

Government Program Rebates and Discounts

Health care companies are making significant contributions to make patient care more affordable by helping finance the expansion of health insurance coverage under health care reform legislation. For biopharmaceutical companies, part of that contribution includes increased rebates under Medicaid—a program that provides health insurance coverage for the poorest Americans—and discounted prices on medications available through the 340B Drug Discount Program. These efforts will facilitate improved patient access to prescription medications. Better access to treatment may lead to improved patient compliance with physician recommendations and treatment regimens. Price relief in the form of rebates and best price calculations help patients obtain access to prescription products while preserving innovation incentives that are lost in health systems with government price controls.

Background

The federal government requires biopharmaceutical companies to provide rebates and discounts on prescription medicines dispensed through the Medicaid program and certain federally funded grantees and other safety net health care providers (including clinics, centers, and hospitals). These rebates and discounts help defray state government spending on public health programs serving low-income and indigent people. In general, the amount of the rebate or discount is calculated based on the average manufacturer price (AMP) of the product; or the difference between the AMP and a product's Best Price (BP). The AMP was historically defined as the average price paid by wholesalers to manufacturers for drugs distributed to the retail pharmacy class of trade.

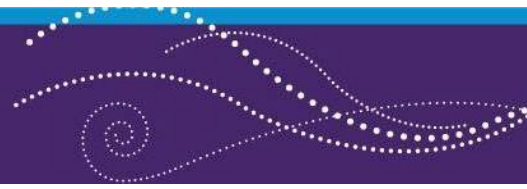
The Affordable Care Act (ACA)¹ makes a number of changes to Medicaid rebates—changing how the rebate is calculated, increasing the amount of the rebate, and extending it to medicines dispensed through Medicaid managed care organizations (MCOs). Key changes include the following:

- Beginning October 1, 2010, the new law changes the definition of AMP and is generally expected to increase a product's AMP.
- Effective January 1, 2010, the law increases the minimum rebate for brand medications from 15.1% to 23.1% of average manufacturer price (AMP); the minimum rebate for generic medications increased from 11% to 13%.²
- For the first time, the law extends the Medicaid rebate for brand and generic medications to Medicaid MCOs effective March 23, 2010.
- The law mandates alternative calculations for the additional rebate (the "CPI penalty") for new formulations of brand medications.

ACA also expands the 340B Drug Pricing Program, which limits the cost of some medications for certain certified safety net health care providers by providing discounts. Under the new law, more entities are able to qualify for access to discounted medicines through the 340B program.

Key Facts and Figures

- **Medicaid Rebates:**
 - In 2008, CMS reported that pharmaceutical companies paid nearly \$8.9 billion in rebates under the Medicaid program. This amounts to a 37.2% average rebate on all medication expenditures under this portion of the program, including the cost of pharmacist dispensing fees and mark-ups.³



- In 2008, generic manufacturers were required to pay a flat 11% rebate on the cost of their medications. Thus, if generic medications were removed from the previous calculation, the average brand rebate would have been much higher.⁴
- Increases in rebates for pharmaceutical companies were scored by the Congressional Budget Office to account for an additional \$38.1 billion over a 10 year period.⁵
- **340B Discounts:**
 - With the enactment of the health care reform law, an estimated 1,500 new entities qualify for the 340B program.⁶
 - No Medicaid rebates are required on medications obtained at a discounted price through the 340B program. However, 340B discounts increased with the increase in Medicaid rebate discounts.

Pfizer's Position

Pfizer is committed to addressing increased costs resulting from implementation of health reform legislation, making prescription medicine coverage more affordable and accessible to all Americans. Proper implementation and equitable application of the various discounts, rebates, and pricing programs are essential to fulfilling this commitment.

- **Medicaid rebate and AMP changes:** The changes to Medicaid, including changes to the AMP definition, have the potential to increase rebate collections and help finance health insurance coverage expansion to lower-income individuals.
- **340B Expansion:** The inclusion of additional covered entities in the program will likely result in increased contributions from biopharmaceutical companies that will go toward expanding patient access to many medications.

How Patients and Health Care Professionals Benefit

Greater access to medicines through the Medicaid and 340B programs helps patients and their health care professionals achieve treatment goals by reducing financial hurdles.

How the Health Care System Benefits

The financial contributions from biopharmaceutical companies will reduce government and insurer financial outlays on prescription medicines.

What It Means for Pfizer

Government price controls for prescription medicines in other parts of the world stifle high-risk investment in researching and developing new and future beneficial products. Price relief in the form of rebates and best price calculations will help lower the cost of medicines for low-income and needy patients without reducing incentives for continued investment in discovering and developing new medicines. These ACA provisions will help patients obtain affordable access to necessary care and treatments, including Pfizer products.

¹ The Patient Protection and Affordable Care Act (PPACA, P.L. 111-148), as amended by the Health Care and Education Reconciliation Act of 2010 (HCERA, P.L. 111-152), is collectively referred to in this paper as the Affordable Care Act of 2010 (ACA).

² Note: Except the minimum basic rebate would only increase to 17.1% of AMP for clotting factors and drugs approved by the FDA "exclusively for pediatric indications."

³ CMS. CMS 64 Report 2008. December 2009.

⁴ CMS. CMS 64 Report 2008. December 2009.

⁵ Congressional Budget Office. Letter from Director Douglas W. Elmendorf to Speaker Nancy Pelosi. March 20, 2010.

⁶ Health Care Reform: Patient Protection and Affordable Care Act Expands Hospital Eligibility for 340B Program, McDermott Newsletters, April 26, 2010, available at http://www.mwe.com/index.cfm/fuseaction/publications.nldetail/object_id/e03a0488-e90f-4653-847a-ebd044ce9440.cfm