

## **SENATE (REID) BILL PROVISIONS RELATING TO PRESCRIPTION DRUGS**

**Sec. 2501. Prescription drug rebates.** The flat rebate for single source and innovator multiple source outpatient prescription drugs would increase from 15.1 percent to 23.1 percent, except the rebate for clotting factors and outpatient drugs approved by the Food and Drug Administration exclusively for pediatric indications would increase to 17.1 percent. The basic rebate percentage for multi-source, non-innovator drugs would increase from 11 percent to 13 percent. Drug manufacturers would also be required to pay rebates for drugs dispensed to Medicaid beneficiaries who receive care from a Medicaid managed care organization (MCO). Total rebate liability would be limited to 100 percent of the average manufacturer price (AMP). Additional revenue generated by these increases will be remitted to the federal government.

**Sec. 2502. Elimination of exclusion of coverage of certain drugs.** Beginning with drugs dispensed on January 1, 2014, smoking cessation drugs, barbiturates, and benzodiazepines would be removed from Medicaid's excludable drug list.

**Sec. 2503. Providing adequate pharmacy reimbursement.** Requires the Secretary to calculate the Federal upper limit (FUL) as no less than 175 percent of the weighted average (determined on the basis of utilization) of the most recently reported monthly average manufacturer prices for pharmaceutically and therapeutically equivalent multiple source drugs available nationally through commercial pharmacies.

**Sec. 3139. Payment for biosimilar biological products.** Sets the add-on payment rate for biosimilar products reimbursement under Medicare Part B at 6 percent of the average sales price of the brand biological product.

### **Subtitle D – Medicare Part D Improvements for Prescription Drug Plans and MA–PD Plans**

**Sec. 3301. Medicare coverage gap discount program.** Requires drug manufacturers to provide a 50 percent discount to Part D beneficiaries for brand-name drugs and biologics purchased during the coverage gap beginning July 1, 2010.

**Sec. 3302. Improvement in determination of Medicare part D low-income benchmark premium.** Removes Medicare Advantage rebates and quality bonus payments from the calculation of the low-income subsidy benchmark.

**Sec. 3303. Voluntary de minimis policy for subsidy-eligible individuals under prescription drug plans and MA–PD plans.** Allows Part D plans that bid a nominal amount above the regional low-income subsidy (LIS) benchmark to absorb the cost of the difference between their bid and the LIS benchmark in order to remain a \$0 premium LIS plan.

Sec. 3304. Special rule for widows and widowers regarding eligibility for low-income assistance. Allows the surviving spouse of an LIS-eligible couple to delay LIS redetermination for one year after the death of a spouse.

Sec. 3305. Improved information for subsidy-eligible individuals reassigned to prescription drug plans and MA–PD plans. Requires HHS, beginning in 2011, to transmit formulary and coverage determination information to subsidy-eligible beneficiaries who have been automatically reassigned to a new Part D low-income subsidy plan.

Sec. 3306. Funding outreach and assistance for low-income programs. Provides \$45 million for outreach and education activities to State Health Insurance Programs, Administration on Aging, Aging Disability Resource Centers and the National Benefits Outreach and Enrollment.

Sec. 3307. Improving formulary requirements for prescription drug plans and MA–PD plans with respect to certain categories or classes of drugs. Codifies the current six classes of clinical concern, removes the criteria specified in section 176 of MIPPA that would have been used by HHS to identify protected classes of drugs and gives the Secretary authority to identify classes of clinical concern through rulemaking.

Sec. 3308. Reducing part D premium subsidy for high-income beneficiaries. Reduces the Part D premium subsidy for beneficiaries with incomes above the Part B income thresholds.

Sec. 3309. Elimination of cost sharing for certain dual-eligible individuals. Eliminates cost sharing for beneficiaries receiving care under a home and community-based waiver program who would otherwise require institutional care.

Sec. 3310. Reducing wasteful dispensing of outpatient prescription drugs in long-term care facilities under prescription drug plans and MA-PD plans. Requires Part D plans to develop drug dispensing techniques to reduce prescription drug waste in long-term care facilities.

Sec. 3311. Improved Medicare prescription drug plan and MA–PD plan complaint system. Requires the Secretary to develop and maintain a plan complaint system to handle complaints regarding Medicare Advantage and Part D plans or their sponsors.

Sec. 3312. Uniform exceptions and appeals process for prescription drug plans and MA–PD plans. Requires Part D plans to use a single, uniform exceptions and appeals process.

Sec. 3313. Office of the Inspector General studies and reports. Requires the OIG to conduct a study comparing prescription drug prices paid under the Medicare Part D program to those paid under State Medicaid programs.

Sec. 3314. Including costs incurred by AIDS drug assistance programs and Indian Health Service in providing prescription drugs toward the annual out-of-pocket threshold under part D. Allows drugs provided to beneficiaries by AIDS Drug Assistance Programs or the Indian Health Service to count toward the annual out-of-pocket threshold.

Sec. 3315. Immediate reduction in coverage gap for 2010. Increases the initial coverage limit in the standard Part D benefit by \$500 for 2010.

## TITLE VI—TRANSPARENCY AND PROGRAM INTEGRITY

### *Subtitle A – Physician Ownership and Other Transparency*

**Sec. 6001. Limitation on Medicare exception to the prohibition on certain physician referrals for hospitals.** Prohibits physician-owned hospitals that do not have a provider agreement prior to February 1, 2010, to participate in Medicare. Such hospitals that have a provider agreement prior to February 1, 2010, could continue to participate in Medicare under certain requirements addressing conflict of interest, bona fide investments, and patient safety issues, and expansion limitations.

**Sec. 6002. Transparency reports and reporting of physician ownership or investment interests.** Requires drug, device, biological and medical supply manufacturers to report transfers of value made to a physician, physician medical practice, a physician group practice, and/or a teaching hospital. Duplicative State or local laws would be preempted by Federal law, however, Federal preemption would not occur for State or local laws that are beyond the scope of this section.

**Sec. 6003. Disclosure requirements for in-office ancillary services exception to the prohibition on physician self-referral for certain imaging services.** Adds an additional requirement to the Medicare in-office ancillary exception that requires the referring physician to inform the patient in writing that the individual may obtain the specified service from a person other than the referring physician, a physician who is a member of the same group practice as the referring physician, or an individual who is directly supervised by the physician or by another physician in the group practice.

**Sec. 6004. Prescription drug sample transparency.** Requires prescription drug manufacturers and distributors to report to the Secretary information pertaining to drug samples currently being collected internally, as required under the Federal Food, Drug and Cosmetic Act.

**Sec. 6005. Pharmacy benefit managers transparency requirements.** Requires a pharmacy benefit manager (PBM) or a health benefits plan that provides pharmacy benefits management services that contract with health plans under Medicare or the Exchange to report to the Secretary information regarding the generic dispensing rate: the rebates, discounts, or price concessions negotiated by the PBM and the payment difference between health plans and PBMs and the PBMs and pharmacies. All disclosed information would be confidential, except for certain specific purposes.

## **Title VII – IMPROVING ACCESS TO INNOVATIVE MEDICAL THERAPIES**

### *Subtitle A—Biologics Price Competition and Innovation*

**Sec. 7001. Short Title.** The “Biologics Price Competition and Innovation Act of 2009.”

**Sec. 7002. Approval pathway for biosimilar biological products.** Establishes a process under which the Secretary is required to license a biological product that is shown to be biosimilar to or interchangeable with a licensed biological product, commonly referred to as a reference product. Prohibits the approval of an application as either biosimilar or interchangeable until 12 years from the date on which the reference product is first approved. If FDA approves a biological

product on the grounds that it is interchangeable to a reference product, HHS is prohibited from making a determination that a second or subsequent biological product is interchangeable to that same reference product until 1 year after the first commercial marketing of the first interchangeable product.

Authorizes HHS to issue guidance with respect to the licensure of biological products under this new pathway, and it includes provisions governing patent infringement concerns such as the exchange of information, good faith negotiations, and initiation infringement actions. Applies certain provisions of the Food, Drug, and Cosmetic Act to this subtitle with respect to pediatric studies of biological products. Requires HHS to develop recommendations for Congress with respect to the goals for the process for the review of biosimilar biological product applications for the first five fiscal years after FY 2012.

**Sec. 7003. Savings.** The Secretary of the Treasury, in consultation with the HHS Secretary, shall for each fiscal year determine the amount of savings to the Federal Government as a result of the enactment of this subtitle. Notwithstanding any other provision of this subtitle, the savings to the Federal Government generated as a result of the enactment of this subtitle shall be used for deficit reduction.

#### *Subtitle B—More Affordable Medicines for Children and Underserved Communities*

**Sec. 7101. Expanded participation in 340B program.** Extends the 340B discounts to inpatient drugs and also extends participation to certain children’s hospitals, cancer hospitals, critical access and sole community hospitals, and rural referral centers.

**Sec. 7102. Improvements to 340B program integrity.** Establishes new auditing, reporting, and other compliance requirements for the Secretary, and for pharmaceutical manufacturers and 340B covered entities.

**Sec. 7103. GAO study to make recommendations on improving the 340B program.** Requires the GAO to make recommendations to Congress within 18 months on improvements to the 340B program.

### **TITLE IX – REVENUE PROVISIONS**

#### *Subtitle A – Revenue Offset Provisions*

**Sec. 9003. Distributions for medicine qualified only if for prescribed drug or insulin.** Confirms the definition of qualified medical expenses for HSAs, FSAs, and HRAs to the definition used for the medical expense itemized deduction. Over-the-counter medicine obtained with a prescription continues to qualify as a qualified medical expense.

**Sec. 9008. Imposition of annual fee on branded prescription pharmaceutical manufacturers and importers.** Imposes an annual flat fee of \$2.3 billion on the pharmaceutical manufacturing sector beginning in 2010. This non-deductible fee would be allocated across the 55 industry according to market share and would not apply to companies with sales of branded pharmaceuticals of \$5 million or less.

**Sec. 9009. Imposition of annual fee on medical device manufacturers and importers.**

Imposes an annual flat fee of \$2 billion on the medical device manufacturing sector beginning in 2010. This non-deductible fee would be allocated across the industry according to market share and would not apply to companies with sales of medical devices in the U.S. of \$5 million or less. The fee does not apply to any sale of a Class I product or any sale of a Class II product that is primarily sold to consumers at retail for not more than \$100 per unit (under the FDA product classification system).

**Sec. 9011. Study and report of effect on veterans health care.** The Secretary of the U.S. Department of Veterans Affairs will review and report to Congress on the effect that the fees assessed on pharmaceutical and medical device manufacturers and health insurance providers have on the cost of medical care provided to veterans and veterans' access to medical devices and branded drugs.

**Sec. 9012. Eliminate deduction for expenses allocable to Medicare Part D.** Eliminates the deduction for the subsidy for employers who maintain prescription drug plans for their Medicare Part D eligible retirees.

**OTHER**

**Sec. 9023. Qualifying therapeutic discovery project credit.** Creates a two year temporary tax credit subject to an overall cap of \$1 billion to encourage investments in new therapies to prevent, diagnose, and treat acute and chronic diseases. The credit would be available for two years.