

Blue Perspective



**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

BCBSA Position on Legislative and Regulatory Issues

Improving Quality & Promoting Savings Through Expanded Access to Generic Drugs

***Issue:** Generic drugs - the chemical equivalent of brand drugs at a fraction of the cost - are powerful tools for improving quality and driving down healthcare costs. With more than 1 in 3 Americans managing a chronic illness that drives three-quarters of our nation's health spending, the availability of safe, effective, and affordable prescription drugs, including generic alternatives, is critically important. However, some government policies and market tactics threaten the ability of health plans and consumers to realize the full potential of generic drugs to lower costs and drive system-wide efficiencies.*

***Position:** Given that generic drugs are a cornerstone for reducing costs and improving quality, BCBSA urges Congress to expand the use and availability of generic drugs by:*

- *Creating a Pathway for Generic Biologics*
- *Preventing Anti-Competitive Arrangements Between Brand and Generic Manufacturers*
- *Increasing Funding to the FDA's Office of Generic Drugs*
- *Encouraging Strong State Generic Substitution Laws*
- *Expanding Generic Drug Choices Through Electronic Prescribing*
- *Preserving Health Plan Utilization Management Tools*

Advancing Access to Generic Drugs Creates Efficiencies

Numerous data show that generic drugs are playing a critical role in driving down health spending. In January 2009, the CMS Office of the Actuary found that 2007 U.S. health spending slowed to its lowest growth rate since 1998. The reduced growth rate was attributed to a 45-year low in the growth rate for prescription drug spending -- driven in large part by steady increases in generic dispensing rates. Currently, generic drugs account for 67 percent of all prescriptions dispensed in the United States, yet represent just 20 percent of all spending on prescriptions. Data show that a one percentage increase in generic drug utilization yields almost \$4 billion in savings.

Congress Should Support Expanded Generic Drug Availability By:

Creating a Workable Pathway for the Approval of Generic Biologics. Biologics are expensive, complex drugs that are usually derived from a living organism. Their use, which was once limited to rare diseases, has expanded significantly in recent years and includes more common diseases such as psoriasis, multiple sclerosis, and arthritis. As a result, labor, business and health plans have seen spending on these products grow 42.9 percent from December 2003 to December 2007; an unsustainable growth trend. The availability of safe and effective generic versions of biopharmaceuticals is critical to ensuring the delivery of high quality care while reducing the soaring costs of these therapies for consumers and payers. BCBSA supports the Promoting Innovation and Access to Life-Saving Medicine Act (H.R. 1427), which builds on the success of the current Hatch-Waxman law by constraining cost growth, expanding competition and choice, and providing needed incentives for innovation.

Preventing Anti-Competitive Tactics by Brand-Name & Generic Drug Makers. Under pay-for delay arrangements, brand manufacturers pay generic manufacturers to delay market entry, which allows brand manufacturers to maintain monopolistic pricing policies by preventing generic competition. According to the Federal Trade Commission, these arrangements can cost consumers and payers billions of dollars in higher drug costs. BCBSA supports legislative initiatives that would protect consumers by limiting anti-competitive pay-for-delay agreements.

Increasing Funding for the FDA’s Office of Generic Drugs. Increased funding for the FDA Office of Generic Drugs is essential to improving approval times for generic drug applications. While the FDA is required to review a generic drug application within 180 days, in practice approvals can take as long as 21 months. Delays in these approvals result in additional unnecessary costs to Federal, State, and private health programs. Most importantly, delayed market entry of new generics results in higher out of pocket costs for consumers and reduced adherence to life-saving therapies.

Encouraging Strong State Generic Substitution Laws. Well-established laws in all 50 states permit a pharmacist to make a generic substitution unless otherwise directed by the prescribing physician. These laws face assault by brand pharmaceutical manufacturers who promote state-based legislation that would severely restrict a pharmacist’s ability to dispense lower cost generic drugs. Adoption of these types of “carve-out” or “continuity of care” bills would result in an estimated \$30 billion increase in drug spending annually. BCBSA supports the implementation of federal policies ensuring that the substitution of generic medicines, when available, cannot be overridden without a valid medical reason.

Expanding Generic Drug Choices through Electronic Prescribing. Electronic prescribing (e-prescribing) technology improves generic utilization by providing patients and their prescribing physician more information – in real time – about the full range of their prescription drug and pharmacy choices, including generics. In addition to reducing drug costs, e-prescribing increases safety by reducing preventable medication errors, such as potential adverse drug-to-drug interactions and allergic reactions. Many individual BCBS Plans are implementing private-sector initiatives to encourage the adoption and use of e-prescribing. BCBSA strongly supports both the recent investments in health information technology, including e-prescribing, in the American Recovery and Reinvestment Act (ARRA) and the Medicare-based initiatives to incent physician adoption in the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA).

Preserving Utilization Management Tools. Health Plans use strategies to increase use of generic medications such as formulary tiering, step therapy, prior authorization, and reference-based pricing, which create efficiencies that benefit both public and private payers as well as consumers. For example, when the Commonwealth of Massachusetts switched to a “generic first” approach that implemented tighter controls on brand drug dispensing, their State Medicaid program experienced a monthly drop in cost from approximately \$10 million to \$300,000 without decreasing patient access or sacrificing quality of care. Current federal law for Medicare Part D limits the ability of Plans to implement utilization management tools for certain classes of drugs, which drives up costs and wastes scarce tax dollars.

The Blue Cross and Blue Shield Association is a national federation of 39 independent, community-based and locally operated Blue Cross and Blue Shield companies that collectively provide healthcare coverage for more than 102 million individuals – nearly one-in-three of all Americans. For more information on the Blue Cross and Blue Shield Association and its member companies, please visit www.BCBS.com.