

PRESCRIPTION DRUG REBATES AND THE HHS PROPOSED RULE

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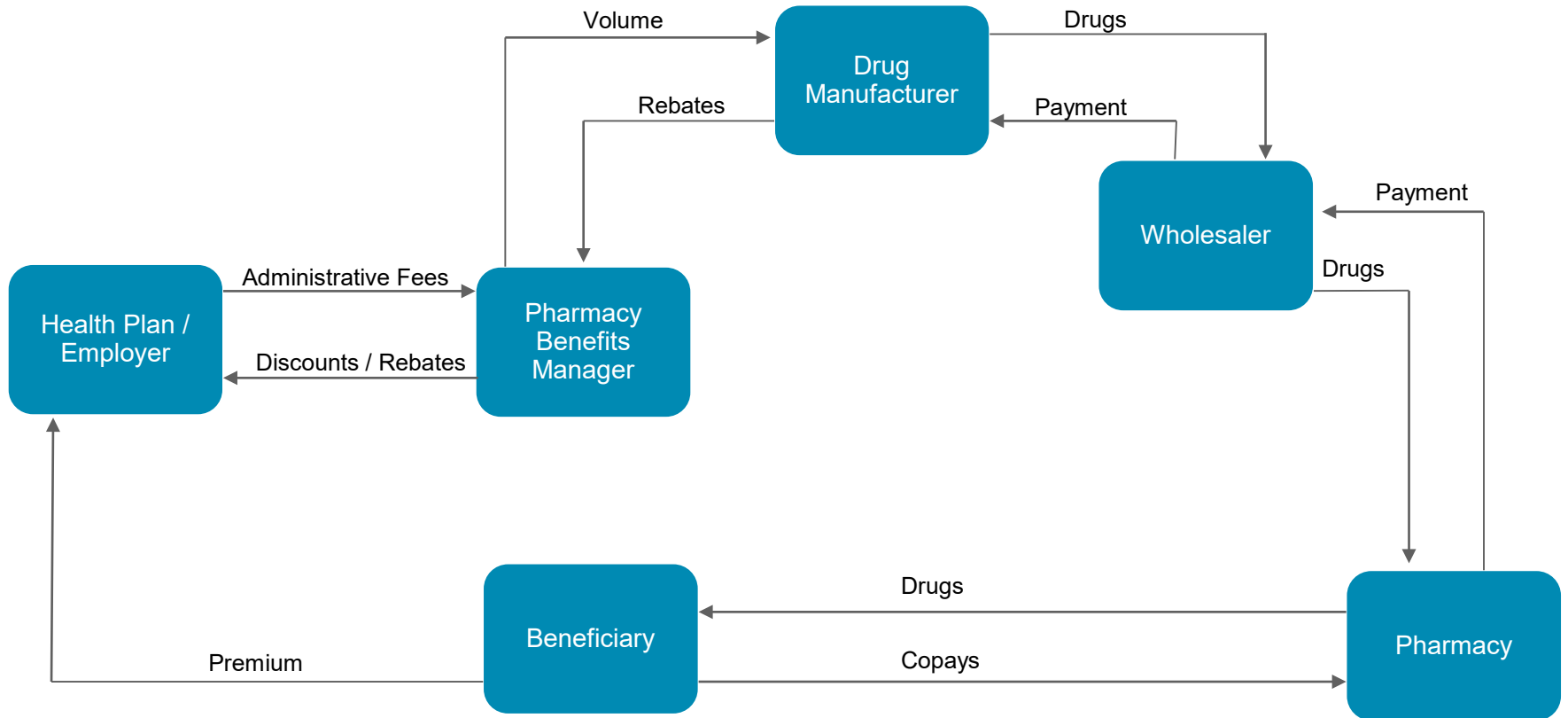
Today's Agenda

- Prescription drug pricing and the stakeholders
- Political pressures and motivations for change
- What's next? Potential shakeups

Section #1 | An overview of Prescription Drug Pricing

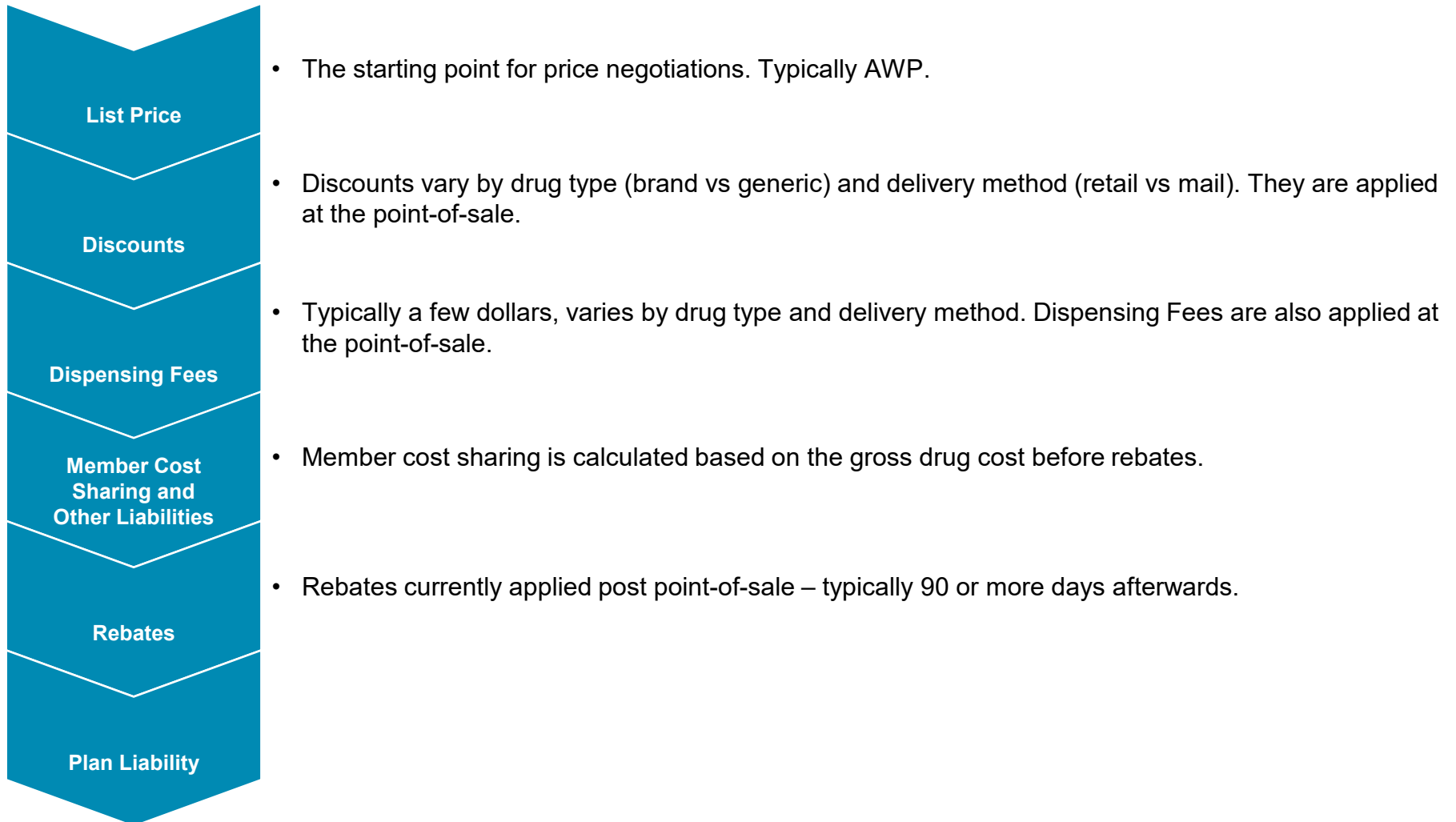
The Stakeholders and Benefits

Pharmacy Benefits Managers (PBMs) Reside in the Center



The Anatomy of Drug Pricing

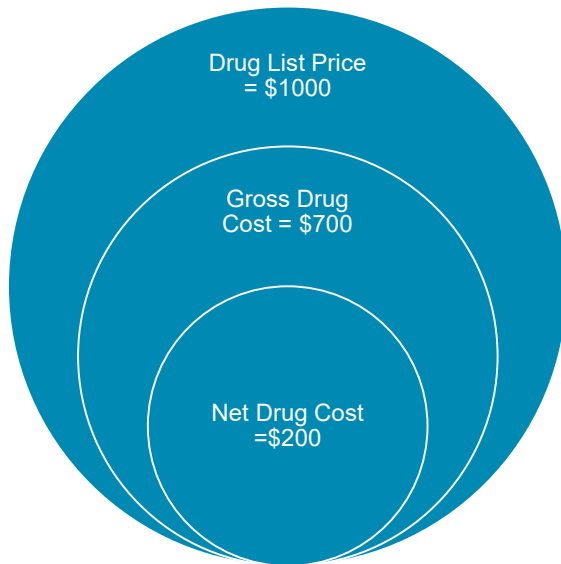
From List Price to Plan Liability



Three Primary Levers for Plan Liability: List Price, Discounts, and Rebates

List price and discount changes impact member cost sharing differently than rebates

Example One



- Assumes \$300 in discounts
- Assumes a \$500 rebate
- Member cost sharing is $\$175 = \$700 \times 25\%$

Example Two



- Assumes \$200 in discounts
- Assumes no rebate
- Member cost sharing is $\$50 = \$200 \times 25\%$



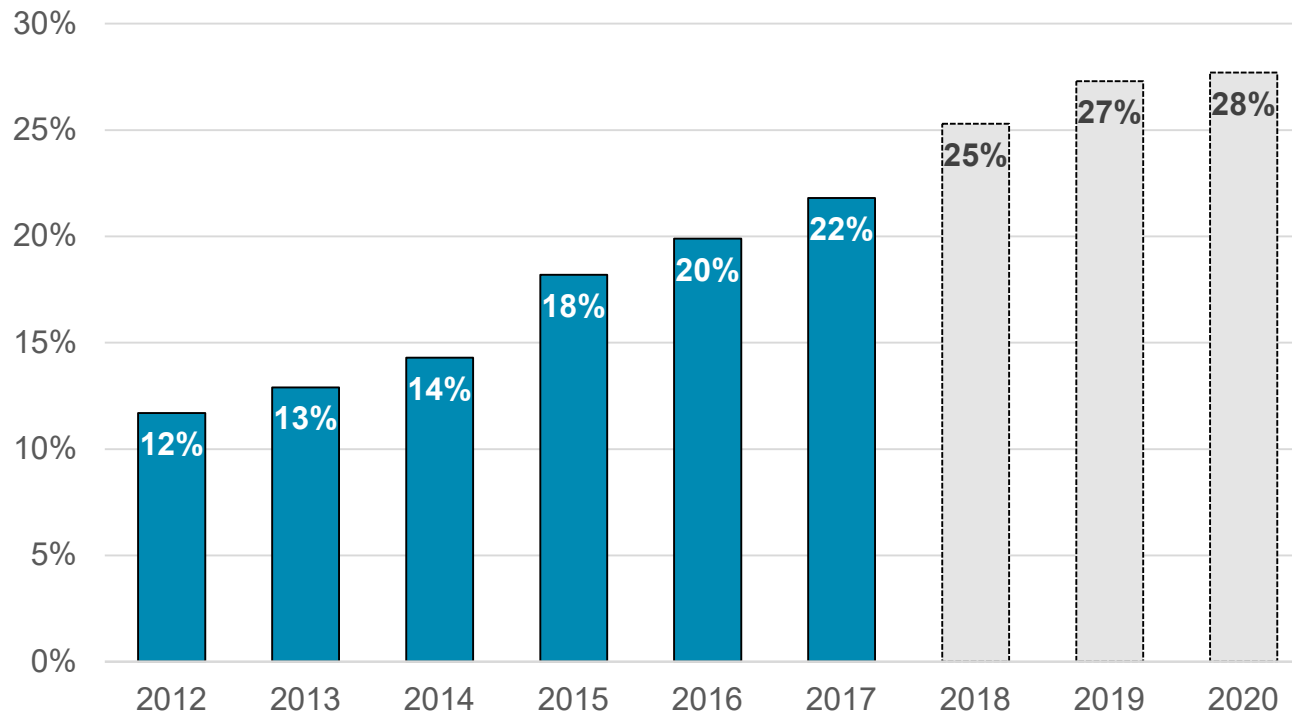
Member cost sharing is calculated on the gross drug cost which is **AFTER** discounts and **BEFORE** rebates

Section #2 | A Brief History of Rx Rebates

Recent History of Rx Rebates

Dramatic Increase from 2012 to 2018

Medicare Part D Rebates as Percentage of Allowed



Source: 2019 Medicare Trustees Report - <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2019.pdf>

Section #3 | The HHS Proposed Rule

Political Pressure Bipartisan Support for Reforming Drug Pricing



Secretary Alex Azar ✓

@SecAzar

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And for those who continue to repeat that list prices don't matter, let's remember: Anyone who hasn't spent through their deductible or has coinsurance is paying all or a percentage of the list price of the drugs they need. List prices matter.

8:13 AM - 9 Jan 2019

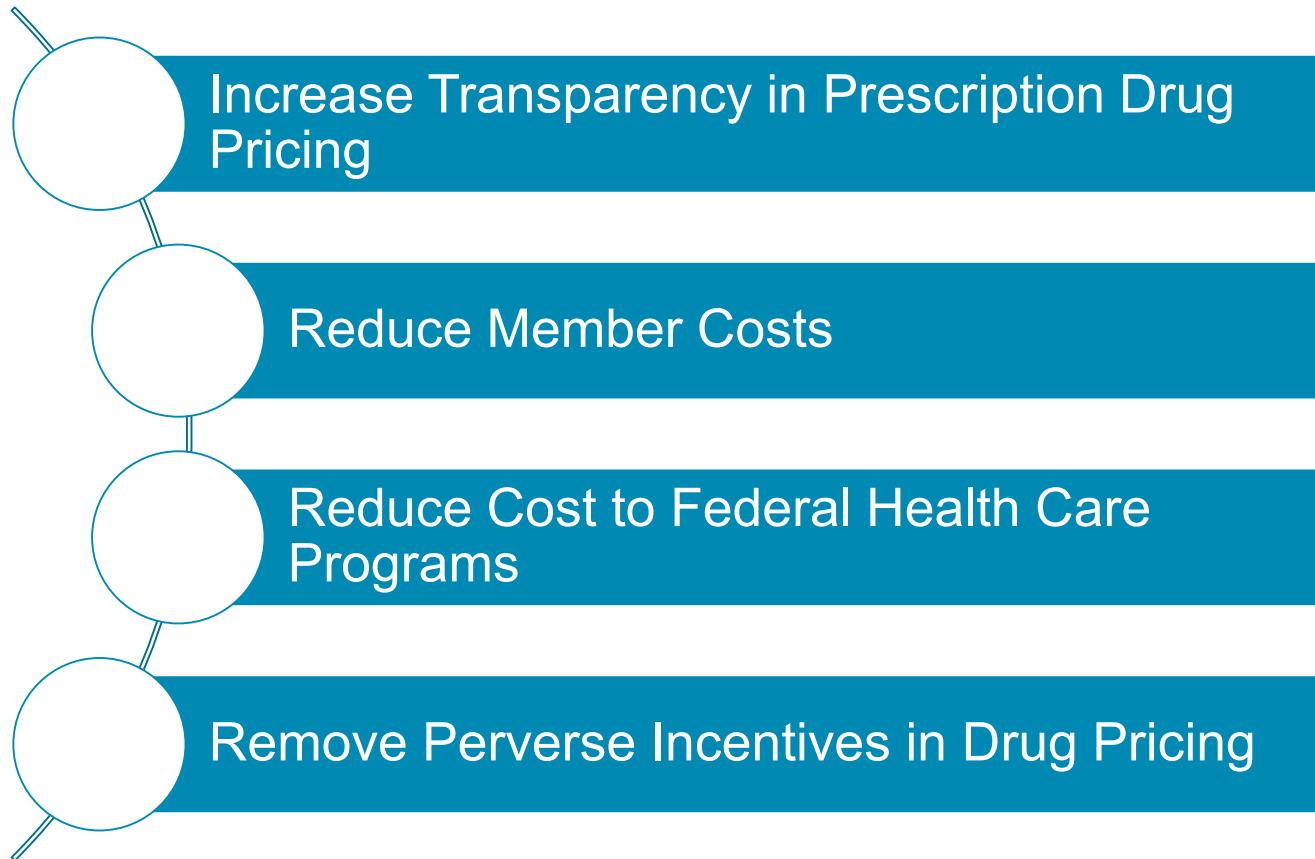
The HHS Proposed Rule

All Price Concessions Move to the Point of Service

- The Proposed Rule would amend the Federal anti-kickback statute, section 1128B(b) of the Social Security Act.
 - Removing post point-of-sale manufacturer's rebates from the discounts eligible for protection from safe harbor.
- Medicare Part D Sponsors and Medicaid MCOs would be impacted. Commercial insurance would remain untouched, other than from the secondary effects.
 - The impact of rebates is significantly different between these three markets, primarily because Medicaid members pay significantly less cost sharing than Medicare Part D.

The HHS Proposed Rule

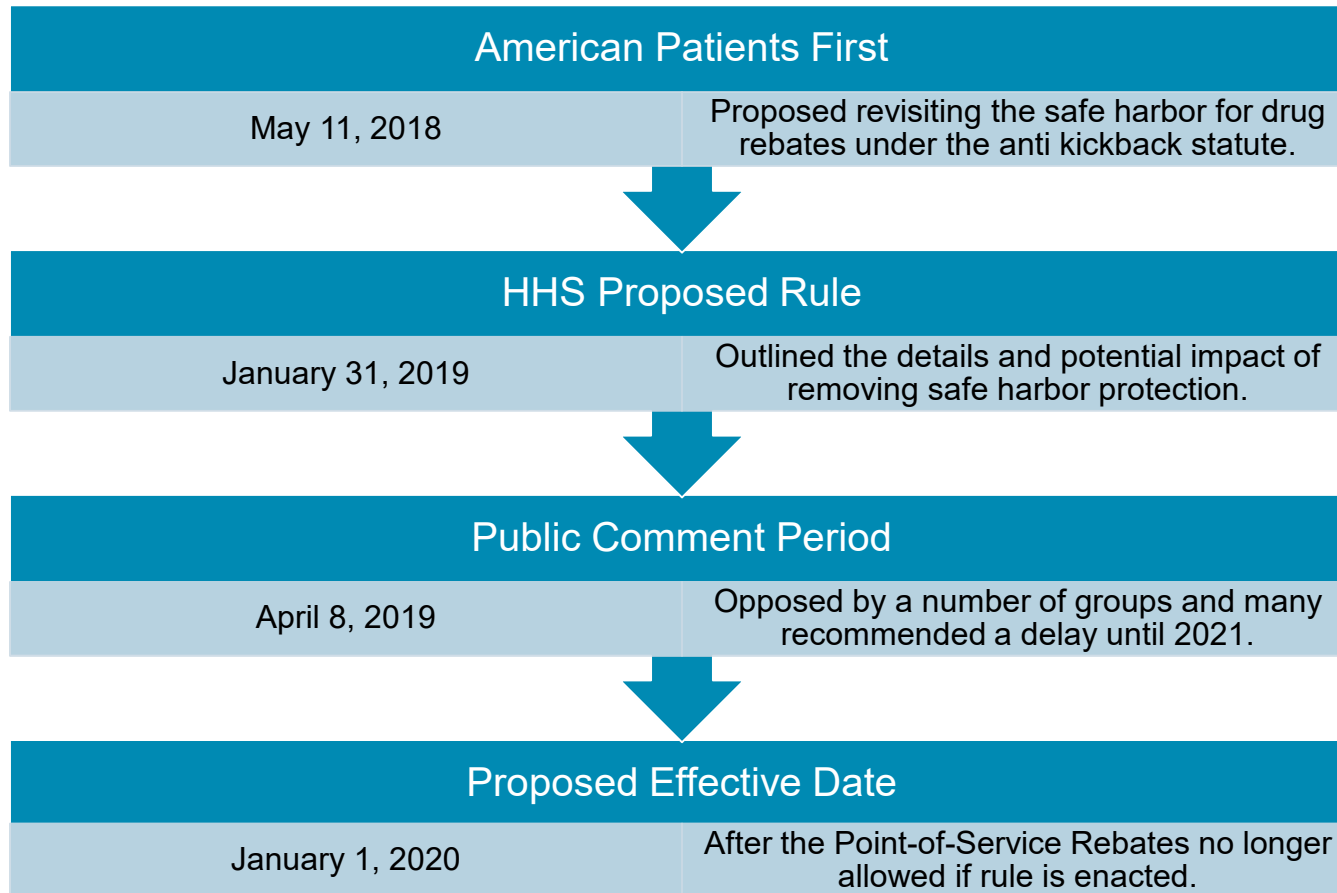
The Goals



Source: <https://www.federalregister.gov/documents/2019/02/06/2019-01026/fraud-and-abuse-removal-of-safe-harbor-protection-for-rebates-involving-prescription-pharmaceuticals>

The HHS Proposed Rule

A tentative timeline



CMS Comments on the Proposed Rule

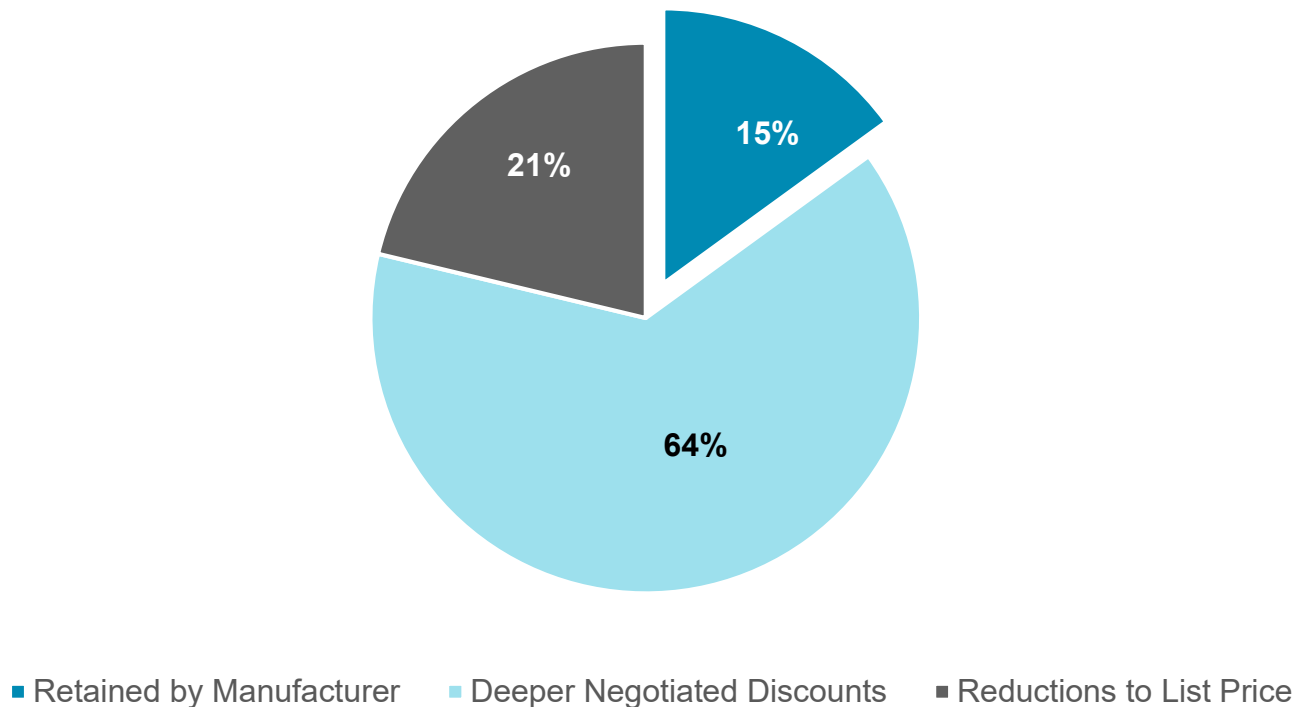
Medicare Part D plans expressed concerns to CMS on the impact of the HHS proposed rule on bids

- On April 8, 2019, CMS held a call to issue guidance on how Medicare Part D Plans should handle 2020 bids in light of the HHS Proposed Rule.
 - Indicated that plans were not required to reflect this impact in their bids (which would result in higher required revenue).
 - Outlined a 2-year demonstration program in which CMS would take 95% of the risk for plans who opted in if the HHS proposed rule was approved for 2020.
 - This demonstration is for individual plans only.
 - This demonstration is not applicable if the rule is finalized for 2021.
 - Confirmed plans would not be able to resubmit their formularies if the HHS Proposed Rule was completed after formulary submission.

Stakeholder Impacts from the HHS Proposed Rule

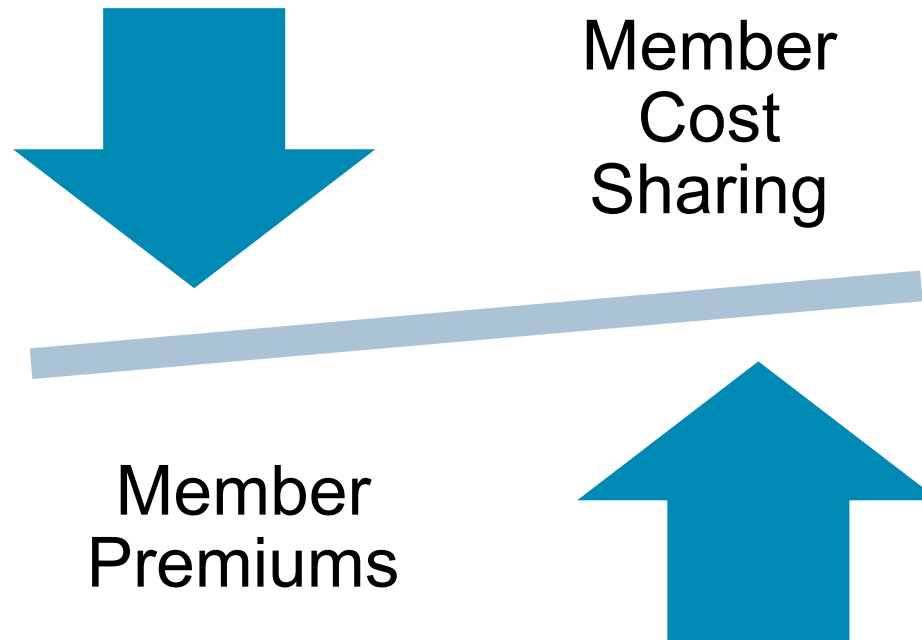
Drug Manufacturers

OACT Assumptions for how Manufacturers will Repurpose Rebates



Source: <https://www.govinfo.gov/content/pkg/FR-2019-02-06/pdf/2019-01026.pdf>

Stakeholder Impacts from the HHS Proposed Rule Members



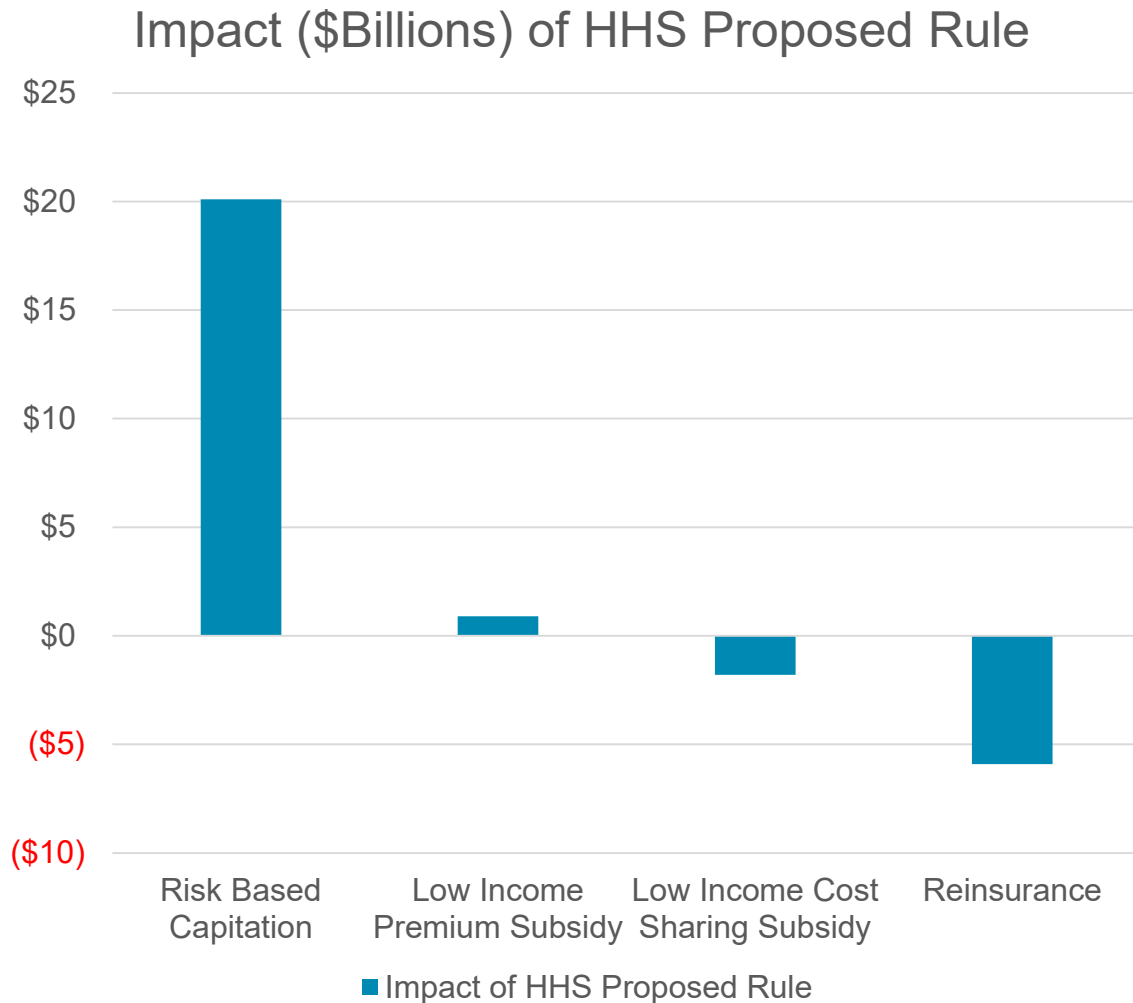
CMS-sponsored analysis concluded member cost sharing would decrease by more than member premiums would increase, resulting in a net positive for beneficiaries.

Stakeholder Impacts from the HHS Proposed Rule

Insurers

- Medicare Part D plans will have to determine whether or not to participate in the CMS demonstration program.
- Insurers will have to renegotiate with their PBMs since virtually all contracts currently include rebates.
- Plans will have to determine how to structure their Part D benefits moving forward after the demonstration program ends.
- Medicare Advantage bidding will be difficult in the first year following the demonstration as plan's try to anticipate how the market will compensate.

Stakeholder Impacts from the HHS Proposed Rule CMS



- CMS makes payments to Medicare Part D plans in the form of risk based capitation payments, subsidies for low income members, and reinsurance payments for catastrophic claims.
- The OACT modeling determined the impacts shown to the left.

Stakeholder Impacts from the HHS Proposed Rule

PBMs

- PBMs currently retain a portion of the manufacturer's rebates and pass the rest to plans. This represents a significant portion of their revenue in addition to fees charged to plans.
- PBMs will have to restructure their contracts and enact creative solutions to maintain their current levels of profitability.
- PBMs will emphasize other avenues in which they add value.

What's Next?

Significant Market Uncertainty

- Insurers await for HHS to rule on an effective date of January 1, 2020.
 - It takes 60 days for a law to be included in the federal registrar, so technically HHS has until ~November 1, 2019 to make a decision.
- Insurers meet with PBMs to determine what new contracting without rebates will look like.
- Insurers debate the pros and cons of participating in the demonstration program.
- Politicians continue to discuss prescription drug pricing amongst other health insurance related items.
- If not 2020, then 2021?

Additional Proposals

Lawmakers Consider a Number of Changes

- Creating a true out of pocket max for Part D.
 - Member's currently pay 5% of catastrophic claims.
- Increasing manufacturer liability on catastrophic claims.
 - Manufacturer's currently have no liability on catastrophic claims.
- Requiring drug advertisements to include the drugs list price.
 - List price isn't especially meaningful to members.

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