Pamela D. Anderson
1527 Kenwood Road
Manning, South Carolina 29102
803-460-3131

March 2, 2015

Mr. Ray Farmer, Director
South Carolina Department of Insurance
Post Office Box 100105
Columbia, South Carolina 29201

Via Facsimile and US Mail

Re: Request for External Review
Complaint
154103

Dear Mr. Farmer:

I am asking for your assistance with this matter. I am not certain whether to proceed with a formal complaint with your agency and/or ask that an external review be completed by your agency. I have health insurance coverage through a policy with BlueCross BlueShield of South Carolina, which was purchased from the federal Marketplace and provides coverage under the federal *Patient Protection and Affordable Care Act* (*Affordable Care Act*).

My policy provides benefits for preventive screenings, including, but not limited to "The United States Preventive Services Task Force (USPSTF) recommended Grade A of B screenings".

For most, the USPSTF recommends colorectal cancer screenings (Grade A) begin at age 50 and be performed every 10 years. The recommendations include those who are at increased risk due to family or personal history of the disease or adenomatous colon polyps, but make special note that those at risk may be screened before age 50 and more frequently than the 10 year intervals.

In the fall of 2014, based on recent family history and my own personal medical history, my primary care provider referred me to a gastroenterologist for a colorectal cancer screening. I contacted BlueCross to confirm network providers and coverage. During that phone call, I was told I had no coverage for a colonoscopy screening because I was not 50. When I attempted to discuss my personal history and family history, I was told, "Family history is no reason to have a colonoscopy".

I discussed coverage concerns with one of my medical providers and we reviewed the recommendations together. The recommendations are clear, readily accessible, and

links that expand the recommendations beyond a simple chart are provided on the Task Force's website.

Furthermore, in the ***FAQs About the Affordable Care Act Implementation Set XII***, issued by the Departments of Labor, Health and Human Services, and the Treasury (a copy of which was enclosed with my original appeal letter and every other letter I sent regarding this matter and a copy of which is enclosed herewith), clarify narrow interpretations of the recommendations as follow:

"Q7: Some USPSTF recommendations apply to certain populations identified as high-risk. Some individuals, for example, are at increased risk for certain diseases because they have a family or personal history of the disease. It is not clear, however, how a plan or issuer would identify individuals who belong to a high-risk population. How can a plan or issuer determine when a service should or should not be covered without cost-sharing?

Identification of 'high-risk' individuals is determined by clinical expertise. Decisions regarding whether an individual is part of a high-risk population, and should therefore receive a specific preventive item or service identified for those at high-risk, should be made by the attending provider. Therefore, **if the attending provider determines that a patient belongs to a high-risk population** and a USPSTF recommendation applies to that high-risk population, that service is required to be covered in accordance with the requirements of the interim final regulations (that is, **without cost-sharing**, subject to reasonable medical management)."

BlueCross BlueShield and other insurance companies providing coverage purchased through the Marketplace in neighboring states have these FAQs prominently posted on their websites. I have also found where Departments of Insurance in other states require providers to comply with the USPSTF recommendation for screenings of high-risk individuals and the above directives of the *Affordable Care Act*

I have no clinical expertise, and I am certain that the BlueCross representative who told me in January, that "Family history is no reason to have a colonoscopy" has none, either.

For clinical expertise, I have relied on: (1) the opinion of the doctor who discovered advanced tubular adenomas and colorectal cancer during my mother's screening; (2) the opinion of the doctor who discovered advanced tubular adenomas in sister's screening; (3) the opinion of the doctor who discovered advanced tubular adenomas in my father's screening; (4) the opinions of the doctors currently treating my mother, who continue to stress the need for all of her children to have early colorectal cancer screenings because of the size, type and location of her polyps and cancer; (5) the advice of my primary care provider, who referred me for colorectal cancer screening; and, (6) the gastroenterologist who completed my colorectal cancer screening.

I believe all of the clinical experts enumerated above agree that my siblings and I all have a higher risk for developing colorectal cancer. I know that, based on the results of my colorectal cancer screening, my daughter was advised that she, too, is at risk and should be screened early.

I am enclosing the latest letter I received from BlueCross BlueShield. I am highly offended by the untrue references Ms. Suber makes to having "previously stated" that she did not receive my February 10, 2015 appeal letter and its attachments. I'm not sure to whom she previously stated this, but it was not to me. In fact, her letter of February 16, 2015 to me acknowledges her receipt of the appeal letter. Such false statements are the reason I copy the South Carolina Department of Insurance and other agencies with my appeal letter, documents, and any follow-up correspondence.

In her letter dated February 26, 2015, Ms. Suber attempts to misconstrue my words. I believe this shows a continued, deliberate refusal on the part of BlueCross to properly investigate my claim/appeal, for no other reason than to delay/wrongfully deny payment.

The quotes she references are only small bits of information from USPSTF Grade A recommendation statement and she has made no effort to read the statement in its entirety. Additionally, her definition of "early age" (language not used in the recommendation) is nothing but a petty and deliberate attempt to deflect the issue. There is no need for such semantics.

I reiterate: USPSTF (Grade A&B) recommendation statement references the need for screening people at higher risk for colorectal cancer because of their family or personal history. Furthermore, according to the Task Force, "It is widely accepted that **colorectal adenomatous polyps are the precursors of the vast majority of colorectal cancer cases**, so the early detection and removal of these lesions are presumed to reduce the incidence and mortality of colorectal cancer. In addition, cases of cancer detected by screening may be in the early stage and therefore curable. Colorectal cancer has many characteristics of a disorder that would be amenable to screening, as recently reviewed by the U.S. Preventive Services Task Force (USPSTF)."

A higher risk for colorectal cancer is not limited by the recommendation statement to only those with a young, first-degree relative with cancer or those with several first-degree relatives with cancer as Ms. Suber attempts to assert.

Please do not hesitate to contact me at 803-460-3131 should you need additional documents or information. I look forward to hearing from you to regarding this matter.

Thank you for your assistance.

Sincerely,

Pamela D. Anderson

/pda
enclosures as stated
cc: Santee Cooper Urgent Care
Sumter Gastroenterology, LLC
Wesmark Ambulatory Surgical Center
US Department of Health & Human Services
The Hon. Kevin L. Johnson, Senator, SC District 36
SC Governor's Office of Ombudsman
Mr. David Pankau, President & CEO, BlueCross BlueShield

South Carolina

February 26, 2015

Ms. Pamela D. Anderson
1527 Kenwood Rd
Manning, SC 29102 7746

RE:		
	Insured:	Pamela D. Anderson
	Patient:	Pamela D. Anderson
	ID#:	ZCR838648228830
	Claim #:	5C21555700000

Dear Ms. Anderson:

This letter is in response to your letter dated February 23, 2015. As previously stated, we did not receive the February 10th appeal letter and its attachments when we completed our initial response to your DoI inquiry. We therefore responded based on the information that was available to us at that time.

We have now received the letter and attachments that were sent to us dated February 10, 2015, and are now responding based on the information sent to us with your February 10th and February 23rd letters. You have stated two reasons why someone would have a screening colonoscopy prior to age 50 years:

1. "for those with first-degree relatives who developed cancer at a younger age"
2. "or those with multiple affected first-degree relatives".

The mother is the only identified family member with colon cancer; since the diagnosis was just established, it would not appear that this would qualify as "early age", generally thought to be 20-40 years of age at diagnosis. The mother, later age, is the only first degree relative known to have colon cancer.

The Business BlueEssentials Gold 1 Policy, Schedule of Benefits, Preventive Care section states:

"The following are covered:

- The United States Preventive Services Task Force (USPSTF) recommended Grade A or B screenings."

Additionally under Covered Services it states:

"**Preventive Screenings** – Benefits will be provided as follows:

- The United Stated Preventive Task Force (USPSTF) recommended Grade A or B screenings."

USPSTF A and B Recommendations

Topic	Description	Grade	Release Date of Current Recommendation
Abdominal aortic aneurysm screening: men	The USPSTF recommends one-time screening for abdominal aortic aneurysm by ultrasonography in men ages 65 to 75 years who have ever smoked.	B	June 2014*
Alcohol misuse: screening and counseling	The USPSTF recommends that clinicians screen adults age 18 years or older for alcohol misuse and provide persons engaged in risky or hazardous drinking with brief behavioral counseling interventions to reduce alcohol misuse.	B	May 2013*
Anemia screening: pregnant women	The USPSTF recommends routine screening for iron deficiency anemia in asymptomatic pregnant women.	B	May 2006
Aspirin to prevent cardiovascular disease: men	The USPSTF recommends the use of aspirin for men ages 45 to 79 years when the potential benefit due to a reduction in myocardial infarctions outweighs the potential harm due to an increase in gastrointestinal hemorrhage.	A	March 2009
Aspirin to prevent cardiovascular disease: women	The USPSTF recommends the use of aspirin for women ages 55 to 79 years when the potential benefit of a reduction in ischemic strokes outweighs the potential harm of an increase in gastrointestinal hemorrhage.	A	March 2009
Bacteriuria screening: pregnant women	The USPSTF recommends screening for asymptomatic bacteriuria with urine culture in pregnant women at 12 to 16 weeks' gestation or at the first prenatal visit, if later.	A	July 2008
Blood pressure screening in adults	The USPSTF recommends screening for high blood pressure in adults age 18 years and older.	A	December 2007
BRCA risk assessment and genetic counseling/testing	The USPSTF recommends that primary care providers screen women who have family members with breast, ovarian, tubal, or peritoneal cancer with one of several screening tools designed to identify a family history that may be associated with an increased risk for potentially harmful mutations in breast cancer susceptibility genes (*BRCA1* or *BRCA2*). Women with positive screening results should receive genetic counseling and, if indicated after counseling, BRCA testing.	B	December 2013*
Breast cancer preventive medications	The USPSTF recommends that clinicians engage in shared, informed decisionmaking with women who are at increased risk for breast cancer about medications to reduce their risk. For women who are at increased risk for breast cancer and at low risk for adverse medication effects, clinicians should offer to prescribe risk-reducing medications, such as tamoxifen or raloxifene.	B	September 2013*
Breast cancer screening	The USPSTF recommends screening mammography for women, with or without clinical breast examination, every 1 to 2 years for women age 40 years and older.	B	September 2002†
Breastfeeding counseling	The USPSTF recommends interventions during pregnancy and after birth to promote and support breastfeeding.	B	October 2008
Cervical cancer screening	The USPSTF recommends screening for cervical cancer in women ages 21 to 65 years with cytology (Pap smear) every 3 years or, for women ages 30 to 65 years who want to lengthen the screening interval, screening with a combination of cytology and human papillomavirus (HPV) testing every 5 years.	A	March 2012*
Chlamydia screening: women	The USPSTF recommends screening for chlamydia in sexually active women age 24 years or younger and in older women who are at increased risk for infection.	B	September 2014*
Cholesterol abnormalities screening: men 35 and older	The USPSTF strongly recommends screening men age 35 years and older for lipid disorders.	A	June 2008
Cholesterol abnormalities screening: men younger than 35	The USPSTF recommends screening men ages 20 to 35 years for lipid disorders if they are at increased risk for coronary heart disease.	B	June 2008
Cholesterol abnormalities screening: women 45 and older	The USPSTF strongly recommends screening women age 45 years and older for lipid disorders if they are at increased risk for coronary heart disease.	A	June 2008
Cholesterol abnormalities screening: women younger than 45	The USPSTF recommends screening women ages 20 to 45 years for lipid disorders if they are at increased risk for coronary heart disease.	B	June 2008
Colorectal cancer screening	The USPSTF recommends screening for colorectal cancer using fecal occult blood testing, sigmoidoscopy, or colonoscopy in adults beginning at age 50 years and continuing until age 75 years. The risks and benefits of these screening methods vary.	A	October 2008
Dental caries prevention: infants and children up to age 5 years	The USPSTF recommends the application of fluoride varnish to the primary teeth of all infants and children starting at the age of primary tooth eruption in primary care practices. The USPSTF recommends primary care clinicians prescribe oral fluoride supplementation starting at age 6 months for children whose water supply is fluoride deficient.	B	May 2014*
Depression screening: adolescents	The USPSTF recommends screening adolescents (ages 12-18 years) for major depressive disorder when systems are in place to ensure accurate diagnosis, psychotherapy (cognitive-behavioral or interpersonal), and follow-up.	B	March 2009
Depression screening: adults	The USPSTF recommends screening adults for depression when staff-assisted depression care supports are in place to assure accurate diagnosis, effective treatment, and follow-up.	B	December 2009
Diabetes screening	The USPSTF recommends screening for type 2 diabetes in asymptomatic adults with sustained blood pressure (either treated or untreated) greater than 135/80 mm Hg.	B	June 2008
Falls prevention in older adults: exercise or physical therapy	The USPSTF recommends exercise or physical therapy to prevent falls in community-dwelling adults age 65 years and older who are at increased risk for falls.	B	May 2012
Falls prevention in older adults: vitamin D	The USPSTF recommends vitamin D supplementation to prevent falls in community-dwelling adults age 65 years and older who are at increased risk for falls.	B	May 2012
Folic acid supplementation	The USPSTF recommends that all women planning or capable of pregnancy take a daily supplement containing 0.4 to 0.8 mg (400 to 800 µg) of folic acid.	A	May 2009
Gestational diabetes mellitus screening	The USPSTF recommends screening for gestational diabetes mellitus in asymptomatic pregnant women after 24 weeks of gestation.	B	January 2014
Gonorrhea prophylactic medication: newborns	The USPSTF recommends prophylactic ocular topical medication for all newborns for the prevention of gonococcal ophthalmia neonatorum.	A	July 2011*
Gonorrhea screening: women	The USPSTF recommends screening for gonorrhea in sexually active women age 24 years or younger and in older women who are at increased risk for infection.	B	September 2014*
Healthy diet and physical activity counseling to prevent cardiovascular disease: adults with cardiovascular risk factors	The USPSTF recommends offering or referring adults who are overweight or obese and have additional cardiovascular disease (CVD) risk factors to intensive behavioral counseling interventions to promote a healthful diet and physical activity for CVD prevention.	B	August 2014*
Hearing loss screening:	The USPSTF recommends screening for hearing loss in all newborn infants.	B	July 2008

newborns			
Hemoglobinopathies screening: newborns	The USPSTF recommends screening for sickle cell disease in newborns.	A	September 2007
Hepatitis B screening: nonpregnant adolescents and adults	The USPSTF recommends screening for hepatitis B virus infection in persons at high risk for infection.	B	May 2014
Hepatitis B screening: pregnant women	The USPSTF strongly recommends screening for hepatitis B virus infection in pregnant women at their first prenatal visit.	A	June 2009
Hepatitis C virus infection screening: adults	The USPSTF recommends screening for hepatitis C virus (HCV) infection in persons at high risk for infection. The USPSTF also recommends offering one-time screening for HCV infection to adults born between 1945 and 1965.	B	June 2013
HIV screening: nonpregnant adolescents and adults	The USPSTF recommends that clinicians screen for HIV infection in adolescents and adults ages 15 to 65 years. Younger adolescents and older adults who are at increased risk should also be screened.	A	April 2013*
HIV screening: pregnant women	The USPSTF recommends that clinicians screen all pregnant women for HIV, including those who present in labor who are untested and whose HIV status is unknown.	A	April 2013*
Hypothyrodism screening: newborns	The USPSTF recommends screening for congenital hypothyroidism in newborns.	A	March 2008
Intimate partner violence screening: women of childbearing age	The USPSTF recommends that clinicians screen women of childbearing age for intimate partner violence, such as domestic violence, and provide or refer women who screen positive to intervention services. This recommendation applies to women who do not have signs or symptoms of abuse.	B	January 2013
Iron supplementation in children	The USPSTF recommends routine iron supplementation for asymptomatic children ages 6 to 12 months who are at increased risk for iron deficiency anemia.	B	May 2006
Lung cancer screening	The USPSTF recommends annual screening for lung cancer with low-dose computed tomography in adults ages 55 to 80 years who have a 30 pack-year smoking history and currently smoke or have quit within the past 15 years. Screening should be discontinued once a person has not smoked for 15 years or develops a health problem that substantially limits life expectancy or the ability or willingness to have curative lung surgery.	B	December 2013
Obesity screening and counseling: adults	The USPSTF recommends screening all adults for obesity. Clinicians should offer or refer patients with a body mass index of 30 kg/m^2 or higher to intensive, multicomponent behavioral interventions.	B	June 2012*
Obesity screening and counseling: children	The USPSTF recommends that clinicians screen children age 6 years and older for obesity and offer them or refer them to comprehensive, intensive behavioral interventions to promote improvement in weight status.	B	January 2010
Osteoporosis screening: women	The USPSTF recommends screening for osteoporosis in women age 65 years and older and in younger women whose fracture risk is equal to or greater than that of a 65-year-old white woman who has no additional risk factors.	B	January 2012*
Phenylketonuria screening: newborns	The USPSTF recommends screening for phenylketonuria in newborns.	B	March 2008
Preeclampsia prevention: aspirin	The USPSTF recommends the use of low-dose aspirin (81 mg/d) as preventive medication after 12 weeks of gestation in women who are at high risk for preeclampsia.	B	September 2014
Rh incompatibility screening: first pregnancy visit	The USPSTF strongly recommends Rh (D) blood typing and antibody testing for all pregnant women during their first visit for pregnancy-related care.	A	February 2004
Rh incompatibility screening: 24–28 weeks' gestation	The USPSTF recommends repeated Rh (D) antibody testing for all unsensitized Rh (D)-negative women at 24 to 28 weeks' gestation, unless the biological father is known to be Rh (D)-negative.	B	February 2004
Sexually transmitted infections counseling	The USPSTF recommends intensive behavioral counseling for all sexually active adolescents and for adults who are at increased risk for sexually transmitted infections.	B	September 2014*
Skin cancer behavioral counseling	The USPSTF recommends counseling children, adolescents, and young adults ages 10 to 24 years who have fair skin about minimizing their exposure to ultraviolet radiation to reduce risk for skin cancer.	B	May 2012
Tobacco use counseling and interventions: nonpregnant adults	The USPSTF recommends that clinicians ask all adults about tobacco use and provide tobacco cessation interventions for those who use tobacco products.	A	April 2009
Tobacco use counseling: pregnant women	The USPSTF recommends that clinicians ask all pregnant women about tobacco use and provide augmented, pregnancy-tailored counseling to those who smoke.	A	April 2009
Tobacco use interventions: children and adolescents	The USPSTF recommends that clinicians provide interventions, including education or brief counseling, to prevent initiation of tobacco use in school-aged children and adolescents.	B	August 2013
Syphilis screening: nonpregnant persons	The USPSTF strongly recommends that clinicians screen persons at increased risk for syphilis infection.	A	July 2004
Syphilis screening: pregnant women	The USPSTF recommends that clinicians screen all pregnant women for syphilis infection.	A	May 2009
Visual acuity screening in children	The USPSTF recommends vision screening for all children at least once between the ages of 3 and 5 years, to detect the presence of amblyopia or its risk factors.	B	January 2011*

†The Department of Health and Human Services, in implementing the Affordable Care Act under the standard it sets out in revised Section 2713(a)(5) of the Public Health Service Act, utilizes the 2002 recommendation on breast cancer screening of the U.S. Preventive Services Task Force. To see the USPSTF 2009 recommendation on breast cancer screening, go to http://www.uspreventiveservicestaskforce.org/Page/Topic/recommendation-summary/breast-cancer-screening.

*Previous recommendation was an "A" or "B."

Current as of: October 2014

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Center for Consumer Info & Ins Oversight

The Center for Consumer Information & Insurance Oversight

Affordable Care Act Implementation FAQs - Set 12

Set out below are additional Frequently Asked Questions (FAQs) regarding implementation of various provisions of the Affordable Care Act. These FAQs have been prepared jointly by the Departments of Labor, Health and Human Services (HHS), and the Treasury (collectively, the Departments). Like previously issued FAQs, these FAQs answers questions from stakeholders to help people understand the new law and benefit from it, as intended.

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Limitations on Cost-Sharing under the Affordable Care Act

Public Health Service (PHS) Act section 2707(b), as added by the Affordable Care Act, provides that a group health plan shall ensure that any annual cost-sharing imposed under the plan does not exceed the limitations provided for under section 1302(c)(1) and (c)(2) of the Affordable Care Act. Section 1302(c)(1) limits out-of-pocket maximums and section 1302(c)(2) limits deductibles for employer-sponsored plans.

Q1:Who must comply with the deductible limitations under PHS Act section 2707(b)?

The HHS final regulation on standards related to essential health benefits implements the deductible provisions described in section 1302(c)(2) for non-grandfathered [1] health insurance coverage and qualified health plans offered in the small group market, including a provision implementing section 1302(c)(2)(C) so that such small group market health insurance coverage may exceed the annual deductible limit if it cannot reasonably reach a given level of coverage (metal tier) without exceeding the deductible limit.[2]

With respect to self-insured and large group health plans, as explained in the preamble to the HHS final regulations, the Departments intend to engage in future rulemaking to implement PHS Act section 2707(b). The Departments continue to believe that only plans and issuers in the small group market are required to comply with the deductible limit described in section 1302(c)(2). Public input is welcome in advance of a future rulemaking, which will implement that only plans and issuers in the small group market will be subject to the deductible limit. Please send comments by April 22, 2013 to e.ohpsca-2707.ebsa@dol.gov.

Until that rulemaking is promulgated and effective, the Departments have determined that a self-insured or large group health plan can rely on the Departments' stated intention to apply the deductible limits imposed by section 1302(c)(2) of the Affordable Care Act only on plans and issuers in the small group market.

Q2:Who must comply with the annual limitation on out-of-pocket maximums under PHS Act section 2707(b)?

As stated in the preamble to the HHS final regulation on standards related to essential health benefits, the Departments read PHS Act section 2707(b) as requiring all non-grandfathered group health plans to comply with the annual limitation on out-of-pocket maximums described in section 1302(c)(1) of the Affordable Care Act.[3]

The Departments recognize that plans may utilize multiple service providers to help administer benefits (such as one third-party administrator for major medical coverage, a separate pharmacy benefit manager, and a separate managed behavioral health organization). Separate plan service providers may impose different levels of out-of-pocket limitations and may utilize different methods for crediting participants' expenses against any out-of-pocket maximums. These processes will need to be coordinated under section 1302(c)(1), which may require new regular communications between service providers.

The Departments have determined that, only for the first plan year beginning on or after January 1, 2014, where a group health plan or group health insurance issuer utilizes more than one service provider to administer benefits that are subject to the annual limitation on out-of-pocket maximums under section 2707(a) or 2707(b), the Departments will consider the annual limitation on out-of-pocket maximums to be satisfied if both of the following conditions are satisfied:

(a) The plan complies with the requirements with respect to its major medical coverage (excluding, for example, prescription drug coverage and pediatric dental coverage); and

(b) To the extent the plan or any health insurance coverage includes an out-of-pocket maximum on coverage that does not consist solely of major medical coverage (for example, if a separate out-of-pocket maximum applies with respect to

prescription drug coverage), such out-of-pocket maximum does not exceed the dollar amounts set forth in section 1302 (c)(1).

The Departments note, however, that existing regulations implementing Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) [4] prohibit a group health plan (or health insurance coverage offered in connection with a group health plan) from applying a cumulative financial requirement or treatment limitation, such as an out-of-pocket maximum, to mental health or substance use disorder benefits that accumulates separately from any such cumulative financial requirement or treatment limitation established for medical/surgical benefits. Accordingly, under MHPAEA, plans and issuers are prohibited from imposing an annual out-of-pocket maximum on all medical/surgical benefits and a separate annual out-of-pocket maximum on all mental health and substance use disorder benefits.

Coverage of Preventive Services

PHS Act section 2713 and the interim final regulations[5] require non-grandfathered group health plans and health insurance coverage offered in the individual or group market to provide benefits for and prohibit the imposition of cost-sharing requirements with respect to, the following:

- Evidenced-based items or services that have in effect a rating of "A" or "B" in the current recommendations of the United States Preventive Services Task Force (USPSTF) with respect to the individual involved;
- Immunizations for routine use in children, adolescents, and adults that have in effect a recommendation from the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) with respect to the individual involved;
- With respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in the comprehensive guidelines supported by the Health Resources and Services Administration (HRSA); and
- With respect to women, evidence-informed preventive care and screening provided for in comprehensive guidelines supported by HRSA, to the extent not already included in certain recommendations of the USPSTF.[6]

If a recommendation or guideline does not specify the frequency, method, treatment, or setting for the provision of that service, the plan or issuer can use reasonable medical management techniques to determine any coverage limitations. [7]

These requirements do not apply to grandfathered health plans.[8]

Out-of-Network Services Generally

Q3: My plan does not have any in-network providers to provide a particular preventive service required under PHS Act section 2713. If I obtain this service out-of-network, can the plan impose cost-sharing?

No. While nothing in the interim final regulations generally requires a plan or issuer that has a network of providers to provide benefits for preventive services provided out-of-network, this provision is premised on enrollees being able to access the required preventive services from in-network providers. Thus, if a plan or issuer does not have in its network a provider who can provide the particular service, then the plan or issuer must cover the item or service when performed by an out-of-network provider and not impose cost-sharing with respect to the item or service.

United States Preventive Services Task Force (USPSTF)

Q4: The USPSTF recommends the use of aspirin for certain men and women when the potential benefit due to a reduction in myocardial infarctions outweighs the potential harm. Aspirin is generally available over-the-counter (OTC) to patients. Are group health plans and health insurance issuers now required to pay for OTC methods such as aspirin?

Aspirin and other OTC recommended items and services must be covered without cost-sharing only when prescribed by a health care provider.

Q5: If a colonoscopy is scheduled and performed as a screening procedure pursuant to the USPSTF recommendation, is it permissible for a plan or issuer to impose cost-sharing for the cost of a polyp removal during the colonoscopy?

No. Based on clinical practice and comments received from the American College of Gastroenterology, American Gastroenterological Association, American Society of Gastrointestinal Endoscopy, and the Society for Gastroenterology Nurses and Associates, polyp removal is an integral part of a colonoscopy. Accordingly, the plan or issuer may not impose cost-sharing with respect to a polyp removal during a colonoscopy performed as a screening procedure. On the other hand, a plan or issuer may impose cost-sharing for a treatment that is not a recommended preventive service, even if the treatment results from a recommended preventive service.

Q6: Does the recommendation for genetic counseling and evaluation for routine breast cancer susceptibility gene (BRCA) testing include the BRCA test itself?

Yes. HHS believes that the scope of the recommendation includes both genetic counseling and BRCA testing, if appropriate, for a woman as determined by her health care provider.

PHS Act section 2713 addresses coverage for evidence-based items or services with a rating of "A" or "B" in the current recommendations of the USPSTF, as well as coverage for preventive care and screenings as provided for in

comprehensive guidelines released by HRSA. The USPSTF recommends with a "B" rating that "women whose family history is associated with an increased risk for deleterious mutations in the BRCA1 or BRCA2 genes be referred for genetic counseling and evaluation for BRCA testing."

The HRSA Guidelines, released by HHS in August 2011, incorporate by reference relevant portions of an Institute of Medicine (IOM) Report, released on July 19, 2011. In some instances, the IOM Committee Report provides additional interpretation of USPSTF recommendations. For the USPSTF BRCA recommendation, the IOM Committee interpreted the recommendation to include "referral for genetic counseling and BRCA testing, if appropriate." Thus, genetic counseling and BRCA testing, if appropriate, must be made available as a preventive service without cost-sharing.

Q7: Some USPSTF recommendations apply to certain populations identified as high-risk. Some individuals, for example, are at increased risk for certain diseases because they have a family or personal history of the disease. It is not clear, however, how a plan or issuer would identify individuals who belong to a high-risk population. How can a plan or issuer determine when a service should or should not be covered without cost-sharing?

Identification of "high-risk" individuals is determined by clinical expertise. Decisions regarding whether an individual is part of a high-risk population, and should therefore receive a specific preventive item or service identified for those at high-risk, should be made by the attending provider. Therefore, if the attending provider determines that a patient belongs to a high-risk population and a USPSTF recommendation applies to that high-risk population, that service is required to be covered in accordance with the requirements of the interim final regulations (that is, without cost-sharing, subject to reasonable medical management).

Advisory Committee on Immunization Practices (ACIP)

Q8: Which ACIP recommendations are required to be covered without cost-sharing by non-grandfathered group health plans and health insurance coverage?

PHS Act section 2713 and the interim final regulations require coverage for immunizations for routine use in children, adolescents, and adults that have in effect a recommendation by the ACIP for routine use. The vaccines must be covered without cost-sharing requirements when the service is delivered by an in-network provider. The ACIP makes routine immunization recommendations for children, adolescents, and adults that are population-based (e.g., age-based), risk-based (e.g., underlying medical conditions, work-related, or other special circumstances that increase risk of illness), or are catch-up recommendations.

In some circumstances, the ACIP makes a recommendation that applies for certain individuals rather than an entire population. In these circumstances, health care providers should determine whether the vaccine should be administered, and if the vaccine is prescribed by a health care provider consistent with the ACIP recommendations, a plan or issuer is required to provide coverage for the vaccine without cost-sharing.

New ACIP recommendations will be required to be covered without cost-sharing starting with the plan year (in the individual market, policy year) that begins on or after the date that is one year after the date the recommendation is issued. An ACIP recommendation is considered to be issued on the date on which it is adopted by the Director of the Centers for Disease Control and Prevention (CDC), which is the earlier of: the date the recommendation is published in the Mortality and Morbidity Weekly Report, or the date the recommendation is reflected in the Immunization Schedules of the CDC. Therefore plans or issuers with respect to a plan can determine annually what vaccines recommended by ACIP must be covered by checking http://www.healthcare.gov/law/features/rights/preventive-care/index.html prior to the beginning of each plan year.

Women's Preventive Services

Q9: Do the recommendations for women's preventive services in the HRSA Guidelines promote multiple visits for separate services?

No. Section 2713 of the PHS Act and its implementing regulations allow plans and issuers to use reasonable medical management techniques to determine the frequency, method, treatment, or setting for a recommended preventive item or service, to the extent this information is not specified in a recommendation or guideline. Although the HRSA Guidelines list services individually, nothing in PHS Act section 2713 or the regulations requires that each service be provided in a separate visit. Efficient care delivery and the delivery of multiple prevention and screening services at a single visit is a reasonable medical management technique, permissible under the regulations. For example, HIV screening and counseling and Sexually Transmitted Infections counseling could occur as part of a single well-woman visit.

Q10: What is included in a "well-woman" visit?

The HRSA Guidelines recommend at least one annual well-woman preventive care visit for adult women to obtain the recommended preventive services that are age- and developmentally-appropriate, including preconception and prenatal care. The HRSA Guidelines recommend that well-woman visits include preventive services listed in the HRSA Guidelines, as well as others referenced in section 2713 of the PHS Act. HHS understands that additional well-woman visits, provided without cost-sharing, may be needed to obtain all necessary recommended preventive services, depending on a woman's health status, health needs, and other risk factors. If the clinician determines that a patient requires additional well-woman visits for this purpose, then the additional visits must be provided in accordance with the requirements of the interim final regulations (that is, without cost-sharing and subject to reasonable medical management).

Q11: What do health care providers need to know to conduct a screening and counseling for interpersonal and domestic violence, as recommended in the HRSA Guidelines?

Screening may consist of a few, brief, open-ended questions. Screening can be facilitated by the use of brochures, forms, or other assessment tools including chart prompts. One option is the five-question Abuse Assessment Screening tool available here: (http://www.cdc.gov/ncipc/pub-res/images/ipvandsvscreening.pdf, page 22). Counseling provides basic information, including how a patient's health concerns may relate to violence and referrals to local domestic violence support agencies when patients disclose abuse. Easy-to-use tools such as patient brochures, safety plans, and provider educational tools, as well as training materials, are available through the HHS-funded Domestic Violence Resource Network, including the National Resource Center on Domestic Violence (http://www.acf.hhs.gov/programs/fysb/programs/family-violence-prevention-services/programs/centers).

Q12: In the discussion of "Identified Gaps" within the Cervical Cancer section of the IOM report, the IOM recognized "co-testing with cytology and high-risk Human Papillomavirus (HPV) DNA testing among women 30 years of age and older as a strategy to increase screening intervals to every three years." When should the HPV DNA test be administered?

The HRSA Guidelines recommend high-risk HPV DNA testing for women with normal cytology results who are 30 years of age or older to occur no more frequently than every 3 years.

Q13: The HRSA Guidelines include a recommendation for annual HIV counseling and screening for all sexually active women. Is the term "screening" in this context defined as actual testing for HIV?

Yes. In this context, "screening" means testing.

Q14: The HRSA Guidelines include a recommendation for all Food and Drug Administration (FDA) approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity, as prescribed by a health care provider. May a plan or issuer cover only oral contraceptives?

No. The HRSA Guidelines ensure women's access to the full range of FDA-approved contraceptive methods including, but not limited to, barrier methods, hormonal methods, and implanted devices, as well as patient education and counseling, as prescribed by a health care provider. Consistent with PHS Act section 2713 and its implementing regulations, plans and issuers may use reasonable medical management techniques to control costs and promote efficient delivery of care. For example, plans may cover a generic drug without cost-sharing and impose cost-sharing for equivalent branded drugs. However, in these instances, a plan or issuer must accommodate any individual for whom the generic drug (or a brand name drug) would be medically inappropriate, as determined by the individual's health care provider, by having a mechanism for waiving the otherwise applicable cost-sharing for the branded or non-preferred brand version. This generic substitution approach is permissible for other pharmacy products, as long as the accommodation described above exists.[9] If, however, a generic version is not available, or would not be medically appropriate for the patient as a prescribed brand name contraceptive method (as determined by the attending provider, in consultation with the patient), then a plan or issuer must provide coverage for the brand name drug in accordance with the requirements of the interim final regulations (that is, without cost-sharing, subject to reasonable medical management).

Q15: Do the HRSA Guidelines include contraceptive methods that are generally available over-the-counter (OTC), such as contraceptive sponges and spermicides?

Contraceptive methods that are generally available OTC are only included if the method is both FDA-approved and prescribed for a woman by her health care provider. The HRSA Guidelines do not include contraception for men.[10]

Q16: Do the HRSA Guidelinesinclude services related to follow-upand management of side effects, counseling for continued adherence, and for device removal?

Yes. Services related to follow-up and management of side effects, counseling for continued adherence, and device removal are included under the HRSA Guidelines and required to be covered in accordance with the requirements of the interim final regulations (that is, without cost-sharing, subject to reasonable medical management).

Q17: Are intrauterine devices and implants contraceptive methods under the HRSA Guidelines and therefore required to be covered without cost-sharing?

Yes, if approved by the FDA and prescribed for a woman by her health care provider, subject to reasonable medical management.

Q18: The USPSTF already recommends breastfeeding counseling. Why is this part of the HRSA Guidelines?

Under the topic of "Breastfeeding Counseling" the USPSTF recommends interventions during pregnancy and after birth to promote and support breastfeeding. The HRSA Guidelines specifically incorporate comprehensive prenatal and postnatal lactation support, counseling, and equipment rental. Accordingly, the items and services described in the HRSA Guidelines are required to be covered in accordance with the requirements of the interim final regulations (that is, without cost-sharing, subject to reasonable medical management, which may include purchase instead of rental of equipment).

Q19: How are certified lactation consultants reimbursed for their services under the HRSA Guidelines?

Reimbursement policy is outside of the scope of the HRSA Guidelines and the Departments' regulations.

Q20: Under the HRSA Guidelines, how long after childbirth is a woman eligible for lactation counseling? Are breastfeeding equipment and supplies unlimited?

Coverage of comprehensive lactation support and counseling and costs of renting or purchasing breastfeeding equipment extends for the duration of breastfeeding. Nonetheless, consistent with PHS Act section 2713 and its implementing regulations, plans and issuers may use reasonable medical management techniques to determine the frequency, method, treatment, or setting for a recommended preventive item or service, to the extent not specified in the recommendation or guideline.

[1] See The Departments interim final regulations relating to grandfather health plans (June 17, 2010) at 75 FR 34538 (June 17, 2010) and amended interim final regulations at 75 FR 70114 (November 17, 2010).
[2] Issued February 20, 2013 and available at: http://www.cms.gov/cciio/Resources/Regulations-and-Guidance/index.html#Plan Management
[3] See section 1251 of the Affordable Care Act, which limits the application of PHS Act section 2707 to non-grandfathered group health plans and health insurance coverage.
[4] See 26 CFR 54.9812-1(c)(3)(v), 29 CFR 2590.712(c)(3)(v), and 45 C.F.R. 146.136(c)(3)(v).
[5] 75 FR 41726 (July 19, 2010).
[6] "Women's Preventive Services: Required Health Plan Coverage Guidelines" (HRSA Guidelines) were adopted and released on August 1, 2012, based on recommendations developed by the Institute of Medicine (IOM) at the request of HHS. These recommended women's preventive services are required to be covered without cost-sharing, for plan years (or, in the individual market, policy years) beginning on or after August 1, 2012.
[7] See 26 CFR 54.9815-2713T(a)(4), 29 CFR 2590.715-2713(a)(4), 45 CFR 147.130(a)(4).
[8] Certain non-grandfathered, non-profit religious organizations are not required to cover the contraceptive services recommendation that is part of the HRSA guidelines. For information on these entities, see 77 FR 8725 and . See also proposed rules published on February 6, 2013, at 78 FR 8456.
[9] See http://www.healthcare.gov/news/factsheets/2011/08/womensprevention08012011a.html
[10] See 78 FR 8456, 8458, footnote 3, which provides that the HRSA guidelines "exclude services relating to a man's reproductive capacity, such as vasectomies and condoms."