2017 PHARMACEUTICAL COMPLIANCE CONGRESS

ASSESS EMERGING RISKS AND THE ROLE FOR COMPLIANCE ACROSS MARKET ACCESS ACTIVITIES

APRIL 27, 2017
PRESENTERS

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AGENDA

1. Market Access Overview
2. Third-Party Distributor, Wholesaler, and Pharmacy Relationships
3. PSPs, PAPs, and Recent Enforcement Trends
4. Role of Compliance to Mitigate Market Access Risks
MARKET ACCESS OVERVIEW
Companies involved in market access activities faced an uptick in scrutiny by the media, the OIG, and states’ attorneys in the past two years.

- **The New York Times**
  - July 14, 2015
  - Specialty Pharmacies Proliferate, Along With Questions

- **Reuters**
  - October 22, 2015
  - Specialty Pharmacies In Spotlight As Valeant Ties Questioned

- **USA Today**
  - June 8, 2016
  - Drug Co-Pay Assistance Programs Facing Increasing State and Federal Scrutiny

- **Bloomberg**
  - February 22, 2017
  - Harvard Pilgrim Expands Use Of Novel Drug Purchasing Deals

- **The Boston Globe**
  - March 15, 2017
  - Middlemen’s Secret Drug Rebates Targeted by Wyden’s Bill

- **Bloomberg**
  - March 21, 2017
  - Sanofi, CVS, Others Accused of Insulin Price Fixing
## THE MARKET ACCESS CONTINUUM – EXAMPLES OF ACTIVITIES CONDUCTED WITH STAKEHOLDERS

<table>
<thead>
<tr>
<th>R&amp;D Investment Choices</th>
<th>Pricing &amp; Contracting</th>
<th>Distribution</th>
<th>Customer Support</th>
<th>Patient Assistance</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Market Research</td>
<td>- Market Research</td>
<td>- Distributors</td>
<td>- Provider &amp; Patient Education</td>
<td>- Product Samples &amp; Voucher Programs</td>
</tr>
<tr>
<td>o Physicians</td>
<td>o PHYSICIANS</td>
<td>o Wholesalers</td>
<td>o Reimbursement &amp; HUB Services</td>
<td>o Coupon &amp; Co-Pay Programs</td>
</tr>
<tr>
<td>o Payors</td>
<td>o Payors</td>
<td>o Specialty Pharmacies</td>
<td>o Prior Authorization</td>
<td>o Patient Assistance Programs</td>
</tr>
<tr>
<td>o Providers</td>
<td>o Providers</td>
<td>o GPOs/PBMs</td>
<td>o Benefits Investigation</td>
<td>o Direct</td>
</tr>
<tr>
<td>o Patients</td>
<td>o Patients</td>
<td>o FMV</td>
<td>o Other</td>
<td>o 3rd Party non-Charity</td>
</tr>
<tr>
<td>- Interactions w/ HCPs</td>
<td>- Interactions w/ HCPs</td>
<td>- Government Price Reporting</td>
<td>- FMV</td>
<td>o 3rd Party Charity</td>
</tr>
<tr>
<td>o Investigators</td>
<td>o Investigators</td>
<td></td>
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<td>o Advisors</td>
<td>o Advisors</td>
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<tr>
<td>- Portfolio Decisions</td>
<td>- Pricing Decisions</td>
<td></td>
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<tr>
<td>- Clinical Trials</td>
<td>o Traditional</td>
<td></td>
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<tr>
<td>o Design</td>
<td>o Emerging (VBC)</td>
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<td>o Analysis</td>
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# RISKS ASSOCIATED WITH MARKET ACCESS ACTIVITIES

<table>
<thead>
<tr>
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<tr>
<td><strong>Govt. Pricing</strong></td>
<td>N/A</td>
<td><strong>Maximize access and revenue</strong></td>
<td><strong>Evaluate agreements</strong></td>
<td><strong>N/A</strong></td>
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<tr>
<td><strong>Off-Label</strong></td>
<td><strong>Data dissemination from research results</strong></td>
<td><strong>Inappropriate use of ad boards and consultants with only one-way communications about pre-approval product</strong></td>
<td><strong>Inappropriate use of promotional materials and/or messages that were not vetted through internal review</strong></td>
<td><strong>Potential that reimbursement support services interfere with the integrity of the HCPs prescription</strong></td>
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<td><strong>Kickbacks</strong></td>
<td><strong>Financial arrangements with HCPs (e.g. lack legitimate business need, do not pass the bona fide services test)</strong></td>
<td><strong>Potential for arrangements that lack legitimate business need, do not pass the bona fide services test</strong></td>
<td><strong>Potential for arrangements that lack legitimate business need, do not pass the bona fide services test</strong></td>
<td><strong>Potential that a company provides reimbursement support to a customer</strong></td>
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POLLING QUESTION #1

Is Compliance currently involved in evaluating your company’s market access activities?

- Yes, compliance is very involved
- Yes, compliance is somewhat involved
- No, compliance is not involved
- I don’t know
POLLING QUESTION #2

What role does Compliance currently play in your company’s market access activities?

- Reviews/develops market access activities
- Reviews but does not approve market access activities
- Reviews and approves each new market access activity
- Does not have a role
- I don’t know
THIRD-PARTY DISTRIBUTOR, WHOLESALER, AND PHARMACY RELATIONSHIPS
CURRENT LANDSCAPE

- For years, government regulators have focused on the pharmaceutical industry’s relationships with physicians, centered on alleged off-label promotion or potential kickback arrangements.

- Additional attention is now being paid to initiatives between pharmaceutical companies and other relationships in the manufacturer’s distribution channels.

- As pharmaceutical companies work to assist HCPs and patients in gaining access to drugs (e.g., drug samples, vouchers, co-pay cards, patient assistance programs), specialty pharmacies have grown in quantity and importance.

- Specialty pharmacies offer comprehensive and coordinated support services, including:
  - Patient Care Coordinators (“PCC”)
  - Education (i.e., specific product, disease state, adherence, etc.)
  - Orders and Refills (e.g., reminder communications and automatic refills)
KEY CHALLENGES

Bona Fide Service Fee

- Manufacturers must conduct bona fide services tests and fair market value analyses to ensure arrangements are fair and serve a legitimate business need

Risk Assessment

- Manufacturers must ensure implementation of consistent risk assessment processes designed to address the entire customer continuum (i.e., activities, customers, brands)

Monitoring

- Manufacturers must conduct appropriate monitoring controls throughout the lifecycle of each customer relationship (e.g., strategic and budget planning, needs assessment and FMV, contract execution, payment and reporting)
POLLING QUESTION #3

Does your company conduct a periodic review of its specialty pharmacy agreements?

- Yes
- No
- I Don’t Know
PSPS, PAPS, AND RECENT ENFORCEMENT TRENDS
## WHAT IS A PATIENT SUPPORT PROGRAM ("PSP")?

**Patient Support Programs**

"...a PSP is defined as a service for direct patient or patient carer interaction/engagement designed to help management of medication and/or disease outcomes (e.g., adherence, awareness and education), or to provide healthcare professionals (HCPs) with support for their patients. A PSP definition will only apply if there is direct contact with patients or patient carers. The intent is to support patient care provided by the MAH [Marketing Authorization Holder] or by a third party on the MAH’s behalf. Patients need to provide informed consent prior to enrolling on PSPs where they will be directly contacted.”

**Source:** The ABPI Pharmacovigilance Expert Network, ABPI Guidance Notes for Patient Safety and Pharmacovigilance in Patient Support Programs (2011)

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**Product Support Services**

“A patient support programme is an organised system where a marketing authorization holder receives and collects information relating to the use of its medicinal products. Examples are post-authorisation patient support and disease management programmes, surveys of patients and healthcare providers, information gathering on patient compliance, or compensation/reimbursement schemes.”

**Source:** European Medicines Agency, Guideline on Good Pharmacovigilance Practices (GVP) – Module VI – Management and reporting of adverse reactions to medicinal products at 29 (2012)

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“Product Support Services. Pharmaceutical manufacturers sometimes offer purchasers certain support services in connection with the sale of their products. These services may include billing assistance tailored to the purchased products, reimbursement consultation, and other programs specifically tied to support of the purchased product. **Standing alone, services that have no substantial independent value to the purchaser may not implicate the anti-kickback statute. However, if a manufacturer provides a service having no independent value (such as limited reimbursement support services in connection with its own products) in tandem with another service or program that confers a benefit on a referring provider (such as a reimbursement guarantee that eliminates normal financial risks), the arrangement would raise kickback concerns.** For example, the anti-kickback statute would be implicated if a manufacturer were to couple a reimbursement support service with a promise that a purchaser will pay for ordered products only if the purchaser is reimbursed by a federal health care program.”

**Source:** HHS-OIG, OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731 at 23,735 (May 5, 2003)
EXAMPLES OF PSP OFFERINGS

- Appeals support
- Appointment scheduling and appointment reminders
- Benefits verification/insurance counseling
- Co-pay cards, coupons, vouchers
- Disease information and resource
- Nurse educators

- Patient surveys/rewards programs
- Prescription refill reminders
- Prior authorization support
- Reimbursement information
- Tele- or online-support (e.g., calls from or access to nurses, PAs)
- Medication management
PSP ENFORCEMENT TRENDS

• Warner Chilcott U.S. Sales LLC
  – DOJ plea and settlement (October 29, 2015)
  – Individual prosecutions, resulting in pleas
  – DOJ indictment of CEO W. Carl Reichel and acquittal (June 17, 2016)

• Novartis
  – DOJ settlement (Nov. 20, 2015)

• InSys
  – DOJ charges six individuals (December 8, 2016)

• Walgreens
  – DOJ settlement (January 19, 2017)
KEY TAKEAWAYS

- The DOJ, particularly the U.S. Attorney’s Offices for the District of Massachusetts and the Southern District of New York, is actively investigating and prosecuting cases involving PSPs
- Following the issuance of the Yates Memorandum, the DOJ remains focused on the investigation and prosecution of individual corporate wrongdoers
- DOJ remains focused on specialty pharmacies and manufacturers’ relationships with those pharmacies
- Prosecutors retain significant discretion in fashioning both individual and corporate settlements
- Civil settlements can include resolution terms that call for expansive and detailed government oversight of PSPs and the individuals responsible for running those programs, from employees to executives
- Manufacturers with PSPs should routinely monitor and audit those programs as a means of identifying areas of risk and remediating, where appropriate
WHAT IS A PATIENT ASSISTANCE PROGRAM ("PAP")?

In its foundational Bulletin on the topic released in November 2005, the HHS OIG broadly characterized PAPs:

*Patient assistance programs (PAPs) have long provided important safety net assistance to patients of limited means who do not have insurance coverage for drugs, typically serving patients with chronic illnesses and high drug costs. PAPs are structured and operated in many different ways. PAPs may offer cash subsidies, free or reduced price drugs, or both. Some PAPs offer assistance directly to patients, while others replenish drugs furnished by pharmacies, clinics, hospitals, and other entities to eligible patients whose drugs are not covered by an insurance program.*

Today, PAPs are typically operated directly by manufacturers or independent charities, which may be supported by manufacturers.
“Pharmaceutical manufacturers may sponsor patient assistance programs that provide financial assistance or drug free product (through in-kind product donations) to low income individuals to augment any existing prescription drug coverage.”

– Centers for Medicare & Medicaid Services

Typical patient eligibility requirements may include:

- Limited or no prescription drug coverage from private or public sources
- A demonstrated financial need based on set income and asset limitations
- Proof of US residence or citizenship
Third-party charitable foundations may offer patient assistance programs based on therapeutic area, disease type (e.g., chronic, life-threatening), patient population, etc.

Examples of charitable patient assistance foundations include:

- NORD®
  National Organization for Rare Disorders

- PAN Foundation

- HealthWell Foundation
  When health insurance is not enough.
HHS OIG guidance on manufacturer and charity-operated PAPs provides legal analysis of these programs under the False Claims Act, federal Anti-Kickback Statute, and similar statutes.

Although the DOJ has not reached any recent settlements with manufacturers regarding their operation of PAPs, current investigations suggest that the DOJ is focusing on whether those programs adhere to the statutes outlined in the applicable guidance.

Companies and individuals alike face the same penalties for violations of law resulting from their operation of PAPs as they would from their operation of PSPs.

Beginning in 2015, Congress, the DOJ, and the press began to increasingly focus on the issue of drug price increases – and on the heels of these press reports, DOJ began issuing subpoenas to a number of manufacturers related to their manufacturer-led and charitable PAPs.
Since 2015, the DOJ, led largely by the U.S. Attorney’s Office for the District of Massachusetts, have issued at least ten subpoenas to manufacturers related to charitable PAPs:

- Gilead Sciences (Mass.) (2016)
- Biogen (Unspecified) (2016)
- Jazz Pharmaceuticals (Mass.) (2016)
- Celgene (Unspecified) (2016)
- DaVita Inc. (Mass.) (2017)
- Fresenius Medical Care (Mass.) (2017)
- Regeneron Pharmaceuticals (Mass.) (2017)
- Pfizer (Mass.) (2017)
- J&J (Mass.) (2017)

At least Gilead and Jazz Pharmaceuticals also received separate requests for their own manufacturer-operated PAPs.
The DOJ, particularly the U.S. Attorney’s Office for the District of Massachusetts, is intently focused on examining charitable PAPs and, to a lesser extent, manufacturer-led PAPs.

The form of the PAP governs, in part, the guidance a manufacturer or charitable foundation should follow in establishing and carrying out the business of the PAP.

The DOJ’s interest in investigating charitable PAPs reflects its interest in determining the extent to which the manufacturers control or otherwise influence those programs.

The resolution of these DOJ investigations could have meaningful implications and lessons for manufacturers that operate in the PAP space.
POLLING QUESTION #4

Does your company operate/participate in any of the following?

- Free-drug programs
- Donates to 501c3 charitable organizations that support patients
- Both free-drug programs and charitable organizations
- My company does not run nor contribute to any patient assistance program
- I don’t know
ROLE OF COMPLIANCE TO MITIGATE MARKET ACCESS RISKS
ROLE OF COMPLIANCE TO MITIGATE MARKET ACCESS RISKS

Other Organizational/Infrastructure Requirements

- **Compliance, Risk Mitigation & Government Reporting**
- **Technology & Analytics**
- **Key Account Management**
- **Policy & Advocacy**

**R&D Investment Choices**
- Develop a platform / process for building a robust value story

**Pricing & Contracting**
- Determine appropriate strategy

**Distribution**
- Establish channel and distribution strategy

**Customer Support**
- Support customers (HCPs, office mgrs., nurses, patients, caregivers) along the access journey

**Patient Assistance**
- Provide patient financial assistance options
Below are key considerations for assessing your company’s market access programs and processes.

- Establish or update standard processes to justify activities and arrangements
- Understand the volume of therapeutic areas and products covered
- Review processes and vendor relationships
- Determine if controls are in place
- Catalog programs and develop risk profiles
- Identify third parties
- Confirm CMS/OIG guidelines
- Include market access activities in auditing and monitoring program
- Require periodic performance reports and certifications
- Review and verify services performed by vendors and foundations
- Review trends, outliers, and program metrics
- Develop a vision
- Identify areas for improved support
- Develop summary of qualifications by vendor and foundation
- Assess approach to optimize operations and compliance

Ongoing Education and Training of Compliance Personnel
### ROLE OF COMPLIANCE TO MITIGATE MARKET ACCESS RISKS

<table>
<thead>
<tr>
<th>OIG “Element”</th>
<th>Market Access Implication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Written Standards</td>
<td>Balance required: integrate Market Access needs into existing policies and procedures where possible to create efficiencies; some specific policies and procedures will be needed however</td>
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<tr>
<td>Organization Structure</td>
<td>Designating individuals responsible for Market Access will create subject matter expertise for Compliance while providing a Liaison for Market Access colleagues to lean on</td>
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<tr>
<td>Education and Training</td>
<td>Integration with existing Compliance education and training is most effective and efficient path</td>
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<td>Effective Lines of Communication</td>
<td>Leverage existing Corporate level means of communication (e.g., Hotline, messages from Executives); also establish regular touchpoints between designated Compliance individuals and Market Access colleagues (e.g., weekly/monthly staff meetings, etc.)</td>
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<tr>
<td>Auditing and Monitoring/Risk Assessment</td>
<td>Along with policies and procedures, the designated individuals will most need to focus on assessing risk and conducting an effective annual cycle of auditing and monitoring activities</td>
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<td>Enforcing Standards</td>
<td>Leverage existing Corporate level policies and procedures outlining disciplinary guidelines</td>
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<tr>
<td>Corrective Action</td>
<td>Leverage existing Corporate level procedures and resources to respond to detected problems, conduct investigations, undertake corrective actions</td>
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THANK YOU

Please contact us if you have any additional questions or would like to discuss this presentation.

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VALUE-BASED CONTRACTING – BACKUP SECTION 1
INCREASE IN VALUE-BASED CONTRACTING

Several industry trends and events suggest that value-based contracting is gaining critical momentum and is even approaching a tipping point.

Societal
Pharmaceutical prices have been the focus of intense public scrutiny in the past 18 months, and the public wants manufacturers to prove the value of their innovations and justify the corresponding prices.

Provider
Since 2012, three prominent provider organizations put forth recommendations & tools to address the high cost of oncology drugs: the Mayo Clinic, the American Society of Clinical Oncology, and Memorial Sloan Kettering Cancer Center.

Payer
In market conditions where access is an increasingly important basis of competition, innovative payer contracting approaches are critical points of differentiation.

Policy
Policymakers continue to advocate for value-based pricing mechanisms (ACA enablement: CMMI, BPCI, MSSP, VBPM; CMS proposed Part B payment model; CMS Commissioner comments;
VALUE-BASED ARRANGEMENTS

**Performance-Based Pricing**
- Upside Model
- Downside Model
- Cohort Performance
- Money-Back Guarantee
- Try-Before-You-Buy

**Course of Therapy Pricing**
- Flat Pricing
- Pricing Cap
- Interest is increasing, but difficult to implement

**Indication-Based Pricing**
- Same product has different pricing depending on indication for which it is used
- Increasing in use/exploration as more drugs are investigated across multiple indications

**Annuity Pricing**
- Product price/cost shared across payers that cover patient across his/her lifetime
- Nascent methodology
KEY CONSIDERATIONS FOR VALUE-BASED CONTRACTING

- Understand how likely your company is to engage in value-based arrangements (may not be within your control… you need to be prepared)

- Understand the infrastructure in place to manage the risks associated with value-based contracting

- Engage with the pricing and contracting teams to understand their current tactics and contracting strategies, as well as their future plans

- Look upstream from pricing and contracting teams (i.e., to Medical, Commercial, Market Access, HEOR teams) to gain insights and communicate the support you can provide

- Conduct contract compliance auditing/monitoring to understand levels of compliance
POLLING QUESTION #1

To what degree has your company engaged in value-based contracting?

- Often
- Somewhat Often
- Rarely
- Never
- I Don’t Know
POLLING QUESTION #2

Does your company have a policy on value-based contracting arrangements?

- Yes
- No
- I Don’t Know
PRICING STRATEGY & GP REPORTING – BACKUP SECTION 2
CURRENT LANDSCAPE

- US healthcare and health insurance costs have risen steadily, with no clear advances in health outcomes
- Government market continues to grow over time
- Drug pricing and transparency of price increases have become a focus in the news and internally
- New cost sharing initiatives have begun and manufacturers are evaluating various new and evolving contracting strategies
- New guidance and increased government scrutiny
- Need to measure the success of the opportunity, understand potential GP and Medicaid impacts, and manage risks from a broader compliance perspective
KEY CHALLENGES

Medicaid Drug Rebate Program
- A significant reduction in price due to a VBC discount could trigger a new BP and a higher Medicaid rebate. Currently, the program does not have policy exemptions associated to these types of agreements.
- Have to evaluate potential Bundling arrangements and translating the data to Medicaid Unit Based calculations
- True-ups could be very problematic

340B Program
- Given the potential for a new BP and a higher Medicaid rebate, via URA, this program could result in higher PHS prices.

Medicare Part B
- Given that VBC discounts have the potential to trigger lower prices this too could lower ASP therefore reducing the amount which doctors are reimbursed
EVALUATING POTENTIAL ARRANGEMENTS: BRIDGING STRATEGY TO OPERATIONS

Discussion is now much along the strategic objectives and value, and the operational considerations, it is important to look at the layers bridging strategy and operational impact.

- **Strategic Objective**
  - Evaluation of a Strategy & Arrangement
  - Look at the Potential Value to the Business

- **Review of Strategy**
  - Legal Review, is it a Bundle, is there a BP Risk
  - What are the Compliance and Pricing Risks

- **Data Requirements**
  - What would we need to model it and evaluate it

- **Modeling of Impact**
  - Look at the impact on both Commercial and Government Pricing
  - Model the Bundling Impact, the BP and Pricing impact

- **Operational Impact**
  - Determine how to operational impact ongoing

- **Decision Point**
  - Coordinate with Legal and the Business to review results and evaluate risks
POLLING QUESTION #3

How often does your company review and evaluate its government pricing strategy?

- Quarterly
- Annually
- Never
- I Don’t Know