# The Drug Pricing Debate in the United States: Status Update

Presentation by Susan Dentzer

Senior Policy Fellow, Duke-Margolis Center for Health Policy

To the 20th Annual Pharmaceutical and Medical Device Compliance Congress

November 6, 2019

# This Presentation At a Glance

- Background: Where we were a year ago with the Trump Administration's drug "Blueprint"
- Where we are today
- Updates on the International Pricing Index, rebate rule, importation
- House and Senate bills ; Democratic presidential candidates' plans
- Prognosis?

# Administration's Drug Pricing Focus

- High and rising list prices for many drugs
- Overpayment in government programs due to lack of negotiation
- High out-of-pocket costs for consumers and patients
- "Foreign governments' free-riding off of American investment in innovation"

# American Patients First

## The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs

MAY 2018

# Key Blueprint Features And Follow-Through

- Bring down out-of-pocket (OOP) costs
    - E.g., cut in Medicare Part B reimbursement for drugs purchased under 340B program; estimated to save enrollees $320 million in OOP costs
- Boost competition
    - E.g., step up approvals of generics; records in FDA approvals set in FY 2017 and 2018; investigate potential to import sole-source drugs with big price spikes

# “International Pricing Index” (IPI) Model For Part B Drug Payment

- Part B drugs (many of them biologics) are administered by infusion or injection in physicians’ offices and hospital outpatient departments, as well as certain drugs furnished by pharmacies and suppliers (e.g., oral cancer drugs).
- Medicare Part B drug cost is 1.8 times higher when compared to an international average of countries
- Key objective: Set the Medicare payment amount for selected Part B drugs to be phased down to more closely align with international prices
- Advance Notice of Proposed Rulemaking (ANPRM) issued October 2018 set forth IPI model
- Would apply to most drugs covered under Part B with five-year phase-in

# Administration's Proposed International Pricing Index (Version 1.0)

- Under proposal, Part B drugs would be reimbursed based on their average cost in a basket of other countries*, plus a mark-up (i.e. 1.26 times the average basket price in the initial HHS case study)

- Would initially focus on Part B drugs that encompass a high percentage of utilization and spending

- Part B drugs (many of them biologics) administered by infusion or injection in physicians' offices and hospital outpatient departments, as well as certain drugs furnished by pharmacies and suppliers (e.g., oral cancer

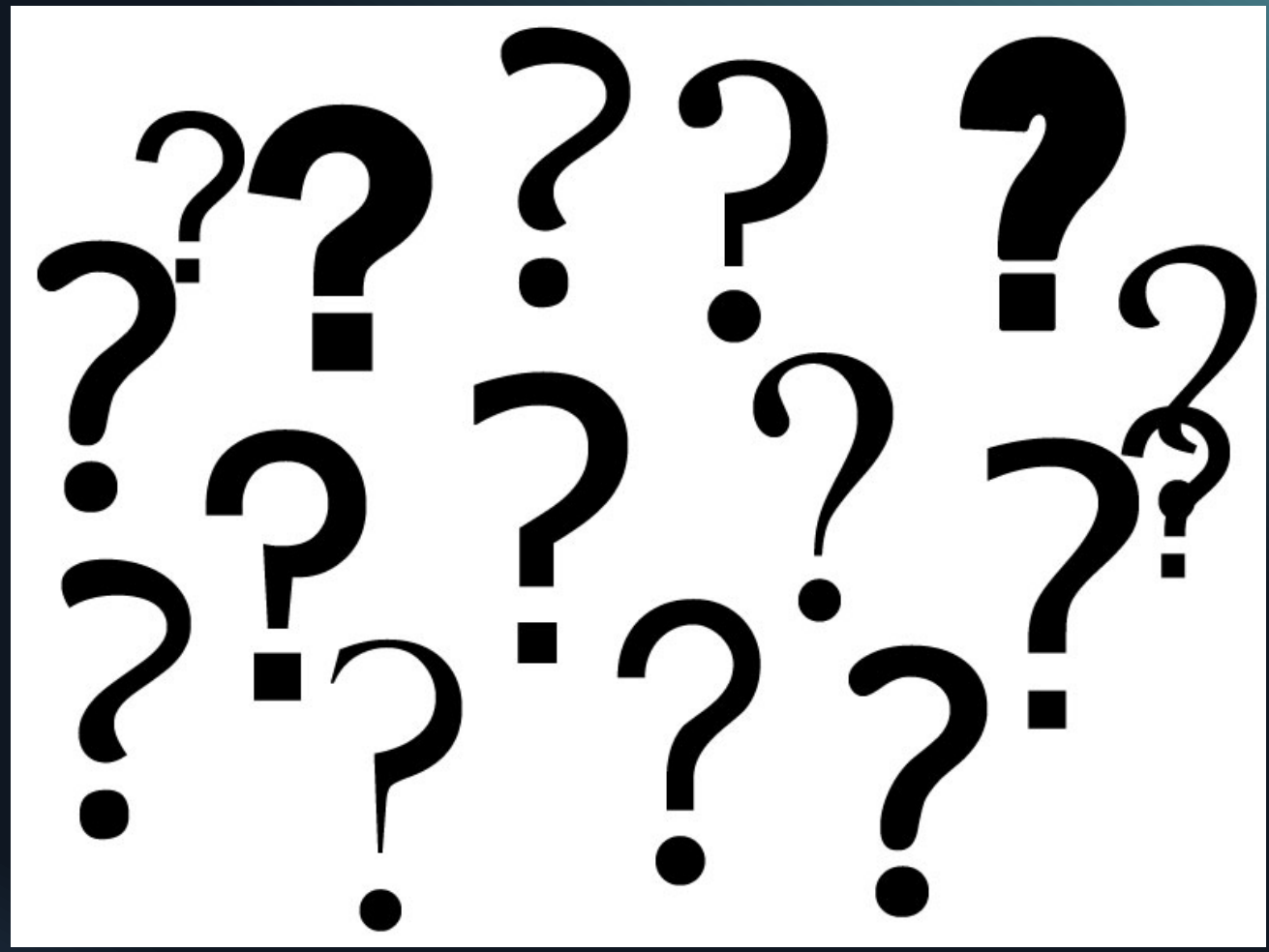
*Initial HHS analysis included Austria, Belgium, Canada, Czech Republic, Finland, France, Germany, Greece, Ireland, Italy, Japan, Portugal, Slovakia, Spain, Sweden, and United Kingdom

# Administration's Proposed International Pricing Index

- HHS to test model under section 1115A of Social Security Act – i.e., structured as experiment undertaken by CMS Innovation Center, with initial roll-out in ½ the country
- Does not require congressional approval.
- The model would operate for five years, from Spring 2020 to Spring 2025, starting in 50% of the Medicare Part B market
- HHS says model will only impact R&D by 1%
- "The pharmaceutical industry will be pressured to fairly allocate the burden of funding innovation across wealthy countries" (i.e. raise prices in Europe, Japan)

# Questions

In paying higher prices for biopharmaceuticals generally, is the U.S. subsidizing more global innovation, more global industry profitability, or both?

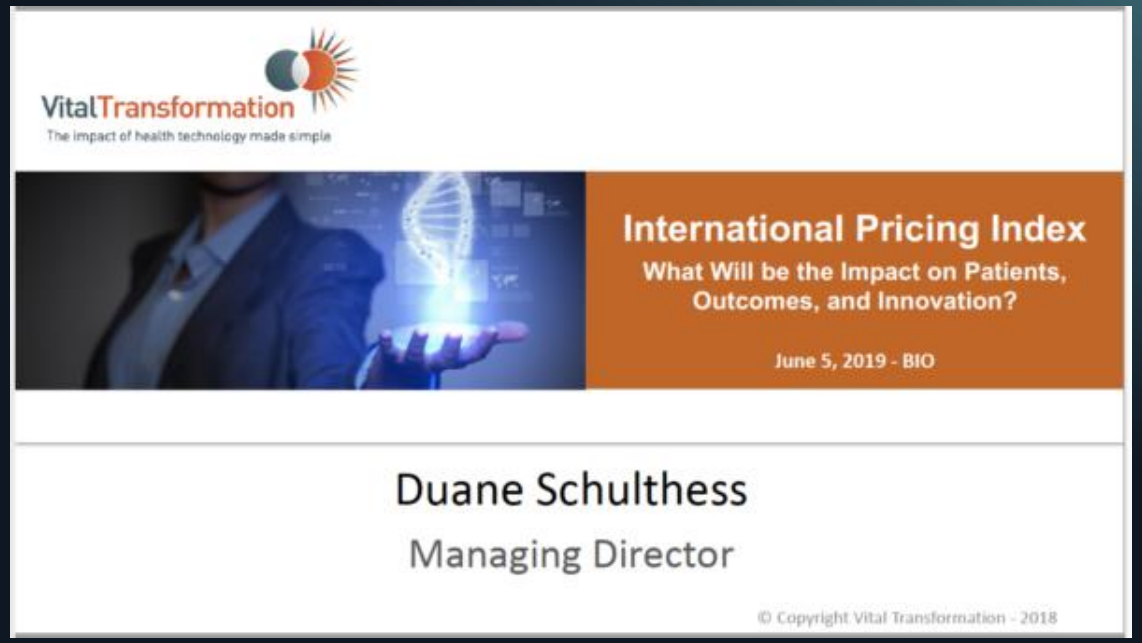



"The administration is imposing foreign price controls from countries with socialized health care systems that deny their citizens access and discourage innovation."

-Stephen Ubl, CEO, PhRMA, statement on 10/25/18

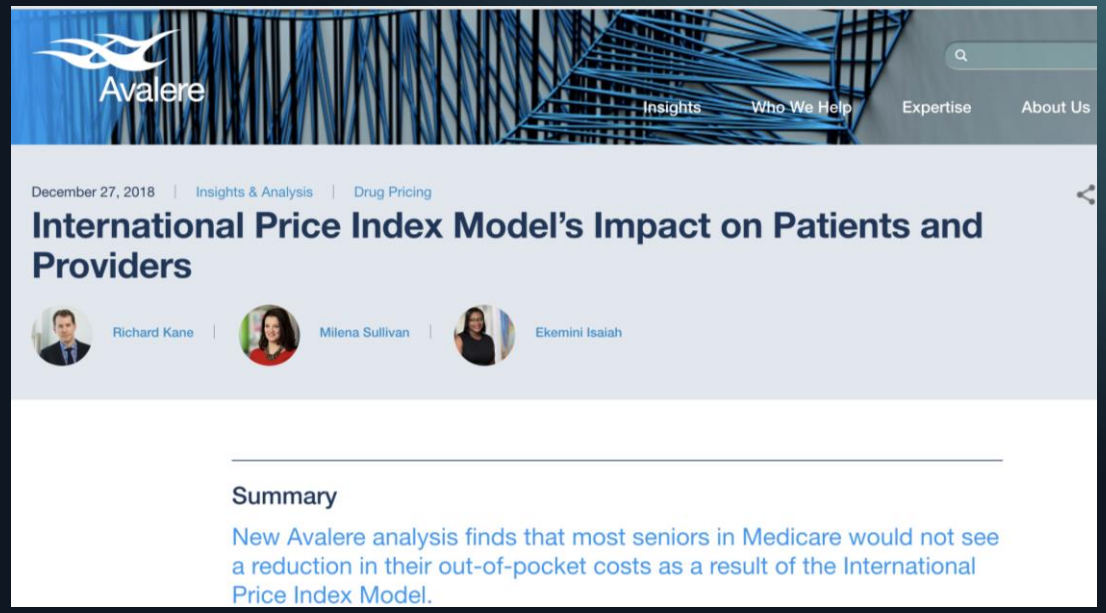
# Various Analyses Have Suggested Negative Impact on Innovation

- E.g., study by Vital Transformation funded by BIO, Gilead, Global Innovation Policy Center (U.S. Chamber), Pfizer
- IPI "will negatively reduce revenues of innovative companies at a rate higher than 1% of R&D"
- "Penalizes innovation, targets companies with the most advanced, newest products in the market for what are often the most challenging diseases"
- "Will skew R&D away from Medicare Part B physician administered drugs"
- "Assumes companies will be able to raise prices in Europe; this is highly unlikely"



# Questions: Would Medicare enrollees benefit?

- Avalere analysis: Medicare beneficiaries would not see a reduction in their out-of-pocket costs as a result of the International Price Index Model.
  - More than 87% of Part B beneficiaries have supplemental coverage (e.g., Medigap, employer sponsored, Medicare Advantage, Medicaid) that covers their cost sharing for Part B drugs.
  - Avalere estimates that less than 1% of Medicare beneficiaries would see reduced OOP costs (in a given year)



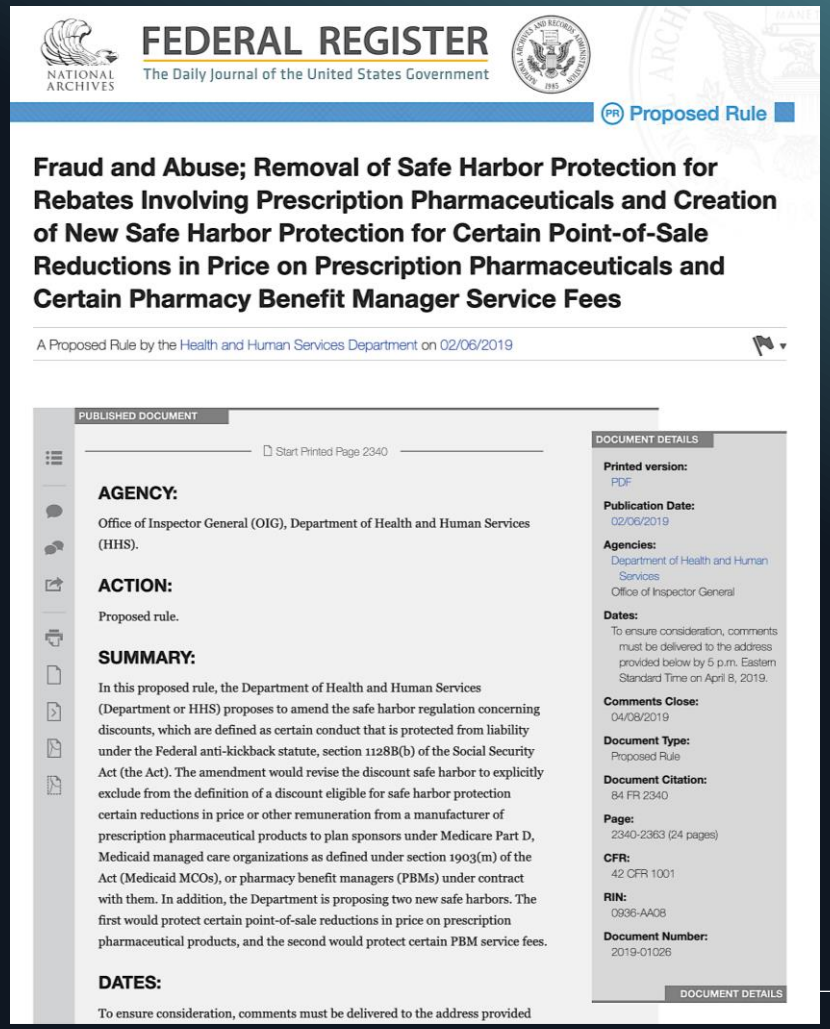
# Result: IPI Model now being “tweaked”

- Sent from HHS to OMB in June ’19

- Domestic Policy Council chief Joe Grogan: Administration taking its time to get the “policy right”

# HHS Proposed Rebate Rule

- Administration advanced proposed rule in February to remove "safe harbor" within Anti-Kickback Statute for rebates off list prices paid by manufacturers to health plans and PBMs.
- Change would effectively make it illegal for a drug manufacturer to pay rebates to PBMs or Part D plans in Medicare and managed care organizations (MCOs) participating in state Medicaid programs, in return for coverage or preferred treatment of the manufacturer's drug under the plan.
- Administration's goal: compress the "gross to net bubble" and eliminate incentives to raise list prices



NATIONAL ARCHIVES

FEDERAL REGISTER

The Daily Journal of the United States Government

Proposed Rule

**Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees**

A Proposed Rule by the Health and Human Services Department on 02/06/2019

PUBLISHED DOCUMENT

Start Printed Page 2340

**AGENCY:**

Office of Inspector General (OIG), Department of Health and Human Services (HHS).

**ACTION:**

Proposed rule.

**SUMMARY:**

In this proposed rule, the Department of Health and Human Services (Department or HHS) proposes to amend the safe harbor regulation concerning discounts, which are defined as certain conduct that is protected from liability under the Federal anti-kickback statute, section 1128B(b) of the Social Security Act (the Act). The amendment would revise the discount safe harbor to explicitly exclude from the definition of a discount eligible for safe harbor protection certain reductions in price or other remuneration from a manufacturer of prescription pharmaceutical products to plan sponsors under Medicare Part D, Medicaid managed care organizations as defined under section 1903(m) of the Act (Medicaid MCOs), or pharmacy benefit managers (PBMs) under contract with them. In addition, the Department is proposing two new safe harbors. The first would protect certain point-of-sale reductions in price on prescription pharmaceutical products, and the second would protect certain PBM service fees.

**DATES:**

To ensure consideration, comments must be delivered to the address provided

DOCUMENT DETAILS

**Printed version:** PDF

**Publication Date:** 02/06/2019

**Agencies:** Department of Health and Human Services; Office of Inspector General

**Dates:** To ensure consideration, comments must be delivered to the address provided below by 5 p.m. Eastern Standard Time on April 8, 2019.

**Comments Close:** 04/08/2019

**Document Type:** Proposed Rule

**Document Citation:** 84 FR 2340

**Page:** 2340-2363 (24 pages)

**CFR:** 42 CFR 1001

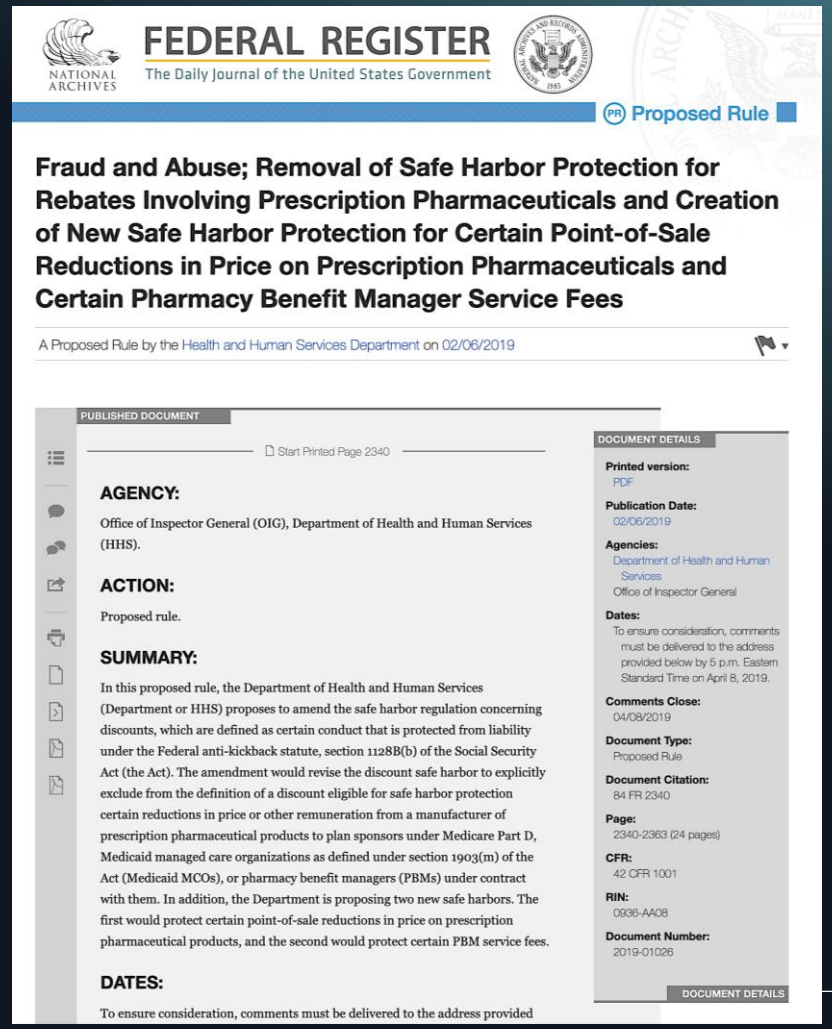
**RIN:** 0936-AA08

**Document Number:** 2019-01026

DOCUMENT DETAILS

# HHS Proposed Rebate Rule: New Safe Harbors

- Administration also proposed creation of two new safe harbors
  - One for rebates which are passed on to the patient at the point of sale – to lower costs for patients
  - Another for flat service fee payments made to PBMs in lieu of rebates – to enable PBMs to adapt to new business model



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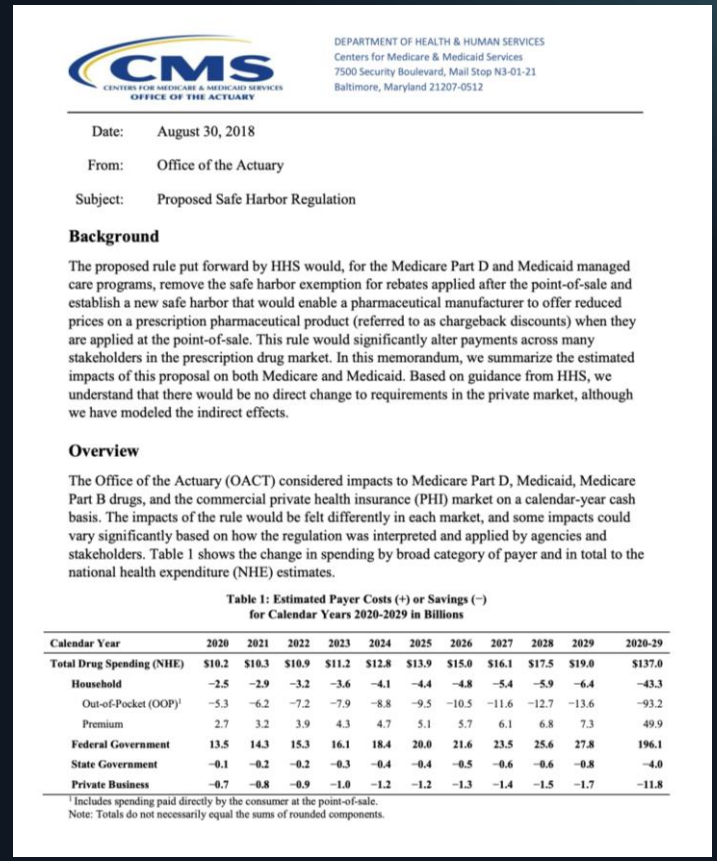
# Cost Estimates, Rebate Rule

- CMS's Office of the Actuary and the Congressional Budget Office estimated costs of proposed rule
- Found that manufacturers would respond by withholding some discounts currently provided via rebates, and renegotiate others with both Part D plans and in Medicaid
- Premiums for Part D plans would rise, which would also boost premium subsidies for low-income people
- Net effect: CMS OACT projected that federal spending for Medicare Part D would rise by about $196 billion on net over the 2020–2029 period; CBO estimated $170 billion
- Medicaid spending increases: CMS estimated net increase of $500 million from 2020-29; CBO estimated $1 billion



Congressional Budget Office
Washington, D.C.

**Incorporating the Effects of the Proposed Rule on Safe Harbors for Pharmaceutical Rebates in CBO's Budget Projections—Supplemental Material for *Updated Budget Projections: 2019 to 2029***



CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES
OFFICE OF THE ACTUARY

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop N3-01-21
Baltimore, Maryland 21207-0512

Date: August 30, 2018

From: Office of the Actuary

Subject: Proposed Safe Harbor Regulation

**Background**

The proposed rule put forward by HHS would, for the Medicare Part D and Medicaid managed care programs, remove the safe harbor exemption for rebates applied after the point-of-sale and establish a new safe harbor that would enable a pharmaceutical manufacturer to offer reduced prices on a prescription pharmaceutical product (referred to as chargeback discounts) when they are applied at the point-of-sale. This rule would significantly alter payments across many stakeholders in the prescription drug market. In this memorandum, we summarize the estimated impacts of this proposal on both Medicare and Medicaid. Based on guidance from HHS, we understand that there would be no direct change to requirements in the private market, although we have modeled the indirect effects.

**Overview**

The Office of the Actuary (OACT) considered impacts to Medicare Part D, Medicaid, Medicare Part B drugs, and the commercial private health insurance (PHI) market on a calendar-year cash basis. The impacts of the rule would be felt differently in each market, and some impacts could vary significantly based on how the regulation was interpreted and applied by agencies and stakeholders. Table 1 shows the change in spending by broad category of payer and in total to the national health expenditure (NHE) estimates.

**Table 1: Estimated Payer Costs (+) or Savings (−) for Calendar Years 2020-2029 in Billions**

| Calendar Year | 2020 | 2021 | 2022 | 2023 | 2024 | 2025 | 2026 | 2027 | 2028 | 2029 | 2020-29 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Total Drug Spending (NHE)** | **$10.2** | **$10.3** | **$10.9** | **$11.2** | **$12.8** | **$13.9** | **$15.0** | **$16.1** | **$17.5** | **$19.0** | **$137.0** |
| **Household** | **−2.5** | **−2.9** | **−3.2** | **−3.6** | **−4.1** | **−4.4** | **−4.8** | **−5.4** | **−5.9** | **−6.4** | **−43.3** |
| Out-of-Pocket (OOP)[1] | −5.3 | −6.2 | −7.2 | −7.9 | −8.8 | −9.5 | −10.5 | −11.6 | −12.7 | −13.6 | −93.2 |
| Premium | 2.7 | 3.2 | 3.9 | 4.3 | 4.7 | 5.1 | 5.7 | 6.1 | 6.8 | 7.3 | 49.9 |
| **Federal Government** | **13.5** | **14.3** | **15.3** | **16.1** | **18.4** | **20.0** | **21.6** | **23.5** | **25.6** | **27.8** | **196.1** |
| **State Government** | **−0.1** | **−0.2** | **−0.2** | **−0.3** | **−0.4** | **−0.4** | **−0.5** | **−0.6** | **−0.6** | **−0.8** | **−4.0** |
| **Private Business** | **−0.7** | **−0.8** | **−0.9** | **−1.0** | **−1.2** | **−1.2** | **−1.3** | **−1.4** | **−1.5** | **−1.7** | **−11.8** |

[1] Includes spending paid directly by the consumer at the point-of-sale.
Note: Totals do not necessarily equal the sums of rounded components.

# Rebate Rule Scuttled

- "Grogan argued that the rule would raise Medicare premiums right before the 2020 election…Azar was the only one advocating for it.
- "Trump himself made the decision to withdraw the plan, according to administration officials."



The Washington Post
Democracy Dies in Darkness

Health

## Trump kills key drug price proposal he once embraced

Health and Human Services Secretary Alex Azar and President Trump. (Alex Brandon/AP)

By **Yasmeen Abutaleb**, **Amy Goldstein** and **Ashley Parker**

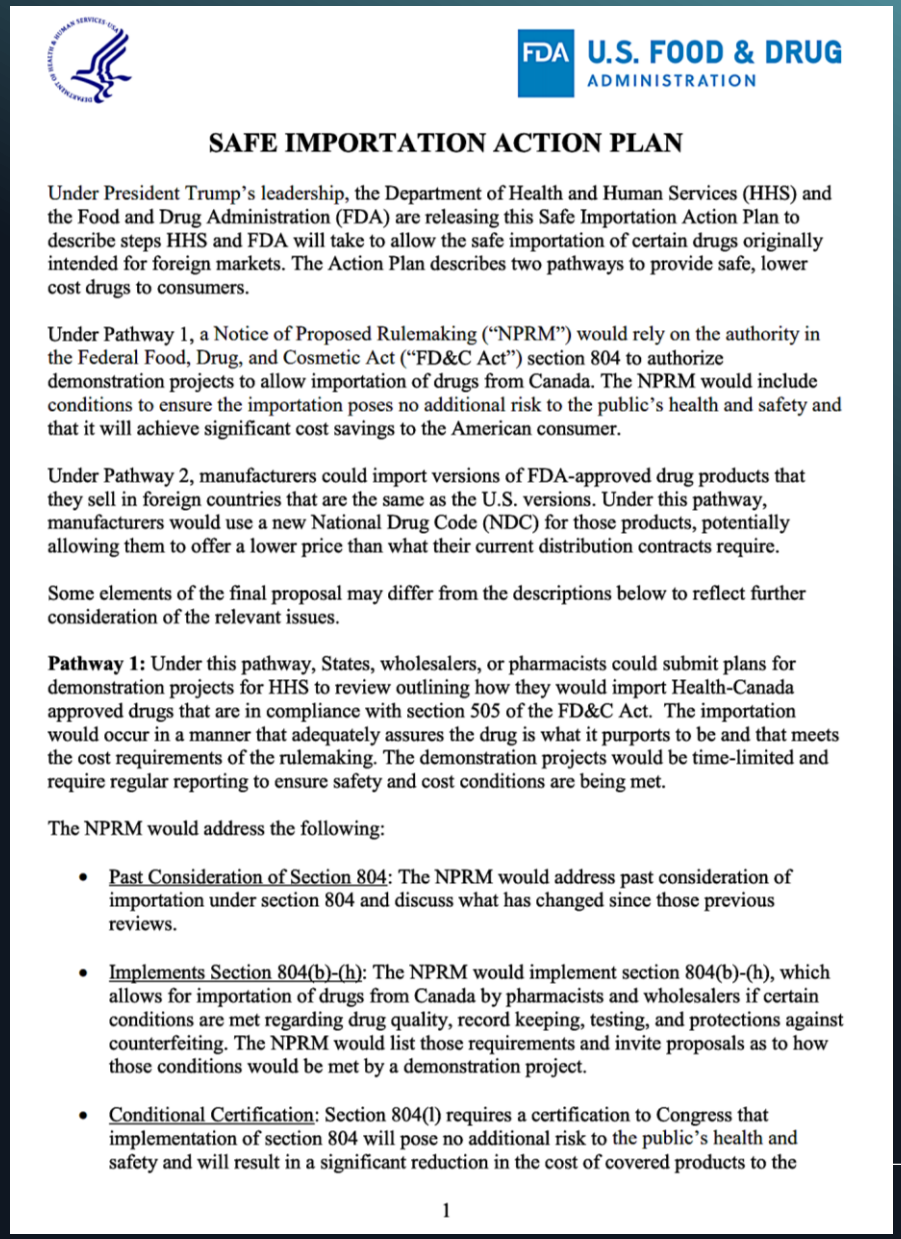
July 11, 2019 at 10:12 a.m. EDT

The Trump administration has withdrawn a key proposal to lower drug prices, which its top health official had touted seven months ago as the most effective way to curb medicine costs for consumers.

The drug rebate rule would have ended a widespread practice in which drugmakers give rebates to insurance middlemen in government programs such as Medicare. The idea was to channel that money to consumers instead.

# Drug Importation

- Longstanding debate over safety, feasibility, and impact of various importation proposals
- Trump embraces concept over initial opposition of Azar and others
- Azar bends; in July, unveils 2 approaches to be set forth in proposed rules under "Safe Importation Action Plan"
  - ➢ HHS and the Food and Drug Administration to authorize pilot programs by states, wholesalers or pharmacists to import Canadian versions of certain FDA-approved drugs.
  - ➢ Also to authorize manufacturers to negotiate new distribution contracts to sell lower-priced foreign versions of large group of drugs, such as insulin and arthritis medication, in United States



U.S. FOOD & DRUG ADMINISTRATION

**SAFE IMPORTATION ACTION PLAN**

Under President Trump's leadership, the Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA) are releasing this Safe Importation Action Plan to describe steps HHS and FDA will take to allow the safe importation of certain drugs originally intended for foreign markets. The Action Plan describes two pathways to provide safe, lower cost drugs to consumers.

Under Pathway 1, a Notice of Proposed Rulemaking ("NPRM") would rely on the authority in the Federal Food, Drug, and Cosmetic Act ("FD&C Act") section 804 to authorize demonstration projects to allow importation of drugs from Canada. The NPRM would include conditions to ensure the importation poses no additional risk to the public's health and safety and that it will achieve significant cost savings to the American consumer.

Under Pathway 2, manufacturers could import versions of FDA-approved drug products that they sell in foreign countries that are the same as the U.S. versions. Under this pathway, manufacturers would use a new National Drug Code (NDC) for those products, potentially allowing them to offer a lower price than what their current distribution contracts require.

Some elements of the final proposal may differ from the descriptions below to reflect further consideration of the relevant issues.

**Pathway 1:** Under this pathway, States, wholesalers, or pharmacists could submit plans for demonstration projects for HHS to review outlining how they would import Health-Canada approved drugs that are in compliance with section 505 of the FD&C Act. The importation would occur in a manner that adequately assures the drug is what it purports to be and that meets the cost requirements of the rulemaking. The demonstration projects would be time-limited and require regular reporting to ensure safety and cost conditions are being met.

The NPRM would address the following:

- Past Consideration of Section 804: The NPRM would address past consideration of importation under section 804 and discuss what has changed since those previous reviews.
- Implements Section 804(b)-(h): The NPRM would implement section 804(b)-(h), which allows for importation of drugs from Canada by pharmacists and wholesalers if certain conditions are met regarding drug quality, record keeping, testing, and protections against counterfeiting. The NPRM would list those requirements and invite proposals as to how those conditions would be met by a demonstration project.
- Conditional Certification: Section 804(l) requires a certification to Congress that implementation of section 804 will pose no additional risk to the public's health and safety and will result in a significant reduction in the cost of covered products to the

1

# Midgame Score on "Blueprint" Goals

- High and rising list prices for many drugs
  - ✓ No evidence as yet of meaningful shift in dynamics
- Overpayment in government programs due to lack of negotiation
  - ✓ No change as yet
- High out-of-pocket costs for consumers and patients
  - ✓ Rebate rule, now scuttled, would have done otherwise; more generic approvals have probably helped somewhat
- "Foreign governments' free-riding off of American investment in innovation"
  - ✓ IPI on hold though reportedly still to be issued

# ICER's New "Unsupported Price Increase" Report

| Drug | Q42016 to Q42018 Percentage Change | | Increase in Spending Impact Due to Net Price Change (in Millions) |
|---|---|---|---|
| | WAC ** | Net Price | |
| **Drugs with Price Increases Unsupported by New Clinical Evidence** | | | |
| Humira® (Adalimumab) | 19.1% | 15.9% | $1,857 |
| Rituxan® (Rituximab) | 17% | 23.6% | $806 |
| Lyrica® (Pregabalin) | 28.3% | 22.2% | $688 |
| Truvada® (TDF/FTC) | 14.3% | 23.1% | $550 |
| Neulasta® (Pegfilgrastim) | 14.6% | 13.4% | $489 |
| Cialis® (Tadalafil) | 26.2% | 32.5% | $403 |
| Tecfidera® (Dimethyl Fumarate) | 16.7% | 9.8% | $313 |
| **Drugs with Price Increases with New Clinical Evidence*** | | | |
| Genvoya® (EVG/COBI/FTC/TAF) | 14.3% | 21.7% | $651 |
| Revlimid® (Lenalidomide) | 25.8% | -- | -- |

*This is **not** a determination that the new evidence necessarily justified these price increases.

**WAC = Wholesale acquisition cost, an estimate of the manufacturer's list price for a drug to wholesalers or direct purchasers; does not include discounts or rebates.

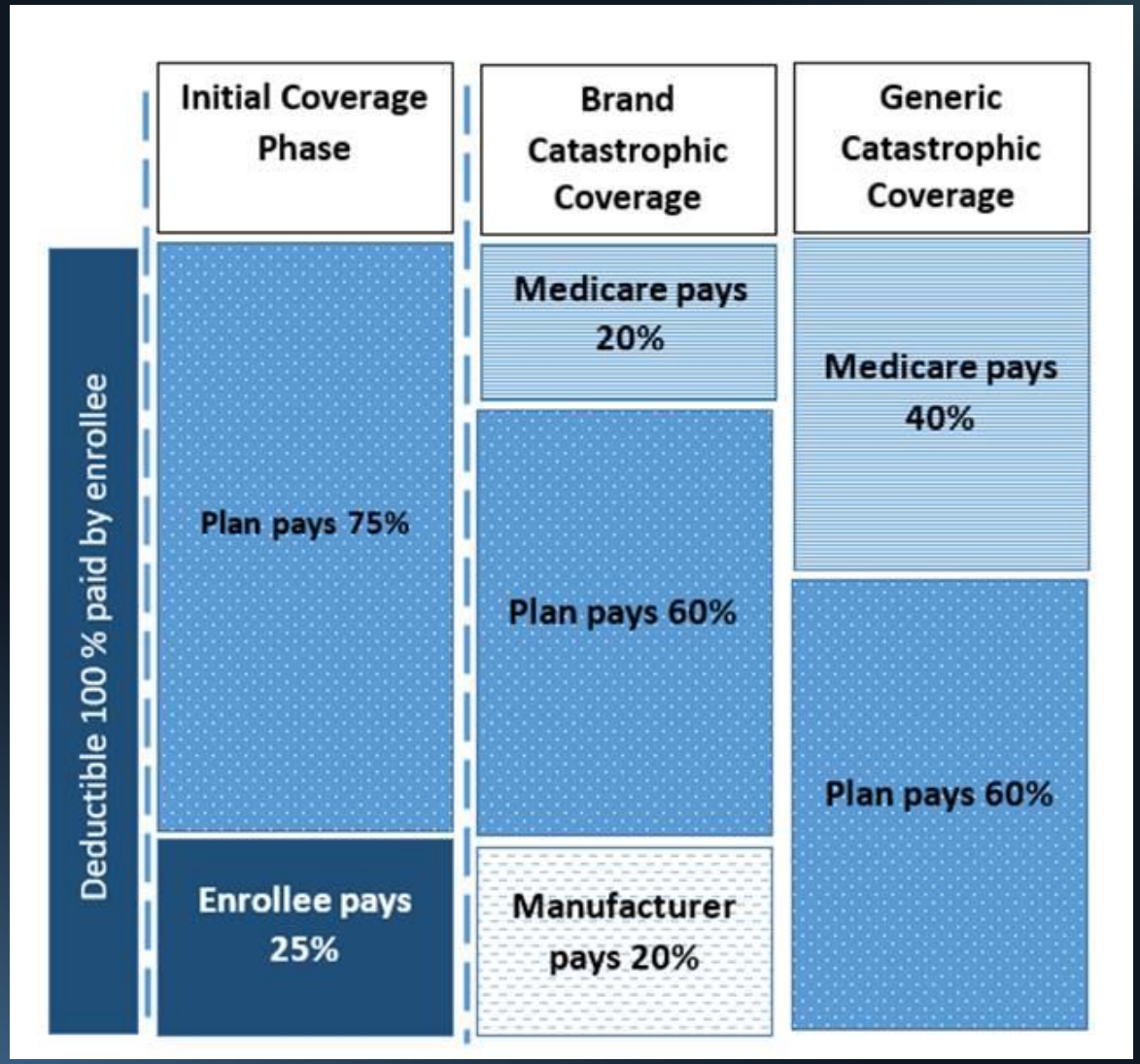
# Proposals in Congress

# In Senate

- Senate Finance Committee Bill (S. 2543), the Prescription Drug Pricing Act of 2019 (PDPRA)
- Key Component: Reforms to Medicare Part D

  - Create new annual out-of-pocket (OOP) spending cap to replace unlimited 5 percent cost-sharing in "catastrophic" level
  - Effective January 2022, OOP limit of $3,100
  - In catastrophic component, shift risk from government (which today pays 80 percent) to plan sponsors and manufacturers (who would pay 80 percent; transition 2022-24)
  - End of industry payments through Coverage Gap Discount Program (50% on branded drugs in "donut hole" today; with no more donut hole, no more payments here)
  - New industry payments to support low-income subsidy; amounts vary by manufacturer and drug

# Senate bill benefit redesign




Source: Ian Spatz, Manatt

# In Senate

- Senate Finance Committee Bill (S. 2543), the Prescription Drug Pricing Act of 2019 (PDPRA)

- Drug Price Inflation Penalties for Medicare Part B and Part D drugs effective 2021

  - Effective 2021, if price increases for Part B above the rate of inflation (CPI-U) since 2019 (or later for newer drugs), trigger rebate
  - Includes brand drugs and biologicals, excludes vaccines and biosimilars
  - Price measured by Part B reimbursement (ASP + 6)
  - Rebates based on number of billing units under Parts B

  - For Part D drugs:
  - Effective 2022, if price increases above the rate of inflation (CPI-U) since 2019 (or later for newer drugs), trigger rebate

  - Includes brand drugs and biologicals, excludes generics and biosimilars
  - Price measured by Wholesale Acquisition Cost (WAC) - *not what any Part D plan pays*
  - Rebates based on number of billing units under Parts D

# In Senate

- Status , S. 2543
  - ➢Approved by Committee on bipartisan vote 7/25/19
  - ➢Nonetheless, opposed by most Republicans
  - ➢Not to date embraced by Majority Leader McConnell
  - ➢Endorsed in broad terms by President Trump
  - ➢Many details not yet worked out – e.g., on industry payments

# In the House of Representatives

- H.R. 3, Lower Drug Costs Now Act of 2019
- Also reforms Part D with OOP limit of $2,000
- No more donut hole
- Also shifts risk in catastrophic phase from government to plan sponsors and manufacturers (in 2022, 30 percent for manufacturers, 50 percent for plan sponsors, 20 percent for government)
- Manufacturers would provide a 10% discount starting after the deductible and up to the catastrophic phase and a 30% discount in catastrophic phase

# In the House of Representatives

- H.R. 3, Lower Drug Costs Now Act of 2019
- Drug Price Inflation Penalties
  - Price increases for Part B above the rate of inflation (CPI-U) since 2016 (or later for newer drugs), trigger rebate to government
  - Includes brand drugs, biologics and biosimilars; excludes vaccines
  - Price measured by Part B reimbursement (ASP + 6)
  - Rebates based on number of billing units under Parts B
  - For Part D drugs: effective 7/2021, price increases above the rate of inflation (CPI-U) since 2016 (or later for newer drugs), trigger rebate
  - Includes brand drugs, biologics and biosimilars; excludes vaccines
  - Price measured by Average Manufacturer Price (AMP) *not what any Part D plan pays*
  - Rebates based on number of billing units under Parts D

# H.R. 3, Lower Drug Costs Now Act of 2019

- Drug Price Controls or Negotiation (or "Negotiation")

- Does not repeal non-interference clause in Medicare Modernization Act with respect to Part D drugs but goes further

- Would require manufacturers of specific prescription drugs to negotiate with the Secretary for
- prices of certain drugs or face an excise tax on the sales of those drugs.

- Negotiations aimed at establishing "maximum fair prices" that would be available to health plans that participate in Medicare Part D, to health plans in the commercial market, and to Part D beneficiaries and those enrolled in commercial insurance plans at the point of sale (also indirectly to Medicaid through Medicaid Best Price)

- Element of reference pricing: Maximum fair prices could not exceed 120 percent of the average price—called the average international market, or AIM, price—for a given drug in Australia, Canada, France, Germany, Japan, and the United Kingdom.

- For drugs without an AIM price, the maximum fair price could not exceed 85 percent of the average manufacturer price (AMP), the average price charged to wholesalers and pharmacists for the retail class of trade.

# H.R. 3, Lower Drug Costs Now Act of 2019

- Drug Price Controls or Negotiation (or "Negotiation")
- Class of drugs eligible for negotiation would be at least 25 and up to 250 annually
- To be drawn from a list of top 125 single-source drugs (drugs without generic or biosimilar competitors) with the highest federal spending in Part D and with the highest net spending in the commercial market (spending net of rebates provided by drug manufacturers).
- HHS informs company that it must negotiate; range of allowed maximum fair price is (at top) 120 percent of average price in 6 ex-US countries and (at bottom) price equal to or less than the lowest price in any of the 6 countries.

# H.R. 3, Lower Drug Costs Now Act of 2019

- Drug Price Controls or Negotiation (or "Negotiation")
- Class of drugs eligible for negotiation would be at least 25 and up to 250 annually
- Would include the top 125 by Part D spend and the top 125 by all spend; new or old drugs, and those without a generic or biosimilar; also all insulins
- HHS informs company that it must negotiate; range of allowed maximum fair price is (at top) 120 percent of average price in 6 ex-US countries and (at bottom) price equal to or less than the lowest price in any of the 6 countries

# H.R. 3, Lower Drug Costs Now Act of 2019

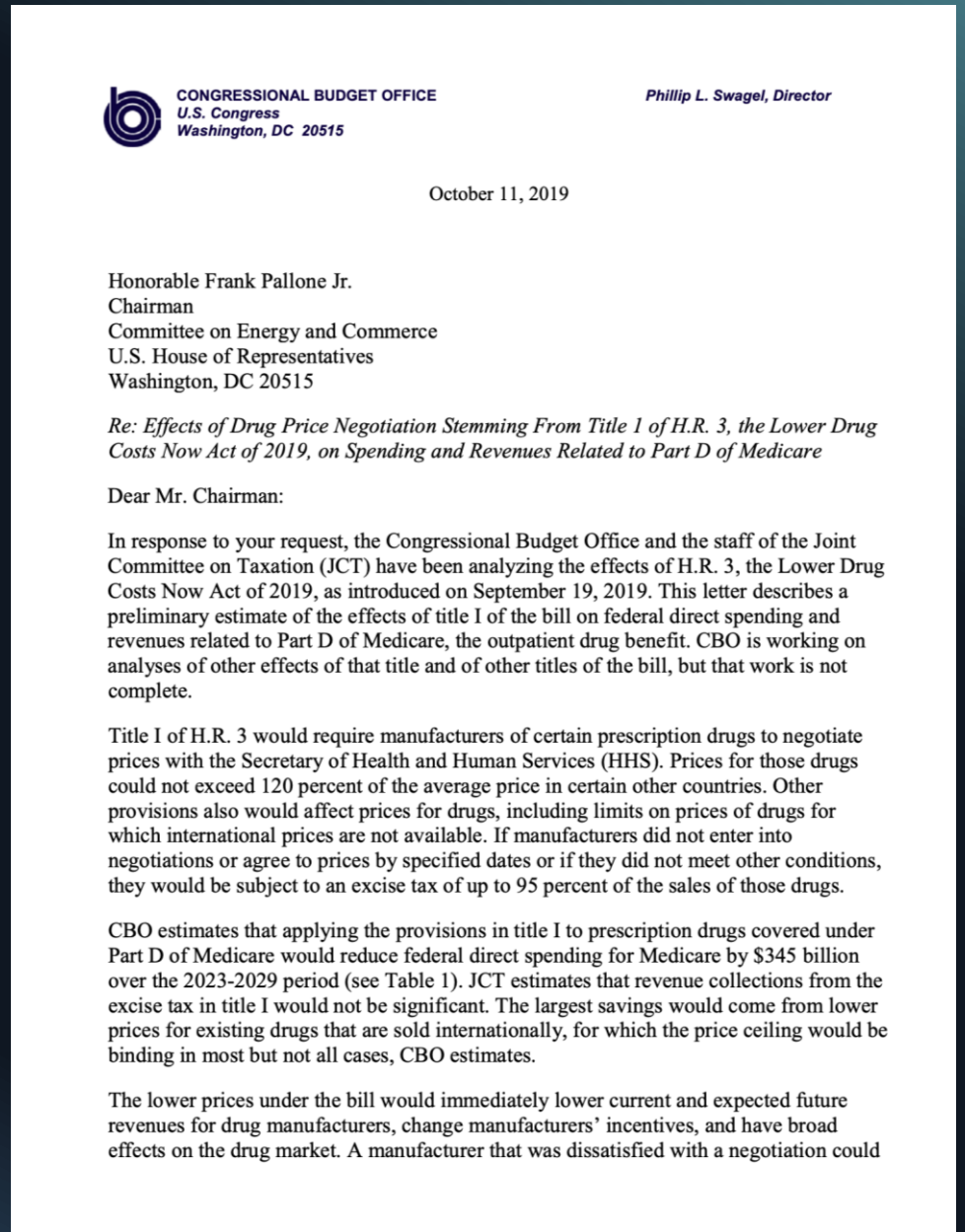
CBO Estimates

Lower total spending for Part D by about $369 billion over the 2023-2029 period.

Beneficiaries' premiums and cost sharing would be lower by about $60 billion

Lower federal direct spending on Part D by about $303 billion

Because Medicare beneficiaries would fill more prescriptions, would reduce federal direct spending on Medicare's Parts A and B by about $42 billion over the 2023-2029 period.



CONGRESSIONAL BUDGET OFFICE
U.S. Congress
Washington, DC 20515

Phillip L. Swagel, Director

October 11, 2019

Honorable Frank Pallone Jr.
Chairman
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

*Re: Effects of Drug Price Negotiation Stemming From Title 1 of H.R. 3, the Lower Drug Costs Now Act of 2019, on Spending and Revenues Related to Part D of Medicare*

Dear Mr. Chairman:

In response to your request, the Congressional Budget Office and the staff of the Joint Committee on Taxation (JCT) have been analyzing the effects of H.R. 3, the Lower Drug Costs Now Act of 2019, as introduced on September 19, 2019. This letter describes a preliminary estimate of the effects of title I of the bill on federal direct spending and revenues related to Part D of Medicare, the outpatient drug benefit. CBO is working on analyses of other effects of that title and of other titles of the bill, but that work is not complete.

Title I of H.R. 3 would require manufacturers of certain prescription drugs to negotiate prices with the Secretary of Health and Human Services (HHS). Prices for those drugs could not exceed 120 percent of the average price in certain other countries. Other provisions also would affect prices for drugs, including limits on prices of drugs for which international prices are not available. If manufacturers did not enter into negotiations or agree to prices by specified dates or if they did not meet other conditions, they would be subject to an excise tax of up to 95 percent of the sales of those drugs.

CBO estimates that applying the provisions in title I to prescription drugs covered under Part D of Medicare would reduce federal direct spending for Medicare by $345 billion over the 2023-2029 period (see Table 1). JCT estimates that revenue collections from the excise tax in title I would not be significant. The largest savings would come from lower prices for existing drugs that are sold internationally, for which the price ceiling would be binding in most but not all cases, CBO estimates.

The lower prices under the bill would immediately lower current and expected future revenues for drug manufacturers, change manufacturers' incentives, and have broad effects on the drug market. A manufacturer that was dissatisfied with a negotiation could

# Avalere Analysis, H.R. 3 – Impact 2020-2029

| | Change in Federal Outlays | Change in Manufacturer Net Revenues |
|---|---|---|
| Medicare Part D | -$570B | -$574B |
| Medicare Part B | -$77B | -$129B |
| **Total Medicare** | **-$647B** | **-$703B** |
| Commercial | -$90B | -$320B |
| **Total Medicare and Commercial** | **-$737B** | **-$1.023T** |

PhRMA: "Nuclear winter" for development of new medicines
(Global pharma spending now approximately $1.9 trillion annually)

# In the House of Representatives

- H.R. 3, Lower Drug Costs Now Act of 2019
- Status:
  - Introduced on 9/19/19
  - Action promised this fall
  - Political uncertainty among Democratic majority: Does it go far enough for progressives? Too far for moderates?

# Democratic Presidential Candidates: Multiple Other Ideas

- Most (not all) propose price negotiation in Medicare, various price constraints and controls, importation
- Some go further, e.g., Sens. Kamala Harris, Elizabeth Warren and Bernie Sanders: Employ "march-in rights" to take away the patents on expensive drugs.
- Law allows the government to award a generic competitor the rights to make and sell a patented drug that was developed using public funding, in certain circumstances.
- Never used to date

# Prognosis?

# THE END