COVINGTON

COVINGTON & BURLING LLP

E-ALERT | Health Care

April 2010

HEALTH CARE REFORM: SUNSHINE PROVISIONS

On March 23, 2010, President Obama signed into law Pub. L. No. 111-148, the Patient Protection and Affordable Care Act (PPACA). Shortly afterwards, on March 30, 2010, President Obama signed into law Pub. L. No. 111-152, the Health Care and Education Affordability Reconciliation Act of 2010 (the Reconciliation Amendments), amending PPACA. PPACA, as now amended by the Reconciliation Amendments (collectively, the Act), will have far-reaching effects for the entire health care sector.

This alert, part of a series explaining the impact of the Act on life sciences companies, will summarize the provisions of the Act relating to new transparency and reporting requirements, also colloquially referred to as the "sunshine provisions." These transparency provisions affect pharmaceutical companies, device and supply manufacturers, and pharmacy benefit managers, and in some cases create significant new reporting obligations for each of those entities.

These provisions can be found in sections 6002, 6004, and 6005 of PPACA.

EXECUTIVE SUMMARY

- **PHYSICIAN PAYMENTS AND OWNERSHIP TRANSPARENCY.** The Act requires certain pharmaceutical companies and device manufacturers to report to the Department of Health and Human Services (HHS), on an annual basis, all payments or transfers of value made to physicians or teaching hospitals, subject to certain exceptions described below. The information submitted pursuant to the Act will be made available to the public, subject to certain protections for payments or transfers related to research and development. These transparency provisions preempt state laws that require disclosure of information of the same type but allow states to impose additional reporting obligations for other categories of information.
- **PRESCRIPTION DRUG SAMPLE TRANSPARENCY.** The Act requires prescription drug manufacturers to report to HHS information regarding the distribution of drug samples. The Act makes it an affirmative obligation to collect and report this information to HHS, whereas the Federal Food, Drug, and Cosmetic Act (FDCA) previously required companies to make available to HHS such information only upon request.
- **PHARMACY BENEFIT MANAGERS TRANSPARENCY.** The Act requires pharmacy benefit managers (PBMs) to report to HHS certain information regarding their dispensing, rebates, discounts, and prices. The reported information will be confidential, subject to certain limited exceptions.

Physician Payments and Ownership Transparency

- **REQUIRED DISCLOSURES.** Pharmaceutical, device, and medical supply manufacturers whose products are eligible for payment under Medicare, Medicaid, or CHIP are required to report, in a manner to be specified, certain payments or transfers of value made to physicians or teaching hospitals. The reports must contain the following details: (1) the name of the recipient; (2) the business address of the recipient; (3) the amount of the payment or transfer; (4) the date of the payment or transfer; (5) the form of the payment or transfer (such as cash, stock, services, etc.); (6) a description of the nature of the payment or transfer (such as consulting fees, gifts, honoraria, food, travel, etc.); (6) the name of the drug or device at issue (if the payment or transfer is related to marketing, education, or research specific to a drug or device); and (8) any other information regarding the payment or transfer that HHS requests.
- **EXEMPTED TRANSACTIONS.** The Act exempts 13 types of transfer from the reporting requirements: (1) transfers of value made through a third party, where the transferor does not know the identity of the recipient; (2) transfers of value less than $10 unless the transferor gives more than $100 to a particular recipient in the calendar year; (3) product samples that are not intended to be sold and are intended for patient use; (4) educational materials that directly benefit patients or are intended for patient use; (5) devices loaned for up to 90 days for trial purposes; (6) items or services provided under a contractual warranty; (7) transfers of value to patients not acting in a professional capacity; (8) discounts (including rebates); (9) in-kind items used for charity care; (10) dividends or profits from publicly traded securities or funds; (11) payments for health care by a manufacturer who offers a self-insured plan for employees; (12) transfers of value to licensed non-medical professionals for their professional services; and (13) transfers of value to physicians for services with respect to civil, criminal, or administrative proceedings.
- **OWNERSHIP DISCLOSURES.** Pharmaceutical and device manufacturers and group purchasing organizations that purchase or arrange for the purchase of drugs, devices or supplies eligible for reimbursement under Medicare, Medicaid, or CHIP must report to HHS any ownership or investment interest (other than investment through a publicly traded security or fund) held by a physician or his immediate family. These reports must contain the dollar amount invested by each physician or family member, the value and terms of the ownership interest, and any payments or other transfers of value made to the physician as described above.
- **PENALTIES.** Penalties for non-compliance range from $1,000 to $10,000 for each payment that is not disclosed, with annual penalties not to exceed $150,000. Knowing violations carry civil money penalties ranging from $10,000 to $100,000, with annual penalties not to exceed $1,000,000.
- **USE OF THE REPORTS.** HHS will make the reports, as well as any penalties imposed under the Act, publicly available by September 30, 2013, and on June 30 of each subsequent year. Pharmaceutical and device manufacturers will have at least 45 days to review and correct the reports before they are made public. Payments relating to product research and development will not be made public until the product is approved by the Food and Drug Administration or four years after the payment was made, whichever is earlier. HHS will also provide the reported information to Congress and states, with each state receiving data related to recipients in that state.
- **PREEMPTION.** The Act preempts any state law requiring pharmaceutical and device manufacturers to report the same type of information that is required under the Act. The Act does not preempt state laws that (1) require entities to disclose any information not covered or exempted from reporting under the Act; (2) apply to an entity not covered by the Act; or (3) require an entity to make disclosures to federal, state or local governments for public health

surveillance, investigation, or other public health or health oversight purposes. Although states may impose additional disclosure requirements, they may not require the disclosure of payments less than $10 that do not exceed $100 in a calendar year.

Prescription Drug Sample Transparency

- **REQUIRED DISCLOSURES.** Under the Act, prescription drug manufacturers and distributors are required to provide to HHS annual reports regarding the distribution of drug samples. The reports must contain the identity and quantity of the drug samples requested and the identity and quantity of drug samples distributed during the calendar year, aggregated by the name, address, professional designation, and signature of the requesting practitioner (or anyone who makes or signs for the request on the practitioner's behalf), as well as any other information that HHS determines to be appropriate. Previously, the FDCA required that these records be made available to HHS only upon request.
- **CONFIDENTIALITY OF THE REPORTS.** The Act is silent with respect to the confidentiality of the reports regarding samples.

Pharmacy Benefit Managers Transparency

- **REQUIRED DISCLOSURES.** PBMs and health benefit plans that offer pharmacy benefit management services under Part D or through an exchange, must report to HHS (and, where relevant, to the plan), on an aggregated basis per "contract year," their percentages of retail and mail order dispensing, their generic dispensing rate, the types and numbers of dispensing pharmacies, the amounts of negotiated volume related rebates, discounts and other price concessions, the amounts passed through to the plan sponsors, and the number of prescriptions dispensed.
- **CONFIDENTIALITY OF THE REPORTS.** The reported information will be confidential except where HHS deems disclosure necessary, to enable Comptroller General or CBO review, or to assist states in establishing health care exchanges.

Effective Date

Transparency Provisions	First Report Due
Drug Samples Transparency Reports	April 1, 2012
Physician Payment and Ownership Reports	March 31, 2013
PBM Transparency Reports	To be specified by HHS

Outstanding Issues and Implementation Challenges

- **UNDEFINED EXEMPTIONS.** The physician payment and ownership sunshine provision contains many exemptions that are undefined. For instance, the statute exempts "Discounts (including rebates)," without any further explanation. We expect defining these exemptions will be an extremely important part of the rulemaking process that HHS must complete by October 1, 2011.
- **PUBLIC AVAILABILITY OF DRUG SAMPLE REPORTS.** The drug sample sunshine provisions do not address whether HHS can publicly release the data that it receives. This is in sharp contrast to the physician payment and ownership sunshine provisions (which mandate public disclosure) and the PBM sunshine provisions (which assure confidentiality). Manufacturers who are concerned about the release of this information may want to consider marking sensitive portions

of the data as trade secrets, on the theory that they are equivalent to a customer list. This may decrease the likelihood of future public release by HHS. The information may also be protected by the Privacy Act of 1974.

- **USE OF THE REPORTS.** Neither the drug sample nor the PBM sunshine provisions explain the purposes of this data collection. Although presumably HHS may use the drug sample data to help prevent sample diversion and abuse, it remains to be seen whether HHS will attempt to use this data or the PBM data for other purposes.
- **VARYING STATE OBLIGATIONS.** Because states can continue to impose certain additional disclosure requirements above and beyond those in the Act, the existing patchwork of disclosure requirements for physician payments will continue. Therefore, device manufacturers and pharmaceutical companies must continue to be mindful that they are subject to the varying rules of multiple jurisdictions.
- **PROCESS FOR COLLECTING AND REPORTING INFORMATION.** These disclosure requirements impose additional collection, categorization, and reporting obligations. Companies affected by the Act must begin to assess what steps they must take to improve their data collection and reporting tools so that they can provide the required information.
- **CATEGORIZING TRANSFERS.** The physician payment and ownership sunshine provisions exempt certain categories of transfer. Companies subject to the reporting requirements must identify the types of payments and transfers of value that they are currently making and assess whether they are exempted from the reports.

* * * * *

There are many detailed changes in the Act. We would be pleased to discuss these changes and their potential impact on your industry, company, or customers.

If you have any questions concerning the material discussed in this client alert, please contact the attorneys listed below:

Erika Lietzan	202.662.5165	elietzan@cov.com
Anna Kraus	202.662.5320	akraus@cov.com
Demetrios Kouzoukas	202.662.5057	dkouzoukas@cov.com
Stefanie Doebler	202.662.5271	sdoebler@cov.com
Judith Tytel	212.841.1051	jtytel@cov.com
Ryan Budish	202.662.5546	rbudish@cov.com

This information is not intended as legal advice. Readers should seek specific legal advice before acting with regard to the subjects mentioned herein.

Covington & Burling LLP, an international law firm, provides corporate, litigation and regulatory expertise to enable clients to achieve their goals. This communication is intended to bring relevant developments to our clients and other interested colleagues. Please send an email to unsubscribe@cov.com if you do not wish to receive future emails or electronic alerts.

© 2010 Covington & Burling LLP, 1201 Pennsylvania Avenue, NW, Washington, DC 20004-2401. All rights reserved.