Pharmaceutical Manufacturers

Patient Protection and Affordable Care Act, Pub. L. No. 111-148 ("PPACA")
Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152 ("Recon")

Provision	Description	Effective Date(s)	CBO 10-Year Score
Medicare Part D			
Closing of the Part D Coverage Gap/ Manufacturer Discount PPACA § 3301; Recon. § 1101	Coverage gap ("doughnut hole") is gradually eliminated by 2020 beginning with a one-time $250 rebate provided by the government to beneficiaries in 2010. Starting in 2011, manufacturers of brand name drugs are required to provide a 50 percent discount on such drugs purchased by beneficiaries in the coverage gap. Discounts count toward the beneficiary's true out-of-pocket expenditures and are excluded from the manufacturer's average manufacturer price (AMP) calculations. Manufacturers are required to enter into agreements with the Secretary of HHS to ensure the discounts are provided. Federal subsidies are gradually expanded for beneficiaries in the coverage gap for both brand name and generic drugs. Subsidies are phased in beginning in 2011 for generics and in 2013 for brand name drugs. In 2020 and beyond, the coverage gap is "closed" through a combination of the manufacturer discount and the government subsidies.	$250 rebate in 2010 50 percent discount on brand name drugs beginning January 1, 2011 Coverage gap agreements—HHS will establish a model agreement no later than 180 days after enactment. For 2011, agreements must be entered into no later than 30 days after establishment of the model agreement. For all subsequent years, agreements must be	Costs $42.6 billion

Health Care Reform Legislation Summary

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		entered into no later than January 30 of the preceding year. Phase-in of federal subsidies begins in 2011 for generic drugs and in 2013 for brand name drugs	
Required Categories or Classes of Drugs in Formularies PPACA § 3307	Codifies the six protected classes of drugs, previously described in Centers for Medicare & Medicaid Services (CMS) guidance, until CMS issues a rule regarding protected classes.	Effective for the plan year 2011 and subsequent plan years	$0
Part D Dual Eligible Rebate PPACA § 3309	Eliminates cost sharing for dual-eligible beneficiaries receiving care in a home or community-based waiver program who otherwise would require institutional care.	Date to be specified by the Secretary (but in no case earlier than January 1, 2012)	Costs $1.1 billion
Part D Medication Therapy Management PPACA § 10328	Requires Part D plans to enroll targeted beneficiaries in Medication Therapy Management Programs, with an ability to opt out, to increase adherence. Prescription drug plans (PDPs) required to assess medication use of at-risk beneficiaries every quarter.	Plan year beginning two years after enactment (2012)	$0

Health Care Reform Legislation Summary

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Other Medicare			
Independent Payment Advisory Board PPACA § 3403	Establishes the Independent Payment Advisory Board (IPAB) to develop and submit proposals to the President and Congress regarding Medicare costs, solvency and quality of care provided to beneficiaries. HHS is generally required to implement IPAB's proposals unless Congress enacts alternative measures that achieve the same level of savings. Members are appointed by the President and confirmed by the Senate for six-year terms and may include health professionals, third-party payers and consumers, but a majority of members must be non-providers.	First report to Congress due no earlier than January 15, 2014	Saves $15.5 billion
340B/Medicaid			
340B Expansion PPACA § 7101; Recon. § 2302	Makes several program expansions, including— ▪ expands eligibility for discounted prices for covered outpatient drugs to include: certain children's hospitals, Prospective Payment System-exempt cancer centers, critical access hospitals, rural referral centers and sole community hospitals (provided they meet various requirements) ▪ improves 340B program integrity ▪ maintains current law regarding group purchasing organizations (GPOs) ▪ exempts orphan drugs from required discounts for new 340B entities.	Applies to drugs purchased on or after January 1, 2010	Saves $38.1 billion (includes all of the Medicaid prescription drug coverage provisions) Recon. § 2303 [sic] ("Drugs Purchased by Covered Entities") costs an additional $2.5 billion

Health Care Reform Legislation Summary

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Expansion of Medicaid PPACA § 2001	Requires state Medicaid programs to extend eligibility to all individuals who are not already Medicare- or Medicaid-eligible and whose income does not exceed 133 percent of the Federal Poverty Level (FPL).	January 1, 2014	Costs $434 billion (includes all Medicaid and CHIP outlays)
Medicaid Rebate PPACA § 2501; Recon. § 1206	Makes several changes to the Medicaid rebate— ▪ extends rebates to drugs dispensed to beneficiaries of Medicaid managed care organizations (MCOs), unless such drugs are subject to 340B discounts ▪ increases minimum rebate percentage from 15.1 percent to 23.1 percent of AMP for brand name drugs ▪ increases minimum rebate percentage from 11 percent to 13 percent of AMP for generics ▪ limits Medicaid rebate for an innovator drug to 100 percent of AMP or less ▪ increases rebates for "line extension" of a single-source drug or an innovator multiple-source drug that is in an oral solid dosage form, with an exception for orphan drugs. "Line extension" is defined as a new formulation, such as an extended-release formulation. Rebate is calculated as the greater of the rebate amount calculated for such new drug or the product of 1) the AMP of the new formulation; 2) the highest additional rebate of any strength of the original drug, calculated as a percentage of AMP; and 3) the total number of units of each dosage form and strength of the line extension.	MCO rebate extension – effective upon enactment (March 23, 2010) Increase in brand and generic minimum rebate percentage – January 1, 2010 Rebate cap – January 1, 2010 Line extension rebates – January 1, 2010	Saves $38.1 billion (includes all of the Medicaid prescription drug coverage and 340B expansion provisions) Recon. § 1206 costs an additional $0.6 billion

Health Care Reform Legislation Summary

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Pharmacy Reimbursement and AMP Definition PPACA § 2503	▪ Federal upper limits (FULs) will be calculated as no less than 175 percent of the weighted average (based on utilization) of the most recent AMPs for pharmaceutically and therapeutically equivalent multiple-source drugs available in retail commercial pharmacies nationally. HHS is required to implement a "smoothing process" for AMPs similar to that used to determine average sales price (ASP). ▪ Redefines AMP to include only sales to wholesalers for drugs distributed in retail community pharmacies. Explicitly excludes prompt pay discounts, bona fide service fees, reimbursement for unsalable returned goods and direct sales and rebates to pharmacy benefit managers (PBMs), health maintenance organizations (HMOs), MCOs, insurers, hospitals, clinics, mail-order pharmacies, long-term care providers, manufacturers and any other entity that does not conduct business as a wholesaler or retail community pharmacy. If, however, any rebate, discount or other payment received by one of these entities is received by, paid by or passed through to a retail community pharmacy, such payment is included in AMP. ▪ Replaces the term "retail pharmacy class of trade" with "retail community pharmacies." ▪ Defines "retail community pharmacy" as an independent pharmacy, a chain pharmacy, a supermarket pharmacy or a mass merchandiser pharmacy that is licensed as a pharmacy and that dispenses medications to the general public. Does not include mail-order pharmacies, nursing home pharmacies, long-term care facility pharmacies, hospital pharmacies, clinics, charitable or not-for-profit pharmacies, government pharmacies or PBMs. ▪ Redefines "wholesaler" to include only entities that engage in wholesale	Oct. 1, 2010 (the first day of the first calendar year quarter that begins at least 180 days after the date of enactment of this Act).	Saves $38.1 billion (includes all of the Medicaid prescription drug coverage and 340B expansion provisions)

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	distribution of prescription drugs to retail pharmacies ▪ Amends provision of Deficit Reduction Act regarding public disclosure of AMP to permit public disclosure of weighted average of most recently reported monthly AMPs.		
Industry Excise Tax/Tax Credit			
Pharmaceutical Industry Excise Tax PPACA § 9008; Recon. § 1404	Annual fee would be apportioned among brand name drug manufacturers each year based on a manufacturer's relative market share of covered domestic sales for the prior year to specified government programs, i.e., Medicare Parts B and D, Medicaid, Veterans Affairs (VA), Department of Defense (DOD), TRICARE retail pharmacy program (with an exception for orphan drugs). Aggregate fee is in the following amounts— 2011 $2.5 billion 2012 – 2013 $2.8 billion 2014 – 2016 $3.0 billion 2017 $4.0 billion 2018 $4.1 billion 2019 and after $2.8 billion There will be joint and several liability among "controlled groups"—parent/subsidiary, brother/sister or other combined group corporations—for payment of the fee.	First payment date to be announced, but in no case later than September 30, 2011	Costs $27 billion (Joint Committee on Taxation estimate)

Health Care Reform Legislation Summary

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Qualifying Therapeutic Discovery Project Tax Credit PPACA § 9023	Makes available tax credits to certain eligible small companies (250 employees or fewer) equaling 50 percent of their "qualified investments" for 2009 and 2010. Qualified investments include the costs of conducting pre-clinical or clinical studies to obtain Food and Drug Administration (FDA) approval; developing molecular diagnostics to guide therapeutic decisions; or developing technologies to advance the delivery of therapeutics.	Effective for amounts paid or incurred after December 31, 2008, in taxable years beginning after that date	Saves $0.9 billion (Joint Committee on Taxation estimate)
Biosimilars			
Pathway for Biosimilars PPACA § 7002	Creates an FDA regulatory approval process and user fee for approval of biosimilars, similar to that for generic versions of brand name drugs. Provides for 12-year exclusivity for innovator products, with an additional six months if pediatric studies are conducted. Provides for at least one-year exclusivity for first biosimilar approved for a particular innovator product.	Effective upon enactment (March 23, 2010)	Saves $7.0 billion (includes payment for biosimilars provision)
Payment for Biosimilars PPACA § 3139	Establishes Medicare Part B payment for biosimilars: CMS will add 6 percent of the lesser of the ASP or wholesale acquisition cost (WAC) of the branded product to the ASP of the biosimilar.	July 1, 2010	Saves $7.0 billion (includes pathway for biosimilars provision)

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Clinical Trial Coverage/Research Incentives			
Coverage for Individuals Participating in Approved Clinical Trials PPACA § 10103	Prohibits group health plan or health insurance issuer offering group or individual health insurance coverage from 1) denying "qualified individuals" participation in an "approved clinical trial"; 2) denying or limiting coverage of routine patient costs for items or services furnished in such a trial; and 3) discriminating against a patient for participating in such a trial. "Qualified individual" means a participant or beneficiary in a health plan or with health insurance coverage who is eligible to participate in a clinical trial, according to the trial protocol, with respect to treatment of cancer or other life-threatening disease or condition. An "approved clinical trial" is a phase I, phase II, phase II or phase IV clinical trial that is related to the prevention, detection or treatment of cancer or other life-threatening disease or condition and is 1) either federally funded or federally approved (per the specific requirements in the legislation), 2) conducted under an investigational new drug application (NDA) reviewed by the FDA or 3) is a drug trial that is exempt from having an NDA.	Jan. 1, 2014	Not scored
Cures Acceleration Network PPACA § 10409	Requires the director of the National Institutes of Health (NIH) to establish a Cures Acceleration Network to award grants and contracts to eligible entities to accelerate the development of high need cures, including through the development of medical products and behavior therapies. A "high need cure" is a drug or device that, in the determination of the director of NIH, is a priority to diagnose, mitigate, prevent or treat harm from any disease or condition and for which the incentives of the commercial market are unlikely to result in its adequate or timely development. Entities eligible for these grants include public or private entities, including research institutions,	No effective date listed; presumably effective as of date of enactment (March 23, 2010)	$0

Health Care Reform Legislation Summary

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	educational institutions, medical centers, biotechnology companies, pharmaceutical companies, disease advocacy organizations, patient advocacy organizations and academic research institutions.		
Labeling			
Presentation of Prescription Drug Benefit and Risk Information PPACA § 3507	Requires HHS, through the commissioner of Food and Drugs, to determine whether the addition of quantitative summaries of the benefits and risks of prescription drugs in a standardized format (such as a table or drug facts box) to the promotional labeling or print advertising of such drugs would improve health care decision-making by insurers, providers and patients. In making such determination, the Secretary is required to review all available scientific evidence and research on decision-making and social and cognitive psychology and consult with drug manufacturers, clinicians, patients and consumers, experts in health literacy, representatives of racial and ethnic minorities and experts in women's and pediatric health. If the Secretary determines that the addition of quantitative summaries would improve health care decision-making, the Secretary shall promulgate proposed regulations.	The Secretary shall submit a report to Congress no later than one year after the date of enactment of the Act (March 23, 2011). If the Secretary promulgates regulations regarding the addition of quantitative summaries, such proposed regulations must be promulgated no later than three years after the date of submission of the Secretary's report.	$0 (includes all health care quality improvement provisions)
Labeling Changes for Generic Drugs PPACA § 10609	Amends Food, Drug, and Cosmetic Act (FDCA) to permit the FDA to approve an abbreviated new drug application (ANDA) notwithstanding certain Reference Listed Drug labeling changes, as long as changes are made within 60 days of a patent expiration, an exclusivity period or a 30-month stay blocking final ANDA approval under the Hatch-Waxman Act.	Effective on the date of enactment (March 23, 2010) and applies to any act or omission that occurs on or after that	Saves $0.1 billion

Health Care Reform Legislation Summary

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	This provision does not include changes to the "Warnings" section of the labeling. Even after a permitted labeling revision, however, if the FDA determines that such labeling adversely impacts the safe use of the drug, then the FDA may decide not to grant final ANDA approval.	date	
Comparative Effectiveness			
Comparative Effectiveness Research PPACA § 6301	Refers to a method of comparing treatment options for a given condition in a particular patient population. Studies may evaluate medical risks and benefits of each option and may include financial costs in the comparisons. Creates a new center to identify comparative effectiveness research (CER) priorities, carry out research and disseminate findings. Contains certain restrictions on using CER findings to make coverage determinations.	FY 2010	Costs $2.2 billion
Transparency/ Fraud and Abuse			
Physician Payment Sunshine Provisions PPACA § 6002	Requires manufacturers that make a payment or other transfer of value to a physician or teaching hospital to report annually specific information to the Secretary of HHS. Certain payments are excluded, including, among others: transfers of less than $10 of value unless the aggregate annual amount transferred exceeds $100; product samples not intended to be sold; education materials that directly benefit or are used by patients; and discounts, dividends or other profit distribution from, or an ownership or investment interest in, a publicly traded security and mutual fund. Information submitted by manufacturers must be made publicly available by HHS on a Web site, in searchable form, no later than September 30, 2013. Manufacturers and GPOs must also report information relating to any	March 31, 2013	$0

Health Care Reform Legislation Summary

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	ownership or investment interest held by a physician. State laws that require reporting of the same types of information are pre-empted, but explicitly not pre-empted are laws that require the disclosure or reporting of information "not of the type required to be disclosed or reported under this law"; laws that require disclosure of information exempted from disclosure under this law; laws that require disclosure by any person or entity other than the entities covered by this law; or laws that require reporting of information for public health purposes.		
Sample Reporting PPACA § 6004	Manufacturers and authorized distributors of record of applicable drugs are required to submit to HHS the identity and quantity of drug samples requested by, and distributed to, each requesting practitioner and the name, address, professional designation and signature of the requesting practitioner.	April 1, 2012	$0
PBM Transparency PPACA § 6005	PBMs that manage drug benefits for a Part D plan or any plan offered through an insurance exchange must disclose to HHS and the plan with which the PBM contracts the aggregate amount and types of rebates, discounts or price concessions negotiated on behalf of the plan; the aggregate amount of the rebates, discounts or price concessions that are passed through to the plan sponsor; and the aggregate amount of the difference between the amount the plan pays the PBM and the amount that the PBM pays retail and mail order pharmacies.	No effective date; therefore, assumption is that provision is effective as of enactment (March 23, 2010)	$0
FDCA-Related Health Care Fraud PPACA § 10606	Revises definition of "health care fraud offense" in federal criminal law (18 USC § 24(a)) to include violations of the FDCA (21 USC § 331), which prohibits the sale of an adulterated or misbranded drug and the adulteration or misbranding of a drug in interstate commerce. Consequently, an FDCA violation can now trigger enforcement under title 18, including the use of administrative subpoenas and criminal forfeiture authorities.	Effective upon enactment (March 23, 2010)	Not scored

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Fraud and Abuse	For provisions of general application that may be relevant to the industry, please see the Fraud & Abuse summary.		