Background on pharmacy benefit managers and specialty pharmacies

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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

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

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

- Health plan
- Health plan’s PBM
- Health plan’s specialty pharmacy

- PBM
- PBM’s specialty pharmacy

- Independent specialty pharmacy

- Manufacturer
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

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*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