Addressing Challenges Related to Specialty Drug Pricing & Contracting

- Assess Patient Adherence Programs & New HIPPA Laws
- Explore Various Coupon/co-pay strategies and best practices
- Deep dive into the OIG Report on co-pay coupons
- Discuss the trend of specialty-at-retail pharmacy
Assess Patient Adherence Programs & New HIPPA Laws

- HIPAA Compliance in healthcare has assumed greater importance since the passage of the HITECH Act of 2009, and the regulations implementing the HIPAA provisions of the Act.

- Consequently, healthcare entities need to get serious integrating these regulations into their operations.

Expansion of HIPAA regulations

- The original HIPAA regulations were issued in 2000 and laid the foundation for a national set of requirements to safeguard the:
  - Confidentiality
  - Integrity
  - Availability of individually identifiable health information

- Over the years, these HIPAA regulations have been modified and expanded, most recently to cover ePHI (protected health information maintained and transmitted electronically), and to specify requirements for notifying patients in the event of an unauthorized disclosure or breach of security.
HIPAA Compliance ... and Penalties for violations

- HIPAA covered entities may be subject to steep penalties for violating these regulations. For general penalties they range from ...
  - A minimum of $10,000 for each violation
  - A maximum of $25,000 for each violation
  - Wrongful disclosure of ePHI can include a maximum fine of $50,000 and imprisonment
Group 1: Patient Adherence Programs & New HIPPA Laws

1. Provide back to the group suggestions and Best Practices in addressing the issues around Patient Adherence and New HIPPA Laws

2. What works as far as tactics to providers and navigating around the laws
Coupon/Co-Pay Strategies & Best Practices

• Prescription copay coupon marketing programs, which lure insured consumers toward more expensive brands, will increase costs by $32 billion over the next decade, according to new research released by the Pharmaceutical Care Management Association (PCMA).

• Drug companies now offer "copay coupons" to undermine efforts by employers, unions, and state governments to reduce costs by assigning higher consumer copays to expensive drugs and lower copays to more affordable drugs.

• Following a flurry of activity and news coverage around this issue, policymakers, the news media, and others are examining possible next stages in this debate.

• Key questions remain....
Deep Dive on the OIG Report on Co-Pay Coupons

- In September 19, 2014, the U.S. Department of Health and Human Services Office of Inspector General (“OIG”) released a study showing that pharmaceutical manufacturer safeguards to prevent Medicare Part D (“Part D”) beneficiaries from using co-pay coupons may not be completely effective.

- The study analyzed 40 co-pay coupons from 30 pharmaceutical companies, along with the disclaimers included with the coupons and the pharmacy claims edits used to identify and disqualify Part D enrollees.

- The study found that these safeguards have had only limited effectiveness because written disclaimers and warnings cannot stop a patient from presenting a coupon at a pharmacy, and while claims edits can prevent a discount from being applied, most manufacturers use inaccurate information to identify Part D enrollees.

- Simultaneously with the issuance of the report, OIG issued a Special Advisory Bulletin stating that manufacturers are responsible for ensuring that their co-pay coupon programs do not induce federal health benefit beneficiaries to purchase their branded drugs over generics.

- Therefore, pharmaceutical manufacturers must take note that the identified deficiencies in Part D enrollment verification could result in criminal and civil enforcement actions under the Federal anti-kickback statute (“AKS”).
Group 2: Coupon/Co-Pay Strategies & Best Practices

1. Consider the following questions and report back to the group navigating around the challenges and regulations to share best practices with solutions in addressing on-going concerns

- Each year, $4 billion is spent marketing copay coupons, which yield a 6:1 return on investment. Besides payers, who pays this $24 billion to manufacturers?

- If the goal of copay coupons is to remove financial barriers to adherence, why do they only target consumers who already have prescription drug coverage (i.e. those with copays) instead of the 50 million Americans who don’t?

- If the goal of copay coupons is to help consumers in financial need, why aren’t they means-tested and targeted toward low-income people?

- Do copay coupons encourage newly diagnosed patients to try expensive brands before trying generics?

- Why are copay coupons banned as illegal kickbacks in Medicare and other federal programs?
Trends of Specialty-at-Retail Pharmacy

- Specialty drugs are prescribed to treat complex conditions such as cancer, HIV and inflammatory diseases.

- While these drugs fulfill the promise of modern medicine by enriching and often extending a patient’s quality of life, they are typically characterized as expensive therapies having a high cost/unit.

- IMS Health defines specialty medicines as ones that meet five or more of the following 8 criteria:
  - Biotech Product
  - Injectable formulation
  - REMS Program
  - Treats a chronic condition
  - Specialist-initiated
  - Requires special handling (cold-chain)
  - Costs in excess of $6K/year
  - Limited distribution
Trends of Specialty-at-Retail Pharmacy

• By 2018, 7 of the 10 top-selling drugs in the United States are expected to be specialty pharmaceuticals

• The change may forever alter the way prescription drugs are distributed and dispensed

• Specialty drugs are shaking up retail pharmacy; their complexity challenges specialty pharmacies to sharpen support services; and their cost gives new importance to the pharmacy benefit manager

• Health plans have more opportunity to manage distribution channels to their advantage by working with the large SPs

• Community retail pharmacists are anxiously watching as the influx of inexpensive generics trim their revenues, within 5 years, generics will account for 85 to 90 percent of retail dispensing
Group 3: Trends of Specialty-at-Retail Pharmacy

Considering Current Trends report back to the group:

1. Working with Healthplans and PBMs in the future share with the group top issues in how to address the payer/manufacturer relationships to close the loop in providing tactics across distribution channel with solutions

2. If you were to have a crystal ball... what will the entry of biosimilars have on the specialty market? Will retailers have a role, what will these products do to the contracting landscape of specialty products?