Reed Smith Health Care Reform Review

The Patient Protection and Affordable Care Act, as Amended by the Reconciliation Act:

Analysis and Implications for Drug, Device and Biotech Manufacturers

June 2010

ReedSmith

The business of relationships.℠

Table of Contents

Introduction

In April 2010, Reed Smith provided an extensive analysis of the recently enacted health reform legislation, H.R. 3590, the Patient Protection and Affordable Care Act (PPACA),[1] as amended by H.R. 4872, the Health Care and Education Reconciliation Act of 2010 (Reconciliation Act)[2]. Together, these sweeping measures expand access to health insurance (including subsidies, mandates, and market reforms); reduce health care spending (particularly in the Medicare program); expand federal fraud and abuse authorities and transparency requirements; impose new taxes and fees on health industry sectors; and institute a variety of other health policy reforms.

In this analysis, we concentrate on those provisions in the new law that will affect life sciences entities: pharmaceutical, device, and biologics manufacturers. These include significant revisions to the Medicaid drug rebate program and the Medicare Part D prescription drug program; an expansion of the Public Health Service section 340B drug discount program; the imposition of substantial new industry fees and excise taxes; creation of an abbreviated approval pathway for follow-on biologics; and sweeping new reporting and disclosure requirements affecting all manufacturers regarding their relationships with physicians and teaching hospitals, among other changes.

Some of the new provisions are effective immediately, while others have delayed effective dates. Many require the Secretary of the Department of Health & Human Services (HHS) to issue implementing regulations; we have referenced those that have been published already, and we will be reporting on additional developments in the coming months.

I. Provisions Affecting Pharmaceutical Manufacturers

A. Medicaid Rebate and Related Sections

Medicaid Drug Rebates (Sec. 2501)

The PPACA amends the Medicaid rebate statute (42 U.S.C. § 1396r-8) in a number of significant ways, including increases to the minimum Medicaid rebate percentages, increased "additional rebates" for new formulations of brand name drugs, the establishment of a maximum rebate amount, and the extension of Medicaid rebates to Medicaid managed care organization utilization. In addition, as discussed further below, section 2503 of PPACA amends the definition of "average manufacturer price," which underlies Medicaid rebate and Public Health Service section 340B program pricing calculations.

---

[1] Public Law No. 111-148. The text of the PPACA as approved is available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:h3590eas.txt.pdf.
[2] Public Law No: 111-152. The text of the Reconciliation Act is available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:h4872enr.txt.pdf.

Increased minimum rebates. Whereas the rebate statute currently requires minimum rebates equal to 15.1% of the average manufacturer price (AMP) for single source and innovator multiple source drugs, and 11% of AMP for noninnovator multiple source drugs, PPACA increases the minimum rebate percentages to 23.1% and 13%, respectively. However, the statute also creates a special rebate percentage of 17.1% for certain clotting factors and for drugs approved exclusively for pediatric indications. These provisions are effective for drugs dispensed on or after January 1, 2010, although it is unclear whether the Centers for Medicare & Medicaid Services (CMS) will require such payments to be made with the upcoming 1Q2010 rebate payments. Notably, the statute also provides that, unlike current Medicaid rebates, the incremental savings associated with the increase to the minimum rebate percentage for brand name drugs will be retained solely by the federal government and not shared with the states. Manufacturers should consider the impact of these provisions on existing arrangements, such as state supplemental Medicaid rebate agreements.

Additional rebates for new formulations of brand name drugs. The rebate statute currently requires manufacturers to pay an "additional" rebate to the extent that a product's AMP increases faster than the consumer price index (CPI) since the time of the product's launch. Because each nine-digit national drug code (NDC) product is considered to be a unique product for purposes of the rebate statute, a new formulation of a product can effectively establish a new launch period and reduce the amount of the "additional" rebate. The statute changes this by requiring that, for "line extensions" of an oral solid dosage form of single source or innovator multiple source drugs, the additional rebate percentage is equal to the greater of (i) the additional rebate percentage calculated under existing law for the old product or (ii) the additional rebate percentage calculated for any strength of the original drug product. The statute defines a "line extension" as "a new formulation" of a drug "such as an extended release formulation."

Two key issues are likely to arise under the amended statute. First, it is not clear what constitutes a new "formulation" of a drug. For example, new formulations might include different ingredient sets, different strengths, or different dosage forms of a single chemical entity, even though these differentiators might not be considered to be "formulation" changes for purposes of the Food, Drug, and Cosmetic Act. Thus, manufacturers will need to consider their product portfolios carefully and implement crosswalks among related products to calculate the additional rebate correctly. Second, these amendments take effect for drugs paid for on or after January 1, 2010. Thus, it is important to recognize that "new" formulations for purposes of the amendments may include pre-existing formulations. Third, manufacturers should consider the utility of maintaining older formulations, or of managing end-of-life pricing for those formulations. It is unclear, however, whether the withdrawal of an original formulation from the market (and eventually its removal from the manufacturer's rebate agreement) would actually have the effect of terminating potential additional rebate liability under this provision.

Maximum rebate cap. For the first time, Congress has established a maximum rebate amount equal to 100% of the AMP . This may reduce or eliminate rebate liability for older products that had significant "additional rebate" exposure. This provision likewise takes effect January 1, 2010.

Rebates for Medicaid Managed Care Organization (MCO) Utilization. The Medicaid rebate statute currently exempts from Medicaid rebate-requirements utilization dispensed through Medicaid managed care organizations. PPACA now requires manufacturers to pay rebates on that utilization. Specifically, the MCOs will be required to report utilization to the states, and that utilization will be included in the quarterly rebate invoices. It is unclear whether state invoices will differentiate fee-for-service and MCO utilization. Further, the statute does not otherwise restrict MCOs' ability to negotiate rebates directly, so manufacturers should review existing MCO arrangements. The statute does not contain a specific effective date for these provisions, though it is appropriate to assume that they could apply to 1Q2010 utilization in the absence of additional guidance.

Elimination of Exclusion of Coverage of Certain Drugs (Sec. 2502)

Effective January 1, 2014, this provision reverses the statutory exclusion of certain drugs from Medicaid coverage, and instead mandates that such drugs shall not be excluded from coverage. The drugs in question are barbiturates, benzodiazepines and agents when used to promote smoking cessation, including such agents approved by the Food and Drug Administration (FDA) through the over-the-counter monograph process.

Note that the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) provided that, on January 1, 2013, the Medicare Part D exclusion of benzodiazepines, and of barbiturates when used in the treatment of epilepsy, cancer or a chronic mental health disorder, will end; since the Part D statutory provisions cross-reference to the Medicaid statute, it appears that as of January 1, 2014, there will be no statutory limitations on Part D coverage of these products.

Providing Adequate Pharmacy Reimbursement (Sec. 2503)

Some background is necessary to understanding the changes in this section of the PPACA.

For "multiple source drugs" (i.e., generic drugs and the branded drugs to which they are equivalent), the Social Security Act provides that CMS must establish a federal upper reimbursement limit (federal upper limit or FUL) price that state Medicaid programs may not exceed with respect to their Medicaid reimbursement to pharmacies.

Prior to the Deficit Reduction Act of 2005 (DRA), FULs were established when there were at least three equivalent products, and CMS set the FUL at 150% of the lowest "published price" (typically wholesale acquisition cost or WAC) of the available products. The DRA changed this, providing that FULs would be calculated when there were two or more equivalent products, and would equal 250% of the lowest AMP. However, CMS's implementation of its regulation to

effectuate this requirement has been enjoined by the District Court of the District of Columbia since December 2007, based upon the court's determination that CMS's regulation did not comply with the statutory definitions of "average manufacturer price" or "multiple source drug," and would cause pharmacies irreparable harm as a result of insufficient reimbursement.[3]

Pursuant to MIPPA, Congress prohibited CMS from implementing the DRA requirement until October 1, 2009, and provided that FULs would continue to be calculated using the old methodology up until that date.

Pursuant to the PPACA, Congress has redefined "average manufacture price" and "multiple source drug," and has established a new formula for calculating FULs. AMP is now defined as the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to "retail community pharmacies" and by retail community pharmacies purchasing directly from manufacturers. However, the term expressly excludes a variety of items: customary prompt payment discounts extended to wholesalers; bona fide service fees paid by manufacturers to wholesalers or retail community pharmacies (including distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative services agreements and patient care programs, such as medication compliance programs and patient education programs); reimbursement for recalled, damaged, expired or otherwise unsalable returned goods; and payments received from, or rebates and discounts provided to, pharmacy benefit managers, managed care organizations, mail order pharmacies, long-term care providers, or any other entity that does not conduct business as a wholesaler or retail community pharmacy. Overall, the changes to the definition used by manufacturers in reporting AMPs to CMS today appear likely to increase reported AMPs—most notably, because of the exclusion of mail order purchases, and possibly as a result of the exclusion of certain wholesaler service fees.[4]

"Retail community pharmacy" is defined to include independent, chain, supermarket, and mass merchandiser pharmacies, but it specifically excludes mail order, nursing home, long-term care, hospital, clinic, charitable, and government pharmacies, as well as pharmacy benefit managers. The definition of "multiple source drug" is revised to require that a drug be available for purchase in the United States, rather than in the given state.

The new formula for FUL requires that the Secretary calculate FULs as "no *less* than 175% of the weighted average (determined on the basis of utilization) of the most recently reported monthly

---

[3] *National Association of Chain Drug Stores, et al. v. Leavitt* (U.S. Dist. D.C., C.A. No. 1:07cv02017)

[4] It bears emphasizing that the statute's clarifications relating to various wholesaler fees refer only to the calculation of AMP. Nevertheless, the amendments may lend some additional support to the conclusion that these types of fees may be considered to be "bona fide service fees" that may be excluded from Medicare Part B "average sales price" calculations.

average manufacturer prices...available for purchase by retail community pharmacies on a nationwide basis" (emphasis added). The Secretary is required to use a smoothing process for AMPs.

In addition to reporting AMPs, manufacturers are required to report to CMS the number of units of the product used to calculate its AMP; this data will be necessary to calculate weighted average AMPs determined on the basis of utilization. Rather than publishing the AMP for each manufacturer's drug, CMS will now be required to publish only the weighted average AMP.

The provisions technically go into effect October 1, 2010; however, as a practical matter, it appears impossible for CMS to calculate new FULs prior to January 1, 2011 at the earliest, since manufacturers will have until November 30, 2010 to report AMPs using the new definition and unit volume. It is unclear whether pharmacy reimbursement will go up or down under the new law, as compared with FULs currently in effect.

B. Medicare Part D Prescription Drug Benefit Sections

Medicare Coverage Gap ("Donut Hole") Discount Program (Sec. 3301)

By way of background, the Medicare Part D prescription drug benefit structure, created pursuant to the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (the MMA), includes a gap in coverage that this new provision addresses in part, beginning in 2011. Specifically, under the "standard" Part D benefit, coverage of prescription drugs extends until the beneficiary hits an "initial coverage limit" of covered Part D drug costs (in 2010, this is $2,830); after that point, the beneficiary has no coverage (technically, 100% co-insurance, referred to as the "coverage gap" or "donut hole") until he or she incurs (or is deemed to have incurred) out-of-pocket costs for covered Part D drugs equal to an out-of-pocket maximum (in 2010, this is $4,450). At that point, the "catastrophic" portion of the Part D benefit structure kicks in, and beneficiaries are required to pay only small copays (e.g., in 2010, $2.50 for generics and $6.30 for branded drugs, subject to some exceptions).

The PPACA requires that, beginning January 1, 2011, manufacturers of "applicable drugs" provide a discount equal to 50% of the "negotiated price" of such drugs when dispensed to "applicable beneficiaries" during the coverage gap. "Applicable drugs" generally refers to branded drugs and biological products that are on the given Part D plan's formulary; specifically, the definition includes covered Part D drugs "approved under a new drug application [NDA] under Section 505(b) of the Federal Food, Drug, and Cosmetic Act or, in the case of a biologic product, licensed under section 351 of the Public Health Service Act (PHSA) (other than a product licensed under subsection (k) of such section)," which are either on the plan's formulary or for which coverage has been granted to the beneficiary through an exception or appeal.

These discounts do not extend to generic drugs, except, presumably, for "authorized generics," which are "generic" versions of drugs manufactured under an NDA.

"Applicable beneficiary" is defined as an individual Part D plan enrollee who is not entitled to low-income subsidies (LIS beneficiaries). "Negotiated price" refers to the price that the beneficiary would otherwise pay for the given drug at the given pharmacy during the coverage gap, other than any dispensing fee; in practice, this generally refers to the price negotiated between the Part D plan sponsor and the pharmacy for the given drug (excluding the dispensing fee).

Manufacturers of applicable drugs are required to agree to provide these discounts during the coverage gap or donut hole in order to have any of their drugs eligible for coverage under Medicare Part D, subject to an exception where the Secretary "has made a determination that the availability of the drug is essential to the health of" Part D beneficiaries, or to the extent the Secretary determines that, during 2011, there were "extenuating circumstances." While it is not clear what the Secretary might require to grant such exceptions, the language suggests that unique drugs or biologics (e.g., cancer drugs for which there are no therapeutic alternatives) could be excepted from the mandatory discount requirement.

The Secretary is required to establish a form of agreement for manufacturers to agree to provide the coverage-gap discounts not later than 180 days after the enactment of this section, and manufacturers must enter into such agreements within 30 days thereafter (per amendments made in the Reconciliation Act). The Secretary is also required to enter into a contract with a third party to administer this "Medicare coverage gap program." It appears that funds are to flow from manufacturers through this third-party contractor to pharmacies, to reimburse them for providing these discounts at the point of sale, with pharmacies entitled to be paid within 14 days for claims submitted electronically, and within 30 days for claims submitted otherwise. This could present a significant operational challenge, since there are no existing mechanisms for transmitting claims information from pharmacies or Part D plan sponsors to such a third-party contractor, or for such contractor to pay such funds to pharmacies. In light of these issues, the legislation includes certain exceptions for CY 2011. Specifically, if it is not practicable to provide discounted prices at the point of sale during 2011, the Secretary may establish procedures to provide such discounts as soon as practicable after the point of sale; and while the Secretary is prohibited from receiving manufacturers' funds, this prohibition does not apply for 2011 if the Secretary determines an exception is necessary in order to begin implementation and provide beneficiaries timely access to the discounts. Part D plan sponsors are required to provide appropriate data to the Secretary for administration of the program.

Importantly, the provision revises the definition of "incurred costs" under Part D, for purposes of determining the point at which a beneficiary has passed through the coverage gap and is eligible for catastrophic coverage. "Incurred costs" now include the entire negotiated price of an applicable drug dispensed to an applicable beneficiary during the coverage gap, regardless of the fact that part of the cost is paid by the manufacturer; however, when the coverage gap starts shrinking in 2011 (see next section), the portion of the negotiated price paid by the Part D plan sponsor pursuant to the revised "standard" Part D benefit does not count toward "incurred

costs." This feature was part of the agreement negotiated by the Pharmaceutical Research and Manufacturers of America (PhRMA) during the days when health reform was being formulated early in 2009, and means that manufacturer funding of these discounts will help to move beneficiaries through the coverage gap to the Part D catastrophic benefit.

Notably, because of the way the term "incurred costs" has been redefined, it appears that there may be significantly greater potential for Part D plan sponsors to offer "supplemental" or "enhanced" Part D benefit plans with more added coverage of branded drugs in the coverage gap. This is because it appears that payments by the Part D plan sponsor for those drugs in the coverage gap as a supplemental benefit to "standard" Part D coverage will now count as "incurred costs" by the beneficiary, meaning the beneficiary will move through the gap as fast as if the beneficiary had paid such costs himself or herself.[5] Under prior law, enhanced benefit coverage of branded drugs in the coverage gap has been rare, since the beneficiary would not exit the gap until he or she incurred the required level of out-of-pocket costs; when drugs were covered in the coverage gap, the beneficiary's out-of-pocket costs were reduced, thereby pushing back the level of total drug costs necessary to exit the gap. Additionally, the plan is required to charge an additional premium for the actuarial value of drugs covered in the gap. The new law could reduce the economic disadvantages that such plans have faced.

CMS released for comment draft program instructions to Part D plan sponsors regarding implementation of the discount program. The comment period closed May 14, 2010. The draft instructions stated that, with the exception of 2011, a drug will only be covered under Part D if the manufacturer has a signed agreement with CMS to provide the discount on coverage-gap claims for all of its applicable drugs. CMS notes that because of the timing of Part D plan formulary submissions, CMS must allow coverage in 2011 of Part D drugs irrespective of manufacturer discount agreements, which could mean that some brand-name drugs on plan formularies will not be discounted in the coverage gap next year. CMS will provide additional guidance if this situation occurs. As also discussed in the draft program instructions, Part D sponsors will be required to provide the applicable discounts at point-of-sale, using funds provided by CMS through monthly prospective payments to pay pharmacies. CMS proposes to use a contractor to collect discount payments from manufacturers quarterly, based on new

---

[5] The PPACA provided that "incurred costs shall include the negotiated price...of an applicable drug...of a manufacturer that is furnished to an applicable beneficiary...under the Medicare coverage gap discount program...regardless of whether part of such costs were paid by a manufacturer under such program." The Reconciliation Act added to this language an exclusion of amounts paid by the Part D plan pursuant to the changes to the "standard" Part D benefit, but that language does not appear to encompass supplemental benefits. This could result in CMS having to apportion drug costs covered by an enhanced benefit Part D plan during the coverage gap between "standard" benefit costs (which will not count as incurred) and "enhanced" benefit costs (which would)—which could prove to be a challenging administrative task, and difficult to explain to beneficiaries. It is possible that CMS will attempt to construe the statutory language as providing only that the 50% manufacturer discounts will count as "incurred" to avoid these issues.

information to be submitted by Part D plan sponsors to CMS as part of prescription drug event data. The guidance also covers such issues as enrollee dispute resolution, program monitoring and oversight, and discounts for beneficiaries with supplemental drug coverage. CMS will accept comments on the draft program instructions until May 14, 2010, and the agency will issue final program instructions after considering all public comments. The draft is available at http://www.cms.gov/PrescriptionDrugCovContra/Downloads/2011CoverageGapDiscount_043010.pdf.

The PPACA also adds a new exception to the federal anti-kickback statute at 42 U.S.C. § 1320a-7b(b)(3), to expressly provide that the new manufacturer discounts will not constitute a violation of that statute; this effectively overrules the 2005 HHS Office of Inspector General (OIG) ruling that manufacturer assistance to beneficiaries during the coverage gap could constitute a violation of that statute.[6]

Closing the Medicare Prescription Drug Benefit Coverage Gap ('Donut Hole') (Reconciliation Act Sec. 1101)

This provision provides a $250 payment to Part D beneficiaries who reach the coverage gap during 2010, and also provides for the gradual elimination of the coverage gap, beginning in 2011 and finishing in 2020.

Specifically, any Part D plan enrollee who, as of the end of a calendar quarter during 2010, has "incurred" costs for covered Part D drugs in excess of the initial coverage limit ($2,830), shall be paid $250 by the Secretary by the 15th day of the third month following the end of such calendar quarter. Notably, such payment is to be made regardless of whether the beneficiary in fact incurs $250 in covered Part D drug costs in the coverage gap.

The provision closes the coverage gap beginning in 2011 by gradually reducing the Part D "standard" benefit coinsurance percentage that beneficiaries pay during the gap to 25%, which is the same coinsurance percentage as applies prior to the gap.[7] The legislation does this separately for "applicable drugs" (as such term is defined for purposes of the Medicare Coverage Gap Discount Program), i.e., branded drugs and biologics, and for covered Part D drugs other than "applicable drugs" (i.e., generics). The coinsurance percentages during the coverage gap for applicable and generic drugs are shown below; please note that, since 50% of the negotiated price of applicable drugs is being picked up by the manufacturer pursuant to the Medicare Coverage

---

[6] "Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees," 70 FR 70623 (Nov. 22, 2005).

[7] In lieu of 25% coinsurance, the vast majority of Part D plans use actuarially equivalent copay tiers for different drugs, e.g., $10 for generics, $30 for preferred brands and $50 for non-preferred brands. The law as revised would also permit such actuarially equivalent tiering in lieu of a single coinsurance percentage during the coverage gap, and we would expect most plans to adopt that approach.

Gap Discount Program, the government will end up paying only approximately 25% of the cost of those drugs in 2020:

Year	Applicable Drug Coinsurance	Generic Drug Coinsurance
2010	100%	100%
2011	50%*	93%
2012	50%*	86%
2013	47.5%	79%
2014	47.5%	72%
2015	45%	65%
2016	45%	58%
2017	40%	51%
2018	35%	44%
2019	30%	37%
2020	25%	25%

*The statutory language does not include a coinsurance percentage for 2011 or 2012; we have assumed this means coinsurance would remain at 100%, less the 50% manufacturer discount. Note that this will not be exactly 50% coinsurance, since the beneficiary must pay the entire dispensing fee in addition to 50% of the drug cost.

Additionally, the Reconciliation Act changes the inflation indexing used to calculate the out-of-pocket limit that defines the upper end of the coverage gap, i.e., the point at which the beneficiary exits the coverage gap and catastrophic coverage applies. Under the MMA, the out-of-pocket limit was to be adjusted upward each year by the percentage increase in average per-capita expenditures for covered Part D drugs in the United States for Part D-eligible individuals (referred to by CMS as the "average percentage increase"); based upon such indexing, the out-of-pocket threshold has increased from $3,600 in 2006 to $4,550 in 2010. Under the new legislation, for each of 2014 and 2015, the adjustment will be the amount of the average percentage increase less 0.25%. For each of 2016 through 2019, the adjustment will be the lesser of (1) the average percentage increase, or (2) the annual percentage increase in the consumer price index for all urban consumers, plus 2%. In 2020, the out-of-pocket limit will be set as though these amendments had not been enacted.

Improvement in Determination of Medicare Part D Low-Income Benchmark Premium; Voluntary 'de minimis' Policy for Subsidy-Eligible Individuals under Prescription Drug Plans and Medicare Advantage Prescription Drug (MA-PD) Plans (Sec. 3302, 3303)

Under current law, Medicare Part D beneficiaries who are "dually eligible" under Medicare and their state Medicaid program pay no premium for their Part D coverage so long as they are enrolled in a Part D plan whose beneficiary premium is at or below the "benchmark" premium in the given prescription drug plan (PDP) region. The "benchmark" premium is essentially the weighted average premium for Part D plans in the given PDP region.

Effective January 1, 2011, the benchmark premium will be determined without regard to any premium reductions for MA-PD Part D plans because of a refund or bonus associated with the medical benefit under the associated MA plan. In the past, MA plan refunds have resulted in some MA-PDs having a zero premium. This will have the effect of raising the benchmark premiums, resulting in more Part D plans falling below the benchmark thresholds.

Additionally, Part D plans whose premium is above the benchmark premium by a "de minimis" amount will be permitted to waive that excess for low-income, subsidy-eligible Part D beneficiaries. "De minimis" is not defined, and presumably will be defined by the Secretary; in the past the Secretary operated a demonstration program that used $2 or $1 as a de minimis amount. This will permit plans waiving that portion of their premium to avoid having their dually eligible enrollees reassigned to other Part D plans, and appears to also permit these plans to receive assignment of new dually eligible enrollees.

Special Rule for Widows and Widowers Regarding Eligibility for Low-Income Assistance (Sec. 3304)

This provision will extend by one year, the effective period of LIS status for a Part D LIS enrollee whose spouse dies. Accordingly, beneficiaries whose income and resources are low enough to qualify them for a given LIS status when measured against the criteria for a married couple will not lose LIS status when measured against the criteria for single individuals, for a period of one year.

Improved Information for Subsidy-Eligible Individuals Reassigned to Prescription Drug Plans and MA-PD Plans (Sec. 3305)

This section requires the Secretary to provide, to those LIS enrollees who are reassigned by the Secretary to a different Part D plan, information on the formulary differences between the old and new plans, and a description of the enrollee's right to request an exception to the new formulary, which may include a request for coverage on a lower cost-sharing tier.

Funding Outreach and Assistance for Low-Income Programs (Sec. 3306)

This section provides additional amounts to fund low-income outreach and assistance by state health insurance programs, area agencies on aging, and similar entities, through 2012. Additionally, the Secretary may request that such entities conduct outreach activities aimed at preventing disease and promoting wellness, and such use of funds by the entities is permitted.

Improving Formulary Requirements for Prescription Drug Plans and MA-PD Plans with Respect to Certain Categories or Classes of Drugs (Sec. 3307)

Through operational guidance, since the beginning of the Part D program in 2006, the Secretary has established six categories of drugs as meriting special formulary treatment. Stated differently, Part D sponsors have been required to include all drugs (or a generic equivalent) in these six categories on their formularies. These classes were anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals and immunosuppressants. MIPPA required that the Secretary establish categories and classes of drugs for which such formulary treatment would be required, specifying criteria for such determinations—e.g., whether "restricted access to drugs in the category or class would have major or life threatening clinical consequences for individuals who have a disease or disorder treated by the drugs in such category or class." The Secretary has engaged in a process to make such determinations for future years, though it is not clear whether this would result in additions and/or subtractions to the current six classes to which such treatment has been extended so far.

The PPACA has replaced the MIPPA provision with language that removes the criteria specified by MIPPA, and instead allows the Secretary to establish these categories and classes using "criteria established by" the Secretary. The Secretary is to establish any such criteria, and any exceptions to the requirement that all drugs in the class be on formulary, through a rulemaking that includes a public notice and comment period. Until such determinations are made, the existing six classes are to be accorded such status.

Reducing Part D Premium Subsidy for High-Income Beneficiaries (Sec. 3308)

Beginning in 2011, Part D enrollees who have "modified adjusted gross income" in excess of specified levels ($85,000 in 2010 for a beneficiary filing an individual income tax return or married and filing a separate return, and $170,000 for a beneficiary filing a joint tax return), will have their Part D premiums adjusted upward. "Modified adjusted gross income" is defined for such purposes as adjusted gross income under the Internal Revenue Code, determined without regard to sections 135, 911, 931 and 933 of the Code.

The amount of the increase is determined pursuant to a formula; while difficult to understand, it appears that monthly premiums could more than double for some of the beneficiaries subject to these adjustments, with smaller increases for others.

These income-related increases in Part D premiums are to be paid through withholding from Social Security checks.

Elimination of Cost Sharing for Certain Dual-Eligible Individuals (Sec. 3309)

Part D beneficiaries receiving both Medicare and Medicaid benefits are relieved from paying cost sharing (e.g., deductibles, copays, and coinsurance in the prescription drug coverage gap) for covered Part D drugs if they are "institutionalized." This term is currently defined to refer to beneficiaries in nursing facilities and certain other medical facilities. This provision will expand such treatment to beneficiaries who would be institutionalized if they were not receiving services outside of such a facility pursuant to a home- and community-based waiver pursuant to a section 1115 Medicaid waiver or a state plan amendment, or through enrollment in a Medicaid managed care organization.

This provision is to be effective when specified by the Secretary, but no sooner than January 1, 2012.

Reducing Wasteful Dispensing of Outpatient Prescription Drugs in Long-Term Care Facilities under Prescription Drug Plans and MA-PD Plans (Sec. 3310)

This provision requires the Secretary to require Part D plan sponsors to "utilize specific, uniform dispensing techniques" as determined by the Secretary, "such as weekly, daily, or automated dose dispensing, when dispensing covered part D drugs to enrollees who reside in a long-term care facility in order to reduce waste associated with 30-day fills."

The provision goes into effect in 2012. The Secretary is to consult with relevant stakeholders, including nursing facility representatives and residents, pharmacists, retail and long-term care pharmacies, Part D plans, and others determined appropriate by the Secretary, in establishing what techniques it will require.

Improved Medicare Prescription Drug Plan and MA-PD Plan Complaint System (Sec. 3311)

The Secretary is required to develop and maintain a complaint system, "that is widely known and easy to use," to collect and maintain information on Part D plan complaints received by the Secretary through the date the complaint is resolved. The system must be able to "report and initiate appropriate interventions and monitoring based on substantial complaints and to guide quality improvement."

The Secretary must promulgate a model electronic complaint form to be used in connection with this system, and the form must be prominently displayed on the front page of the Medicare.gov website, and on the Internet website of the Medicare Beneficiary Ombudsman.

This section does not specify an effective date; as such, it appears to be effective immediately.

Uniform Exceptions and Appeals Process for Prescription Drug Plans and MA-PD Plans (Sec. 3312)

Effective January 1, 2012, Part D plan sponsors are required to use a single, uniform exceptions-and-appeals process (including, to the extent the Secretary determines feasible, a single, uniform model form for use under such process) for determining prescription drug coverage for their Part D enrollees. They must also provide "instant access to such process through a toll-free telephone number and an internet website."

Office of the Inspector General (OIG) Studies and Reports (Sec. 3313)

The OIG is required to prepare and deliver reports on the following:

- Part D plan formularies' inclusion of drugs commonly used by dual eligibles, to be delivered to Congress annually, by July 1 of each year (beginning with 2011).
- Prescription drug prices under Part D and Medicaid, including a comparison, for the 200 most frequently dispensed drugs, of the prices (taking into account rebates) paid by Part D plans and state Medicaid programs. Notwithstanding any other provision of law, the OIG shall be able to collect any information related to such prices necessary to carry out such comparison. The report is to be submitted to Congress by October 1, 2011, but shall not include proprietary information or information that OIG determines is likely to negatively impact the ability of Part D plan sponsors to negotiate prices.

Including Costs Incurred by AIDS Drug Assistance Programs and Indian Health Service in Providing Prescription Drugs Toward 'Incurred Costs' Threshold under Part D (Sec. 3314)

Effective January 1, 2011, Part D drug costs paid by a state pharmaceutical assistance program, the Indian Health Service, an Indian tribe or tribal organization, an urban Indian organization, or an AIDS drug assistance program, will be treated as "incurred" by the beneficiary for purposes of the annual out-of-pocket threshold. As such, beneficiaries of such programs will move out of the coverage gap and into the catastrophic coverage portion of the Part D benefit more quickly.

Improvement in Part D Medication Therapy Management (MTM) Programs (Sec. 10328)

Under the MMA, Part D plan sponsors are required to conduct MTM programs for "targeted beneficiaries," defined as those who have multiple chronic diseases, are taking multiple covered Part D drugs, and are expected to incur annual costs for covered Part D drugs that exceed a level specified by the Secretary. In the MMA, Congress did not impose specific requirements for MTM programs; CMS has established these through operational guidance, initially leaving the content of such programs largely up to Part D plan sponsors, and more recently imposing more specific requirements.

Beginning in 2013, Part D plan sponsors will be required to offer targeted beneficiaries an annual comprehensive medication review furnished person-to-person or using telehealth technologies (as defined by the Secretary) by a licensed pharmacist or "other qualified provider."

The review "may result in the creation of a recommended medication action plan or other actions in consultation with the individual and with input from the prescriber to the extent practicable," and shall include providing the individual with a written summary of the results of the review. The Secretary, in consultation with relevant stakeholders, is required to develop a standardized format for the action plan.

The MTM program is also required to include "[f]ollow-up interventions as warranted based on the findings of the annual medication review or the targeted medication enrollment and which may be provided person-to-person or using telehealth technologies...."

Part D plan sponsors are required to have in place "a process to assess, on at least a quarterly basis, the medication use of individuals who are at risk but not enrolled" in the MTM program, including beneficiaries who have experienced a transition in care, if they have access to that information.

Part D plan sponsors must also have a process for automatically enrolling targeted individuals and individuals identified at risk in the MTM program, and to permit such beneficiaries to opt out of such program.

C. Public Health Service Section 340B Discounts

Public Health Service Section 340B Program Amendments (Sec. 7101-7103, Reconciliation Act Sec. 2302)

The Public Health Service (PHS) section 340B drug discount program (42 U.S.C. § 256B) requires manufacturers of "covered outpatient drugs" to charge specified "covered entities" no more than a maximum discounted price that is equal to the difference between a drug's Medicaid AMP and the average total Medicaid rebate. Covered entities include a variety of entities receiving grants from the PHS to provide services to medically underserved populations, as well as certain disproportionate share hospitals.

In addition to the fact that PHS discounts are likely to increase as a result of the amendments to the Medicaid rebate statute described above (e.g., the modifications to AMP, the increase in the minimum rebate percentage, and the modifications to the additional rebate formula for line extensions of brand name drugs), PPACA further extends the 340B program to additional covered entities, and authorizes significant new oversight of the program. However, because of amendments in the Reconciliation Act, the statute does not extend 340B program discounts to covered entities' purchases of products for inpatient use.

Expanded classes of covered entities. PPACA authorizes Medicare PPS-exempt children's hospitals and cancer hospitals that meet disproportionate share eligibility criteria, critical access hospitals, and rural referral centers or sole community hospitals with disproportionate share adjustments of greater than or equal to 8%, to qualify as "covered entities." However, these entities will not be able to purchase FDA-designated orphan drugs at PHS discounted prices. These provisions take effect January 1, 2010.

Program Integrity. The PPACA also contemplates a significant expansion of administrative oversight of the 340B program, which has historically been relatively modest. These provisions are subject to appropriations.

First, the PPACA authorizes the PHS to develop a system to verify the accuracy of ceiling prices calculated and charged by manufacturers to covered entities. Second, PHS must establish procedures for manufacturers to issue refunds to covered entities in cases of overcharges (including those resulting from both routine adjustments to Medicaid pricing data and non-routine overcharge situations). Third, the statute authorizes PHS to develop an Internet website through which covered entities may obtain the PHS prices. Fourth, the statute contemplates a system to report additional rebates that may lower PHS prices and to provide credits to covered entities in those instances. Fifth, the PHS must audit both manufacturers and wholesalers with respect to program compliance. Sixth, the statute would authorize civil money penalties of up to $5,000 against manufacturers that knowingly and intentionally overcharge covered entities.

PPACA also contemplates improvements for covered entity compliance and identification, including a system to update current information, the development of a unique identifier, and the imposition of sanctions where a covered entity diverts products for non-covered uses or otherwise fails to comply with program requirements.

Finally, but perhaps most importantly, PPACA requires PHS to establish administrative dispute resolution (ADR) procedures to address claims of both manufacturer and covered entity noncompliance. These regulations are to be promulgated within 180 days of the enactment of the statute. These procedures would include discovery from manufacturers and third parties by covered entities, and would permit the hearing entity to consolidate claims from multiple claimants, to allow joint claims by covered entities, and to allow associations, rather than the covered entities themselves, to assert claims. Manufacturers should consider appropriate steps now to prepare for potential ADR claims, as some covered entities and their trade associations have been relatively aggressive in such matters.

D. Pharmaceutical Industry Fees

Pharmaceutical Manufacturer and Importer 'Industry Fees' (Sec. 9008, Reconciliation Act Sec. 1404) Beginning in 2011, manufacturers and importers of branded prescription drugs and

biologics[8] will be assessed an annual "fee." The amount of the aggregate industry fees is specified by the statute ($2.5 billion in 2011, $3 billion in 2012-16, $3.5 billion in 2017, $4.2 billion in 2018, and $2.8 billion each year thereafter). These fees are to be transferred to the Medicare Part B trust fund, and are not deductible for income tax purposes. The civil action procedures for excise taxes apply to these fees, although the fees are not explicitly characterized as excise taxes for purposes other than non-deductibility.

The Secretary of the Treasury determines each manufacturer or importer's share of the aggregate fee based on the ratio of (1) its "branded prescription drug sales" in a taxable year to specified government programs, to (2) that of the aggregate "prescription drug sales" of all manufacturers and importers to such programs in such year (i.e., roughly based on its market share). However, the determination of a manufacturer's or importer's "branded prescription drug sales" is subject to several important statutory provisions. First, such sales include sales of branded drugs and biologics, but not orphan drugs. Second, PPACA specifies primary (though not exclusive) source data for the Secretary to consider when determining such "branded prescription drug sales." This data includes: (1) Medicare Part D utilization and per-unit ingredient costs, net of manufacturer discounts; (2) Medicare Part B utilization and average sales prices; (3) Medicaid utilization and per-unit ingredient costs net of Medicaid rebates and state supplemental rebates; (4) VA purchases and costs; and (5) DOD purchases of costs and TRICARE retail utilization and per-unit ingredient costs, net of manufacturer refunds. In other words, branded prescription drug "*sales*" are not actually determined based on manufacturer sales revenue, but rather on government net dispensing costs.[9] Third, all manufacturers' or importers' branded prescription drug sales are not weighted equally in the calculation. Instead, larger manufacturers' sales count in full, and only a portion of smaller manufacturers' sales count according to the following table:

---

[8] The statute does not appear to contain an exemption for vaccines. Nor does the statute specify whether combination products will be considered to represent "drugs and biologics" for purposes of the pharmaceutical industry fees or medical devices for purposes of the medical device excise taxes described below.

[9] It bears note that most of the government utilization and dispensing cost data under these programs will be compiled on the basis of product NDCs. Thus, while the statute is not explicit in this regard, it is possible that the government will at least in the first instance deem the "manufacturer" of a product to be the entity whose NDC labeler code is on the product.

Manufacturer Sales	Portion of Sales Counting in the Calculation
Up to $5 million	0%
>$5 million up to $125 million	10%
>$125 million up to $225 million	40%
>$225 million up to $400 million	75%
>$400 million	100%

The statute also specifies that certain Internal Revenue Code control group tests will be applied for purposes of determining the aggregate scope of a manufacturer's or importer's sales, and establish joint and several liability among entities within the control group. Although exceptions may exist, a "control group" is generally determined through ownership of value of voting shares in a corporation, or partnership, or capital interest in a partnership, in most cases above certain thresholds of percentage ownership, including direct or indirect ownership, and ownership deemed to exist through ownership of an option for the shares or interest.

Aside from the obvious financial implications of these fees, they may also have implications with respect to corporate and deal structures, product launches, and future and existing license agreements. For example, manufacturers might wish to consider the implications of various business and ownership structures under the control group tests specified in the statute. Second, manufacturers – particularly smaller new manufacturers – might consider whether the timing of a product launch of new products (e.g., at the end of a taxable year) might defer or minimize liability. Third, with respect to licensing and royalty agreements, it is not entirely clear whether the "fees" should be viewed as taxes, overhead costs, reductions in revenue, or user fees for purposes of "net sales" or other royalty calculation mechanisms. This issue can be addressed prospectively through specific language, but may raise potential disputes under existing agreements where the calculation clauses do not specifically contemplate these fees. Fourth, if manufacturer's sales are attributed to entities on the basis of NDC labeler codes, the parties to product-disposition transactions should pay careful attention to the implications of existing inventory bearing the seller's labeler code.

E. Medicaid Exclusion from Participation Relating to Certain Ownership, Control, and Management Affiliations (Sec. 6502)

The PPACA imposes significant changes to multiple program integrity provisions that could impact many manufacturers. We will be issuing a separate alert relating to fraud and abuse issues, but want to highlight here one change of potential significance for pharmaceutical manufacturers.

Section 6502 of the PPACA requires Medicaid agencies to exclude individuals or entities from participating in Medicaid for a specified period of time if the entity or individual owns, controls, or manages an entity that: (1) has failed to repay overpayments during the period as determined by the Secretary; (2) is suspended, excluded, or terminated from participation in

any Medicaid program; or (3) is affiliated with an individual or entity that has been suspended, excluded, or terminated from Medicaid participation.

In recent years, a number of pharmaceutical and device manufacturers that have been subject to investigation and enforcement activity by the Office of Inspector General, the Department of Justice, and/or state entities, have opted to have subsidiaries – sometimes all but defunct ones – plead guilty to a criminal kickback charge for which they are excluded from participation in Medicare and Medicaid under the mandatory exclusion provisions of 42 U.S.C. § 1320a-7(a). The parent organization or another subsidiary then has continued to conduct business as usual, though typically subject to a Corporate Integrity Agreement.

The cited provision in the PPACA legislation could be interpreted to mean that, if a pharmaceutical manufacturer's subsidiary or affiliate takes a plea and is excluded, then state Medicaid programs must exclude the parent company from Medicaid participation. This in turn means that the parent's products will not be reimbursed by Medicaid programs – in effect, that patients will not have access to that manufacturer's products. This is a draconian measure not previously contemplated as a mandatory matter. Further, such an action could be a predicate for Medicare exclusion as well. Some undefined terms remain in the legislation (for example, the period of exclusion), and it is unclear whether state Medicaid agencies might interpret the provision to allow them to adopt some type of "permissive exclusion" process, rather than having exclusions be automatic.

While at first blush this provision appears to be adverse to manufacturers in the sense that it authorizes additional sanctions, its practical implications in the context of global resolutions of dual-track criminal-civil investigations are less clear. On the one hand, it could arguably provide even greater leverage to prosecutors than already exists. On the other hand, since the exclusion implications of a criminal kickback plea would likely be wholly unacceptable to a manufacturer, it could either act as a barrier to global resolutions, or alternatively might force the parties to consider other sorts of pleas that are not subject to mandatory exclusion (e.g., pleas to FDA violations).

II. Provisions Affecting Device Manufacturers

A. Medical Device Excise Taxes

Section 9009 of PPACA, as amended by section 1405 of the Reconciliation Act, establishes similar "industry fees" applicable to medical device manufacturers and importers, but the Reconciliation Act replaced these provisions with a simpler excise tax, effective for sales on or after January 1, 2013. Specifically, manufacturers, producers, and importers of taxable medical devices must pay as an excise tax 2.3% of the price for which the devices are sold. "Taxable medical devices" generally include devices intended for human use, except for (1) eyeglasses,

(2) contact lenses, (3) hearing aids, and (4) other devices determined by the Secretary of the Treasury to be purchased by the general public at retail for individual use.[10] Again, the statute does not specifically address the treatment of combination products. The statute also limits certain exemptions from tax under sections 4221 and overpayment recoveries under section 6416 of the Internal Revenue Code for sales for supplying vessels or aircraft, to state or local governments, to nonprofit educational institutions, and blood collection organizations.

B. Durable Medical Equipment, Prosthetics, Orthotics and Supplies

Manufacturers of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) may be indirectly affected by a number of Part B reimbursement and fraud and abuse provisions in the PPACA affecting DMEPOS suppliers. For example:

- **Durable Medical Equipment (DME).** The PPACA eliminates the full inflation update to the DME fee schedule for 2011 through 2014, in addition to a 2% add-on scheduled to be applied in 2014 to those items that had been selected for inclusion in the first round of the DMEPOS competitive bidding program, and that had been subject to a 9.5% fee schedule reduction in 2009. Instead, for 2011 and each subsequent year, DME rates will be increased by the rate of increase in the CPI-U less the productivity adjustment.

- **Prosthetic Devices, Orthotics, Prosthetics, Medical Supplies, and Other Items.** Beginning in CY 2011, the PPACA applies a productivity adjustment factor to the inflation update for prosthetic devices, orthotics, and prosthetics, and to the update for any fee schedule established for medical supplies, home dialysis supplies and equipment, therapeutic shoes, parenteral and enteral nutrients, equipment, and supplies, electromyogram devices, salivation devices, blood products, and transfusion medicine.

- **DME Competitive Bidding.** The PPACA requires the Secretary to expand the number of areas to be included in round 2 of the DME competitive bidding program from 79 to 100 of the largest MSAs. In addition, the PPACA requires (rather than permits) the Secretary to use information regarding payments determined under competitive bidding to adjust DMEPOS payments in areas outside of competitive bidding areas beginning in 2016. Likewise, for items furnished on or after January 1, 2016, the Secretary is directed to continue to adjust prices as additional information is obtained when new items are subject to competitive bidding or when contracts are recompeted.

[10] Note that an earlier version of the Reconciliation Act would have exempted Class I medical devices from this tax, but the final version did not include an exemption for Class I devices.

III. Provisions Affecting Biotech Entities

A. Payment for Biosimilar Biological Products

Section 3139 of the PPACA amends section 1847A of the Social Security Act (42 U.S.C. § 1395w-3a) (average sales price methodology) by adding a new subparagraph C that provides that Medicare Part B payment for a "biosimilar" biologic product is the average sales price plus 6% of the "reference" or brand biological product. A biosimilar biological product is defined as "a biological product approved under an abbreviated application for a License of a biological product that relies in part on data or information in an application for another [licensed] biological product...." The payment provisions apply on the "first day of the second calendar quarter after enactment of legislation providing for a biosimilar pathway (as determined by the Secretary)."

B. Abbreviated Approval Pathway for Follow-On Biologics

The PPACA amends the PHSA to establish, for the first time, an approval pathway for generic versions of biologics ("follow-on" or "biosimilars") licensed under section 351 of the PHSA, which may provide more affordable alternatives to branded ("pioneer") biologics. The legislation amends section 351(i) of the PHSA to provide, among other things, 12 years of exclusivity to the manufacture of a pioneer biologic (i.e., the branded biologic reference product). The PPACA defines a biosimilar product as a product that is "highly similar" to a reference product "notwithstanding minor differences in clinically inactive components," and for which there are "no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency of the product."

Biosimilar Approval Process (Sec. 7002)

Biosimilar Applications and Interchangeability

Biosimilar applications may not be submitted until four years after the date on which the reference product was approved. Each application must include information demonstrating that the new product is biosimilar to its branded biologic reference product based on:

- Analytical studies demonstrating that the biological product is "highly similar to the reference product notwithstanding minor differences in clinically inactive components"
- Animal studies, including the assessment of toxicity
- A clinical study or studies ("including the assessment of immunogenicity and pharmacokinetic or pharmacodynamics") that are sufficient to demonstrate "safety, purity, and potency" in one or more conditions of use for which the reference product is licensed and intended to be used, and for which licensure is sought for the biosimilar.

The PPACA gives the Secretary the flexibility to waive any of these studies.

Although not required by the PPACA, applications for biosimilar products may include information demonstrating that the biosimilar product is "interchangeable" with its reference product. An interchangeable product is one that is biosimilar to the reference product and "can be expected to produce the same clinical result" as the reference product in any given patient.[11] For products that are administered more than once to an individual, an interchangeable determination is possible only if "the risk in terms of safety or diminished efficacy of alternating or switching" between the products is not greater than "the risk of using the reference product without such alteration or switch."

In an effort to consolidate the approval and regulation of biosimilars under the PHSA, the PPACA requires applications for biosimilar products to be submitted under section 351 of the PHSA, except when (1) the product is part of a class of products where an approved application under section 505 of the FDCA existed on the date the PPACA became law, and (2) the biosimilar application is submitted for approval within 10 years after the date the PPACA became law. Further, a biosimilar application may not be submitted under section 505 of the FDCA if another biological product is approved under section 351 of the PHSA. The PPACA also deems all approved applications for biological products under section 505 of the FDCA to be licenses under section 351 of the PHSA 10 years after the date the PPACA became law.

Exclusivity

The PPACA prohibits the approval of an application as either biosimilar or interchangeable until 12 years from the date on which the reference product is first approved, or 18 months if pediatric studies are conducted. These exclusivity provisions do not apply to a license for, or approval of, a supplement to the reference product, including a change that results in "a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength," or a modification to the structure of the product that does not result in a change in safety, purity, or potency. The PPACA also extends the exclusivity time frame for a biological product designated for a rare disease or condition.[12]

A biosimilar that is deemed "interchangeable" will be granted exclusivity until the earlier of (1) one year after the first commercial marketing of the product as interchangeable; (2) 18 months after a final court decision on all patent suits in an action against the applicant, or the dismissal of such suit with or without prejudice; (3) 42 months after approval of the initial application if the applicant has been sued; or (4) 18 months after approval of the initial application if the applicant has not been sued.

---

[11] Sec. 7002(a), amending § 351 of the PHSA (42 U.S.C. § 262(k)(3), (4)).

[12] These products are granted orphan drug designation under section 526 of the FDCA for a rare disease or condition. *See* 21 U.S.C. § 360bb.

Risk Evaluation and Mitigation Strategy

The PPACA permits the Secretary to require applicants to submit a proposed risk evaluation and mitigation strategy (REMS) as part of the application if the Secretary determines that a REMS is necessary to ensure that the benefits of a drug outweigh its risks. FDA was granted authority to require REMS under the Food and Drug Administration Amendments Act of 2007.

Guidance Documents

The PPACA permits the Secretary to issue guidance documents about the biosimilar approval process, and requires that all product class-specific guidance include a description of the criteria the Secretary will use to determine whether a product is "highly similar" (i.e., biosimilar) to, and – if available when the Secretary issues the guidance – interchangeable with, a reference product in the class. The issuance (or non-issuance) of a guidance document will not preclude the review of, or action on, an application. The Secretary may, however, indicate in a guidance document that the current state of science and the Secretary's experience with respect to certain products or product classes (not including recombinant proteins) prevent the Secretary from approving any applications related to such products or product classes.

Patent Issues (Sec. 7002)

The PPACA sets forth provisions governing the exchange of confidential information related to patents for biological products, requires good faith negotiations between the reference-product sponsor and an applicant, and sets forth a complicated scheme for patent infringement lawsuits. The PPACA requires each applicant to provide to the reference-product sponsor and patent owner(s) "confidential access to the application" and any other information the applicant determines, "in its sole discretion, to be appropriate" for the sole and exclusive purpose of determining, with respect to each patent related to the reference product, whether a claim of patent infringement could be reasonably asserted for the biosimilar product (amending section 351 of the PHSA (42 U.S.C. § 262(l)(1)(B)). The PPACA requires the reference-product sponsor and applicant to follow a negotiation process before commencing patent infringement lawsuits. This process has six major steps:

- **Notice**. When the FDA notifies an applicant that the application has been accepted for review, the applicant must provide the reference-product sponsor a copy of the application and "such other information that describes the process or processes used to manufacture" the biosimilar. A sponsor may also provide additional information requested by or on behalf of the reference-product sponsor.
- **Sponsor Patent List**. No later than 60 days after the receipt of the application, the reference-product sponsor must provide the applicant with a list of patents for which the sponsor believes a claim of patent infringement could reasonably be asserted by the

sponsor, and an identification of the patents on this list that the sponsor (or patent owner) would be prepared to license to the applicant.

- **Applicant Response**. No later than 60 days after receipt of the sponsor's patent list, the applicant must provide to the sponsor, with respect to each patent identified by the sponsor: (1) a detailed statement that the patent claim is invalid, unenforceable, or will not be infringed by the commercial marketing of the biosimilar ("detailed statement"); or (2) a statement that the applicant does not intend to begin commercial marketing of the biosimilar before the date that the patent expires. Further, the applicant must respond to any indication that the sponsor is prepared to license specific patents to the applicant. The applicant may provide the sponsor with a list of patents for which the applicant believes a claim of patent infringement is valid.
- **Sponsor Response**. No later than 60 days after receipt of the applicant's patent list and detailed statement, the sponsor must provide a comprehensive response disputing the applicant's detailed statement.
- **Negotiation and Litigation**. The applicant must engage in good faith negotiations to agree on a final and complete list of patents to be litigated. If the parties reach agreement within 15 days of beginning negotiations, the reference-product sponsor must bring an action for patent infringement within 30 days after such agreement. If the parties do not reach agreement within 15 days, the applicant must provide the sponsor with a final list of patents the applicant believes are invalid, unenforceable, or will not be infringed by the marketing of the product. The parties have five days to consider this list before simultaneously exchanging a final list of patents that each respective party believes should be subject to an action for patent infringement. The reference-product sponsor has 30 days to bring an action for patent infringement after this exchange. Applicants must submit to the Secretary copies of any patient complaints filed by the product sponsor within 30 days of receipt of service. The Secretary will publish in the *Federal Register* a notice of the receipt of the complaint(s).
- **Commercial Marketing Notice and Declaratory Judgment Actions**. Applicants must notify reference-product sponsors no later than 180 days before the date of the first commercial marketing of a biosimilar product. Unless the applicant failed to comply with certain provisions of the PPACA (e.g., failing to provide the product sponsor with a copy of the biosimilar application within 20 days of submitting the application to the Secretary for review), the reference-product sponsor must wait until it receives the commercial marketing notice before bringing a declaratory judgment action.

PPACA includes additional penalties for non-compliance with this negotiation and litigation process. A product sponsor may, for example, be prohibited from filing a patent infringement claim if the patent was not included in the initial list of patents exchanged between the parties when they began negotiations.

User Fees and Savings (Sec. 7002-7003)

Beginning not later than October 1, 2010, the PPACA requires that the Secretary develop recommendations for the goals for the review process of biosimilar applications; collect and evaluate data regarding the cost of reviewing such applications; and determine whether to alter the user fee applicable to such applications. The PPACA urges Congress to authorize the collection of user fees as of October 1, 2012.

C. Qualifying Therapeutic Discovery Project Credit

Section 9023 of the PPACA provides for a new credit (Credit), which is contained in section 48D of the Internal Revenue Code (the Code), equal to 50% of eligible costs incurred by small biotech companies in developing new therapies to prevent, diagnose and treat acute and chronic diseases. Some taxpayers may be eligible to elect to receive a cash grant in lieu of the Credit (Cash Grant).

Known as the "qualifying therapeutic discovery project credit," the Credit/Cash Grant program is limited to $1 billion and is only available for taxable years beginning in 2009 and 2010. The Secretary of the Treasury had until May 22, 2010 to establish a program to consider and award certifications to qualifying therapeutic discovery project sponsors. Because it will be a competitive application process, eligible biotech companies will need to move quickly and submit their applications promptly once the Treasury Department issues guidance on the program. Since the Credit/Cash Grant program includes eligible costs incurred in 2009, biotech companies should review their 2009 costs now so that they have the data to complete their applications as soon as program details are released.

Overview of the Credit

Qualifying therapeutic discovery project. The Credit consists of 50% of certain expenses paid or incurred by an eligible taxpayer in taxable years beginning in 2009 and 2010 with respect to any "qualifying therapeutic discovery project." A "qualifying therapeutic discovery project" is a project that is designed either:

- To treat or prevent diseases or conditions by conducting pre-clinical activities, clinical trials, and clinical studies, or by carrying out research protocols, for the purpose of securing approval of a product under section 505(b) of the Food, Drug, and Cosmetic Act, or section 351(a) of the Public Health Service Act
- To diagnose diseases or conditions, or to determine molecular factors related to diseases or conditions, by developing molecular diagnostics to guide therapeutic decisions
- To develop a product, process or technology to further the delivery or administration of therapeutics

Eligible expenses. Expenses eligible for the Credit are those costs paid or incurred during the taxable year for expenses necessary for and directly related to the conduct of the qualifying therapeutic discovery project, but not in excess of the amount certified by the Treasury Secretary as eligible for the Credit. Expenses that are not eligible for the Credit include: any cost for compensation paid to certain high-level executives of a public company, interest expenses, facility maintenance expenses (mortgage or rent payments, insurance payments, utility and maintenance costs, and the cost of maintenance personnel), and so-called "service costs" (departments such as personnel, accounting, data processing, security, legal and other similar departments). The Treasury Secretary may also determine other expenses that are not eligible for the credit.

Eligible taxpayer. An "eligible taxpayer" is any taxpayer that employs not more than 250 employees in all businesses of the taxpayer. All employees within a controlled or affiliated group are counted, as are employees within an affiliated service group for qualified plan purposes. For this reason, some small companies with joint operating arrangements with large pharmaceutical companies may not be eligible.

Cash Grant Option. Many biotech companies have net operating loss carryforwards and therefore will be unable to make immediate use of the Credit. Section 48D allows any eligible taxpayer who applies for certification to elect to receive a Cash Grant in lieu of the Credit amount. As with the Credit, Cash Grants are available only for eligible expenses paid or incurred in taxable years beginning in 2009 and 2010. Cash Grants must be paid by the Treasury Department to the applicant during the 30-day period beginning on the later to occur of the date of the application for the Cash Grant, or the date the eligible expenses are incurred. Cash Grants are not subject to income tax.

Ineligible Taxpayers. Certain taxpayers are not eligible for the Credit or a Cash Grant. These include any federal, state or local government, any tax-exempt organization under section 501(c) of the Code, and certain foreign entities. In addition, any partnership or other pass-through entity, of which any of the foregoing is a partner or other holder of an equity or profits interest, is ineligible for the Cash Grant; however, it may be eligible for the Credit. The partnership rule means that biotech companies who partner with, or who grant a profits interest to, governmental or tax-exempt entities such as universities, will be ineligible for the Cash Grant, but may be eligible for the Credit.

Certification Process. An aggregate of $1 billion in Credits and Cash Grants will be available under the program. To qualify, taxpayers must apply to the Treasury Secretary under an application and certification program that the Treasury Secretary, in consultation with the Secretary of Health & Human Services, is required to adopt on or before May 22, 2010.

In determining which qualifying therapeutic discovery projects will be awarded Credits or Cash Grants, the Treasury Secretary must take into consideration only those projects that show reasonable potential to:

- Result in new therapies that either
  - Treat areas of unmet medical need, or
  - Prevent, detect or treat chronic or acute diseases and conditions
- Reduce long-term health care costs in the United States, or
- Significantly advance the goal of curing cancer within the next 30 years

Additionally, the Secretary must take into consideration which projects have the greatest potential (1) to create and sustain (directly or indirectly) high-quality, high-paying jobs in the United States, and (2) to advance United States competitiveness in the fields of life, biological and medical sciences.

Each applicant for certification must submit an application containing the information required by the Secretary. The Secretary must take action to approve or deny an application within 30 days of the submission of the application. An application may request an allocation of Credits or Cash Grants for both 2009 and 2010.

Until the Treasury Secretary establishes the program and provides more details on the application and selection process, it is not known whether certification will be on a first-come, first-served basis, or some other, more selective basis.

Because the program will be administered under a competitive application process, eligible biotech companies will need to move quickly and submit their applications promptly once the Treasury Department releases details of the program. A similar program for manufacturers of renewable energy property was oversubscribed, and credit availability was exhausted very soon after the program was adopted.

Special Rules

Section 48D contains special rules regarding the interplay of the Credit with other sections of the Code, such as bonus depreciation and the research credit in order to prevent a taxpayer from receiving a double tax benefit. Also, if a Credit or Cash Grant is allowed with respect to depreciable property, the taxpayer must reduce the basis of depreciable property by the full amount of the Credit/Cash Grant. Both the Credit and the Cash Grant are subject to recapture if the technology or other property created as a result of the qualifying therapeutic discovery project is transferred within five years.

IV. Provisions Affecting All Manufacturers

A. Transparency Reports and Reporting of Physician Ownership or Investment Interests

Section 6002 of the PPACA incorporates many of the provisions of the Physician Payment Sunshine Act that Sen. Charles Grassley (R-Iowa) introduced several years ago to encourage greater transparency in the relationships between drug and device companies and physicians.

Beginning March 31, 2013, and annually thereafter, any manufacturer of a covered drug, device, biological or medical supply[13] that provides a payment or other transfer of value to a "covered recipient" – a physician or a teaching hospital – must submit to the Secretary, in electronic form, the following information:

- The covered recipient's name and business address
- If a physician, the physician's specialty and national provider identifier
- The amount of the payment or other transfer of value and the dates on which it was provided to the covered recipient
- A description of the form of the payment or other transfer of value (e.g., cash or cash equivalent, in-kind items or services, stock or stock options)
- A description of the nature of the payment or other transfer of value (e.g., consulting fees, honoraria, gift, entertainment, food, travel, education, research, charitable contribution)
- If the payment or other transfer of value is related to the marketing, education, or research specific to a covered drug, device, biological, or medical supply, the name of such drug, device, biological, or medical supply
- Any other categories of information that the Secretary determines to be appropriate

If a manufacturer provides a payment or other transfer of value to an entity or individual *at the request of or designated on behalf of* a covered recipient, the manufacturer must disclose that payment or other transfer of value under the name of the covered recipient.

In addition, the PPACA requires manufacturers and group purchasing organizations (GPOs) that purchase, arrange for, or negotiate the purchase of covered products to submit to the Secretary certain information regarding ownership or investment interests held by a physician (or an immediate family member of the physician) in the manufacturer or GPO during the preceding year. This reporting requirement does not include a physician's ownership or investment interest in a publicly traded security and mutual fund.

[13] A "covered drug, device, biological, or medical supply" is any product for which payment is available under a federal health care program, such as Medicare or Medicaid.

Beginning September 30, 2013, and on June 30 of each year thereafter, the Secretary will make all payment, ownership interest, and enforcement information publicly available on the Internet via a searchable website.

That said, the PPACA provides for delayed publication of payments made under product research or development agreements, and for clinical investigations. Specifically, for payments or other transfers of value made to covered recipients under product research or development agreements for services furnished in connection with research on a potential new medical technology; or a new application of an existing technology; or the development of a new drug, device, biological, or medical supply; or in connection with a clinical investigation of a new drug, device, biological, or medical supply—the information will not be made available to the public until the earlier of the following: the date of FDA approval or clearance of the product; or four calendar years after the date such payment or other transfer of value is made.

The definition of "payment or other transfer of value" does not include the following, and as such, these items do not need to be reported to the Secretary:

- Payments or transfers of value of less than $10, unless the aggregate amount transferred to, requested by, or designated on behalf of the covered recipient by the manufacturer during the calendar year exceeds $100 (adjusted annually for inflation)
- Product samples that are not intended to be sold and are intended for patient use
- Educational materials that directly benefit patients or are intended for patient use
- Loan of a covered device for a short-term trial period, not to exceed 90 days
- Items or services provided under a contractual warranty, where the terms of the warranty are set forth in the purchase or lease agreement for the covered device
- A transfer of anything of value to a covered recipient when the covered recipient is a patient and not acting in his or her professional capacity
- Discounts and rebates
- In-kind items used for the provision of charity care
- A dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security and mutual fund
- In the case of a manufacturer who offers a self-insured plan, payments for the provision of health care to employees under the plan
- In the case of a covered recipient who is a licensed non-medical professional, a transfer of anything of value to the covered recipient if the transfer is payment solely for the non-medical professional services of such licensed non-medical professional
- Compensation paid by a manufacturer to a covered recipient who is directly employed by and works solely for that manufacturer or distributor

The penalties for failure to report include civil monetary penalties of not less than $1,000, but not more than $10,000, for each payment or other transfer of value or ownership or investment interest that is not reported (not to exceed $150,000). A "knowing" failure to report will result in

even higher penalties. Funds collected by the Secretary as a result of the imposition of a civil monetary penalty will be used to carry out this law.

Not later than October 11, 2011, the Secretary shall establish procedures for manufacturers and GPOs to submit information to the Secretary and for the Secretary to make such information available to the public. In addition, effective January 1, 2012, this law will preempt any state laws that require a manufacturer to disclose or report the type of information described above regarding payments or other transfers of value made to covered recipients. However, the law will *not* preempt any state laws that require the disclosure or reporting of information that falls outside of the scope of the above requirements.

Currently, five states – Maine, Massachusetts, Minnesota, Vermont and West Virginia, as well as the District of Columbia – have enacted unique laws regarding the financial arrangements between drug and/or device companies and health care professionals. Other states, such as California and Nevada, require companies to adopt a marketing code of conduct, which is not addressed at all in the PPACA. This means that companies will have to continue to report certain expenditures and make compliance certifications to state authorities.

Most significantly, the new law applies only to payments or other transfers of value to physicians and teaching hospitals, whereas many of the state laws cover payments made to a broad range of individuals and entities, including hospitals, nursing homes, pharmacists, and all individuals authorized to prescribe, dispense, or purchase prescription drugs or medical devices. In addition, while under the federal law many items are exempt from the reporting requirements, such as loans of medical devices and charitable contributions, some states, such as Vermont, require that these types of interactions with covered recipients be disclosed.

B. Comparative Clinical Effectiveness Research

Section 6301 establishes a private, nonprofit corporation to be called the Patient–Centered Outcomes Research Institute (PCORI or Institute), governed by a public-private Board of Governors appointed by the Comptroller General, to include the Director of NIH and the Director of the Agency for Healthcare Quality and Research. The Institute will identify national priorities for comparative effectiveness research, taking into account, among other factors, disease incidence, burden, gaps in clinical evidence, and "the effect on national expenditures" of a health care treatment strategy. The Institute's work will be transparent, with the public afforded an opportunity to comment on the research agenda, as well as on published reports of research. In addition, CMS may use the research findings of the Institute in making coverage decisions only through a transparent process that includes public comment. The Institute will carry out the comparative effectiveness research agenda through contracts with existing federal agencies, academic research centers, and the private sector.

The research to be pursued is completely open-ended and will include studies to measure the comparative clinical effectiveness, risks and benefits of: health care interventions, treatment

protocols, medical devices, drugs, biologics, and any other treatments or strategies being used in prevention, diagnosis, or management of illness and injury. One specific enhancement to the authority of the Institute is access to the claims data collected by CMS. Researchers have long maintained that the Medicare Parts A, B, C and D claims databases contain highly valuable information – for example, on disease occurrence and effectiveness measured by inpatient readmission – that has never been mined and developed. In addition, the Institute will have authority to allow research organizations to pay copayments and coinsurance for study subjects to facilitate a blinded study, or to otherwise preserve the integrity of the protocol.

The activities of PCORI will be paid for by a tax on insurance policies of $2 per covered life beginning in 2012. The CBO estimates that the tax would raise $2.6 billion through 2019.

Finally, upon the enactment of the Act, section 6302 terminates the prior authority to create the "Federal Coordinating Council for Comparative Effectiveness Research" contained in ARRA.

C. Cures Acceleration Network (CAN)

Section 10409 of PPACA requires that NIH establish a CAN within the Office of the Director of NIH. CAN will conduct and support "revolutionary advances" in basic research, and will award grants and contracts, and provide resources necessary to accelerate the development of "high need cures," including through the development of medical products and behavioral therapies. High-need cures are defined as drugs, devices, or biological products that NIH determines are a priority to diagnose, mitigate, prevent or treat harm from a disease or condition, and for which commercial incentives are unlikely to result in adequate or timely development. In addition to awarding grants and contracts to accelerate development of high-need cures, CAN will reduce barriers between lab discoveries and clinical trials for new therapies, help interested parties utilize technical assistance available under the federal Food, Drug, and Cosmetic Act, and facilitate regular and ongoing communication and coordination with FDA to expedite the development and approval of high-need cures.

NIH will award contracts, grants, or cooperative agreements under CAN to eligible entities, which include biotechnology companies, pharmaceutical companies, private or public research institutions, institutions of higher education, medical centers, patient advocacy organizations, or academic research institutions. Grants will be awarded to promote innovations that support advanced research and development and production of high-need cures; accelerate the development of high-need cures; or help establish FDA-compliant protocols. Awards will not be more than $15 million per project for the first FY for which the project is funded; additional funding in subsequent FYs can be applied for. Initial appropriations of $500 million are authorized for FY 2010.

The CAN Review Board, which will advise and provide recommendations to the Director of NIH on the activities of CAN, will be comprised of 24 members serving four-year terms. Review Board members will represent the fields of basic research, medicine,

biopharmaceuticals, discovery and delivery of medical products, bioinformatics and gene therapy, medical instrumentation, regulatory review and approval of medical products, and disease advocacy organizations, as well as venture capital or private equity organizations. Ex-officio members will include representatives from NIH, the Department of Defense Office of Health Affairs, the Veterans Administration, the National Science Foundation, and FDA.

V. Conclusion

We will continue to keep you posted on developments in this area. In the meantime, please call us with any questions.

Contributors

Elizabeth Carder-Thompson
+1 202 414 9213 (Washington)
ecarder@reedsmith.com

Carol C. Loepere
+1 202 414 9216 (Washington)
cloepere@reedsmith.com

Debra McCurdy
+1 703 641 4283 (Falls Church)
dmccurdy@reedsmith.com

Jennifer A. Goldstein
+1 202 414 9237 (Washington)
jgoldstein@reedsmith.com

Robert J. Hill
+1 202 414 9402 (Washington)
rhill@reedsmith.com

Kevin M. Madagan
+1 202 414 9236 (Washington)
kmadagan@reedsmith.com

Joseph W. Metro
+1 202 414 9284 (Washington)
jmetro@reedsmith.com

If you have questions or would like additional information on the material covered in this Alert, please contact one of the contributors or the Reed Smith lawyer with whom you regularly work.