POINT OF VIEW: *The Trump Administration's Blueprint to Lower Consumer Drug Prices*

The pharmaceutical industry's greatest fears did not come to pass on Friday, May 11, 2018 when the Trump Administration rolled out its plan to lower prescription drug prices for consumers. The Administration's "historic plan for bringing down the high price of drugs and reducing out of pocket costs for the American consumer" reads more as a menu of ideas and suggestions to be taken up by HHS (including the FDA and CMS) through creative interpretations of existing laws, rule-making or program demonstrations or by Congress, and legislation that would change certain provisions of Medicare or the Affordable Care Act.

In an agency Request for Information, published on May 16, 2018, HHS issued dozens of policy questions aimed at virtually every challenge or idea that was mentioned in the blueprint, as well as related ideas put out by policy makers, industry associations and think tanks over the past few years.

Ultimately, we can expect HHS to authorize some demonstration projects, waivers and experiments along the lines of the blueprint that could possibly lower drug prices for Medicare beneficiaries. But most of these actions would not take effect until 2020 at the earliest.

The Trump Administration proposes 4 approaches to lower drug costs:

- *Improved Competition*
- *Better Negotiation*
- *Incentives for Lower List Prices*
- *Lowering Out-of-Pocket Costs*

Missing from the blueprint: 2 tactics the President promised during his election campaign:

- *Drug Reimportation*
- *Direct Negotiation for Medicare Drug Prices*

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Which proposals in the Trump Administration's blueprint may gain traction within the next couple of years? From our point of view, the most likely candidates are:

- **Tactics to encourage biosimilar development.** Preventing manufacturers from using limited distribution models or REMS rules to limit access to adequate samples for drug development is cited as a hurdle that delays biosimilar development. But it remains to be seen how much of an impact biosimilars will have on consumer drug prices when their development costs are still high and their interchangeability with reference biologics remains unproven.

- **Sharing a portion of rebates.** CMS already floated (and deferred) consideration of pass-through of a portion of rebates to Medicare beneficiaries for the 2019 Part D plan year. Plan sponsors pushed back, insisting that premiums would rise as a result. This shared rebate idea is likely to resurface for further consideration: a small increase in premium spread across all plan members is likely to have far less negative impact than the positive impact of a reduction in coinsurance for a single beneficiary at the point of sale. At the same time, the blueprint suggests that negotiation of Part B drugs in the manner of Part D drugs could bring down drug prices. This would likely involve more rebates and more legislation on pass-through of savings to Part B beneficiaries,

- **Waivers or demonstrations to permit value-based contracts (VBC) or indication-based pricing, exempting manufacturers from anti-kickback consequences or inclusion in AMP calculations.** Value-based contracting has shown uncertain promise. The existence of many of these arrangements is not publicly disclosed, nor are the actual terms. Their impact on drug prices paid by consumers remains unclear. The benefit to consumers is often coverage of the drug by their plan or PBM, rather than a lower price (unless the VBC also impacts the drug's tier placement). Vertically-integrated entities that sponsor Medicare Advantage, commercial health plans, and/or Medicare Part D plans that have their own PBMs are more likely to be interested in these arrangements.

- **Moving some Part B drugs to Part D**. Some Part B drugs are already being "brown bagged" or shipped direct to physician offices but purchased through Part D benefits due to patient or physician preferences. If this were made official policy, the copays for redesignated Part B drugs could pose issues for some beneficiaries, especially those who rely on Medicare supplemental policies to cover coinsurance for Part B drugs. Moreover, Part B drugs increasingly target complex conditions with tailored approaches to treatment. It is likely that few Part B drugs will fit comfortably into the Part D benefit design.

For more information on how Entrée Health can help your organization navigate these potential market access changes and communicate value to payers, contact Andrew Gottfried at agottfried@entreehealth.com ***or 212-896-8026.***

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