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ADVISORY

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UPDATE: HEALTHCARE REFORM: A POCKET GUIDE FOR PHARMACEUTICAL AND DEVICE MANUFACTURERS

On March 30, 2010, President Obama signed into law HR 4872, the Health Care and Education Reconciliation Act of 2010 (the Reconciliation Act).[1] The Reconciliation Act supplements and "fixes" several provisions of the Patient Protection and Affordable Care Act (PPACA),[2] 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 and device 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 program requirements; revamp the Medicare, Medicaid, and Section 340B programs 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 and device manufacturers of payments to healthcare professionals.

This advisory summarizes the major provisions of PPACA and the Reconciliation Act that are of particular interest to pharmaceutical and medical device manufacturers. Several key requirements are scheduled to take effect very quickly (or, in fact, potentially retroactively back to January 1, 2010). To help the reader keep track of these deadlines, the advisory lists effective dates for the provisions summarized below in the "Effective Dates" section.

I. HEALTHCARE FRAUD AND ABUSE (PPACA §§ 6402, 6501-6502, 10104, 10606; RECONCILIATION §§ 1301-1304)

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

1 *Available at* http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:h4872enr.txt.pdf.

2 *Available at* http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:h3590enr.txt.pdf.

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US Healthcare Reform

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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, PPACA weakens the Anti-Kickback Statute's intent requirement. 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. This dilution in the intent requirement for an anti-kickback violation could be problematic, because the Anti-Kickback Statute has very broad language that—as Congress has previously recognized—may sweep in healthcare practices that are innocuous or even socially beneficial. A reduced intent requirement, which will override the higher intent requirement adopted by certain courts,[3] 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.[4] 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 Congress enacted last year in the Fraud Enforcement and Recovery Act.[5]

First, PPACA narrows the types of information that could trigger the public disclosure bar. Under the new law, a whistleblower suit cannot be barred unless "substantially the same allegations or transactions [alleged in the suit] were publicly disclosed" in: (1) "a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party"; (2) "a congressional, [GAO], or other Federal report, hearing, audit, or investigation"; or (3) "from the news media." Before PPACA, the public disclosure bar applied to information disclosed "in a criminal, civil, or administrative hearing, in a congressional, administrative, or [GAO] report, hearing, audit, or investigation, or from the news media."

Second, PPACA broadens the definition of "original source." Previously, an original source needed direct and independent knowledge of the information on which the allegations were based and must have voluntarily provided that information to the government before filing

3 *Compare Hanlester Network* v. *Shalala*, 51 F.3d 1390, 1400 (9th Cir. 1995) (construing "knowingly and willfully" in the Anti-Kickback Statute as requiring appellants to "(1) know that [the Statute] prohibits offering or paying remuneration to induce referrals, and (2) engage in prohibited conduct with the specific intent to disobey the law"), with *United States* v. *Starks*, 157 F.3d 833, 838-39 (11th Cir. 1998) (rejecting the argument that "willfully" requires knowledge that one is violating the specific anti-kickback rule); *United States* v. *Davis*, 132 F.3d 1092, 1094 (5th Cir.1998) (reasoning that the Anti-Kickback Statute at most "requires knowledge only that the conduct in question was unlawful, and not necessarily knowledge of which particular statute makes the conduct unlawful"); *United States* v. *Jain*, 93 F.3d 436, 440 (8th Cir. 1997) (upholding jury instructions that defined "willfully" in the Anti-Kickback Statute to mean "unjustifiably and wrongfully, known to be such by the defendant").

4 *See, e.g., United States ex rel. Kosenske* v. *Carlisle HMA, Inc.*, 554 F.3d 88, 94 (3d Cir. 2009) (stating that falsely certifying compliance with the Anti-Kickback Statute in connection with a claim submitted to a federally funded insurance program is actionable under the FCA); *United States ex rel. Barrett* v. *Columbia/HCA Healthcare*, 251 F. Supp.2d 28, 32-34 (D.D.C. 2003) (applying implied certification theory to recognize potential FCA liability based upon alleged violation of the Anti-Kickback Statute); *United States ex rel. Thompson* v. *Columbia/HCA Healthcare*, 125 F.3d 899, 902 (5th Cir. 1997) (holding that defendants submitted false claims by falsely certifying that services were rendered in compliance with the Anti-Kickback Statute).

5 *See* Arnold & Porter advisory, "Fraud Enforcement Recovery Act Increases the Scope of False Claims Act Liability, June, 2009, *available at* http://www.arnoldporter.com/resources/documents/Advisory_FraudEnforcement&RecoveryActIncreasesTheScope_060509.pdf.

an FCA suit based on that information. PPACA expands the definition of "original source" to include any individual who has knowledge that is "independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the government" before filing the suit.

Third, PPACA also provides that if the whistleblower suit is based on publicly disclosed information (as described above) and the whistleblower is **not** an "original source," then "the court shall dismiss [the suit], **unless opposed by the Government**." (Emphasis added.) In contrast, prior to PPACA, the FCA mandated that "no court shall have jurisdiction over" a whistleblower suit based on publicly-disclosed information unless the whistleblower is an original source. PPACA therefore seems to allow whistleblower suits that would otherwise be barred if the government opposes dismissal of the suit. How this provision will apply in practice is subject to judicial interpretation.

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 willfully execute, or attempt to execute, a scheme or artifice to defraud any healthcare benefit program or to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property of a health care benefit program 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 willful 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 Programs

PPACA contains provisions clarifying or amending the current law regarding exclusion of entities from participation in federal healthcare programs for violations of healthcare fraud statutes. PPACA requires States to terminate individuals or entities from their State Medicaid programs if they have been terminated from Medicare or another State's Medicaid program. State Medicaid programs 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 program audits and investigations.

Sentencing Guidelines

PPACA amends the sentencing guidelines applicable to persons convicted of federal healthcare offenses involving federal healthcare programs. The US Sentencing Commission will be required to review the federal sentencing guidelines and policy statements in this area and, where appropriate, provide increased penalties. In addition, the law specifically directs the Commission to increase the offense levels for defendants convicted of a federal healthcare offense related to a government healthcare program, by 20 to 50 percent for crimes that involve more than US$1 million in losses.

PPACA also provides that, in applying the sentencing guidelines, the aggregate dollar amount of fraudulent bills submitted to a government healthcare program shall constitute prima facie evidence of the amount of the "intended loss" by the defendant.

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) authorizing 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 authorizes 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 program. 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' enrollment in or transfer between plans, employment and contracting practices, marketing violations, or the misrepresentation or falsification of information.

Health Care Fraud and Abuse Control Account

PPACA increases funding for the Health Care Fraud and Abuse Control (HCFAC) Account for fiscal years 2011 through 2020 by US$10 million annually. The Reconciliation Act allocates an additional US$250 million to the account between 2011 and 2016.

II. MEDICAID DRUG REIMBURSEMENT AND REBATES

Federal Upper Limits (PPACA § 2503)

Under current law, the Centers for Medicare & Medicaid Services (CMS) must establish Federal Upper Limits (FULs) to cap Medicaid programs' pharmacy reimbursements for certain multi-source drugs.[6] (Federal matching funds are generally unavailable to a State Medicaid program to the extent that the program'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 utilization) 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 (PPACA § 2503)

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).[7] 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.[8]

The law has complicated (and sometimes ambiguous) AMP provisions; but it would clearly change AMP calculations in certain cases (e.g., most sales to

6 42 U.S.C. § 1396r-8(e).

7 42 U.S.C. § 1396r-8(k)(1); 42 C.F.R. § 447.504(e), (f).

8 Prior to PPACA, Medicaid rebates for innovator drugs equaled the greater of AMP minus Best Price, or 15.1 percent of AMP, plus an additional rebate. Prior to PPACA, non-innovator drugs' rebates equaled 11 percent of AMP. As discussed below, both of these minimum rebate percentages change under PPACA.

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.[9] 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 (PPACA § 2501, Reconciliation § 1206)

Medicaid rebates for innovator drugs currently include two components: the basic rebate and the additional rebate. Prior to PPACA, the basic rebate for innovator drugs was AMP minus Best Price, or 15.1 percent of AMP, whichever was greater. Thus, the minimum basic rebate for innovator drugs was 15.1 percent of AMP.[10]

Increase in the Basic 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.

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."

PPACA included provisions on new formulations that were replaced by the provisions of the Reconciliation Act quoted above. PPACA provides that its new formulation changes would have taken effect for "drugs that are paid for by a State after December 31, 2009," and the Reconciliation Act provides that its amendments to the additional rebate paragraph "take effect as if included in the enactment of [PPACA]."

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

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

III. THE 340B DRUG DISCOUNT PROGRAM

A. EXPANSION OF THE 340B PROGRAM (PPACA § 7101, RECONCILIATION § 2302)

PPACA extends 340B eligibility to certain children's hospitals that are excluded from the Medicare prospective payment system, free standing cancer hospitals excluded

9 42 C.F.R. § 447.504(g)(3), (h)(4). Currently, if the manufacturer cannot determine whether a sale to a hospital is for outpatient or inpatient use, the sale is excluded from AMP. *Id.*

10 42 U.S.C. § 1396r-8(c)(1)(B)(i).

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 organizations (GPOs).

PPACA provides, "(1) IN GENERAL.—The amendments made by this section [7101 expanding 340 eligibility] and section 7102 [on 340B program integrity] shall take effect on January 1, 2010, and shall apply to drugs purchased on or after January 1, 2010." However, the new categories of covered entities would need to register with the Health Resources and Services Administration (HRSA) as covered entities and appear in the covered entity database before they could access 340B pricing.

B. 340B PROGRAM INTEGRITY PROVISIONS (PPACA § 7102)

Manufacturer Compliance

PPACA requires HRSA to make a number of "improvements" designed to enforce manufacturer compliance with 340B program requirements. Given the significant burdens these changes could create for drug manufacturers, it will be important for manufacturers to participate in any notice and comment procedures implementing these new requirements.

Under PPACA, the Pharmaceutical Pricing Agreement (PPA) between a manufacturer and HHS must be amended to require that the manufacturer provide HRSA with quarterly reports of the ceiling price for each covered outpatient drug subject to the agreement. The PPA must also require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the ceiling price if such drug is made available to any other purchaser at any price.

The law also requires HRSA to establish a process to verify the accuracy of 340B ceiling prices calculated by manufacturers and charged to covered entities. As part of this process, HRSA must publish guidance and/or regulations on the "standards and methodology" for calculating 340B ceiling prices.

HRSA must also 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 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 authorizes CMPs if a manufacturer "knowingly and intentionally" charges a covered entity a price that exceeds the 340B ceiling price, not to exceed US$5,000 for each instance of overcharging a covered entity that may have occurred.

Covered Entity Compliance

PPACA also requires that HRSA provide for improvements in covered entities' compliance in order to prevent diversion and duplicate discounts. These improvements must include developing procedures requiring covered

entities to update their information in the HRSA covered entity database, and a system for HRSA to verify the accuracy of this information.

HRSA must also develop more detailed guidance describing the methodologies that covered entities may use for billing 340B drugs to State Medicaid agencies in a manner that avoids duplicate discounts.

PPACA authorizes limited additional sanctions for covered entities that violate the statutory prohibition against diverting 340B drugs to individuals who are not patients of the covered entity. The 340B statute provides that a covered entity that engages in diversion is liable to the manufacturer for the amount equal to the reduction in the price of the diverted drug. Under PPACA, where a covered entity "knowingly and intentionally" violates the prohibition against diversion, the entity shall also be required to pay the manufacturer a monetary penalty in the form of interest on the amount due. If HRSA finds that the violation was "systematic and egregious," the covered entity may also be removed from the 340B program for a reasonable period of time determined by HRSA.

Administrative Dispute Resolution Process

HRSA must develop an administrative process to resolve: (1) claims by covered entities that manufacturers have violated the terms of their 340B agreements with HRSA; and (2) claims by manufacturers that covered entities have violated the prohibitions on diversion or double discounting.

This process must include procedures by which a covered entity may discover and obtain relevant information from manufacturers and third parties. The process must also include a requirement that manufacturers conduct an audit of a covered entity as a prerequisite to initiating dispute resolution proceedings.

The dispute resolution process must permit multiple covered entities jointly to assert claims of overcharges by the same manufacturer, and it must permit such claims to be asserted on behalf of covered entities by representative associations or organizations. The process must also allow the dispute resolution body to consolidate, at the request of a manufacturer or manufacturers, claims brought by more than one manufacturer against the same covered entity, if in the judgment of the body consolidation is appropriate and consistent with the goals of fairness and economy of resources.

IV. SELECTED MEDICARE ISSUES

A. MEDICARE PART D

Coverage Gap Phase-Out (Reconciliation § 1101)

The Reconciliation Act provides rebates of US$250 to Medicare Part D enrollees who enter the Part D coverage gap (the donut hole) 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 program, discussed further below, for brand-name drugs. No such program is in place for generic drugs. The Reconciliation Act also slows the growth rate of the catastrophic coverage attachment point between 2014 and 2019.

Coverage Gap Discounts (PPACA § 3301, Reconciliation § 1101)

PPACA requires 50 percent manufacturer discounts from the "negotiated price" (minus a dispensing fee) for all brand-name drugs dispensed to Part D enrollees (except beneficiaries eligible for income-related subsidies) in the Part D coverage gap. The Reconciliation Act provides that the coverage gap discount program will begin January 1, 2011. The Reconciliation Act also extends some of the more unrealistic deadlines for the program 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 program 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.

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

Part D Protected Classes (PPACA § 3307)

PPACA essentially repeals the provisions in section 176 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) on Part D protected classes and substitutes a new protected classes provision. The new provision takes effect as of plan year 2011.

PPACA directs CMS to issue regulations that establish criteria for identifying protected classes. Through regulations, CMS could also create exceptions to the general rule that all drugs in a protected class must be included on Part D formularies. Unlike MIPPA's protected classes provision, the new law gives CMS no guidance concerning the criteria it should adopt for identifying protected classes (nor does the law suggest when exceptions might be appropriate). However, until CMS issues regulations establishing criteria to identify protected classes, protection must be maintained for the existing six protected classes—anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants for the treatment of transplant rejection.

B. INDEPENDENT PAYMENT ADVISORY BOARD (PPACA §§ 3403, 10320)

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."[11] 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 program. These reports would be genuinely advisory, and could include recommendations to revise payments to Medicare providers and suppliers that are exempt from the Board's

11 Furthermore, a separate provision of PPACA states that "[n]othing in the provisions of, or amendments made by, this Act shall result in a reduction of guaranteed benefits under [Medicare]." PPACA § 3601(a).

"non-advisory" recommendations until 2020. 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, utilization, 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.

IV. BIOSIMILARS (PPACA §§ 7001-7003, 3139)

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 labeling 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 (PPACA § 3139)

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 6 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 § 3507)

PPACA requires FDA to determine whether adding quantitative summaries of the benefits and risks of prescription drugs in a standardized format, such as a table or drug facts box, to promotional labeling or print advertising would improve healthcare decision making by doctors, patients, and consumers. In making that decision, FDA must review all available scientific evidence and research, and consult with drug manufacturers, doctors, patients, consumers, representatives of racial and ethnic minorities, and other experts. FDA must submit a report outlining its determination, as well as its reasoning and analysis, to Congress within one year of enactment of the statute. If FDA determines that adding quantitative summaries to labeling and advertising would improve healthcare decision making, it has three years from submission of the report to promulgate proposed regulations.

VII. GENERIC DRUG LABELING (PPACA § 10609)

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 labeling of the listed drug has been approved by Secretary within 60 days of such expiration. This provision is not applicable where the above-referenced labeling revision includes a change to the "Warnings" section of the listed drug's labeling. In addition, the sponsor of the ANDA must agree to submit revised labeling 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 labeling of the listed drug (prior to revision) adversely impacts the safe use of the drug.

VIII. PHYSICIAN PAYMENT SUNSHINE/ TRANSPARENCY (PPACA §§ 6002, 6004)

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, including: (1) transfers of value less than US$10, unless the aggregate amount exceeds US$100 during the calendar year; (2) educational materials that directly benefit patients or are intended for patient use; (3) the loan of a covered device for less than 90 days for evaluation by the covered recipient; (4) items or services provided under a contractual warranty; (5) a transfer of anything of value to a covered recipient when the covered recipient is a patient and not acting in a professional capacity; (6) discounts (including rebates); (7) in-kind items used for the provision of charity care; (8) profit distribution from, or ownership or investment interest in, a publicly traded security or mutual fund; (9) payments for the provision of healthcare to employees under a self-insured plan; (10) a transfer of value to a licensed non-medical professional if the transfer is payment solely for non-medical professional services; and (11) a transfer of value to a physician if the transfer is payment solely for the services of the covered recipient with respect to a civil or criminal action or an administrative proceeding. Although product samples are also exempted from the transparency report, not later than April 1 of each year (beginning in 2012), drug manufacturers (and authorized distributors of record) will report to HHS prescription drug samples distributed to practitioners separately from the transparency report.

HHS must make the information it receives publicly available on the internet, in a searchable format. Failure by a covered manufacturer to meet reporting requirements could subject it to civil money penalties ranging from

US$1,000 to US$10,000 per payment, transfer of value, or investment interest not disclosed (up to a maximum of US$150,000 per annual submission). Penalties for a knowing failure to report in a timely manner range from US$10,000 to US$100,000 per payment not reported, not to exceed US$1 million per annual report. For purposes of this provision, the term "knowing" is defined consistent with the False Claims Act to include actual knowledge of the falsity of the information, deliberate ignorance of the truth or the falsity of the information, or reckless disregard of the truth or falsity of the information. No specific intent to defraud is required.

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 MEDICAL DEVICE AND PHARMACEUTICAL MANUFACTURERS AND IMPORTERS

Annual Fee on Pharmaceutical Manufacturers and Importers (PPACA § 9008, Reconciliation § 1404)

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), which includes reference biologics but excludes follow-on biologics. (Follow-on biologics will be licensed under section 351(k) of the 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 program will count as sales for purposes of this calculation; sales are generally considered net of rebates that the manufacturers paid to these programs. Formulas to compute the sales figures for each program 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.

Tax on Medical Device Sales (Reconciliation § 1405)

The Reconciliation Act replaces PPACA's medical device manufacturer fees with a new tax on sales of medical devices. The tax will be levied at the rate of 2.3 percent on sales starting January 1, 2013. Excluded from taxation are eyeglasses, contact lenses, hearing aids, and any other device the Secretary of the Treasury determines is generally purchased "by the general public at retail for individual use." Class I devices are not automatically exempt.

X. COMPARATIVE EFFECTIVENESS RESEARCH (PPACA §§ 6301-6302, 10602)

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. In addition, PPACA prohibits the Secretary from considering the extension of life of the elderly, disabled or terminally ill to be of lesser value than extension of life for other populations and from discouraging choice of treatment options based on how an individual values the trade-off between extending life and the risk of disability. However, this provision would not: (1) "limit the application of differential copayments under [Medicare] based on factors such as cost or type of service"; or (2) prevent HHS from using CER findings "in determining coverage, reimbursement, or incentive programs under [Medicare] based upon comparison of the difference in the effectiveness of alternative health care treatments in extending an individual's life due to that individual's age, disability, or terminal illness." The Institute is not allowed to use a measure of dollar-per-quality-adjusted-life-year in determining cost-effectiveness or making its recommendations.

PPACA creates a new trust fund to support CER activities that is initially funded by appropriated money (US$210 million for 2010-12). Beginning in 2013, funds will be available from the Medicare trust funds and fees from insured and self-insured health plans based on the average number of covered lives.

XI. HEALTH INSURANCE REFORMS (PPACA TITLE I, II, X, RECONCILIATION)

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 penalizing 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."

Overall, the CBO estimates that the reforms introduced by PPACA and the Reconciliation Act will reduce the number of nonelderly people who are uninsured by about 32 million.

XII. EFFECTIVE DATES

The PPACA and Reconciliation Act provisions discussed in this advisory take effect on a variety of dates potentially preceding, coinciding with, or following the enactment of these laws. Selected relevant effective dates are as follows:

- **Coverage Gap Reductions (Reconciliation § 1101):** the US$250 coverage gap rebate is in place for plan year 2010. The phase out of the donut hole will begin in 2011.
- **Coverage Gap Discounts (Reconciliation § 1101):** effective for costs incurred on or after January 1, 2011.
- **Part D Protected Classes (PPACA § 3307(b)):** effective for plan year 2011 and subsequent plan years.
- **Federal Upper Limit Amendments (PPACA § 2503(d)):** effective the first day of the first calendar year quarter that begins at least 180 days after the date of enactment of PPACA (i.e., the revised FUL provision is effective October 1, 2010).
- **Revised Definition of Average Manufacturer Price (PPACA § 2503(d)):** effective the first day of the first calendar year quarter that begins at least 180 days after the date of enactment of PPACA (i.e., the revised AMP definition is effective October 1, 2010).
- **Medicaid Basic Rebate Increase (PPACA § 2501(a)):** effective "for rebate periods beginning…after December 31, 2009."
- **Medicaid Rebate For "New Formulations" of Drugs (PPACA § 2501(d); Reconciliation Act § 1206(b)):** PPACA provides that its new formulations provisions would have taken effect for "drugs that are paid for by a State after December 31, 2009," and the Reconciliation Act provides that its new formulations provisions "take effect as if included in the enactment of [PPACA]."
- **Medicaid Rebates for Enrollees in Medicaid Managed Care Organizations (PPACA § 2501(c)):** no effective date specified.
- **340B New Covered Entities (PPACA § 7101(e)):** "IN GENERAL.—The amendments made by this section [7101—adding new categories of 340B covered entities] and section 7102 [on 340B program integrity] shall take effect on January 1, 2010, and shall apply to drugs purchased on or after January 1, 2010." However, the new categories of covered entities would need to register with HRSA as covered entities and appear in the covered entity database before they could access 340B pricing.
- **340B Program Integrity Provisions (PPACA § 7101(e)):** the same effective date provision listed immediately above applies; however, HRSA would need to issue regulations and/or guidance to implement the program integrity provisions.
- **Payment for Biosimilars (PPACA § 3139(b)):** effective the first day of the second calendar quarter after enactment of legislation providing for a biosimilar pathway (as determined by the HHS Secretary).
- **Tax on Sales of Medical Devices (Reconciliation § 4191(c)):** effective for medical device sales after December 31, 2012.Annual Fee on Pharmaceutical Manufacturers (Reconciliation § 1404): effective January 1, 2011 (for branded prescription drug sales after December 31, 2009).

XIII. NEXT STEPS

Now that PPACA and the Reconciliation Act have been signed into law, HHS, CMS, HRSA, FDA, and other agencies will be issuing regulations and guidance implementing a number of provisions of the health reform laws. Arnold & Porter LLP will continue to monitor the action in the Executive Branch as implementation efforts commence, and we will keep our clients and friends

apprised of any major developments. Additional information on this topic is also available on our healthcare reform website.[12]

We hope that you had found this advisory useful. If you have additional questions, please contact your Arnold & Porter attorney or:

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