

# The Escalating U.S. Policy Environment



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## 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- Several regulatory proposals are still under debate, and some have been withdrawn following public comment periods.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 our 2018 analysis here: <https://tinyurl.com/ybwy2d32>.



*In recent years, health policy pushes have seen an increasingly nuclear focus on drug costs and pricing processes. We are witnessing regulatory moves at unforeseen speed towards combining volume control with regulations on pharmacy costs on the federal level. At the same time there is an escalation in various state legislatures to regulate drug pricing transparency, co-pay assistance, importation, rate setting, price gouging, spending targets, group purchasing and biosimilar substitution.*



– **ULRICH NEUMANN,**  
Sr. Director, Certara

## 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 103% 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),<sup>57</sup> 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.<sup>58</sup>
- A 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).*

	H.R. 3, Elijah Cummings Lower Drug Costs Now Act	H.R. 19, Lower Costs, More Cures Act	Senate Prescription Drug Pricing Reduction Act
<b>Beneficiaries</b>	25% coinsurance in initial coverage limit \$2,000 OOP cap	15% in initial coverage limit \$3,100 OOP cap	25% coinsurance in initial coverage limit \$3,100 OOP cap
	Beneficiaries that would exceed OOP cap with first fill of year would have option to amortize payments across remainder of plan year		
<b>Plan sponsors</b>	50% in Catastrophic	60% in Catastrophic	60% in Catastrophic
<b>Manufacturers</b>	10% in initial Coverage Limit 30% in Catastrophic	10% throughout benefit	7% in initial Coverage Limit 14% in Catastrophic
<b>Medicare</b>	20% in Catastrophic	20% in Catastrophic 30% in Catastrophic for multiple-source drugs	20% in Catastrophic (2024+)
<b>Estimated savings (10 year)</b>	\$90 Billion	No CBO score yet	\$3.39 Billion

Figure 1.  
Key legislative proposals impact on Part D re-design<sup>59</sup>

## Policy Dashboards: Positioning payers on drug pricing proposals

- Figure 2 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.

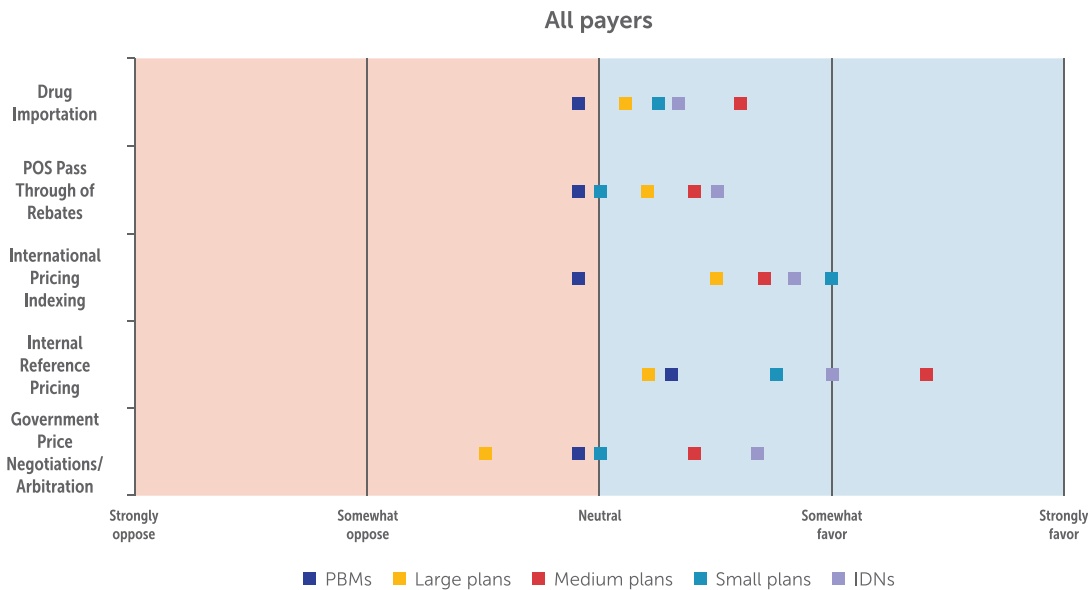


Figure 2.  
Average level of support for legislative proposals around drug pricing

- 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.

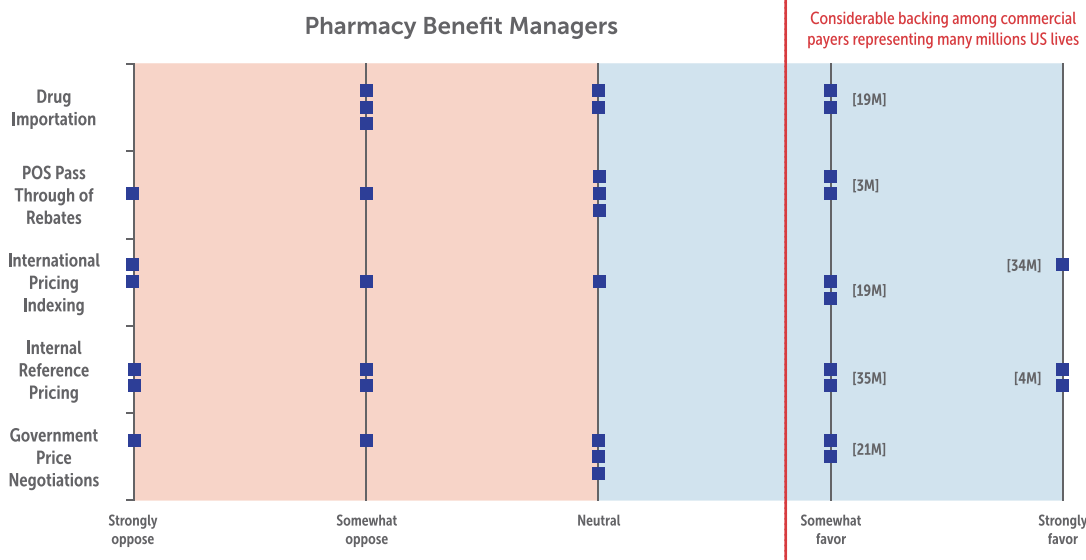


Figure 3. Average level of support for legislative proposals concerning drug pricing PBMs<sup>ee</sup>

- 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.

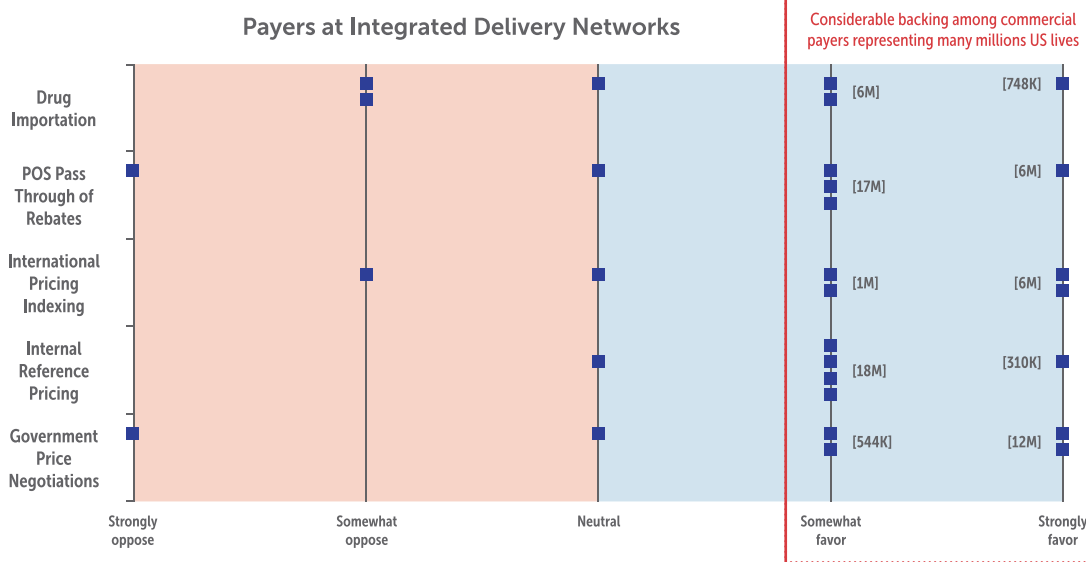


Figure 4. Average level of support for legislative proposals concerning drug pricing for IDNs<sup>ff</sup>

- Overall, legislations around internal reference pricing has the strongest support from IDN payer respondents with five 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.

<sup>ee</sup> n=7; 59.9M lives    <sup>ff</sup> n=6; 24.4M lives

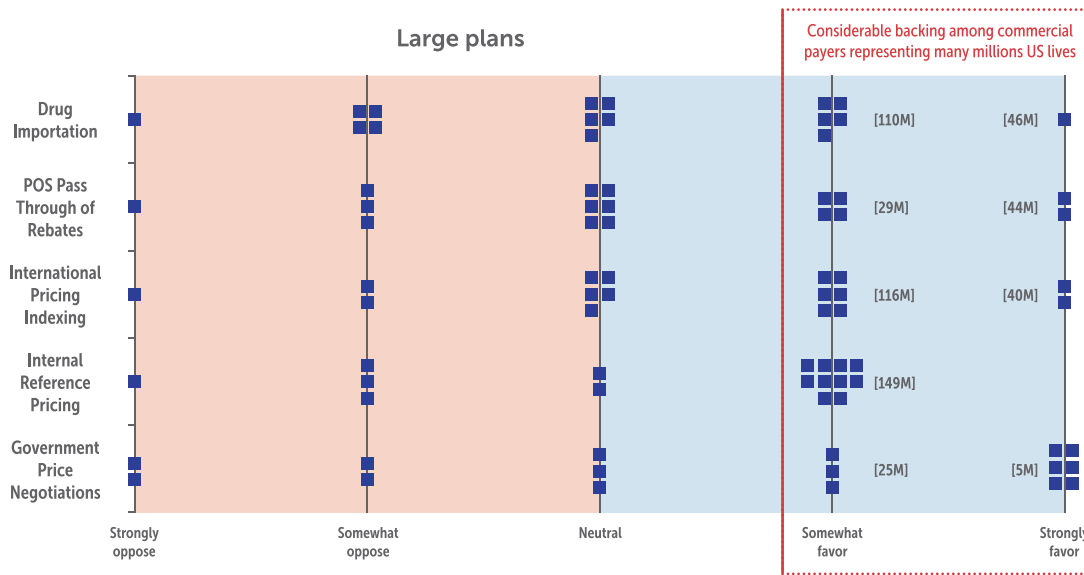


Figure 5. Average level of support for legislative proposals concerning drug pricing for Large plans <sup>99</sup>

- 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.

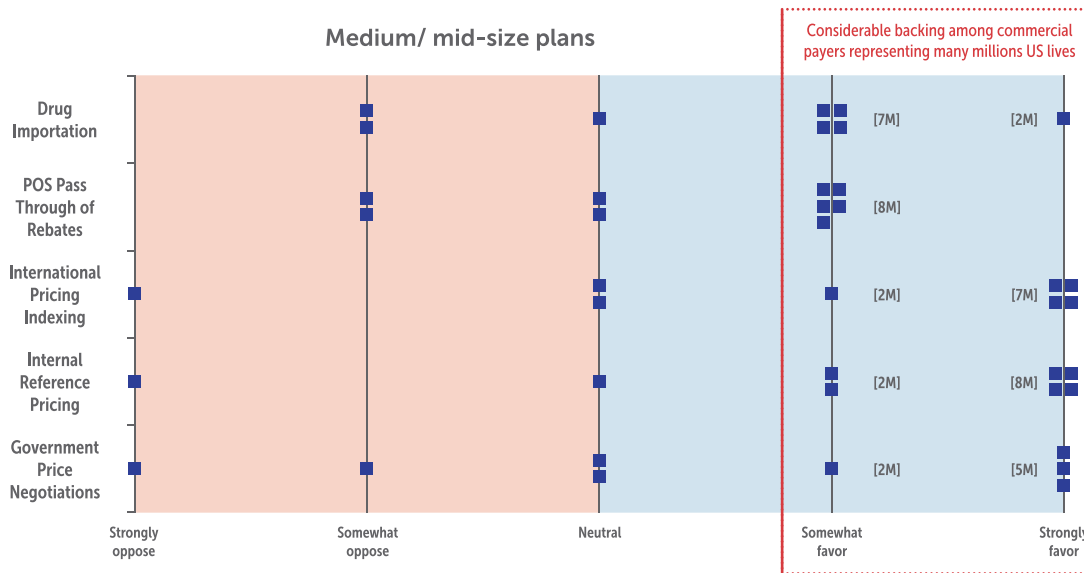


Figure 6. Average level of support for legislative proposals concerning drug pricing for Medium/mid-sized plans <sup>hh</sup>

- 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.

<sup>99</sup> n=16, 182M lives    <sup>hh</sup> n=8; 13.5M lives

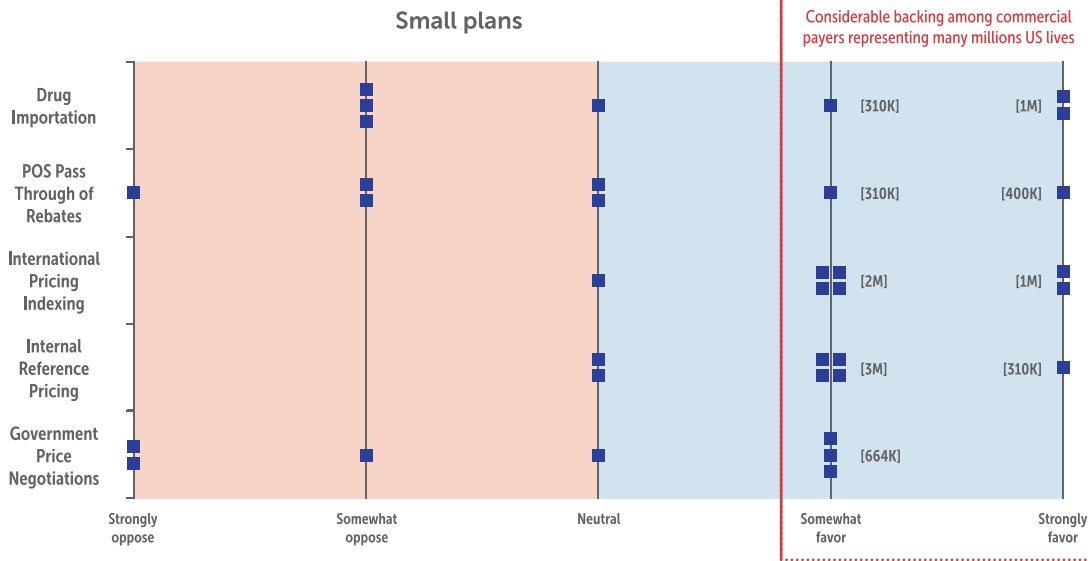
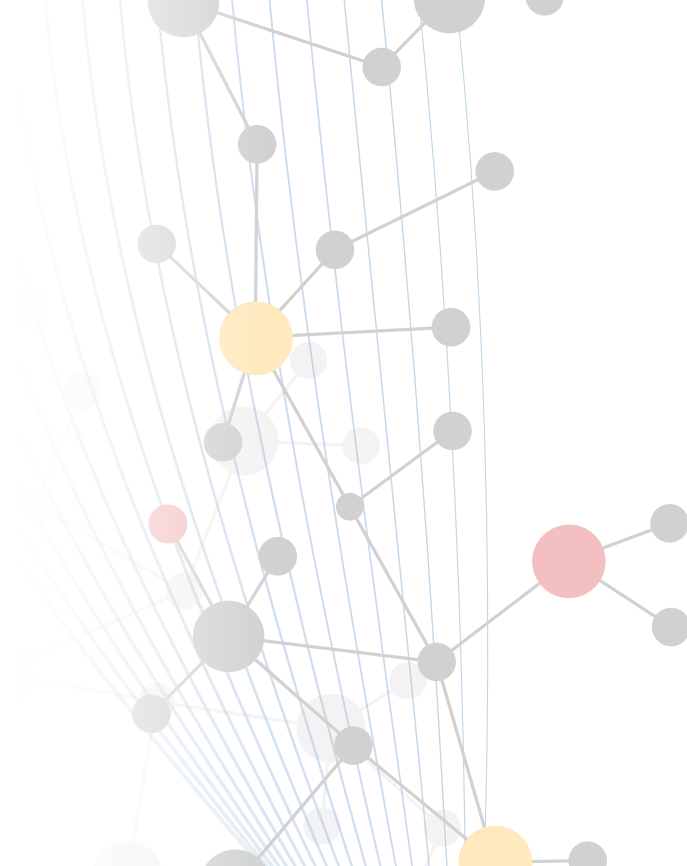


Figure 7. Average level of support for legislative proposals concerning drug pricing for Small plans <sup>ii</sup>

- 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.

## MANUFACTURER TAKEAWAYS

- 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 than ever to demonstrate their legislative resolve. The election of a Biden administration may postpone CMS action to 2021, but the policy priorities in both parties are unlikely to shift the direction of travel

A network diagram in the background of the top half of the page. It consists of numerous grey circular nodes of varying sizes connected by thin grey lines. A few nodes are highlighted in yellow and red. The diagram is set against a light blue background with faint, curved lines suggesting a molecular or data network structure.

57 Cole M, Brantley K, Stengel K. The Public Option: Single Payer on the Installment Plan. Impact of H.R.3 Scenarios on Federal Spending and Drug Manufacturer Revenues. [https://www.heritage.org/sites/default/files/2020-02/BG3462\\_0.pdf](https://www.heritage.org/sites/default/files/2020-02/BG3462_0.pdf). Accessed June 1, 2020.

58 Vital Transformations (2019). H.R. 3 – Medicare Part D Reform. Calculating the Impact of International Reference Pricing on California’s Biopharmaceutical Innovation Ecosystem. Retrieved from <https://califesciences.org/wp-content/uploads/2019/10/FINAL-Vital-Transformation-HR-3-Analysis-for-CLSA-10.30.19.pdf>

59 Sources: Andel, M. Getting Up to Speed on Prescription Drug Pricing Reform Efforts. AMCP Briefing. 2019, H.R. 3 Bill Text: <https://www.congress.gov/116/bills/hr3/BILLS-116hr3eh.pdf>; H.R. 3 CBO Score: [https://www.cbo.gov/system/files/2019-12/hr3\\_complete.pdf](https://www.cbo.gov/system/files/2019-12/hr3_complete.pdf); Senate Legislative Bill Text: <https://www.finance.senate.gov/imo/media/doc/Prescription%20Drug%20Pricing%20Reduction%20and%20Health%20and%20Human%20Services%20Improvements%20Act.pdf>; Senate CBO Score: <https://www.finance.senate.gov/imo/media/doc/2020-03-13%20PDPRA-SFC%20CBO%20Table.pdf>

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