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Administration presents plans to lower drug prices

May 14, 2018

- **Mix of general and specific, with promises of more to come**
- **Likelihood, timing of implementation unclear**
- **Request for public comment on many topics**

On May 11, 2018, President Trump and Department of Health and Human Services (HHS) Secretary Alex Azar delivered highly anticipated speeches regarding the Administration's plan to reduce drug prices. Concurrently with the speeches, the White House issued a Fact Sheet summarizing the plan, and HHS published the President's Blueprint for reducing drug prices. As detailed below, the Blueprint sets forth a list of administrative actions the Administration is considering and seeks comments from stakeholders on a broad range of topics. It is important to review the Blueprint in detail to identify areas for comment or consideration that may be relevant to your organization. Comments will be due 60 days from the date the Blueprint is published in the Federal Register, which is expected to occur on May 16, 2018. **As such, comments are expected to be due on Monday, July 16, 2018.**

The Blueprint identifies the following challenges in the American pharmaceutical market:

- "High list prices for drugs";
- "Seniors and government programs overpaying for drugs due to lack of the latest negotiation tools";
- "High and rising out-of-pocket costs for consumers"; and
- "Foreign governments freeloading off of American investment and innovation."

To address these challenges, the Blueprint says that "President Trump has called on the Administration to propose new strategies to take bold actions to

1. Improve competition and end the gaming of regulatory processes,
2. Support better negotiation of drug discounts through government insurance programs,
3. Create incentives for pharmaceutical companies to lower list prices, and
4. Reduce consumer out-of-pocket spending at the pharmacy and other care settings."

The President first announced legislative and administrative proposals to implement these four strategies in his Fiscal Year (FY) 2019 Budget, which we addressed in a February 2018 client alert. The Blueprint identifies steps the Administration is considering to build on the FY 2019 Budget proposals and implement each strategy. They are:

1. **Improved competition:** HHS may support improved competition by "[t]aking steps to prevent gaming of regulatory processes" and "[p]romoting innovation and competition for biologics." Such steps may include:
    - FDA "issu[ing] guidance to address some of the ways in which manufacturers may seek to use shared system REMS to delay or block competition from generic products entering the market."
    - FDA "issu[ing] new policies to improve the availability, competitiveness, and adoption of biosimilars as affordable alternatives to branded biologics."
    - FDA "continu[ing] to educate clinicians, patients, and payors about biosimilar and interchangeable products as we seek to increase awareness about these important new treatments."
2. **Better negotiation:** The following are immediate actions to support better negotiation may include the following proposals regarding innovative drug pricing models, Medicare Part D, Medicare Part B, and reducing prices in the U.S. compared to other countries:
    - Innovative drug pricing models:
        - "Directing Centers for Medicare & Medicaid Services (CMS) to develop demonstration projects to test innovative ways to encourage value-based care and lower drug prices," which would "hold manufacturers accountable for outcomes, align with CMS's priorities of value over volume and site-neutral payments, and provide Medicare providers, payers, and states with additional tools to manage spending for high-cost therapies."
        - "Evaluating options to allow high-cost drugs to be priced or covered differently based on their indication," such as "permit[ting] Part D plans to choose to cover or pay a different price for a drug, based on the indication."
    - Medicare Part D:
        - "Allowing Part D plans to adjust formulary or benefit design during the benefit year if necessary to address a price increase for a sole source generic drug," which "could ensure Part D plans can respond to a price increase by the only manufacturer of a generic drug."
        - "Providing plans full flexibility to manage high cost drugs that do not provide Part D plans with rebates or negotiated fixed prices, including in the protected classes," which "could allow Part D plans to use the tools available to private payers outside of the Medicare program to better negotiate for these drugs."
        - "Updating the methodology used to calculate Drug Plan Customer Service star ratings for plans that are appropriately managing utilization of high-cost drugs," which "could provide Part D plan sponsors with the ability to

appropriately manage high-cost changes, while holding sponsors accountable primarily using other successful enforcement mechanisms."

- Medicare Part B:
    - "Sending the President a report identifying particular drugs or classes of drugs in Part B where there are savings to be gained by moving them to Part D."
    - "Taking steps to leverage the authority created by the Competitive Acquisition Program (CAP) for Part B Drugs & Biologicals," which "may provide opportunities for Federal savings to the extent that aggregate bid prices are less than 106 percent of ASP, and provides opportunities for physicians who do not wish to bear the financial burdens and risk associated with being in the business of drug acquisition."
- Reducing prices in the U.S. compared to other countries:
    - "Working in conjunction with the Department of Commerce, the U.S. Trade Representative, and the U.S. Intellectual Property Enforcement Coordinator to develop the knowledge base necessary to address the unfair disparity between the drug prices in America and other developed countries."

3. **Incentives for lower list prices:** With respect to promoting lower list prices, HHS may:
    - "Call on the FDA to evaluate the inclusion of list prices in direct-to-consumer advertising."
    - "Direct CMS to make Medicare and Medicaid prices more transparent, hold drug makers accountable for their price increases, highlight drugs that have not taken price increases, and recognize when competition is working with an updated drug pricing dashboard."
    - "Develop proposals related to the Affordable Care Act's Maximum Rebate Amount provision, which limits manufacturer rebates on brand and generic drugs in the Medicaid [Drug Rebate] program to 100% of the Average Manufacturer Price."
4. **Lowering out-of-pocket costs:** The following are proposals to reform Medicare Part D to lower patient out-of-pocket costs:
    - "Prohibit Part D plan contracts from preventing pharmacists from telling patients when they could pay less out-of-pocket by not using their insurance - also known as pharmacy gag clauses."
    - "Require Part D Plan sponsors to provide additional information about drug price increases and lower-cost alternatives in the Explanation of Benefits they currently provide their members."

This list is not exhaustive; the Blueprint states that "HHS is considering even bolder actions to bring down prices for patients and taxpayers," including "new measures to increase transparency; fix the incentives that may be increasing prices for patients; and reduce the costs of drug development." To this end, HHS is seeking public comment regarding "how the department can take action to improve competition and end the gaming of regulatory processes, support better

negotiation of drug discounts through government insurance programs, create incentives for pharmaceutical companies to lower list prices, and reduce consumer out-of-pocket spending at the pharmacy and other care settings." Section V of the Blueprint sets forth a list of topics and questions about which HHS is specifically seeking comment, signaling high-priority areas where HHS may issue future proposals. These topics include:

- Increasing competition
  - **Underpricing or cost shifting**, particularly with respect to "incentives to obtain affordable prices on safe and effective drugs," whether the Medicaid Drug Rebate Program Best Price reporting requirement "pose[s] a barrier to price negotiation and certain value-based agreements in other markets, or otherwise shift costs to other markets," and "underpricing of generic drugs";
  - **Access to reference product samples**, particularly with respect to distribution restrictions and samples for biosimilars and interchangeables; and
  - **Biosimilar development, approval, education, and access**, particularly with respect to improving the Purple Book, educating providers and patients, and interchangeability.
- Better negotiation
  - **Improving price transparency** in Medicare, Medicaid, and other forms of health coverage;
  - **Value-based arrangements and price reporting**, particularly with respect to "allowing manufacturers to exclude from statutory price reporting programs discounts, rebates, or price guarantees included in value-based arrangements";
  - **Indication-based payments**, particularly with respect to how indication-based pricing could support value-based purchasing;
  - **Long-term financing models**, particularly with respect to who should bear the risk of spreading payments over multiple years;
  - **Part B Competitive Acquisition Program (CAP)**, particularly with respect to the "changes vendors and providers need to see relative to the 2007-2008 implementation of this program in order to successfully participate in the program";
  - **Part B to D**, particularly with respect to "[w]hich drugs or classes of drugs would be would be good candidates for moving from Part B to Part D";
  - **Fixing global freeloading**, particularly with respect to decreasing the pricing disparity between the U.S. and other developed countries;
  - **Site neutrality for physician-administered drugs**, particularly with respect to the effect that site-neutral payment for drug administration services would "have on the location of the practice of medicine"; and
  - **Site neutrality between inpatient and outpatient setting**, particularly with respect to ensuring that inpatient and outpatient providers are appropriately paid, regardless of where treatment is administered.

- Incentives for lower list prices
  - **Establishing a fiduciary duty for Pharmacy Benefits Managers (PBMs)**, particularly with respect to whether PBMs should "be obligated to act solely in the interest of the entity for whom they are managing pharmaceutical benefits" and whether PBMs should be "prohibited from receiving any payment or remuneration from manufacturers";
  - **Reducing the impact of rebates,** particularly with respect to steps CMS could take to restrict or reduce the use of rebates;
  - **Incentives to lower or not increase list prices**, particularly with respect to providing incentives to manufacturers who have not increased prices over a set period of time;
  - **Inflationary rebate limits**, particularly with respect to potentially "removing the cap on the inflationary rebate";
  - **Exclusion of certain payments, rebates, or discounts from the determination of AMP and BP**, particularly with respect to the exclusion of PBM rebates from the determination of AMP and BP;
  - **Copay discount cards**, particularly with respect to whether such patient assistance programs actually lead to higher list prices; and
  - **The 340B Drug Discount Program**, particularly with respect to reforms related to program eligibility and duplicate discounts.
- Lowering out-of-pocket costs
  - **Part D end-of-year statement on drug price changes and rebates collected**, particularly with respect to adding additional information to explanations of benefits and informing consumers regarding changes in drug prices;
  - **Federal preemption of contracted pharmacy gag clause laws**, particularly with respect to the purpose these clauses serve and strategies to provide price information to consumers at the point of sale; and
  - **Inform Medicare beneficiaries with Medicare Part B and Part D about cost-sharing and lower-cost alternatives**, particularly with respect to identifying tools that can reduce the out-of-pocket spending of Medicare patients.

Comments on each of these topics will be due 60 days after the Blueprint is published in the Federal Register, which is expected to occur on May 16, 2018. **As such, we expect comments will be due on July 16, 2018.**

The Blueprint and other Administration statements are a mixture of general principles and specific actions, with the likelihood and timing of implementation decidedly unclear. Given this uncertainty, the suggestion that additional proposals are in the works, and the request for comment on an extensive list of topics, companies should closely review the Blueprint to consider whether there are subjects that merit submitting views to HHS. Hogan Lovells will continue to monitor developments and issue updates, but please reach out to us if you have any questions or would like to discuss these developments.

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