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For more information, contact:

**Laura Loeb**

+1 (202) 661 7836  
lloeb@kslaw.com

**Beverly Lorell, M.D.**

+1 (202) 383 8937  
blorell@kslaw.com

**Seth Lundy**

+1 (202) 626 2924  
slundy@kslaw.com

**Chris Markus**

+1 (202) 626 2926  
cmarkus@kslaw.com

**Josh O'Harra**

+1 (202) 626 5582  
jo'harra@kslaw.com

**John D. Shakow**

+1 (202) 626 5523  
jshakow@kslaw.com

**Elaine Tseng**

+1 (415) 318 1240  
etseng@kslaw.com

**King & Spalding  
Washington, D.C.**

1700 Pennsylvania Avenue, NW  
Washington, D.C. 20006-4707  
Tel: +1 (202) 737 0500  
Fax: +1 (202) 626 3737

**San Francisco**

101 Second Street, Suite 2300  
San Francisco, CA 94105  
Tel: +1 (415) 318 1200  
Fax: +1 (415) 318 1300

[www.kslaw.com](http://www.kslaw.com)

**Passage of Health Care Reform:  
Key Provisions Impacting Manufacturers of  
Pharmaceuticals, Biologics and Devices**

On March 23, 2010, President Obama signed into law historic changes to our nation's health care system. The new law, P.L. 111-148, H.R. 3590 (available by clicking [here](#)), passed the Senate on December 24, 2009 with the votes of all 60 Democratic Senators and no Republican support. The House passed the legislation on March 21, 2010 by a vote of 219 to 212, again with no Republican support.

On that same day, the House also passed a budget reconciliation bill, H.R. 4872, by amendment in the nature of a substitute to that bill (available by clicking [here](#)), that contains significant changes to the health care reform law. These changes were necessary to garner the requisite support in the House for the reform legislation. The Senate is considering the House-passed reconciliation bill this week, with a vote slated for the end of this week.

The Senate, in following the so-called Byrd rule, must drop any provision from a budget reconciliation bill that fails to have a budgetary impact or that affects the Social Security trust fund. The Senate Parliamentarian will make a determination on any Byrd rule challenge raised. Sixty votes may waive a Byrd rule point of order. Because Democrats lack 60 members in the Senate, it appears almost impossible for them to muster the 60 votes to keep extraneous provisions in the bill. Even a one-word change to the reconciliation bill by the Senate would mean the House would have to vote again on the revised bill.

However, policy analysts believe that no provisions significant to manufacturers will be stripped from the Senate reconciliation package and that the House would approve any minor changes to the reconciliation bill that the Senate might be forced to make under the Byrd rule.

Provisions included in the health care reform bill signed into law and the reconciliation legislation passed by the House and pending before the Senate which are of importance to manufacturers of pharmaceuticals, biologics, and devices are described below.



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Certainly, overarching provisions already signed into law as part of health care reform, such as the Comparative Effectiveness Research Institute, established outside of the Department of Health and Human Services (DHHS), the increased prominence of value-based purchasing and quality and efficiency measures, as well as the new efforts at bundled payments, all will have a significant impact on manufacturers. Lawyers and consultants from King & Spalding will discuss these issues, as well as the specific issues listed below during an audioconference for life science manufacturers on April 9. A separate invitation/registration form will be disseminated next week regarding this briefing. As always, personnel at King & Spalding are happy to discuss any questions you might have in this area.

**I. Physician Payment Transparency Reporting (Physician Payment Sunshine Act)**

Section 6002 of the new law requires pharmaceutical, biologic, and medical device manufacturers to annually report to the DHHS payments and other transfers of value furnished to physicians and teaching hospitals (deemed “covered recipients”). In addition, the law requires manufacturers and group purchasing organizations (GPOs) to report ownership or investment interests held by a physician in the reporting manufacturer or GPO. The first such transparency reports are due by March 31, 2013, for a reporting period of calendar year 2012. Reports for subsequent years will be due by the 90th day of each calendar year, for a reporting period of the previous calendar year.

Beginning January 1, 2012, this provision will preempt any state statute or regulation that requires life sciences manufacturers to report the type of information required under the federal reporting requirements. The law, however, will not preempt state reporting requirements that require life sciences manufacturers to disclose types of information excluded from the federal obligations (*e.g.*, educational materials), nor requirements to disclose payments to covered recipients that manufacturers are not required to report under federal obligations (*e.g.*, nurses).

Specifically, the new federal law requires life sciences manufacturers to report certain information regarding anything of value furnished to a covered recipient, unless specifically excluded by the law. Such express exclusions include, *inter alia*: payments made indirectly to a covered recipient through a third party where the manufacturer does not know the identity of the covered recipient; anything less than \$10 in value, unless the aggregate payments or transfers of value during the calendar year to the particular covered recipient exceed \$100 in value; product samples intended for patient use; certain educational materials; loans of a medical device for a short-term trial period; certain items or services provided under a contractual warranty; discounts and rebates; in-kind items used in the provision of charity care; and dividends and investment interest in a publicly traded security or mutual fund.

For each reportable payment or other transfer of value a manufacturer furnishes to a covered recipient, the manufacturer must disclose to DHHS, *inter alia*: the name of the covered recipient; the business address of the covered recipient; the amount of the payment or transfer of value; a description of the form of the payment or transfer of value (*e.g.*, cash, in-kind item, stock, etc.); a description of the nature of the payment or transfer of value (*e.g.*, consulting fees, food, travel, etc.); the name of the product to which the payment relates (if the payment is related to a specific product); and any other category of information the Secretary of DHHS deems appropriate.



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In addition, the law requires manufacturers and GPOs to report certain information regarding any ownership or investment interest held by a physician (or his/her immediate family member) in the reporting manufacturer or GPO. Specifically, manufacturers and GPOs must provide: the dollar amount invested by each physician holding such an interest; the value and terms of each such interest; information regarding any payment or other transfer of value provided to a physician holding such an interest; and any other information the Secretary of DHHS deems appropriate.

Importantly, beginning September 30, 2013, DHHS will render information manufacturers and GPOs submit in transparency reports publicly available through a searchable website that is clear and understandable. Payments or other transfers of value to covered recipients pursuant to product research or development agreements, or in connection with clinical investigations, are subject to delayed publication on the website—specifically, publication is delayed until the reporting period after the earlier of (1) the date of the approval or clearance of the product or (2) four calendar years after the date of the payment. In addition to detailed information on payments and ownership interests, the web site will contain a description of enforcement actions taken, background information on industry-physician relationships, and other information the Secretary of DHHS believes would be helpful to the average consumer.

Manufacturers that fail to disclose reportable payments, transfers of value, or ownership interests, will be subject to a civil money penalty of not less than \$1,000, nor more than \$10,000, for each payment, transfer of value, or ownership interest not reported. “Knowingly” failing to report will subject a manufacturer to a civil money penalty of not less than \$10,000, nor more than \$100,000, for each payment, transfer of value, or ownership interest not reported.

## **II. Manufacturer Taxes**

Section 1405 of the House-passed reconciliation bill would implement in 2013 a 2.9% excise tax on the first sale for use of certain medical devices. However, devices such as Class I devices, eyeglasses, contact lenses, hearing aids, and any device of a type that is generally purchased by the public at retail for individual use would be exempt. The new health care reform law would implement an industry fee in 2011.

Section 1404 of the House-passed reconciliation bill would delay the tax on drug manufacturers and importers by one year to 2011 and would increase the revenue raised by the fee by \$4.8 billion from the pharmaceutical industry’s voluntary agreement with the Senate Finance Committee and White House, which was included in the new reform law. That agreement was for \$2.3 billion per year for a 10-year period to total \$23 billion. The fee included in the House-passed reconciliation bill would go into effect in 2011 and would be assessed based on market share. The fee in the reconciliation bill would total \$2.5 billion in 2011 and increase each year reaching \$4.1 billion in 2018, and then in 2019 and thereafter being \$2.8 billion annually.



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**III. Payment for Advanced Imaging Services**

The 2010 final rule for payments to providers under the Medicare physician fee schedule, as published in the *Federal Register* on November 25, 2009, uses an assumption in valuing imaging services that advanced imaging equipment (such as MRI and CT scanners) are being used 90% of the time (as opposed to 50% in prior years). This utilization rate was derived from the Medicare Payment Advisory Council (MedPAC) recommendation based on studies that surveyed the actual use of the equipment in hospital outpatient and freestanding settings.

Section 3135 of the new law changes the utilization rate assumption for calculating the payment for advanced imaging equipment from 50% to 65% for 2010 through 2012. Thus, the 90% rate in the *Federal Register* will not be implemented. The rate would have further increased to 70% for services provided in 2013 and 75% for services provided in 2014 under the new law. However, Section 1107 of the House-passed reconciliation bill sets the utilization rate at 75% in 2011 and in subsequent years. So, assuming that the reconciliation bill passes the Senate, the 50% current utilization rate will continue throughout 2010 and be changed to 75% in 2011 and in subsequent years.

**IV. Enhanced Fraud and Abuse Provisions for Durable Medical Equipment (DME) Suppliers**

The new law includes a provision that would provide the Secretary with the authority to impose enhanced screening and oversight measures on providers enrolling and re-enrolling in Medicare. Section 1305 of the House-passed reconciliation bill would require the Secretary to withhold payment to DME suppliers for 90 days in instances where the Secretary determines that there is a significant risk of fraud.

**V. Changes to the Medicare Part D Outpatient Prescription Drug Benefit**

Medicare law establishes a defined standard benefit package under the Part D prescription drug benefit that includes a gap in coverage, commonly referred to as the “doughnut hole.” For 2010, the standard benefit includes a \$310 deductible and a 25% coinsurance until the Medicare beneficiary reaches \$2,830 in total covered drug spending (Medicare and beneficiary spending combined). After this initial coverage limit is reached, the beneficiary is responsible for the full cost of drugs until total costs hit the catastrophic threshold, which is \$6,440 in 2010. In general, in 2010, Part D enrollees who do not receive assistance in the form of the Part D low-income subsidy would be responsible for a total of \$4,550 in out-of-pocket costs before reaching the catastrophic coverage phase (\$310 deductible, \$630 in co-insurance in the initial coverage phase, and \$3,610 in the coverage gap).

The new law in Section 3301 makes a number of changes to the Medicare Part D program including requiring that beginning in 2010, drug manufacturers provide certain Part D enrollees with discounts of 50% for brand name drugs during the coverage gap. Plan enrollees who are either receiving the low-income subsidy, enrolled in an employee-sponsored retiree drug plan, or have annual incomes that exceed the Part B income thresholds, as determined under current law (\$85,000 for singles and \$170,000 for couples in 2009), would not be eligible for the discount. The new law also would increase the initial coverage limit by \$500



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in 2010 (Section 3315). This 50% brand name drug discount is consistent with the voluntary agreement that the White House and Finance Committee reached with the pharmaceutical industry.

Section 1101 of the House-passed reconciliation bill would repeal Section 3315 of the new law (H.R. 3590), and instead of increasing the coverage limit by \$500, the reconciliation bill would provide rebates of \$250 to Part D enrollees who enter the doughnut hole in 2010. Additionally, under the reconciliation bill the discount begins January 1, 2011 instead of July 1, 2010, and higher-income enrollees are eligible to receive the discount. The reconciliation bill also would phase out the Part D coverage gap by gradually reducing the amount of enrollee cost sharing for both generic and brand name drugs through the coverage gap. In 2020 and beyond, beneficiary cost sharing would equal or be actuarially equivalent to 25%. The beneficiary co-payments and the value of the manufacturer discount for brand name drugs would count towards the calculation of Part D enrollees' out-of-pocket costs in determining when the catastrophic coverage threshold would be reached, and the Medicare-covered portion would not be included in this calculation.

### **VI. Biosimilarity Pathway with 12-Year Exclusivity for Branded Products**

**Biosimilarity.** The new law creates a pathway for the approval of biosimilar and interchangeable biological products under the Public Health Service (PHS) Act. The law permits applicants to establish biosimilarity to an approved biological product, known as a “reference product.” Biosimilarity means “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 applicant must submit information demonstrating biosimilarity based on data derived from:

- analytical studies demonstrating the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components;
- animal studies (including the assessment of toxicity); and
- a clinical study or studies sufficient to demonstrate safety, purity, and potency in one or more appropriate conditions of use for which the reference product is licensed and intended to be used and for which licensure is sought for the biological product.

In addition, an application submitted under this subsection must include information demonstrating that:

- the biological product utilizes the same mechanism(s) of action as the approved reference product for the condition or conditions of use prescribed, recommended, or suggested in the product label;
- the condition(s) of use prescribed, recommended, or suggested in the labeling proposed for the biological product have been previously approved for the reference product;
- the route of administration, the dosage form, and the strength of the biological product are the same as those of the reference product; and



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- the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent.

An application shall also include publicly-available information regarding the previous determination of the reference product's safety, purity and potency. However, the new law also grants FDA the authority to waive, at its discretion, any or all of the above requirements, if it deems them unnecessary to demonstrate biosimilarity. The law provides little in the way of guidance or limits on FDA's determination to waive these requirements.

**Interchangeability**. The new law also provides a pathway for biosimilar products to be approved as interchangeable with a reference product and, thus, to be substituted by a pharmacist for the reference product without specific authorization from the patient or prescriber. This determination carries tremendous significance, yet the law again provides little guidance regarding the approval requirements for interchangeable products. The law states only that FDA shall determine a biological product interchangeable if it is biosimilar to the reference product; it can be expected to produce the same clinical result; and the risk in terms of safety or diminished efficacy from switching between the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch.

**Innovator Exclusivity**. The new law provides an exclusivity period for the first interchangeable biological product approved. To counterbalance the new biosimilars pathway, the bill provides a 12-year exclusivity period for reference products, starting from the date on which the reference product was first licensed. The exclusivity period precludes FDA from making effective any approval of a biosimilar citing the reference product until the period expires. The bill defines first licensure to exclude supplemental approvals for a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength, or modifications to the structure of the biological product that do not result in a change in safety, purity, or potency.

The statutory amendments permit an additional 6-month period of exclusivity to be granted for pediatric studies under certain circumstances.

**Patent Challenges**. The new law establishes specific procedures and timelines according to which biosimilar applicants and reference product sponsors must exchange patent information and engage in patent resolution negotiations before an infringement lawsuit is commenced. Additionally, the law provides for prior notice to reference product sponsors of a biosimilar applicant's intent to begin commercial marketing, and allows reference product sponsors an opportunity to seek a preliminary injunction against such marketing. The law also prescribes conditions under which biosimilar applicants or reference product holders would or would not be entitled to seek declaratory judgments.

**Other Matters**. The new law also addresses other issues, including user fees for biosimilar applications and a transitional period to bring biosimilars approved under the Federal Food, Drug, and Cosmetic Act within the newly established PHS Act pathway.



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### VII. Government Price Reporting for Drugs and Biologics

The new law and House-passed reconciliation bill contain provisions that dramatically impact Medicaid government price reporting, Medicaid rebate calculation, and the scope and operation of the 340B drug discount program.

Drug and biologics manufacturers will have to undertake significant implementation measures, chiefly with respect to the determination of Average Manufacturer Price (AMP). The statutory changes to this critical metric will affect Medicaid rebate liability, 340B prices, and reimbursement amounts (for multiple source drugs).

Drug manufacturers will likely see their Medicaid rebate obligations rise under the new law. The basic rebate percentages go up 50% for most innovator drugs, line extensions will bear a heavier burden, and Medicaid managed care utilization will be subject to rebates. The changes in AMP will very likely lead to higher unit rebate amounts (URAs). A URA cap may mitigate these effects in extreme circumstances.

Also important is the virtual overhaul of the 340B program. The new law expands the number of eligible Covered Entities, calls for the creation of a mechanism by which overpayments (of any size or origin) must be reconciled, and creates new integrity obligations covering all participants in the program.

The following summary of the key pricing provisions will give government pricing and legal personnel direction in forecasting implementation and impact.

#### Effective January 1, 2010

- ***Increased Minimum Medicaid Rebate Amount For Innovator Drugs.*** The new law establishes a new minimum basic Medicaid rebate amount of 23.1% of AMP for most innovator drugs. Under current law, the basic rebate amount is 15.1%. *Section 2501(a)(1)(A).*
- ***Increased Medicaid Rebate Amount For Non-Innovator Drugs.*** The new law establishes a new Medicaid rebate amount of 13% of AMP for non-innovator drugs. Under current law, the rebate amount is 11%. *Section 2501(c).*
- ***Increased Medicaid Rebate Amount For Clotting Factors and Pediatric Drugs.*** The new law grants favorable treatment to certain clotting factors and drugs with only a pediatric indication by subjecting them to rebates of 17.1% of AMP. *Section 2501(a)(1)(B).*
- ***Alternative Medicaid Unit Rebate Amounts for Line Extensions.*** The House-passed reconciliation bill requires a potential substitute Medicaid rebate calculation for “line extensions” of oral solid dosage forms of innovator products. For these products, the Medicaid rebate will be the greater of (a) the usual calculation or (b) AMP times the highest additional rebate for any strength of the original expressed as percentage of AMP. It is unclear in the statute how this alternative calculation will actually be undertaken. *Section 1206 of the House-passed reconciliation bill.*



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- **Maximum Medicaid Unit Rebate Amounts.** The new law creates a maximum Medicaid unit rebate amount (basic rebate plus the additional rebate) for innovator drugs at 100% of AMP. It is unclear from the statute from which periodic AMP will be used as the basis for a cap is to be drawn, but one suspects it is the AMP for the reporting quarter. *Section 2501(e).*
- **New 340B Covered Entities.** The new law expands the universe of 340B Covered Entities to include certain (a) children’s hospitals (b) free standing cancer hospitals, (c) critical access hospitals, (d) rural referral centers, and (e) sole community hospitals. *Section 7101(a).*
- **Exclusion Of Orphan Drugs For Certain Covered Entities.** For the new Covered Entities added above, the term “covered outpatient drug” would not include a drug designated for rare conditions by the Secretary under section 526 of the Federal Food, Drug, and Cosmetic Act under the House-passed reconciliation bill. *Section 2302 of the House-passed reconciliation bill.*
- **340B Integrity Provisions: Quarterly Manufacturer Reporting.** The reform bill requires the development of a system that will permit the Secretary (presumably the Health Resources and Services Administration, “HRSA”) to verify the accuracy of ceiling prices. To this end, the HRSA must publish “precisely defined” standards for the calculation of ceiling prices; regularly compare HHS-calculated ceiling prices with those reported quarterly by manufacturers; perform “spot checks” of sales to Covered Entities; and investigate and resolve pricing discrepancies. *Section 7102(a).*
- **340B Integrity Provisions: Refunding Overpayments.** The new law also includes integrity provisions to require manufacturers to issue refunds to Covered Entities that are overcharged by the manufacturers and to explain why and how the overcharge occurred, how the refunds will be calculated, and to whom the refunds will be issued. HRSA must then ensure that the refunds are issued accurately and within a reasonable period of time, both in routine instances of retroactive adjustment to relevant pricing data and in exceptional circumstances such as erroneous or intentional overcharges for covered drugs. *Section 7102(a).*
- **340B Integrity Provisions: Posting 340B Prices.** The new law calls for the establishment of a password-protected website that will permit Covered Entities to view verified 340B ceiling prices, presumably in real time. *Section 7102(a).*
- **340B Manufacturer Compliance Provisions: Audit Rights and Penalties.** The new law permits HRSA to selectively audit manufacturers’ and wholesalers’ compliance with the requirements of the 340B program. It also grants HRSA the authority to impose civil monetary penalties (not to exceed \$5,000 for each instance of overcharging a Covered Entity) in the event of knowing and intentional overcharges. *Section 7102(a).*
- **Medicaid Prescription Drug Rebates for Medicaid Managed Care Organizations.** The reform bill extends Medicaid rebate liability to drugs dispensed to Medicaid Managed Care beneficiaries. This provision also requires Medicaid MCOs to report their drug utilization to States and the States to report these data to CMS. **Note:** It is unclear from the new law whether



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this provision will be effective retroactively to January 1, 2010 or if it will take effect on the date of enactment. *Section 2501(c)*.

**Effective October 1, 2010<sup>1</sup>**

- ***Establishment of the Federal Upper Limit (FUL)***. Under the reform bill, the FUL for multiple source drugs will be 175% of the average of monthly AMPs weighted by manufacturer utilization for drug products that are “available for purchase by retail community pharmacies on a nationwide basis.” This provision also calls for CMS to implement a smoothing process for AMP that is similar to the smoothing used for Medicare Average Sales Price (ASP). This requirement, on its face, appears redundant of the existing 12-month rolling average methodology of 42 CFR 447.504, and it is unclear whether such a mechanism would apply to single- as well as multiple-source drugs. *Section 2503(a)(1)*.
- ***Definition of Multiple Source Drug***. The new law modifies the definition of multiple source drug by omitting the requirement that a drug be listed in a pricing compendium that publishes AWP. Instead, products with at least one pharmaceutically equivalent or bioequivalent competitor marketed in the United States will be defined as a “multiple source drug.” *Section 2503(a)(3)*.
- ***Definition of Average Manufacturer Price (AMP)***. Under the reform bill, AMP is redefined to include only the prices received from (a) wholesalers distributing to retail community pharmacies and (b) retail community pharmacies purchasing directly. *Section 2503(a)(2)(A)*.
- ***Definition of Retail Community Pharmacy (RCP)***. A “retail community pharmacy”(“RCP”) is (a) an independent pharmacy, a chain pharmacy, a supermarket pharmacy, or a mass merchandiser pharmacy (b) that is licensed as a pharmacy by the State and that (c) dispenses medications to the general public (d) at retail prices. What exactly is meant by “general public” and “retail prices” is not explained in the statute and will be subject to interpretation. RCPs do NOT include mail order pharmacies, nursing home pharmacies, long-term care facility pharmacies, hospital pharmacies (presumably both inpatient and outpatient), clinics, charitable pharmacies, government pharmacies, or PBMs. This narrowed definition of AMP-eligible pharmacies excludes (traditionally discounted) mail order, which may have the effect of raising AMP for many drugs. *Section 2503(a)(4)*.
- ***Definition of Wholesaler***. The reform bill narrows the definition of “wholesaler” from the way it was very broadly defined in the AMP regulations at 42 CFR 447.504(f). Under the reform bill, a wholesaler is an entity that actually conducts wholesale distribution of drugs, including manufacturers, repackagers, chain drug warehouses and distributors. *Section 2503(a)(4)*.

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<sup>1</sup> The effective date of these provisions is actually “the first day of the first calendar year quarter that begins at least 180 days after the date of enactment of this Act, without regard to whether or not final regulations to carry out such amendments have been promulgated by such date.” If this bill is enacted before April 1, 2010, then October 1, 2010 is the effective date.



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- **Payments Excluded from AMP.** The new law expands the list of statutory exclusions from AMP. It continues to exclude customary prompt pay discounts paid to wholesalers (the law is silent with respect to customary prompt pay discounts paid to RCPs who make direct purchases). The reform law excludes *bona fide* service fees paid to wholesalers and RCPs, and gives examples of services that are potentially *bona fide*: distribution services, inventory management agreement services, stocking allowances and administrative services. Reimbursement for recalled, expired, damaged, and returned goods is excluded from AMP, as are the associated costs. PBM, MCO, HMO, insurer, hospital, clinic, mail order, LTC and manufacturer price concessions (and where appropriate payments) are all excluded from AMP. Finally, discounts under § 1860D-14A (*i.e.*, the Medicare coverage gap discount program) are now officially out of AMP and Best Price. All other discounts to wholesalers and retail community pharmacies will be included in AMP. *Sections 2503(a)(2)(C), 2503(a)(2)(B) of the new law and Section 1101(c) of the House-passed reconciliation bill.*
- **AMP Disclosures to the Public.** The new law changes the current (but currently enjoined) requirement that CMS post AMPs for multiple source drugs on a public website to a requirement that it disclose the “weighted average of the most recently reported monthly” multiple source AMPs on-line. This change also requires manufacturers to report to CMS the total number of units used to calculate the monthly AMP for covered multiple source outpatient drugs so CMS may perform weighting. *Section 2503(b).*

### **VIII. Significant Provisions NOT in New Law or Reconciliation Bill**

- Creating a national registry of medical devices for all Class III and implantable, life-sustaining Class II products;
- Allowing DHHS to negotiate with drug manufacturers regarding Medicare Part D prices;
- Extending Medicaid rebates into Medicare Part D; and
- Banning patent settlements in which a company with a brand-name drug pays a company with a generic drug to delay marketing
- Expansion of 340B to inpatient.

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