DEMYSTIFYING THE U.S. DRUG INSURANCE & REIMBURSEMENT STRUCTURE
The U.S. drug insurance and reimbursement structure has been one of the most perplexing of all topics for several people to comprehend, yet of paramount importance to the healthcare industry. The challenge in understanding this structure majorly arises from the complex flow of elements involving various participants. The U.S. pharmaceutical distribution chain is unlike simple distribution ones, in which products flow from manufacturers to C&F agents, to wholesalers, retailers, and finally to patients. Instead, the U.S. involves numerous third party organizations such as Medicare, Medicaid, MCOs, PBMs, and MCOs to govern the reimbursement for a drug. The involvement of third party organization complicates the distribution and reimbursement process in the U.S., and paradoxically are the major cause of higher drug pricing, although are intended to reduce costs for patients in the country.

**Fig 1: Decision Makers in the U.S. Reimbursement System**
Private health insurance accounts for a lion’s share in the U.S. health insurance market. In 2016, 65.0% of the U.S. population aged below 65 years were covered under private health insurance, while only 26.3% were covered under public health insurance. While, the share of public insurance in this age group, increased from 22.0% in 2010 to 26.3% in 2016, share of private insurance also increased from 61.2% in 2010 to 65% in 2016. The percentage of uninsured population in the U.S. has decreased from 16.0% in 2010 to 9.0% in 2016.
**GOVERNMENT ORGANIZATIONS**

*Medicare has the largest share in total healthcare spending*

Medicare spending increased by 3.6% in 2016 to US$ 672.1 billion (20% of total NHE) compared to that in 2015, while that of Medicaid increased by 3.9% to US$ 565.5 billion in 2016 (17% of total NHE). Simultaneously, the spending by the private health insurance increased by 5.1% to US$ 1,123.4 billion in 2016 (34% of total NHE).

**Fig 3: Difference between Medicare and Medicaid**

**Medicare**
- Federally funded
- Same program/coverage plan nationwide
- Benefits people over the age of 65 years
- Participants pay deductibles and for part of coverage
- Paid for by a trust fund, funded with Payroll taxes
- Divided into Part A, B, C and D

**Medicaid**
- Federally and state funded
- Coverage varies from state to state
- Benefits people with low income, disabilities and pregnant women
- Participants pay very little or no part of coverage
- Paid for by Federal, State and Local taxes
- Participants receive regular dental and vision exams

**Children’s Health Insurance Program (CHIP):**
- Funded by State and Federal Governments
- Administered by states, according to Federal requirements
- Health coverage for eligible uninsured children up to 19 years of age
- Provides coverage through Medicaid and separate CHIP programs
PRIVATE ORGANIZATIONS

HMOs and PPOs are the most widely preferred MCOs

Managed Care Organizations and PBMs are major private organizations working in the drug reimbursement system in the U.S. MCO consists of four different organizations offering different health plans to patients as mentioned in the below table.

<table>
<thead>
<tr>
<th></th>
<th>HMO</th>
<th>PPO</th>
<th>POS</th>
<th>EPO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Predefined Provider Network</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Designate a PCP</td>
<td>✓</td>
<td></td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>PCP Referral Required</td>
<td>✓</td>
<td></td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Can visit out of network of providers</td>
<td></td>
<td>✓</td>
<td>✓</td>
<td></td>
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</tbody>
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As per the total healthcare expenditure data of 2016:

- Physician and clinical services expenditures increased by 5.4% to US$ 664.9 billion in 2016, a slower growth than the 5.9% in 2015
- Prescription drug spending increased by 1.3% to US$ 328.6 billion in 2016, slower than the 8.9% growth in 2015

Fig 4: Types of MCOs

- Health Maintenance Organization (HMO)
  - Has a network of providers
  - Member does not designate a primary care physician
  - PCP referral is required to visit a specialist
  - Out-of-network providers are not covered
  - No need to submit claims form
  - Lower premium and Co-pays

- Preferred Provider Organization (PPO)
  - Has a network of physicians, hospitals, labs and health care facilities
  - Member is free to choose a provider outside the network of PPO plan
  - Member does not have to mandatorily designate a primary care physician
  - PCP referral is not required to visit a specialist
  - Out-of-network providers are covered at a percentage of the actual and accepted costs
  - Member has to submit claims form for reimbursement
  - Higher premium and Co-pays

- Point of Service (POS)
  - Has a network of providers and care providers
  - Members designate a PCP within the network
  - Member can visit or use the care providers outside of network without PCP referral, with an additional cost
  - Lower premium if providers within the network are preferred
  - Hybrid of HMO and PPO plans

- Exclusive Provider Organization (EPO)
  - Services are covered only if the member uses doctors, specialists, or hospitals in the plan’s network (except in an emergency)
  - Out-of-network care is not provided
  - Primary care provider is not necessary
  - PCP referral is not necessary
PHARMACY BENEFIT MANAGERS (PBMs)

PBMs negotiate with drug manufacturers and create drug formularies to reduce the drug cost to patient. They administer the Rx drug as part of health plans on behalf of employers and insurance companies. Their major role lies in reducing expenditure on drugs and increasing accessibility to medications. In short, a PBM is an isthmus between the employers, wholesalers, pharmacies, members, and drug manufacturers that work to facilitate cost-effective health outcomes. With diminishing transparency, PBMs today earn huge profits through escalation of prices to drug plans. The three largest PBMs – CVS Health, Express Scripts and OptumRx, control over 80% of the health plan related drug purchases. The PBMs are compensated through rebates, administrative fees or pharmacy spread.

As the PBMs connect all the stakeholders in healthcare system, they get rebates, margins or fees from those stakeholders. By negotiating with drug manufacturers it gets rebates and collaborating with insurers, pharmacies and members/patients earns him service/administrative fees.

PBMs have instead increased the burden to health plans through their lack of transparency in pricing and plans. These games are:

- Spread game
- Repackaging and repricing game
- Rebate game
- Mail order waste game

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Preference for White and Brown bagging has shifted the product coverage from medical benefit to pharmacy benefit

The traditional Buy and Bill channel is getting displaced with the growing popularity of White bagging and Brown bagging channels. For around 25% of the oncology products in the U.S. market, white- and brown-bagging channels are followed.

Fig 5: Flow of Different Physician Administered Drug Distribution Channels

- In Buy and Bill, the provider bills the payer for reimbursement/claims for medications and related services
- In White Bagging and Brown Bagging, pharmacies bill the payers for cost of drugs and prescribers/providers bill the payers for drug’s administration and related services

Through white and brown bagging, the payers are able to purchase products at a lower cost from the pharmacies than an oncology practice. White bagging includes logistical challenges as the provider needs to stock and store the medication until it is administered to the patient. This adds to the cost of therapy for the patient.

In view to sail in the lucrative oncology drugs market, many payers and oncology practices have established their in-house specialty pharmacy. Moreover, payers have also mandated white and brown bagging channel for a few products. Nearly 60% of the cancer care in the U.S. is provided by community-based oncology practices.
APPENDIX

C&F Agents – Clearing and Forwarding Agents
HHS - Department of Health and Human Services (HHS)
MCOs - Managed Care Organizations
PBMs - Pharmacy Benefit Managers
CMS – Centers for Medicare & Medicaid Services
CDER – Center for Drug Evaluation and Research
CHIP – Children’s Health Insurance Program
HMO – Health Maintenance Organization
PPO – Preferred Provider Organization
EPO – Exclusive Provider Organization
POS - Point of Service
REFERENCES:

- CDC
- cms.gov
- U.S. FDA
- American Medical Association

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