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Chapter 1

U.S. Healthcare Reform and the Pharmaceutical Industry

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Introduction

On March 30, 2010, President Obama signed into law HR 4872, the Health Care and Education Reconciliation Act of 2010 (the Reconciliation Act). The Reconciliation Act supplements and "fixes" several provisions of the Patient Protection and Affordable Care Act (PPACA), the comprehensive healthcare reform law signed by the President on March 23, 2010.

Together, PPACA and the Reconciliation Act will profoundly affect the US healthcare system and all its stakeholders, including pharmaceutical manufacturers. In addition to making broad insurance reforms and eventually providing coverage to an estimated 32 million uninsured people, the new laws will boost penalties for violating healthcare programme requirements; revamp government healthcare programme requirements in critical ways; institute a new framework for US Food and Drug Administration (FDA) approval of biosimilar products; and create a new transparency regime requiring public disclosure by drug manufacturers of payments to healthcare professionals. This article summarises some of the major provisions of PPACA and the Reconciliation Act that are of particular interest to pharmaceutical manufacturers.

I. Healthcare Fraud and Abuse

PPACA makes several important changes in the law that—taken individually or collectively—pave the way for more whistleblower and government suits charging healthcare "fraud and abuse" violations. It also increases penalties for fraud and abuse violations.

The Anti-Kickback Statute and the False Claims Act

By relaxing some key requirements to prove violations of the Anti-Kickback Statute and the False Claims Act (FCA), PPACA will make it easier for whistleblowers and the government to charge anti-kickback and FCA violations. First, under PPACA, a person need not have actual knowledge of the Anti-Kickback Statute or the specific intent to violate the statute in order to be subject to its penalties. A reduced intent requirement, which will override the higher intent requirement adopted by certain courts, could allow prosecutors to base anti-kickback charges on normal and apparently legitimate practices by individuals or companies acting without any intent to violate the law or knowledge that they were doing so.

Beyond making it easier to establish anti-kickback claims, PPACA also transforms many anti-kickback claims into potential FCA cases by codifying certain court decisions holding that an anti-kickback violation can establish the "falsity" of a claim for FCA purposes. PPACA amends the Anti-Kickback Statute to provide that "a claim that includes items or services resulting from a violation [of the Anti-Kickback Statute] constitutes a false or fraudulent claim for purposes of [the FCA]". The controversial "implied certification" theory is thus now law in circumstances where items or services included in a claim "result[] from" anti-kickback violations.

Finally, PPACA heightens potential FCA liability by allowing more whistleblower suits alleging FCA violations. It makes several changes that narrow the FCA's public disclosure bar, which prohibits whistleblower suits based on information that has been publicly disclosed in certain ways, unless the whistleblower qualifies as an "original source" of the information. These amendments supplement the expansive changes to the FCA that the U.S. Congress enacted last year in the Fraud Enforcement and Recovery Act.

Health Care Fraud Statute

PPACA also weakens the intent requirement for the Health Care Fraud Statute (18 U.S.C. § 1347). The Health Care Fraud Statute makes it unlawful to knowingly and wilfully execute, or attempt to execute, a scheme or artifice to defraud any healthcare benefit programme or to obtain, by means of false or fraudulent pretences, representations, or promises, any of the money or property of a health care benefit programme in connection with the delivery of or payment for healthcare benefits, items, or services. PPACA amends the Health Care Fraud Statute to provide that establishing knowing and wilful conduct in this context does not require proof that the defendant had actual knowledge of the Health Care Fraud Statute or specific intent to violate the Statute.

Exclusion from Federal Healthcare Programmes

PPACA contains provisions clarifying or amending the current law regarding exclusion of entities from participation in federal healthcare programmes for violations of healthcare fraud statutes. PPACA requires States to terminate individuals or entities from their State Medicaid programmes if they have been terminated from Medicare or another State's Medicaid programme. State Medicaid programmes must also exclude an individual or entity that owns, controls, or manages another entity that has failed to repay overpayments, been suspended, terminated, or excluded from Medicaid participation, or is affiliated with any such entity.

PPACA also expands the permissive exclusion authority of the US Department of Health and Human Services (HHS) Office of the Inspector General (OIG) under section 1128 of the Social Security Act (SSA) to apply in instances of obstruction of programme audits and investigations.

Healthcare Fraud Offenses

PPACA updates the definition of "health care fraud offense" in the federal criminal code (18 U.S.C. § 24(a)) to include violations of the Anti-Kickback Statute, section 301 of the Federal Food, Drug, and Cosmetic Act (which prohibits adulteration and misbranding, among other acts), and certain provisions of the Employee Retirement Income Security Act (ERISA). These changes will enable increased enforcement by: (1) making the proceeds of these offenses subject to criminal forfeiture; (2) rendering obstruction of an investigation of these offenses a crime; (3) including these offenses as specified unlawful activity for purposes of money laundering; and (4) authorising the use of administrative subpoenas for the production of documents.

Increased Sanctions

PPACA creates new or enhanced penalties for certain types of conduct. In particular, it empowers HHS to impose civil monetary penalties (CMPs) of US$15,000 per day on any person who fails to grant timely access to the OIG for purposes of audits, evaluations, investigations, or other statutory functions. It also authorises a CMP of US$50,000 for any false record or statement material to a false or fraudulent claim for payment of items and services that a person may knowingly make, use, or cause to be made or used under any federal healthcare programme. Other provisions imposing new or enhanced sanctions and CMPs apply specifically to Medicare Advantage and Part D plans that engage in "prohibited conduct" with respect to individuals' enrolment in or transfer between plans, employment and contracting practices, marketing violations, or the misrepresentation or falsification of information.

II. Medicaid Drug Reimbursement and Rebates

Federal Upper Limits

Under current law, the Centers for Medicare & Medicaid Services (CMS) must establish Federal Upper Limits (FULs) to cap Medicaid programmes' pharmacy reimbursements for certain multi-source drugs. (Federal matching funds are generally unavailable to a State Medicaid programme to the extent that the programme's aggregate payments to pharmacies for these drugs exceed the FUL plus reasonable dispensing fees.) The Deficit Reduction Act of 2005 (DRA) set the FUL at 250 percent of the lowest Average Manufacturer Price (AMP) in a group of two or more multi-source drugs, although ongoing litigation over CMS' rule implementing that law still blocks the law from taking effect.

Under PPACA, FULs would only apply to products with **three** or more multiple source drugs. Medicaid FULs would be "**no less than** 175 percent of the weighted average (determined on the basis of utilisation) of the most recently reported monthly average manufacturer prices for pharmaceutically and therapeutically equivalent multiple source drug products that are available for purchase by retail commercial pharmacies on a nationwide basis". (Emphasis added.) The FUL changes take effect October 1, 2010.

Revised Definition of Average Manufacturer Price

Currently, AMP generally equals the manufacturer's average price to "wholesalers" (which CMS defines broadly to include virtually any purchaser) for drugs distributed to the "retail pharmacy class of trade" (which CMS also defines very broadly). PPACA revises the AMP definition effective October 1, 2010, in a way that would generally increase AMP.

The new definition of AMP is the manufacturer's average price (1) to "retail community pharmacies" (defined much more narrowly than CMS now defines the "retail pharmacy class of trade"); and (2) to "wholesalers" (defined more narrowly than currently) for drugs distributed to "retail community pharmacies". As a result, PPACA may increase calculated AMPs; given the formula for calculating Medicaid rebates, higher AMPs would generally increase manufacturers' rebate payments. The law has complicated (and sometimes ambiguous) AMP provisions; but it would clearly change AMP calculations in certain cases (e.g., most sales to hospitals, physicians, clinics, and mail-order pharmacies). Currently, sales to "hospital outpatient pharmacies" are included in AMP, but sales to hospitals for inpatient use are excluded. In addition, sales to physicians, clinics, and mail order pharmacies are currently included in AMP. By contrast, PPACA excludes "hospital pharmacies" from AMP. It also excludes sales to physicians, because they fall outside the definition of "retail community pharmacy" (i.e., "an independent pharmacy, a chain pharmacy, a supermarket pharmacy, or a mass merchandiser that is licensed as a pharmacy by the state and that dispenses medications to the general public at retail prices"). In addition, PPACA excludes sales to clinics and mail order pharmacies from AMP.

Increases in Medicaid Rebates

Medicaid rebates for innovator drugs currently include two components: the basic rebate; and the additional rebate. For "rebate periods beginning…after December 31, 2009", PPACA increases the minimum basic rebate to 23.1 percent of AMP, except the minimum basic rebate would only increase to 17.1 percent of AMP for clotting factors and drugs approved by the FDA "exclusively for pediatric indications". PPACA also caps the basic plus additional rebate at 100 percent of AMP. The rebate for generic drugs also increases from 11 percent to 13 percent of AMP.

Additional Rebate for "New Formulations" of Drugs

The Reconciliation Act also amends the additional rebate paragraph of the Medicaid rebate statute, to add the following:

> In the case of a drug that is a line extension of ... [an innovator drug] that is an oral solid dosage form, the rebate obligation with respect to such drug under this section shall be the amount computed under this section for such new drug or, if greater, the product of— (i) the ... [AMP] of the line extension of ... [an innovator drug] that is an oral solid dosage form; (ii) the highest additional rebate (calculated as a percentage of ... [AMP]) under this section for any strength of the original ... [innovator] drug; and (iii) the total number of units of each dosage form and strength of the line extension product paid for under the State [Medicaid] plan in the rebate period ....

The Reconciliation Act defines a "line extension" of a drug as "a new formulation of the drug, such as an extended release formulation".

Medicaid Rebates for Enrolees in Medicaid Managed Care Organizations (MCOs)

PPACA requires drug manufacturers to pay Medicaid rebates on drugs dispensed to Medicaid MCO enrolees. Manufacturers will pay these rebates directly to the States. The law does not specify an effective date for this change, or whether it prohibits Medicaid MCOs from negotiating with manufacturers for rebates above Medicaid's statutory rebates.

III. Expansion of the 340B Drug Discount Program and Compliance Provisions

The 340B Program provides substantial discounts on many pharmaceutical products to more than 13,000 eligible entities such as certain health centres, disproportionate share hospitals and government grantees. PPACA extends 340B eligibility to certain children's hospitals that are excluded from the Medicare prospective payment system, free standing cancer hospitals excluded from the Medicare prospective payment system, critical access hospitals, rural referral centers, and sole community hospitals (in each case provided statutory definitions and requirements are met). The Reconciliation Act exempts orphan drugs from the requirement to sell drugs at or below the 340B ceiling price to these new categories of covered entities. The Reconciliation Act also deleted a PPACA provision expanding the 340B Program to the hospital inpatient setting and deleted a PPACA provision that would have created exceptions to the statutory prohibition against purchasing 340B drugs through group purchasing organisations (GPOs).

PPACA also requires that the government agency that runs the 340B Program, the Health Resources Services Administration (HRSA), make a number of "improvements" designed to enforce manufacturer compliance with 340B Program requirements, which could create significant burdens for drug manufacturers. For example, under the new law, manufacturers will report 340B ceiling prices to HRSA on a quarterly basis. PPACA also requires that HRSA establish a process for inquiring into any identified discrepancies between ceiling prices and manufacturer pricing data and taking, or requiring manufacturers to take, corrective action in response to such discrepancies, including the issuance of refunds. HRSA must also establish procedures for manufacturers to issue refunds in the event there is an overcharge to 340B covered entities. These procedures must include oversight to ensure that refunds are issued accurately and within a reasonable time, "both in routine instances of retroactive adjustment to relevant pricing data and exceptional circumstances such as erroneous or intentional overcharging for covered drugs". HRSA also must develop mechanisms for manufacturers to report "rebates and other discounts provided by manufacturers to other purchasers subsequent to the sale of covered drugs to [340B] covered entities", and issue "appropriate credits and refunds…to covered entities if such discounts or rebates have the effect of lowering the applicable ceiling price for the relevant quarter". The statutory language does not specifically address whether covered entities must issue refunds to manufacturers in the event that incorrect or subsequently adjusted ceiling prices resulted in covered entities being charged a price that was below the correct statutory ceiling price. The law also authorises CMPs if a manufacturer "knowingly and intentionally" charges a covered entity a price that exceeds the 340B ceiling price.

HRSA must also provide for improvements in covered entity compliance, and develop an administrative process to resolve: (1) claims by covered entities that manufacturers have violated the terms of their 340B agreements with HHS; and (2) claims by manufacturers that covered entities have violated the prohibitions on drug diversion or "double discounting".

IV. Selected Medicare Issues

A. MEDICARE PART D

Coverage Gap Phase-Out

The Reconciliation Act provides rebates of US$250 to Medicare Part D enrolees who enter the Part D coverage gap (also known as the "donut hole") in Part D coverage) in 2010. The Reconciliation Act would also gradually phase out the donut hole beginning in 2011, such that by 2020 and beyond, beneficiary cost sharing for both brand name and generic drugs would be reduced to 25 percent (similar to cost sharing during the initial coverage phase). This reduction in cost sharing would be funded in part by the coverage gap discount programme, discussed further below, for brand-name drugs. No such programme is in place for generic drugs.

Coverage Gap Discounts

PPACA requires 50 percent manufacturer discounts from the "negotiated price" (minus a dispensing fee) for all brand-name drugs dispensed to Part D enrolees (except beneficiaries eligible for income-related subsidies) in the Part D coverage gap. The Reconciliation Act provides that the coverage gap discount programme will begin January 1, 2011. The Reconciliation Act also extends some of the more unrealistic deadlines for the programme as created by PPACA. For example, the requirement to establish a Model Agreement between CMS and participating manufacturers that establishes the terms of the discount programme has been pushed back from April 1, 2010 to 180 days after enactment of PPACA. The manufacturer discounts and beneficiary cost sharing will both count toward the out-of-pocket threshold that advances a beneficiary from the coverage gap to catastrophic coverage. The Reconciliation Act slows the growth rate of the catastrophic coverage attachment point between 2014 and 2019.

Coverage gap discounts are expressly excluded from the calculation of Medicaid AMP and Best Price.

B. INDEPENDENT PAYMENT ADVISORY BOARD

PPACA creates an Independent Payment Advisory Board, which is tasked with developing "recommendations" to cut Medicare spending if projected Medicare spending exceeds a specified growth rate. The legislation also specifies the amount by which Board recommendations (when required) must cut Medicare spending. The Board's recommendations will become effective unless: (1) Congress enacts legislation blocking the Board's recommendations from taking effect (or, enacts legislation in 2017 ending the process of Board recommendations and ultimately terminating the Board); or (2) beginning in 2019, certain other limited circumstances apply.

Beginning January 15, 2014 and annually thereafter, the Board must recommend Medicare spending reductions for the upcoming year whenever the CMS Chief Actuary projects that Medicare's spending per beneficiary for the upcoming year would grow faster than the average of the growth rates of the consumer price index for medical services (CPI-M) and the overall CPI for all urban consumers. The Board must submit its proposals concurrently to the President and Congress. If Congress does not enact legislation within six months of receiving the recommendations (i.e., by August 15), then HHS must implement the Board's recommendations, "[n]otwithstanding any other provision of law". (A limited additional exception also applies starting with the Board recommendations for 2019.)

The Board is subject to certain constraints. It may not make any recommendations that "ration healthcare, raise revenues or Medicare beneficiary premiums [under Part A or B], increase Medicare beneficiary cost-sharing, or otherwise restrict benefits or modify eligibility criteria". Additionally, for years before 2020, the Board cannot recommend cuts in Medicare payments to certain providers and suppliers (i.e., those whose payment rates meet certain criteria regarding their annual payment updates). The Congressional Budget Office (CBO) has identified hospitals and hospices as meeting the criteria for this pre-2020 exemption.

However, the legislation expressly permits the Board to recommend certain types of reductions in Medicare payments under Parts C and D, such as reductions in direct subsidy payments to Medicare Advantage and prescription drug plans related to administrative expenses or denying high bids or removing high bids for Part D coverage from the calculation of the national average monthly bid amount.

Beginning January 15, 2014, the Board may also develop and submit to Congress "advisory reports" on other matters related to the Medicare programme. Not later than July 1, 2014, and annually thereafter, the Board must also publish a public report concerning system-wide healthcare costs, patient access to care, utilisation, and quality of care. By January 15, 2015, and at least every two years thereafter, the Board must also submit to Congress and the President advisory recommendations to slow the growth in non-federal healthcare expenditures.

V. Biosimilars

PPACA creates a new framework for FDA review and approval of biosimilar and interchangeable versions of innovator biologic products, new exclusivity protections for such products, and a process for resolution of patent disputes between biosimilar applicants and innovators.

Definitions

An applicant may submit information to FDA demonstrating that its proposed product is either biosimilar to, or interchangeable with, a reference innovator biologic product. PPACA defines "biosimilar" to mean "that the biological product is highly similar to the reference product, notwithstanding minor differences in clinically inactive components" and "there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product". An "interchangeable" product is one that: (1) is biosimilar to the reference product; (2) can be expected to produce the same clinical result as the reference product in any given patient; and (3) for a biological product that is administered more than once to an individual, "the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch". If FDA determines that a product is interchangeable, that product "may be substituted for the reference product without the intervention of the healthcare provider who prescribed the reference product".

Application Requirements

Key to a successful biosimilar application under PPACA are the requirements for demonstrating similarity to the reference product. A biosimilar applicant must include information demonstrating that: (1) "the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components"; (2) the products "utilize the same mechanism or mechanisms of action for the condition or conditions of use prescribed, recommended, or suggested in the proposed labeling"; (3) FDA has previously approved, for the reference product, the condition(s) of use prescribed, recommended, or suggested in the proposed labelling for the biosimilar product; and (4) the route of administration, dosage form, and strength of the biosimilar product are the same as those of the reference product.

Guidance Documents

PPACA does not require FDA to issue guidance documents, although it does require FDA to establish a process for the public to provide input regarding priorities for issuing guidance. The issuance or non-issuance of guidance does not preclude the review of, or action on, a biosimilar application under either bill. If FDA chooses to issue product class-specific guidance, the guidance must include a description of: (1) the criteria FDA will use to determine whether a biological product is highly similar to a reference product in that product class; and (2) the criteria, if available, that FDA will use to determine whether a product is interchangeable with the reference product. FDA may also issue guidance indicating that, as of the date of such guidance, science and experience are insufficient to allow approval of a biosimilar product in a particular product class, but may subsequently amend or reverse such guidance.

Exclusivity

PPACA provides that no application for a biosimilar product may be approved until 12 years after the date on which the reference product was first licensed, and no application may be submitted until four years after the date of first licensure. Products deemed interchangeable (as opposed to biosimilar) are also eligible for exclusivity. Under PPACA, FDA may not approve a second interchangeable product until the earlier of: (1) one year after the first commercial marketing of the first interchangeable product; (2) 18 months after either a final court decision on all patents under suit, or the dismissal with or without prejudice of actions brought by the reference product sponsor against the biosimilar applicant; (3) 42 months after approval of the first interchangeable product if a patent suit is still ongoing within that 42-month period; or (4) 18 months after approval of the first interchangeable product if the reference product sponsor did not sue the applicant.

Patent Disputes

Within 20 days of receipt for review of the biosimilar application by FDA, the biosimilar applicant must send a copy of the application to the innovator. Within 60 days of receipt of the biosimilar application, the innovator must send the biosimilar applicant a listing of patents believed to be infringed if the biosimilar were to be marketed. Within 60 days of receipt of the patent list, the biosimilar applicant must provide a notice of patent certification regarding non-marketing, non-infringement, invalidity and/or unenforceability. Within 60 days of receipt of the patent certification, the innovator must respond with a counter-position and response regarding infringement, validity, and/or enforceability.

After exchanging these statements, the parties shall engage in good faith negotiations to agree on a list of patents to be asserted. If within 15 days of the start of negotiations the parties do not agree on the list of patents, the parties will exchange lists of patents each believes should be asserted. The biosimilar applicant will first notify the innovator of the number of patents it will list, and then the patents lists will be simultaneously exchanged within five days. The innovator's list may not be longer than the biosimilar applicant's list, unless the biosimilar applicant does not list any patents, in which case the innovator may list one patent. After 15 days, if the parties have not reached an agreement, the innovator must file suit within 30 days of the exchange of patent lists for all listed patents. If the parties have reached an agreement, then the innovator must file suit within 30 days of agreement on the asserted patents.

Medicare Part B Payment for Biosimilars

Under PPACA, biosimilar and interchangeable products would be subject to the same payment methodology for Medicare Part B payment purposes. The payment amount for a biosimilar product under PPACA would be based on its own average sales price (ASP) (or a volume weighted ASP of all the product's national drug codes if it has more than one), plus six percent of the ASP of the reference product as calculated for a single source biologic product. The reference biologic continues to be paid at 106 percent of its own ASP.

VI. Prescription Drugs Facts Box

PPACA requires FDA to determine whether adding quantitative summaries of the benefits and risks of prescription drugs in a standardised format, such as a table or drug facts box, to promotional labelling or print advertising would improve healthcare decision making by doctors, patients, and consumers. If FDA determines that adding quantitative summaries to labelling and advertising would improve healthcare decision making, it has three years from submission of the report to promulgate proposed regulations.

VII. Generic Drug Labelling

PPACA amends section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) to provide that a drug which is the subject of an Abbreviated New Drug Application (ANDA) will be eligible for approval, and will not be considered misbranded, where the ANDA is: (1) otherwise eligible for approval but for the expiration of a patent, an exclusivity period, or of a delay in approval due to an action brought for infringement of the patent; and (2) a revision to the labelling of the listed drug has been approved by Secretary within 60 days of such expiration. This provision is not applicable where the above-referenced labelling revision includes a change to the "Warnings" section of the listed drug's labelling. In addition, the sponsor of the ANDA must agree to submit revised labelling of the drug not later than 60 days after notification by the Secretary of any required changes. Finally, the Secretary has discretion to find that this provision is not applicable in certain situations, specifically where the Secretary determines that the continued presence in interstate commerce of labelling of the listed drug (prior to revision) adversely impacts the safe use of the drug.

VIII. Physician Payment Sunshine/Transparency

PPACA requires "applicable manufacturers" of "covered" drugs, devices, biologicals, or medical supplies that provide payments (or other transfers of value) to a physician or teaching hospital to submit information about those payments to the Secretary of HHS beginning March 31, 2013, and annually thereafter. PPACA defines an "applicable manufacturer" as a manufacturer of a covered drug, device, biological, or medical supply, "which is operating in the United States, or in a territory, possession, or commonwealth of the United States", and defines covered drugs, devices, biologicals, or medical supplies as those products for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program.

A "payment or other transfer of value" subject to reporting is defined as a transfer of anything of value, unless the transfer is excluded; transfers of value do not include a transfer made indirectly to a covered recipient (a physician or teaching hospital) through a third party where the manufacturer is unaware of the identity of the covered recipient. The required "transparency" reports must include the name and address of the physician/recipient (and, if a physician, the specialty and national provider identifier number); the amount, date and a description of the nature of the payment or transfer of value (e.g., cash or cash equivalent, in-kind items or services, stock, stock option, ownership interest, dividend, profit, or other); the identity of the drug, device, or medical supply to which the payment relates (if related to the promotion of a particular item); and other information. Additionally, beginning March 31, 2013, and annually thereafter, manufacturers and GPOs must submit information regarding certain ownership or investment interests held by a physician or a physician's family member in the manufacturer or GPO. PPACA provides a number of exclusions from the payments or transfers that must be reported.

HHS must make the information it receives publicly available on the internet, in a searchable format. Failure by a covered manufacturer to report in a timely manner can subject the manufacturer to civil money penalties. PPACA preempts any state law or regulation requiring applicable manufacturers to disclose "the type of" physician and teaching hospital payment information that PPACA requires to be reported, effective January 1, 2012; however, PPACA does not preempt state laws or regulations requiring the reporting of other types of information, including most information within PPACA's reporting exclusions.

PPACA provides that not later than October 1, 2011, the Secretary of HHS shall "establish procedures" for the submission and posting to the internet of payment information, and provide additional definitions of terms.

IX. Annual Fees on Pharmaceutical Manufacturers and Importers

Beginning in 2011, PPACA, as amended by the Reconciliation Act, will impose annual fees on domestic and foreign "covered entity" drug manufacturers or importers with gross receipts above US$5 million from "branded prescription drug sales". Branded prescription drugs are defined as drugs for which a new drug application was submitted to FDA and any biologic licensed under section 351(a) of the Public Health Service Act (PHSA). Fees will not be assessed on sales of certain orphan drugs (i.e., drugs or biologicals for which a credit was allowed under section 45C of the Internal Revenue Code, but not after the date FDA approves the drug for any indication other than the orphan indication for which this tax credit was allowed).

The aggregate annual fee will be equal to US$2.5 billion in 2011, gradually increasing to US$4.1 billion in 2018 and then decreasing again to US$2.8 billion for 2019 and thereafter. The US Department of the Treasury will apportion the aggregate fee among covered entities each year based on each covered entity's relative share of "branded prescription drug sales" in the preceding calendar year. Only sales made to or "pursuant to coverage under" Medicare Parts D and B, Medicaid, US Department of Veterans Affairs procurements, US Department of Defense procurements, and the TRICARE retail pharmacy programme will count as sales for purposes of this calculation; sales are generally considered net of rebates that the manufacturers paid to these programmes. Formulas to compute the sales figures for each programme are specified in the law and will use information reported by the respective departments to Treasury. A graduated scale will be used in determining a covered entity's relative share of the aggregate fee, with a covered entity's first US$400 million in sales not fully counting in the calculation. This fee will not be deductible for US income tax purposes.

X. Comparative Effectiveness Research

PPACA defines comparative clinical effectiveness research (CER) as "research evaluating and comparing health outcomes and the clinical effectiveness, risks, and benefits of 2 or more medical treatments, services, and items". It creates a private, nonprofit corporation called the "Patient Centered Outcomes Research Institute" to "assist patients, clinicians, purchasers, and policy-makers in making informed health decisions by advancing the quality and relevance of evidence concerning the manner in which diseases, disorders, and other health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored, and managed through research and evidence synthesis". The Institute will be run by a 19-member Board of Directors, appointed by the US Government Accountability Office (GAO), with scientific and clinical expertise; seven seats are reserved for representatives of physicians and providers, including four members representing physicians—one of whom is a surgeon—and three for representatives of pharmaceutical, device, or diagnostics manufacturers.

The Institute must identify national priorities; establish a research agenda, methodological standards for research, and a peer review process; and sponsor CER. Research must be designed to take into account potential differences across subpopulations. The Institute would not be permitted to mandate coverage, reimbursement, or other policies for any public or private payer.

PPACA also creates the Office of Communication and Knowledge Transfer within the Agency for Healthcare Research and Quality, which will work with the National Institutes of Health (NIH) to disseminate research findings from the Institute. The Office's activities are not to be construed as mandates, guidelines, or recommendations for payment, coverage, or treatment.

PPACA explicitly addresses the use of CER in Medicare coverage decision-making. CER research does not supersede any national or local coverage determinations by Medicare. CER research can only be used in making Medicare coverage determinations if the process of making such determinations is iterative and open for public comment and the CER research is not the only basis for denying coverage.

XI. Health Insurance Reforms

PPACA includes a number of provisions that expand health insurance coverage to the uninsured. The Act contains numerous insurance market reforms, including standards and limitations for health insurance policies, and restrictions on the ability of insurers to limit benefits or deny coverage. PPACA also allows unmarried dependants up to age 26 to remain on their parents' health insurance.

PPACA expands insurance coverage through an individual mandate and by penalising certain employers that do not provide coverage; by providing tax credits to help individuals and employers purchase insurance coverage; and by expanding Medicaid eligibility, beginning in 2014, to include all non-elderly Americans with incomes at or below 133 percent of the federal poverty level (FPL). By 2014, each state must establish an American Health Benefit Exchange (or face strong penalties if they do not). To participate in an Exchange, an insurer would need to meet numerous quality and actuarial standards. The law requires the federal Office of Personnel Management (OPM) to contract with health insurers to offer at least two multi-state insurance plans through Exchanges in each state. PPACA does not include a government-run "public option".

Most of the above provisions are subject to various effective dates, and HHS, CMS, HRSA, FDA, and other agencies are now beginning to issue regulations and guidance implementing a number of provisions of the health reform laws.

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The EU lifesciences team, headed by Ian Dodds-Smith and based in London, has unrivalled experience in advising on every aspect of the regulation of medicines, devices, cosmetics, foods and borderline products. The team includes a number of lawyers with scientific qualifications, including three physicians. It is regularly ranked as the leading firm providing regulatory advice and specialist litigation services to the lifesciences sector.

The team of 15 lawyers specialising in this field in London is complemented by Arnold & Porter's highly regarded pharmaceutical and medical devices regulatory practice headed by Dan Kracov in Washington DC, with a team of 20 lawyers.

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