Background on pharmacy benefit managers and specialty pharmacies

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MEDPAC

Roadmap for this presentation

- What are specialty drugs?
- Key roles of pharmacy benefit managers (PBMs) and specialty pharmacies (SPs)
- Manufacturers' limited distribution networks
- Three examples of ownership arrangements for SPs
- Policy issues related to Medicare

What are specialty drugs?

- Treat complex conditions
- Some drugs under medical benefit / Part B (e.g., infusibles), others under pharmacy benefit / Part D (e.g., orals, self-injectables)
- Patient education and support, data reporting, more challenging logistics
- Very high prices and high per-user spending
  - In 2014, 2% of Part D specialty-tier prescriptions accounted for 16% of Part D spending
  - In 2016, 1%-2% of all U.S. retail prescriptions for specialty drugs made up about 1/3 of drug spending

Specialty drugs with largest 2015 spending in Part D

Brand name	Examples of use	Gross annual spending per user	Total gross Part D spending ($bns)
Harvoni	Hepatitis C	$92,847	$7.0
Revlimid	Anemia, oncology	68,217	2.1
Humira	RA, psoriasis, Crohn's	29,278	1.7
Enbrel	RA, psoriasis	27,117	1.4
Copaxone	MS	50,048	1.4
Sovaldi	Hepatitis C	89,297	1.3
Gleevec	Oncology	81,152	1.2
Tecfidera	MS	46,579	0.9
Xtandi	Oncology	46,751	0.8
Zytiga	Oncology	46,569	0.8

Notes: $bns (billions of dollars), RA (rheumatoid arthritis), MS (multiple sclerosis). Gross spending refers to prescription drug event amounts prior to rebates.
Source: MedPAC based on CMS Dashboard Data.

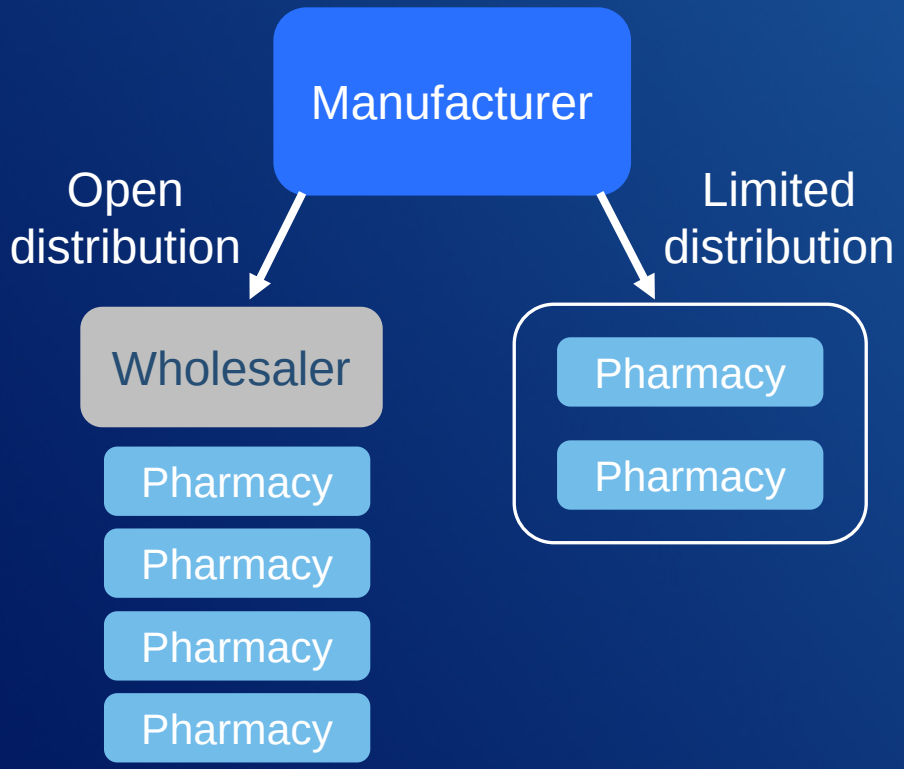
PBM industry is evolving

- PBM industry has consolidated
- In Part D, plan sponsors must report rebates received by their PBMs (pass-through pricing)
- More commercial payers ask PBMs to pass through rebates, receive administrative fees
- All major PBMs own specialty pharmacies
- Conflicting interests?
  - Manage pharmacy spending for PBM clients (plan sponsors and payers)
  - Expand specialty pharmacy revenues

Specialty pharmacy (SP) industry

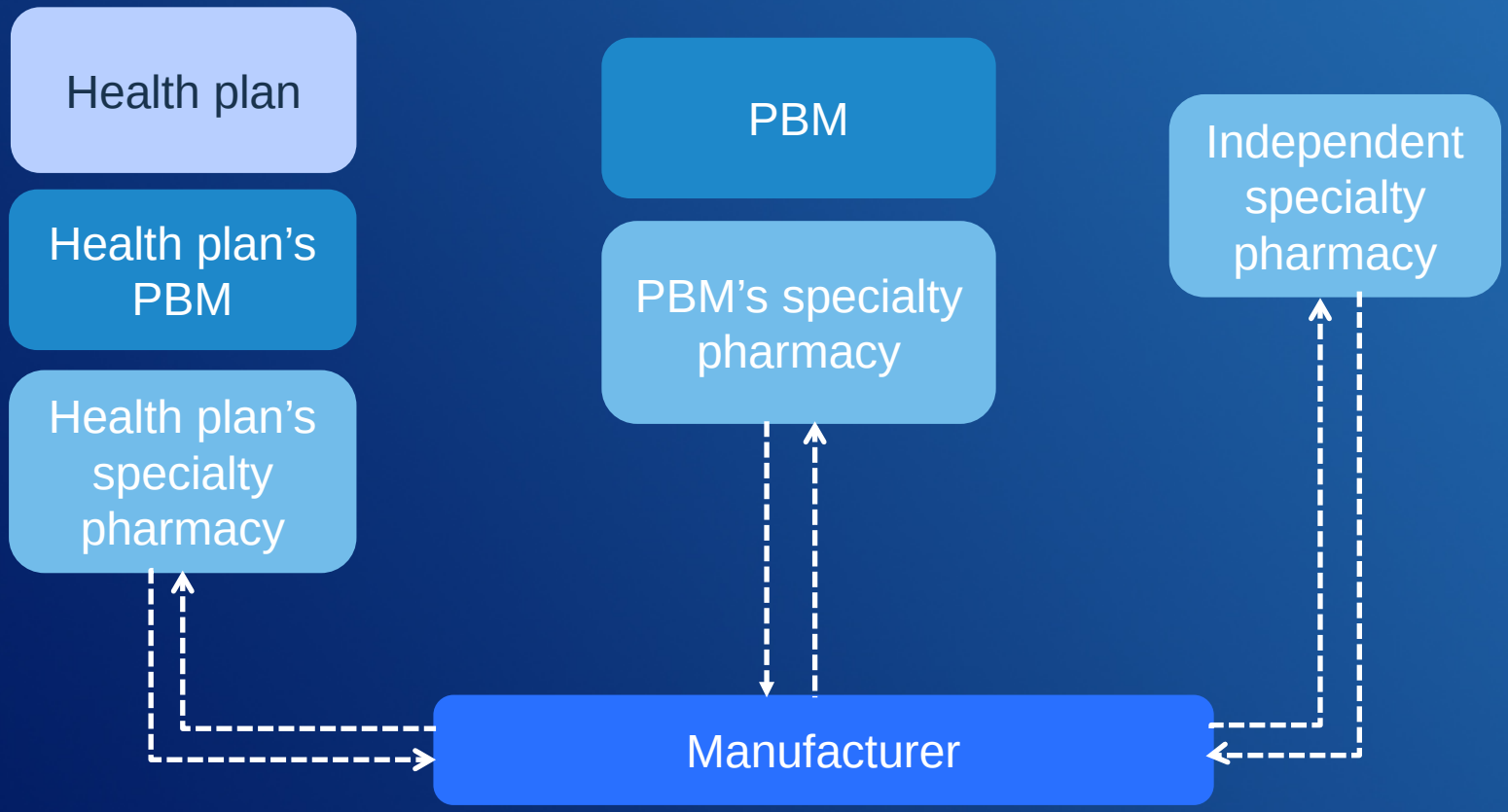
- Developed to address particular challenges of dispensing specialty drugs
- Most provide home delivery
- Not as concentrated as PBMs, with a variety of ownership arrangements
- Manufacturers generally do not own SPs, but can still have influence
  - Data reporting
  - Service fees and rebates
  - Limited distribution

Manufacturers often launch new specialty drugs through limited distribution



- Manufacturers use competitive process to select smaller number of SPs
- Greater control over product integrity and security
- More consistency in patient services and data collection
- Smaller numbers may give SPs more leverage when negotiating with PBMs over pharmacy payments

Three examples of SP ownership



Is there a role for exclusive specialty pharmacy networks in Part D?

- Payers using exclusive networks claim lower costs and higher quality
- Exclusive networks in Part D and competitive concerns
  - Not permitted (any-willing-pharmacy rule), but PBMs may get around this rule by instituting fees that discourage pharmacy participation
  - Reduced competition among specialty pharmacies
  - PBM-owned specialty pharmacies may face mixed incentives

➔ For Medicare, potential effects on program costs

Rebates and fees reported in Part D

- CMS requires plan sponsors and PBMs to report all payments from manufacturers and pharmacies:
  - DIR (Direct and indirect remuneration): all price concessions (e.g., rebates, discounts)
  - Non-DIR: all other payments (i.e., administrative fees paid for "bona fide" services)
    - BUT any amount exceeding "fair market value*" is a DIR
- Medicare payments reduced by DIR, not affected by non-DIR
- Rebates and fees received by subsidiaries (e.g., specialty pharmacies) are not reported

*CMS does not define "fair market value (FMV)". Instead, CMS notes that the determination is inherently subjective and therefore can be a range of values. Manufacturers may be asked to provide assumptions, methodology, and rationale used to justify that a fee does not exceed the FMV.

Should CMS facilitate PBMs' disclosure of data to plan sponsors?

- DIR/non-DIR data reported to CMS used to
  - Reconcile payments with actual costs and ensure savings are passed on to taxpayers and beneficiaries
  - Allow sponsors to evaluate PBM performance (but not all sponsors have access to their data)
- CMS could provide access to plan's own data
- Some oppose more PBM data transparency
  - Harm competition
  - Unnecessary because PBM industry is competitive
- But transparency may not be achieved if PBMs:
  - Shift away from rebates (DIR) to service fees (non-DIR)
  - Receive more of their rebates and fees through specialty pharmacies, not required to report to CMS or plans

Should MA-PDs manage specialty drugs that are under the medical benefit?

- Specialty drugs are covered under both medical and pharmacy benefits
- Formularies and certain management tools are not available under the medical benefit
- Use of consistent management tools under both medical and pharmacy benefits may improve clinical outcomes and program efficiency
  - Treatments chosen based on clinical effectiveness, safety, and value regardless of the site of service
  - May drive more competition on pricing among manufacturers
- May require programmatic changes

Summary

- Specialty drugs will increasingly drive growth in drug spending
- Complex transactions and incentives in the drug supply chain for specialty drugs
- Potential policy questions for managing specialty drugs in Medicare
  - Exclusive specialty pharmacy networks
  - CMS data transparency requirement
  - Allow MA-PDs to manage specialty drugs under the medical benefit