FOLEY HOAG LLP

Health Reform 2010
Key Provisions Affecting the Pharmaceutical Industry
March 30, 2010

<table>
<tr><th></th><th>Patient Protection and Affordable Care Act (P.L. 111-148; H.R. 3590) and
Health Care and Education Affordability Reconciliation Act (P.L. 111-152; H.R. 2872)
March 30, 2010</th></tr>
<tr><td><u>MEDICARE PART D</u>

Part D Coverage Gap</td><td>
<u>Coverage Gap Discount</u>. Effective January 1, 2011, requires manufacturers to contribute 50% of a brand drug's or biologic's negotiated price used by an eligible Part D beneficiary in the coverage gap; subsidy-eligible beneficiaries or beneficiaries with annual income exceeding the Part B income thresholds are not eligible for the manufacturer's discounts.

<u>Model Agreement</u>: Industry is required to enter into a model agreement with HHS 180 days after enactment (October 3, 2010). Manufacturers must enter into agreements 30 days after the model agreement reached (November 2, 2010).

<u>Federal Contribution to Coverage Gap</u>. Narrows the beneficiaries brand drug coinsurance to 25% in 2020 and subsequent years.
<table>
<tr><th></th><th colspan="3">Required Contribution (%)</th></tr>
<tr><th>Year</th><th>Industry</th><th>Government</th><th>Beneficiary</th></tr>
<tr><td>2011-2012</td><td>50</td><td>0</td><td>50</td></tr>
<tr><td>2013-2014</td><td>50</td><td>2.5</td><td>47.5</td></tr>
<tr><td>2015-2016</td><td>50</td><td>5</td><td>45</td></tr>
<tr><td>2017</td><td>50</td><td>10</td><td>40</td></tr>
<tr><td>2018</td><td>50</td><td>15</td><td>35</td></tr>
<tr><td>2019</td><td>50</td><td>20</td><td>30</td></tr>
<tr><td>2020</td><td>50</td><td>25</td><td>25</td></tr>
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<u>Out of Pocket Costs</u>. Manufacturer discounts will count toward true out-of-pockets costs ("TrOOP"). Federal coverage gap contribution does not towards TrOOP.
<u>Coverage Gap Rate of Growth</u>. Effective 2014, the rate of growth of the out-of-pocket threshold faced by beneficiary is changed from tracking drug spending to a fixed rate of 0.25%. In 2016 and through 2019, the rate is changed from 0.25% to CPI + 2%. The growth rate control sunsets in 2020 and returns to the growth in per capita drug cost under Part D.

<u>Immediate payment</u>. Provides $250 for Part D beneficiaries incurring Part D costs in the coverage gap in 2010 (instead of $500). (Payment does not count toward the TrOOP limit).

<u>AMP</u>. Clarifies that manufacturer discount is exempt from AMP calculation.

<u>Best Price</u>. Exempts discount program from Medicaid best price determination.
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	Patient Protection and Affordable Care Act (P.L. 111-148; H.R. 3590) and Health Care and Education Affordability Reconciliation Act (P.L. 111-152; H.R. 2872) March 30, 2010
	Application to generic drugs. Provides for a reduction in beneficiary obligation regarding generic drug costs incurred in the coverage gap. In 2011, the beneficiary responsibility is 93% and decreases by 7 percentage points each year until 2020, when it becomes and remains 25%. Effective January 1, 2011.
MEDICAID Rx **Medicaid Prescription Drug Provisions**	Base rebate. Effective January 1, 2010, increases the Medicaid rebate for innovator drugs from 15.1% to 23.1%, except the rebate for clotting factors and exclusively pediatric drugs is increased only to 17.1%. Increases the rebate for non-innovator, multiple source drugs, from 11% to 13% of average manufacturer's price ("AMP"). Limits total rebate liability on an individual single source or innovator multiple source drug to 100% of AMP. Revenue generated from rebate increases will be remitted to the federal government. Reformulations. Effective January 1, 2010, extends the additional (penalty) Medicaid rebate to line extensions (such as extended release formulations) of single source drug ***or** innovator multiple source drugs that are oral solid dosage form. (Effectively exempting non-oral-solid dosage form of multiple source drugs from the rebate extension). Managed Care Organizations ("MCO"). Effective upon enactment, extends rebate amounts to MCOs. Rebates are paid directly to the states based on MCOs actual cost experiences. Does not prohibit MCOs from additional negotiations. Federal Upper Limit ("FUL"). Effective on the first day of the first calendar year quarter that begins at least 180 days after enactment of the Act, sets FUL at no less than 175% of the weighted average (determined on the basis of utilization) of the most recently reported monthly AMPs for pharmaceutically and therapeutically equivalent multiple source drug products that are available for purchase by retail community pharmacies on a nationwide basis. Requires the Secretary to implement a "smoothing" process for AMPs similar to the process used under average sales price ("ASP"). Definition of AMP. Includes in the definition of AMP, the average price paid by wholesalers for drugs distributed to retail community pharmacies and retail community pharmacies that purchase drugs directly from the manufacturer. Excludes from the calculation of AMP customary prompt pay discounts extended to wholesalers, such as bona fide service fees paid to wholesalers or retail community pharmacies, including (but not limited to) distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative services agreements and patient care programs (such as medication compliance programs, patient education programs); reimbursements by manufacturers for certain types of recalled, damaged, or expired goods; and payments received from, and rebates or discounts provided to PBMs, MCOs, HMOs, insurers, hospitals, clinics, mail order pharmacies, LTC providers, manufacturers, or any other entity that does not conduct business as a wholesaler or a retail community pharmacy.
INDUSTRY TAXES **Pharmaceutical Industry Excise Tax**	Impact. Establishes an aggregate annual fee on branded prescription drug manufacturers and importers to total $23 billion from 2011-2019, beginning in 2011. Establishes an aggregate fee, beginning in 2011 in the amounts of: ▪ 2011: $2.5 billion ▪ 2012-2013: $2.8 billion ▪ 2014 – 2016: $3.0 billion ▪ 2017: $4.0 billion

	▪ 2018: $4.1 billion ▪ 2019 and thereafter: $2.8 billion Determination. Fee is to be apportioned among those manufacturing or importing branded prescription drugs for sale in the US and is based on specified program sales (Medicare Parts B and D, Medicaid, VA and TRICARE retail pharmacy program). Prescription drug includes drugs approved under section 505(b) of the Federal Food, Drug, and Cosmetic Act, and biological products approved under section 351 of the Public Health Service Act. Individual assessment for each calendar year is the total fee multiplied by the ratio of: (1) the covered entity's "branded prescription drug sales" taken into account during the preceding calendar year to (2) the aggregate branded prescription drug sales of all covered entities taken into account during such preceding calendar year. Orphan drugs are exempt from calculation of sales. Calculation. For purposes of calculating the individual manufacturer's fee, 0% of a covered entity's branded prescription drug sales for the preceding calendar year up to $5 million are taken into account; 10% of sales between $5 million and $125 million are taken into account; 40% of sales from $125 million to $225 million are taken into account; 75% of sales from $225 million to $400 million are taken into account; and 100 % of over $400 million are taken into account. Credited to Medicare Trust Fund. Fees collected are credited to the Medicare SMI trust fund. Nondeductible. Fees are nondeductible for income tax purposes. Provides for joint and several liability.
340B	"Covered Entity" expansion. Expands entities eligible for 340B price discounts to free-standing children's hospitals, free-standing cancer hospital, rural referral centers, certain sole community hospitals, and critical access hospitals. Effective January 1, 2010. Orphan drug exclusion. Provides that orphan drugs are excluded from the program only in regards to the new covered entities. Oversight. Strengthens 340B manufacturer oversight and compliance requirements. GAO Study**:** recommendations on program improvement due to Congress within 18 months.
MEDICARE PART D **Low-income Subsidies**	Effective in 2011, requires the Secretary to exclude Medicare Advantage ("MA") rebates and bonus payments from the MA-PDP premium amount when calculating the regional low income subsidy ("LIS") benchmarks. Effective Jan. 1, 2011 permits the Secretary to allow PDPs and MA-PDPs to waive de minimis PDP premiums, and allows the Secretary to auto-enroll low-income subsidized beneficiaries in PDPs or MA-PDPs that waive such premiums; within 30 days of automatic enrollment or reassignment to a new plan, the Secretary must provide beneficiaries with information regarding formularies, coverage determination, and wavier/grievance processes.

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MEDICARE PART D **Elimination of Deduction**	Removes the rule allowing Part D subsidy payments to employers to be excluded from tax determinations. Effective 2013.
MEDICARE PART D **Protected Classes**	Effective January 1, 2011, requires PDPs to include all covered Part D drugs in the categories and classes identified by the Secretary, with certain limited exceptions. Provides HHS with authority to identify new categories and classes of drugs of "clinical concern" as determined by the Secretary according to criteria promulgated in regulations; until the identification of new classes according to the new regulations, codifies the current six protected classes (anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants for treatment of transplant rejection).
MEDICARE PART D **Premium Reduction**	Reduces the Part D premium subsidy for beneficiaries with incomes above the Part B income thresholds.
MEDICARE PART D **Dual Eligibles**	Effective no earlier than Jan. 1, 2012, eliminates cost-sharing for dual-eligible beneficiaries enrolled in home or community-based waiver programs, who otherwise would require institutional care. No later than March 1, 2010, establishes the Federal Coordinated Health Care Office (CHCO) within CMS to bring together Medicare and Medicaid officials to: more effectively integrate benefits under the Medicare and Medicaid programs, and (2) improve the coordination between the Federal and state governments for dual eligibles to ensure that such individuals get full access to the items and services to which they are entitled. Requires the Secretary to submit an annual report to Congress with recommendations for legislation that would improve care coordination and benefits for dual eligibles.
MEDICARE PART D **Part D Medication Therapy Management**	Medication Therapy Management Program. Requires PDPs to enroll target beneficiaries in medication therapy management programs (MTMPs), with an ability to opt-out, to increase medication adherence. MTMPs must include an annual medication review, which may be followed by a medication action plan or other result to improve beneficiary adherence, and necessary follow-up interventions. Quarterly Assessment. Requires PDPs to assess medication use of at-risk beneficiaries every quarter. Effective Date. Effective for plan year beginning two years after enactment.

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BIOSIMILARS **Biosimilar Pathway**	Pathway. Amends the Public Health Service Act to provide for an FDA approval pathway for biosimilar and interchangeable biosimilar biological products. Provides requirements for applications and safety standards. Exclusivity. Extends 12 years data exclusivity for reference biological products and 6 additional months for conducting pediatric studies. Intellectual Property. Create a new patent notification and exchange program to manage the interactions among patent holders and biosimilar applicants. (**For a detailed chart on the biosimilar provisions, please email us.*)
BIOSIMILARS **Payment for Biosimilars**	Provides for separate billing codes for Part B biosimilar products. Mandates that the add-on payment for a biosimilar equal 6% of the reference product's ASP.
Independent Payment Advisory Board (IPAB)	Creates new Independent Payment Advisory Board (IPAB) tasked with presenting Congress with comprehensive proposals to reduce excess cost growth and improve quality of care for Medicare beneficiaries and in the private health care system. Purpose and Overview. IPAB's mission is to present Congress with comprehensive proposals to reduce the per capita rate of growth in Medicare spending (defined as Medicare A, B, and D net of premiums) and to improve quality of care for Medicare beneficiaries. In any year beginning with 2014 that the IPAB is not required to submit a proposal under this section, the Board shall submit to Congress an advisory report related to the Medicare program. IPAB is also tasked with making advisory recommendations to Congress and the President for non-Federal health care programs—specifically, recommendations that the Secretary or Federal agencies can implement administratively, that State or local governments may enact legislation to implement, or that private sector entities can voluntarily implement, to slow the growth in national health expenditures (in the private health care system) while preserving or enhancing quality of care. Proposal Development. The CMS Chief Actuary shall determine whether the requirement for IPAB to submit recommendations is triggered. If the actuary determines that the projected Medicare per capita growth rate exceeds the target growth rate for a year, the IPAB must make recommendations to reduce the projected growth rate. HHS is required to implement the IPAB's recommendations unless Congress enacts alternative measures that achieved the same level of savings. This alternative provision could be considered on a fast-track basis by Congress. The IPAB would be prohibited from making proposals that reduce Medicare benefits or change eligibility, increase the Part B premium, raise taxes, or ration care. IPAB Membership. The IPAB is to be composed of 15 members appointed by the President, with the advice and consent of the Senate, to 6-year terms. The Secretary of HHS, CMS and HRSA Administrators are ex-officio members. Appointees would be individuals with backgrounds and expertise in specified areas such as health care finance, economics, and policy. IPAB Proposals. Proposals must be submitted to the President by January 15 of each year beginning January 15, 2014 (if triggered by the CMS Actuary's determination of excessive per-capita growth in Medicare). The IPAB cannot make recommendations affecting institutional providers and physicians prior to December

31, 2019. Proposals can include reductions in payments to Medicare Advantage plans and prescription drug plans, although those reductions cannot impact beneficiary premiums for Part D plans. Proposals could also include reductions in payment for other Medicare-covered items and services such as durable medical equipment and drugs covered under Part B.

Proposal Requirements

- The IPAB's recommendations must meet a "savings target" which in the bill is defined as the lesser of 1.5% of total Medicare spending (increasing gradually from 0.5% beginning in 2015 over a four-year period) or the excess identified by the CMS actuary.
- Each proposal shall be designed such that, if implemented, it would not be expected to result, over the 10-year period starting with the implementation year, in any increase in total amount of net Medicare program spending.
- Each proposal must include: (i) recommendations to reduce Medicare spending by targeted amounts compared to the trajectory of Medicare spending, (ii) explanation of each recommendation contained in the proposal and the reasons for including such recommendation, (iii) actuarial opinion by the Chief Actuary of CMS certifying that the proposal meets the requirements, (iv) legislative proposal that implements the recommendations, and (v) other information determined appropriate by the IPAB.
- IPAB must submit recommendations to MedPAC and the HHS Secretary for review by September 1. By March 1 of the following year, the Secretary is required to submit the results of the Secretary's review to Congress. The IPAB would also, on Jan. 15 (beginning in 2014), submit its recommendations to the President.
- Specific procedures are established for expedited Congressional review of the IPAB's recommendations.

Advisory Reports. Beginning January 15, 2014, the IPAB, regardless of whether it submits a proposal for a given year, may submit an advisory report on matters related to the Medicare program. For years prior to 2020, the advisory report may include recommendations for improvements to payment systems for providers of services and suppliers not otherwise subject to the scope of IPAB's recommendations. Such advisory report would not be subject to rules for Congressional consideration established under this section.

Consumer Advisory Council. Creates an IPAB Consumer Advisory Council composed of 10 consumer representatives appointed by the Comptroller General to advise the IPAB on the impact of Medicare payment policies on consumers..

Funding. Authorizes $15,000,000 for IPAB for FY 2012; and for each subsequent fiscal year, the amount appropriated for the previous fiscal year increased by the annual percentage increase in the CPI for All Urban Consumers as of June of the previous year.

GAO Studies and Reports. Requires a GAO study on changes to payment policies, methodologies, and rates and coverage policies and methodologies under Medicare as a result of the recommendations contained in IPAB's proposals, including an analysis of the effect of such recommendations. Not later than July 1, 2015, the Comptroller General shall submit to Congress a report containing recommendations for legislation and administrative action as GAO determines appropriate. GAO shall periodically conduct additional studies and submit reports to Congress on changes to Medicare payments policies.

Annual Public Report. Not later than July 1, 2014, and annually thereafter, the IPAB shall produce a public report containing standardized information on system-wide health care costs, patient access to care, utilization, and quality of care that allows for comparison by region, types of services, types of providers, and both private payers and Medicare. Each report shall include information on: (A) quality and costs of care, (B) beneficiary and consumer access, patient experience, cost-sharing or out-of-pocket burden on patient, (C) epidemiological and demographic changes, (D) proliferation, effectiveness, and utilization of health care technologies, and (E) any other areas the Board determines affect overall spending and quality of care in the private sector.

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	Biennial Recommendations. Beginning in 2020, and biennially thereafter, the IPAB shall, if the CMS Actuary has made a determination that the projected growth rate of national health expenditures exceeds the Medicare growth rate, design its proposal to help reduce the growth rate in national health expenditures while maintaining or enhancing Medicare beneficiary access to quality care.
Physician "Sunshine" Provision	Reporting. Beginning March 31, 2013 and on the 90th day of each calendar year beginning thereafter, requires any applicable manufacturer that provides a payment or other transfer of value to a covered recipient (or to an entity or individual at the request of or designated on behalf of a covered recipient), to report to the Secretary of HHS the amount of the payment, the name and address of the recipient of the payment, the date(s) of payment, and a description of the payment. • Applicable manufacturer is any manufacturer of a covered drug, device, or medical supply operating in the U.S. • Covered drug, device, biological, or medical supply is any such product for which payment is made under Medicare or Medicaid. • Covered recipients are physicians or teaching hospitals. Physician Ownership. Similarly directs any applicable manufacturer or group purchasing organization to submit to the Secretary information relating to any ownership or investment interest held by a physician in the applicable manufacturer or group purchasing organization. Preemption. Effective January 1, 2012; preempts related state laws or regulations. Exceptions for information beyond scope of this legislation. Reporting threshold. Requires reporting for transfers of value greater than $10, or if annual transfers of value exceed $100 in the aggregate. Exempts certain transfers of value from reporting, such as product samples and education materials. Payment report. Requires annual reporting beginning March 31, 2013, in electronic form; starting September 30, 2012 and on June 30 of subsequent years, submitted information must be available on a searchable Internet website. Requires the HHS OIG to issue a report on the effect of the reporting requirements, and requires HHS annual report starting in 2013. Delays reporting for payment for clinical trials. Penalties. Manufacturers or group purchasing organizations are subject to a civil money penalty of $1,000-10,000 for each payment/transfer not reported; total to not exceed $150,000 for any annual submission; knowing failure increases fines to $10,000 -%100,000 and maximum is the greater of $1 million *or* 0.1 percentage of annual revenues of the manufacturer.
Comparative Effectiveness Research	Establishes a nonprofit corporation ('Institute') to assist patients, clinicians, purchasers & policy makers in making health decisions by conducting research that would compare the clinical effectiveness, risk and benefits of two or more medical treatments, services or items. Defines treatment, services and items as health care interventions, protocols for treatment, care management and delivery, procedures, medical devices, diagnostics tools, pharmaceuticals and any strategies or items used in the treatment, management and diagnosis of or prevention of illness or injury, in patients. Duties. Institute shall identify priorities; carry out research agenda; study the feasibility of conducting research in-house; collect appropriate data from CMS; appoint advisory panels; support patient & consumer representatives; establish a methodology committee; provide for a peer-review process; release research findings;

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	coordinate research; and submit annual reports to the Congress, the president and the public. Includes preference in the contracting process for AHRQ & NIH, so long as research is authorized by governing statutes. Transparency/Patient Protections. Ensures that research is designed to take into account potential differences in outcomes among different subpopulations and different characteristics of treatment modalities. Precludes the Institute from mandating coverage, reimbursement or other polices for any public or private payer. Ensures that none of the reports or findings are construed as mandates, guidelines, or policy recommendations. Establishes limitations around the use of the Institute's research findings which include: 1) requiring the Secretary to use an iterative and transparent process when using the research in making coverage determinations; 2) allows stakeholders to provide information to inform the determination, review draft proposals and submit public comments on draft proposals; and 3) prohibits Secretary from using the Institute's research as sole evidence in making a determination. Reaffirms the "reasonable and necessary" standard. Discrimination prohibition. Prohibits the Secretary from using the research in determining coverage for a treatment in ways that discriminate based on age, disability, or diagnosis of terminal illness. Also protects against discouraging care based on how the individual values the tradeoff between extending life and the risk of disability. Establishes oversight and audit requirements. Establishes transparency procedures. Funding. Creates a Trust Fund to provide funding for the Institute. Amounts equal to $600 million/year, which would come from mandatory appropriations, the Medicare trust funds and a fee on health plans. Twenty percent of the funds in the Fund to go the Secretary to carry out this section the below Office of Communication; and of the 20%, 80% goes to AHRQ and 20% stays with the Secretary. AHRQ Office of Communication and Knowledge Transfer. Designated as the key agency for the dissemination of Institute's research findings (as well as other government-funded research relevant to comparative clinical effectiveness research). Other. Terminates the Federal Coordinating Council for Comparative Effectiveness Research.
Cures Acceleration Network	NIH Grant Program. Creates the Cures Acceleration Network (CAN) within the Office of the Director of NIH to follow recommendations of the new CAN Review Board and to award grants to eligible entities to accelerate the development of "high need cures." CAN Review Board. Among other things, CAN Review Board is tasked with identifying translational barriers to product development, providing recommendations for reducing such barriers, and streamlining FDA approval of "high need cures." Authorization. Authorizes $500 million for CAN or FY2010 and such sums as may be necessary for subsequent fiscal years.
Medical Device Industry Tax	Tax. Imposes an excise tax on "taxable medical device" sales equal to 2.3% of the price of the device, effective for taxable years after December 31, 2012 Definition and Exempt devices. A "taxable medical device" is any medical device as defined in section 201(h) of the FFDCA. Devices exempt from the tax include

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	eyeglasses, contact lenses, hearing aids, and other devices that are "generally purchased by the general public at retail for individual use" as determined by Treasury.
INSURANCE REFORMS **Lifetime & Annual Limits**	Effective six months after enactment, prohibits all health insurance plans, new and grandfathered, from establishing lifetime limits on the dollar value of "essential benefits" as described in section 1302(b). Prohibits new and grandfathered group plans from establishing annual limits on the dollar value of "essential benefits" in 2014; prior to 2014, plans are permitted to impose "restricted" annual limits on "essential benefits", as defined by the Secretary of HHS.
INSURANCE REFORMS **Employer-based Wellness Programs**	Rewards for Participation in Wellness Programs. Codifies HIPAA non-discrimination regulations to allow rewards to be provided to employees for participation in or for meeting certain health standards related to a wellness program. Allows the award for participating in a wellness program to include insurance premium discounts, rebates or waiver of cost-sharing. Provides that wellness programs that provide rewards based on an individual satisfying a standard that is related to a health factor do not violate the HIPAA non-discrimination rules if certain requirements are met. Reward Cap. Caps reward at 30% of the employee-only coverage under the plan, but provides protections for plan participants that cannot meet the applicable standard due to a medical condition or because it is medically inadvisable to do so. Provides Secretaries of HHS, Labor and Treasury discretion to increase the reward to 50% if they deem it is appropriate. Demonstration. Establishes 10-state demonstration project to begin not later than July 1, 2014 whereby states would receive grants to support wellness programs. Provides discretion to Secretaries to expand the demonstration project in 2017. Regulations may be promulgated. Report. Requires a report to Congress on the program within 3 years of enactment of the legislation.

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