September 30, 2011

BlueCross BlueShield Association

An Association of Independent Blue Cross and Blue Shield Plans

1310 G Street, N.W.
Washington, D.C. 20005
202.626.4780
Fax 202.626.4833

Donald M. Berwick
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services

The Honorable Phyllis C. Borzi
Assistant Secretary
Employee Benefits Security Administration
U.S. Department of Labor

Steven T. Miller
Deputy Commissioner for Services and Enforcement
Internal Revenue Service
U.S. Department of the Treasury

Submitted via the Federal Rulemaking Portal: http://www.regulations.gov

Re: Comments on Amendments to Interim Final Rules Relating to Coverage of Preventive Services under the Patient Protection and Affordable Care Act (CMS–9992–IFC2)

Dear Administrator Berwick, Secretary Borzi, and Commissioner Miller:

The Blue Cross and Blue Shield Association ("BCBSA") – representing the 39 independent, community-based and locally-operated Blue Cross and Blue Shield Plans ("Plans") that collectively provide health coverage for more than 99 million, one in three Americans – appreciates the opportunity to submit comments on the amendment to the Interim Final Rules (the "Rule") for Group Health Plans and Health Insurance Issuers ("plans") Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act ("ACA") as issued in the *Federal Register* on August 3, 2011 (76 Fed. Reg. 46621).

Our comments focus on the comprehensive health plan coverage guidelines for women's preventive care and screening supported by the Health Resources and Services Administration (HRSA), and largely seek clarification of ambiguities in the new coverage requirements.

Blue Cross and Blue Shield Plans are strongly committed to promoting preventive health and encourage women to take full advantage of their preventive care benefits. However, some of the HRSA guidelines contain ambiguities that will make it difficult to administer the new benefits

and will lead to variations in coverage determinations. Such variation will waste resources, no small consideration in light of continuing cost pressures. Moreover, any variation will complicate development of performance metrics for preventive care because measured differences in utilization of preventive services across plans may have less to do with the plans' ability to promote good care, and more to do with reasonable differences in how to interpret and code for ambiguities in the guidelines.

Therefore, BCBSA respectfully requests that the Departments provide timely clarifications for three guidelines:

- ***Well-woman visits*.** Costs could be impacted significantly if the scope of well-woman visits expands to include pre-natal care services, and if utilization increases because the guidelines recognize that "several visits [a year] may be needed."

- ***Contraceptive methods and counseling.*** Costs could be impacted significantly if coverage expands to include methods that can be purchased over the counter and if utilization of generic drugs declines.

- ***Breastfeeding support, supplies, and counseling.*** Costs could be impacted significantly if the duration of support extends over an undefined period and if scope expands to include counseling by unqualified providers.

In addition, BCBSA requests the Departments issue sub-regulatory guidance providing that when insurers rely on employers to determine eligibility for religious accommodation, then insurers should be deemed to have complied with the preventive services coverage requirement and will not be liable for penalty.

Plans need considerable lead-time to reprogram information systems and codes to cover the new benefits; work must start before the end of the year to be ready for plan years beginning after August 1, 2012. Therefore, we urge the Departments to provide clarifications and additional guidance by no later than the beginning of December of this year.

The following comments provide detail on each of the above requests.

*** * ***

I. Well-Woman Visits

Issue. The guideline calls for plans to cover a well-woman preventive care visit for adult women to obtain the recommended preventive services, including preconception and prenatal care. Although the recommended frequency is annual, the guideline also states: HHS recognizes that several visits may be needed to obtain all necessary recommended preventive services, depending on a woman's health status, health needs, and other risk factors.

The reference to prenatal/preconception care is ambiguous because expectant mothers typically visit their health care providers repeatedly during the prenatal period for ultrasound, laboratory, and diagnostic tests, and possibly other procedures and therapies. If all these tests and services were considered to be preventive care and the associated prenatal/preconception visits were treated as well-woman visits – which would be consistent with the recognition that several visits may be needed – then there would be an overly broad application of the Rule.

Combine inclusion of prenatal/preconception care in the well-women visit with the requirement to cover several visits, and the guidelines could be construed as requiring that plans pay for all prenatal/preconception services as preventive benefits.

More generally, allowing for "several visits" may invite an overly broad application of the Rule by inducing churning of patients. Inappropriate utilization of more than one annual well-woman visits could have significant cost impacts because, as the Departments noted in the July 2010 interim final regulations, "The increased prevalence of the application of zero cost sharing would lead to increased premiums compared with the chosen option, without a meaningful additional gain in access to preventive services."

> **Recommendation.** To avoid any ambiguity, BCBSA requests the Departments clarify that prenatal care and preconception care in general does not fall under the scope of the HRSA guideline for well-woman visits, and that plans must cover without cost-sharing only those prenatal/preconception services specifically stipulated in the HRSA guidelines or in the mandated U.S. Preventive Services Task Force recommendations.
>
> Further, BCBSA requests the Departments clarify that since the need for more than one well-woman visit depends on a woman's health status, health needs, and other risk factors – all factors that plans generally take into account when determining the medical necessity or medical appropriateness of an item or service – that plans will be able to use reasonable medical management techniques to limit coverage of multiple well-woman visits based on medical necessity or medical appropriateness criteria.

II. Contraceptive Methods and Counseling

Issue. The guideline calls for covering all Food and Drug Administration approved contraceptive methods, as prescribed. It appears that by specifying "as prescribed," the guidelines seek to obviate covering over-the-counter (OTC) contraceptive methods such as contraceptive sponges and spermicides. However, nothing would prevent physicians from writing prescriptions for such OTC contraceptives, which would force plans to cover the OTC methods with no cost-sharing.

> **Recommendation.** BCBSA requests the Departments clarify that "as prescribed" means that health plans should cover contraceptive methods that can only be purchased with a prescription. The law in New Jersey provides a good example of how to clarify: "For the purposes of this section, 'prescription female contraceptives' means any drug or device used for contraception by a female, which is approved by the federal Food and Drug Administration for that purpose, that can only be purchased in this State with a prescription written by a health care professional licensed or authorized to write prescriptions [17B:26-2.1y]." This would clarify, for example, that plans must cover emergency contraceptives available at the pharmacy only with a prescription for minors younger than age 17 years, but not for those age 17 years and older for whom the contraceptives are available at the pharmacy without a prescription.

Issue. The July 2010 interim final rules permit reasonable medical management techniques, where plans "may rely on established techniques and the relevant evidence base to determine the frequency, method, treatment, or setting for which a recommended preventive service will be available without cost-sharing requirements to the extent not specified in a recommendation or guideline." Subsequent sub-regulatory guidance clarified that "established techniques"

generally "limit or exclude benefits based on medical necessity or medical appropriateness using prior authorization requirements, concurrent review, or similar practices," and that it is permissible to impose a copayment for a preventive service (e.g., a colonoscopy) when performed in one network setting (an in-network ambulatory surgery center) but not in another (an in-network outpatient hospital setting) provided the plan accommodates any individuals for whom it would be medically inappropriate to have the preventive service provided in the preferred setting.

The HHS News Release accompanying release of the new guidelines notes that through using reasonable medical management, plans will have the flexibility to control costs and promote efficient delivery of care by, for example, continuing to charge cost-sharing for branded drugs if a generic version is available and is just as effective and safe for the patient to use. However, ambiguity remains because this example appears in neither the rule nor subregulatory guidance.

> **Recommendation.** BCBSA requests the Departments clarify in subregulatory guidance that plans have the flexibility to control costs and promote efficient delivery of care by promoting activities such as using generic drugs that are just as safe and effective for patients to use as a branded drug. This would include not only charging cost-sharing for branded drugs if a generic drug is available, but other medical management strategies such as step therapy (where before members can use a listed brand-name drug they must first try a similar, alternative generic medication), or incentivizing members to use mail-order pharmacy or a particular provider for their contraceptives.

Issue. The guideline calls for covering the broad category of "sterilization procedures." This could be construed as including hysterectomies, which are an irreversible method of birth control and absolute sterilization. A hysterectomy is major surgery and generally used to correct serious medical conditions, not for sterilization. Complications after hysterectomy, such as infection or blood loss, occur in 10% to 20% of cases and the risk of death is much greater than it is for more common sterilization methods.

> **Recommendation.** BCBSA requests the Departments clarify in subregulatory guidance that contraception should always be considered a secondary benefit of hysterectomy and not a sole reason to have the procedure.

III. Breastfeeding Support, Supplies, and Counseling

Issue. The guideline requires comprehensive lactation support and counseling, by a trained provider during pregnancy and/or in the postpartum period, and costs for renting breastfeeding equipment. However, neither the guidelines nor the underlying Institute of Medicine recommendations address who qualifies to be a trained provider. Individuals may present themselves as trained providers even if they have no state-recognized licensure or certification.

International Board Certified Lactation Consultants (IBCLCs) are the only health care professionals certified in lactation care. They have specific clinical expertise and training in the clinical management of complex problems with lactation. However, because there is a shortage of IBCLCs, plans will need flexibility to tailor coverage to local practices and available supply.

In many areas, counseling will be provided by nurses in the hospital during the immediate post-partum period. The costs of these services will be included in the global payment commonly

used to reimburse providers for maternity care. Therefore, it may not be possible to parse out the costs of lactation support and counseling and adjust any cost-sharing that otherwise would apply to the package of maternity care.

> **Recommendation.** BCBSA requests the Departments clarify that plans have the flexibility to provide reimbursement only for providers who have appropriate, state-recognized licensure or certification. Further, BCBSA requests the Departments clarify that if a recommended prenatal or postpartum service is not billed separately because providers receive a global payment, then a plan may continue to impose cost-sharing requirements with respect to the maternity stay.

Issue. Three ambiguities in the breastfeeding support guidelines could inadvertently lead to additional unnecessary costs. First, the guideline could be construed as requiring an open-ended commitment of a postpartum period of indefinite duration. This would have significant cost impacts: for example, a 3-million member BCBS Plan found that providing an open-ended benefit that covered the costs of renting equipment for all breastfeeding mothers for an unrestricted period cost millions of dollars.

Second, because the guideline speaks to "costs for renting" breastfeeding equipment, it could be construed as preventing plans from purchasing equipment when it is more cost-effective to do so. For example, it may be less costly to the plan and equally efficacious for the mother to purchase a simple electric breast pump than to pay for the rental of a hospital-grade pump.

Third, although the guideline only refers to "breastfeeding equipment," the header of the requirement ("Type of Preventive Service") refers broadly to "supplies." This could be construed as requiring plans to cover without cost-sharing not only breastfeeding equipment but also supplies available over the counter such as nursing bras, pads, plastic bags for storing breast milk, and so on.

> **Recommendation.** BCBSA requests the Departments clarify that (1) plans may use reasonable medical management techniques to determine coverage limitations that would prevent costly, open-ended commitments to covering breastfeeding support and supplies; (2) plans may treat breastfeeding equipment as falling under durable medical equipment policies, which could, for example, allow purchasing equipment for members if that would be more cost-effective than covering costs for equipment rentals; and (3) breastfeeding supplies not specified in the guideline are not required.

IV. *Religious Accomodation*

***Issue*.** To provide for a religious accommodation, the Departments permit exempting certain religious employers from the guideline for contraceptive methods and counseling. The rule defines a religious employer as one that has the inculcation of religious values as its purpose, primarily employs persons who share its religious tenets, primarily serves persons who share its religious tenets, and is a non-profit , tax-exempt organization that is a church, a church's integrated auxiliary, a convention or association of churches, or the exclusively religious activities of any religious order. However, the rule provides no guidance on how to administer this exemption, leaving uncertain the responsibilities of employers and plans.

Recommendation. BCBSA requests the Departments issue subregulatory guidance providing that plans may conclusively rely upon an employer's determination of being a religious employer. If the employer provides a determination and the plan exempts coverage from

contraceptive methods and counseling, then the plan should be deemed to have complied with the law and not be liable for civil penalties under the Public Health Service Act or subject to lawsuits under ERISA for exempting contraceptive methods and counseling.

* * *

We appreciate your consideration of our comments on the HRSA guidelines and thank you for considering our requests for clarification and additional guidance. We look forward to continuing to work with the Departments on implementation issues related to ACA. If you have any questions, please contact Joel Slackman at 202.626.8614 or Joel.Slackman@bcbsa.com.

Sincerely,

Justine Handelman
Vice President, Legislative and Regulatory Policy
Blue Cross Blue Shield Association