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# BENEFITS BRIEF

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## Trump Administration Issues Request for Information on Drug Costs

On May 16, 2018, the Department of Health & Human Services ("HHS") published a request for information ("RFI") related to drug costs entitled "HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs." The RFI was issued just days after the HHS released a similar public blueprint entitled "Putting American Patients First." While the RFI focuses mostly on drug companies and federal health care programs, it also has important long term ramifications for insurers and PBMs, particularly with respect to drug rebates, as well as potentially for employers that obtain prescription drug services in connection with their group health plans.

The RFI is a part of President Trump's administrative agenda to reduce drug pricing, lower list prices and reduce consumer out-of-pocket spending at the pharmacy. In February 2018, the President's Council of Economic Advisors released a report, "Reforming Biopharmaceutical Pricing at Home and Abroad" that reiterated President Trump's commitment to drug pricing reforms and presaged many of the issued addressed in the Blueprint and the RFI. The White House also included drug pricing reform proposals in its fiscal year 2019 budget, several of which are reiterated in the Blueprint and RFI.

The release of the RFI indicates that the Trump Administration, working primarily through HHS, is now seeking to take more concrete regulatory steps toward reducing drug costs. This is an immensely complicated area of policy-making and proposals in the RFI on which HHS is seeking feedback would involve multiple federal government entities, including the HHS, the Centers for Medicare & Medicaid Services ("CMS"), and the Food and Drug Administration ("FDA"), to implement.

The RFI outlines "actions the President may direct HHS to take immediately" and actions on which HHS is seeking comment. Many of these "immediate actions" are discussed in the RFI, along with the areas for which HHS seeks additional information. Notably, HHS has already taken some immediate action that may be of interest to plan sponsors and health insurance issuers: the RFI discusses updating Medicare's drug-pricing dashboard and an update of the dashboard was announced on May 15. Similarly, the RFI discusses prohibiting Part D contracts from preventing pharmacists from advising patients when they could pay less out-of-pocket by not using insurance and a CMS memo prohibiting "unacceptable pharmacy gag clauses" was issued on May 18.

Comments for the RFI are due July 16, 2018.

Some of the key points outlined in the RFI include–

- Whether to impose a fiduciary duty on pharmacy benefit managers and restricting their ability to receive any payment or remuneration from manufacturers, including rebates or fees calculated as a percentage of list prices.

- Whether copay discount cards drive increases in manufacture list prices, what effect excluding drug discount card programs has on the determination of average manufacturer price and the determination of best price, and whether beneficiaries of federal health care programs like Medicare should be able to use drug discount cards.

- Which drugs or classes of drugs would be good candidates for moving from Part B to Part D and how the proposal could be implemented to help reduce out-of-pocket costs for individuals who do not have Medicare prescription drug coverage.

**Details on the HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs**

The RFI asks stakeholders to submit comments on four key strategies for drug price reform: (1) improved competition; (2) better negotiation of drug discounts in government-funded insurance programs; (3) incentives for lower list prices; and (4) lowering out-of-pocket costs. As discussed in more detail below, the RFI outlines a series of immediate actions in each of these areas and solicits feedback on additional proposals that HHS is contemplating. HHS noted that the RFI is for information and planning purposes and does not constitute a notice of proposed rulemaking. That said, the RFI signals potentially significant changes for pharmacy benefit managers and Medicare Part D plans.

1. **Improved Competition**. The RFI outlines immediate actions designed to increase prescription drug competition that are primarily directed at the FDA, such as directing the FDA to issue guidance to address the ways in which manufacturers may seek to use existing regulations to delay or block competition from generic products entering the market and adopting measures to promote innovation.

   ***Solicitation of Comments***: The RFI solicits public comments on whether HHS programs contain the correct incentives to obtain affordable prices on safe and effective drugs and how the new Affordable Care Act's excise tax and increase in the Medicaid drug rebate amount have impacted manufacturer list prices. The RFI also solicits comments on how to encourage sharing of samples needed for generic drug development and additional efforts to promote the use of biosimilars.

2. **Better Negotiation**. The RFI outlines immediate actions HHS has taken to support better negotiation, including experimenting with value-based purchasing in federal programs, allowing more substitution in Medicare Part D to address price increases and leveraging the Competitive Acquisition Program in Medicare Part B. The RFI also proposes permitting Part D plans to price or cover high-cost drugs differently based on their indication.

   ***Solicitation of Comments***: The RFI solicits public comments on the benefits that would accrue to Medicare and Medicaid beneficiaries by allowing manufacturers to exclude from statutory price reporting programs discounts, rebates or price guarantees and regulatory changes that Medicaid Managed Care organizations would find helpful in negotiating value based purchasing supplemental rebates with manufactures and how these changes would affect Medicare or the 340B program.

The RFI also asks whether there are particular sections of the Social Security Act—for example, the anti-kickback statute—or other statutes or regulations that can be revised to assist with value-based designs, including how to spread the cost of high-cost treatments over multiple years and other novel value-based arrangements. The Competitive Acquisition Program for Part B drugs is also open for comment, with HHS particularly interested in what changes would be needed to encourage participation in the program. Additionally, the President's Budget requested the authority to move some drugs from Medicare Part B to Medicare Part D. HHS asks for good candidates for drugs that should move. HHS is also interested in comments on site-neutral payment policies.

- ***Key Point for Medicare Part D Plans****: The RFI makes several proposals that could have a material impact on Medicare Part D plans, including employer group waiver plans, such as:*

    - *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. Presently, Part D plans are not permitted to change their formulary or benefit design without CMS approval in response to price increases. This change could allow plans greater flexibility to respond to a price increase by the only manufacturer of a generic drug.*

    - *Allowing plans the flexibility to negotiate lower prices for high-cost drugs without competition.*

    - *Expanding information for participants about cost-sharing and lower cost alternatives.*

  **GROOM COMMENT**: Employers and health insurance issuers that contract with the government to sponsor a Medicare Part D plan must remember other existing Federal regulations that may impose additional restrictions on their ability to differentiate in drug prices based on their indication. Final rules implementing section 1557 of the Patient Protection and Affordable Care Act ("ACA") prohibit discrimination on the basis of race, color, national origin, sex, age, or disability, for any health program or activity, any part of which receives federal funding or assistance, or under any program or activity that is administered by an executive agency or any program or activity administered by an entity established by title I of the ACA. It is not clear how these existing regulations would be addressed if HHS provided greater flexibility in pricing high-cost drugs differently based on their indication.

3. **Incentives for Lower List Prices**. The RFI provides that HHS may call on the FDA to evaluate the inclusion of list prices in direct-to-consumer advertising.

   ***Solicitation of Comments*****:** The RFI solicits comments on additional measures that are directed at the use of rebates by pharmacy benefit managers, insurers and pharmacies that could have significant impact in the way that drugs are priced in the marketplace including revising the safe harbor under the Anti-Kickback statue for drug rebates, changes to HHS' regulations regarding drug copay discount cards and additional reforms to the rebating system. The 340B drug discount program is also a subject of interest, with comments specifically solicited on eligibility and duplicate discounts.

- ***Key Points for Health Insurance Issuers and Pharmacy Benefit Managers ("PBMs")****:*

    - ***Increased Regulation of PBMs:*** *The RFI contemplates imposing fiduciary duties on pharmacy benefit managers including the requirement to act solely in the interest of the entity for whom they are managing pharmaceutical benefits and being forbidden from receiving any payment or remuneration from manufacturers and including rebates or fees as a percentage of list prices. The RFI does not reference ERISA or any other statutory authority to impose fiduciary duties on PBMs. HHS has asked a number of questions with respect to this proposal including the effect imposing this fiduciary duty on PBMs would have on consumers and any unintended consequences on beneficiary out-of-pocket spending and government program spending could result from these changes.*

    - ***Rebates****: The RFI also discusses the possibility of requiring rebates to be shared with customers at the point of sale, as proposed in President Trump's FY 2019 budget.*

    **GROOM COMMENT**: The RFI signals a potentially significant shift in policy from existing guidance from the Department of Labor with respect to rebates and manufacturer administrative fees received by PBMs. In Supplemental Frequently Asked Questions about the 2009 Schedule C, FAQ 27, published on February 4, 2010, the Department of Labor announced reporting relief for certain types of indirect compensation earned by PBMs, explaining that "discount and rebate revenue" paid to PBMs by drug manufacturers need not be reported on a plan's Schedule C as indirect compensation pending further guidance. This is an area to watch as agency guidance with respect to rebates may signal a shift in the DOL's reporting relief for rebates for Form 5500 reporting purposes.

4. **Lowering Out-of-Pocket Costs**. The RFI solicits feedback on actions that HHS may take to reduce out-of-pocket spending, including prohibiting Part D plan contracts from preventing pharmacists from telling patients when they could pay less on out-of-pocket costs and requiring Part D Plan sponsors to provide additional information about drug price increases and lower-cost alternatives in the Explanation of Benefits they provide their members. The RFI also solicits information on how providing information on formulary options, expected cost-sharing and lower-cost alternatives specific to individual patients could reduce out-of-pocket spending for people with Medicare

    ***Solicitation of Comments***: The RFI includes a request for additional suggestions to improve the affordability and accessibility of prescription drugs, and notes that HHS is actively working to reduce regulatory burdens. HHS has asked to what extent current regulations or government policies related to prescription drug pricing impose burdens and whether the burdens outweigh the benefits.

The Trump Administration is calling the RFI a call for immediate action to lower drug prices and reduce out-of-pocket costs. Commenting presents an opportunity to shape policy and educate the regulators and the administration on the complexities and nuances that are inherent in the pharmacy benefit management landscape and partner with regulators as they develop what may be a new regulatory framework for prescription drugs.