SAVINGS: HEALTH CARE (PHARMACEUTICAL PROPOSALS)

Multi-Agency

The Administration proposes to give consumers more access to affordable pharmaceuticals by: 1) modifying the length of exclusivity to facilitate faster development of generic biologics; and 2) giving the Federal Trade Commission (FTC) the authority to prohibit brand and generic drug companies from entering into anticompetitive or "pay-for-delay" agreements intended to keep more generic drugs and biologics off the market. The Administration is also proposing to streamline pharmacy benefit contracting in the Federal Employee Health Benefits Program (FEHB) to obtain greater value for enrollees.

Funding Summary
(In millions of dollars)

.	2013	2014	2015	2016	2017	2013-2017	2013-2022
Baseline Outlays (Medicare and Medicaid)	810,817	902,972	958,393	1,041,686	1,089,376	4,803,245	11,492,619
Baseline Outlays (FEHB Government Payment for Annuitants)	10,970	11,704	12,557	13,515	14,542	63,288	154,631
Proposed Changes from Current Law, Total (HHS and OPM)	-694	-766	-1,016	-1,452	-1,639	-5,566	-16,490
DEPARTMENT OF HEALTH AND HUMAN SERVICES:							
Modify length of exclusivity to facilitate faster development of generic biologics	-19	97	8	-327	-426	-667	-3,825
Prohibit brand and generic drug companies from delaying the availability of new generic drugs	-675	-791	-870	-960	-1,037	-4,333	-10,991
OFFICE OF PERSONNEL MANAGEMENT:							
Streamline pharmacy benefit contracting in the FEHB program	0	-72	-154	-165	-176	-566	-1,674

Note: The savings estimates for these proposals may not include all interactions.

Justification

Modify the length of exclusivity to facilitate faster development of generic biologics. Access to affordable lifesaving medicines is essential to improving the quality and efficiency of health care. The Budget proposes to accelerate access to affordable generic biologics by modifying the length of exclusivity on brand name biologics. Beginning in 2013, this proposal would award brand biologic manufacturers seven years of exclusivity rather than twelve years under current law and prohibit additional periods of exclusivity for brand biologics due minor changes in product formulations, a practice often referred to as "evergreening." Reducing the exclusivity period increases the availability of generic biologics by encouraging faster development of generic biologics while retaining appropriate incentives for research and development for the innovation of breakthrough products.

Prohibit "pay for delay" agreements to increase the availability of generic drugs and biologics. The high cost of prescription drugs places a significant burden on Americans today. The Administration proposes to increase the availability of generic drugs and biologics by authorizing FTC to stop companies from entering into anti-competitive deals, known also as "pay for delay" agreements, intended to block consumer access to safe and effective generics. Such deals can cost consumers billions of dollars because generic drugs are typically priced significantly less than their branded counterparts. These agreements reduce competition and raise the cost of care for patients both directly, through higher drug and biologic prices, and indirectly through higher health care premiums.

FEHB Program Pharmacy Benefit Contracting. The FEHB program pays over $40 billion per year for health coverage, and drugs represent about 30 percent of claims expenditures. Under current law, health plans participating in the FEHB program contract with pharmacy benefits managers who negotiate prices with drug manufacturers and pharmacies on behalf of their enrollees. This fragmented purchasing strategy does not take full advantage of the combined purchasing power of the nearly eight million enrollees in the FEHB program. The Administration proposal would give the Office of Personnel Management authority to contract directly for pharmacy benefit management services on behalf of all FEHB enrollees and their dependents. This will allow the FEHB program to more efficiently leverage its purchasing power to obtain a better deal for enrollees and taxpayers.

Citations

[1] Federal Trade Commission, *Emerging Health Care Issues: Follow-on Biologic Drug Competition,* p.27 (June 2009).