The ACA Medicaid Rebate Rule Change: Impact on Pricing and Innovation

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Motivation I: How do firms respond to government pricing & subsidies?

- Price regulation/subsidies are common in welfare programs
  - Medicare/Medicaid reimbursement
  - Premium subsidies for insurance plans
  - Rent control/public housing vouchers
  - Federal financial aid for colleges
  - Food stamps

- Regulation leads to distortions
  - Government benchmarks can anchor private prices (e.g. Medicare reimbursement rates)
  - Fluctuating benchmarks that are tied to equilibrium prices will change firm strategic incentives
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Motivation II: the Medicaid Drug Rebate Program


- have higher prices
- introduce more line extensions
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However:
  ▶ Cross-sectional evidence on list prices only
  ▶ MDRP contains provisions than DSM06 doesn’t consider
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However:
  ▶ Cross-sectional evidence on list prices only
  ▶ MDRP contains provisions than DSM06 doesn’t consider
  ▶ Medicaid has changed since 2006:
    ▶ Medicare Part D covers dual eligibles
    ▶ MDRP formula increased minimum rebate in 2010
    ▶ New data on estimated net prices is available
We find that the MDRP has a more nuanced impact than previously thought

Main takeways

- Drugs with high Medicaid exposure:
  - Increase prices at a lower rate
  - Give lower commercial rebates
  - Launch line extensions at a higher rate

- (Not today): Little evidence of higher launch drug prices

- 2010 increase in minimum rebate enhanced positive/reduced negative effects
Overview of the Medicaid Drug Rebate Program
Medicaid initially pays for drugs at list prices

List price reimbursement + dispensing fee

List price reimbursement

Cost sharing
Manufacturers then send lump-sum rebates
Quarterly rebate is a fraction of list price

Basic rebate = AMP x 15.1%
Formula implies the price is anchored to launch price

Basic rebate = AMP x 15.1%

Medicaid Price

Price at launch

Price today

Additional rebate (CPI adjustment)
And that prices fall if price growth exceeds inflation.
There are a few other relevant features of the program

- Medicaid is entitled to the “best price” if it is lower than $AMP - 15.1\%$
  - Difference between $AMP$ and best price becomes new rebate %
  - Basically a “most-favored nation” clause

- Line extensions “reset the clock” on price
  - Line extensions are versions of the drug with the same active ingredient but different form/strength
  - Firms get to set a new initial price for line extensions
CMS changed the formula starting in January 2010

Two main changes:

- Base rebate increased from **15.1%** to **23.1%** of AMP
- Max rebate capped at **100%**
Optimal firm behavior

Setting

- Increasing demand
- Medicaid demand inelastic
- Maximum initial price bounded
- Firm sets AMP, discount
- Medicaid formula:

\[ p_{t}^{\text{Med}} = \min(p_0, p_t) - p_t \times \max(r, d_t) \]

where

- \( p_0 \) is the launch AMP
- \( p_t \) is the AMP in period \( t \)
- \( d_t \) is the discount granted to commercial payer
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From the model we derive a few testable hypotheses

Drugs with high Medicaid exposure will have:

1. Slower list price growth (but possibly higher launch price)
2. Lower discounts to commercial payers (to avoid triggering the best-price clause)
3. Higher probability of introduction of line extensions
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After the formula changes:

1. Even slower list price growth (unless discount is at 100%)
2. Higher-than-before discounts to commercial payers
3. Even higher probability of line extensions
Data and Empirical Strategy
Data

- SSR Health (~1,000 brand drugs, quarterly from 2007-2019)
  - Gross sales, volume
  - Net sales (obtained from SEC filings)
  - Product name level (e.g. ABILIFY)

- Medicaid PUF (quarterly from 1990-2019)
  - Gross sales, volume
  - NDC level (product-form-strength), e.g. ABILIFY-TABLET-20MG
Key variables

- **Medicaid Market Share:**
  \[ MMS = \frac{\text{Medicaid sales}}{\text{Invoice sales}} \]

- **List price:** measured as Wholesale Acquisition Cost (WAC)

- **Non-Medicaid discount:** estimated as
  \[ 1 - \frac{\text{Net sales} - \text{net Medicaid sales}}{\text{Invoice sales} - \text{Medicaid sales}} \]

- **Number of line extensions:** new NDC with new form or strength
Issue: invoice sales are underreported for many drugs

- Problem for many specialty, physician-administered drugs
- Example: Eylea (Aflibercept, macular degeneration)
  - WAC sales (2013): ~6 million
  - Medicaid sales: ~5 million
Issue: invoice sales are underreported for many drugs

- Problem for many specialty, physician-administered drugs
- Example: Eylea (Aflibercept, macular degeneration)
  - WAC sales (2013): ~6 million
  - Medicaid sales: ~5 million
  - Net sales: ~1.5 billion
- Solution: drop drugs with net sales > invoice sales over the life-cycle
Estimation exploits variation in exposure to Medicaid to estimate diff-in-diff around 2010

- Two independent variables of interest
  1. Medicaid Market Share → matters for price
  2. Medicaid sales → matters for line extensions

- Sample: drugs launched in 2007 w/ positive sales in 2009

- Two regression designs:
  1. Linear interaction of MMS/Sales with policy change
  2. Interaction of quartiles of MMS/sales with policy change
Results I: Price Distortions
List price of drugs with high MMS grows more slowly

\[
\log(WAC_{it}) = \alpha_i + \delta_t + \beta_1 \times \text{MMS}_i \times (t - 2007)
\]
List price of drugs with high MMS grows more slowly

\[ \log(WAC_{it}) = \alpha_i + \delta_t + \beta_1 \times MMS_i \times (t - 2007) \]
and even more slowly after 2010

\[ \log(WAC_{it}) = \alpha_i + \delta_t + \beta_1 \times MMS_i \times (t - 2007) + \beta_2 \times MMS_i \times PostACA_t \times (t - 2010) \]
Drugs with high MMS have lower discounts

\[ \text{Discount}_{it} = \delta_t + \beta_1 \times \text{MMS}_i \]
Drugs with high MMS have lower discounts

\[ \text{Discount}_{it} = \delta_t + \beta_1 \times MMS_i \]
but less so after the change in the formula

\[ \text{Discount}_{it} = \delta_t + \beta_1 \times MMS_i + \beta_2 \times MMS_i \times \text{PostACA}_t \]
Results II: Innovation Distortions
Line extensions are more likely for drugs with high Medicaid sales

$$\lambda (\text{age} | X) = \lambda_0 (\text{age}) \times \exp (X)$$
Line extensions are more likely for drugs with high Medicaid sales

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<table>
<thead>
<tr>
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<tbody>
<tr>
<td>High Med Sales</td>
<td>2.278**</td>
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<td>(0.367)</td>
</tr>
<tr>
<td>Post-ACA</td>
<td></td>
</tr>
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<td>High Med Sales ( \times ) Post-ACA</td>
<td>2.078*</td>
</tr>
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<td>( N )</td>
<td>552</td>
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and even more so after the ACA

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<td>(0.364)</td>
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<tr>
<td>Post-ACA</td>
<td>0.947</td>
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<td>(0.246)</td>
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Which line extensions are more profitable under Medicaid rules?

Intuition

- Key of a line extension is to get people to switch
- Higher quality line extensions can get more people to switch
- Marginal gain from extra switchers increases with base rebate
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[Graph showing within-molecule Medicaid market share over quarters since launch for new strength and new form.]
Firms develop higher-quality line extensions post-ACA

\[ \lambda (\text{age} \mid X) = \lambda_0 \text{(age)} \times \exp(X) \]

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<th>New Strength</th>
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<td><strong>High Med Sales</strong></td>
<td>2.459**</td>
<td>2.370**</td>
</tr>
<tr>
<td></td>
<td>(0.600)</td>
<td>(0.404)</td>
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<tr>
<td><strong>Post-ACA</strong></td>
<td>0.937</td>
<td>1.110</td>
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<tr>
<td></td>
<td>(0.348)</td>
<td>(0.304)</td>
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<tr>
<td><strong>High Med Sales \times Post-ACA</strong></td>
<td>3.029*</td>
<td>1.697</td>
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<tr>
<td></td>
<td>(1.500)</td>
<td>(0.589)</td>
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Conclusion

The Medicaid Drug Rebate Program affects pricing and R&D strategies of firms

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Predicting effect of policy change is not easy

- Simple prediction: $\uparrow$ mandatory rebate $\implies$ $\uparrow$ distortion
- But firms face a lot of constraints that are hard to model
- These constraints affect predictions
- In this case, the reform turns out to be relatively benign