American Patients First

Policy Overview of Trump Administration's Drug Cost Policy Plan

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Agenda

- **Executive Summary**
- Details of American Patients First

Executive Summary

The Trump Administration's American Patients First plan is designed to lower drug prices for consumers but was poorly received as weak handed

1. On Friday, May 11th, 2018, President Trump released his American Patients First plan, detailing **>50 regulatory and legislative measures** to reduce drug costs for American consumers

2. The proposals are organized in **four categories**: increasing competition, bettering negotiations, lowering list prices, and lowering out of pocket costs

3. The document received **poor reception** by the public, largely due to the Administration's choice to exclude two major populist proposals: letting Medicare negotiate directly for lower drug prices and promoting the import of low cost medicines

Source: The New York Times; American Patients First; Drug Channels; EY-Parthenon Analysis

Executive Summary

The proposal contains 4 main solution themes along various levels of development – from "accomplishments" to requests for public comment

American Patients First, Plan Outline
2018

Solution Theme
Administration categorization of initiatives

Description
General goal of initiatives

Mechanisms of Action
Summary of policy approaches to bring about change

	Solution Theme	Description
1	Increasing Competition	Increasing generic / biosimilar market share
2	Bettering Negotiations	Improving Medicare Part D
3	Lowering List Prices	Ensuring discounts and rebates are passed along to the intended patients
4	Lowering Out-of-Pocket Costs	Helping patients understand drug prices, rebates, and treatment alternatives

Claimed "Accomplishments"
Current and pending administration achievements, especially FY2019 Budget Proposals

HHS Directives
The Department of Health and Human Services can take these actions "to the extent permissible by law"

Policies and Issues Open for Public Comment
The Department of Health and Human Services are requesting public comments on these broad issue and policy concepts

Source: American Patients First; EY-Parthenon Analysis

A Long Summer of Blueprint Implementation

NEGOTIATION

1. CMS included a Request for Information on the **Competitive Acquisition Program** in the CY 2019 HOPPS Proposed Rule (July 25th)
2. CMS provided Medicare Advantage plans the option to apply **step therapy** for physician-administered drugs (August 7th)
3. CMS approved Oklahoma's Medicaid State Plan Amendment to permit negotiating **supplemental rebate agreements** involving value-based contracts (June 27th)
4. Administration negotiates a new trade deal with Mexico that provides **10 years of data protection** for biologic drugs (August 28th)
5. CMS provided Part D sponsors the flexibility to create **indication-based formulary** designs for CY 2020 (August 29th)

LOWERING OUT OF POCKET COSTS

1. CMS proposed **reducing the Part B drug launch price** to WAC+3%
2. in the CY 2019 Physician Fee Schedule Proposed Rule (July 12th)
3. CMS proposed **340B reforms** for biosimilars without pass-through status and off-campus provider-based departments in the CY 2019 HOPPS Proposed Rule (July 25th)
4. HHS provided technical support to Rep. Burgess who introduced a bill to remove the cap on the **Medicaid Drug Rebate** Program's inflation penalty (July 31st)

COMPETITION

1. FDA released draft guidance to create a **new approval pathway** for "nonprescription drug products" (July 17th)
2. FDA released the **Biosimilars Action Plan** to promote biosimilar innovation, efficiency, and competition (July 18th)
3. FDA approved 126 generic drugs, the **most generic approvals ever** in a month (July 31st)
4. FDA approved the first generic version of EpiPen, which is the first approval under an **expedited review pathway** of generics for brand drugs without competition (August 16th)

INCENTIVES FOR LOWER LIST PRICES

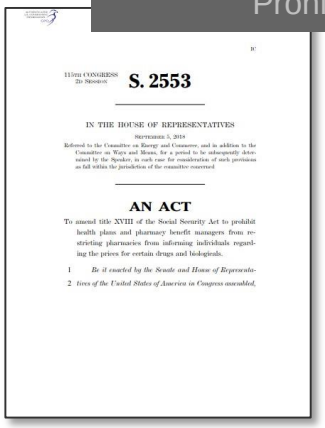
1. OIG has a **Rebate Safe Harbor reform** proposed rule in internal Administration clearance (July 18th)
2. Secretary Azar directed the FDA to form a working group on evaluating **drug importation** (July 19th)
3. CMS has a Drug Pricing Transparency proposed rule in internal Administration clearance, which is expected to address **direct to consumer (DTC) advertising** (August 21st)
4. OIG released a Request for Information on reforming the **Anti-Kickback Statute** to foster value-based care arrangements, including potential reforms impacting pharmaceutical adherence (August 24th)

Pharmacist Gag Clause Prohibitions Enacted Into Law

On October 10th, President Trump signed into law two bills to prohibit pharmacist gag clauses

Becoming the first initiatives from the Drug Pricing Blueprint to become law

Pharmacist Gag Clause Prohibitions



115TH CONGRESS 2D SESSION **S. 2553**

IN THE HOUSE OF REPRESENTATIVES

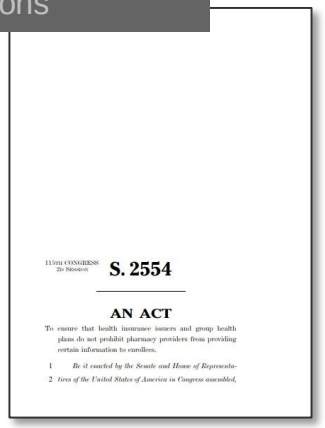
SEPTEMBER 5, 2018

Referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

AN ACT

To amend title XVIII of the Social Security Act to prohibit health plans and pharmacy benefit managers from restricting pharmacies from informing individuals regarding the prices for certain drugs and biologicals.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,



115TH CONGRESS 2D SESSION **S. 2554**

AN ACT

To ensure that health insurance issuers and group health plans do not prohibit pharmacy providers from providing certain information to enrollees.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

Public Law 115-162
Prohibits gag clauses in Medicare Advantage and Part D

Public Law 115-163
Prohibits gag clauses in commercial insurance plans

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Details of American Patients First

Policies to increase competition are broadly designed to increase generics and biosimilar share of US pharma spending

1 **Increasing Competition** | 2 Bettering Negotiations | 3 Lowering List Prices | 4 Lowering Out-of-Pocket Costs

Description	• Increasing generic / biosimilar market share
Mechanisms of Action	• Accelerating FDA approval of generics and biosimilar • Increasing price and science transparency across payers, clinicians, patients, and other stakeholders • Addressing anticompetitive practices like using REMS to limit generic distribution or withholding of reference samples
Claimed "Accomplishments"	• FDA approved >1000 generic drugs in 2017, more than in any previous year • FDA established a Drug Competition Action Plan to improve generic review process and close "loopholes" for branded drugs • FDA announced it will facilitate more information sharing across stakeholders • FY2019 budget proposes to end "indefinite"180 day exclusivity extensions for first to file generics • Finalizing a policy to identify each biosimilar with its own Medicare billing code increase price competition
HHS Directives	• Provide guidance regarding how manufactures uses REMS to delay or block generic competition • Support biosimilar development • Educate clinicians, patients, and payers about biosimilar and other interchangeable products

Policies and Issues Open for Public Comment	• Changing HHS pricing incentives – ex. Best Price reporting requirement of the Medicaid Drug Rebate Program
	• Affordable Care Act taxes and rebates
	• Access to reference product samples
	  ◦ Distribution restrictions, particularly related to REMS
	  ◦ Difficulty of obtaining samples for biosimilar and generic development
	• Biosimilar Development, approval, education, and access
	  ◦ Resources and tools for the FDA – which new tool and resources need to be developed?
	  ◦ Improving the Purple book
	  ◦ Educating providers and patients

Source: American Patients First; EY-Parthenon Analysis

Details of American Patients First

Improving negotiations mostly involves revisiting categorizations related to rebate programs, formularies and treatment guild lines within Medicare Part D

1 Increasing Competition | 2 **Bettering Negotiations** | 3 Lowering List Prices | 4 Lowering Out-of-Pocket Costs

Description	• Improving Medicare Part D
Mechanisms of Action	• Scrutiny of drug categorizations across rebate programs, formularies, and treatment guidelines • Demonstration projects • Capping prices increases
Claimed "Accomplishments"	• FY2019 Budget Proposes updating formulary standards to allow for better negotiating leverage with drug manufacturers (ex. Allowing for a min of 1 drug per category or class rather than 2) and leveraging Medicare Part D plans to negotiate lower prices for Part B drugs • FY2019 Budget proposes establishing an inflation limit for Medicare Part B Drugs and increasing pricing scrutiny • FY2019 Budget proposes more carefully redefining branded drugs so they can't be incorrectly categorized as "generics" • FY2019 Budget proposes a 5 state experiment of drug covering and financing reforms, especially related formularies • HHS has already increased scrutiny around the Medicaid Drug Rebate Program – including manual drug-by-drug reviews
HHS Directives	• CMS directed to develop value-based care demonstration projects • Allow Medicare Part D to update formulary / benefit design mid-year to address price changes • Provide plans "full flexibility" to negotiate • Update Drug Plan Consumer Service star rating methodology to improve utilization of high-cost drugs • Allow for high-cost drugs to be reimbursed at different levels based on the target indication • Send president a report of drugs in Part B that would benefit from moving to Part D • Bolster the Competitive Acquisition Program (CAP) for Part B drugs • Develop knowledge base about price disparities across borders
Policies and Issues Open for Public Comment	• Value-based arrangements and price reporting • Indication-based reimbursement schemes • Long-term financing models (spreading high cost payments over multiple years) • Part B Competitive Acquisition Program (CAP) • Moving drugs from Part B to Part D • Policies to fix global "freeloading" (proposed policies unspecified) • Site neutral payment policies for physician administered drugs and inpatient vs outpatient settings (Part A vs Part B) • Price data set review

Source: American Patients First; EY-Parthenon Analysis

Details of American Patients First

Policies to lower list prices are focused on increasing transparency, especially for discount and rebate programs for 340b patients and Medicare Part D

1 Increasing Competition | 2 Bettering Negotiations | 3 Lowering List Prices | 4 Lowering Out-of-Pocket Costs

Description	• Ensuring discounts and rebates are passed along to the intended patients
Mechanisms of Action	• Increasing discount and rebate transparency so discounts and rebates get passed on to patients • Re-examining eligibility and macro impact of 340b • Increasing price transparency through Medicare and Medicaid
Claimed "Accomplishments"	• FY2019 Budget proposes excluding manufacturer discount from calculation of beneficiary out of pocket costs in the Part D coverage gap • FY2019 Budget proposes reforming 340b program to ensure it benefits low income patients and others are not free riding
HHS Directives	• Evaluate inclusion of list prices in direct-to-consumer advertising • Create Medicare and Medicaid drug price dashboard tool so consumers can predict costs • Re-evaluate the ACA Maximum Rebate Amount (100% of average manufacturer price) provision

Policies and Issues Open for Public Comment	• Establishing fiduciary duty for PBMs
	• Restricting federal rebate programs that inflate drug prices for the public
	• Incentives to discourage large price increases
	  ◦ Protected classification
	  ◦ Healthcare Common Procedure Coding System – earlier assignment if manufacturers commit to certain price for period of time
	• Inflationary rebate limits
	• Exclusion of certain payments, rebates, or discounts from Average Manufacturer Price or Best Price calculation
	• Copay Discount Cards
	• 340 B Drug discount program
	  ◦ Program growth – has it effected list prices and cross-subsidized
	  ◦ Program eligibility – might currently be too broad
	  ◦ Duplicate Discounts – 340b + Medicaid drug rebate

Source: American Patients First; EY-Parthenon Analysis

Details of American Patients First

Much like policies to lower list prices, policies to lower out of pocket costs are generally directed at increasing patient knowledge around treatments and costs

	1 Increasing Competition	2 Bettering Negotiations	3 Lowering List Prices	4 Lowering Out-of-Pocket Costs
Description				• Helping patients understand drug prices, rebates, and treatment alternatives
Mechanisms of Action				• Increasing price and rebate transparency pre-pharmacy visit • Increasing rebates and subsidies at point of sale, especially for low income and 340b beneficiaries • Forcing payers and pharmacies to be more forthright about low cost alternatives for patients
Claimed "Accomplishments"				• Finalizing Medicare Outpatient Prospective Payment System (OPPS) to reduce 340b beneficiary out of pocket spending • Requesting information and comment on increasing price transparency for Medicare and rebates • Updating Part C and D regulation that allows low income patients to receive subsidies for biosimilar purchases • FY2019 Budget 5 proposes eliminating cost sharing on generic drugs for low income beneficiaries • FY2019 Budget 5 proposes requiring Part D plans to apply a substantial portion of rebates at the point of sale
HHS Directives				• Prohibit Part D plans from using gag clauses to prevent pharmacists from disclosing cheaper alternatives • Require Part D sponsors to provide more information about drug price increases and alternatives to members
Policies and Issues Open for Public Comment				• Part D end of year statement on drug price changes and rebates collected • Federal preemption of contracted pharmacy gag clauses • Increasing information to Medicare beneficiaries about cost sharing and lower cost alternatives

Source: American Patients First; EY-Parthenon Analysis


LIVE
10:25 am ET
C-SPAN3
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- While those testifying pushed back on the governments' plans to remove rebates from their toolbox as a way to get lower prices, there seemed to be more agreement on another criticism of the PBM industry, a concept known as spread pricing. With spread pricing, a PBM may pay out one amount to a pharmacy (say, $110), and turn around and charge the health plan it works with a higher amount (in this example $140) for its services.
- Among those represented at the hearing, Cigna and CVS said they both practice spread pricing, while Humana said it only did it for one type of plans, its self-funded businesses which account for about 200,000 members. UnitedHealth only offers the option for spread pricing to its commercial plans, while Prime was the only organization that did not practice spread pricing.
- When Democratic Senator Ron Wyden of Oregon asked if the companies would oppose legislative moves to ban spread pricing, Cigna, CVS, and Humana said they would support a ban. Prince said he was neutral, while Prime's Kolar said he wouldn't oppose such a move.

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