The Escalating US Policy Environment

Payer Views on Current Drug Pricing Proposals
Research background

■ Using Certara’s Compass research network, we conducted an online survey among active voting members of P&T committees in US managed care organizations (MCOs), followed by a set of semi-structured interviews for further interpretation and probing of key trends. In-depth interviews often help to clarify the gap between expressions in survey research and reality on the ground.

■ A targeted literature review was conducted to contextualize the research in the current landscape of the specialty pharmacy category.

■ Of 31 respondents, 19 were pharmacy directors and 12 were medical directors. These payers represent a total of 198.8M US lives (169.6M Commercial and 29.2M Medicare lives). All 31 respondents were responsible for Commercial lives and 25 of the 31 responsible for Medicare as well.

■ Respondents were comprised of national (n=17) and regional health plans (n=14), pharmacy benefit managers (PBMs; n=7) and integrated delivery networks (IDNs; n=6).

■ MCOs were also categorized by size, based on the number of covered lives, into large, mid-sized and small health plans

- Small plans: <920,000 lives; n=7 plans
- Mid-sized/medium plans: (≥920,000 lives and <3.4M lives) (n=8 plans)
- Large plans: (≥3.4M lives) (n=11 plans)
- PBMs: 59.5M lives (6 unique organizations)
- IDNs: 24.4M lives (6 unique organizations)
- Small plans: 3.4M lives (7 unique plans; includes PBMs and IDNs)
- Mid-sized/medium plans: 13.5M lives (8 unique plans; includes PBMs and IDNs)
- Large plans: 182M lives (11 unique plans; includes PBMs and IDNs).

■ Parts of the analysis presented in this report have been accepted for publication as posters by the American Academy of Managed Care Pharmacy (AMCP) in 2020, one of which has been awarded a prestigious gold ribbon in professional review.1,2

Limitations

The estimates and findings in this report are based on a qualitative research methodology. Throughout this report, the numbers of covered Commercial and Medicare lives per health plan type are reported to illustrate, and provide a deeper understanding of, the research findings. The numbers of reported lives are approximations provided by research respondents.

Certara has not accounted for any overlap in covered lives between health plans. As such, findings on the trends we document should be considered indicative rather than conclusive.

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1 Bangia I, Garcia Padilla J, Neumann U, Vargas M. A Survey-Based Analysis of Formulary Decision Making and Utilization Management Trends Across Managed Care Organizations. In Journal of Managed Care and Specialty Pharmacy; April 2020; Houston, TX.

2 Neumann U, Bangia I, Garcia Padilla J, Vargas M. A Systematic Comparison of Status Quo and Future Expectations for Novel Drug Financing Strategies Across Managed Care Organizations. In Journal of Managed Care and Specialty Pharmacy; April 2020; Houston, TX.
Legislative context

- In the 2020 campaign for the US White House, the pharmaceutical industry had become a prime target of bipartisan outrage. We should note that the healthcare debate’s focus on drug costs and pricing processes is not new – it has been a matter of public debate for over thirty years. The recent inflation of regulatory rule-making in Washington and the degree of disruption likely to be caused by key legislative proposals, are seen by many as historically unprecedented.

- With the so-called “Blueprint”, the Trump Administration released an aggressive set of drug pricing reform concepts in May 2018, aiming to combine volume control with limitations on branded drug spending, followed by rule-making activity at unforeseen levels.

- Several regulatory proposals are still under debate, some have been withdrawn following public comment periods. By many accounts one of the most disruptive and the furthest progressed towards becoming law, is the International Pricing Index Proposal (IPI) that seeks to peg Part B prices on averaged Ex-US prices. It is currently pending under OMB. Listen to our 2018 analysis here: https://tinyurl.com/ybwy2d32.

Passed regulations

- Final rule-making with respect to Medicare Part B:
  - Allowing Medicare Advantage plans to use step therapy for physician-administered drugs.
  - Payment reduction for drugs purchased with 340B discount to ASP - 22.5%.
  - Changes to new drug reimbursement (prior to ASP data availability) to 1035 of WAC (with sequestration cuts, effectively WAC +1.35%).

- Final rule-making with respect to Medicare Part D:
  - Plans given broader flexibility to make formulary maintenance changes mid-year immediately upon generic approval.
  - Announcement of the voluntary “Senior Savings Model”, offering alternative Part D options with OOP cost caps for a set of plan-formulary insulins at $35/30-day supply for both standalone PDPs and Medicare Advantage (MA-PD) with beginning CY 2021 participating developers Lilly, Novo Nordisk and Sanofi.
Major congressional legislation

- Key piece of legislation passed in the House of Representatives is H.R.3, the “Lower Drug Costs Now Act”, combining various measures in three main categories: Inflation-based rebates, caps on patient out-of-pocket spending and direct price negotiations. The latter would be run by the federal government but grants access to prices to all commercial plans, applied to at least 25 and at most 250 drugs, leveraging tax penalties for developers who refuse to come to accept agreements within 2 months which can range to from 65% and up to 95% of sales proceeds. Estimates suggest the bill would reduce net revenues of developers by up to $1 trillion or roughly 58% of companies’ earnings before interest and taxes (EBIT), and the non-partisan Congressional Budget Office predicted that $456bn savings to the government over 10 years may come with the effect of 30 fewer novel drugs coming to market given reduced innovation incentives. Other health economic studies indicate that the impact on small and emerging biotech could be more dramatic, resulting in small biotech in states like California developing 88% fewer drugs.4

- Major bill under discussion in the Senate is the bi-partisan legislation passed within the Senate Financing Committee. The “Prescription Drug Pricing Reduction Act” by Senators Grassley and Widen is drawing on inflation caps and benefit re-designs, aiming to reduce government spending on drugs by $100 billion across Medicare and Medicaid programs over the next decade. The bill received support from the White House, but at the time of publication of this report has yet to be brought to a Senate floor vote by Senate Majority Leader McConnell.

- If we dissect the major drug pricing reform bills that are currently debated in both houses of Congress, and under consideration for rule making by HHS, we find a cluster of core policies suggestions:
  - Government Drug Price Negotiation (e.g. in H.R. 3),
  - Importation of Products (proposed by HHS in Dec. 2019, such as from Canada),
  - Pass-Through of Rebates (to Point-of-Sale, e.g. HHS proposal in 2019),
  - External Reference Pricing (i.e. adjusted by international price basket of selected countries, proposed as the HHS IPI Model for Part B),
  - Internal Reference Pricing (i.e. adjusted with a price basket of similar therapeutics, a called pre-specified equivalence class).

### FIGURE 1

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<tr>
<td><strong>Beneficiaries</strong></td>
<td><strong>Plan sponsors</strong></td>
<td><strong>Manufacturers</strong></td>
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<td>25% coinsurance in initial coverage limit</td>
<td>50% in Catastrophic</td>
<td>10% in initial Coverage Limit</td>
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<tr>
<td>$2,000 OOP cap</td>
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<td>30% in Catastrophic</td>
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<td>20% in Catastrophic</td>
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<tr>
<td>20% in Catastrophic</td>
<td>20% in Catastrophic for multiple-source drugs</td>
<td>20% in Catastrophic (2024+)</td>
</tr>
<tr>
<td><strong>Estimated savings (10 year)</strong></td>
<td><strong>Estimated savings (10 year)</strong></td>
<td><strong>Estimated savings (10 year)</strong></td>
</tr>
<tr>
<td>$90 Billion</td>
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Policy dashboards: Positioning payers on drug pricing proposals

- Figure 53 shows the overall level of support of key payer archetypes for the core reform policies. PBMs tend to be least enthusiastic about current price reform proposals being on average “neutral” across all policies. With the exception of large plans, which fall in slightly opposing territory on government price controls, we must note that at least on average no other payers are opposed, or strongly opposed to any of the legislative proposal though.

- Internal reference pricing and drug importation are most supported by mid-sized plans, small plan representatives lead support on international price referencing, while IDNs lead support across all other policy categories. Except for internal reference pricing, which receives strong marks from mid-size plan representatives, looking across the mean the level of support is in broad summary not enthusiastic but still mildly in favor.

![FIGURE 2](image)

Average level of support for legislative proposals around drug pricing

- Given the potentially drastic consequences of these proposals on pharmaceutical spending and innovation as well as the very nature of payer-pharma engagements, we decided to present six panels with a closer look on various payer types. These deep dives reveal the level of support for the current proposals within archetypes, as well as the noticeable range of opinions among their individual payer representatives. While we underscore that these results are qualitative in nature and not a representative survey of the US payer universe, they offer unique insights into the considerable support that exists among so many commercial insurers, responsible for millions of US lives, for a set of policies that are historically antithetical to the free market-based drug pricing paradigm that distinguished the US from the rest of the world for many decades. We believe that a shift in political and public opinion has made its mark on payer sentiments, a trend our research will closely document in future editions of this report.

- Overall, most payers are in favor of drug pricing proposals, with IDNs and mid-sized/medium plans the most supportive and PBMs the least supportive. Proposals around internal reference pricing and international pricing indexing draw the most support across all payer archetypes.
Overall, legislations around internal reference pricing has the strongest support from IDN payer respondents, with 5 respondents, responsible for 18.4M total lives somewhat or strongly in favor. Government price negotiations is the second most supported legislation by IDNs (n=4) representing 12.1M lives.

Overall, there is most PBM support for legislation around internal reference pricing, with strong or somewhat favorable support from 4 PBM representatives, responsible for 21.9M US lives. Outside of this, strong support is only seen by 1 PBM respondent responsible for 34M covered lives around international pricing indexing legislation.

Overall, legislations around internal reference pricing has the strongest support from IDN payer respondents, with 5 respondents, responsible for 18.4M total lives somewhat or strongly in favor. Government price negotiations is the second most supported legislation by IDNs (n=4) representing 12.1M lives.
Large plans, representing 121.6M lives, support international pricing indexing. The second most supported pricing proposal across large plans, by those responsible for 115.9M lives, are around internal reference pricing.

Across mid-sized plans, the most supported legislative proposal is for internal reference pricing, favored by plans representing 10M lives. International Pricing Indexing is the second most supported proposal across plans responsible for 9.5M lives.
Almost all respondents of small plans, responsible for 3.0M lives, are in favor of international pricing indexing pricing. Proposals around internal reference pricing is the next most supported among respondents representing 2.8M lives.

Some proposals discussed here are in the rule-making stage, others supported by individual states and some by the US House of Representatives and the Senate Minority. The 2020 elections will determine how some of the proposals will fare in the near-term future. Most entail relatively drastic consequences on the nature of the relationship and negotiations between innovators and payers.

Except for large plans, payer representatives on average do not oppose government price setting or drug importation. Moreover, payer representatives responsible for over $150M favor drug importation and international price indexing.

Manufacturers need to monitor payer sentiment carefully. While payers in our survey would not implement individual policy proposals except for internal reference pricing, their views represent a critical expression on the dissatisfaction with current price-setting mechanisms in the specialty category. Substantial support has evolved for a set of historically antithetical policies to the free, market-based US pricing system. We expect these pressures to further escalate, and would highlight that applying historic probabilities to the likelihood of such proposals advancing in the legislative path may result in a false sense of comfort.

In view of the intensifying public sentiment against the current drug pricing system, bipartisan groups in the Congress and contenders for the White House are more unafraid then ever to demonstrate their legislative resolve. The November elections may postpone action to 2021, but their outcome is unlikely to shift the direction of travel.
FIGURE 7

Average level of support for legislative proposals concerning drug pricing for Small plans.
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