Disclosure Requirements for Drug Manufacturers, Medical Device Companies and Pharmacy Benefit Managers Contained in Health Reform Law

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Transparency and Disclosure Requirements for Life Sciences Companies and Pharmacy Benefit Managers

Effective March 31, 2013, a manufacturer of covered drugs, biologicals, medical devices or medical supplies that provides a payment or other transfer of value to a physician or a teaching hospital must report to the government the recipient, the amount of the payment or other transfer, a description of the payment or transfer, and the purpose of the payment or transfer. The manufacturer specifically must disclose whether the payment or other transfer is related to marketing, education, or research specific to a product, and must specify the product to which the payment or transfer relates.

The Act applies to payments and transfers made by a manufacturer only if the manufacturer knows the identity of the recipient of the payment or transfer. Thus, items distributed at trade shows and similar events are likely to be exempt. Payments of less than $10.00, product samples, educational materials, warranties, discounts, and dividends from publicly traded securities are exempt from the reporting requirement.

Additionally, manufacturers and group purchasing organizations must disclose ownership or investment interests held by physicians (other than ownership of publicly traded securities or through mutual funds). Such disclosure must include the amount of the investment, the value and terms of the investment interest, and any transfers of value (e.g. dividends or other distributions) made to such investors. Failure to provide the required reports can result in the imposition of civil monetary penalties.

The Act requires that the reports be made publicly available on a government website in a searchable format. Payments made pursuant to product research and development agreements or for clinical research will not be publicly disclosed until the earlier of the date of approval of the product by the Food and Drug Administration or four calendar years after the date such payment or transfer was made.

The provisions of the federal statute preempt any state act relating to the same transfers or payments, but do not preempt additional reporting requirements imposed by state act, or laws that require reports for public health or oversight purposes.

Prescription Drug Sample Transparency

Effective April 1, 2012 and each year thereafter, drug manufacturers and their authorized distributors shall report the distribution of drug samples to the Secretary of Health and Human Services. Reports must include the name, address, and signature of each recipient.

Pharmacy Benefit Manager Transparency for Government-Funded Health Plans

Pharmacy Benefit Managers (PBMs) that administer pharmacy benefits under contract with a Medicare Part D prescription drug plan sponsor, a Medicare Advantage plan, or a qualified health benefits plan offered through a health insurance exchange must file reports with the Secretary and the applicable health plan. The reports must include the percentage of prescriptions filled by retail and mail order pharmacies, the generic dispensing rate, and a breakdown of retail pharmacy types that actually dispense covered drugs.

Significantly, the reports must disclose all rebates, discounts, and price concessions received from manufacturers, the amounts of such payments that are passed on to the plan sponsor, and the total number of prescriptions dispensed. Bona fide service fees, such as distribution fees, inventory management fees, and patient education program fees, need not be reported. The reports must also disclose the margin between amounts paid to the PBM by the health benefits plan and amounts paid by the PBM to dispensing pharmacies.

Information disclosed by plans and PBMs is confidential, but can be used to create aggregate reports that do not disclose the identity of PBMs and health plans, and for internal government purposes.

The timing, form and manner of reporting shall be as set forth in regulations to be promulgated by the Secretary of Health and Human Services.