Pharmaceuticals: Can or Should We Do Anything About Rising Drug Costs?

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Avalere Health | An Inovalon Company
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Public Focus on Drug Prices Increased Dramatically in 2016

MEDIA COVERAGE OF DRUG PRICES OVER LAST 10 YEARS

To conduct our review of media coverage over the last 10 years, we used the paid news archive service Factiva.com. Review includes print (newspaper), online (online newspapers and blogs), and broadcast* (affiliate and cable) and excludes paid subscription-based trades, press releases, duplicate news stories (e.g., wire pickups or reruns on broadcast news).
Drug Costs Remain a Modest Share of Overall Health Spending

When accounting for non-retail prescription drug spending, medicines constitute just over 13% of NHE and are projected to remain stable.

EXPENDITURES BY SERVICE, AS PERCENT OF NHE, 2014

- Hospital Care, 32.1%
- Physician Services, 26.4%
- Prescription Drugs, 9.8%
- Cost of Health insurance, 6.4%
- Investment, 5.1%
- Nursing Care Facilities, 5.1%

2014 Spending = $3.031 trillion

Prescription Drug Spending Grew Substantially in 2014 Due to Introduction of New Treatments

ANNUAL PERCENT INCREASE IN SPENDING ON PRESCRIPTION DRUGS VS OVERALL NHE

- Prescription Drugs
- NHE

<table>
<thead>
<tr>
<th>Year</th>
<th>Prescription Drugs</th>
<th>NHE</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012</td>
<td>0.2%</td>
<td>3.8%</td>
</tr>
<tr>
<td>2014</td>
<td>2.4%</td>
<td>2.9%</td>
</tr>
<tr>
<td>2016*</td>
<td>4.5%</td>
<td>5.3%</td>
</tr>
<tr>
<td>2018*</td>
<td>5.7%</td>
<td>5.4%</td>
</tr>
<tr>
<td>2020*</td>
<td>6.2%</td>
<td>5.5%</td>
</tr>
<tr>
<td>2022*</td>
<td>6.3%</td>
<td>5.5%</td>
</tr>
<tr>
<td>2024*</td>
<td>6.6%</td>
<td>6.2%</td>
</tr>
</tbody>
</table>

NHE = National Health Expenditure

1 Projected. The projections begin after the latest historical year (2014) and go through 2024
### Rapid Growth in Specialty Drugs Is Drawing Attention

<table>
<thead>
<tr>
<th>Payer-Reported Specialty Drug Trend</th>
<th>20-25%</th>
<th>20-25%</th>
</tr>
</thead>
<tbody>
<tr>
<td>annual per capita growth in spend for payers and PBMs$^{1,2}$</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Spending Drivers for the Future</th>
<th>40%</th>
<th>60%</th>
</tr>
</thead>
<tbody>
<tr>
<td>of drugs under development are considered specialty$^3$</td>
<td>of new drugs expected to be approved in the near-term are specialty$^4$</td>
<td></td>
</tr>
</tbody>
</table>

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Plans must increasingly consider the pharmaceutical pipeline when they set rates—particularly in low-margin programs like Medicaid.

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$1$ Ha T. Tu, Divya R. Samuel. Center for Studying Health System Change, April 2012.  
$2$ CVS Caremark, 2013.  
$3$ Milliman, 2012  

2 PBM: Pharmacy Benefit Manager
Public Concern with Drug Prices Drives Interest of Political Candidates and Public Figures

In general, do you think the cost of prescription drugs is reasonable or unreasonable?

- Reasonable, 24%
- Unreasonable, 72%
- Don’t know/Refused, 4%

What items should be a top healthcare priority for the President and Congress?

<table>
<thead>
<tr>
<th>Top Healthcare Priorities for the President and Congress</th>
<th>Total</th>
<th>Democrats</th>
<th>Republicans</th>
</tr>
</thead>
<tbody>
<tr>
<td>Make sure high-cost drugs for chronic conditions (HIV, hepatitis, mental illness, cancer) are affordable</td>
<td>77%</td>
<td>85%</td>
<td>73%</td>
</tr>
<tr>
<td>Government action to lower prescription drug prices</td>
<td>63%</td>
<td>74%</td>
<td>56%</td>
</tr>
<tr>
<td>Making sure health plans have sufficient provider networks</td>
<td>58%</td>
<td>63%</td>
<td>55%</td>
</tr>
<tr>
<td>Repeal the entire health care law</td>
<td>37%</td>
<td>28%</td>
<td>58%</td>
</tr>
</tbody>
</table>

ACA: Affordable Care Act
1 Kaiser Family Foundation Health Tracking Poll: August 2015 (conducted August 6-11, 2015).
2 Kaiser Family Foundation Health Tracking Poll: October 2015 (conducted October 14-20, 2015).
Stakeholders Have Outlined a Range of Proposals Addressing Drug Prices and Spending

<table>
<thead>
<tr>
<th>Transparency</th>
<th>Medicare Price Controls</th>
<th>Value-based Payments</th>
<th>R&amp;D Spending Minimums</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Require manufacturers to disclose drug-specific R&amp;D costs, sales and marketing budgets, cost of production, and profit</td>
<td>• Permit government price negotiations in Part D</td>
<td>• Create value frameworks to assess relative product benefit</td>
<td>• Require manufacturers to invest a minimum percentage of revenue on R&amp;D</td>
</tr>
<tr>
<td></td>
<td>• Extend Medicaid rebate to Part D low-income subsidy (LIS)</td>
<td>• Tie contracts and/or Medicaid rebates to product value</td>
<td></td>
</tr>
<tr>
<td>Drug Importation</td>
<td>Promote Competition</td>
<td>Reduce Exclusivity</td>
<td>Limit Consumer OOP Costs</td>
</tr>
<tr>
<td>• Permit importation of drugs from Canada or other countries</td>
<td>• Antitrust waiver to allow PBMs to collectively negotiate rebates</td>
<td>• Reduce biologic exclusivity from 12 to 7 years</td>
<td>• Cap cost-sharing for drugs in commercial and exchange plans</td>
</tr>
<tr>
<td></td>
<td>• Modify FDA policies to accelerate second-to-market drugs</td>
<td>• Prohibit “Pay-for-Delay” patent settlements</td>
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</table>
Secretary Clinton Offered a Detailed Proposal Focused on Drug Pricing

- Allow Drug Importation for Personal Use
- Reduce the Biologic Exclusivity Period
- Prohibit “Pay-for-Delay” Patent Settlements
- Expedite Review of Next Marketed Products
- Fully Fund FDA to Clear Generic Backlog
- Pharmaceutical Competition
- Require Minimum R&D Spending for Manufacturers
- Give an Independent Organization Authority to Recommend Prices
- Permit Medicare to Negotiate Lower Drug Prices
- Implement Part D LIS Rebates
- Implement Part D LIS Rebates
- Manufacturer Pricing / Profits
- Cap Out-of-Pocket Spending at $250/month for Drugs
- Limit Direct-to-Consumer (DTC) Advertising
- Consumer Protections

Source: Hillary Clinton’s Plan for Lowering Prescription Drug Costs.
Twelve States Have Initiated Legislation To Increase Drug Pricing Transparency and Address High Drug Costs

STATE DRUG PRICING INITIATIVES

*CA has a ballot initiative awaiting public balloting in November 2016.
**OH has a ballot initiative awaiting legislative approval before being placed on public ballot.
Note: Map only includes active legislation and ballot initiatives at the time of publication.
Source: Avalere State Reform 360, May 16, 2016.
Alignment Between Pharma and Plans Will Exist for Some Policies and Not Others

Pharma

Acceptable

- Innovative Contracting
- FDA Reform
- Risk-Adjustment

Unacceptable

Dramatic Reduction in Exclusivity

Plans

Acceptable

Restrictive Copay Policies

Unacceptable

Heavy Price Controls