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), 371 (uncomplicated cesarean section), 372 (complicated vaginal delivery), 373 (uncomplicated vaginal delivery) 374 (uncomplicated vaginal delivery with sterilization and/or dilatation & curettage) 375 (vaginal delivery with operation room procedure except sterilization and/or dilatation & curettage)
Selected delivery related procedures	ICD-9-CM = 720, 721, 7221, 7229,7231, 7239, 724, 726 (forceps) 7251, 7252, 7253, 7254 (breech extraction) 7271, 7279 (vacuum extraction) 728, 729 (other specified and unspecified delivery) 7322 (internal and combined version and extraction) 7359 (other manually assisted deliveries) 736 (episiotomy)740, 741, 742, 744, 7499 (cesarean section)

Exclusions	ICD-9 = CM 630 (hydatidiform mole) 631 (other abnormal product of conception) 633 (ectopic pregnancy) 632 (missed abortion) 634 (spontaneous abortion) 635 (legally induced abortion) 636 (illegal abortion) 637 (unspecified abortion) 638 (failed attempted abortion complication) 639 (complications following abortion and ectopic and molar pregnancies) 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 79021 Impaired fasting glucose 79022 Impaired glucose tolerance test (oral) 79029 Other abnormal glucose 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 7852 Undiagnosed cardiac murmurs 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 5891 Bilateral small kidneys 5899 Small kidney, unspecified
128	10 m	Asthma	49381 Exercise induced bronchospasm 49382 Cough variant asthma
132	10 m	Lung disease due to external agents	
133	2y	Other lower respiratory disease	78600 Respiratory abnormality, unspecified 78601 Hyperventilation

			78602 Orthopnea 78605 Shortness of breath 78606 Tachypnea 78607 Wheezing 78606 Tachypnea 78607 Wheezing 7862 Cough 7864 Abnormal sputum 78652 Painful respiration 7866 Swelling, mass, or lump in chest 7867 Abnormal chest sounds 7868 Hiccough 7931 Nonspecific (abnormal) findings on radiological and other examination of lung field 79311 Solitary pulmonary nodule 79319 Other nonspecific abnormal finding of lung field 7942 Nonspecific abnormal results of pulmonary function study V126 Personal history of diseases of respiratory system V1260 Personal history of unspecified disease of respiratory system V1261 Personal history of pneumonia (recurrent) V1269 Personal history of other diseases of respiratory system
59, 61, 63, 64	2y	59. Deficiency anemias 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 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 642.01 Threatened abortion delivered 642.03 Threatened abortion antepartum 640.80 Other specified hemorrhage in early pregnancy unspecified as to episode of care 640.81 Other specified hemorrhage in early pregnancy delivered 640.83 Other specified hemorrhage in early pregnancy antepartum 640.90 Unspecified hemorrhage in early pregnancy unspecified as to episode of care 640.91 Unspecified hemorrhage in early pregnancy delivered 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 642.31 Transient hypertension of pregnancy with delivery 642.32 Transient hypertension of pregnancy with delivery with postpartum complication 642.33 Antepartum transient hypertension 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 345xx	*10m*	*Epilepsy*
V23.49	*10m*	*Poor OB history*

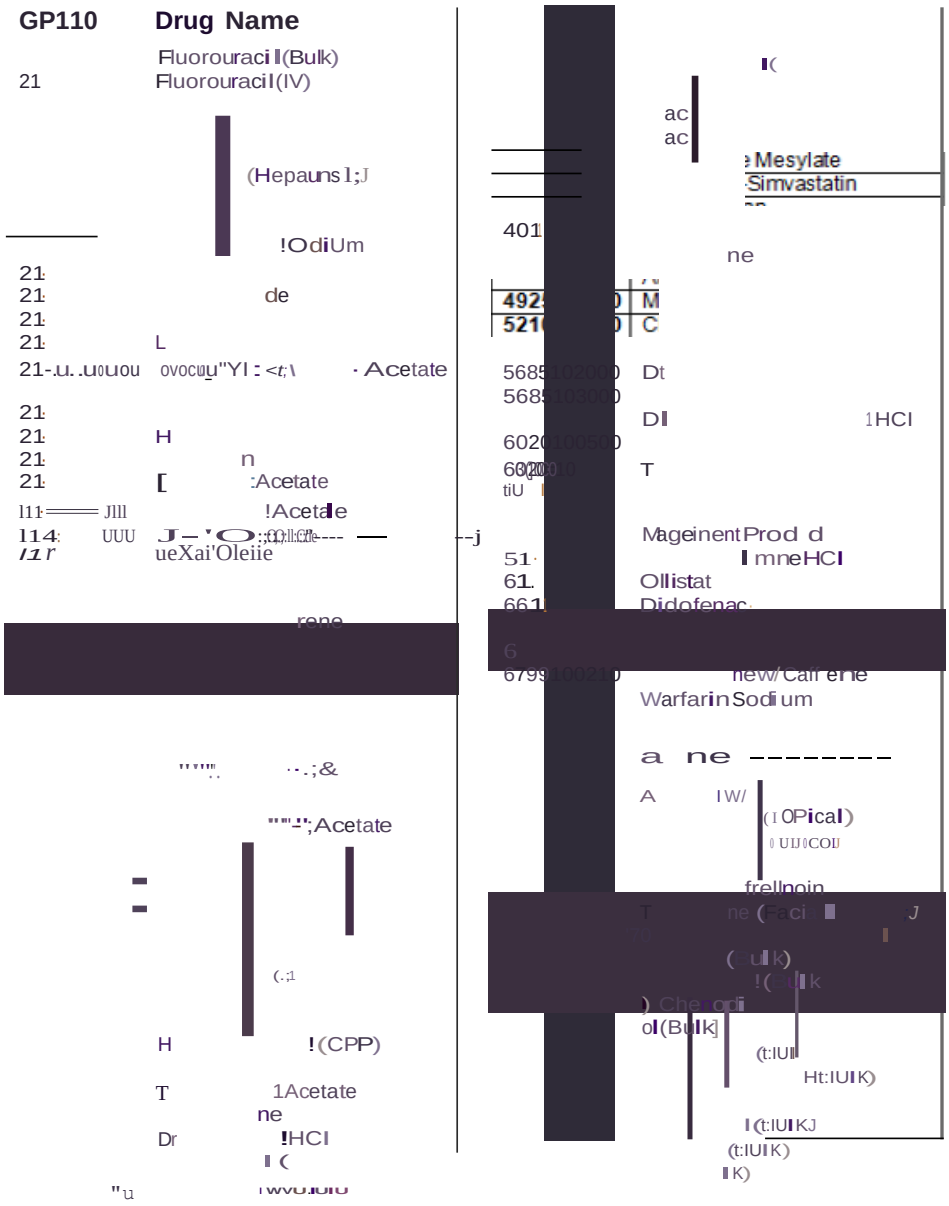
V23.41	*10m*	*History of preterm labor*
V27.1		*Singleton stillborn*
V27.3 or V27.4		*One twin stillborn; both twins stillborn*
V27.6		*Other multiple birth with stillborn*
V27.7		*Other multiple birth all stillborn*
768xx		*Intrauterine hypoxia and birth asphyxia*
656.4x		*Intrauterine death affecting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



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 Eligible Time for Numerator Events – Months Before Delivery 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%