describes the proportion of women who fill prescriptions for Class X medications within 12 months prior to their delivery date by Urban Influence Code.

**Table 7: Teratogen Use Stratified by Urban Influence Code**

| UIC | Deliveries | Number Who Filled Class X Prescriptions within 12 Months of Delivery | Percent |
|---|---|---|---|
| **All Deliveries** | 101980 | 1164 | 1.14% |
| **1** | 83657 | 1030 | 1.23% |
| **2** | 12872 | 76 | 0.59% |
| **3** | 1339 | 14 | 1.05% |
| **4** | 214 | 1 | 0.47% |
| **5** | 2212 | 19 | 0.86% |
| **6** | 1091 | 14 | 1.28% |
| **7** | 77 | 2 | 2.60% |
| **8** | 365 | 6 | 1.64% |
| **9** | 153 | 2 | 1.31% |

Pairwise comparisons revealed that UIC 1 had higher rates of teratogen use as compared with UIC 2-9 ($p<.0001$) and UIC 2 had lower rates of teratogen use as compared with UIC 1, 3-9 ($p<.0001$). These results may suggest that practice patterns vary between large urban cities versus smaller cities.

## VII.E. Limited English Proficiency (LEP) Populations

Not assessed, but there is nothing intrinsic to the measure to inhibit its use in that population so long as the LEP characteristic can be linked to the pregnancy or delivery data.

# SECTION VIII.
# 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.[10] Using the following sections, explain the methods used to determine the feasibility of implementing the measure.

## VIII.A. Data Availability

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

The definitions were specified to allow their use with data elements that are available in administrative data, including health plan or state Medicaid programs. While zip code is sometimes a hidden or non-public variable when such data sets are released, it generally is available to a responsible entity, such as an insurer and a Medicaid program. Race and ethnicity are typically available to Medicaid programs and are on institutional medical records (e.g. hospitals). They are often but not always recorded in insurance databases. We have data from a feasibility study conducted that confirms that both data elements are generally available in the medical record, frequently electronically. The rapid expansion of data gathering from electronic health records can help augment administrative data review in measure assessment.

The CAPQuaM High-Risk OB measures seek to assess the proportion of high risk women that are exposed to teratogens (Class X medications) during their pregnancy. As such, the data elements of interest include:

- Prescription fill data
- Outpatient claims data
- Documentation of conditions that would classify a woman as "high risk"

For stratification purposes:

- Race and ethnicity
- Insurance type (Medicaid, Private, Uninsured)
- Managed care insurance – Yes/No (where applicable)
- Benefit category (for Medicaid and CHIP eligible cohorts)
- Income level (as recorded for Medicaid and CHIP eligible cohorts)
- County equivalent and State, or Zip Code of residence

Several of these data elements are readily available through hospital administrative data. For

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[10] The definition is adapted from: Centers for Medicare & Medicaid Services Quality Measurement and Health Assessment Group glossary, as part of the Measures Management System Measure Development Overview. Available at: http://www.cms.gov/MMS/19_MeasuresManagementSystemBlueprint.asp#TopOfPage. Accessed February 6, 2012.

example, identification of women with “high risk” conditions can be achieved through use of the appropriate ICD9, CCS, and/or revenue codes. Prescription fill data can be achieved through administrative data. Additionally, benefit type is typically recorded in health plan, Medicaid and CHIP administrative data sets.

As part of our feasibility assessment, CAPQuaM partnered with New York State Medicaid to conduct a variety of analyses using their administrative data set. The findings from these analyses indicated that the administrative data elements are readily available at the state-level, and can be abstracted and used for calculating and reporting the CAPQuaM HROB measures. Further, we have specified several variables, for SES, and urbanicity by linking county of residence at the time of delivery to publicly available data sets.

Payment source (insurance type) should be available in a health plan data base and is also easily obtained from administrative data.

**VIII.A.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?

The data required for the CAPQuaM HROB measures are generally available in the existing data systems. Enhancement of linkages between mothers and babies, the routine reporting of estimated gestational age at delivery or date of conception, and similar data infrastructure would extend the capacity for refined reporting of these sort of HROB measures. Enhancement of collection of patient reported race-ethnicity data into existing administrative systems would also be valuable.

## VIII.B. Lessons from Use of the Measure

**VIII.B.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.

New measure.

**VIII.B.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?

The measure is not currently in use.

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

The measure is not currently in use.

# SECTION IX.
# 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 Section XVI. 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. Table IX-1 shows the questions (in columns) about the measure's use at different levels of aggregation for quality reporting (in rows) included in the CPCF.

Table IX-1. Questions about the measure's use at different levels of aggregation for quality reporting

| **Level of aggregation (Unit) for reporting on the quality of care for children covered by Medicaid/CHIP†** | **Intended use: Is measure intended to support meaningful comparisons at this level? (Yes/No)** | **Data Sources: Are data sources available to support reporting at this 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?** | **In Use: Have measure results been reported at this level previously?** | **Reliability & Validity: Is there published evidence about the reliability and validity of the measure when reported at this level of aggregation?** | **Unintended consequences: What are the potential unintended consequences of reporting at this level of aggregation?** |
|---|---|---|---|---|---|---|
| State level*: Can compare States | ☒Yes<br>☐No | Yes | Minimum size specified for analysis is 250. Study of HROB deliveries in MAX data in 18 states using slightly less sensitive criteria than those specified herein found range from 1637 (VT) to 55,382 (NY). The Median is 14,500, with 25% less than 4,000 deliveries. | No | No | None anticipated |
| Other geographic level: Can compare other geographic regions (e.g., MSA, HRR) | ☒Yes<br>☐No | Yes | Minimum size specified for analysis is 250. Study of HROB deliveries in MAX data in 18 states using slightly less sensitive criteria than those specified herein found range from 1637 (VT) to 55,382 (NY). The Median is 14,500, with 25% less than 4,000 deliveries. We specify using urban influence codes which allows for a variety of analyses. | No | No | None anticipated |
| Medicaid or CHIP Payment model: Can compare payment models (e.g., managed care, primary care case management, FFS, and other models) | ☒Yes<br>☐No | Yes | Minimum size specified for analysis is 250. Study of HROB deliveries in MAX data in 18 states using slightly less sensitive criteria than those specified herein found range from 1637 (VT) to 55,382 (NY). The Median is 14,500, with 25% less than 4,000 deliveries. | No | No | None anticipated |

| Level of aggregation (Unit) for reporting on the quality of care for children covered by Medicaid/CHIP† | Intended use: Is measure intended to support meaningful comparisons at this level? (Yes/No) | Data Sources: Are data sources available to support reporting at this 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? | In Use: Have measure results been reported at this level previously? | Reliability & Validity: Is there published evidence about the reliability and validity of the measure when reported at this level of aggregation? | Unintended consequences: What are the potential unintended consequences of reporting at this level of aggregation? |
|---|---|---|---|---|---|---|
| Health plan*: Can compare quality of care among health plans. | ☒Yes<br>☐No | Yes | Minimum size specified for analysis is 250. Study of HROB deliveries in MAX data in 18 states using slightly less sensitive criteria than those specified herein found range from 1637 (VT) to 55,382 (NY). The Median is 14,500, with 25% less than 4,000 deliveries. | No | No | None anticipated |
| **Provider-level*** Individual practitioner: Can compare individual health care professionals | ☐Yes<br>☒No | No | Not specified for this purpose | No | No | Not specified for this purpose |
| Hospital: Can compare hospitals | ☐Yes<br>☒No | No | Not specified for this purpose | No | No | Not specified for this purpose |
| Practice, group, or facility:** Can compare: (i) practice sites; (ii) medical or other professional groups; or (iii) integrated or other delivery networks | ☐Yes<br>☒No | No | Not specified for this purpose | No | No | Not specified for this purpose |

† There could be other levels of reporting that could be of interest to Medicaid agencies such as markets and referral regions.

* Required in CHIPRA legislation.

** There is no implication that measures that are applicable at one level are automatically applicable at all three of the levels listed in this row.

# SECTION X.
# 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).

The focus of this CAPQuaM measure is women's exposure to teratogenic drugs before and throughout pregnancy which is a marker for failure of preconception (inter-conception, where appropriate) care. At the individual level the use of teratogens during pregnancy represents a failure of patient safety. While surely there are individual circumstances for which the anticipated benefits of use of a Class X medication is greater than the anticipated risk, by definition such circumstances are rare and should be considered to be extenuating. We consider variations or use of these medications at the population level to represent a marker for differences in the availability of safe and effective preconception high risk obstetrical services.

We have not tested combining these measures into an index but could imagine some states or other entities wanting to do that. We will consider that for our future development work.



Understandability is at the heart of CAPQuaM's measure development process. Throughout development, CAPQuaM brought together diverse stakeholders – clinicians, scientists, payers, purchasers, consumer organizations, and others – to ensure their iterative engagement in advancing quality measures that are understandable, salient and actionable. CAPQuaM employed a 360° method, designed to involve key stakeholders in meaningful ways.

Our development process for this measure cultivated formal input from:

- Medical literature (both peer reviewed and gray, including state websites)
- Relevant clinicians
- Organizational stakeholders (our consortium partners, as well as advisory board members, see below)
- Multi-disciplinary, geographically diverse expert panel including clinicians and academicians; and,
- CAPQuaM's scientific team.

Clinical criteria, including consideration of inclusion and exclusion criteria, were developed using a modified version of the RAND/UCLA modified Delphi Panels. CAPQuaM sought recommendations from major clinical societies and other stakeholders to identify academic and clinician expert panel participants with a variety of areas of backgrounds, clinical and regional settings, and expertise. The product of this process was participation by a broad group of experts in the development of clinically detailed scenarios leading to the measures.

CAPQuaM integrated perspectives from a national consortium, Steering Committee, and

Senior Advisory Board at each step of the process, in addition to a continuing collaboration with AHRQ. Our team far exceeded the required minimums for expertise outside of the mainstream medical system, ensuring understandability at various levels, and by a variety of audiences.

Alpha testing was performed to assess feasibility, mechanisms of data collection and operational aspects of collecting and analyzing data for the measure.

Beta testing was performed by the NY State Office of Health Insurance Programs (Medicaid) in close collaboration with the CAPQuaM team.

The route to measure specification included development of relevant scenarios and issues for formal processing by our expert panel who participated in a two round RAND/UCLA modified Delphi panel that culminated in a two-day long in person meeting and moderated by a pediatrician and an obstetrician-gynecologist. The output from that panel meeting was summarized in the form of a boundary guideline that was then used to guide the measure specification and prioritization.

# SECTION XI.
## 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 calculation of the measure.

### XI.A. Health IT Enhancement

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

As health information systems advance, perhaps the administrative data at the heart of this measure could migrate from billing and management systems to the EHR. We are not yet there.

### XI.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?

### XI.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.

Other than perhaps the race/ethnicity data, the clinical data are a part of routine administrative data systems. The migration of diagnosis data from the EMR directly to administrative systems could conceivably improve the accuracy of the data in the future, although this is not clear.

### XI.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: http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov__standards_ifr/1195)?

No.

If yes, please describe.

### XI.E. Health IT Calculation

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

Not applicable.

## XI.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 on the measure?

Not applicable.

## SECTION XII.
## 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).

The definition of high risk obstetrical care is based upon a careful, evidence driven consensus process that was highly engaged and guided by an extraordinary and multidisciplinary panel of national experts. The CAPQuaM team carefully operationalized their conclusions and maintained dialogue as we did so. Still there were infinite combinations of qualifying criteria and we had to specify one. We are confident that the specifications are strong, the conditions meaningful, and the population is at increased risk. But these were designed from the outset and explicitly discussed at the expert meeting to be population-based measures. They are intended for the measurement of performance across populations, not for the assessment of the quality of an individual's care. The inevitable noise in the measures was designed to be dwarfed by the signal when applied to large numbers of pregnant women, but not for any given individual.

This measure requires prescription fill data specified in state Medicaid data, health plans, and other administrative data sources. Our colleagues at the New York State Department of Health and other members of our Steering Committee have confirmed that this is a feasible and valid way to assess teratogenic drug exposure. However, because of limitations in the current data system, we can only assess prescription fill at this time rather than the actual use of such medications. Finally, our inclusion of only Class X medications enhances the sensitivity of this meaning for identifying avoidable pharmacological risk during pregnancy at the expense of sensitivity.

## SECTION XIII.
## 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 innovative measure addresses a complex and critical idea: How available is the preconception component of high risk obstetrical services by estimating the use of teratogenic medications before and during pregnancy. Specifically, how often are women exposed to potentially harmful teratogens during their pregnancy because they lack availability of preconception or inter-conception care. We set forth specifications to identify pregnancies that constitute high risk and those that are exposed to teratogens.

These measures respond to the assignment to CAPQuaM, an AHRQ-CMS CHIPRA Center of Excellence in the Pediatric Quality Measurement Program. We have used a rigorous and systematic process that was highly engaged with clinicians, stakeholders, and experts to

develop these measures. We began with the evidence base and the literature.

Four million births occur annually and our data demonstrate that in any given state between one- and two-thirds of pregnancies are high risk. Exposure to teratogens during pregnancy is associated with significant adverse outcomes and occurs with some frequency. The rapidly rising rate of teratogenic drug use and associated complications point out the need for increased availability of preconception (inter-conception) HROB care.

These are important measures regarding quality and patient safety. Given the number and severity of fetal effects that can occur with many different medications, discussing medication use with women of reproductive age and child-bearing ability is critical, as is avoiding the concurrence of pregnancy with teratogenic medications whenever possible. However, data suggests that counseling occurs in only a quarter to half of cases. There is a growing need to address preconception care as a means of reducing risk among women and their offspring. This measure addresses one component of preconception care by estimating the use of teratogenic medications before and during pregnancy. It is both a safety measure for these women and a population marker for preconception care more generally.

Our validation tests showed that rates of teratogen use vary by race and geography. We found the sub-measures to be complementary and not duplicative. The sub-measures were sensitive to differences in race, and urbanicity. We found they could be implemented in New York State Medicaid data. The measures performed well.

# SECTION XIV.
# IDENTIFYING INFORMATION FOR THE MEASURE SUBMITTER

Complete information about the person submitting the material, including the following:

a. Name: Lawrence Kleinman

b. Title: Director, Mount Sinai CAPQuaM

c. Organization: Icahn School of Medicine at Mount Sinai

d. Mailing Address: One Gustave L. Levy Place, Box 1077, New York, NY 10029

e. Telephone: 212-659-9556

f. Email: lawrence.kleinman@mssm.edu

g. Signed written statement guaranteeing that all aspects of the measure will be publicly available, as defined in the Public Disclosure Requirements.

## 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 (Section XIV: Identifying Information for the Measure Submitter).

# SECTION XV.
# GLOSSARY OF TERMS

| TERM # | TERM | DEFINITION | SOURCES |
|---|---|---|---|
| 1. | DENOMINATOR | The number or population representing the total universe in which an event might happen: the number at risk used to calculate a rate, proportion, or percentage. | Cohn, 2001 |
| 2. | MEDICAL GROUP | A medical group is a self-defined "parent" provider organization which may exist within a broader network structure and is generally comprised of multiple practice sites, but can represent a single, large multi-specialty practice site.<br>- They often have integrated administrative systems and procedures.<br>- Some represent hospital affiliated provider organizations. | PQMP Result Aggregation Workgroup, 2012 |
| 3. | NETWORK | A network is an overarching affiliation of medical groups and/or practice sites with an integrated approach to quality improvement that health plans regard as a contracting entity for these provider organizations.<br>- Most represent a collection of ambulatory practice sites whose integrated systems and procedures support clinical and administrative functions (e.g. scheduling, treating patients, ordering services, prescribing, keeping medical records and follow-up).<br>- Some embody a collection of hospital affiliated providers. | PQMP Result Aggregation Workgroup, 2012 |
| 4. | NUMERATOR | A subset of those in the denominator who have experienced the event of interest (e.g., death, morbidity, screening) used to calculate a rate, proportion, or percentage. | RTI |
| 5. | OUTCOME | A particular state of health, often defined for purposes of quality measurement as a result of the performance (or nonperformance) of functions or processes of care. | Adapted from CMS |
| 6. | OUTCOME MEASURE | Measure that indicates the results of the performance (or nonperformance) of functions or processes. A measure that focuses on achieving a particular state of health. | CMS |
| 7. | PROCESS MEASURE | Measure that focuses on a health care process that leads to a certain outcome. For a process measure to be valid, a scientific basis exists for believing that the process, when executed well, will increase the probability of achieving a desired outcome. | Adapted from CMS |
| 8. | PRACTICE SITE | A practice site is one or a group of providers who practice together at a single location (i.e. same mailing address down to the Suite # level).<br>- The single location is the site where care is provided during specific periods of time.<br>- The same systems and procedures support clinical and administrative functions (e.g. scheduling, treating patients, ordering services, prescribing, keeping medical records and follow-up).<br>- Medical records for all patients treated at the practice site are available to and shared by all providers, as appropriate. | Adapted from National Committee on Quality Assurance's practice site methodology |
| 9. | PROCESS (of care) | Process of care denotes what is actually done to the patient in the giving and receiving of care. As examples: the provider could immunize the patient against a communicable disease; the provider could prescribe a medication for the patient; the provider could screen an asymptomatic patient for developmental disorders. | Adapted from IOM, 2006, Appendix E |

| TERM # | TERM | DEFINITION | SOURCES |
|---|---|---|---|
| 10. | PROVIDER | Provider is any individual, organization, facility or group that delivers direct health care to children; depending on the measurement context, this may be a hospital, medical group, or individual clinician. | PQMP Result Aggregation Workgroup, 2012 |
| 11. | QUALITY (in health care) | Health care quality has been defined in several ways. In 1990, the Institute of Medicine (IOM) defined quality as the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge (IOM, 1990). Eisenberg defined quality as the right care for the right person at the right time in the right way. In 2001, the IOM defined quality as having six aims: Safety, Timeliness, Effectiveness, Equity, Efficiency, and Patient-Centeredness. The Affordable Care Act defines quality of care as a measure of performance on IOM's six aims for health care. CHIPRA defines a clinical quality measure as "a measurement of clinical care that is capable of being examined through the collection and analysis of relevant information, that is developed in order to assess one or more aspects of pediatric health care quality in various institutional and ambulatory health care settings, including the structure of the clinical care system, the process of care, the outcome of care, or patient experiences in care." | IOM, 2001; IOM, 1990; Eisenberg, 1997; CHIPRA, 2009; Patient Protection and Affordable Care Act, 2010 |
| 12. | QUALITY MEASURE | A quality measure is in effect a rule (or the result of a rule) that assigns numeric values to a specific quality indicator. Quality measures generally consist of a descriptive statement or indicator, a list of data elements necessary to construct and/or report the measure, detailed specifications that direct how the data elements are to be collected (including the source of data), the population on whom the measure is constructed, the timing of data collection and reporting, the analytic models used to construct the measure, and the format in which the results will be presented. | Adapted from IOM, 2006, Appendix E; NQMC Glossary |
| 13. | RELIABILITY | Measure reliability: The results of the measure are reproducible a high proportion of the time when assessed in the same population (e.g., the measure has high inter-rater reliability, no calculation errors).<br>**Internal consistency reliability** (http://en.wikipedia.org/wiki/Internal_consistency) assesses the consistency of results across items within a test, where "test" refers to a series of questions, ratings, or other items designed to determine knowledge, ability, or health status.<br>**Inter-rater reliability** (http://en.wikipedia.org/wiki/Inter-rater_reliability) is a measure of the variation in measurements when taken by different individuals but with the same method or instruments.<br>**Test-retest** (http://en.wikipedia.org/wiki/Test-retest_reliability) is a statistical method used to determine a test's **reliability** (http://en.wikipedia.org/wiki/Reliability_(statistics). The test is performed twice; in the case of a questionnaire, this would mean giving a group of participants the same questionnaire on two different occasions. If the **correlation** (http://en.wikipedia.org/wiki/Correlation) between separate administrations of the test is high (~.7 or higher), then it has good test-retest reliability. It is important to consider the time interval between testing and retesting and the nature of the measurement. Quality measures optimally would show improvement in scores over time. | CMS; Wikipedia based on The Standards for Educational and Psychological Testing, 1999***; The Free Dictionary by Farlex |

| TERM # | TERM | DEFINITION | SOURCES |
|---|---|---|---|
| 14. | STRUCTURE | Structure refers traditionally to the attributes of settings in which providers deliver health care, including material resources (e.g., electronic health records), human resources (e.g., staff expertise), and organizational structure (adapted from IOM, Performance Measurement, 2006; Appendix E). Some have suggested that structural attributes should include organizational characteristics such as leadership and culture (Kunkel, 2007) and system attributes beyond individual health care delivery settings. | Adapted from IOM, 2006, Appendix E |
| 15. | STRUCTURAL MEASURE | Measures of structure assess the capacity of health care professionals and organizations to provide safe, timely, effective, equitable, efficient and patient-centered processes of care and positive health outcomes. | Adapted from AHRQ |
| 16. | STRUCTURE-PROCESS-OUTCOMES MODEL | As identified by Donabedian (1988), the classic paradigm for assessing quality of care based on a three-component approach. Donabedian's model proposes that each component has a direct influence on the next (Donabedian, 1980): Structure influences Process, which in turn influences Outcomes. | IOM, 2006, Appendix E |
| 17. | VALIDITY | Measure accurately represents the concept being evaluated and achieves the purpose for which it is intended (to measure quality). In **science** (http://en.wikipedia.org/wiki/Science) and **statistics** (http://en.wikipedia.org/wiki/Statistics), validity has no single, agreed-upon definition but generally refers to the extent to which a concept, conclusion, or measurement is well founded and corresponds accurately to the real world. The word "valid" is derived from the Latin *validus*, meaning strong.<br>**Concurrent validity** (http://en.wikipedia.org/wiki/Concurrent_validity) refers to the degree to which the measure correlates with other measures of the same construct that are measured at the same time. Using a testing example, a test administered to current employees and then correlated with their scores on current performance reviews would have good concurrent validity if those who scored well on the test also did well on performance reviews.<br>*Construct validity* is the extent to which a measure measures the concept or construct that it is intended to measure. For example, a measure that measures the quality of diabetes care by whether a provider conducted an HbA1c test on a patient with diabetes has relatively good construct validity because high HbA1c levels are associated with diabetes crises.<br>*Content validity*. In **psychometrics** (http://en.wikipedia.org/wiki/Psychometrics), content validity refers to the extent to which a measure represents all facets of a given **construct** (http://en.wikipedia.org/wiki/Social_construct). For example, a depression scale may lack content validity if it only assesses the affective dimension of depression but fails to take into account the behavioral dimension. Using the diabetes care example, a combination of three different measures (HbA1c testing, foot examinations, and eye examinations) would have better content validity than a single measure of HbA1c testing. | CMS, Wikipedia, based on The Standards for Educational and Psychological Testing, 1999 *** |

| TERM # | TERM | DEFINITION | SOURCES |
|---|---|---|---|
| 17. (cont.) | VALIDITY (cont.) | **Criterion validity** (http://en.wikipedia.org/wiki/Criterion_validity) involves the correlation between a measure and a criterion variable (or variables) taken as representative of the construct. In other words, it compares the test with other measures or outcomes (the criteria) already held to be valid. For example, IQ tests are often validated against measures of academic performance (the criterion). If the test data and criterion data are collected at the same time, this is referred to as *concurrent validity* evidence. If the test data are collected first in order to predict criterion data collected at a later point in time, then this is referred to as *predictive validity* evidence.<br>*Face validity* is the validity of a measure at face value. Generally face validity means that the measure "looks like" it will work, as opposed to "has been shown to work."<br>**Predictive validity** (http://en.wikipedia.org/wiki/Predictive_validity) refers to the degree to which the measure can predict (or correlate with) other measures of the same construct that are measured at some time in the future. In job selection, for example, this would mean that tests are administered to applicants, all applicants are hired, their performance is reviewed at a later time, and then their scores on the two measures are correlated. If there is a strong correlation between test scores and future performance, the test would be said to have good predictive validity.<br>*Measures should be assessed against all relevant criteria at all intended levels of aggregation.* | continued |

***A revised version is expected after 2012.

# SECTION XVI.
# SOURCES FOR PQMP CPCF FORM


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August 6, 2014

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**Measure:** Assessing the availability of the preconception component of High Risk Obstetrical Services by Estimating the Use of Teratogenic Medications Before and During Pregnancy

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