PUBLICATION

President Trump Releases Drug Pricing Blueprint

Authors: Sheila P. Burke, Nicole Diane Carelli, Tiffani Vivienne Williams
May 16, 2018

On Friday, May 11, President Donald Trump and Department of Health and Human Services (HHS) Secretary Alex Azar presented the Administration's long-awaited plan to address drug pricing. The proposed framework, entitled, "American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs" aims to achieve four goals:

- **Increase competition for generic and biosimilar drugs;**
- **Improve drug price negotiation in Medicare Part B and Part D;**
- **Provide incentives for drug manufacturers to lower list prices; and**
- **Reduce consumer out-of-pocket spending.**

While the blueprint is fairly high-level and will require additional administrative and congressional action over time to implement, the proposed plan represents a pivotal step in the drug pricing debate and opens the door for stakeholders to weigh-in on the proposed policies. To that end, on May 14, HHS issued a Request for Information (RFI) on dozens of drug pricing proposals with a 60-day comment period.

See Baker Donelson's alert: "HHS Solicits Comments on Possible 340B Program Changes to Reduce Drug Prices"

Summary of Trump Administration Drug Pricing Blueprint

The blueprint outlines four major challenges facing the U.S. drug market: 1) high list prices for drugs; 2) seniors and government programs overpaying for drugs due to lack of the latest negotiation tools; 3) high and rising out-of-pocket costs for consumers; and 4) foreign governments free-riding off of American investment in innovation.

In response, the blueprint proposes two phases of action: 1) actions the President may direct HHS to take immediately, and 2) actions HHS is actively considering, on which feedback is being solicited.

Immediate Actions

- **Improve Competition.**
  - The Food and Drug Administration (FDA) will issue guidance to address some of the ways in which manufacturers may seek to use shared system Risk Evaluation and Mitigation Strategies (REMS) to delay or block competition from generic products entering the market.
  - FDA will issue new policies to improve the availability, competitiveness, and adoption of biosimilars as affordable alternatives to branded biologics and continue education about biosimilar and interchangeable products.
- **Better Negotiation.** HHS may:

- Direct the Centers for Medicare and Medicaid Services (CMS) to develop demonstration projects to test innovative ways to encourage value-based care and lower drug prices.
- Allow 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.
- Provide plans with 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, by allowing Part D plans to use the tools available to private payers outside of the Medicare program to better negotiate for these drugs.
- Update the methodology used to calculate Drug Plan Customer Service star ratings for plans that are appropriately managing utilization of high-cost drugs.
- Evaluate options to allow high-cost drugs to be priced or covered differently based on their indication.
- Send a report to the President on whether lower prices on some Medicare Part B drugs could be negotiated for by Part D plans.
- Take steps to leverage the Competitive Acquisition Program in Part B, which may provide opportunities for federal savings to the extent that aggregate bid prices are less than 106 percent of Average Sales Price (ASP) and provide opportunities for physicians who do not wish to bear the financial burdens and risk associated with being in the business of drug acquisition.
- Work 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.

- **Lowering List Prices.** HHS may:

  - Call on the FDA to evaluate requiring manufacturers to include 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 (ACA) Maximum Rebate Amount provision, which limits manufacturer rebates on brand and generic drugs in the Medicaid program to 100 percent of the Average Manufacturer Price.

- **Reduce Patient Out-of-Pocket Spending.** HHS may:

  - Prohibit Part D contracts from preventing pharmacists telling patients when they could pay less out-of-pocket by not using insurance (i.e., 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.

Further Actions Under Review and Opportunities for Feedback

HHS is interested in public comments about 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. HHS is also interested in public comments about the general structure and function of the pharmaceutical market, to inform these actions.

The blueprint and RFI include an extensive list of questions for consideration across numerous topics, which are listed below.

- **Increasing Competition.**

- **Underpricing or Cost-Shifting** (HHS program incentives; Best Price rule; potential underpricing of generics)
- **ACA Taxes and Rebates** (impact on list prices; whether cross-subsidization is occurring)
- **Access to Reference Product Samples** (additional evaluation of existing REMS; terms/other steps that could expand access; other steps necessary to facilitate access to samples)
- **Biosimilar Development, Approval, Education, and Access** (FDA resources and tools to reduce development costs; improvements to Purple Book; provider and patient education; improvements to/impact of interchangeability)

- **Better Negotiation.**

  - **Steps to Improve Price Transparency**
  - **Value-Based Arrangements and Price Reporting** (merit/impact of excluding pricing in value-based arrangements from statutory price reporting; extending reporting times to reflect value-based pricing arrangements; potential modifications to Medicaid rebate program; regulatory changes to assist Medicaid managed care organizations in negotiating value-based arrangements; other changes to the Social Security Act or Anti-Kickback Statute to facilitate value-based arrangements)
  - **Indication-Based Payments** (merit to changing pricing model; regulatory changes and improvements needed; adequacy of CMS data reporting/stakeholder information)
  - **Long-term Financing Models** (potential models and impact; regulatory and other barriers; assurances necessary to encourage participation)
  - **Part B Competitive Acquisition Program** (program changes needed to be successful; vendor interest in participation; implementation details; other approaches that could lower Part B spending)
  - **Part B to D** (which drugs would be good candidates; implementation details; availability of data showing price differences for Part B drugs in OECD countries, and potential/impact of moving this set of drugs to Part D)
  - **Fixing Global Freeloading** (policies that can help protect IP rights and spread burden for incentivizing new drug development)
  - **Site Neutrality for Physician-Administered Drugs** (impact of site neutrality policy)
  - **Site Neutrality Between Inpatient and Outpatient Setting** (access challenges resulting from/rationale for current payment policy; policy options to ensure providers are reimbursed appropriately and care is provided in the least expensive setting)
  - **Accuracy of National Spending Data** (whether current reports obscure the true costs of drugs; value of improved reports; ways reports could more accurately collect and report gross and net spending while preserving proprietary/confidential information; value of reporting Part D rebates separately for small molecule drugs, biologics, and high-cost drugs)

- **Create Incentives to Lower List Prices.**

  - **Fiduciary Duty for Pharmacy Benefit Managers (PBMs)** (whether current structure creates incentives to keep list prices high; impact on beneficiaries; how to change incentives; potential/impact of banning PBM remuneration from manufacturers and banning inclusion of rebates/fees as a percentage of list price in contracts; potential/impact of imposing fiduciary duty on PBMs on behalf of consumers)
  - **Reducing the Impact of Rebates** (potential ways CMS could restrict use of rebates, including prohibition in Part D contracts or removing safe harbor; impact on marketplace)
  - **Incentives to Lower or Not Increase List Prices** (potential of banning drugs with certain price increases from protected classes or treating those drugs differently when determining exceptions

criteria; other incentives to encourage manufacturers not to raise prices in Parts D and B; potential of allowing immediate Healthcare Common Procedure Coding System (HCPCS) codes for new Part B drugs if manufacturer commits to a price for certain time period; impact of potential proposals)
  - **Inflationary Rebate Limits** (potential/impact of removing limitation on rebates in Medicaid to 100 percent of Average Manufacturer Price (AMP))
  - **Exclusion of Certain Payments, Rebates, or Discounts from the Determination of Average Manufacturer Price and Best Price** (potential/impact of removing exclusion of PBM rebates from determination of Best Price; potential/impact of excluding PBM rebates/discounts from AMP determination)
  - **Copay Discount Cards** (impact on costs; impact of eliminating exclusion of card programs from AMP and Best Price determination; circumstances in which the benefits of allowing the use of copay cards in federal health care programs would outweigh drawbacks)
  - **340B Drug Discount Program** (consequences of program growth; impact of explicit general regulatory authority; impact of changing definition of "patient"; effectiveness of current mechanisms to prevent duplicate discounts and potential solutions)
    - See Baker Donelson's alert: "HHS Solicits Comments on Possible 340B Program Changes to Reduce Drug Prices"

- **Reduce Patient Out-of-Pocket Spending.**

  - **Part D End-of-Year Statement on Drug Price Changes and Rebates Collected** (including additional information in Part D end-of-year statement on drug price changes; options to share this information via pharmacists)
  - **Federal Preemption of Contracted Pharmacy Gag Clause Laws** (impact of pharmacy gag clauses and any other communication restrictions; potential of requiring pharmacists to ask patients in federal programs if they'd like to know about lower-cost alternatives; other options to provide price information at point-of-sale)
  - **Inform Medicare beneficiaries with Medicare Part B and Part D About Cost-Sharing and Lower-Cost Alternatives** (availability of tools to inform consumers; burden on providers and pharmacists)

Implications for Stakeholders

The Administration's blueprint and RFI could have a significant impact on the way in which prescription drugs are priced and reimbursed. The full extent of implications will depend on the specific actions HHS and Congress takes in the months to come. Stakeholders have an important opportunity to provide input during the 60-day comment period, beginning on May 16. Baker Donelson policy advisors and attorneys are available to assist clients with drafting comments in response to the Administration.

If you have any questions about this alert, please contact Sheila Burke, Niki Carelli or Tiffani Williams.