Pharmaceutical and Medical Device Provisions in Pending Senate Health Care Legislation

The health care reform bill currently under discussion by the full Senate, The Patient Protection and Affordable Care Act, includes numerous provisions that would directly impact drug and device manufacturers. The most important of these provisions are grouped into topical categories and briefly summarized below. None of these provisions are yet law, and the legislation is sure to be amended during Senate floor action and, if passed, and must be reconciled with the House bill before it is sent to the president for approval.

**Medicare**

**Medicare coverage gap discount program.** Requires drug manufacturers to provide a 50 percent discount to Part D beneficiaries for brand-name drugs and biologics purchased during the coverage gap beginning July 1, 2010. Sec. 3301.

**Improving formulary requirements for prescription drug plans and MA-PD plans with respect to certain categories or classes of drugs.** Codifies the current six classes of clinical concern, removes the current criteria that would have been used by Health and Human Services (HHS) to identify protected classes of drugs and gives the HHS Secretary authority to identify classes of clinical concern through rulemaking. Sec. 3307.

**Office of the Inspector General studies and reports.** Requires the OIG to conduct a study comparing prescription drug prices paid under the Medicare Part D program to those paid under state Medicaid programs. Sec. 3313.

**Immediate reduction in coverage gap for 2010.** Increases the initial coverage limit in the standard Part D benefit by $500 for 2010. Sec. 3315.

**Amendments to prohibition on physician referrals for hospitals.** Prohibits physician-owned hospitals that do not have a provider agreement prior to February 1, 2010, from participating in Medicare. Such hospitals that have a provider agreement prior to February 1, 2010, could continue to participate in Medicare under certain requirements addressing conflict of interest, bona fide investments, patient safety issues and expansion limitations. Sec. 6001.

**Medicaid**

**Prescription drug rebates.** The flat rebate for single source and innovator multiple source outpatient prescription drugs would increase from 15.1 percent to 23.1 percent, except the rebate for clotting factors and outpatient drugs approved by the Food and Drug Administration exclusively for pediatric indications would increase to 17.1 percent. The basic rebate percentage for multi-source, non-innovator drugs would increase from 11 percent to 13 percent. Drug manufacturers also would be...
required to pay rebates for drugs dispensed to Medicaid beneficiaries who receive care from a Medicaid managed care organization (MCO). Total rebate liability would be limited to 100 percent of the average manufacturer price (AMP). Additional revenue generated by these increases will be remitted to the federal government. Sec. 2501.

**Elimination of exclusion of coverage of certain drugs.** Beginning with drugs dispensed on January 1, 2014, smoking cessation drugs, barbiturates and benzodiazepines would be removed from Medicaid’s excludable drug list. Sec. 2502.

**AMP.** Amends the AMP definition to include only sales to wholesalers for drugs distributed to retail community pharmacies, and direct sales to retail community pharmacies. Definition would exclude prompt pay discounts, as under current law, and (1) bona fide service fees (including distribution service fees and product stocking allowances); (2) reimbursement for returned goods; (3) direct sales or rebates to PBMs, HMOs, managed care organizations, insurers, hospitals, clinics, mail order pharmacies, long term care providers, manufacturers or any other entity that does not conduct business as a wholesaler or community retail pharmacy. Revises the definition of “wholesalers” and provides that discounts, rebates, payments or other transactions received from the manufacturer by, or passed through to, community retail pharmacies would be includable in AMP. Community retail pharmacies would not include mail order pharmacies or long-term care pharmacies. Sec. 2503.

**AMP Disclosure.** DRA provision authorizing HHS to disclose manufacturer AMPs on a Web site would be amended to permit only disclosure of “weighted” AMP. Sec. 2503.

**Pharmacy reimbursement.** Requires the HHS Secretary to calculate the federal upper limit as no less than 175 percent of the weighted average (determined on the basis of utilization) of the most recently reported monthly average manufacturer prices for pharmaceutically and therapeutically equivalent multiple source drugs available nationally through commercial pharmacies. Sec. 2503.

**340B Program**

**Expanded participation in 340B program.** Extends the 340B discounts to inpatient drugs and also extends participation to certain children’s hospitals, cancer hospitals, critical access and sole community hospitals, and rural referral centers. Sec. 7101.

**Improvements to 340B program integrity.** Manufacturers would be required to submit to HHS quarterly reports of 340B ceiling prices and the components used to calculate them. The bill also would expand the compliance oversight authority of HHS by authorizing the HHS Secretary, among other things, to publish standards for, and verify the accuracy of, manufacturer 340B ceiling price calculations; establish procedures for manufacturers to refund overcharges; publish 340B prices on a database accessible only to covered entities and state Medicaid agencies; audit manufacturers and covered entities; establish an administrative dispute resolution process; and issue regulations establishing civil monetary penalties for knowing and intentional violations by manufacturers, which may not exceed $5,000 per violation. Sec. 7102.

**GAO study on 340B program.** Requires the GAO to make recommendations to Congress within 18 months on improvements to the 340B program. Sec. 7103.
**Fraud and Abuse**

**Disclosure of payments by manufacturers (payment sunshine provisions).** Beginning on March 31, 2011, drug, device, biological and medical supply manufacturers would be required annually to electronically report information on payments or other transfers of value made during the prior year to a physician, physician medical practice, a physician group practice and/or a teaching hospital. Exemptions exist for de minimis transfers ($10 or less unless the aggregate annual transfers to a recipient exceed $100, with both dollar amounts to be indexed); samples intended for patients; patient educational materials; a short-term (i.e., less than 90 days) loan of a device for evaluation; and discounts and rebates. Duplicative state or local laws would be preempted by federal law. However, federal preemption would not occur for state or local laws that are beyond the scope of this section. *Sec. 6002.*

**Prescription drug sample transparency.** Requires prescription drug manufacturers and authorized distributors of record to report to the HHS Secretary information pertaining to drug samples currently being collected internally, as required under the federal Food, Drug and Cosmetic Act. *Sec. 6004.*

**Pharmacy benefit managers transparency requirements.** Requires a pharmacy benefit manager (PBM) or a health benefits plan that provides pharmacy benefits management services that contract with health plans under Medicare or the Exchange to report to the HHS Secretary information regarding the generic dispensing rate: the rebates, discounts or price concessions negotiated by the PBM and the payment difference between health plans and PBMs and the PBMs and pharmacies. All disclosed information would be confidential, except for certain specific purposes. *Sec. 6005.*

**Patient-centered outcomes research.** Establishes a private, nonprofit entity (the Patient-Centered Outcomes Research Institute) governed by a public-private sector board appointed by the comptroller general to identify priorities for and provide for the conduct of comparative outcomes research. Requires the Institute to ensure that subpopulations are appropriately accounted for in research designs. Prohibits any findings to be construed as mandates on practice guidelines or coverage decisions and contains patient safeguards to protect against discriminatory coverage decisions by HHS based on age, disability, terminal illness or an individual’s quality of life preference. Provides funding for the Institute and authorizes and provides funding for the Agency for Health Research and Quality to disseminate research findings of the Institute, as well as other government-funded research, to train researchers in comparative research methods and to build data capacity for comparative effectiveness research. *Sec. 6301.*

**Compliance programs.** By a date determined by the HHS Secretary, certain providers and suppliers would be required to establish a compliance program. The requirements for the compliance program would be developed by the HHS Secretary and the HHS OIG. *Sec. 6401.*

**Anti-kickback amendments.** Provides that a claim that includes items or services resulting from an anti-kickback law violation constitutes a false claim for purposes of the Federal False Claims Act. Also amends the intent provisions of the statute to provide that a person need not have actual knowledge of the anti-kickback law or specific intent to commit a violation. Finally, adds an exception for discounts offered to beneficiaries under the Medicare Part D coverage gap discount program.
Increased fraud/abuse enforcement funding. Increases Health Care Fraud and Abuse Control (HCFAC) funding by $10 million each year for fiscal years 2011 through 2020. The provision would also permanently apply the CPI-U adjustment to HCFAC and Medicare Integrity Program funding. Sec. 6402.

Biosimilars

Approval pathway for biosimilar products. Establishes a process under which the HHS Secretary is required to license a biological product that is shown to be biosimilar to or interchangeable with a licensed biological product, commonly referred to as a reference product. 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. If FDA approves a biological product on the grounds that it is interchangeable to a reference product, HHS is prohibited from making a determination that a second or subsequent biological product is interchangeable to that same reference product until one year after the first commercial marketing of the first interchangeable product. Sec. 7002.

Authorizes HHS to issue guidance with respect to the licensure of biological products under this new pathway, and it includes provisions governing patent infringement concerns such as the exchange of information, good faith negotiations and initiation infringement actions. Applies certain provisions of the Federal Food, Drug, and Cosmetic Act to this subtitle with respect to pediatric studies of biological products. Requires HHS to develop recommendations for Congress with respect to the goals for the process for the review of biosimilar biological product applications for the first five fiscal years after FY 2012. Id.

Fees and Taxes

Annual fee on branded prescription pharmaceutical manufacturers. Imposes an annual flat fee of $2.3 billion on the pharmaceutical manufacturing sector beginning in 2010. This non-deductible fee would be allocated across the industry according to market share and would not apply to companies with sales of branded pharmaceuticals of $5 million or less. Sec. 9008.

Annual fee on medical device manufacturers. Imposes an annual flat fee of $2 billion on the medical device manufacturing sector beginning in 2010. This non-deductible fee would be allocated across the industry according to market share and would not apply to companies with sales of medical devices in the U.S. of $5 million or less. The fee does not apply to any sale of a Class I product or any sale of a Class II product that is primarily sold to consumers at retail for not more than $100 per unit (under the FDA product classification system). Sec. 9009.

Cosmetic procedure tax. Imposes a five percent excise tax on voluntary cosmetic surgical and medical procedures performed by a licensed medical professional. The tax would be collected by the medical professional at the point of service. The definition of voluntary cosmetic procedures generally would be the same as the definition of cosmetic surgery or similar procedures that are not treated as included in medical care under the current Section 213(d)(9) definition. Sec. 9017.