PBM 2015: State of the Industry

Pharmacy Benefit Oversight & Compliance Conference

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PBM 2015: State of the Industry

1. Changing PBM Landscape
2. National Debate over Drug Prices
3. Value-Based Pricing and Purchasing
4. Enforcement Trends
5. Medicare Part D Updates
Changing PBM Landscape
Turn and Face the Strange…Ch-Ch-Changes

- Wave of merger activity in the PBM industry.
  - **February 2015**: Rite-Aid acquires Envision Pharmaceutical Services
  - **March 2015**: United/OptumRx acquires Catamaran Corp.
  - **May 2015**: CVS Caremark acquires Omnicare
  - **June 2015**: CVS Caremark acquires Target Pharmacies
  - **July 2015**: Aetna acquires Humana
  - **July 2015**: Anthem acquires Cigna
  - **October 2015**: Walgreens acquires Rite-Aid
Turn and Face the Strange…Ch-Ch-Changes

- Industry consolidation is reshaping the traditional PBM industry paradigms

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<thead>
<tr>
<th>Payor Affiliated PBMs</th>
<th>Pharmacy Affiliated PBMs</th>
<th>Stand-Alone PBMs</th>
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<tr>
<td>• OptumRx (United)</td>
<td>• CVS Caremark (Omnicare)</td>
<td>• ESI (largest PBM in the US by volume of Rx processed)</td>
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<td>• Humana (Aetna – currently using CVS Caremark)</td>
<td>• EnvisionRx (Walgreens – Rite-Aid)</td>
<td>• Prime</td>
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<td>• ** Cigna – Anthem (currently using ESI)</td>
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<td>• MedImpact</td>
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<td>• Others</td>
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<td>• What does the future hold?</td>
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What are the driving forces behind this M&A frenzy?

1. Desire to generate increased negotiating power and economies of scale in face of rising costs and fewer discount opportunities
   - Drug spending relatively stable in recent years as blockbuster treatments lost patent protection and went generic
   - Prescription-drug spending rose more than 12% last year in the U.S., the biggest annual increase in more than a decade
   - Recent rise of expensive new specialty medicines has put increased pressure on PBMs to demonstrate they have the tools to help employers rein in costs
   - Insurers and employers reeling from the cost of new treatments for hepatitis C, cancer, and high cholesterol
Turn and Face the Strange…Ch-Ch-Changes

- What are the driving forces behind this M&A frenzy?

2. Desire to adapt to new forms of payment encouraged by Affordable Care Act

- Affordable Care Act has spurred government and private payor focus on value-based purchasing and pricing
- Companies with integrated payor and provider operations (including expanded access to data critical for analytics) may be in a better position to save costs and compete in the market
  - Outcomes Arrangements
  - Prescription Drug Adherence Programs
Turn and Face the Strange...Ch-Ch-Changes

What are the driving forces behind this M&A frenzy?

3. Desire to capture market opportunities presented by aging population and ACA expansion of access to health care coverage

• Medicare is seen as growth engine for the industry, as baby boomers age into eligibility and choose MA-PD plans and PDPs
  – Following merger, Humana and Aetna will likely have biggest Medicare market share
  – With aging baby boomers, the LTC industry is expected to grow rapidly in coming years

• ACA and related health care reform initiatives have created greater access to health care coverage and prescription drug services
  – Anthem-Cigna transaction would create a company with a significant commercial insurance footprint available to employers and consumers
What are the driving forces behind this M&A frenzy?

4. Desire to control wider spectrum of distribution thereby creating economies of scale
   - Evidenced by CVS Caremark, United and Walgreens transactions
   - Allows employers and other purchasers to one-stop shop
National Debate Over Drug Prices
Drug Pricing in the Hot Seat

Hillary Clinton
@HillaryClinton

Price gouging like this in the specialty drug market is outrageous. Tomorrow I'll lay out a plan to take it on. -H

The New York Times @nytimes
Overnight, the price of a 62-year-old drug jumped to $750 a tablet from $13.50
nyti.ms/1PgyCpC

PhRMA @PhRMA

@TuringPharma does not represent the values of @PhRMA member companies.
Drug Pricing in the Hot Seat

• **Seeds of Controversy in 2014:**
  - Dramatic generic drug inflation
  - Furor over cost of Hepatitis C Treatments

• **Launch of PCSK9s:**
  - July 2015: Sanofi/Regeneron launch Praluent
  - August 2015: Amgen launches Repatha

• **Turing and Valeant Debacles:**
  - September 2015: Turing increases price of Daraprim (around since 1953) 5000% from $13.50/pill to $750/pill
  - September 2015: Valeant dramatically increases price of acquired heart medications by 525% and 212%
  - Philidor specialty pharmacy relationship questioned
Drug Pricing in the Hot Seat

• **Political Response:**

  – Proposed legislation
    • Sen. Bernie Sanders
    • Presidential Candidate Hillary Clinton
  – Congressional inquiries and hearings
    • House Democrats Affordable Drug Pricing Task Force
  – Subpoenas
    • MA AG and NY AG have requested documents related to pricing decisions and patient assistance programs
  – Antitrust Investigations
    • NY AG investigation of Turing tactics to protect monopoly pricing power
    • Sen. Amy Klobuchar has urged FTC to investigate manufacturers' use of limited distribution programs to thwart generic competition
# Drug Pricing in the Hot Seat

<table>
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<tr>
<th>Sanders Proposal</th>
<th>Clinton Proposal</th>
<th>Center for American Progress</th>
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<td>- Authorizes CMS to negotiate drug prices with pharmaceutical companies</td>
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<td>- Endorses independent comparative effectiveness body to assess benefits of new drugs</td>
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<td>- Includes tougher penalties for drug companies that commit fraud</td>
<td>- Allows drug re-importation</td>
<td>- Publicized on drug labels and in marketing</td>
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<td>- Bans pay-for-delay arrangements between brand and generic manufacturers</td>
<td>- Eliminates tax breaks for direct-to-consumer advertising</td>
<td>- Used to tailor Medicaid drug rebates to a drug’s value</td>
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<td>- Lowers barriers for re-importing drugs</td>
<td>- Calls for $250 limit on consumer deductibles</td>
<td>- Recommends incentives for &quot;reasonable prices&quot; (e.g., loss of patent to competitor)</td>
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<td>- Requires full disclosure of R&amp;D and manufacturing costs, profits, and pricing in other countries</td>
<td>- Curtails brand drug market exclusivity</td>
<td>- Group PBMs and private payors together for greater purchasing power</td>
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<td>- Limits pay-for-delay</td>
<td>- Limits and requires information on patient cost-sharing</td>
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<td>- Creates ratio for % of revenue drugmakers must spend on R&amp;D</td>
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Drug Pricing in the Hot Seat

• Proposals Stand Limited Likelihood of Success

• Congressional scrutiny of drug pricing unlikely to lead to legislation in Republican-majority Congress

• If any legislative steps are taken, drug industry will be part of the debate and comprise likely

• BUT given public outcry and presidential election on the horizon, proposals should not be dismissed outright

• Drug manufacturers will likely self-regulate price increases going forward to avoid scrutiny
  • Valeant recently stated it will no longer make "underpriced" drugs part of its M&A strategy and predicts limiting price increases to 10% per year
Drug Pricing in the Hot Seat

• **Pharmaceutical Industry Response:**
  
  – Distances traditional pharma from Turing and Valeant
  
  – Emphasis on costs of R&D
  
  – Regulation will hurt innovation and slow development of needed treatments
  
  – Prices not high compared to long-term costs for hospitalizations and other complications
  
  – Payors are increasingly shifting the cost burden to patients
    
    • Consumers facing higher medical costs under HDHPs with significant deductibles, coinsurance, co-pays, and exclusionary formularies
  
  – Expansion of patient assistance programs
    
    • Pfizer recently announced it is doubling its income threshold (4x FPL) for patients to qualify for free drugs
Drug Pricing in the Hot Seat

• **Spotlight on Captive Specialty Pharmacies**
  - Valeant accused of using its relationship with specialty pharmacy Philidor to inflate its top line with "phantom sales"
  - Allegations of fraudulent billing practices
  - In the wake of Valeant's Philidor saga, PBMs are taking a closer look at captive pharmacies – those that derive most of their prescription volume from one drugmaker or one therapy
    • Philidor removed from many PBM pharmacy networks
Drug Pricing in the Hot Seat

• **Biosimilars – Breakthrough Year**
  - First biosimilar approved and on the market – Zarxio (Neupogen)
    • Humira and Remicade biosimilars in the pipeline
  - CMS released guidance on Medicare Part B, Medicare Part D, and Medicaid reimbursement of biosimilars
    • Treatment like brand drug in some instances and like generic in others
  - Cost-saving potential is highly anticipated by the industry
    • But will payors, PBMs, and prescribers embrace them?
  - Regulatory hurdles to adoption
    • Lack of interchangeability – need for safety and efficacy data
    • State legislation – theoretical for now
      - Notification and record-keeping requirements
Drug Pricing in the Hot Seat

• **What does this mean for the PBM Industry?**
  – Increasing relevance of PBMs due to their role in reducing drug costs and their ability to assist employers and payors with population health strategies
  – Competition within drug classes for preferred formulary position has created negotiating leverage for PBMs
    • Hepatitis C Market – Gilead and AbbVie
      – Gilead average discount in 2015 = 46%
    • PCSK9 Market – Sanofi/Regeneron and Amgen
  – PBMs must create clinical eligibility criteria
    • For PCSK9s – documentation of diagnosis, cholesterol levels, statin use, diet
Drug Pricing in the Hot Seat

• **What does this means for the PBM Industry?**
  
  – But PBM models will need to evolve:
    
    • Traditional Model = fill as many Rxs as possible and drive down costs through use of generics, tiered formularies, and mail order utilization
    
    • Evolving Strategic Model = focus on population health, integration of medical and drug benefits, and value-based payment models
Value-Based Pricing and Purchasing
Value-Based Purchasing

• Move to Value-Based Purchasing and Outcomes Based Pricing
  – PBMs can assist payors and pharmacies in advancing more quickly to value-based payments
  – PBMs can also lead the way in value-based pricing arrangements with pharmaceutical manufacturers
    • So far Payors and PBMs hesitant to adopt
    • Regulatory challenges – Federal Anti-Kickback Statute
  – Move towards integration of medical and drug benefits
    • Potential accelerated by recent payor/PBM merger activity
    • Challenges to collect the right data
    • Potential for risk arrangements
Value-Based Purchasing

• Data's Critical Role

  – Big Data potential to identify which drugs work in which patients
    • Allows use of medications as precisely targeted therapies
    • Potential to prevent unnecessary spending on futile therapies
    • Outcomes data provides evidence for development of treatment guidelines

  – PBMs can use claims and data analytics to engage members, increase adherence, reduce hospitalizations
    • CBO estimates that 1% increase in adherence translates to decreased medical spending
Value-Based Purchasing

- **Amgen – Harvard Pilgrim Ink Pay-for-Performance PCSK9 Deal**
  - Provides Repatha with exclusive spot on payor formulary in return for up-front discounts and future rebates if Repatha doesn't perform as outlined
  - Parties agreed on specific cholesterol targets for various patient groups, and if Repatha doesn't help patients hit those goals, Harvard Pilgrim can collect additional rebates
  - Additional rebates would be due if spending surpasses an agreed-upon threshold
Value-Based Purchasing

• CMS Letters to State Medicaid Directors and Drug Manufacturers

  May Signal Policy Change Away from FFS Drug Purchasing

  – This month, CMS sent letters to Medicaid directors of all 50 states, as well as Hepatitis C manufacturers Gilead, AbbVie, J&J, and Merck

  – CMS interested in learning about "value-based" pricing arrangements which may affect drug prices and state Medicaid discounts

  – CMS also warned state Medicaid agencies against limiting access to the drugs on the basis of cost
Enforcement Trends
Enforcement Impacting PBMs

- **Copay Cards**
    - Kmart settled with the U.S. for (i) improperly permitting beneficiaries of federal health programs to redeem drug manufacturer coupons and (ii) offering customers discounts on gasoline purchases at participating gas stations in order to incentivize beneficiaries of federal health programs to use Kmart pharmacies.
    - Declined Qui Tam

- **Formulary Preference – Bundled Rebates**
  - *AstraZeneca Settlement, February 2015*
    - AstraZeneca agreed to pay the United States for $7.9 million to settle allegations that it paid kickbacks to Medco to maintain Nexium's "sole and exclusive" status on Medco formularies in violation of the Anti-Kickback Statute.
Enforcement Impacting PBMs

- **Performance/Adherence Rebates and Kickbacks**
  - **Novartis/Kester Settlement, October 2015**
    - Novartis agreed to pay $390 million to settle allegations that the company induced specialty pharmacies to increase prescriptions for Novartis drugs by paying kickbacks in the form of rebates.
    - BioScrip settled for $15M in January 2014 and Accredo settled in May 2015 for $60M
    - CVS is still proceeding with potential litigation over the allegations.
  - **PharMerica Settlement, October 2015**
    - PharMerica agreed to pay $9.25 million to settle allegations that it received kickbacks, in the form of rebates, educational grants, and other financial support from Abbott labs in exchange for promoting Depakote to its nursing facility residents.
Enforcement Impacting PBMs

• Pharmacies and PBMs are Enforcement Targets
  – Settlements highlight DOJ's recent focus on relationships pharmaceutical manufacturers have with pharmacies and PBMs
  – HHS-OIG has focused on arrangements between pharmaceutical manufacturers and pharmacies in its Work Plan, special bulletins and advisory opinions

"We will continue to pursue pharmaceutical companies that pay kickbacks to pharmacy benefit managers"
Enforcement Impacting PBMs

• **Yates Memo**
  - Released September 2015 and represents formal policy shift
  - Instructs prosecutors to focus on individual accountability of corporate misconduct.

• **Application of Yates Memo: Warner Chilcott**
  - In October 2015, Warner Chilcott agreed to plead guilty to felony healthcare fraud charges and pay $125 million in connection with illegal marketing of certain drugs.
  - Former president arrested and charged with conspiring to pay kickbacks to physicians.

"Today’s enforcement actions demonstrate that the government will seek not only to hold companies accountable, but will identify and charge corporate officials responsible for fraud"
State Enforcement Impacting PBMs

- State Attorney Generals have targeted pharmacies for automatically shipping drugs to patients homes and lack of proof of delivery:
  - New York Attorney General settles with Trinity Homecare LLC for $2.5M for undocumented delivery by the pharmacy of infusion drugs (June 2015).
  - Massachusetts Attorney General settles with pharmacy for more than $1.5 million to settle allegations that it "improperly billed and received payments from the state’s Medicaid program when it automatically refilled prescription medications that were not specifically requested by MassHealth patients or caregivers (January 2015).
Medicare Part D Updates
Federal Oversight of PBMs

• OIG 2016 Workplan and Part D
  – Continued focus on Sponsor Compliance with Part D:
    • Reconciliation of payments – Continued focus on compliance with Direct and Indirect Remunerations (DIR)
    • Conflicts of Interest – OIG to determine steps CMS has taken to improve oversight of P&T committees
  – CMS Audits
    • 2015 started new audit cycle
    • Failure to report universe data timely results in an ICAR. Potential for significant ICARs for data issues
  – CMS Sanctions and Civil Monetary Penalties (CMP)
    • Between January 1, 2015 and September 2015, CMS levied 21 CMPs and/or sanctions.
    • In April 2015, CMS issued largest sanction for $1 million for "non-network retail pharmacies [that] were erroneously identified by Aetna as “retail in-network” for 2015 on its website and through its call center customer service."
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