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Health Care Reform Informational Series

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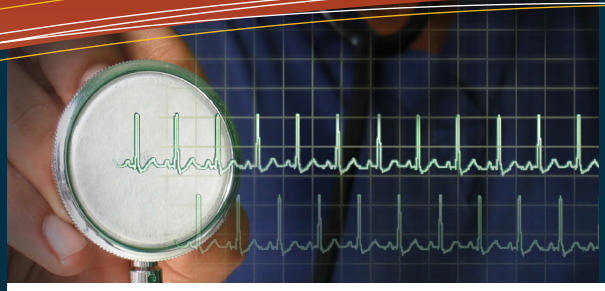

Part II: Health Law

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Impact On The Biotechnology, Pharmaceutical and Medical Device Industries

The Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010 (collectively, the "PPACA") is a comprehensive reform act that extensively restructures public and private health insurance and the health care industry. The PPACA contains many provisions that directly and indirectly apply to pharmaceutical, biotechnology or medical device companies. In this alert, we have summarized the PPACA's key provisions affecting the pharmaceutical, biotechnology and medical device industries so that they may identify the applicable opportunities and regulatory requirements.

Taxes, Fees, Rebates, Discounts and Reimbursement

Annual Fees for Branded Pharmaceutical Manufacturers and Importers. Commencing January 1, 2011, a "manufacturer or importer with gross receipts from branded prescription drug sales" must pay an annual fee to the Secretary of the Department of the Treasury (the "Treasury") based on its relative market share which will be nondeductible for federal income tax purposes. The total fee is set at $2.5 billion in 2011, and will increase annually until it peaks in 2018 at $4.1 billion. Thereafter, the fee drops down to, and remains at, $2.8 billion in 2019 and for subsequent years. The Treasury will calculate the amount of each entity's fee based on its relative market share of branded prescription drug sales only, and will set a date for payment of the fee which will be no later than September 30th of each calendar year. "Branded prescription drug sales" are sales of branded prescription drugs to government sponsored programs such as Medicare, Medicaid, and TRICARE and do not include sales of generic drug products or orphan drugs. These government programs will also be required to provide the Treasury with an annual report of the prior year's sales to each program by branded prescription drug manufacturers. For additional information on these fees, click here or visit: http://www.shipmangoodwin.com/files/upload/HealthCareReformTaxLawVol1.pdf.

New Excise Tax on Medical Devices. A new 2.3% excise tax will be imposed on the sale, by manufacturers, producers or importers, of medical devices other than eyeglasses, contact lenses, hearing aids and any other medical device generally purchased by the public at retail for individual use. The new tax will go into effect January 1, 2013. For additional information on this new excise tax, click here or visit: http://www.shipmangoodwin.com/files/upload/HealthCareReformTaxLawVol1.pdf.

Qualified Therapeutic Discovery Project Tax Credit or Grant. Companies that develop products or technologies encouraging the administration of therapeutic products which are considered

"qualifying therapeutic discovery projects" ("QTDP") may be eligible to apply for a tax credit or grant equal to 50% of a qualified investment made during the 2009 or 2010 taxable year. A QTDP is defined as a project to: (i) treat or prevent diseases by conducting pre-clinical activities, clinical trials or studies or by carrying out research protocols; (ii) diagnose diseases or conditions; or (iii) develop a product, technology or process to further the delivery or administration of therapeutics. A qualified investment, with certain exclusions, is the aggregate of expenses paid or incurred by the taxpayer during its 2009 or 2010 taxable year that are necessary for or directly related to the conduct of a QTDP and that have been certified by the IRS. To be considered for a tax credit or grant, eligible taxpayers are required to complete an application and a Project Information Memorandum detailing the specifics of the project no later than July 21, 2010. For a more detailed analysis of the Qualified Therapeutic Discovery Project Tax Credit or Grant and how to apply, click here or visit: http://www.shipmangoodwin.com/files/upload/HealthCareReformTaxAlert3.pdf.

Research Issues

Improving Women's Health. Offices on women's health will be established at various federal agencies with the general goal of improving prevention, treatment, and research for women in health programs. In particular, an Office on Women's Health (the "Office") will be established within the Office of the Commissioner of the FDA. The Office will, among other things: (i) report on women's participation in clinical trials and the analyses of data by sex in the testing of drugs, medical devices, and biological products across age, biological, and sociocultural contexts; (ii) consult with pharmaceutical, biologics and device manufacturers; health professionals with expertise in women's issues; consumer organizations; and women's health professionals on FDA policy with regard to women; and (iii) make annual estimates of funds needed to monitor clinical trials and analysis of data by sex in accordance with identified needs.

CURES Grant for Biotechnology and Pharmaceutical Companies. Public and private entities, including research institutions, institutions of higher education, medical centers, biotechnology companies, pharmaceutical companies, patient advocacy organizations and academic research companies may be eligible for a grant to accelerate the development of high need cures. The term "high need cure" means a drug, biological product, or device that, in the opinion of the U.S. National Institutes of Health ("NIH"): (1) is a priority to diagnose, mitigate, prevent, or treat harm from any disease or condition; and (2) for which the incentives of the commercial market are unlikely to result in its adequate or timely development. The PPACA establishes the Cures Acceleration Network ("CAN") which can award grants of up to $15,000,000.00 per project per fiscal year to eligible entities to accelerate the development of high need cures. CAN will: (i) conduct and support revolutionary advances in basic research; (ii) provide the resources necessary for eligible entities to develop high need cures; (iii) reduce the barriers between laboratory discoveries and clinical trials for new therapies; and (iv) facilitate review by the FDA of the high need cures funded by CAN to expedite the development and approval of the products. CAN will offer two types of grants, one of which will require the eligible entity to match $1 for every $3 awarded by CAN and another which is a straight grant without any matching requirement. Although the PPACA does not specify when entities can apply for the grants, $500,000,000 has been appropriated to fund these grants for fiscal year 2010.

Program for Education and Training in Pain Care. The Secretary of the Department of Health and Human Services ("HHS") will, together with the Institute of Medicine of the National Academies, convene a "Conference on Pain" to (i) evaluate the adequacy of treatment, assessments and management of acute and chronic pain; (ii) identify barriers to pain care; and (iii) establish an agenda for public and private action to improve pain care research. The conference will submit its findings to Congress no later than June 30, 2011. In addition, the NIH Pain Consortium, an existing public-private partnership housed at the NIH, will develop annual recommendations for the funding of pain research initiatives through the NIH's Common Fund. Finally, HHS will establish an

interagency Pain Research Coordinating Committee to, among other things, identify gaps in clinical research and make recommendations on how to expand public/private partnerships regarding pain care. That committee will consist of 31 members, 6 of whom will be scientists, physicians, or health care professionals and 6 of whom will be researchers or representatives of service organizations geared towards individuals with pain related conditions. The PPACA also authorizes HHS to award grants and agreements to health professions schools and other public and private entities for the development of programs that provide education and training to health care professionals regarding pain care. For additional information, click here or visit: http://www.shipmangoodwin.com/files/upload/PPACA Grants.pdf#page=39.

Funds for Patient Centered Outcomes Research. The PPACA authorizes the establishment of a nonprofit Patient Centered Outcomes Research Institute ("PCORI") in order to identify research priorities and establish research agendas for health care treatment, including gaps in clinical outcomes. The PCORI will offer contracts and awards to both public and private entities that consult with an advisory panel, meet methodological standards, and adhere to certain conflicts of interest criteria. The PCORI's board of directors will consist of both private and public representatives, including the Director of the NIH. Funding will be provided from existing Medicare funds, a fee imposed on insurance plans, and other sources.

Fraud and Abuse Related Provisions

New Reporting Requirements for Manufacturers and Group Purchasing Organizations Related to Drugs, Medical Devices and Medical Supplies. The PPACA imposes new reporting requirements on manufacturers of drugs, medical devices and biological or medical supplies for which payment is available under Medicare, Medicaid or Children's Health Insurance Program ("CHIP") and any group purchasing organization ("GPO") that purchases, arranges for or negotiates the purchase of such items.

- **Payments to Physicians and Teaching Hospitals.** Beginning January 1, 2012, affected manufacturers and GPOs are required to keep track of and report certain information regarding monetary payments or other transfers of value they make to physicians or teaching hospitals or a designee thereof (each a "recipient"). Reports must be filed with HHS by March 31, 2013 for the preceding year and then each year thereafter. The PPACA requires that the report include information such as the name and address of the recipient, the date and amount of the payment or the value of the property transferred, a description of the form of payment (e.g. cash, in-kind services, stock), a description of the nature of payment (e.g. gift, consulting fees, charitable contribution) and any other information as may be required by HHS. If the payment or gift is related to marketing, education or research specific to a drug, medical device or medical supply, the report must also contain the name of such drug, medical device or medical supply. Transfers to a recipient of items with a value of less than $10 individually and less than $100 in the aggregate annually are exempt from such reporting requirements. Other exemptions and exclusions are listed in the PPACA.

- **Physician Ownership.** Also beginning March 31, 2013 and each year thereafter, affected manufacturers and GPOs must report to HHS certain information regarding any ownership or investment interest held by a physician in such manufacturer or GPO for the preceding year. This report must include the dollar amount invested by such physician, the value and terms of the physician's ownership and any payment or transfer of value made by the manufacturer or GPO to such physician as a result of such ownership.

The penalties for failure to report are civil and range from $1,000 for an individual failure up to $1,000,000 per year. HHS is required to make the reported information publicly available through

an internet website together with information regarding any penalties assessed and specific industry-physician relationships. The PPACA preempts state disclosure laws to the extent that the state law requires a manufacturer to disclose or report the same information required by the PPACA with respect to payments, gifts and other transfers of value. This preemption is effective for transfers of value occurring on or after January 1, 2012.

New Reporting Requirements for Manufacturers and Distributors of Drug Samples. As discussed in our recent Compliance Alert (http://www.shipmangoodwin.com/files/upload/HealthCareReformHealthLawVol1.pdf#page=3), beginning January 1, 2011, the PPACA requires manufacturers and distributors of prescription drugs to keep track of and report certain information regarding the distribution of drug samples to licensed practitioners or to pharmacies of hospitals or other health care entities. The first report must be filed with HHS by April 1, 2012 for the preceding year and each year thereafter. The report must include information such as the identity and quantity of drug samples requested by a licensed practitioner, the identity and quantity of drug samples distributed pursuant to such request, the name, address, professional designation and signature of the practitioner (or his or her designee) making the request and any other information deemed appropriate by HHS.

Enhanced Medicare and Medicaid Program Integrity. Payment and claims data related to Medicare, Medicaid, CHIP, programs administered by the Departments of Defense and Veterans Affairs and the Indian Health Service must now be included in the Centers for Medicare and Medicaid Services' ("CMS") Integrated Data Repository. The Office of Inspector General will have authority to obtain information from: (i) beneficiaries; (ii) providers or suppliers of medical items; or (iii) individuals that "directly or indirectly" provide orders, manufacture or supply medical or other items in order to protect the integrity of Medicare and Medicaid. The information gathered will include records necessary to evaluate the efficiency and effectiveness of the Medicare and Medicaid programs. The PPACA also permits the suspension of payments to providers or suppliers involved in pending fraud investigations.

Expansion of the Medicaid 340B Program. HHS must develop procedures to monitor refunds by pharmaceutical manufacturers to covered entities as a result of overcharging by such manufacturers. Manufacturers will be required to report refunds to HHS with an explanation as to how such overcharging occurred. Additionally, HHS has the authority to conduct selective audits on manufacturers to identify potential incidents of overcharging. HHS has the authority to impose penalties, which can not exceed $5,000, for knowing or intentional overcharging. HHS will also now review price ceilings related to pharmaceutical sales and the calculation of such ceilings.

Drug Manufacturers: FDA Related Provisions

Accelerated Approval of Biosimilar or Interchangeable Products. The PPACA authorizes the FDA to grant accelerated approval of a product if it is "biosimilar" or "interchangeable" with a previously approved FDA product (a "reference product"). Reference products will be given a 12 year exclusivity period such that accelerated approval under the PPACA for biosimilar products will only be available 12 years after the reference product is approved by the FDA. Applications for approval as a "biosimilar product" may, however, be submitted 4 years after the date the reference product was first approved. A product may be approved as a "biosimilar product" by demonstrating a high degree of similarity to a specific reference product as evidenced by analytical studies, animal studies and studies that show the safety, purity and potency in one or more appropriate "conditions of use" for which the reference product is approved. The biosimilar product must also demonstrate a use that is the same as that approved for the reference product, but the FDA may choose to waive any of the aforementioned requirements for "biosimilar products." This approval process would not apply to "off-label" uses.

"Interchangeable" products are a subset of biosimilar products that: (i) are expected to produce the same clinical effect as the reference product; and (ii) will not be less effective if switched with the reference product if multiple doses are required. The first interchangeable product approved based on a given reference product will be granted exclusive approval such that other interchangeable products may not receive FDA approval for a minimum of 1 year from the date of commercial marketing of the interchangeable product.

The PPACA also establishes new dispute resolution procedures related to potential patent infringement claims made by the reference product sponsor against the biosimilar product applicant. Specifically, the biosimilar product applicant and the reference product sponsor will now exchange information regarding potential patent infringement claims prior to FDA approval through a multistep process. The reference product sponsor may litigate certain patent infringement claims prior to regulatory approval of the biosimilar product, but only based on a list of claims that are acceptable to the biosimilar product applicant. Furthermore, the reference product sponsor's failure to timely file a suit of infringement based on the preapproved list of claims will limit the reference product sponsor's relief to only reasonable royalties for infringement. Additionally, if the reference product sponsor fails to list a potential infringement claim in its initial exchange of information with the biosimilar product applicant, it may not thereafter file an infringement claim for that particular biosimilar product.

Abbreviated Application for Generic Drugs Despite Labeling Changes. A generic drug manufacturer can use the FDA's abbreviated application process despite labeling differences between the generic drug and its corresponding brand name drug if those differences are due to changes made in the labeling for the brand name drug shortly before the expiration of the brand name drug's patent. Prior to enactment of the PPACA, the FDA allowed abbreviated applications for a new generic drug that is the same as a brand name drug (i) that is listed by the FDA (each a "Listed Drug"), and (ii) for which an applicable patent or exclusivity period has expired, so long as, among other things, the labeling on the generic drug is the same as the labeling on the Listed Drug. Following enactment of the PPACA, a generic drug can still use the abbreviated application notwithstanding labeling differences between the generic drug and the Listed Drug if such differences (x) are due to a revision to the labeling of the Listed Drug within 60 days of the expiration of a patent or exclusivity period and (y) do not implicate the "warnings" section of the label.

Presentation of Prescription Drug Benefit and Risk Information. HHS is tasked with determining whether the addition of quantitative summaries detailing the benefits and risks of prescription drugs in a standardized format to the promotional labeling or print advertising of such drugs would improve health care decision-making by clinicians, patients, and consumers. In making this determination, HHS shall consult with certain entities, including drug manufacturers, clinicians, patients, consumers, and experts in health and literacy. HHS shall submit a report to Congress of the determination no later than March 23, 2011. If HHS determines that the addition of the standardized format of the quantitative summaries to the promotional labeling or print advertising of prescription drugs would improve health care decision-making by clinicians, patients, and consumers, then HHS shall, not later than 3 years after submission of the initial report, promulgate proposed regulations as necessary to implement such format.

Prescription Drug Rebates. Medicaid rebates by drug manufacturers will increase from 15.1% to 23.1% for innovator products and 11% to 13% for non-innovator products. New formulations of single source or innovator multiple drugs in oral solid form, known as "line extensions," are currently subject to an additional rebate that has also been increased in accordance with the calculation enumerated in the PPACA. Manufacturers will be required to pay for rebates for drugs dispensed to individuals enrolled in Medicaid managed care organizations. The total amount of the rebate for

an innovator drug has been capped at 100%, and the changes to prescription drug rebates apply retroactively to all drug rebates issued after December 31, 2009.

Elimination of Exclusion of Certain Drugs. Effective January 1, 2014, smoking cessation drugs, barbiturates, and benzodiazepines will no longer be on the Medicaid excludible drug list.

Providing Adequate Pharmacy Reimbursements. Effective October 1, 2010, the calculation of drug manufacturing rebates due by states to manufacturers under Medicaid will be modified so that the Federal Upper Limit is not less than 175% of the weighted average (based on utilization) of the average manufacturers' price for pharmaceutically or therapeutically equivalent multiple source drug products available for purchase by retail pharmacies nationwide. Because the PPACA only establishes the minimum for the Federal Upper Limit, HHS may set the Federal Upper Limit to an amount greater than 175%, at its discretion.

Drug Manufacturers Required to Offer Fifty Percent Discount on Brand Name Medicare Part D Covered Drugs. Beginning January 1, 2011, drug manufacturers must give certain Medicare beneficiaries a 50% discount on brand name drugs covered by Medicare. In an attempt to close the "donut hole" created by the coverage gap under the Medicare Part D drug plan, HHS will establish the Medicare Coverage Gap Discount Program (the "Discount Program"). The Discount Program requires manufacturers of Part D covered drugs to provide a discount to Medicare beneficiaries that find themselves in the donut hole. The discount on each brand name covered Part D drug is 50% of such drug's negotiated price. The discounted prices will be provided to the applicable beneficiary at the pharmacy or other point-of-sale. Manufacturers will be required to enter into an agreement with HHS to participate in the Discount Program and to provide applicable discounts on coverage gap claims for all of its Part D covered drugs. For the plan year beginning on January 1, 2010, the initial coverage limit for the Medicare Part D prescription coverage gap will be increased to $500. It should be noted that this increase only applies to the 2010 plan year, and not subsequent or prior plan years.

Modification of Equipment Utilization Rates for Advanced Imaging Services. Currently, payments to providers under the Medicare physician fee schedule are based on the assumption that advanced imaging equipment is being used 50% of the time. The PPACA increases the utilization rate for advanced imaging equipment from 50% to 65% for the years 2010-2012. The rate will then be increased to 70% in 2013 and 75% in 2014. Additionally, the utilization rate for expensive diagnostic imaging equipment (i.e. diagnostic imaging equipment that costs over $1 million) will remain at 50% for the 2010 fee schedule and will thereafter be increased to 75% for 2011 and subsequent years.

Reimbursement for Biosimilar Biological Products and Medical Devices. Effective July 1, 2010, Medicare Part B reimbursement amounts for biosimilar biological products will be based on the average sale price plus 6% of the average sale price of the reference product. The PPACA also modifies the reimbursement rates for certain durable medical equipment, orthotics, and prosthetics.

Revision to Market Basket Updates. Under the current system, CMS utilizes market baskets to update payment amounts under CMS administered programs. A market basket is an index that measures price changes of goods and services. Under the PPACA, market basket updates for durable medical equipment and prosthetic devices, orthotics, and supplies will now include a productivity adjustment equal to the 10 year moving average of changes in the annual economy-wide private non-farm business multi-factor productivity. Manufacturers of durable medical

equipment, prosthetic devices, orthotics and supplies may be impacted by this change in the calculation of reimbursement rates.

Health Plans Required to Cover Routine Patient Costs Furnished in Connection with Certain Clinical Trials. Entities conducting clinical trials for the treatment of cancer or other life threatening conditions should be aware that group health plans or insurance issuers can no longer deny or limit a beneficiary's coverage of "routine patient costs" for items and services furnished to such beneficiary in connection with such clinical trials. A health plan must cover routine patient costs so long as either (i) the beneficiary was referred to such clinical trial by a participating healthcare provider that has concluded such trial is appropriate for the individual; or (ii) the beneficiary provides medical and scientific information establishing that participation in such clinical trial is appropriate. Routine patient costs do not include investigational items, devices or services, items and services provided solely to satisfy data collection and analysis needs and items and services that are clearly inconsistent with widely accepted and established diagnosis. Health plans in effect on March 23, 2010 are exempt from these new coverage requirements. This provision will take effect in 2014 and will preempt state law only to the extent state law does not require that health plans include clinical trial coverage to the extent required by the PPACA.

Questions or Assistance?

For more information on topics covered by this alert, please visit Shipman & Goodwin LLP's Health Care Reform Resource Center located at http://www.shipmangoodwin.com/healthcarereformresourcecenter/ or contact one of the following Bioscience partners:

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