Session 15, Actuaries and Pharmaceutical Manufacturers: Friend or Foe?

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Actuaries and Pharmaceutical Manufacturers: Friend or Foe?

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SOCIETY OF ACTUARIES®

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Panel

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Agenda

Who?	What?	How Long?
Karl	• Introductions and Context	10 mins
Jason	• Current Plan & Manufacturer Interactions • Pharma Constraints & Considerations	25 mins
Whitney	• Key Assumptions Actuaries Could Get from Pharma • Contract Considerations	25 mins
All	• Q&A	15 mins

How did we get to this podium?

Language?

Value Drivers?

Methods?

Culture?

Context (Continued)

- Due to high and variable pharmacy costs and utilization trends, actuaries have become more involved in drug formulary decisions
  - How can actuaries and pharmaceutical manufacturers better work together to improve market predictions and provide access to necessary drugs?
  - What discussions are currently taking place between manufacturers and payers?
  - Is there value in these discussions that actuaries are missing?
- This panel discussion:
  - Provides both actuarial and manufacturer perspectives
  - Is intended to contribute to an enhanced mutual understanding
  - Will (hopefully) lead to different interactions and better communication with pharmaceutical manufacturers
  - Describe applicable pharma-provided assumptions
  - Explore contract negotiations with pharmaceutical manufacturers

Agenda

- Current Plan & Manufacturer Interactions
- Pharma Constraints & Considerations
- Key Assumptions Actuaries Could Get from Pharma
- Contract Considerations

Agenda

Current Plan & Manufacturer Interactions

Pharma Constraints & Considerations

Key Assumptions Actuaries Could Get from Pharma

Contract Considerations

Pharma Company Interactions

Interactions between Health Plans and Pharmaceutical Companies (Pharma)

Current Plan & Manufacturer Interactions

Face-to-Face Discussions

- Coincide with commercial and Medicare premium bid cycles
- Provide value proposition of drug/ device
  - Clinical & economic value
  - Marketing/forecasting

Discussion Time-Frame

- 20-30min per Therapeutic Area (TA)
- Higher cost of TA results in more discussion time

Pipeline Discussions

- New drugs/devices expected to enter the market
  - Clinical trial designs
  - Targeted population
- Discussions between Medical/HEOR at pharma and health plan
- These are longer discussions occurring ~ 1 time/year

Key Data Sources Used/Provided by Pharma

Market Utilization Data (National & Plan)

- External prescribing data sources (IQVIA is common)
- Trade channel distribution (e.g., long term care vs hospital vs retail)
- Reviewing different drug classes within the disease state to determine prescribing patterns to inform strategies and tactics
- Commercially-available claims databases

Clinical Trial Data

- Created by manufacturer to prove causation in the condition for which the drug acts
- Used for regulatory approval through the FDA
- Also used for potential future indications

Models Provided by Pharma

HEOR Study Examples

- **Budget Impact Model (BIM)**
  - Scenarios comparing costs of current versus alternative treatments
  - Primarily consider pharmacy costs, but may also include direct medical costs
  - Reviews impact of cost per patient and cost to overall impacted population
- **Cost-Effectiveness Model (CEM)**
  - Evaluate incremental costs relative to incremental health effects of competing drugs
  - Provided to health plan as a resource that may be used to make decisions maximizing health effects with fixed resources

Pharma Goals

1. Access to plan formulary

2. Improve utilization through formulary design and utilization management programs

3. Manage net price over time

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- **Pharma Constraints & Considerations**
- Key Assumptions Actuaries Could Get from Pharma
- Contract Considerations

Pharma Considerations

Food & Drug Administration (FDA)

Code of Federal Regulations (CFR)

Ensure fair and balanced pharmaceutical promotions

FDA Guidance on Communication with Payers

- On-label health care economic information
- Off-label
- Unapproved products

FDA Guidance Regarding Pharma Communication with Health Plans

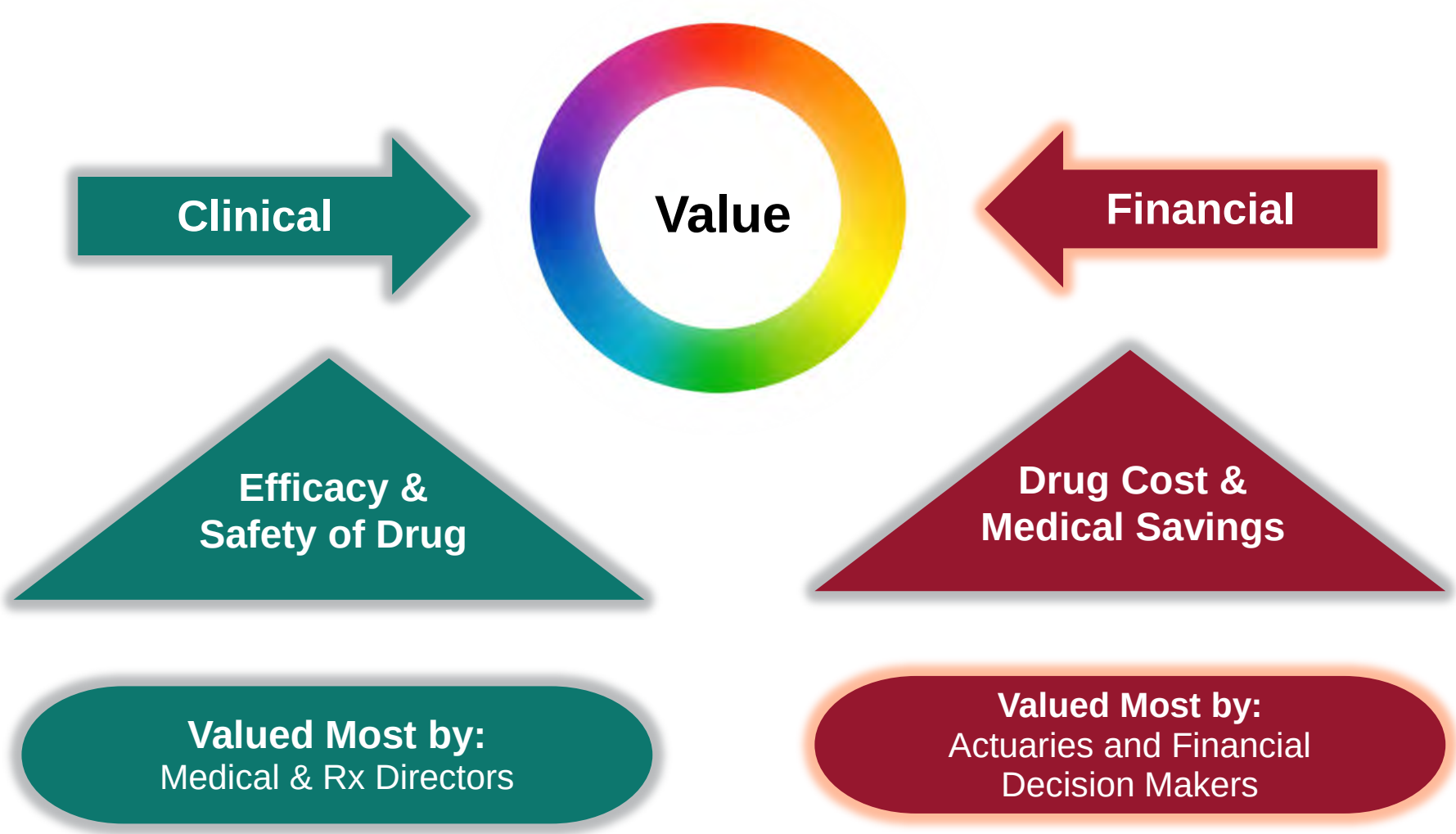
Pharma Constraints & Considerations

Already Approved Drugs
Duration of treatment
Health care setting
Burden of illness
Dosing/use regimen
Patient subgroups
Length of hospital stay
Surrogate or intermediate endpoints
Clinical outcome assessments or other health measures (e.g. quality-adjusted life year)
Compliance/adherence
Persistence
Comparisons (drug or intervention or no treatment)

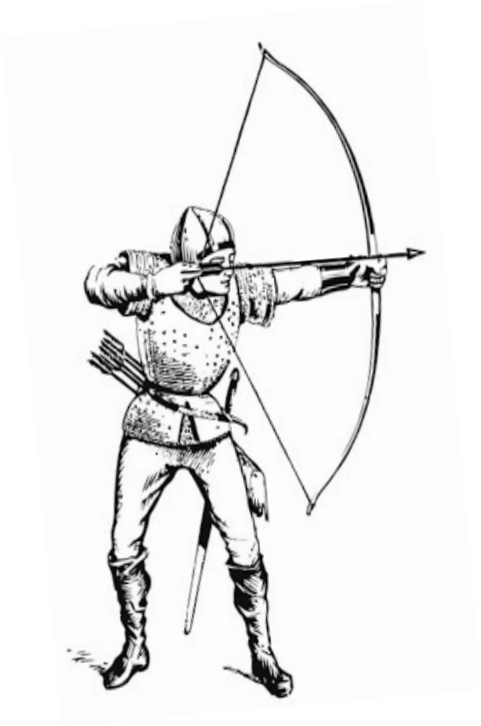
Unapproved Uses and Drugs Waiting for Approval
Product information (e.g. drug class)
Indication(s) being sought
Clinical study protocol(s)
Endpoint(s) being studied
Patient population under investigation (e.g. number of subjects enrolled, subject enrollment criteria, subject demographics)
Anticipated timeline for possible FDA approval
Product pricing
Patient utilization projections (e.g. epidemiological data projection on incidence and prevalence)
Product-related programs or services (e.g. patient support programs)
Factual presentations of results from studies, including clinical studies (without characterizations or conclusions about safety or effectiveness of the unapproved product or use)
Stage of clinical development

U.S. Department of Health and Human Services, Food and Drug Administration. (2018). *Drug and Device Manufacturer Communications with Payors, Formulary Committees, and Similar Entities—Questions and Answers.* (FDA: Maryland).

Pharma's Definitions of Value



Pharma's Major Competitive Threats



- Product Differentiation
- Competitor New Mechanism of Action (MOA)
- Product Class Commoditization
- Volume Growth Inhibitors
- Other Brands & Generics as Patents Expire

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- **Key Assumptions Actuaries Could Get from Pharma**
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New Drug to Saturated Market

Key Assumptions Actuaries Could Get from Pharma

Scenario

- Population is known
- Direct drug competitors already on the market

Example

- Additional SGLT-2s to diabetes market

Actuarial Methods

- Use historical experience to anticipate cost and frequency

Pharmacy Could Provide…

- No big/changing events, so no need for external info

New Method of Action (MOA) to Established Market

Key Assumptions Actuaries Could Get from Pharma

Scenario

- Population is known
- ***No direct drug competitors*** on the market

Example

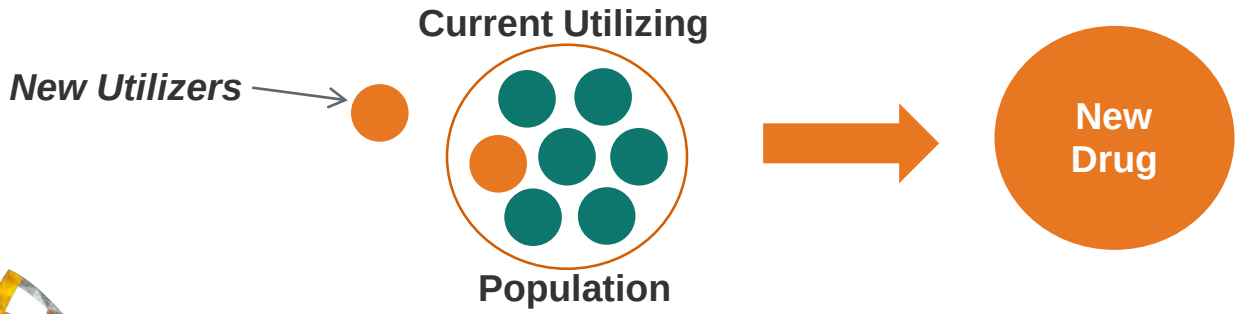
- New oral product in RA

Actuarial Methods

- Estimate shift to new drug using similar scenarios for different drugs
- Estimate cost using published reports, expert opinion (i.e. Health Technology Pipeline)

Pharmacy Could Provide…

- Expected shift percent
- Expected costs



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Key Assumptions Actuaries Could Get from Pharma

New MOA to Unsatisfied Market

Scenario

- Population is ***unknown***
- ***No direct drug competitors*** on the market

Example

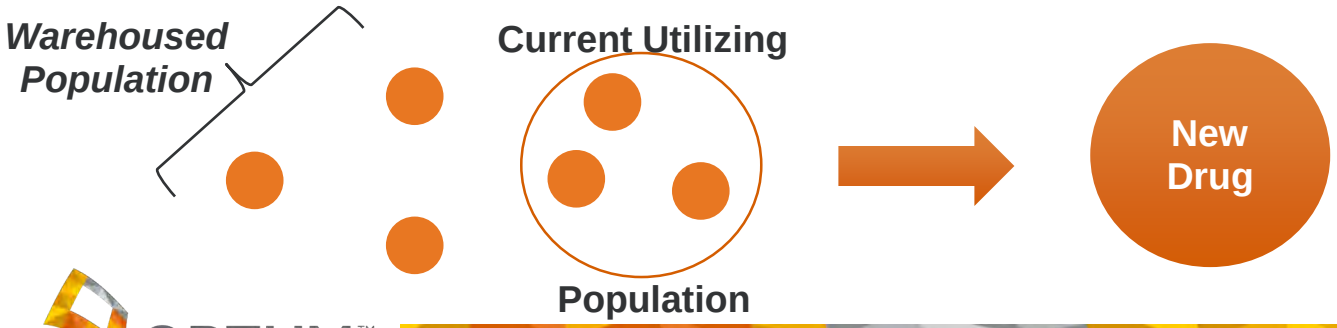
- First Launches of New Hepatitis C

Actuarial Methods

- Similar to New MOA in established market
- Additionally, estimate "warehoused" population through historical diagnoses and online research

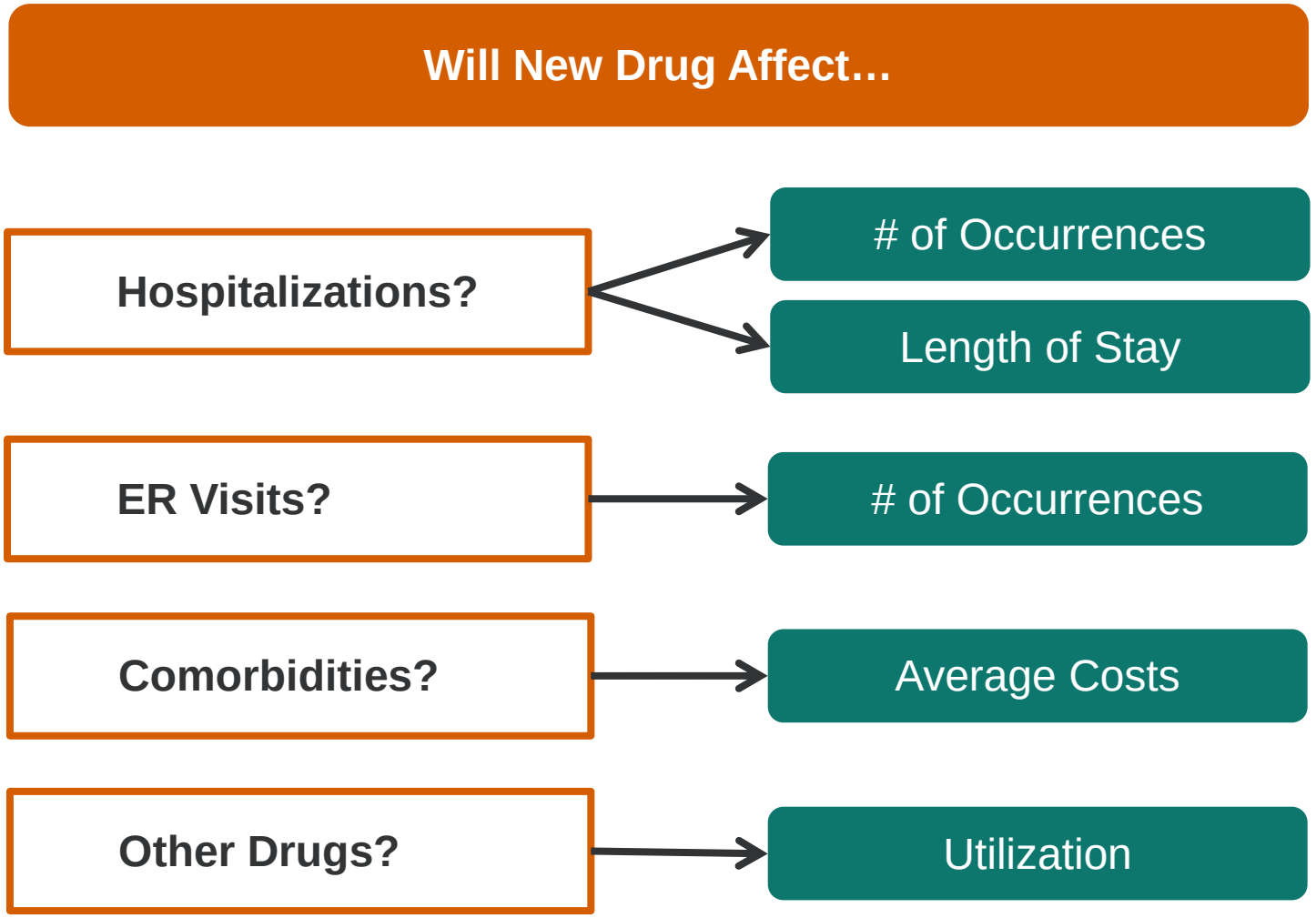
Pharmacy Could Provide…

- Expected shift percent & costs
- Estimate of disease in total insured population



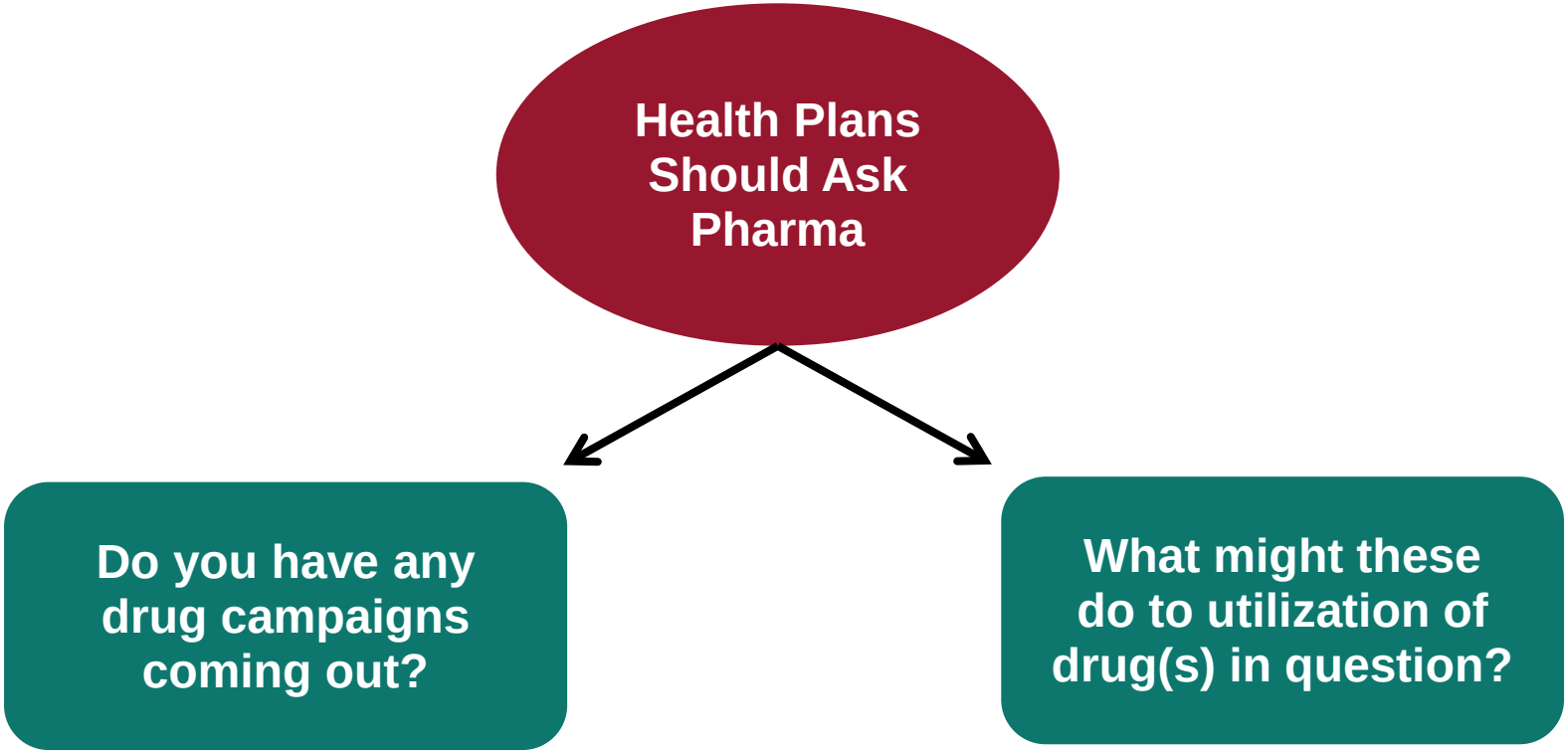
Medical Cost Impacts

Key Assumptions Actuaries Could Get from Pharma



Marketing Impact on Behavior

Key Assumptions Actuaries Could Get from Pharma



- Pharma invests a lot in direct to consumer (DTC) advertising.
- Pharma may be able to provide estimated impacts on utilization due to advertising, but not all.

Pharma Assumptions

Key Assumptions Actuaries Could Get from Pharma

- ***Pharma assumptions are sourced differently***
  - Fully focused on one disease state
  - Lots of research done on previous analyses
  - Perform disease/drug-specific clinical testing
  - Tests developed prove drug causes clinical change

- ***Challenges with pharma assumptions***
  - Usually based on a tightly defined population
    - Difficult to apply to a broader population
    - Not likely to be presented on a PMPM or a per 1000 members basis
  - Pharma research findings tend to report current findings
    - Trend is unlikely to be applied to models

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- Key Assumptions Actuaries Could Get from Pharma
- **Contract Considerations**

Definition of AWP and WAC

Average Wholesale Price (AWP)

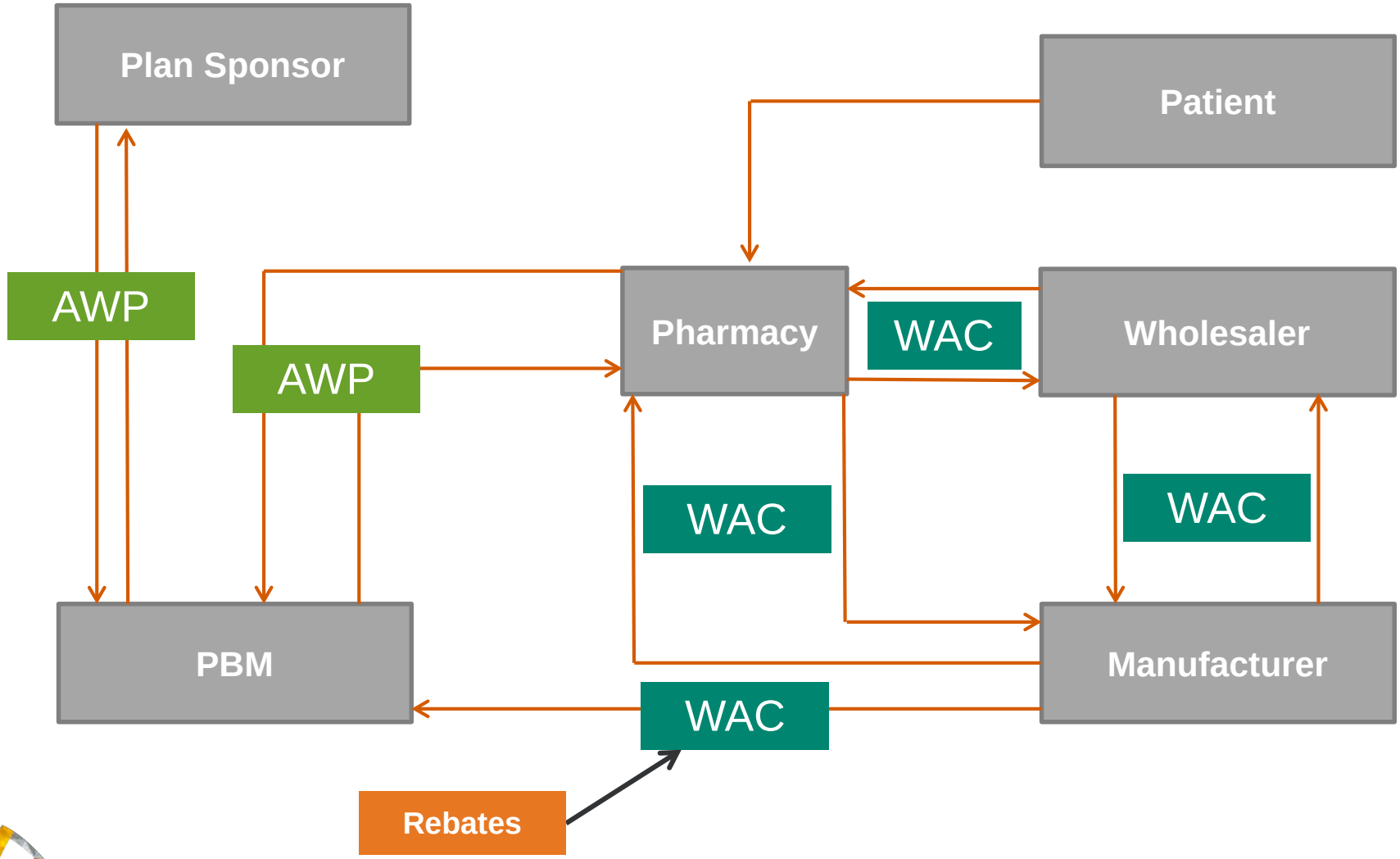
AWP is based on data obtained from manufacturers and distributors, but it's not an average nor is it based on any actual prices paid by anyone.

Wholesale Acquisition Price (WAC)

WAC is the manufacturer's suggested list price, which may also be used as a sale price to the wholesaler.

Drug Type	AWP & WAC Relationship	Reason Behind Relationship
Brand Drugs	AWP = 1.20 * WAC	Each drug has a unique manufacturer.
Generic Drugs	No Direct Correlation	Each manufacturer has a distinct WAC, whereas the AWP is typically the same for all generics.

Use of WAC vs AWP in Contracts



Risk Sharing Agreements

Risk sharing agreements are a way for payers to reduce risk through Financial or Outcomes-Based Contracts.

Financial-Based Contracts

- Focused on the financial arrangements between the manufacturer and purchaser; not tied to specific performance metrics
- Includes the following:
  - Traditional rebates/discounts
  - Price-volume agreements
  - Quantity limits
  - Treatment initiation

Outcomes-Based Contracts

- Contracts tied to specific performance metrics such as biomarkers, clinical outcomes, or other metrics (e.g., hospitalizations, total cost of care)
- Includes the following:
  - Coverage with evidence development
  - “Guarantee” type contracts

Outcomes-Based Contracts are becoming an increasingly popular topic of discussion as the US health system moves to a pay-for-performance model.

Constructing Win-Win Risk Share Agreements

A systematic approach to designing and implementing risk share agreements:

Research

- Target patient?
- Current real-world outcomes?
- Historical agreement structure strengths and weaknesses?
- Target performance measures?

Design

- Agreement model simulation results?
- Proposed structure(s)?
- Accompanying interventions?
- How do we collect data and how frequently?
- What could go wrong and how do we avoid?

Pilot

- How well does it work?
- Opportunities to improve?
- Considerations for scale?

Scale

- Final agreement structure?
- Roll out plan?
- Adjudication process?

Oversight checkpoints after each phase

Source: "Private Sector RSAs in the United States", September 2015 issue of American Journal of Managed Care, Vols. 21, No. 9