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Client Alert

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New Reporting Requirements for Manufacturers and Distributors in the New Health Care Reform Law

On March 23, 2010, President Barack Obama signed into law H.R. 3590, the Patient Protection and Affordable Care Act (the Act) (Pub. L. No. 111-148). Subsequently, on March 30, 2010, President Obama signed a companion bill, H.R. 4872, to amend certain provisions contained in H.R. 3590 and to reconcile the Senate and the House versions of the legislation. As a result, this article will discuss H.R. 3590, as amended by H.R. 4872.

The new federal law amends Title XI of the Social Security Act (42 U.S.C. § 1301) and contains several transparency initiatives that address new reporting requirements for the pharmaceutical and medical device industries. For example, section 6004 specifically addresses the reporting of information relating to drug samples, and section 6002 of the Act imposes significant obligations on drug and device manufacturers by requiring annual disclosure filings that detail their financial relationships with physicians and teaching hospitals. Section 6005 discusses information to be reported by pharmacy benefit managers (PBMs) and health benefits plans. A summary of significant provisions of the new law are addressed below.

This article focuses on the provisions on reporting requirements, as noted above, but the new law addresses many other areas of potential interest, which are mentioned briefly at the end of the summary.

I. Section 6004 — Drug Samples

By April 1, 2012, and each subsequent year, manufacturers and authorized distributors of record of drugs covered under Medicare or Medicaid must submit information to the Department of Health and Human Services (HHS) regarding the identity and quantity of drug samples requested by, and provided to, individual practitioners. The provision indicates that such information must be aggregated by the name, address, professional designation and signature of the practitioner making the request (or by any individual acting on behalf of the practitioner). In addition, HHS is authorized to request that information be aggregated by any other category.

II. Section 6002 — The "Sunshine" Provision

Section 6002 of the Act, commonly referred to as the "Sunshine" provision, requires "applicable manufacturers" to disclose annually to the Secretary of

HHS the payment or other transfer of value to a covered recipient (or to an entity or individual at the request of, or designated on behalf of, a covered recipient). An applicable manufacturer subject to the reporting requirements is defined as "any manufacturer of drugs, devices, biologics, or medical supplies that operates in the U.S." A manufacturer may include an entity under common ownership, which assists or supports the "production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution." A "covered recipient" is "a physician or teaching hospital."

The reporting requirements below are not effective immediately. By October 1, 2011, HHS is required to establish procedures for submitting information and public disclosure. The first annual reports, covering the 2012 calendar year, are due on March 31, 2013. Applicable manufacturers must submit reports electronically. Further, the information reported must be made available by HHS on an internet website, in a searchable format, no later than September 30, 2013. However, disclosure of payments made under a product development agreement or clinical trial will be kept confidential and not made public until either the new product is approved by the Food and Drug Administration or four years after the payment or transfer is made, whichever comes first.

- **Payments or other transfers of value defined**
  The transfer of anything from an applicable manufacturer to a covered recipient with a value greater than $10 must be reported (or if the aggregate amount for the calendar year exceeds $100).[1] However, there are also a limited number of express exemptions, including:
  1. product samples that are not intended to be sold and are intended for patient use;
  2. educational materials that directly benefit patients or are intended for patient use;
  3. short-term loans (i.e., fewer than 90 days) of covered devices (i.e., medical devices eligible for coverage under Medicare, Medicaid or the State Children's Health Insurance Program (SCHIP)), to permit evaluation of the covered device by the covered recipient;[2]
  4. discounts and rebates;
  5. transfers to covered recipients as patients (e.g., when a doctor is acting as a patient and not as a doctor);
  6. in-kind items for charity care;
  7. items or services provided under a contractual warranty (which may also include the replacement of a covered device);
  8. dividends or profit distributions from a publicly-traded security or mutual fund;
  9. payments for the provision of health care to employees under the plan (for applicable manufacturers who offer self-insured plans);
  10. transfers to a covered recipient for non-medical professional services, which that individual is licensed to provide; and
  11. payments to a physician solely for services with respect to a civil or criminal action or an administrative proceeding.

1 After 2012, the dollar amount will be increased by the same percentage increase in the Consumer Price Index.
2 "Covered drug, device, biological, or medical supply" is defined as "any drug, biological product, device, or medical supply for which payment is available under [Medicare] or a State plan under [Medicaid], or [SCHIP] (or a waiver of such a plan)."

- **Reporting Requirements**
  For each payment or transfer of value, the applicable manufacturer must disclose the following information to HHS:
  1. the name and business address of the recipient and the specialty and National Provider Identifier (for recipients who are physicians);[3]
  2. the amount and date of the payment or transfer;
  3. a description of the form of payment or transfer of value (i.e., cash or a cash equivalent, in-kind items or services, stock or any other form of payment to transfer of value);
  4. a description of the nature of the payment or other transfer of value, such as consulting fees, honoraria, gifts, entertainment, food, travel, education, research grants, charitable contributions, royalties, current/prospective ownership or investment interests, or compensation for serving as faculty or a speaker for a medical education program;
  5. whether the payment or transfer is related to marketing, education or research specific to a product, and the name of the product; and
  6. any other information specified by regulation.

- **Special Rule for Certain Payments or Other Transfer of Value**
  Where an applicable 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 applicable manufacturer must disclose that payment or other transfer of value under the name of the covered recipient.

- **Physician Ownership**
  Applicable manufacturers and group purchasing organizations (GPOs) in the United States must report ownership or investment interests (other than publicly-traded securities) held by physicians or an immediate family member in the manufacturer or GPO during the preceding year.

- **Penalties**
  Failure to report is subject to civil monetary penalties ranging from $1,000 to $10,000 per payment, transfer of value or ownership interest now disclosed (up to a maximum of $150,000 per year). Penalties for knowing failure to report are significantly increased: $10,000 to $100,000 per payment, transfer of value or ownership interest not reported, not to exceed $1,000,000 in one year or 0.1 percent of revenues for that year. For purposes of this provision, the term "knowing" is defined consistent with the False Claims Act to include actual knowledge of the falsity of the information or reckless disregard of the truth or falsity of the information. No specific intent to defraud is required.

- **Preemption**
  Section 6002 preempts state reporting requirements that duplicate the new federal reporting requirements on payments or other transfers of value. However, any additional and more stringent reporting requirements that states may choose to impose are not preempted.

3 The National Provider Identifier (NPI) is a unique identification number for covered healthcare providers that must be used in certain administrative and financial transactions.

III. Section 6005 — Pharmacy Benefit Managers Transparency

Section 6005 requires a PBM or health benefits plan that manages prescription drug coverage under a contract with Medicare (e.g., Part D Plans) or Health Benefit Exchanges, established pursuant to the Act, to provide certain information, noted below, to HHS (or, as applicable, to the health benefit plan contracting with the PBM).[4] Any information disclosed pursuant to this new requirement is confidential and cannot be disclosed by HHS (or by the health plan receiving the information). However, HHS may disclose the information in a form that does not identify the specific PBM, plan or drug prices as needed, to carry out the Act or to allow review by other federal agencies, such as the Comptroller General or the Congressional Budget Office. PBMs that fail to provide the required information on a timely basis or that knowingly provide false information will be subject to monetary penalties and potential suspension of the manufacturer's rebate agreement with HHS, according to the Social Security Act.

PBMs must report:

- the percentage of prescriptions provided through retail pharmacies compared to mail-order pharmacies and the generic drug dispensing rate, based on pharmacy type;
- the aggregate amount and type of rebates, discounts and other price concessions (excluding bona fide service fees) negotiated by the PBM, including the amount of such items that are passed through the plan sponsor, and the total number of prescriptions dispensed; and
- the difference in payment between the health plan's payment to the PBM and the PBM's payment to all pharmacies (retail and mail-order) and the total number of prescriptions dispensed.

IV. Other Provisions in the New Law of Potential Interest

In addition to the new reporting requirements discussed, the new healthcare reform law contains several provisions, not detailed here, of potential interest to the pharmaceutical industry including, but not limited to:

- a one-time rebate of $250 for all Medicare Part D enrollees who enter the "donut hole" in 2010 with plans to close the coverage gap completely by 2020;[5]
- a directive to HHS to create a Medicare coverage gap discount program by January 1, 2011, with a requirement for manufacturers to participate as a condition for coverage of drugs;
- the creation of a pathway for the approval of generic versions of biological products (i.e., follow-on biologics, biosimilars or biogenerics) that is biosimilar to, or interchangeable with, a licensed biological product with a provision to grant a 12-year period of exclusivity for the reference product;
- an expansion of the 340B drug discount program (which limits the cost of outpatient drugs to certain federal grantees) to allow for participation of certain children's hospitals, freestanding cancer hospitals, critical access hospitals and rural referral centers;

4 Medicare Part D Plans are a comprehensive prescription drug benefit that is offered under the Medicare program to subsidize the cost of prescription drugs.

5 The Medicare Part D Prescription Drug Program "donut hole" refers to the coverage gap in many Medicare Part D Programs during which the consumer must pay 100 percent of the costs for drug purchases.

- the imposition of annual fees on branded prescription pharmaceutical manufacturers and importers, beginning in 2011; and
- the creation of a limited exception to the statutory requirement that a generic drug have the same labeling as the innovator drug.

Despite the passage of the new healthcare reform legislation, several questions about the implementation and interpretation of these provisions remain, which will likely result in regulation promulgation and potential lawsuits.