

Rx COMPLIANCE REPORT

EXCLUSIVELY DEVOTED TO PHARMACEUTICAL
SALES AND MARKETING COMPLIANCE

Bracing for Increased FCPA Enforcement in the Pharmaceutical and Device Industries

By Kirk Ogrosky

The Department of Justice (DOJ) announced the Foreign Corrupt Practices Act (FCPA) pharmaceutical and device industry Initiative (the Initiative) in November of 2009. Almost five months later, the FBI's Washington field office is still in the early stages of its operational plan. In the meantime, DOJ's leadership has been transitioned and its prosecutorial resources increased.

Since the FCPA was enacted, approximately 160 cases have been brought by the Fraud Section at DOJ. In recent years, both the number of active investigations and the size of these settlements have grown exponentially. Unlike other federal crimes where 93 separate U.S. Attorneys' Offices utilize a variety of tactics, FCPA enforcement rests exclusively at Main Justice. One key feature of the initiative is that it couples traditional Anti-Kickback Statute prosecutor resources with FCPA trained agents.

This article updates the status of the Initiative and outlines some key issues for the upcoming year.

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Aggregate Spend

Leveraging Aggregate Spend Initiatives

By Benjamin Carmel and Natasha Thoren

Manufacturer payments to health care professionals and healthcare organizations (HCP/O) are poised to receive increased scrutiny in 2010. At the federal level, passage of the Physician Payment Sunshine Act provisions has forced pharmaceutical and medical device firms to review their aggregate spend reporting practices. Meanwhile, eight states currently have spend disclosure laws, and several states with high populations of HCPs, such as Connecticut, New York, and New Jersey have introduced legislation in this area.

Given the likelihood of new legislation from additional states stemming from the weak federal preemption clause of the federal statute, pharma is facing the prospect of a turbulent compliance environment for the foreseeable future.

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Bracing for Increased FCPA Enforcement in the Pharmaceutical and Device Industries

Why—Origin of the Initiative

Given ten years of investigations related to promotional activities in the United States, many industry legal counsel are asking why DOJ elected to focus on global sales and marketing efforts of pharmaceutical and device companies. Over the past three years, the FBI received widespread information that internal controls at pharmaceutical and device companies were insufficient to prevent conduct like that seen in prior investigations. Closer examination by DOJ led to the conclusion that the intersection between the pharmaceutical and device industries and foreign government officials provided ripe opportunities for violations.

Within government, the most noteworthy case in this area is Syncor. The matter arose when Cardinal Health discovered during due diligence that Syncor made over \$500,000 in cash payments to physicians in Taiwan and Mexico who controlled utilization and referral decisions at state-owned hospitals.

In Mexico, Syncor allegedly: 1) inflated invoices to state-owned hospitals then kicked the price difference back to physicians, 2) provided \$200,000 to physicians in the form of trips to conferences, charitable donations and computers, and 3) made loans to physicians that were never repaid. Another government investigation established that a device company operating in China made over \$1.5 million in payments to physicians who controlled purchasing decisions for state-owned hospitals. The fact patterns in these prior matters is a good place to start to understand the government's approach to the Initiative.

Where—Countries of Focus

The Initiative will focus on business practices in over 30 countries. Investigations in Western Europe appear to be leading the first wave of matters due largely to law enforcement cooperation. As a starting point, companies should focus on high-risk conduct in Germany, Greece, Italy, Poland, Spain, and Turkey.

What—Areas of Enforcement Activity

Law enforcement personnel in the United States are focusing on the following types of conduct:

- 1) inflated invoices where excess amounts are being paid to physicians;
- 2) payments to consulting companies with ties to distributors;
- 3) charitable donations to foundations at the direction of physicians;
- 4) loans to individuals in positions to control utilization;
- 5) payments of any type to tender committee members;
- 6) trips to conferences with little or no educational value; and
- 7) excessive payments to investigators at state facilities related to post marketing studies.

“Over the past three years, the FBI received widespread information that internal controls at pharmaceutical and device companies were insufficient to prevent conduct like that seen in prior investigations.”

For the past few years, FCPA enforcement personnel have made significant strides in understanding foreign health systems and identifying systemic weaknesses where the risk of bribery is high. Federal agents have identified key officials with authority to impact utilization decisions in their target countries.

Based on this backdrop, those with the highest risk include young medical device manufacturers due to a perception that these companies regularly use aggressive promotional practices and lack developed compliance plans. Companies promoting implantable devices and pharmaceuticals that are administered in an in-patient setting are also at higher risk.

How—Ensuring Compliance

While there is no perfect way to avoid investigation, diligence in compliance and identification of systemic weaknesses can be done through basic auditing and testing. For example, when foreign sales divisions seek to retain third-parties as intermediaries, auditing should be able to establish documentation supporting the fact that the third party intermediary:

- a) was not a government official;
- b) had sufficient expertise to execute the task required;
- c) had physical offices;
- d) did not have prior convictions; and
- e) was not retained at the specific direction of a government official

A warning sign that might mandate a more extensive examination of the purpose of the transaction might be as simple as an inordinately large number of third-party intermediaries in a particular country. Finally, watch for payments made to third-parties, payments to bank accounts in different countries, and payments based on percentage of sales.

With regard to funded travel for conferences, understand who within your organization has authority to approve such travel. For foreign physicians, ask if there is transparency within the foreign organization and if all approvals have been received. Make sure that the type of conference is focused on educational activity, not leisure. Minimize trappings that draw attention to travel such as first-class airfare, expensive hotels, excessive entertainment, and cash per diem. Finally, compliance with the PhRMA Code's guidance on educational programs is a positive first step to ensure that relationships with foreign physicians, who may be deemed foreign officials, are not the subject of investigation.

Who—Leadership Changes

Starting in April of 2010, Acting Deputy Chief Charles Duross will take over supervision of the FCPA group. At the same time, the new Initiative will remain under the supervision of Acting Deputy Chief Hank Walther, who began heading up

healthcare fraud enforcement in March. Duross has over ten years of prosecutorial experience having served as an Assistant U.S. Attorney in the Miami office prior to 2007. Walther, one of the first prosecutors to head up a Medicare Fraud Strike Force (MFSF) team in Miami, recently indicted a series of FCPA cases leading to arrests in Las Vegas. Both Duross and Walther became prosecutors after spending several years in private practice. In particular, Walther was recruited by DOJ having handled criminal investigations for pharmaceutical manufacturers. The Criminal Division is expected to make final leadership selections before summer.

What's Next—UK and SFO

In addition to the U.S. activity, there have been two major developments within the last few weeks in the UK. First,

Parliament passed comprehensive bribery legislation that is expected to go into effect in late summer 2010. The Bribery Act brings the UK into compliance with the Organization for Economic Cooperation and Development Convention on Combating Bribery of Foreign Public Officials in International Business Transactions. While the new law largely tracks the FCPA, it creates an additional offense for a company's failure to prevent bribery by "a person who performs services" on behalf of the company. However, the scope of enforcement authorities in the UK remains unsettled. Lord Justice Thomas in the Southwark Crown Court recently remarked that the Serious Fraud Office did not have the power to enter into a binding plea agreement with a negotiated monetary penalty on March 26, 2010. Whether the court is bound by penalties negotiated by the SFO complicates the SFO's initiative to establish a U.S. style voluntary disclosure regime. ■

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Leveraging Aggregate Spend Initiatives

The Opportunity

Complying with these growing regulations presents a challenge. But the wealth of data generated by efficient implementation of aggregate spend solutions can also provide an excellent opportunity to improve overall compliance, process efficiencies, and technologies. In addition, enhancing systems that track aggregate spend can generate important benefits for a company's business operations. By thinking more broadly about compliance and aligning reporting requirements with a company's overall business and technology needs, business teams can leverage new compliance obligations in ways that benefit many areas within a company.

In order to accomplish these multiple objectives, companies must implement three specific technology components along with effective process controls on these technologies. The key technology items fall under spend capture systems, customer master, and reporting tools. These systems must not only be designed with the goal of satisfying disclosure requirements, but must also efficiently capture the detailed information necessary to support enhanced business analysis and decision making. One indicator of success is an aggregate spend system that collects information with minimal intervention and impact on the business and IT groups. The data must also be easily and quickly accessible to all business practice areas within the company.

Spend Capture Systems

The starting point for a more comprehensive, effective aggregate spend function is the spend capture system, which represents an organization's point of entry and recording for all recipient payments. Through a combination of manual and automated processes, spend capture systems typically document time and expense, clinical trials, grant management, speaker/consultant payments, sales force automation, and finance-and investigator-initiated studies. As companies upgrade their systems, they may find that the processes and details in place are insufficient for current and future reporting requirements.

Most companies will need to implement further automation, along with enhancements both to remove manual errors and to allow unique customer identifiers to be sent to upstream systems, tying payments to unique individuals at the onset of the process. Where automation is not a viable option, development of a catch-all portal with access for internal and external users can enforce processes, limit mistakes, and ensure adherence to data standards.

While these upgrades to the spend capture process may seem complex and expensive at first glance, they can significantly benefit both compliance and business teams in the long run.

Compliance teams. For compliance teams, these systems provide the ability to assert controls around data collection and to ensure that compliance requirements are incorporated into technology workflows. These enhancements help simplify aggregate spend data consolidation and allow teams to evaluate limits and caps on recipient payments. Systems decrease the time and energy spent collecting payment information, provide built-in audit trails and ensure data accuracy, which is sure to make compliance officers sleep better at night.

Business teams. For business teams, automation and enhancements decrease the demands of administrative tasks and provide accurate, real time information that was previously unavailable. This information allows teams to evaluate programs across the organization and to expedite the delivery of information to various groups. Business teams will gain greater peace of mind knowing that they can spend less time worrying about potential compliance requests, since they will already be embedded in business processes.

“The wealth of data generated by efficient implementation of aggregate spend solutions can also provide an excellent opportunity to improve overall compliance, process efficiencies, and technologies.”

Customer Master System

The core of any successful aggregate spend initiative is the customer master. It is the source of the unique customer identifier and the single customer profile. Though many companies already track health practitioner expenditures, often these systems are not integrated and may not contain a common identifier for individuals who work across multiple business areas within a company.

In order to comply with current aggregate spend requirements, compliance executives must invest in developing a customer master that will enrich existing data with specific attributes that can be used to construct a foundation of robust profiles and a sound affiliation structure.

Building unique customer profiles allows an organization to tie spend to a particular individual regardless of the source of payment. These profiles can be sent upstream to spend capture systems, allowing companies to incorporate standard identifiers into these systems, ensuring that information is allocated to a proper recipient. Profiles can also be sent downstream to data warehouses and/or aggregate spend databases for consolidation and reporting. The ability to accurately record spend by identifying distinct payment recipients and confirming that these individuals/entities are the intended beneficiaries is an essential part of complying with the new regulations.

Reporting System

A robust reporting system is the key value-add component for business teams. It can provide a host of parameters, filters and levels of granularity. When properly implemented, linking data from company systems and data warehouses, as well as vendor networks, provides an unparalleled level of detailed analysis and reporting.

Reporting systems linked through the customer master to the underlying spend data allow companies to address all disclosure requirements. These systems also create the

opportunity to actively monitor compliance controls such as spend caps per HCP, speaker utilization levels, and evaluation of compliance with fair market value. In

general, reporting capabilities will allow firms to better monitor their overall compliance programs and highlight areas where audits or corrective action is required.

The wealth of data that is centralized onto a single reporting platform also provides tremendous benefits to the business. Much like compliance, these groups will now have access to total spend and program information for an HCP or group of HCPs.

“A robust reporting system is the key value-add component for business teams.”

Four Considerations When Implementing Aggregate Spend

1. Legal Interpretation – Compliance and legal should determine thresholds and definitions for activities they want to include for aggregate spend capture. These definitions will drive compliance with state statutes and set the foundation for an aggregate spend initiative.

2. Standard Operating Procedures & Policies – To ensure consistent behavior throughout the company, state law and aggregate spend specific policies and SOPs should be implemented. Policies and SOPs should provide guidance on interacting with physicians, and reporting requirements and process, including utilization of any systems required to capture reporting.

3. Training – Training will socialize the legal interpretation, SOPs and policies. It is also crucial in ensuring all employees are aware of what to do, where to go for assistance and why compliance is important. Effective training should include compliance discussions and utilization of systems to ensure accurate data capture and accurate disclosures.

4. Auditing – Many companies audit sales and marketing functions regularly. However, auditing of implemented aggregate spend initiatives is a relatively new concept. Auditing an aggregate spend initiative should become a regular audit activity, as it is prudent for a company to understand how compliant the initiative is with state laws.

Business intelligence reports and dashboard capabilities often reserved for isolated data sets in sales and marketing can be configured to review programs and evaluate spend effectiveness. Programs themselves can be reviewed to identify areas that justify more or less budget. Reports can be generated to review prior year spend, see current planned HCP spend, and be used during the budget process. Overall, the information can be utilized to determine compliance risks and return on investment consolidating two of the main goals of many companies.

Bringing It All Together

By implementing these system components, a company can leverage this accurate and complete data set for business purposes, driving additional value beyond compliance. Though there are many potential uses for this data, the most exciting opportunities enabled by aggregate spend are around analytics and predictive modeling. These areas are rarely considered when companies collect data for compliance purposes. Furthermore, this data, once available, can be fed back upstream to source systems, and can be used to enhance control and decision-making processes – for example, the ability to alert systems and users when a threshold is being neared in order to avoid over-spending on a particular individual.

The key to getting the most value out of aggregate spend initiatives is for companies to design spend capture systems, customer master and reporting capabilities from the perspective of the business users. Pharmaceutical companies have already begun the process of allocating budget and resources for aggregate spend initiatives in response to the current and potential disclosure requirements from federal and state laws as well as evolving industry practice. The smartest companies, however, know that aggregate spend initiatives can do much more than improve compliance; they are a valuable opportunity to streamline process and enhance business capabilities. By taking advantage of current aggregate spend initiatives, companies can leverage their investment to provide a solution for the entire organization. ■

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Inaugural West Coast Forum on Tracking State Laws and Aggregate Spend

Capture and Disclose Spend Data in Compliance with Changing State and Federal Requirements

San Diego, CA, April 21 - 22, 2010

www.cbinet.com/aggspendwest

AGENDA

Day One – Wednesday, April 21, 2010

- 1:15 Understanding the Federal Sunshine Provisions Passed with Comprehensive Healthcare Reform
- 2:00 State Panel Discussion: State Transparency Initiatives – Insight from the Trenches
- 3:10 What Looms Ahead – The Countdown to First Time Massachusetts and Vermont Reporting
- 3:50 Making the Business Case for Resources to Implement and Improve Aggregate Spend Solutions
- 4:30 Panel Discussion: Training and Communication of Aggregate Spend Initiatives
- 5:10 Building for and Managing Change around an Aggregate Spend Solution

Day Two – Thursday, April 22, 2010

- 8:15 Create a Roadmap for Implementing an Aggregate Spend Solution
- 8:55 Examine the Benefits and Shortcomings of Spend Tracking Solutions
- 9:35 An Aggregate Spend Business Process Integration Project – Using Business Process Integration from A to Z
- 10:45 Lessons Learned from Preparing for the Federal Sunshine Act and Applicability for Possible CIA Reporting Requirements
- 11:25 Use KPIs to Discover Findings in Data that Provide Intelligence Back to the Business Units
- 12:05 The Silver Lining to the Aggregate Spend Pain
- 2:00 Working Group Discussions
- 3:00 Hear Best Practices and Practical Solutions Developed from Working Group Discussions

Medicaid Drug Rebate Program

Four Key Considerations For Implementing Medicaid Drug Rebate Program Reform

On March 23, 2010, President Obama signed the “Patient Protection and Affordable Care Act” (PPACA), into law. This legislation includes significant revisions to Section 1927 of the Social Security Act, which governs the Medicaid Drug Rebate Program (MDRP). Following the enactment of PPACA, the “Health Care and Education Reconciliation Act of 2010” was enacted into law on March 30, 2010, “reconciling” and revising portions of PPACA.

Below are several considerations outlined by Epstein, Becker & Green attorneys to assist pharmaceutical and biotech manufacturers in understanding the impact of this legislation with respect to the MDRP.

1. Assess the Preparedness of Your Government Pricing Function

PPACA makes significant changes to the definition of average manufacturer price (AMP) and to the formulae and methodologies used to calculate MDRP rebates.

Among other things, AMP would be redefined to replace the concept of “distributed to the retail pharmacy class of trade” with the concept of “distributed to community retail pharmacies.” This change likely will require revisions to policies, procedures, systems, and processes regarding, for example, coding of particular classes of trade as “eligible” or “ineligible” for purposes of the AMP calculation. It also may have unintended consequences on the calculation of AMP for certain products that are not traditionally sold to community retail pharmacies, including, for example, drugs and biologicals that are purchased by physicians for administration in their offices.

Certain of the MDRP changes under PPACA, such as the increases to the basic rebate percentages, the change to calculation of “additional” rebates for new formulations of existing drugs, and the extension of MDRP rebates to utilization by beneficiaries of Medicaid managed care plans, according to their terms, are effective for rebate periods beginning after December 31, 2009. As a practical matter, although the delayed passage of the law may leave these retroactive effective dates subject to legal challenge, CMS may attempt to

enforce these effective dates and calculate 1Q10 unit rebate amounts (URA) based on the higher “basic” rebate percentages and potentially higher “additional” rebates.

2. Determine the Potential Impact on Your Financial Liability

The extension of MDRP rebates to Medicaid Managed Care Organization (MCO) utilization and increases to the MDRP rebate percentages represent relatively straightforward increases to manufacturers’ MDRP liability that should be assessed for financial impact. (In addition, Medicaid enrollment will likely increase as a result of other provisions of PPACA.) But there also may be “hidden” increases that manufacturers should consider.

Various discounts to certain entities previously considered “retail pharmacy class of trade” (such as mail-order pharmacies and hospital outpatient pharmacies) will no longer be included in AMP calculations, potentially resulting in relatively higher AMPs, and, thus higher Medicaid rebates, to the extent these entities received

PPACA makes significant changes to the definition of average manufacturer price (AMP) and to the formulae and methodologies used to calculate MDRP rebates.

greater discounts than “community retail pharmacies.” There may be crossover from this impact into other programs, such as the 340B Program (to be addressed in a forthcoming client communication), as well as state programs that rely on AMP for rebate and/or reimbursement purposes.

The public disclosure of AMP, which was required by the DRA, continues to be enjoined in connection with ongoing litigation in *National Association of Chain Drug Stores v. Sebellius*, Civ. Action No. 1:07cv02017 (RCL) (D.D.C.). However, it is possible that the litigation may be moot in light of the redefinition of AMP under PPACA, thus

permitting the disclosure of noninnovator drugs' AMPs, as outlined in the sidebars.

Assessing the impact of the provisions regarding new formulations may be challenging, as there are many open questions regarding the definitions and applicability of these provisions. In a March 10, 2010 report to CMS, the Office of Inspector General (OIG) attempted to evaluate the impact of calculating additional rebates of different "versions" of drugs under the MDRP.¹ The OIG stated that "new forms or strengths... of an active ingredient previously approved for marketing in the United States" were considered different "versions." The OIG also stated that it considered drugs "with variations of the same brand name (e.g., drug ABC and ABC XR, for which the 'XR' represented extended release) to be the same drug if they had the same active chemical ingredients." Although this interpretation is not binding on CMS, it may be helpful for manufacturers to consider as they assess the potential impact of this change.

In addition to the increased MDRP liability that may result from the change in the formula for calculating "additional" rebates for new formulations of existing products, "additional" rebates for all "S" and "I" drugs could increase unless CMS allows manufacturers to recalculate their "base date" AMPs used to calculate "additional" rebates under the AMP methodology, as revised by PPACA. In connection with changes previously made by the DRA and its implementing regulations, CMS permitted manufacturers to recalculate their "base date" AMPs under the revised AMP methodology, provided they had actual data from the "base date" quarter to use in those recalculations.

3. Review and Update Your Rebate and Discount Contracts

Several of the changes under PPACA have implications for manufacturers' rebate and discount contracting practices. For example, it is relatively common for payors to include Medicaid MCO utilization in commercial rebate contracts. Therefore, manufacturers may be contractually liable to pay duplicate rebates on this utilization.

Also, the extension of MDRP rebates to Medicaid MCO utilization would not prohibit manufacturers from offering deeper discounts to Medicaid MCOs. However, whereas Medicaid rebates are exempt from manufacturers' Best Price calculations, these deeper discounts may not be.

4. Analyze Whether MDRP Changes Impact Research and Development (R&D) Business Strategy

Provisions that may affect manufacturers' current and prospective R&D business strategies include: 1) the change in the MDRP "additional" rebate calculation that applies to new product formulations; and 2) a relatively lower minimum "basic" rebate percentage for drugs that are approved exclusively for pediatric use.

The new formulations provision is intended to limit the ability of manufacturers to charge premium pricing for new formulations of solid oral dosage form products, as

such new formulations will potentially be penalized under the MDRP for essentially the difference between the new formulation's AMP and the "base date" AMP for the original formulation, if any. Operationalizing this provision may be challenging, especially in cases where the units and strengths of the formulations are not easily converted to like measures.

The relatively lower minimum "basic" rebate for innovator products approved exclusively for pediatric indications is intended to serve as an incentive for manufacturers to study and seek approval of products with exclusively pediatric indications. However, this provision may have the unintended consequence of acting as a disincentive to conduct further adult trials with respect to those products, once approved.² ■

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¹ U.S. Department of Health & Human Services, Office of Inspector General, "Review of Additional Rebates for Brand-Name Drugs with Multiple Versions," A-06-09-00033 (March 2010).

² There also is a potentially incongruous interplay between this provision and the new formulation provision, to the extent that a pediatric version of a product might be deemed a "new formulation" and thus subject to an "additional" rebate calculation that uses the "base date" AMP of the original formulation, while also subject to the lower minimum "basic" rebate.

Several of the changes under PPACA have implications for manufacturers' rebate and discount contracting practices.

Mark your calendar!

CBI's Upcoming Pharmaceutical & Biotech Conferences

CBI's Pharmaceutical & Biotech conferences cover the spectrum of compliance and regulatory fields. Below is a list of upcoming events.

For more information on these events, visit: www.cbinet.com/conferences.cfm?verticalId=1

Inaugural West Coast Forum on Tracking State Laws and Aggregate Spend
Apr 21–22, 2010 • San Diego, CA

Premier Event on Effective Preparation for FDA Advisory Committees
Apr 26–27, 2010 • Alexandria, VA

5th Forum on Clinical Trial Registries and Results Databases
Apr 26–27, 2010 • Arlington, VA

12th Annual Medicaid Rebates Conference
May 12–14, 2010 • Lake Buena Vista, FL

7th Annual Forum on Dissemination of Scientific Information
May 24–25, 2010 • Philadelphia, PA

2nd Forum on Clinical Trial Registries and Results Databases
Jun 1–2, 2010 • London, United Kingdom

6th Annual Medical Device and Diagnostic Compliance Congress
Jun 8–9, 2010 • Boston, MA

Disease Education and Bio/Pharmaceutical Product Promotion Using Social Media Tools
Jun 22–23, 2010 • Alexandria, VA

8th Annual Product Complaints for Bio/Pharmaceuticals and Medical Devices
Jun 23–25, 2010 • Alexandria, VA

4th Annual Tracking State Laws and Aggregate Spend
Aug 16–18, 2010 • Washington, DC



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