President Trump's Drug Pricing Blueprint:

Plan Reiterates Budget Proposals But Leaves Most Other Elements To Be Determined

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On May 11, 2018, President Donald Trump and Secretary of Health and Human Services Alex Azar announced "American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs" (the "Blueprint") in televised speeches to an audience in the White House Rose Garden.[1]

Immediately following the speeches by the President and the Secretary, the Department of Health and Human Services (HHS) released a 39-page document containing the Blueprint.[2] However, rather than laying out a comprehensive set of new policy changes the Administration will implement or is proposing, the Blueprint largely repeats proposals previously made in the President's fiscal year (FY) 2019 Budget proposal,[3] coupled with a wide-ranging list of issues on which the Administration is seeking public input before determining any additional reforms it will implement or propose. In contrast to Secretary Azar's comments suggesting immediate action, the Blueprint is in large part a very open-ended invitation for additional discussion on what should be done.

Moreover, despite the President's remarks indicating the Blueprint will result in prices at the pharmacy counter starting to come down very soon, nearly all of the most significant changes contemplated would require congressional action, and would likely be fiercely opposed by affected industry participants. Even the steps that the Administration could potentially take on its own would typically require notice-and-comment rulemaking, and in many cases may be subject to challenge on statutory or constitutional grounds. Most of the changes would normally require a period of years to implement.

While the substance of the Blueprint arguably does not match the Rose Garden claims about it, the potential significance of the dramatic range of issues under consideration – including radical changes such as removing anti-kickback discount safe harbor protection for payor rebates – should not be minimized. Perhaps most importantly, the Blueprint includes the FY 2019 Budget proposal to give the Administration authority to move coverage of certain drugs from Medicare Part B to Part D so that their pricing is subject to private-sector negotiation, and this has been emphasized by Secretary Azar in further remarks.[4] Indeed, he has asserted that HHS has the authority to take such actions without congressional legislation, through a demonstration program.[5] The Blueprint also states that the Administration will take steps to allow Part D plans to restrict coverage of Part D protected class drugs in order to promote competition – changes which, while likely requiring notice and comment rulemaking and a period for implementation and rebate negotiation, could eventually have significant impacts on Part D plan costs for, and beneficiary access to, drugs in the affected classes. More immediately, comments from Secretary Azar warn manufacturers that continue to raise list prices that they may face the wrath of the President – threats which, if heeded, could have near-term impacts on prices.

It is important to recognize that the Blueprint does not necessarily reflect a coherent definition of or approach to the perceived "drug pricing" problem. For example, while the Blueprint identifies lowering manufacturer list prices and reducing patient out-of-pocket expenses as objectives, most of its proposals do not appear to directly address these issues. Moreover, it does not seek to balance competing policy imperatives for "access" to drugs.

Ultimately, however, the Blueprint's broad list of issues for consideration includes many potential reforms that, if pursued, could have significant impacts on virtually every segment of the health care industry involved in the drug distribution system –

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[1] "Remarks by President Trump on Lowering Drug Prices," May 11, 2018, available at https://www.whitehouse.gov/briefings-statements/remarks-president-trump-lowering-drug-prices/ (accessed May 14, 2018). Alex M. Azar II, "Remarks in the White House Rose Garden," May 11, 2018, available at https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-in-the-white-house-rose-garden.html (accessed May 14, 2018).

[2] "American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs," available at https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf (accessed May 14, 2018).

[3] FY 2019 "Budget in Brief," available at https://www.hhs.gov/sites/default/files/fy-2019-budget-in-brief.pdf (accessed May 18, 2018).

[4] Alex M. Azar II, "Remarks on Drug Pricing Blueprint," May 14, 2018, available at https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-on-drug-pricing-blueprint.html (accessed May 14, 2018) ("Azar Remarks").

[5] "HHS May Test Changes to How Medicare Pays for Expensive Drugs," Bloomberg Law, May 15, 2018, available at https://www.bloomberglaw.com/document/X4I514OC000000?emc=bhlnw_hlt%3A2 (accessed May 15, 2018).

including brand and generic manufacturers, private and public payors, pharmacy benefit managers (PBMs), wholesalers and distributors, pharmacies, 340B program stakeholders and, of course, patients. **HHS has released a request for information (RFI) soliciting comments on the numerous ideas and questions raised in the Blueprint, with responses due by July 16, 2018**.[6] Given the political emphasis being placed upon this topic by the Administration and the scope of changes being discussed, industry participants would be well-advised to engage on these issues and take the Blueprint, as it evolves, into account in planning strategy.

Themes and structure of the Blueprint

The Blueprint states that the Administration has identified four key strategies for reform:

- Improved competition
- Better negotiation
- Incentives for lower list prices
- Lowering out-of-pocket costs

The Blueprint further states that the strategy encompasses two phases: (1) actions the President may direct HHS to take immediately; and (2) actions HHS is actively considering, on which feedback is being solicited. As the following discussion reflects, there is a substantial blurring of lines between those "changes" that constitute past accomplishments versus proposals for further action. For example, the FY 2019 Budget proposals are identified as accomplishments, despite the fact none has yet been adopted by Congress. There is also ambiguity regarding whether various changes will be implemented or only considered.

Blueprint list of Trump Administration accomplishments

The Blueprint section on "Trump Administration Accomplishments on Drug Pricing" contains a mix of claimed accomplishments (such as more approvals of generics) and legislative proposals included in the President's FY 2019 Budget. Since the Budget proposals appear to form the core of the Blueprint proposals, we list them here.

- ***Preventing "parking" of generic applications with 180-day exclusivity.*** The Blueprint states that generic manufacturers that have "been awarded 180-day exclusivity for being the first generic to file can 'park' their application with the Food and Drug Administration (FDA), preventing additional generic manufacturers from entering the market." The President's FY 2019 Budget proposed that the 180-day exclusivity period would begin "in certain circumstances when another generic is ready for approval, but is blocked solely by such first applicant's 180-day exclusivity."
- ***Changing Part D formulary standards.*** The FY 2019 Budget proposed "changing Part D plan formulary standards to require a minimum of one drug per category or class instead of two."
- ***Part B drug inflation limit and other changes.*** The FY 2019 Budget proposed "establishing an inflation limit for reimbursement of Medicare Part B drugs, reducing wholesale acquisition cost (WAC)-Based Payment when Average Sales Price (ASP) isn't available, and improving manufacturers' reporting" of ASP.
- ***Medicaid rebate changes.*** The FY 2019 Budget proposed to clarify when drugs should be classified as brands versus generics.
- ***Medicaid formulary demonstration.*** The FY 2019 Budget requested "new Medicaid demonstration authority for up to five states … to determine their own drug formularies … and negotiate drug prices directly with manufacturers."
- ***Moving Part B drugs to Part D.*** The FY 2019 Budget proposed "to authorize the Secretary to leverage Medicare Part D plans' negotiating power for certain drugs covered under Part B." Secretary Azar's subsequent comments on the Blueprint have taken this idea much further, stating ***"the President has called on us to merge Medicare Part B into Part***

[6] "HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs," 83 Fed.Reg. 22692 (May 16, 2018) (the "RFI").

D."[7] Secretary Azar has also claimed that action along these lines could be taken by HHS without congressional approval, through Centers for Medicare & Medicaid Services (CMS) demonstration authority.[8]

- ***Exclusion of Part D coverage gap discounts from TrOOP.*** The FY 2019 Budget proposes not counting discounts manufacturers are required to pay in the Part D "coverage gap" toward beneficiary out-of-pocket costs (aka "TrOOP"). This would effectively expand the coverage gap and thereby increase the drug utilization on which coverage gap discounts must be provided, as well as delay beneficiaries' entry into the catastrophic portion of the Part D benefit.

- ***340B changes.*** The Blueprint states that the FY 2019 Budget "proposes reforms to improve 340B program integrity and ensure that the benefits derived from participation in the program are used to benefit patients, especially low-income and uninsured populations." Most notably, the Budget proposed that certain hospitals could access 340B pricing only if they provide a minimum level of charity care.

- ***Part D pass-through of rebates and generic cost-sharing.*** The FY 2019 Budget proposed that Part D plans be required "to apply a substantial portion of rebates at the point of sale," and that cost-sharing on generic drugs be eliminated for low-income beneficiaries. Notably, these proposed changes would require significant increases in federal Part D subsidies ($42 billion over 10 years).

Blueprint "immediate actions"

The Blueprint section on "Responding to President Trump's Call to Action" describes a number of actions "HHS may support."

- ***Guidance on using shared-system risk evaluation and mitigation strategy (REMS) to avoid providing product for equivalence testing.*** "FDA will issue 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."[9] On May 17, 2018, FDA posted information on more than 50 specifically-identified drugs for which it had received inquiries from prospective generic drug applicants indicating that they would like to develop a generic version of the drug but are unable to obtain the necessary samples of the reference (branded) drug from its manufacturer.[10] The posting also includes information on letters FDA has sent relative to REMS requirements.

- ***Promoting biosimilar development and education.*** "FDA will issue new policies to improve the availability, competitiveness, and adoptions of biosimilars as affordable alternatives to branded biologics" and "will also continue to educate clinicians, patients and payors about biosimilar and interchangeable products…" While the substance of any new policies is unclear, this appears to be a continuation of FDA's previously-announced actions to provide additional guidance to streamline development of biosimilar drugs and provide education on their use.

- ***Value-based care demonstrations.*** HHS may direct CMS "to develop demonstration projects to test innovative ways to encourage value-based care and lower drug prices. These models should 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." The details of the contemplated demonstration projects have not been announced.

- ***Part D formulary changes related to single-source generics.*** The Blueprint calls for "[a]llowing 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." It is not clear what the permitted formulary "adjustment" would be, particularly in cases where continued coverage of the generic drug at issue is necessary for the formulary to satisfy Part D formulary requirements. One possibility is that CMS will simply allow the branded equivalent to be substituted for the generic.

- ***Additional utilization management flexibility for Part D plans on protected class drugs.*** The Blueprint endorses "[p]roviding 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." It should be noted that under current Part D statutory requirements, it

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[7] Azar Remarks, Id.

[8] *See* article cited in note 4, *supra*.

[9] REMS are requirements imposed by FDA on certain drugs (e.g., to prevent them from being dispensed to pregnant women); shared system REMS refers to an integrated REMS program applicable both to the innovator drug and to generic equivalents or biosimilars.

[10] *See* https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm607738.htm (accessed May 17, 2018).

appears that CMS must engage in a notice and comment rulemaking for these types of changes.[11] In 2014, CMS proposed to remove protected class status for three of the six categories of drugs that currently have such status. This action drew a chorus of opposition from Congress and others, and CMS decided not to make these changes.[12]

- ***Part D star ratings changes.*** HHS will consider "[u]pdating the methodology used to calculate Drug Plan Customer Service star ratings" associated with appeals of adverse coverage determinations by enrollees or prescribers, which "may discourage Part D plan sponsors from appropriately managing utilization of high-cost drugs." While the substance of the contemplated changes is unclear, changes to star rating calculations are normally implemented by CMS as part of its annual "call letter" notice and comment process (already completed for 2019), with changes becoming effective only after a multi-year implementation period.

- ***Indication-based pricing.*** HHS will be "[e]valuating options to allow high-cost drugs to be priced or covered differently based on their indication.… This change could permit Part D plans to cover or pay a different price for a drug, based on indication." It is not clear that there is at present any legal restriction on Part D plans paying a different price for a given drug (e.g., through payment of a different rebate level to the manufacturer) based upon the indication for which the drug is used. However, the major obstacle to doing so is the lack of data on the indication for which a drug was prescribed in the pharmacy claims data normally submitted for rebates.

- ***Report on moving drugs from Part B to Part D.*** The Blueprint states that HHS will be "[s]ending a report to the President identifying particular drugs or classes of drugs where there are savings to be gained by moving them to Part D." This may suggest that this report will precede any proposal or demonstration to move drugs from Part B to Part D.

- ***Part B CAP.*** HHS expects to be "[t]aking steps to leverage the authority created by the Competitive Acquisition Program (CAP) for Part B Drugs and Biologicals." Use of a CAP, under which a vendor purchases Part B drugs and provides them to physicians and other providers for administration in lieu of the current "buy and bill" system where provider reimbursement includes a profit margin, was authorized as part of the Medicare Modernization Act. A previous CAP tried during 2007-2008 is generally considered to have failed, and was terminated. Secretary Azar has stated that "[i]n short order, we will be issuing a request for proposal to make use of [a CAP]."[13]

- ***Foreign drug reimbursement "knowledge base."*** The Blueprint states HHS will be "[w]orking 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 drug prices in America and other developed countries." In his Rose Garden speech, President Trump identified foreign governments that "extort unreasonably low prices from U.S. drug makers," resulting in Americans having to "pay more to subsidize the enormous cost of research and development," as an issue his Administration would address.

- ***Requiring inclusion of list prices in DTC advertising.*** HHS may "[c]all on the FDA to evaluate the inclusion of list prices in direct-to-consumer advertising." There are significant questions regarding whether FDA has authority to impose such a requirement, and whether such a requirement would be compliant with the First Amendment. Moreover, list price information may not be meaningful in light of distribution channel discounts or because consumers may be more focused on insurance copayment amounts.

- ***Drug pricing dashboard.*** HHS may "[d]irect 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.[14] This tool will also provide patients, families and caregivers with additional information to make informed decisions and predict their cost sharing." On May 15, 2018, CMS released the updated "dashboards"; ironically, these tools do not include drug list prices, but rather other statistics, such as average spending per dosage unit, and will not necessarily bear a relationship with cost-sharing amounts determined by insurers.

- ***Maximum Medicaid rebate amount.*** HHS may "[d]evelop proposals related to the Affordable Care Act's Maximum Rebate Amount provision, which limits manufacturer rebates on brand and generic drugs in the Medicaid program to 100% of the

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[11] 42 U.S.C. § 1395w-104(b)(3)(G).

[12] 79 Fed. Reg. 29844, 29865 (May 23, 2014).

[13] Azar Remarks, *supra* note 4.

[14] *See* CMS Press Release, "CMS Unveils Enhanced "Drug Dashboards" to Increase Transparency on Drug Prices," available at https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2018-Press-releases-items/2018-05-15.html(accessed May 15, 2018).

Average Manufacturer Price." Note that the elimination of the maximum rebate cap may cause some manufacturers to pay rebates to state Medicaid programs in excess of the cost of their drugs.

- ***Pharmacist "gag clauses."*** HHS may "[p]rohibit 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 'gag clauses'." CMS subsequently sent a memorandum, dated May 17, 2018, to all Part D plan sponsors stating that "CMS finds any form of 'gag clauses' unacceptable and contrary to our efforts to promote drug pricing transparency and lower drug prices."[15] It is not clear that this memorandum is legally binding upon Part D plan sponsors or their PBMs, or more generally whether CMS currently has authority to prohibit such clauses, particularly in light of the statutory Part D "non-interference clause," which prohibits HHS from interfering in negotiations between Part D plan sponsors and pharmacies.

- ***Part D explanation of benefits.*** HHS may "[r]equire 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."

Blueprint "further actions under review and opportunities for feedback"

The Blueprint states that "HHS is considering even bolder actions to bring down prices for patients and taxpayers." HHS is "interested in public comments about how the department can 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." Furthermore, HHS seeks comments on "the general structure and function of the pharmaceutical market, to inform these actions." The Blueprint then sets forth a veritable laundry list of questions regarding various issues and ideas on which it is requesting public input, with comments due by July 16, 2018.[16]

As an example of the extremely broad scope of the questions raised in the Blueprint and accompanying RFI, the following is the first paragraph of this portion of the Blueprint:

> ***"Underpricing or Cost-Shifting.*** Do HHS programs contain the correct incentives to obtain affordable prices on safe and effective drugs? Does the Best Price reporting requirement of the Medicaid Drug Rebate Program pose a barrier to price negotiation and certain value-based agreements in other markets, or otherwise shift costs to other markets? Are government programs causing underpricing of generic drugs, and thereby reducing long-term generic competition?"

While it is not within the scope of this alert to catalogue every question in the Blueprint, the following encompasses all of the topics raised and the most significant questions:

- ***Access to reference product samples for development of generics and biosimilars.*** "Are there terms that could be included in REMS, or provided in addition to REMS, that could expand access to products necessary for generic development? Are there other steps that could be taken to facilitate access to products that are under distribution limitations imposed by the manufacturer? …What actions should be considered to facilitate access to reference product samples by [biosimilar product developers]?"

- ***Best price exemptions for value-based arrangements.*** HHS set forth many detailed questions on potential Medicaid Best Price exemptions for pricing under value-based contracts (a/k/a outcomes-based rebates), reflecting the interest previously expressed by Secretary Azar in making changes along these lines:

  - "What benefits would accrue to Medicare and Medicaid beneficiaries by allowing manufacturers to exclude from statutory price reporting programs discounts, rebates, or price guarantees included in value-based arrangements?"

  - "How would excluding these approaches from Average Manufacturer Price (AMP) and Best Price (BP) calculations impact the Medicaid Drug Rebate program and supplemental rebate revenue?" "How would these exclusions affect Average Sales Price (ASP) and 340B Ceiling Prices?"

  - "What benefits would accrue to Medicare and Medicaid beneficiaries by extending the time for manufacturers to report restatements of AMP and/or BP reporting, as outlined in 42 CFR §447.510, to accommodate adjustments

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[15] The CMS memo is available at https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/Other-Content-Types/2018-05-17.pdf (accessed May 18, 2018).
[16] 83 Fed. Reg. 22692 (May 16, 2018).

because of possible extended [Value-based Purchasing (VBP)] evaluation timeframes? Is there a timeframe CMS should consider that will allow manufacturers to restate AMP and BP without negative impact on state rebate revenue?"

- "What modifications could be made to the following regulatory definitions in the current Medicaid Drug Rebate Program that could facilitate the development of VBP arrangements: 1) bundled sale; 2) free good; 3) unit; or 4) best price? Would providing specific AMP/BP exclusions for Value-based Purchasing (VBP) pricing used for orphan drugs help manufacturers that cannot adopt a bundled sale approach?"
- "What regulatory changes would Medicaid Managed Care organizations find helpful in negotiating VBP supplemental rebates with manufacturers? How would these changes affect Medicare or the 340B program?"
- "Are there particular sections of the Social Security Act (e.g., the anti-kickback statute), or other statutes and regulations that can be revised to assist with manufacturers' and states' adoption of value-based arrangements?"

- ***Indication-based pricing.*** "Should Medicare or Medicaid pay the same price for a drug regardless of the indication for which it is used? How could indication-based pricing support value-based purchasing? … Are there unintended consequences of current low-cost drugs increasing in price due to their identification as high-value? How and by whom should value be determined? Is there enough granularity in coding and reimbursement systems to support indication-based pricing? Are changes necessary to CMS's price reporting program definitions or how the FDA's National Drug Code numbers are used in CMS price reporting programs? Do physicians, pharmacists and insurers have access to all the information they need to support indication-based payments?"

- ***Long-term financing models.*** "Long-term financing models are being proposed to help states, insurers, and consumers pay for high-cost treatments by spreading payments over multiple years. Should the state, insurer, drug manufacturer, or other entity bear the risk of receiving future payments? How should Medicare or Medicaid account for the cost of disease averted by a curative therapy paid for by another payer? What regulations should CMS consider revising to allow manufacturers and states more flexibility to participate in novel value-based pricing arrangements? What effects would these solutions have on manufacturer development decisions? What current barriers limit the applicability of these arrangements in the private sector? What assurances would parties need to participate in more of these arrangements, particularly with regard to public programs?"

- ***Part B CAP.*** "What changes would 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.*** "Which drugs or classes of drugs would be good candidates for moving from Part B to Part D? How could this proposal be implemented to help reduce out-of-pocket costs for the 27% of beneficiaries who do not have Medicare prescription drug coverage, or those who have Medicare supplemental benefits in Part B? What additional information could inform how this proposal could be implemented and operated?""…[S]hould Part B drugs sold by manufacturers offering lower prices to OECD nations be subject to negotiation by Part D plans? Would this lead to lower out-of-pocket costs on behalf of people with Medicare? How could this affect access to medicines for people with Medicare?"

- ***Fixing global freeloading.*** "What can be done to reduce the pricing disparity and spread the burden for incentivizing new drug development more equally between the U.S. and other developed countries? What policies should the U.S. government pursue in order to protect IP rights and address concerns around compulsory licensing in this area?"

- ***Site neutrality for physician-administered drugs.*** "What effect would a site neutral payment policy for drug administration procedures have on the location and practice of medicine? How would this change affect the organization of health care systems? How would this change affect competition for health care services, particularly for cancer care?"

- ***Site neutrality between inpatient and outpatient setting.*** "Do the differences between Medicare's Part A and Part B drug payment policies create affordability and access challenges for beneficiaries? What policies should CMS consider to ensure inpatient and outpatient providers are neither underpaid nor overpaid for a drug, regardless of where it was administered?"

- ***Fiduciary duty for pharmacy benefit managers.*** The Blueprint also raises numerous questions addressing potential transparency and other impacts of price concessions to distribution and payment system "middlemen" such as pharmacy benefits managers:

- "Do PBM rebates and fees based on the percentage of the list price create an incentive to favor higher list prices (and the potential for higher rebates) rather than lower prices? Do higher rebates encourage benefits consultants who represent payers to focus on high rebates instead of low costs? Do payers manage formularies favoring benefit designs that yield higher rebates rather than lower net drug costs? How are beneficiaries negatively impacted by incentives across the benefits landscape (manufacturer, wholesaler, retailer, PBM, consultants and insurers) that favor higher list prices? How can these incentives be reset to prioritize lower out of pocket costs for consumers, better adherence and improved outcomes for patients?"

- "Should PBMs be obligated to act solely in the interest of the entity for whom they are managing pharmaceutical benefits? Should PBMs be forbidden from receiving any payment or remuneration from manufacturers, and should PBM contracts be forbidden from including rebates or fees calculated as a percentage of list prices? What effect would imposing this fiduciary duty on PBMs on behalf of the ultimate payer (i.e., consumers) have on PBMs' ability to negotiate drug prices? How could this affect manufacturer pricing behavior, insurance, and benefit design? What unintended consequences for beneficiary out-of-pocket spending and federal health program spending could result from these changes?"

- ***Reducing the impact of rebates***

  - "What should CMS consider doing to restrict or reduce the use of rebates? Should Medicare Part D prohibit the use of rebates in contracts between Part D plan sponsors and drug manufacturers, and require these contracts to be based only on a fixed price for a drug over the contract term?"

    - Regarding this last idea, it is not clear how fixed-price contracts would be implemented without rebates, since the negotiated price would implicitly involve a discount on the list price paid by the pharmacy. Notably, it is possible to calculate a rebate as the difference between the list price and an agreed fixed net price.

    - It is also highly questionable whether CMS could prohibit or restrict the use of rebates under existing law, given the statutory "non-interference clause" that prohibits government interference in negotiations between Part D plan sponsors and manufacturers.

  - "What incentives or regulatory changes (e.g., **removing the discount safe harbor**) could restrict the use of rebates and reduce the effect of rebates on list prices? How would this affect the behavior of drug manufacturers, PBMs, and insurers? How could it change formulary design, premium rates, or the overall structure of the Part D benefit?"

- ***Incentives to lower or not increase list prices***

  - "Should manufacturers of drugs who have increased their prices over a particular look-back period or have not provided a discount be allowed to be included in the protected classes? Should drugs for which a price increase has not been observed over a particular look-back period be treated differently when determining the exceptions criteria for protected class drugs? What should CMS consider doing, under current authorities, to create incentives for Part D drug manufacturers committing to a price over a particular lookback period?"

  - "Should [HCPCS Codes] be available immediately at launch for manufacturers committing to a price over a particular lookback period? What should CMS consider doing, under current authorities, to create incentives for Part B drugs committing to a price over a particular lookback period? How long should the lookback period be?"

- ***Limits on Medicaid rebates due to price increases exceeding inflation.*** "When is the [limitation on Medicaid rebates to 100% of AMP] a valid constraint upon the rebates manufacturers should pay? What impacts would removing the cap on the inflationary rebate have on list prices, price increases over time, and public and private payers?"

- ***Exclusion of certain amounts from determination of AMP and best price.*** "What impact would [eliminating the exclusion of PBM rebates from determination of AMP and Best Price] have on list prices, prices increases over time, and public and private payers?"[17]

- ***Copay discount cards***

[17] Is not clear that manufacturers consistently exclude PBM rebates from BP consideration.

- "Does the use of manufacturer copay cards help lower consumer cost or actually drive increases in manufacturer list price?
- Does the use of copay cards incent manufacturers and PBMs to work together in driving up list prices by limiting the transparency of the true cost of the drug to the beneficiary? What data would support or refute the premise described above?"
- "What effect would eliminating [the exclusion of payments under manufacturer-sponsored drug card from AMP and Best Price] have on drug prices?"
- "Would there be circumstances under which allowing beneficiaries of federal health care programs to utilize copay discount cards would advance public health benefits such as medication adherence, and outweigh the effects on list price and concerns about program integrity? What data would support or refute this?"

- ***340B***
  - "How has the growth of the 340B drug discount program affected list prices? Has it caused cross-subsidization by increasing list prices applicable in the commercial sector? What impact has this had on insurers and payers, including Part D plans? Does the Group Purchasing Organization (GPO) exclusion, the establishment of the Prime Vendor Program, and the current inventory models for tracking 340B drugs increase or decrease prices? What are the unintended consequences of this program? Would explicit general regulatory authority over all elements of the 340B Program materially affect the elements of the program affecting drug pricing?"
  - "Would changing the definition of 'patient' or changing the requirements governing covered entities contracting with pharmacies or registering off-site outpatient facilities (i.e., child sites) help refocus the program towards its intended purpose?"
  - "Are the current mechanisms for identifying and preventing duplicate discounts effective? Are drug companies paying additional rebates over the statutory 340B discounts for drugs that have been dispensed to 340B patients covered by commercial insurance? What is the impact on drug pricing given that private insurers oftentimes pay commercial rates for drugs purchased at 340B discounts? Do insurers, pharmacy, PBM, or manufacturer contracts consider, address, or otherwise include language regarding drugs purchased at 340B discounts? What should be considered to improve the management and the integrity of claims for drugs provided to 340B patients in the overall insured market? What additional oversight or claims standards are necessary to prevent duplicate discounts in Medicaid and other programs?"

- ***Part D end-of-year statement on drug price changes and rebates collected.*** "What additional information could be added [to Part D Explanations of Benefits] about the rate of change in [drug] prices over the course of the benefit year? Alternatively, could pharmacists be empowered to inform beneficiaries when prices for their drugs have changed? … Could CMS improve transparency for Medicare beneficiaries without violating the Part D program's confidentiality protections?"
  - Notably, the portion of the Blueprint's title to this section (quoted above) relative to "rebates collected," together with the question regarding confidentiality, suggests that the "additional information" CMS may want to provide to beneficiaries may include rebate information.

- ***Federal preemption of contracted pharmacy "gag clause" laws; informing beneficiaries about cost-sharing and lower-cost options***
  - "What purpose do these clauses serve other than to require beneficiaries pay higher out-of-pocket costs? What other communication barriers are in place between pharmacists and patients that could be impeding lower drug prices, out-of-pocket costs, and spending? Should pharmacists be required to ask patients in Federal programs if they'd like information about lower-cost alternatives? What other strategies might be most effective in providing price information to consumers at the point of sale?"
  - "How could [new tools for informing prescribers and pharmacists about formulary options, cost-sharing and lower-cost options] reduce out-of-pocket spending for people with Medicare? … Should Medicare require the use of systems that support providing this information to patients? … Does this create unreasonable burdens for prescribers or pharmacists?"

- ***Additional feedback.*** "We are interested in all suggestions to improve the affordability and accessibility of prescription drugs, including reflections and answers to questions not specifically asked above. …What other regulations or government policies may be increasing list prices, net prices, and out-of-pocket drug spending? … To what extent do the planned actions described in this document impose burden, and do these burdens outweigh the benefits?"

Conclusion

The RFI released by CMS states that "[a]n unprecedented re-examination of the whole system and opportunities for reform is long overdue."[18] The Blueprint reflects the Administration's interest in considering a wide range of potentially-significant changes to core distribution, regulatory programs, and pricing standards in the United States, and a desire to move forward on changes along the lines proposed in the President's FY 2019 Budget.

Reed Smith will continue to closely monitor developments with respect to the Blueprint, including any regulatory or legislative initiatives to implement the proposed framework.

Contact

If you have questions or would like additional information on the material covered in this document, please contact one of the authors – listed below – or the Reed Smith lawyer with whom you regularly work.

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[18] 83 Fed. Reg. at 22692 (May 16, 2018).

Reed Smith is a dynamic international law firm, dedicated to helping clients move their businesses forward.

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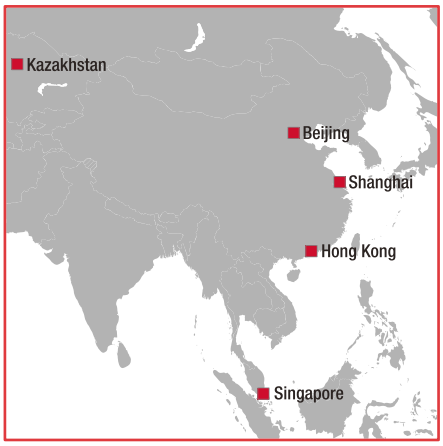

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