Reducing prescription drug costs

Policy options for a public plan

Notes

This report was prepared by Thomas Hwang and Aaron Kesselheim at the Program on Regulation, Therapeutics, and Law ("PORTAL") at the request of the Urban Institute and should only be considered in its entirety. **The work summarized in this report has been submitted for peer review and may be revised or updated prior to publication in scientific and legal journals.**

Cite as: (as of December 2020)

Hwang TJ, Kesselheim AS. Reducing prescription drug costs: Policy options for a public plan. Report for the Urban Institute.

Hwang TJ, Kesselheim AS. Prescription drug pricing for a public option: lessons from public payers. J Law Med Ethics 2021: In Press.

Contents

1. Executive Summary

- Prescription drug spending by private health insurers is higher than that of public payers and is projected to grow by 5-6% annually over the next decade. Addressing high levels and rates of growth of drug costs may be necessary for a Public Plan to meaningfully lower premiums.
- We reviewed the drug pricing systems for Medicaid, Medicare (Part B and Part D), and the Department of Veterans Affairs; we then analyzed three policy options for how a Public Plan could reduce prescription drug costs.[1]
- Option (a) would establish a minimum statutory rebate on covered drugs equal to the "basic" rebate in Medicaid, or 23.1% of average manufacturer prices for brand-name drugs. This policy option, which approximates the total discounts currently achieved by the Medicare Part D program, is projected to decrease net drug spending by 9-15% relative to current private insurance spending.
- Option (b) would establish a statutory rebate on covered drugs equal to the total Medicaid rebate, which is comprised of the minimum basic rebate and an additional inflation-linked rebate to address annual price increases. This policy option is projected to decrease net drug spending by 46-49% relative to current private insurance spending. However, this policy may have effects on drug prices for private payers.
- Option (c) would establish a statutory rebate on covered drugs equal to the rebate offered to Big 4 agencies, which is at least 24% for brand-name drugs and any additional inflation-linked discounts. This policy option is projected to decrease net drug spending by 28-34% relative to current private insurance spending. However, this policy may have effects on Big 4 prices and net prices for other private payers.

	Option (a)	**Option (b)**	**Option (c)**
Summary of rebate policy option	Basic Medicaid rebate	Total Medicaid rebate	Big 4 rebate
Minimum rebate for brand-name drugs	Yes	Yes	Yes
Inflation-linked rebates	No	Yes	Yes
Estimated Decrease in Net Drug Costs versus Current Private Payers	**9-15%**	**46-49%**	**28-34%**

[1] The policy options in this report focused on rebates to payers and pharmacy benefit managers (PBMs).

2. Introduction

Policymakers at the federal and state levels are currently debating a variety of approaches to contain rising health care costs. One proposal, in particular, that has attracted attention is a "public option" or "public plan" ("**Public Plan**"). A Public Plan is a health insurance plan structured and administered by the government, or a private contractor acting on behalf of the government, that would be offered alongside private plans in the non-group and/or commercial group insurance markets. Proponents of a Public Plan argue that it could reduce health care spending, improve competition and access to insurance, and promote greater efficiency in care delivery. To date, there has been relatively little information on the potential magnitude of savings from a Public Plan or the implications for coverage and costs.

This report examines ways that a Public Plan could reduce prescription drug costs.[2] Section 3 of this report provides a comparative review of drug pricing systems, focusing on the Medicaid and Medicare programs and the Department of Veterans Affairs. Section 4 summarizes the methods; details of the model parameters and study drug basket are provided in the Appendix. Section 5 evaluates the potential benefits, costs, and other key considerations for three selected drug pricing policy options for a Public Plan.

For each policy option, projected prescription drug expenditures after rebates are compared under the selected policy option versus estimated private insurance spending in 2020.

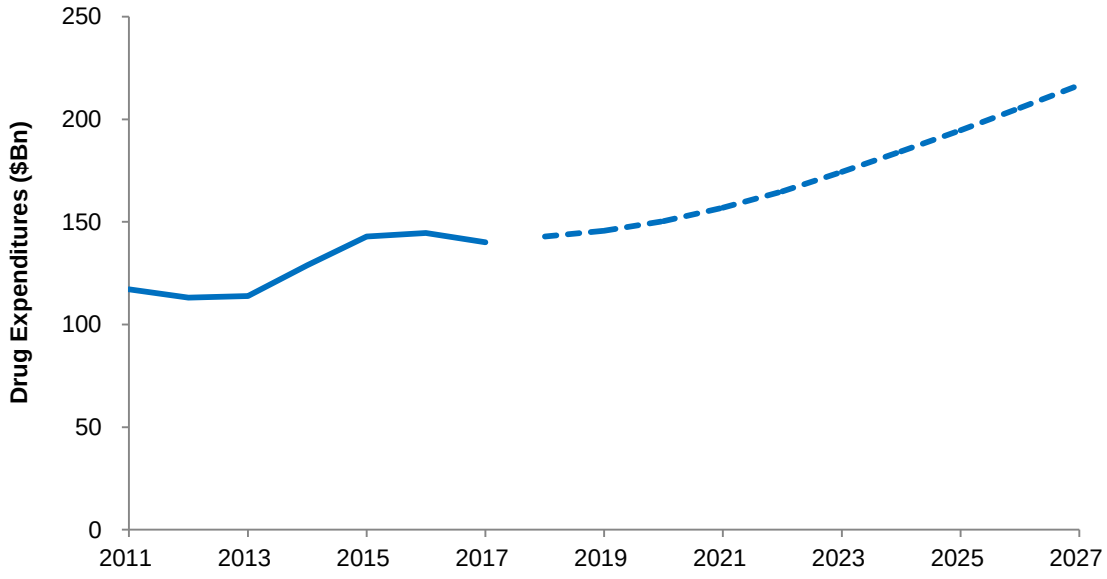
[2] The Urban Institute engaged members of the Program on Regulation, Therapeutics, and Law (PORTAL), an interdisciplinary research team in the Division of Pharmacoepidemiology and Pharmacoeconomics at Brigham and Women's Hospital and Harvard Medical School, to examine ways that a Public Plan could reduce prescription drug costs. This report was commissioned by the Urban Institute to help inform the assumptions built into the microsimulation model (HIPSM) on the likely effects of a Public Plan.

3. Comparative Review of Drug Pricing Systems

A. Background

Prescription drugs are an important contributor to health care costs in the commercial market. Drug spending after rebates (or "net" drug costs) was estimated to account for 19% of employer health benefits[3] and 12% of plan premiums (excluding member cost-sharing) in 2017.[4] In the coming decade, national prescription drug spending is projected to increase faster than other major health care goods and services, driven by the introduction of costly new specialty drugs as well as price increases on existing drugs.[5] The Centers for Medicare and Medicaid Services (CMS) Office of the Actuary estimates that drug expenditures by private health insurers in particular will grow at a rate of 5-6% annually from 2022-2027.[3]

Historical and Projected Prescription Drug Expenditures by Private Health Insurers in Billions of Dollars, National Health Expenditure Data



Thus, addressing high levels and rates of growth of drug costs may be necessary for a Public Plan to meaningfully lower health insurance premiums.

3 Peterson-Kaiser Health System Tracker. What are the recent and forecasted trends in prescription drug spending? Available at: https://www.healthsystemtracker.org/chart-collection/recent-forecasted-trends-prescription-drug-spending

4 California Department of Managed Health Care. Prescription Drug Cost Transparency Report. SB 17.

5 Centers for Medicare and Medicaid Services, Office of the Actuary. National Health Expenditure Accounts Projections, 2017-2026. CMS, 2018.

B. Overview

Overall, commercial payers receive substantially less valuable rebates and discounts from drug manufacturers than public purchasers. In 2017, rebates and discounts accounted for an estimated 10-15% of total ("pre-rebate" or "gross") prescription drug costs for private payers.[2] [6] By contrast, rebates represented 22% of total drug costs for the Medicare Part D program[7] and approximately 55% of total drug costs for Medicaid in 2017.[8] This wide variation in net drug costs reflects differences in the drug pricing systems—and associated statutory protections and bargaining power—that have been implemented over the past three decades for these public programs.

In this section, we focus on the following key payers and drug pricing systems:

- Medicaid – the Medicaid Drug Rebate Program;
- Medicare Part B – the Average Sales Price;
- Medicare Part D; and
- Department of Veterans Affairs (VA)

We will also discuss the drug pricing system used in Canada, a peer high-income country, which may hold lessons for reforms in the US.

The included payers use a combination of statutory rebates and other pricing systems to control prescription drug costs. In contrast to Medicaid and the VA, the Medicare program has relatively few mandatory rebates. In Medicare Part D, private prescription drug plans negotiate with manufacturers, and CMS is not permitted to "interfere" in those negotiations; in Part B, Medicare is a price-taker, i.e., there is no active negotiation of drug prices by CMS or health plans on Medicare's behalf.

A summary table of the key drug pricing systems used by the included payers is provided below.[9] The specific mechanisms are reviewed in greater detail in the subsequent subsection (§ 3 (B)(1)).

---

6 Centers for Medicare and Medicaid Services. Medical Loss Ratio Data. CCIIO, 2019.

7 Centers for Medicare and Medicaid Services. 2019 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds. CMS, 2019.

8 Centers for Medicare and Medicaid Services. Medicaid Drug Rebate Program Data. CMS, 2019.

9 The policy options in this report focused on rebates to payers and pharmacy benefit managers (PBMs); there may be other policy mechanisms beyond rebates to reduce drug prices.

	Medicaid	Medicare – Part B	Medicare – Part D	VA
Minimum rebate	**Yes**	No	Partly (coverage gap discount)	**Yes**
Inflation-linked rebate	**Yes**	No	No	**Yes**
Domestic price referencing	**Yes**	**Yes**	No	**Yes**
International price referencing	No	No*	No	No
Health technology assessment	No	No	No	Partly (May consult ICER)

Notes: ICER = Institute for Clinical and Economic Review; VA = Department of Veterans Affairs.
* In November 2020, CMS published an interim final rule that would establish international price referencing for certain high-cost drugs in Medicare Part B.

B.1. Mechanisms for Statutory Rebates

Across the drug pricing systems included in this report, there are five prominent mechanisms employed to reduce prescription drug costs. The first, and simplest, mechanism is a minimum rebate, which is a fixed rebate percentage that is defined in statute. Second, an inflation-linked rebate can require additional discounts if drug prices rise faster than inflation. Third, a payer can tie its drug costs to (or "reference") the average or lowest price paid by another purchaser. The externally referenced purchaser can be a payer in the US (domestic price referencing) or in selected other countries (international price referencing). Finally, a payer may conduct health technology assessment, in which drug reimbursement is based on cost-effectiveness and comparative effectiveness analyses.

Although it will not be explored in this report, payers may collect administrative and non-rebate discounts from supply chain entities other than manufacturers, such as pharmacies and wholesalers. In general, these administrative and supply chain discounts are a small fraction of overall total rebates and discounts. Therefore, for the purposes of this report, we have focused on manufacturer rebates. (Also note that this report does not account for a final rule published by CMS in November 2020 that would remove safe harbor protection for rebates under Medicare Part D.)

B.1.1. *Minimum rebate*

A minimum statutory rebate is determined based on a fixed percentage of drug costs. The minimum rebate may vary by drug type (such as treatment modality) and therapeutic area. In addition, the definition of the drug costs that serve as the denominator for the minimum rebate can vary.

For Medicaid, the benchmark drug cost is the average manufacturer price (AMP), which is confidential. The AMP is defined as the average price paid to a manufacturer by a wholesaler for drugs distributed to retail community pharmacies and by retail community pharmacies that purchase drugs directly from the manufacturer, with certain exclusions. For example, the AMP excludes price concessions to other federal programs (e.g., Medicare Part D) and certain rebates to pharmacy benefit managers (PBMs).

The minimum rebate for brand-name (single-source and innovator multiple-source) drugs in the Medicaid Drug Rebate Program is statutorily defined as 23.1% of AMP. This minimum rebate was increased by the Affordable Care Act from its previous level of 15.1%. For blood clotting factors and for drugs approved exclusively for pediatric indications, the minimum rebate is 17.1% of AMP. For generic (non-innovator) drugs, the minimum rebate is 13% of AMP.

There is no minimum rebate in Medicare Part B.[10] In Medicare Part D, manufacturers pay a minimum rebate for brand-name drug purchases made by eligible beneficiaries (mainly those not receiving the low-income subsidy) in the coverage gap (known as the “coverage gap discount”). The Bipartisan Budget Act of 2018 increased the coverage gap discount from 50% to 70% (starting in 2019). As of 2017, this discount represented nearly $6 billion or approximately 5% of total Part D spending.

For the VA, the benchmark drug cost is the non-federal average manufacturer price (non-FAMP), which is confidential.[11] The minimum rebate for brand-name (single-source and innovator multiple-source) drugs is 24% of the non-FAMP.

[10] As part of budget sequestration, the add-on for Medicare’s reimbursement of providers for Part B drugs was reduced from 6% to 4.3%. This payment reduction could be considered a minimum ‘discount,’ but it was applicable to providers and not to manufacturers.

[11] The non-FAMP is defined as the average price paid to the manufacturer by wholesalers (or others who purchase directly from the manufacturer) for drugs distributed to nonfederal purchasers, taking into account any cash discounts or similar price reductions given to those purchasers.

B.1.2. *Inflation-linked rebate*

An inflation-linked rebate requires that manufacturers pay an additional discount if drug prices rise faster than inflation. For the calculation of the inflation-linked rebate, the inflation index and/or definition of the baseline date can vary.

For Medicaid, the inflation index is the Consumer Price Index for All Urban Users (CPI-U). The baseline date is based on the date of the drug's market launch. Medicaid's inflation-linked rebate aims to return all of the price increases for a drug since its launch date. (Note that the Affordable Care Act established a cap on the total Medicaid rebate, such that it cannot exceed 100% of AMP.)

There is no inflation-linked rebate in Medicare Parts B and D.

For the VA, the inflation index is also the CPI-U. However, the baseline date is based on the date that the contract with the VA for the covered drug goes into effect. The VA's inflation-linked rebate aims to return price increases for a drug over the life of the contract (e.g., every 5 years for multi-year contracts).

B.1.3. *Domestic price referencing*

Domestic price referencing determines drug prices based on the average or lowest price paid by another ("referenced") payer in the US. The referenced payer or group of payers can vary. External price referencing is commonly understood to involve requiring a rebate to achieve the referenced price. (Note that a payer can also require disclosure of prices negotiated by other purchasers. In such cases, allowing one payer to observe terms provided to most favored customers may have implications similar to external reference pricing.)

In general, domestic price referencing excludes most public programs—that is, one public payer generally cannot reference the price paid by another public payer. In 1990, Congress initially included the VA in Medicaid's determination of the lowest price available to the market; that provision was rescinded in 1992.[12] In 2016, a California ballot initiative (Proposition 61) would have

[12] Scott Morton F. The strategic response by pharmaceutical firms to the Medicaid most favored-customer rules. The RAND Journal of Economics 1997;28(2):269-290.

required the state's Medicaid program pay no more than the VA for drugs; the referendum failed in 2016 by a margin of 47-53%.[13]

Medicaid references the lowest price paid by private payers, known as the "best price." More precisely, the minimum rebate for brand-name drugs is defined as the greater of 23.1% of AMP or the difference between AMP and the best price. "Best price" is defined as the lowest price available to any private payer, wholesaler, retailer, or provider in the US, with certain exceptions.[14] Medicare, the VA, 340B entities, and other federal agencies are excluded from best price.

Medicare Part B references the average price paid by private payers, known as the "average sales price" (ASP). Payments by Medicare for Part B drugs, primarily injected, infused, and other physician-administered drugs, are based on the ASP plus an add-on amount. The ASP differs from the AMP (used to calculate the Medicaid rebate) because it includes certain rebates and discounts to private payers. The ASP excludes rebates to private insurers in Medicare (Part D, Medicare Advantage, and qualified retiree plans); ASP also excludes public payers, including Medicaid, VA, and 340B entities.[15]

There is no external price referencing in the Medicare Part D program.

The VA, through delegated authority from the General Services Administration, administers the Federal Supply Schedule (FSS) for drugs and other medical supplies and equipment. The FSS is open to the Big 4 agencies as well as other federal agencies in the executive, legislative and judicial branches, and several other purchasers, including the Bureau of Prisons, District of Columbia, and Indian tribal governments. Under federal procurement regulations for the FSS, the VA should "seek to obtain the offeror's best price (the best price given to the most favored customer)"; however, this is a negotiation objective and not a requirement.[16] Note that there is no explicit relationship between the "best price" for FSS procurement and the "best price" in the Medicaid program.

The VA also negotiates contracts for drug purchases at prices below the FSS price. With each contract, the VA and manufacturer may agree on a customer or category of customers (the "tracking customer") subject to a price reductions clause. Any price reductions, discounts, or other commercial arrangements that

13 Hwang TJ, Kesselheim AS. Public referendum on drug prices in the US: will it bring relief? BMJ 2016;355:i5657.

14 See § 1927(c)(1)(C)(i) of the Social Security Act.

15 See 42 USC § 1395w-3a(c)(3).

16 See 48 CFR § 538.270-1 ("However, the Government recognizes that the terms and conditions of commercial sales vary and there may be legitimate reasons why the best price is not achieved.")

could affect price and that are provided to the tracking customer must also be extended to the government. Sales to federal agencies as well as state and local government agencies that purchase at the FSS price are exempted.

B.1.4. *International price referencing*

International price referencing determines drug prices based on the average or lowest price paid by other countries. International price referencing schemes differ primarily based on the countries included in the "reference basket."

International price referencing is not generally used by any included US payers. In October 2018, the Centers for Medicare and Medicaid Services (CMS) issued an advance notice of proposed rulemaking to replace Medicare Part B's current payment system (based on domestic price referencing) with international pricing referencing. CMS initially proposed to calculate an average international price weighted by Medicare Part B spending, and establish a target price by multiplying this international price index with pre-specified model goals.[17] In November 2020, CMS issued an interim final rule that would use the lowest price in the basket of referenced countries for certain high-cost drugs in the Part B program.[18]

International reference pricing is used more frequently outside the US. For example, several European countries use external reference pricing formally or informally (through required price disclosure), to some degree, in determining reimbursement. In Canada, the Patented Medicine Prices Review Board (PMPRB) references the median prices paid in comparable countries, including Australia, France, Germany, Japan, and the United Kingdom.[19] (Note that Canada recently finalized changes in PMPRB regulations that removed the United States and Switzerland from its list of referenced countries; the amended regulation is anticipated to enter into force in 2021.)

International reference pricing is controversial, and these systems have been associated with manufacturer gaming and delays in product launch, particularly in smaller markets and lower-income countries.

---

17 CMS proposed to phase-in the target price over five years, declining from a blend of 80% of ASP and 20% of the target price in year 1 to 100% of the target price in year 5.

18 See 85 FR 76180 (2020).

19 Government of Canada. Regulations Amending the Patented Medicines Regulations. GC, 2017.

B.1.5. *Health technology assessment*

Health technology assessment (HTA) involves the use of cost-effectiveness and comparative effectiveness analyses to guide drug pricing negotiations with manufacturers and inform ultimate reimbursement. HTA decisions may involve a benchmark or threshold for cost-effectiveness, based on measures such as quality-adjusted life-years (QALY) or life-years gained.

Many peer high-income countries have a centralized HTA body, such as the National Institute for Health and Care Excellence (NICE) and Scottish Medicines Consortium in the UK and the Canadian Agency for Drugs and Technologies in Health (CADTH) in Canada. In general, NICE will not recommend coverage of a drug if its cost does not meet its stated cost-effectiveness thresholds.

In the US, there is no public HTA body. However, recently, some payers have cited cost-effectiveness analyses conducted by the independent non-profit Institute for Clinical and Economic Review (ICER):

- In 2017, the VA announced that it would partner with ICER to use ICER's analyses in drug coverage and price negotiations with manufacturers;
- In April 2018, New York's state Medicaid program recommended a supplemental rebate for a cystic fibrosis drug based on the price determined by ICER to achieve $150,000 per QALY gained; and
- In August 2018, a large pharmacy benefit manager (PBM), CVS Caremark, initiated a program to allow clients to exclude a drug launched at a price greater than $100,000 per QALY from their plan.

Note that the Affordable Care Act prohibited Medicare from using an "adjusted life year (or such a similar measure) as a threshold to determine coverage, reimbursement, or incentive programs."[20]

B.2. Supplemental Rebates

In addition to statutory rebates, payers can benefit from supplemental rebates that have the potential to increase the rebate fraction (rebates as a proportion of total drug costs) by up to 5-10 percentage points. For example,

[20] See Section 1182 of the Social Security Act.

- In the Medicaid program, states can individually or collectively negotiate supplemental rebates. Medicaid managed care plans can negotiate their own rebates with manufacturers;
- 340B covered entities can individually or through the government[21] negotiate additional discounts below the 340B ceiling price; and
- The VA and the Department of Defense's military treatment facilities can negotiate drug prices below the Federal Ceiling Price.

Manufacturers may be incentivized to offer these additional discounts for competitive drug classes with multiple therapeutically comparable products. Additional discounts can allow manufacturers to gain more favorable formulary placement or less restrictive utilization management.

The magnitude of these supplemental rebates depends primarily on the payer's ability to control the formulary and drug benefit design. Formulary and coverage requirements vary substantially across payers. In the commercial market, qualified health plans and certain other plans are required to cover the greater of 1 drug per class or the number covered by a benchmark plan. In Medicare Part D, prescription drug plans are required to cover at least 2 drugs per class; in addition, for six protected classes (including cancer drugs), Part D plans are required to cover all or substantially all drugs. Medicaid has the most expansive coverage requirements among payers in the US: it is required to cover generally all drugs approved by the FDA.

The clinical implications of "closed" formularies (i.e., allowing exclusion of certain drugs) remain controversial. Proponents argue that, when appropriately designed, formularies can help payers better align the purchasing of drugs with evidence-based care and lower costs. Critics argue that implementing a formulary may deprive patients of treatments and increase administrative burdens on physicians. Nonetheless, formularies do affect bargaining power. The creation of the VA's national formulary was associated with reduced drug spending as well as negotiated price reductions considerably below the lowest prices available to other purchasers.[22] Meanwhile, the protected class

[21] 340B covered entities can participate in the voluntary prime vendor program managed by the federal Health Resources and Services Administration (HRSA) or negotiate directly with manufacturers for discounts below the statutorily defined ceiling price (sub-340B ceiling price).

[22] Huskamp HA, Epstein AM, Blumenthal D. The impact of a national prescription drug formulary on prices, market share, and spending: lessons for Medicare? Health Affairs 2003;22(3):149-58.

requirements were estimated by Part D plans to result in rebates that are 10-20% lower than those that could be achieved without such requirements.[23]

A summary of the prescription drug coverage policies is provided below:

	Individual Market	Medicaid	Medicare Part D	VA
Mandatory coverage of all FDA-approved drugs	No	Yes	No, except for all or substantially all drugs in certain protected classes (see below)	No
Use of closed drug formulary	Yes	No	Yes	Yes
Required number of drugs per class	Greater of: 1 drug per class or the number covered by a benchmark plan*	All drugs per class	2 drugs per class	No requirement
Required coverage of certain drug classes	No	All drug classes	Yes, 6 protected classes: immunosuppressants, antidepressants, antipsychotics, anticonvulsants, antiretrovirals, and antineoplastics	No

Notes: * Requirements for prescription drug coverage in the individual market are provided under the Affordable Care Act's essential health benefits.

[23] See 74 Federal Register 2881; Office of Inspector General. Concerns with rebates in the Medicare Part D program. OIG, 2011.

4. Data and Methods

We used the Truven MarketScan database to identify all prescription drug claims for the commercially insured population in the most recent year of data available, calendar year (CY) 2017. Our aim was to define a basket of high-spend drugs that account for a "substantial proportion" of brand-name pharmaceutical expenditures. We first extracted the top 100 drugs by spend from MarketScan. To validate this basket of high-spend drugs, we cross-referenced our identified drugs with those highlighted by commercial payers:

- Maine All-Payer Claims – under new state drug transparency legislation, we obtained a list of the most costly drugs for commercial payers in Maine for the period 2017-2018; and
- Blue Cross Blue Shield – list of the top 30 medications for all commercially insured members of Blue Cross Blue Shield plans nationwide in 2017[24]

After excluding generic drugs (since rebates are typically not provided to plans for generics), this resulted in identification of 75 high-spend drugs that accounted for approximately $15 billion in total expenditures in MarketScan. This basket represented 67% of brand-name drug spending and nearly half of overall drug spending (see Appendix § B for details).

The MarketScan data cover approximately 25 million commercially insured lives, implying plan per-member-per-year (PMPY) spend on prescription drugs of approximately $1,130. We conducted a review of public disclosures and industry reports to benchmark the PMPY spend versus other private payers. This MarketScan drug PMPY is broadly consistent with the experience of commercial insurers nationally, based on data available from the State of California, Health Care Cost Institute (HCCI), Express Scripts, and Blue Cross Blue Shield. Thus, the MarketScan estimates may be applied directly to the Urban Institute model on a PMPY basis without needing further adjustment.

Next, we obtained drug-level rebate estimates from SSR Health, an investment research firm that maintains the industry-leading database of this information. The database aggregates public and commercially proprietary sales data to estimate total gross and net sales (i.e., net of all rebates and discounts) at the standard drug unit level. This database, which is updated quarterly, covers over 1,000 brand-name prescription drugs marketed by publicly traded companies.

[24] Blue Cross Blue Shield. The Health of America Report. https://www.bcbs.com/sites/default/files/file-attachments/health-of-america-report/BCBS.HealthOfAmericaReport.RisingCostsPatentedDrugs_1.pdf

The rebate estimates reflect all discounts and concessions between a drug's gross and final net cost for the non-Medicaid commercial and total markets.[25]

Since the Urban Institute model will begin in CY 2020, we trended forward the MarketScan data using the National Health Expenditures (NHE) estimates for growth in gross prescription drug expenditures by private health insurance[26]:

Annual Percent Change in Prescription Drug Expenditures in the Commercial Market

Calendar Year	2018	2019	2020
National Health Expenditures – Private Health Insurance only (ESI and Marketplace)	2.0%	1.9%	3.2%

The latest projections from CMS suggest that manufacturer rebate growth in Part D will decline from a 3% increase (year-over-year) in 2019 to around 1% by 2021. IQVIA (previously IMS Health) estimates that net price increases for the total US market will be approximately 0-2% from 2017-2020. We have conservatively assumed that rebates will increase proportionally to gross drug expenditures. If rebates grow more slowly than gross spending, the projections in this report may underestimate actual differences in net spending.

Using methods that we published previously,[27] we assessed net price differences for Medicaid and the "Big Four" federal purchasers of drugs (the VA, Department of Defense, Public Health Service, and Coast Guard). For each drug, we calculated the Medicaid basic rebate using CMS' published formula and wholesale acquisition costs from Truven and Medi-Span (Wolters Kluwer).[28] To calculate the additional rebate, we obtained inflation (CPI-U) data from the Bureau of Labor Statistics.[29]

25 For each drug, to smooth possible quarter-to-quarter volatility in inventory and net sales, we extracted trailing four-quarter average rebate rates as of the fourth quarter ended December 31, 2017. Note that price and volume data may not be consistently available for products with low (or unreported) sales or those with restricted or highly specialized distribution channels.

26 Drug spending by private health insurers is expected to increase by 4.4% in 2021 and between 5-6% in 2022-2027.

27 Hwang TJ, Kesselheim AS. Public referendum on drug prices in the US: will it bring relief? BMJ 2016;355:i5657.

28 Average manufacturer prices are confidential by rule. The Office of the Inspector General has found that the wholesale acquisition cost (WAC) differs from AMP by a median of 4% for single-source brand-name drugs and 8% for multi-source brand-name drugs. Therefore, WAC was used as the best available approximation for average manufacturer prices.

29 US Department of Labor, Bureau of Labor Statistics. Databases: Inflation & Prices.

Generic drugs typically do not have rebates to payers. A notable exception, as discussed in § 3(B), is the Medicaid Drug Rebate Program, which includes a statutory rebate of 13% of AMP for generic (non-innovator) drugs. For Policy Option (b), this statutory Medicaid rebate for generic drugs was applied to the roughly one-quarter of overall (brand and generic) drug spending in MarketScan accounted for by generic drugs. No rebate for generic drugs was included in the net spending estimates for Policy Options (a) and (c).

We obtained, on a drug-by-drug basis, Big 4 prices from the VA National Acquisition Center for 2017 (June 2017 used as the reference date) under Freedom of Information Act request. This analysis excluded the impact of pharmacy dispensing fees, the VA's distribution rebate, and confidential state supplemental rebates as well as final-stage negotiations by the VA, which may further reduce actual net prices. For all policy options, we used the lesser of the projected prices and estimated commercial net prices.

Finally, for the foreign price comparison, we extracted published unit drug prices from the Drug Benefit Formulary of the Ontario Ministry of Health and Long-term Care as of March 2019.[30] For each drug in the study basket, we identified the largest per-unit difference between the Canadian price and the estimated net price for commercial payers in the US (updated to the first quarter of 2019) across all package sizes, dosages, strengths, and formulations. Price differences were then weighted by drug utilization in the MarketScan data. We also manually reviewed prices from the formularies for four other provinces: Alberta, British Columbia, Newfoundland and Labrador, and Saskatchewan. Since prices for the reviewed drugs were substantively similar across all five provinces, we report results from Ontario only. Currency was converted to US dollars at the spot exchange rate as of April 15, 2019.

Note that the study database and assumptions were locked in April 2019 and therefore do not account for the impact of the COVID-19 pandemic.

[30] Data from the Canadian government were broadly consistent with the prices reviewed in § 5(B).

5. Policy Options for the Public Plan

Based on our review of the drug pricing systems included in this report, we analyzed three possible policy options for how a Public Plan could reduce prescription drug costs. Those three options are:

1. **Option (a)**: Medicaid basic rebate – minimum statutory rebate defined as a fixed rebate percentage (23.1% for brand-name drugs – which approximates the total discounts currently achieved by Medicare Part D);
2. **Option (b)**: Medicaid total rebate – combined minimum statutory rebate and inflation-linked rebate; and
3. **Option (c)**: Big 4 rebate – minimum statutory rebate based on the Big 4 price (VA, Department of Defense, Public Health Service, and Coast Guard)

For each policy option, we applied a consistent framework to assess the possible associated benefits, costs, and other key considerations. First, we outline how the statutory rebates could be structured for the Public Plan. We also examine the possibility of the Public Plan negotiating supplemental rebates in addition to the rebates mandated in law. Second, we evaluate the benefits and projected rebates under the policy option. We compare projected net drug spending under the policy option versus current private insurance spending in 2020, with and without the impact of any supplemental rebates. We also benchmark the projected rebate fraction—that is, rebates as a percentage of gross drug spending—for the Public Plan under that policy option versus the commercial market, Medicare Part D, and Medicaid. Finally, the mechanisms for setting pharmaceutical prices are complex, and policy changes can result in dynamic effects on market participants, particularly when prices for one payer are tied to those for another. To provide additional context, we qualitatively assess the potential administrative complexity, effects on drug prices and other purchasers, and formulary and coverage considerations for each policy option.

Details of the methodology, model parameters, and study drug basket are provided in the Appendix. Note that the projections in this section do not account for beneficiary cost-sharing; premiums; dynamic changes in pharmaceutical prices, market behavior, or drug mix and utilization; or other interactions that may be relevant, particularly over the long term. We have assumed that the eventual policy option is fully operationalized and implemented sometime before the 2020 plan year. In reality, there may be some lag between policy enactment and rebate receipts. In addition, for the

purposes of this report, we have not included the potential impact of policy proposals or regulatory changes that could affect pharmaceutical pricing but that have not been enacted as of August 2019. For these reasons, the projections provided in this report may vary from a Congressional Budget Office (CBO) score, as well as actual experience, if a policy option were enacted.

These limitations notwithstanding, the quantitative and qualitative factors reviewed herein may assist in developing a more comprehensive and rigorous model of a potential Public Plan. A summary table of key considerations for the three included policy options is provided below:

	Option (a)	**Option (b)**	**Option (c)**
Summary of rebate policy option	Basic Medicaid rebate	Total Medicaid rebate	Big 4 rebate
Minimum rebate for brand-name drugs	Yes (23.1% of AMP)	Yes (23.1% of AMP)	Yes (24% of non-FAMP)
Inflation-linked rebates	No	Yes	Yes
Estimated Decr. in Net Drug Costs vs. Current Commercial Payers*	**9-15%**	**46-49%**	**28-34%**
Potential for supplemental rebates	Moderate	Low	Moderate
Administrative complexity	Low	Low	Moderate-High
Likelihood of effects on drug prices for other private payers	Low-Moderate	Moderate-High	Moderate-High
Likelihood of effects on drug prices for other public payers	Low	Low	Moderate-High
Likelihood of bargaining restrictions and other political involvement	Low	High	Low

Notes: AMP = average manufacturer price. Non-FAMP = non-federal average manufacturer price. * Relative to current estimates net drug prices for private payers in the commercial market.

A. Policy option (a): basic Medicaid rebate

A.1. Summary

Option (a) would establish a minimum statutory rebate on covered drugs equal to the "basic" rebate in Medicaid—currently 23.1% of the average manufacturer price for brand-name drugs (which approximates the total discounts currently achieved by the Medicare Part D program). This policy option is projected to decrease net drug spending by 9-15% relative to current private insurance spending. The upper bound of this estimate reflects the possibility of the Public Plan negotiating supplemental rebates with manufacturers, particularly for competitive drug classes with multiple therapeutically comparable products.

A.2. Background

As part of the Omnibus Budget Reconciliation Act of 1990, Congress created statutorily-defined rebates for Medicaid through the Medicaid Drug Rebate Program.[31] The Medicaid Drug Rebate Program was expanded under the Affordable Care Act, which increased the minimum, or "basic," rebate rate from 15.1% to 23.1%; the ACA also extended the rebate requirements to include drugs paid through managed Medicaid plans. The Medicaid Drug Rebate Program is technically voluntary. However, because participation is required for payment under Medicare and other public programs, most manufacturers have entered into rebate agreements pursuant to this program.

Under section 1927 of the Social Security Act, manufacturers are required to report the average manufacturer price (AMP) for covered drugs to CMS each quarter. Based on this price reporting (which is confidential to states and the public), CMS calculates the per-unit rebate amount and sends it to state Medicaid agencies.[32] State Medicaid agencies use the unit rebate amount from CMS to invoice manufacturers for rebates; manufacturers then pay rebates to the states. Note that states' collection of federal Medicaid rebates each quarter from manufacturers is separate from states' reimbursement of pharmacies and providers for drugs: every state receives the same per-unit rebate, but how much is paid to pharmacies and providers may vary by state.

[31] Omnibus Budget Reconciliation Act of 1990. Pub. L. 101–508.

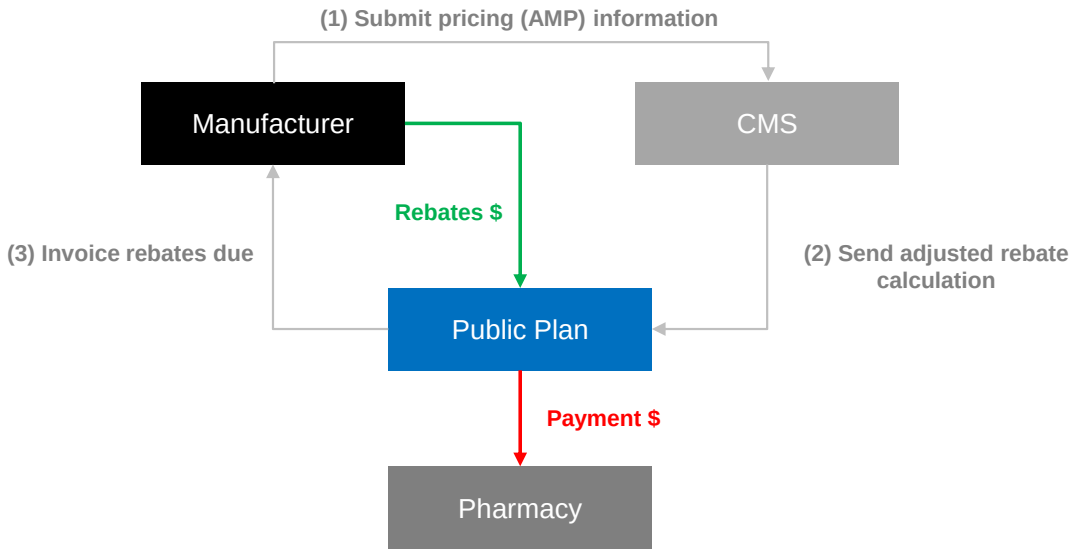
[32] CMS also calculates the unit rebate offset amount. Under the Affordable Care Act, increased Medicaid rebates are applied, on a dollar-for-dollar basis, against the amounts that CMS reimburses to the states for Medicaid under the state's federal medical assistance percentage (FMAP).

A.3. Implementation

A.3.1. *Statutory rebates*

Under Option (a), the Public Plan would receive a minimum rebate on covered drugs equal to the "basic rebate" in Medicaid, which is currently 23.1% of AMP for brand-name drugs (single-source or innovator multiple-source drugs).[33] The implementation of this policy option may be simplified by relying on the operational architecture already in place for the Medicaid program.

Specifically, manufacturers already report the AMP each quarter to CMS, and CMS calculates and sends unit rebate information to the states. Thus, Option (a) may be implemented as follows:



First, the enacting statute may update existing national rebate agreements so as to require that manufacturers provide rebates for the Public Plan to receive payment under Medicaid, Medicare, or other public programs.[34] (For example, similar requirements compel manufacturers to provide discounts to 340B entities to be reimbursed by Medicaid.) Second, CMS would need to send unit rebate information to the Public Plan each quarter, although such rebate information would need to be adjusted to exclude additional (inflation-linked)

[33] The basic Medicaid rebate is equal to 17.1% of AMP for blood clotting factor drugs and drugs approved exclusively for pediatric indications, and 13% of AMP for generic drugs (non-innovator multiple-source drugs). Note that, for the purposes of this policy option, we are not considering the best price provision for brand-name drugs.

[34] Since AMP reporting is already required under the Medicaid Drug Rebate Program, no specific new requirements for price reporting are likely needed.

rebates due to Medicaid but not the Public Plan.[35] Finally, the Public Plan would invoice manufacturers for the statutory rebates, and these rebates would be paid directly to the Public Plan. Unlike the Medicaid program, we assume that there is no federal offset or sharing of rebates between the Public Plan and the federal government; CMS would act solely as an intermediary for confidential pricing and rebate calculation data.

A.3.2. *Supplemental rebates*

We assume that the Public Plan will be offered alongside private plans in the non-group and/or commercial group insurance markets, and will function like other private plans with respect to the pharmacy benefit: control formulary design and apply utilization management.[36] For competitive drug classes with multiple therapeutically comparable products, manufacturers may be incentivized to offer additional discounts in exchange for market share vis-à-vis more favorable formulary placement (e.g., preferred status) or less restrictive utilization management (e.g., prior authorization). As such, it is possible that the Public Plan will be able to negotiate supplemental rebates directly with manufacturers. For example, in the Medicaid program, states can individually or collectively negotiate supplemental rebates; in addition, Medicaid managed care plans can negotiate their own rebates with manufacturers. Similarly, 340B covered entities can individually or through the government[37] negotiate additional discounts below the 340B ceiling price.

It is also possible that the Public Plan could competitively bid its drug benefit administration to a pharmacy benefit manager (PBM), such as in the Medicare Part D and Federal Employees Health Benefits programs. Beyond manufacturer rebates, a PBM could generate additional savings through negotiating discounts from pharmacies through competitive pharmacy contracting, specialty pharmacy networks, and mail-order pharmacies. However, any such savings may be offset by PBM fees and retained rebates. For the purposes of this report, we have not modeled any potential savings or costs for the Public Plan associated with contracting a PBM.

---

35 Note that, for the purposes of this policy option, we are not considering the best price provision for brand-name drugs.

36 Subject to the same limitations as other private plans, e.g., essential health benefits (EHB) coverage requirements established under the Affordable Care Act.

37 340B covered entities can participate in the voluntary prime vendor program managed by the federal Health Resources and Services Administration (HRSA) or negotiate directly with manufacturers for discounts below the statutorily defined ceiling price (sub-340B ceiling price).

A.4. Benefits and projected rebates

Option (a) would establish a minimum statutory rebate on covered drugs equal to the "basic rebate" in Medicaid. This policy option is projected to decrease net drug spending (i.e., after rebates) for the Public Plan by 9-15% relative to current private insurance spending.

The minimum rebate (equal to 23.1% of the average manufacturer price for brand-name drugs) exceeds the current average rebate in the commercial market. For novel therapies, as well as drugs with limited competition, this minimum rebate may be superior to what some private payers could negotiate on their own. However, Option (a) would have smaller effects on highly competitive drug classes, which can have rebate levels already exceeding the minimum rebate, and also would not address price increases for existing drugs.

Table 1: Projected Total Gross and Net Drug Spending on PMPY Basis under Current Private Insurance Spending and Policy Option (a) in Calendar Year 2020

Per Member Per Year (PMPY) in CY 2020	Current	Option (a)
No supplemental rebates assumed		
Total prescription drug spending	1,214.3	$1,214.3
Estimated total rebates	(206.4)	(293.0)
Est. net drug spending	1,007.9	921.3
Difference vs. current ($)		**(86.6)**
Difference vs. current (%)		**(8.6%)**
Supplemental rebates @ 5% gross spend		
Total prescription drug spending	1,214.3	$1,214.3
Estimated non-supplemental rebates	(206.4)	(293.0)
Estimated supplemental rebates	—	(60.7)
Est. net drug spending	1,007.9	860.6
Difference vs. current ($)		**(147.3)**
Difference vs. current (%)		**(14.6%)**

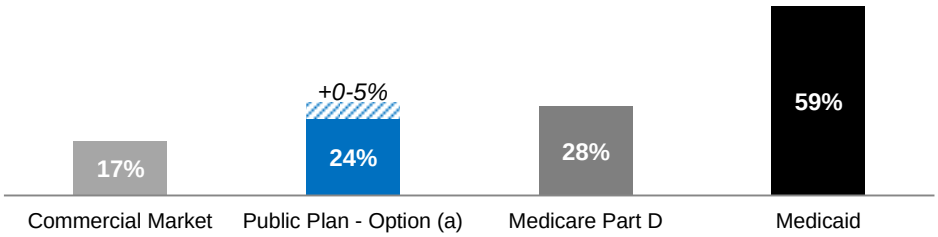
For competitive drug classes with multiple therapeutically comparable products, the Public Plan may be able to negotiate supplemental rebates with manufacturers. The magnitude of these supplemental rebates is uncertain. In Medicaid, state supplemental rebates account for roughly 2-5% of gross drug

expenditures.[38] If it is not subject to limitations on its bargaining ability or pharmacy benefit design, the Public Plan may be able to achieve supplemental rebates in line with some state Medicaid agencies. Considering this, we estimate that supplemental rebates negotiated by the Public Plan could account for up to 5% of gross drug spending.

Projected gross and net drug spending in CY 2020 under current private insurance spending and Option (a) are provided in Table 1. These projections reflect total spending, inclusive of the beneficiary share; we have not made any assumptions on the level of patient cost-sharing for prescription drugs that may be required by the Public Plan. Note that, for the purposes of this report, we have also not modeled any potential savings or costs for the Public Plan associated with contracting a PBM, or the potential impact of policy proposals or regulatory changes that could affect pharmaceutical pricing but that have not been enacted as of August 2019.

Including the impact of supplemental rebates, a comparison of the rebate fraction (rebates as a percentage of gross drug spending) across payers is provided below:

Figure 1: Estimated Rebate Fraction across Payers in Calendar Year 2020



Note: Projected rebate fractions in CY 2020 are presented as a fraction of total drug costs.

Thus, rebates achieved by the Public Plan under Option (a) are projected to be similar to, or slightly better than, those for Part D plans. However, net prices for drugs under Option (a) are likely to remain less favorable than those for other public programs, primarily due to the lack of inflation-linked rebates provided in the Medicaid program and to “Big 4” purchasers.

[38] Office of Inspector General. States' Collection of Offset and Supplemental Medicaid Rebates. OEI-03-12-00520. OIG, 2014.

A.5. Challenges and other considerations

To provide some context for this policy option, we have also qualitatively evaluated the potential administrative complexity, effects on drug prices and other purchasers, and formulary and coverage considerations.

A.5.1. *Administration*

We have assumed that the Public Plan will be administered by CMS and/or will be principally regulated by CMS. Since Option (a) relies on rebate systems that are already in place for the Medicaid program, the administrative complexity of this policy option is likely low.

Under section 1927 of the Social Security Act, manufacturers are required to report the average manufacturer price (AMP) for covered drugs to CMS each quarter. CMS uses the reported AMP to calculate the unit rebate, which it then sends to state Medicaid agencies. After the close of each reporting quarter, CMS could transmit this unit rebate calculation to the Public Plan, as it does for the states. However, for Option (a), the Public Plan's unit rebate would differ from the total Medicaid rebate and would need to be adjusted to exclude Medicaid's additional (inflation-linked) rebate.

The AMP is defined as the average price paid to a manufacturer by a wholesaler for drugs distributed to retail community pharmacies and by retail community pharmacies that purchase drugs directly from the manufacturer, with certain exclusions.[39] The AMP is not a list price and is, by rule, confidential. Under Option (a), it is possible that the AMP could be inferred from the unit rebate to the Public Plan (e.g., by backing out the 23.1% rebate). Although the possible legal ramifications are beyond the scope of this report, we note that there may be additional complexity if, as a result, the Public Plan needed to use an alternative to AMP or if CMS were unable to provide its unit rebate calculation.

A.5.2. *Effects on prices and other purchasers*

Given competing pressures on drug pricing, the potential impact of this policy option on manufacturer pricing and negotiations with other purchasers is uncertain. The magnitude of any possible effects is likely to be determined in

[39] For example, the AMP excludes price concessions to other federal programs (e.g., Medicare Part D) and to pharmacy benefit managers (PBMs).

part by the size of the Public Plan and corresponding manufacturer profit/loss. We have assumed that total enrollment and gross drug spending for the Public Plan will be smaller than that for Medicaid and Medicare Part D.

To offset the costs of providing the new rebates under Option (a), manufacturers may have an incentive to raise drug prices, both at and after launch, although other market forces will constrain their ability to do so. Consistent with prior analyses by the Congressional Budget Office and others, this effect on prices is probably small (less than 3% overall on average), but likely to vary by drug, with larger increases anticipated for drugs with few substitutes.[40] Under Option (a), the Public Plan would not be guaranteed additional rebates if drug prices rose faster than inflation. For drugs with little or no competition, the Public Plan may not be able to negotiate rebates that completely offset these price increases. As the proportion of drug spending accounted for by such products expands, it is possible that the rebates achieved by the Public Plan may decline somewhat over the long term.

If Option (a) were enacted, manufacturers would still have to negotiate with insurers and other public payers for formulary placement. Option (a) would not create new relationships or dependencies (e.g., external price referencing) that are likely to materially alter this negotiating equilibrium.[41] Therefore, consistent with the CBO, we assume that net prices for other purchasers would be largely unaffected by this policy option.

A.5.3. *Formularies and coverage*

In addition to utilization management requirements, such as prior authorization and step therapy, plans use formularies to negotiate discounts with manufacturers. Plans may offer “preferred” status with lower patient cost-sharing or fewer utilization management requirements; they may also attempt to exclude coverage of a drug altogether. To maximize its negotiating power, the Public Plan would need to have control over its drug benefit design, including the formulary.

Under Option (a), we assume that the Public Plan would be permitted to establish a closed formulary, subject to coverage requirements in place for other plans in the private non-group or group markets. For qualified health plans and certain other plans, the Affordable Care Act established the essential

[40] Congressional Budget Office. Letter to Ranking Member Paul Ryan. November 4, 2010.

[41] We assume that any rebates provided to the Public Plan, similar to rebates offered to Part D plans, will be excluded from the “best price” provision in Medicaid.

health benefits requirement, which, for prescription drugs, requires coverage of the greater of 1 drug per class or the number covered by a benchmark plan. By contrast, in the Medicare Part D program, prescription drug plans are required to cover at least 2 drugs per class; in addition, for six protected drug classes (including cancer drugs), Part D plans are required to cover all or substantially all drugs. These protected class requirements are estimated by Part D plans to result in rebates that are 10-20% lower than those that could be achieved without such requirements.[23 42] Imposing restrictions on formulary design are likely to similarly decrease the aggregate value of rebates negotiated by the Public Plan. If legislators enacted coverage requirements that applied only to the Public Plan but not to competing private plans, the difference in net drug costs projected in the prior section may be further diminished.

A.6. Conclusions

Option (a) would establish a minimum statutory rebate on covered drugs equal to the "basic" rebate in Medicaid, which is currently 23.1% of the average manufacturer price for brand-name drugs. This policy option is projected to decrease net drug spending by 9-15% relative to current private insurance spending. The upper bound of this estimate reflects the possibility of the Public Plan negotiating supplemental rebates with manufacturers, particularly for competitive drug classes with multiple therapeutically comparable products. The administrative complexity of this policy option is expected to be low.

Without an inflation-linked rebate, the Public Plan may not be able to negotiate rebates that completely offset future drug price increases, and the rebates achieved by the Public Plan could decline somewhat over the long term. The lack of an inflation-linked rebate also explains the gap in rebates projected for Option (a) versus the other policy options considered in this report. Finally, the ability of the Public Plan to achieve lower net drug prices than other private plans may be mitigated by restrictions on bargaining power imposed through legislation, rulemaking, or other political mechanisms.

[42] Hwang TJ, Dusetzina SB, Feng J, Maini L, Kesselheim AS. Price Increases of Protected-Class Drugs in Medicare Part D, Relative to Inflation, 2012-2017. JAMA 2019;322(3):267-269.

B. Policy option (b): total Medicaid rebate

B.1. Summary

Option (b) would establish a statutory rebate on covered drugs equal to the total Medicaid rebate, which is comprised of the minimum basic rebate (23.1% of the average manufacturer price for brand-name drugs) and the additional (inflation-linked) rebate. This policy option is projected to decrease net drug spending by 46-49% relative to current private insurance spending. Option (b) is expected to result in net prices that are substantially lower than those for other payers. However, the Public Plan may be subject to Medicaid's drug coverage requirements and other restrictions on bargaining power.

B.2. Background

The Medicaid Drug Rebate Program was established by the Omnibus Budget Reconciliation Act of 1990.[43] Congress agreed to mandatory coverage of generally all drugs approved by the FDA in exchange for statutory rebates. These rebates were intended to ensure that Medicaid received the lowest (or "best") price offered to private payers and to insulate Medicaid from price increases exceeding inflation. Initially, rebates were only required for drugs paid through fee-for-service Medicaid. Under the Affordable Care Act, the minimum, or "basic," rebate rate was increased from 15.1% to 23.1%, and the rebate requirements were extended to include drugs paid by managed Medicaid plans.

Nearly thirty years after the program's creation, the federal government and states collect over $30 billion in Medicaid drug rebates annually, the majority attributed to inflation-linked, or "additional," rebates. The system for determining applicable rebates involves CMS, state Medicaid agencies, and manufacturers. Each quarter, under section 1927 of the Social Security Act, manufacturers provide confidential pricing data for covered drugs to CMS. Based on this, CMS calculates the per-unit rebate amount and transmits it to state Medicaid agencies. The states use the unit rebate amount from CMS to invoice manufacturers for rebates; manufacturers then pay rebates to the states. These rebates are shared by CMS and the states on the basis of each state's federal medical assistance percentage (FMAP). Note that states' collection of federal Medicaid rebates each quarter from manufacturers is entirely separate from their payments to pharmacies. Every state receives the same per-unit rebate,

[43] Omnibus Budget Reconciliation Act of 1990. Pub. L. 101–508.

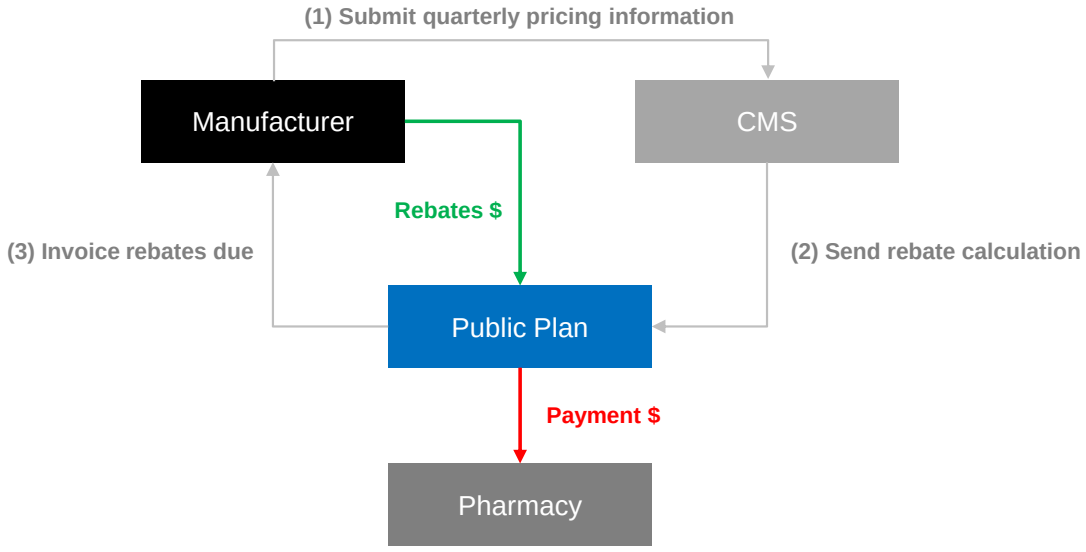
but how much is paid to pharmacies and providers may vary by state; as a result, the net price for drugs can vary by state.

B.3. Implementation

B.3.1. *Statutory rebates*

Under Option (b), the Public Plan would receive a minimum rebate on covered drugs equal to the total Medicaid drug rebate, which is comprised of the "basic" rebate (the greater of 23.1% of the average manufacturer price [AMP] for brand-name drugs[44] or the difference between AMP and the "best price") and the "additional" (i.e., inflation-linked) rebate.[45] "Best price" is defined as the lowest price available to any private non-governmental payer, wholesaler, retailer, or provider in the US, with certain exceptions.[46] The "additional" rebate is defined as the amount that a drug's current quarter AMP exceeds its baseline AMP trended to the current period by the Consumer Price Index for All Urban Consumers (CPI-U). The Affordable Care Act capped the maximum total Medicaid rebate (sum of the basic and additional rebates) at 100% of AMP. The implementation of this policy option may be simplified by relying on the operational architecture already in place for the Medicaid program.

Specifically, CMS already calculates and sends unit rebate information to the states. Thus, Option (b) may be implemented as follows:



44 Defined as single-source or innovator multiple-source drugs.

45 The basic Medicaid rebate is equal to 17.1% of AMP for blood clotting factor drugs and drugs approved exclusively for pediatric indications, and 13% of AMP for generic drugs.

46 See § 1927(c)(1)(C)(i) of the Social Security Act.

To receive federal payment for covered drugs under Medicaid, manufacturers enter into national rebate agreements with the Secretary and pay quarterly rebates to states. The Medicaid Drug Rebate Program is technically voluntary, but participation is required for payment under Medicare and other public programs. As such, most manufacturers have entered into rebate agreements pursuant to this program. For the purposes of this report, we have assumed that total enrollment and gross drug spending for the Public Plan will be smaller than that for Medicaid and Medicare Part D. It is possible that some manufacturers may threaten to refuse to pay these new statutory rebates for previously privately-insured individuals. The statute enacting Option (b) could direct the agency to update existing rebate agreements so as to require that manufacturers provide rebates for the Public Plan to receive payment under Medicaid, Medicare, or other public programs.[47] There is precedent for such an approach: manufacturers are required to provide discounts to 340B entities and the VA—both of which are considerably smaller in size than Medicaid—to be reimbursed by Medicaid.

In addition, the Public Plan would invoice manufacturers for the statutory rebates, and these rebates would be paid directly by manufacturers to the Public Plan. For state Medicaid agencies, CMS calculates the unit rebate offset amount: increased Medicaid rebates under the ACA are applied on a dollar-for-dollar basis against the amounts that CMS reimburses to the states for Medicaid in accordance with the state's FMAP. We assume that there is no federal offset or sharing of rebates between the Public Plan and the federal government; CMS would act solely as an intermediary for confidential pricing and rebate calculation data.

B.3.2. *Supplemental rebates*

As discussed in § 5(A)(3), in general, the Public Plan could potentially negotiate supplemental rebates with manufacturers for certain drugs, most likely for competitive drug classes with multiple therapeutically comparable products. These supplemental rebates may be offered by manufacturers in exchange for more favorable formulary placement (e.g., preferred status) or less restrictive utilization management (e.g., prior authorization).

[47] Since AMP reporting is already required under the Medicaid Drug Rebate Program, no specific new requirements for price reporting are likely needed.

In the Medicaid program, states can individually or collectively negotiate supplemental rebates; Medicaid managed care plans can also negotiate their own rebates with manufacturers. Consistent with a report by the Office of Inspector General,[48] we assume that the potential for supplemental rebates is likely to be lower under Option (b), as compared to Option (a), since the size of the statutory rebates is much higher.

It is also possible that the Public Plan could competitively bid its drug benefit administration to a pharmacy benefit manager (PBM), such as in the Medicare Part D and Federal Employees Health Benefits programs. Beyond manufacturer rebates, a PBM could generate additional savings through negotiating discounts from pharmacies through competitive pharmacy contracting, specialty pharmacy networks, and mail-order pharmacies. However, any such savings may be offset by PBM fees and retained rebates. For the purposes of this report, we have not modeled any potential savings or costs for the Public Plan associated with contracting a PBM.

B.4. Benefits and projected rebates

Option (b) would establish a statutory rebate on covered drugs equal to the total Medicaid rebate, which is comprised of the minimum basic rebate (23.1% of AMP) and the additional (inflation-linked) rebate. This policy option is projected to decrease net drug spending (i.e., after rebates) for the Public Plan by 46-49% relative to current private insurance spending.

Option (b) is expected to result in net prices for the Public Plan that are substantially lower than those for private payers and most other public payers in the US. Even without the inflation-linked rebate, the basic Medicaid rebate alone exceeds the current average rebate in the commercial market. For novel therapies, as well as drugs with limited competition, this minimum rebate may be superior to what some private payers could negotiate on their own. In addition, for highly competitive drugs and drugs with repeated price increases, the additional (inflation-linked) rebate can be substantial. The Medicaid and CHIP Payment and Access Commission (MACPAC) estimates 18.5% of brand-name drugs have a total rebate of at least 100%–that is, net costs to states are zero–because of price increases since market launch.[49]

[48] Office of Inspector General. States' Collection of Offset and Supplemental Medicaid Rebates. OEI-03-12-00520. OIG, 2014.

[49] Medicaid and CHIP Payment and Access Commission (MACPAC). April 2019 Public Meeting.

For competitive drug classes with multiple therapeutically comparable products, the Public Plan may be able to negotiate supplemental rebates with manufacturers. As discussed in § 5(B)(3), consistent with OIG, we assume that the potential for supplemental rebates is likely to be lower under Option (b), as compared to Option (a), since the size of the statutory rebates is much higher. Considering this, we estimate that supplemental rebates negotiated by the Public Plan could account for up to 2% of gross drug spending.

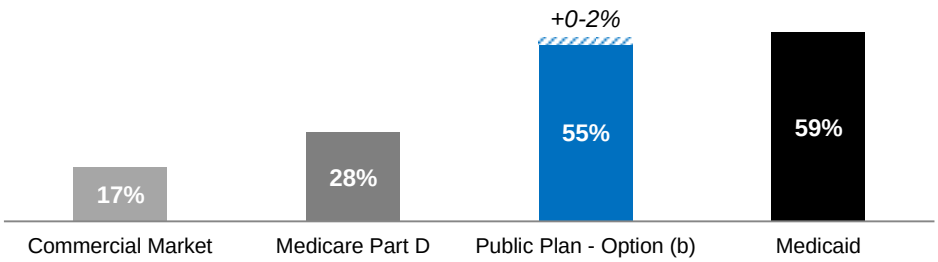
Projected gross and net drug spending in CY 2020 under current private insurance spending and Option (a) are provided in Table 2. These projections reflect total spending, inclusive of the beneficiary share; we have not made any assumptions on the level of patient cost-sharing for prescription drugs that may be required by the Public Plan. Note that, for the purposes of this report, we have also not modeled any potential savings or costs for the Public Plan associated with contracting a PBM, or the potential impact of policy proposals or regulatory changes that could affect pharmaceutical pricing but that have not been enacted as of August 2019.

Table 2: Projected Total Gross and Net Drug Spending on PMPY Basis under Current Private Insurance Spending and Policy Option (b) in Calendar Year 2020

Per Member Per Year (PMPY) in CY 2020	Current	Option (b)
No supplemental rebates assumed		
Total prescription drug spending	1,214.3	$1,214.3
Estimated total rebates	(206.4)	(671.7)
Est. net drug spending	1,007.9	542.6
Difference vs. current ($)		**(465.3)**
Difference vs. current (%)		**(46.2%)**
Supplemental rebates @ 2% gross spend		
Total prescription drug spending	1,214.3	$1,214.3
Estimated non-supplemental rebates	(206.4)	(671.7)
Estimated supplemental rebates	—	(24.3)
Est. net drug spending	1,007.9	518.3
Difference vs. current ($)		**(489.6)**
Difference vs. current (%)		**(48.6%)**

Including the impact of supplemental rebates, a comparison of the rebate fraction (rebates as a percentage of gross drug spending) across payers is provided below:

Figure 2: Estimated Rebate Fraction across Payers in Calendar Year 2020



Note: Projected rebate fractions in CY 2020 are presented as a fraction of total drug costs.

Thus, rebates achieved by the Public Plan under Option (b) are projected to be substantially better than those for Part D plans and the commercial market. We anticipate that net prices for the Public Plan under Option (b) may be marginally less favorable than those for Medicaid overall, due to smaller supplemental rebates provided to the Public Plan as compared to state Medicaid programs.

B.5. Challenges and other considerations

The mechanisms for setting pharmaceutical prices are complex, and analyzing the effects of any policy option on those prices is necessarily uncertain. To provide some context for this policy option, we have also qualitatively evaluated the potential administrative complexity, effects on drug prices and other purchasers, and formulary and coverage considerations.

B.5.1. *Administration*

We have assumed that the Public Plan will be administered by CMS and/or will be principally regulated by CMS. Since Option (b) relies on rebate systems that are already in place for the Medicaid program, the administrative complexity of this policy option is likely low.

In contrast to Option (a), no adjustment to the unit rebate calculation would be needed in Option (b) since the Public Plan will be receiving the total Medicaid rebate, i.e., inclusive of Medicaid's basic and additional rebates. Thus, after the

close of each reporting quarter, CMS would transmit the standard unit rebate calculation to the Public Plan, as it does for the states.

B.5.2. *Effects on prices and other purchasers*

Given competing pressures on drug pricing, the potential impact of this policy option on manufacturer pricing and negotiations with other purchasers is highly uncertain. To offset the costs of providing the new rebates under Option (b), manufacturers may have an incentive to raise drug prices, although other market forces will constrain their ability to do so. In particular, the mandatory rebates will insulate the Public Plan from price increases that exceed inflation,[50] and competition in drug classes with multiple therapeutically comparable products may also help to limit the extent to which manufacturers can charge higher prices for certain products. Consistent with the CBO's prior analyses of pharmaceutical policies, it is possible that Option (b) could result in a small to moderate increase in drug prices, possibly in the range of 4-7% overall on average. This effect on prices could grow over time with changes in drug mix due to introduction of costly new therapies, but the rebates achieved by the Public Plan would likely continue to be substantially greater than those in the commercial market.

Option (b) is likely to amplify the effects of the "best price" provision (that Medicaid and the Public Plan pay an amount less than or equal to the lowest price paid by any private purchaser in the US) in the Medicaid Drug Rebate Program, which could have implications for other private payers. This provision has been reported to discourage manufacturers from offering rebates larger than the minimum Medicaid rebate to private payers, because any such rebates would automatically trigger a larger rebate to Medicaid (and the Public Plan).[51] Option (b) may contribute to the widening gap in rebates and net prices for private versus public payers over the long term. The magnitude of any possible effects may be determined in part by the size of the Public Plan. If the Public Plan were to capture a substantial proportion of the commercial market, and if drug spending by the Public Plan were to exceed that of Medicaid and Medicare Part D, we cannot exclude the possibility of a material effect of this policy option on net prices for other purchasers.

[50] Manufacturers may attempt to circumvent the inflation penalty by introducing new formulations or versions, which traditionally have been considered "new" products for the purposes of the Medicaid Drug Rebate Program. In response, the Affordable Care Act established the line extension rebate, although implementation of this rebate has been delayed by uncertainty around the definition of a line extension. The definition of a line extension as a new formulation was formalized in a final rule issued in March 2019.

[51] Congressional Budget Office (CBO). How the Medicaid rebate on prescription drugs affects pricing in the pharmaceutical industry. CBO, 1996.

B.5.3. *Formularies and coverage*

Plans use formularies and utilization management requirements (such as prior authorization) to negotiate discounts with manufacturers. For example, plans may offer "preferred" status with lower patient cost-sharing or fewer utilization management requirements, in exchange for steeper rebates. They may also attempt to exclude coverage of a drug if multiple therapeutically comparable products are already covered in a given drug class.

We assume that the Public Plan would face strong pressure under Option (b) to conform to the drug coverage requirements that apply to Medicaid, since it would be benefiting from the full Medicaid rebate amount. As discussed in § 5(B)(2), the Medicaid Drug Rebate Program reflects a legislative compromise that established statutory rebates in exchange for a federal mandate for coverage of generally all drugs approved by the FDA. An attempt by Massachusetts to request a waiver under Section 1115 of the Social Security Act from this federal coverage requirement was denied by CMS. The state proposed to establish a closed formulary and exclude coverage of drugs with limited evidence of clinical benefit. In its decision, CMS stated that Massachusetts would have to forgo all Medicaid rebates to implement a closed formulary as the state initially requested. Requiring the same level of drug coverage as Medicaid would likely constrain the negotiating ability of the Public Plan and would probably decrease the aggregate value of supplemental rebates achieved by the Public Plan relative to Option (a).

States cannot exclude coverage, but they may use prior authorization and preferred drug lists to manage spending on costly drugs. Even so, restrictions on coverage may be subject to lawsuits: in fact, courts have consistently ruled against state Medicaid restrictions over the years.[52] [53] For example, in November 2015, CMS notified state Medicaid programs that restrictions on a class of new drugs for hepatitis C infection may be contrary to federal law.[54]

[52] Mello MM, Studdert DM, Brennan TA. The pharmaceutical industry versus Medicaid--limits on state initiatives to control prescription-drug costs. N Engl J Med 2004;350(6):608-13.

[53] B.E. *v.* Teeter, Case No. C16-227-JCC (W.D. Wash. May 27, 2016)

[54] Centers for Medicare and Medicaid Services (CMS). Medicaid Drug Rebate Program Notice: Assuring Medicaid beneficiaries access to hepatitis C (HCV) drugs. November 5, 2015.

B.6. Conclusions

Option (b) would establish a statutory rebate on covered drugs equal to the total Medicaid rebate, which is comprised of the minimum basic rebate (23.1% of AMP) and the additional (inflation-linked) rebate. This policy option is projected to decrease net drug spending by 46-49% relative to current private insurance spending. Option (b) is expected to result in net prices that are substantially lower than those for private payers in the US. The administrative complexity of this policy option is expected to be low.

However, since it would be benefiting from the full Medicaid rebate amount, the Public Plan may be required to conform to Medicaid's drug coverage requirements (covering essentially all drugs approved by the FDA). The Public Plan may be subject to other restrictions on its bargaining power imposed through legislation, rulemaking, or other political mechanisms. Finally, this policy option may have effects on net prices for other purchasers to the extent that Medicaid's "best price" provision discourages manufacturers from offering rebates larger than the minimum Medicaid rebate to private payers.

C. Policy option (c): Big 4 drug rebate

C.1. Summary

Option (c) would establish a statutory rebate on covered drugs equal to the rebate offered to Big 4 agencies, which is at least 24% of the non-federal AMP and any additional inflation-linked discounts. This policy option is projected to decrease net drug spending by 28-34% relative to current private insurance spending. Although Option (c) is expected to result in greater rebates than those for private payers in the US, it is possible that this policy may have effects on Big 4 drug prices and net prices for other private payers.

C.2. Background

The VA pharmaceutical pricing system was established by the Veterans Health Care Act of 1992, which created new requirements for manufacturers selling drugs to the VA and other federal agencies. Under the Veterans Health Care Act, manufacturers were required to offer a Federal Ceiling Price (FCP; synonymous with “Big 4 price”), defined as no more than 76% of the non-federal average manufacturer price (non-FAMP), minus any additional (inflation-linked) discounts as determined each year. The non-FAMP is defined as the average price paid to the manufacturer by wholesalers (or others who purchase directly from the manufacturer) for drugs distributed to nonfederal purchasers, taking into account any cash discounts or similar price reductions given to those purchasers. The FCP was made available to four federal agencies: VA, Department of Defense, Public Health Service (including Indian Health Service), and Coast Guard.

The VA, through delegated authority from the General Services Administration, also administers the Federal Supply Schedule (FSS) for drugs and other medical supplies and equipment. The FSS is open to the Big 4 agencies as well as other federal agencies in the executive, legislative and judicial branches, and several other purchasers, including the Bureau of Prisons, District of Columbia, and Indian tribal governments. Manufacturers can choose to offer separate FCP and FSS prices (dual pricing) or offer a FSS price equal to the FCP (single pricing). For both FCP and FSS prices, the VA’s National Acquisition Center awards multi-year contracts, which set out price conditions and reporting requirements (including disclosure of pricing for most favored commercial customers). There is no minimum rebate required for FSS prices. Under federal procurement regulations, the VA should “seek to obtain the

offeror's best price (the best price given to the most favored customer)"; however, this is a negotiation objective and not a requirement.[55]

The VA and Department of Defense (military treatment facilities) can negotiate additional discounts below the FCP and FSS prices by leveraging their closed formularies. The VA established a national formulary in 1997, replacing its previous system of local formulary decisions. The creation of the VA national formulary was associated with reduced drug spending as well as negotiated price reductions considerably below the lowest prices available to other purchasers.[56]

Note that there is no explicit relationship between the "best price" referenced for FSS procurement and the "best price" in the Medicaid Drug Rebate Program. In fact, the early years of Medicaid's drug rebates influenced VA pharmaceutical purchasing. In 1990, Congress established the Medicaid Drug Rebate Program as part of the Omnibus Budget Reconciliation Act of 1990.[57] Initially, the VA was included in the "best price" rule, thus entitling the Medicaid to any price reductions negotiated by the VA and other federal purchasers. However, early studies after the legislation's passage suggested that this provision was associated with somewhat increased prices for the VA.[58] The resulting political pressure led Congress to exclude the VA from the Medicaid best price rule in the Veterans Health Care Act passed two years later.

C.3. Implementation

C.3.1. *Statutory rebates*

Under Option (c), the Public Plan would receive a minimum statutory rebate on covered drugs equal to the rebate offered to the "Big 4" agencies, which is defined as 24% of the non-federal average manufacturer price (non-FAMP) and any additional inflation-linked discounts. The FCP can be lower than or equal to the Federal Supply Schedule (FSS) price, which is negotiated by the VA for both Big 4 and non-Big 4 government agencies with the objective of meeting the manufacturer's most favored commercial customers. Option (c) could be modified to specify that the Public Plan would pay no more than the lesser of

55 See 48 CFR § 538.270-1 ("However, the Government recognizes that the terms and conditions of commercial sales vary and there may be legitimate reasons why the best price is not achieved.")

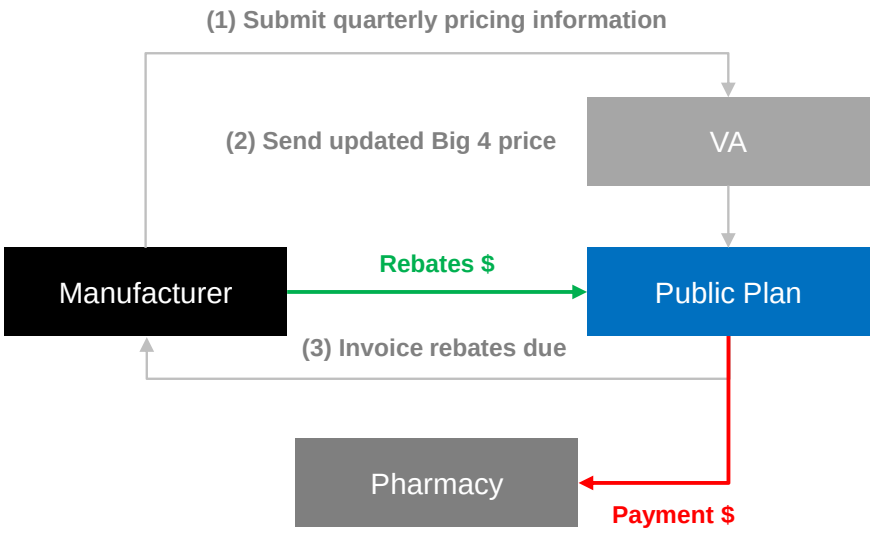
56 Huskamp HA, Epstein AM, Blumenthal D. The impact of a national prescription drug formulary on prices, market share, and spending: lessons for Medicare? Health Affairs 2003;22(3):149-58.

57 Omnibus Budget Reconciliation Act of 1990. Pub. L. 101–508.

58 Scott Morton F. The strategic response by pharmaceutical firms to the Medicaid most favored-customer rules. The RAND Journal of Economics 1997;28(2):269-290.

the FCP or FSS price. For the drugs analyzed in the study basket, none had FSS prices that were lower than the FCP. Therefore, for the purposes of this report, we have simplified Option (c) to focus on the Big 4 price (FCP).

Manufacturers enter into "master agreements" with the Secretary of Veterans Affairs, under which FSS (and FCP) prices are provided for covered drugs. During the life of the contract for a given drug, manufacturers must report non-FAMP each quarter. Prior to contract award, the VA and manufacturer may also agree on a price reductions clause: the manufacturer is required to report all price reductions offered to pre-specified customers or category of customers, and, if applicable, provide the same discounts to the government. To implement Option (c), the enacting statute for a Public Plan could require that manufacturers directly report the non-FAMP, and any applicable additional discounts, directly to the Public Plan; alternatively, the VA could be directed to share that pricing data with the Public Plan. For example, Option (c) may be implemented as follows:



Manufacturers are already required to participate in the FSS program to receive payment from the Big 4 agencies and Medicaid.[59] Since non-FAMP reporting is required under the VA's contracts and master agreements, it is unclear if specific new requirements for price reporting are needed. However, the enacting statute could direct the VA to update the master agreements to make explicit that manufacturers must provide rebates for the Public Plan to receive payment from the Big 4 agencies and Medicaid. In addition, these contracts may need to be updated to allow either the VA or the manufacturer to share

[59] See 38 U.S.C. 8126 (a)(4).

contract terms (pricing, price reduction clause, as applicable, etc.) with the Public Plan.

Big 4 drug purchases are often made through a distributor or other intermediary, and the FCP represents the maximum price for such purchase. In this simplified Big 4 system, the published price is equal to the net price. By contrast, the Public Plan would likely pay for drugs similarly to the vast majority of payers in the US (Medicaid, Part D plans, and private plans), which involves a list price and *post hoc* rebates. In that case, the Public Plan would need to require that manufacturers pay rebates equal to the difference between its reimbursed cost (or at some list price benchmark to be agreed) and the Big 4 price. For the purposes of this report, we have not considered the possibility of the Public Plan adopting the centralized drug procurement system used by the VA or other Big 4 agencies.

C.3.2. *Supplemental rebates*

We assume that the Public Plan will be offered alongside private plans in the non-group and/or commercial group insurance markets, and will function like other private plans with respect to the pharmacy benefit: control formulary design and apply utilization management.[60] For competitive drug classes with multiple therapeutically comparable products, manufacturers may be incentivized to offer additional discounts in exchange for more favorable formulary placement (e.g., preferred status) or less restrictive utilization management (e.g., prior authorization). As such, it is possible that the Public Plan will be able to directly negotiate supplemental rebates with manufacturers. Notably, the VA can, and does, negotiate drug prices below the FCP offered to the Big 4 agencies. From 2012-2014, approximately a quarter of VA drug spending was at prices that were a median of 9% to 43% lower than the Big 4 price.[61] Similarly, the Department of Defense's military treatment facilities can negotiate further discounts using its preferred formulary.

It is also possible that the Public Plan could competitively bid its drug benefit administration to a pharmacy benefit manager (PBM), such as in the Medicare Part D and Federal Employees Health Benefits programs. Beyond manufacturer rebates, a PBM could generate additional savings through negotiating discounts from pharmacies through competitive pharmacy

60 Subject to the same limitations as other private plans, e.g., essential health benefits (EHB) coverage requirements established under the Affordable Care Act.

61 Report for the US Department of Veterans Affairs: Assessment J (Supplies). McKinsey & Company, Inc. September 1, 2015.

contracting, specialty pharmacy networks, and mail-order pharmacies. However, any such savings may be offset by PBM fees and retained rebates. For the purposes of this report, we have not modeled any potential savings or costs for the Public Plan associated with contracting a PBM.

C.4. Benefits and projected rebates

Option (c) would establish a statutory rebate on covered drugs equal to the rebate offered to Big 4 agencies, which is defined as 24% of the non-federal AMP and any additional inflation-linked discounts. This policy option is projected to decrease net drug spending (i.e., after rebates) for the Public Plan by 28-34% relative to current private insurance spending.

Option (c) is expected to result in net prices for the Public Plan that are lower than those for private payers. For novel therapies, as well as drugs with limited competition, the minimum rebate of 24% of non-FAMP may be superior to what some private payers could negotiate on their own. For competitive drug classes with multiple therapeutically comparable products, the Public Plan may be able to negotiate supplemental rebates with manufacturers. The magnitude of these supplemental rebates is uncertain. The VA can leverage its closed formulary to negotiate prices that are a median of 9-43% lower than the Big 4 price for drugs accounting for roughly a quarter of its drug spending. However, it appears unlikely that the Public Plan could achieve net prices as favorable as the VA's, which are the lowest or among the lowest in the country. The VA's disproportionate pricing power relative to its size may be explained by the fact that it operates an integrated health care system; it plays an important role in the training of physicians and other healthcare professionals; and it uses a centralized pharmaceutical distribution system for virtually all drug spending, receiving an additional discount from its distributor (known as the prime vendor). Considering this, we estimate that supplemental rebates negotiated by the Public Plan could account for up to 5% of gross drug spending.

Projected gross and net drug spending in CY 2020 under current private insurance spending and Option (a) are provided in Table 3. These projections reflect total spending, inclusive of the beneficiary share; we have not made any assumptions on the level of patient cost-sharing for prescription drugs that may be required by the Public Plan. Note that, for the purposes of this report, we have also not modeled any potential savings or costs for the Public Plan associated with contracting a PBM, or the potential impact of policy proposals

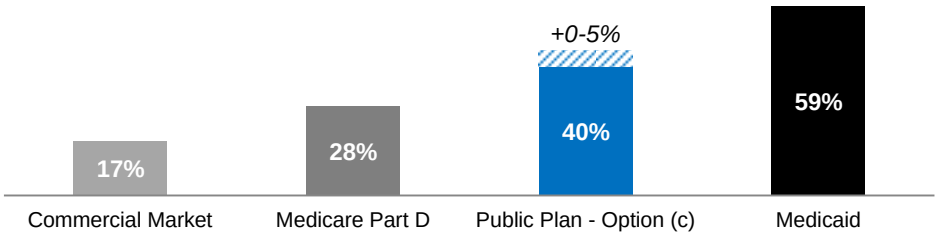
or regulatory changes that could affect pharmaceutical pricing but that have not been enacted as of August 2019.

Table 3: Projected Total Gross and Net Drug Spending on PMPY Basis under Current Private Insurance Spending and Policy Option (c) in Calendar Year 2020

Per Member Per Year (PMPY) in CY 2020	Current	Option (c)
No supplemental rebates assumed		
Total prescription drug spending	1,214.3	$1,214.3
Estimated total rebates	(206.4)	(488.8)
Est. net drug spending	1,007.9	725.5
Difference vs. current ($)		**(282.4)**
Difference vs. current (%)		**(28.0%)**
Supplemental rebates @ 5% gross spend		
Total prescription drug spending	1,214.3	$1,214.3
Estimated non-supplemental rebates	(206.4)	(488.8)
Estimated supplemental rebates	—	(60.7)
Est. net drug spending	1,007.9	664.8
Difference vs. current ($)		**(343.1)**
Difference vs. current (%)		**(34.0%)**

Including the impact of supplemental rebates, a comparison of the rebate fraction (rebates as a percentage of gross drug spending) across payers is provided below:

Figure 3: Estimated Rebate Fraction across Payers in Calendar Year 2020



Note: Projected rebate fractions in CY 2020 are presented as a fraction of total drug costs.

Thus, rebates achieved by the Public Plan under Option (c) are projected to be substantially better than those for Part D plans and the commercial market. We anticipate that net prices for the Public Plan under Option (c) would be less favorable than those for Medicaid overall, primarily due to differences in calculation of the inflation-linked rebate.

C.5. Challenges and other considerations

The mechanisms for setting pharmaceutical prices are complex, and analyzing the effects of any policy option on those prices is necessarily uncertain. To provide some context for this policy option, we have also qualitatively evaluated the potential administrative complexity, effects on drug prices and other purchasers, and formulary and coverage considerations.

C.5.1. *Administration*

We have assumed that the Public Plan will be administered by CMS and/or will be principally regulated by CMS, whereas necessary drug pricing and rebate information would be housed within the Department of Veterans Affairs. Since Option (c) will likely require new rebate systems, the administrative complexity of this policy option is higher than Options (a) and (b) above.

The Federal Supply Schedule and the Big 4 (or Federal Ceiling Price [FCP]) prices are administered by the National Acquisition Center of the VA under master agreements between manufacturers and the VA. Currently, each quarter, the VA provides the Department of Health and Human Services (HHS) with a list of manufacturers that have entered into master agreements. To implement this policy option, the quarterly information sharing between VA and HHS could be expanded to include the FCP (and FSS price, if applicable) for all covered drugs. It may not be necessary to require disclosure of the non-FAMP or specific contract terms. To the extent that the FCP and FSS prices are publicly available and not commercially sensitive, this may simplify the administrative and legal complexity of this policy option.

We have assumed that the Public Plan would pay for drugs similarly to the vast majority of payers in the US (Medicaid, Part D plans, and private plans), which involves a list price and separate *post hoc* rebates. In this case, Option (c) would require converting the Big 4's FCP into an applicable rebate for the Public Plan. For example, suppose that the pharmacy (or list) price for a drug is $100, and the FCP negotiated for the Big 4 agencies is $80. In this case,

- The VA would pay its distributor directly (through its centralized distribution system) $80 for the drug; whereas
- The Public Plan would reimburse the pharmacy $100 and would receive a separate rebate from the manufacturer for $20 (*list price minus FCP*)

State Medicaid agencies similarly reimburse pharmacies based on pharmacies' acquisition costs, while the rebates are defined as a percentage of AMP.[62] The Public Plan would need to define which benchmark list price (allowed cost, pharmacy acquisition cost, wholesale acquisition cost, etc.) will serve as the basis for the rebate.

C.5.2. *Effects on prices and other purchasers*

Given competing pressures on drug pricing, the potential impact of this policy option on manufacturer pricing and negotiations with other purchasers is highly uncertain. To offset the costs of providing the new rebates under Option (c), manufacturers may have an incentive to raise drug prices, although other market forces will constrain their ability to do so. The Public Plan will be partly shielded from price increases: over the life of the contract (e.g., every 5 years), additional discounts are required if price increases exceed inflation. However, since the index year may reset with each contract cycle, the inflation-linked discounts may be less favorable than those under Option (b); in Medicaid, price increases are compared to the date of market launch. Manufacturers may also attempt to circumvent the inflation penalty by introducing new formulations or versions, which could be considered "new" products for the purposes of Big 4 contracting.[63] Meanwhile, competition in drug classes with multiple therapeutically comparable products could help to limit the extent to which manufacturers can charge higher prices for certain products. Overall, consistent with prior analyses by the Congressional Budget Office and others, the net effect on prices is probably small (less than 3% overall on average), but likely to vary by drug, with larger increases anticipated for drugs with few substitutes.

Option (c) may have effects on Big 4 drug prices and possibly on net prices for private purchasers. Enrolling just 4-8 million people in the Public Plan could double the value of purchases possible at the Big 4 rate. Manufacturers may decline to offer discounts to Big 4 agencies except only those required by law,

62 Note that the AMP in Medicaid is defined differently from the non-federal AMP for the Big 4 agencies.

63 Similar concerns in the Medicaid program led to the development of the line extension rebate under the Affordable Care Act, although implementation of this rebate was subsequently delayed by uncertainty around the definition of a line extension.

and Big 4 prices may rise, converging at the statutory level. Manufacturers may also shift some discounts to confidential rebates that are available to Big 4 agencies but not reflected in the published Big 4 price; the VA and Department of Defense already individually negotiate such rebates with manufacturers. One commonly-cited precedent occurred in 1990, when Congress initially included the VA in the best price provision of the Medicaid Drug Rebate Program. Early studies after the legislation's passage suggested that this provision was associated with increased prices for the VA.[64]

Option (c) may have implications for other private payers, similar to the mechanism discussed in § 5(B)(5) above with the best price provision in Medicaid. Manufacturers are required to disclose commercial sales practices (prices, discounts, and concessions to commercial customers) so that the VA can assess the fairness of the offered contract prices. The VA will "seek to obtain the offeror's best price (the best price given to the most favored customer)," though this is a negotiation objective and not a requirement.[65] With each contract, the VA and manufacturer may agree on a customer or category of customers (the "tracking customer") subject to a price reductions clause. Any price reductions, discounts, or other commercial arrangements that could affect price and that are provided to the tracking customer must also be extended to the government. Thus, similar to the best price provision in Medicaid, the Big 4 contracts could further discourage manufacturers from offering rebates larger than the minimum statutory rebate to private payers, because any such rebates would automatically trigger a larger rebate to not only the Big 4 agencies but also the Public Plan. The magnitude of any possible effects may be determined in part by the size of the Public Plan.

C.5.3. *Formularies and coverage*

To maximize its negotiating power, the Public Plan would need to have control over its drug benefit design, including formulary and utilization management requirements. Under Option (c), we assume that the Public Plan would be permitted to establish a closed formulary, subject to coverage requirements in place for other plans in the private non-group or group markets.[66] The VA and other Big 4 agencies use closed formularies. For over two decades, the VA has

64 Scott Morton F. The strategic response by pharmaceutical firms to the Medicaid most favored-customer rules. The RAND Journal of Economics 1997;28(2):269-290.

65 See 48 CFR § 538.270-1 ("However, the Government recognizes that the terms and conditions of commercial sales vary and there may be legitimate reasons why the best price is not achieved.")

66 For qualified health plans and certain other plans, the Affordable Care Act established the essential health benefits requirement, which requires coverage of the greater of 1 drug per class or the number covered by a benchmark plan.

operated a national formulary intended to leverage the agency's purchasing power to obtain deeper discounts than individual facilities and to ensure consistency of care across the VA system. This is contrast to Medicaid, which is required to cover essentially all approved drugs approved by the FDA. We anticipate that the ability of the Public Plan to establish a formulary would allow it to obtain supplemental rebates in the range of values discussed in § 5(C)(4) above. However, imposing restrictions on formulary design are likely to decrease the aggregate value of rebates achieved by the Public Plan. If legislators enacted coverage requirements that applied only to the Public Plan but not to competing private plans, the difference in net drug costs projected in the prior section may be further diminished.

C.6. Conclusions

Option (c) would establish a statutory rebate on covered drugs equal to the rebate offered to Big 4 agencies, which is defined as 24% of the non-federal AMP and any additional inflation-linked discounts. This policy option is projected to decrease net drug spending by 28-34% relative to current private insurance spending. The upper bound of this estimate reflects the possibility of the Public Plan negotiating supplemental rebates with manufacturers, particularly for competitive drug classes.

Option (c) is expected to result in net prices that are substantially lower than those for private payers in the US. However, the administrative complexity of this policy option is expected to be higher than other policy options considered in this report. In addition, Option (c) may have effects on Big 4 drug prices and net prices for other private payers. Manufacturers may shift some discounts to confidential rebates that are available to Big 4 agencies but are not reflected in the public Big 4 price that would be referenced by the Public Plan. Finally, the ability of the Public Plan to achieve lower net drug prices than other private plans may be mitigated by restrictions on bargaining power imposed through legislation, rulemaking, or other political mechanisms.

6. Foreign Price Comparison

We also examined drug pricing systems used in peer high-income countries, namely Canada, Germany, Switzerland, and the United Kingdom. As discussed, for the purposes of this section, we have focused on Canada.

A. Background

Canada uses a combination of international price referencing, health technology assessment, and other methods to control prescription drug costs. In general, responsibility for health care in Canada is shared between the federal government and the provinces. For prescription drug coverage, there is not only inter-provincial variation in drug coverage but also parallel public and private drug plans. However, this fragmentation is balanced by federal regulation of drug prices that does not occur in the US; moreover, in recent years, there have been increasing efforts by provinces to cooperate on drug procurement and reimbursement.

The Patented Medicine Prices Review Board (PMPRB) is an independent, quasi-judicial agency established by Parliament under the Patent Act of 1987. The PMPRB regulates the maximum or ceiling (ex-factory) price for patented drugs that can be charged by manufacturers to pharmacies, hospitals, wholesalers, and other distributors in Canada. If the price of a drug is determined to be “excessive”, PMPRB can order a reduction of the price to a “non-excessive” level and clawback excess revenues earned. The PMPRB relies on international reference pricing. Note that Canada recently finalized changes in PMPRB regulations that removed the United States and Switzerland from its list of referenced countries; the amended regulation is anticipated to enter into force in 2021.

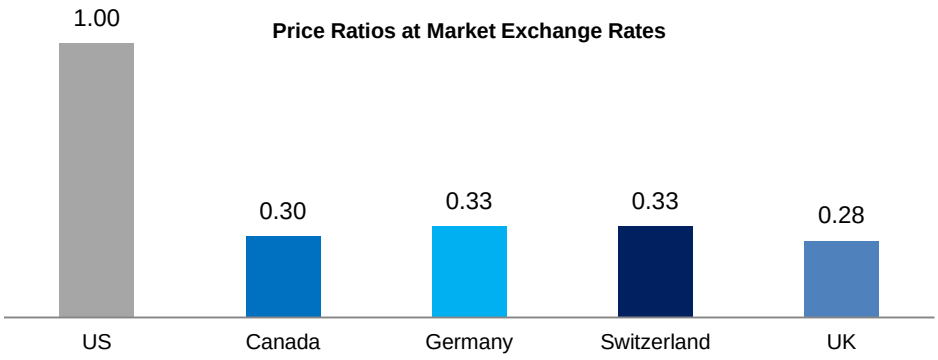
Separately from the PMPRB, federal, provincial, and territorial public drug plans determine which drugs, and what prices, are listed on their respective formularies for reimbursement. Public drug plans can conduct joint provincial/territorial/federal negotiations for brand name drugs through the pan-Canadian Pharmaceutical Alliance. In addition, the Canadian Agency for Drugs and Technologies in Health is a national health technology assessment (HTA) agency, which administers the Common Drug Review and pan-Canadian Oncology Drug Review; these HTA reviews lead to recommendations for which drugs should be reimbursed by participating public drug plans.

B. Price Comparison

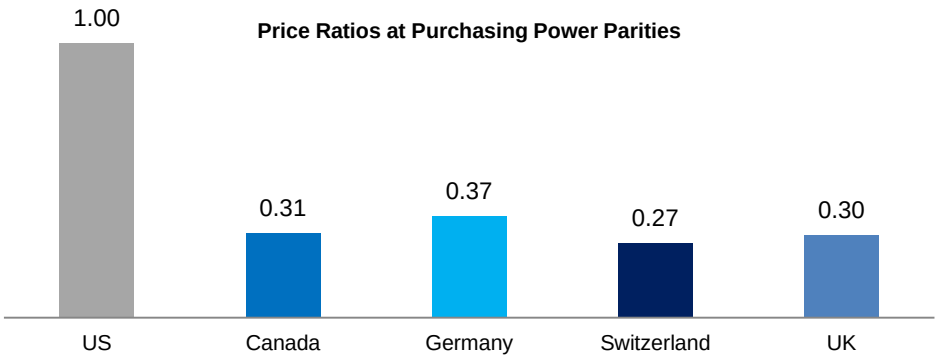
We extracted published unit drug prices from the public Drug Benefit Formulary of the Ontario Ministry of Health and Long-term Care as of March 2019. For each drug in the study basket, we identified the largest price difference between the Canadian price and the estimated net price for commercial payers in the US (updated to the first quarter of 2019) across all package sizes, dosages, strengths, and formulations. Price differences were then weighted by drug utilization for commercially insured lives in the US using the MarketScan database, as described in Appendix § B. Ontario is the most populous of the thirteen Canadian provinces and territories, accounting for nearly 40% of the country's population. We also manually reviewed prices from CADTH as well as the formularies for four other provinces: Alberta, British Columbia, Newfoundland and Labrador, and Saskatchewan. Since prices for the reviewed drugs were substantively similar across all five provinces, we report results from Ontario only.

The median price difference was 0.37 (interquartile range: 0.27-0.47) between the published Canadian price and the estimated net price (after rebates) for commercial payers. Weighted by MarketScan utilization, the published Canadian prices were 65% lower than estimated net prices (after rebates) for US commercial payers.

These results are broadly consistent with data collected by the PMPRB. Average foreign-to-US price ratios at market exchange rates in 2017 for the 1,381 drugs regulated by the PMPRB are provided below:



Average foreign-to-US price ratios in 2017 were similar using purchasing power parities, rather than market exchange rates, as shown below:



These data are not directly comparable, because they involve a much larger number of drugs and are weighted by Canadian (rather than US) utilization. Nonetheless, the PMPRB data show that Canadian prices are 69-70% lower on average than US prices, which is broadly consistent with our estimate of 65% (based on MarketScan utilization for our study basket).

C. Commentary

The foreign prices in the preceding subsection are provided as a qualitative comparison. These international price comparisons do not represent possible savings and are not intended to be directly compared with projections for the three policy options described in § 5 of this report.

Other countries often pay less for prescription drugs than public payers in the US, even after rebates. However, modeling the impact of international price referencing is challenging because of the likely compensatory changes in drug pricing by manufacturers. Such changes would be amplified if a US payer were to adopt this approach given how much more profitable the US market is compared to foreign countries.

International price referencing programs have been associated with manufacturer gaming as well as greater delays in product launch, particularly in smaller and lower-income countries. If the Public Plan were required to pay the same prices as Canada, manufacturers could attempt to circumvent this policy, e.g., by:

- Raising the referenced prices in Canada, shrinking the anticipated price differential (and therefore expected savings);
- Offering Canadian payers “secret” discounts unobservable under US law, while eliminating differences in list prices between the US and Canada;

- Delaying launch in Canada to prevent the Public Plan from being able to identify a comparable Canadian price; and
- Developing country-specific drug formulations, packages, or variations, to hinder the Public Plan's ability to identify a comparable Canadian price

Critics of international price referencing argue that it can distort pharmaceutical markets, by creating an incentive for manufacturers to withhold drugs from countries with lower willingness to pay and by preventing manufacturers from being able to price discriminate between purchasers. For example, international price referencing was associated with drug launch delays of up to three years on average for Eastern European countries, as compared to wealthier Western European countries.[67] In addition, these programs may accelerate the incentive for both countries and manufacturers to negotiate confidential rebates (the so-called "gross-to-net bubble") that could obviate any potential savings. Some commentators have suggested that international reference pricing contributed to the introduction of confidential pricing methods in France and the UK, which are among the most commonly referenced countries; net prices in both countries are now no longer available.[68] Given controversy around international price referencing, some countries, such as Germany and Canada, have shifted focus from external price referencing to cost-effectiveness analyses and health technology assessment.[69] [70]

[67] Maini L, Pammolli F. Reference pricing as a deterrent to entry: evidence from the European pharmaceutical market; Carone G, Schwierz C, Xavier A. Cost-containment policies in public pharmaceutical spending in the EU.

[68] European Commission. External reference pricing of medicinal products: simulationbased considerations for crosscountry coordination. Final report. EC, 2014.

[69] Ruggeri K, Nicole E. Pharmaceutical pricing: the use of external reference pricing. RAND Europe, 2013.

[70] Government of Canada. Regulations Amending the Patented Medicines Regulations. GC, 2017.

7. Appendix

A. Agreed Assumptions

Adjustment of MarketScan data for total commercial market

We analyzed whether estimates of gross and net drug spending in MarketScan may be applied to the total commercial market or whether an adjustment would be needed (e.g., to scale up MarketScan estimates to the total commercial market). Our review (see Methods for details) suggests that drug spending on a per-member basis in MarketScan is in line with the experience of commercial insurers nationally. Thus, we have agreed that the MarketScan drug spending estimates may be applied to the Urban Institute model on a per-member-per-year (PMPY) basis.

Trending current year forward to Urban Institute model start date (CY 2020)

We understand that the Urban Institute model for the Public Plan will begin in CY 2020. However, drug spending data from MarketScan reflect actual CY 2017 experience. Thus, we have agreed that the National Health Expenditures estimates (specific to private health insurance) will be used to trend forward gross drug spending estimates to CY 2020.

Accounting for member cost-sharing

In the commercial market, member cost-sharing (out-of-pocket costs) can account for up to 10% of total drug spending for brand-name drugs. We have agreed that all projections will be on the basis of total drug spending. We have not made any assumptions on the level of patient cost-sharing for prescription drugs that may be required by the Public Plan.

B. Study Drug Basket

Brand Name(s)
Humira
Enbrel
Stelara
Vyvanse
Lantus, Toujeo
Copaxone
Novolog
Tecfidera
Victoza
Norditropin, Humatrope
Humalog
Harvoni
Trulicity
Truvada
Cialis
Gilenya
Januvia
Genvoya
Lialda
Advair
Lyrica
ProAir
Revlimid
Cosentyx
Janumet
Xyrem
Otezla
Atripla
Triumeq
Invokana
Viagra
Xarelto
Levemir
Ibrance
Avonex
Farxiga
Jardiance
Xolair
Gleevec
Rebif
Symbicort

Brand Name(s)
Aubagio
Tresiba
Latuda
Xeljanz
Eliquis
Orkambi
Duexis
Restasis
Cimzia
Epclusa
Sprycel
Bystolic
Creon
NuvaRing
Stribild
Simponi
Dexilant
Breo Ellipta
Zetia
Taltz
Odefsey
Linzess
Premarin
Xifaxan
Orencia
Spiriva
Afinitor
Chantix
Imbruvica
Tivicay
Descovy
Vimpat
Forteo
Tasigna