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The New Federal Blueprint to Lower Drug Prices

On Friday, May 11, 2018, President Trump vowed to fix "the injustice of high drug prices" by announcing the "Blueprint to Lower Drug Prices" (the Blueprint)[1] to address the following challenges:

1. Excessively high drug prices
2. Seniors and government programs overpaying for drugs
3. High out-of-pocket costs for consumers
4. Lack of transparency in drug pricing
5. Free-riding by foreign nations as to US investment in innovation

The US Department of Health & Human Services (HHS) followed up with additional information about the President's Blueprint[2] with American Patients First, an overview of reforms in the following areas:

1. Drug oversight by the US Food & Drug Administration (FDA)
2. Coverage of drugs by government programs such as Medicare and Medicaid
3. Drug manufacturer rebates
4. Drug pricing disparities between the US and foreign nations

The following is a summary and analysis of the President's Blueprint.

Proposed FDA Reforms

Accelerate FDA approval of generics

The FDA has taken steps to prioritize its review of generic drug applications, streamline its review of generic drugs for approval, and prevent brand name drug manufacturers from impeding generic development and approval.[3]

Stop generic manufacturers from gaming the system to forestall competition

Generic drug manufacturers are awarded an 180-day exclusivity period for being the first generic to file with the FDA and can "park" their applications, preventing other generic manufacturers from receiving FDA approval.[4] The Blueprint seeks legislative changes to start a company's 180-day exclusivity clock when another generic application is ready for approval.[5]

Reform FDA Risk Management and Mitigation Strategies (REMS) requirements

Drug manufacturers must adopt REMS to ensure that the benefits of drugs outweigh their risks.[6] REMS often include restrictions on the distribution of drugs, which manufacturers may use to withhold drug samples from generic drug manufacturers to stop generic drug development. The Blueprint seeks to reform the way in which manufacturers use REMS to block generics.[7]

Bring transparency to the list prices

The Blueprint directs the FDA to evaluate the inclusion of list prices on direct-to-consumer advertising of drugs.[8]

Proposed Medicare Part D Reforms

Amend formulary rules to reduce drug costs

The Blueprint seeks to amend Medicare Part C and Part D regulations to allow for faster mid-year substitution of lower cost generic drugs onto formularies.[9]

Increase the bargaining power of Part D plans

Currently, Part D formularies must cover at least two drugs from each therapeutic category or class.[10] The Blueprint proposes to amend these standards to require giving only one drug per category or class, giving Part D plans greater bargaining power.[11] The Blueprint would also allow Part D plans to reimburse and cover drugs based on indications, so coverage can be aligned with cost and effectiveness.[12]

Amend Part D member cost sharing

The Blueprint proposes to amend Part D cost sharing rules as follows:

- Exclude discounts in calculating the out-of-pocket maximum (OOP Max) in the Part D coverage gap
- Establish an OOP Max for drugs in the Part D catastrophic phase, creating incentives for Part D plans to negotiate down drug prices
- Eliminate or reduce cost sharing for low income beneficiaries
- Apply manufacturer rebates to drug prices at point of sale, reducing member cost sharing[13]

1 *President Donald J. Trump's Blueprint to Lower Drug Prices (May 11, 2018).*
2 *American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs, U.S. Department of Health & Human Services (May 11, 2018).*
3 *Id., at 18-19.*
4 21 U.S.C. § 355 (j)(5)(B)(iv).
5 *American Patient First, supra, at 19.*
6 21 U.S.C. § 355-1.
7 *American Patient First, supra, at 23.*
8 *Id., at 25.*
9 *Id., at 19.*
10 42 C.F.R. § 423.120 (b)(2).
11 *American Patient First, supra, at 20.*
12 *Id., at 24.*
13 *Id., at 21-22.*

Increase transparency of drug pricing

The Blueprint would prohibit Part D plans from preventing pharmacies from telling members they can pay less without using insurance, and require Part D plans to provide information about drug price increases and lower cost alternatives on Explanation of Benefits (EOBs).[14] As to this reform, it should be noted that many states have already adopted similar requirements.

Proposed Medicare Part B Drug Reforms

Move drugs from Part B to Part D

Drugs administered in physician offices and hospital outpatient facilities are covered by Part B (medical) rather than Part D (drug) benefits. Medicare usually pays for Part B drugs based on Average Sales Price (ASP) plus 6%, which may be greater than what Part D plans would pay for the same drugs.[15] To lower drug costs, the Blueprint proposes to transfer some Part B drugs to Part D coverage.[16]

Reduce prices paid by Part D plans

If the ASP is not available for a single source drug, Medicare may pay for the drug based on the Wholesale Acquisition Cost (WAC).[17] WAC represents the manufacturer's list price and does not take into account rebates, discounts or price reductions, whereas ASP is the average price paid to the manufacturer, including rebates, discounts and reductions. Because WAC pricing is the list price without discounts or rebates, the Blueprint calls for a reduction WAC prices paid. In addition, the Blueprint proposes inflation limits on price increases for Part B drugs.[18]

Begin to actively negotiate Part B drug pricing

The Blueprint proposes to leverage the Competitive Acquisition Program (CAP) for Part B drugs to give physicians a choice of whether to pay for drugs based on a price negotiated through competitive bidding or by purchasing at a price based on ASP.[19]

Proposed Medicaid Drug Reforms

Clarify drug classifications for Medicaid rebate purposes

For drugs purchased by Medicaid, drug manufacturers pay rebates to Medicaid based on classifications, such as generic and brand name. The Blueprint directs HHS to clarify how drugs are classified to prevent manufacturers from misclassifying drugs to pay lower rebates.[20]

Allow states to establish formularies and negotiate prices

Medicaid currently has an open formulary, with manufacturers paying rebates to lower prices.[21] The Blueprint would permit states to establish demonstration projects to establish their own formularies, including closed formularies, and negotiate prices with manufacturers.

States with closed formularies would be required to adopt a process whereby consumers could access non-formulary drugs in appropriate circumstances.[22]

Allow greater rebates to be paid to Medicaid

The ACA sets a limit on the total rebate a manufacturer must pay Medicaid for each single source or innovator multiple source drug at 100% of the Average Manufacturer Price (AMP).[23] The Blueprint would change rebate limits to allow for greater rebates.[24]

Addressing Disparities in the International Market

The Blueprint seeks to address international disparities related to drug pricing. Although no specific action is proposed, the Blueprint indicates the Administration will update historical studies that analyze drug prices in countries that are part of the Organisation of Economic Co-operation and Development (OECD). HHS is also seeking information from interested parties related to the difference in list and net prices paid in the US compared to OECD nations and what can be done to reduce the price disparity.[25]

Solicitation of Comment as to Bolder Action

In addition to the proposals above, HHS is considering bolder action to bring down drug costs. In this regard, HHS is seeking public comment on actions HHS can take to improve competition, end gaming of regulatory processes, support negotiation, create appropriate incentives and reduce out-of-pocket spending. On May 16, HHS published in the Federal Register a Request for Information asking for responses to specific questions, some of which broadly relate to the pharmaceutical market and industry, and others targeted at specific proposals.[26] Examples of the questions asked by HHS include the following:

- Do HHS programs contain the correct incentives to obtain affordable prices on safe and effective drugs?
- Are government programs being cross-subsidized by higher list prices and excess costs paid by individuals and employers in the commercial markets?
- What steps can be taken to improve price transparency . . . so that consumers can seek value when choosing and using their benefits?
- What can be done to reduce the pricing disparity and spread the burden for incentivizing new drug development more equally between the US and other developed countries?
- What should CMS consider doing to restrict or reduce the use of (drug manufacturer) rebates?

HHS also has sought comment on the specific proposals identified above.

14 *Id., at 25-26.*
15 42 C.F.R. § 414.904 (a).
16 *American Patient First, supra, at 24.*
17 42 C.F.R. § 414.904 (d).
18 *American Patient First, supra, at 20.*
19 *Id., at 25.*
20 *Id. at 20.*
21 42 U.S.C. § 1396r-8.
22 *Id. at 20-21.*
23 42 C.F.R. § 447.509 (a)(5).
24 *American Patient First, supra, at 24.*
25 *Id. at 21, 31-21.*
26 *HHS Blueprint to Lower Drug Prices and Reduced Out of Pocket Costs, Policy Statement and Request for Information, 83 Fed. Reg. 22692 et seq. (May 16, 2018).*

Contacts

For more information about the Federal Blueprint to Lower Drug Costs, including how it might affect market participants, and the opportunities to shape the development of Administration policy and agency action, please contact one of the lawyers cited.

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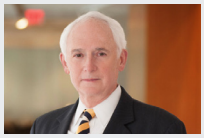

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