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Michael Ceballos
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Mark Gordon
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MEMORANDUM

Date: October 1, 2020

To: Joint Labor, Health, and Social Services Interim Committee
Joint Appropriations Committee

From: Michael A. Ceballos, Director
Wyoming Department of Health

Subject: Legislative report: Prescription Drug Costs in Wyoming

Ref: C-2020-537

Both House Enrolled Act 45 and Section 7 of House Enrolled Act 94 from the 2020 Budget Session require the Department to report to the Joint Labor, Health and Social Services Committee and Joint Appropriations Committee on several policy options for lowering prescription drug costs.

The legislative report that answers these requirements is attached.

MAC/SJ/ff/jg

c: Governor Mark Gordon
Legislative Service Office (electronic copy)
State Department Depository (electronic copy)

PRESCRIPTION DRUGS IN WYOMING

Evaluating State policy options for lowering costs

Wyoming Department of Health
October 1st, 2020

LEGISLATIVE REQUIREMENTS

House Enrolled Act 45 from the 2020 Budget Session requires the Department to study the feasibility of a prescription drug importation program. Section 1 reads:

(a) Not later than October 1, 2020, the department of health shall complete a study on the feasibility of establishing a prescription drug importation program for distributing prescription drugs to voluntarily participating, state-licensed pharmacies in Wyoming for retail sale to persons in Wyoming with valid prescriptions.

As part of this study, the department shall consider the following:

> (i) The potential savings Wyoming residents and state agencies may gain from the implementation of a prescription drug importation program;
>
> (ii) Which prescription drugs may have the highest potential for consumer savings and budget savings through importation including the amounts and dosages needed for the most commonly prescribed drugs;
>
> (iii) The need for any necessary federal certification for implementation of a prescription drug importation program in Wyoming, including complying with the federal importation requirements of 21 U.S.C. § 384 and the federal Drug Supply Chain Security Act and the procedures necessary to achieve that certification;
>
> (iv) Any impacts that a prescription drug import program may have on payers, pharmacies, other health care providers and suppliers in Wyoming;
>
> (v) Any impacts that a prescription drug import program may have on Wyoming consumers, including the impact imported prescription drugs may have on overall consumer costs and the impact imported drugs may have on the accessibility of prescription drugs throughout Wyoming;
>
> (vi) The establishment of a process and any necessary procedures for the department of health, the state board of pharmacy and any other state agency involved with the procurement, storage and distribution of prescription drugs

for implementing a prescription drug importation program in Wyoming;

(vii) Any administrative costs, impacts and savings to the department of health, the state board of pharmacy and any other state agency that provides healthcare to persons in Wyoming associated with the implementation and supervision of a prescription drug importation program in Wyoming;

(viii) Any funding, spending or borrowing authorization necessary to maintain a month-to-month cash flow of funds necessary for administering a prescription drug importation program.

(b) In completing the study provided under subsection (a) of this section, the department shall study for comparative purposes other factors affecting access to, and the affordability of, prescription drugs in Wyoming, including but not limited to:

(i) The methods health insurers and pharmacy benefit managers use to manage prescription drug costs;

(ii) The use of pharmaceutical manufacturer rebates and discounts used by health insurers and pharmacy benefit managers;

(iii) The portion of prescription drug prices attributable to drug manufacturer:

(A) Costs for research and development; and

(B) Profit margins.

(iv) Other arrangements, including direct contracts with prescription drug suppliers, statewide distribution agreements with wholesale or retail prescription drug providers, price agreements and the possibility of group purchasing with other states;

(v) The group purchasing of Hepatitis C drugs in conjunction with other states to meet the needs of both the Medicaid program and the department of corrections. This study shall not be deemed to prevent implementation of a group purchasing effort for these drugs prior to the completion of the study.

In addition to this bill, House Enrolled Act 94 also requires the Department to study the idea of bulk purchasing prescription drugs. Section 7 reads:

> (a) Not later than October 1, 2020, the department of health and department of corrections shall complete a study on the bulk purchase of medication and report the results to the joint appropriations committee and the joint labor, health and social services interim committee. In conducting the study, the departments shall:
>
> > (i) Investigate opportunities to join other state agencies and other states to solicit one (1) or more bids for the bulk purchase of medications that could be purchased at a lower price through bulk purchasing or strategic sourcing, including hepatitis C treatments that are used within the correctional system or that are used by state health care programs;
> >
> > (ii) Consider the methods and limitations of joint contracting between agencies and with other states;
> >
> > (iii) Estimate the potential savings that could result from bulk purchase of the medications in accordance with this subsection.

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EXECUTIVE SUMMARY

Two bills from the 2020 Budget Session require the Department to study three policy levers that might be able to lower prescription drug costs to payers and consumers in Wyoming:

1. Importing prescription drugs from Canada;
2. Purchasing drugs as a group; and,
3. Alternative "subscription" or "bulk purchasing" models.

After considering these levers in the context of the prescription drug industry and the economic fundamentals involved, the Department does not believe any of these options, as currently conceived, will achieve any meaningful cost reductions.

Drug importation will likely not create sustainable savings

Drug payment systems are exceptionally complex, and the State has limited regulatory control over most actors. This makes it virtually impossible to guarantee that consumers will actually see savings, particularly in the case of Canadian drug importation. Basic economics also suggests fundamental problems with this plan that make it unsustainable in the long-run.

Group purchasing or alternative purchasing models are unlikely to work for Wyoming

Unfortunately, we do not believe group purchasing or "subscription"-type models have much promise in reducing drug costs either. Wyoming Medicaid, for example, is one of the largest purchasers of drugs in the State, but the program enjoys a unique statutory authority that significantly reduces the effective price it pays. This authority cannot be comingled with other State programs in a group purchasing arrangement.

Because drug prices are effectively determined in negotiations between payers (or their agents) and manufacturers, and because the result of those negotiations is function of how much buying power those payers have, Wyoming's small population likely precludes it from implementing any effective State-level purchasing solutions to lower overall drug costs.

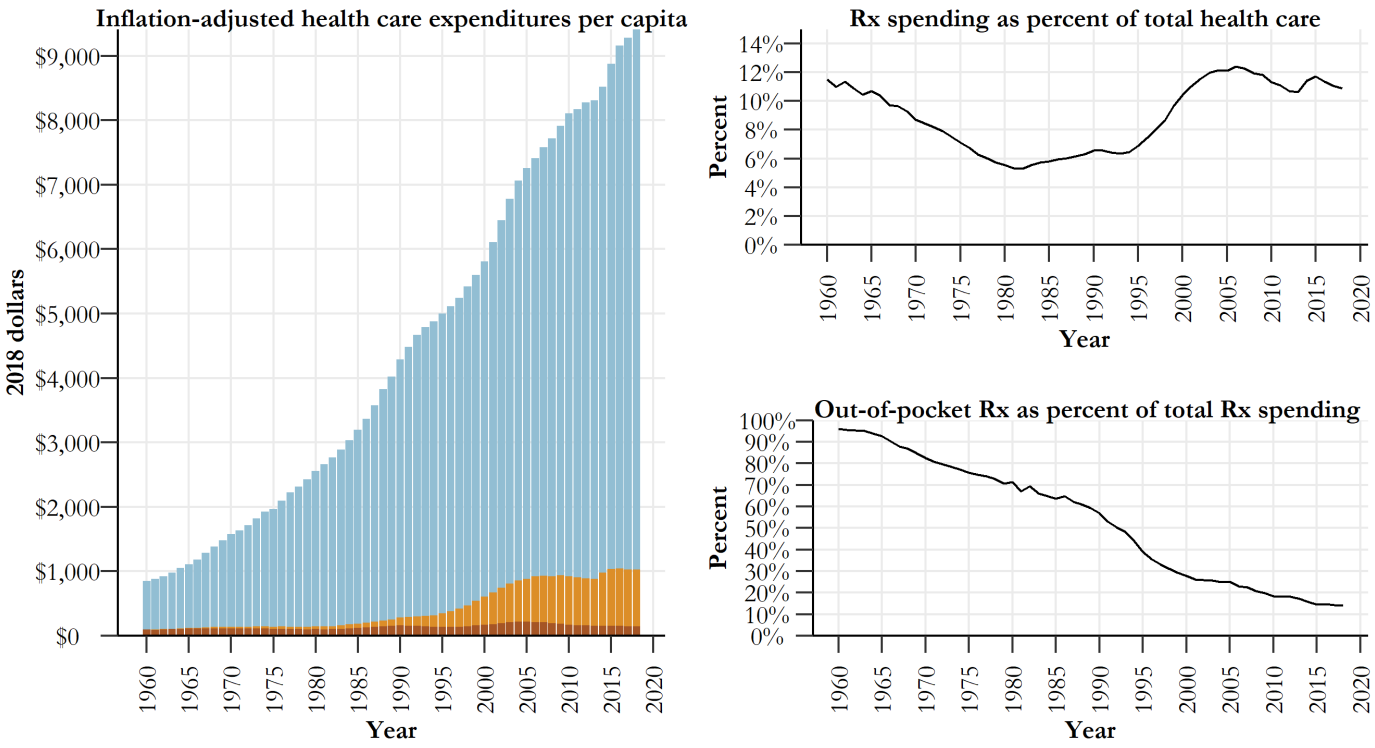
BACKGROUND

This section provides a brief overview of how drugs get into the hands of consumers. It identifies most of the actors involved, and, in describing how product and payment flows operate, it lays out some of the economic fundamentals driving pharmaceutical costs and prices. This high-level foundation is critical to understanding why policy levers may or may not work in containing costs.

Cost trends

We begin with looking at overall trends on prescription drug spending for the United States, in Figure 1, below. On the left, the light blue column shows total personal health care expenditures, the orange bars show prescription drug expenditures, and the brown bars show out-of-pocket prescription drug expenditures.

Figure 1: Health care and prescription drug spending in the United States.[1]



[1] 2018 National Health Expenditures, CMS. GDP price deflator used to adjust to 2018 dollars.

Several trends are evident on Figure 1:

- Per-capita personal health care costs continue to increase, even after adjusted for inflation. As of 2018, they stand at over $9,400 per person — representing over $3 trillion in aggregate spending per year.

- Drug costs have grown more slowly. Total prescription drug spending makes up approximately $335 billion of total personal health care costs, or just over 10%. This percentage has fluctuated over time, reaching a low of ~ 5% in the 1980s. It's true that, on an inflation-adjusted per-capita basis, **total drug spending** has increased from ~ $100 per person in 1960 to ~ over $1,000 per person in 2018, but note the flattened curve since 2005.

- Total inflation-adjusted per-capita **out-of-pocket spending** on prescriptions steadily increased from ~ $100 per person to ~ $200 per person between 1960 and 2005, before falling to ~ $145 today. The recent decease is likely attributable to the implementation of Medicare Part D in 2006.

- In the 1960s, **virtually all** pharmacy spending was out-of-pocket. Today, very little is (< 15%).

Taken together, these trends would imply that the cost of prescription drugs is less of problem than the overall cost of health care. Where it is a problem, it's a problem for those paying full freight: insurers, employers, and people without insurance.

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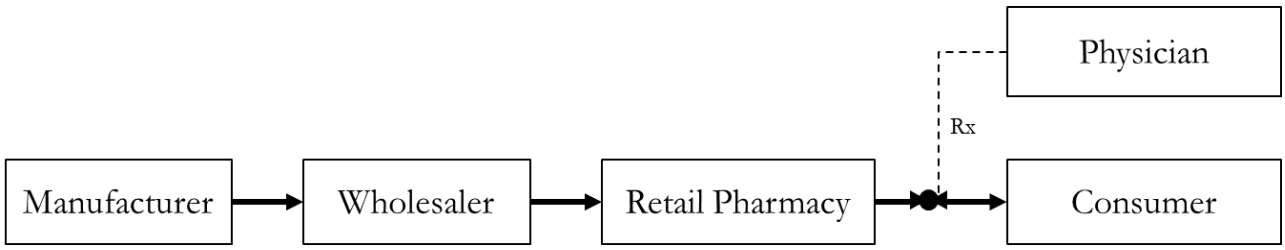
The prescription drug product pipeline

The actual flow of pharmaceuticals, from manufacturers to the end consumer, is fairly straightforward, as shown in Figure 2, below.

Figure 2: Flow of pharmaceutical products from manufacturers to consumers



As is the case with most other goods, prescription drugs pass from manufacturers, to wholesalers, to retailers, and finally to the consumer.

One main complication, however, is that a physician needs to write a **prescription** ("Rx" in the figure, connected to the globe valve symbol on the diagram) before the consumer can actually purchase the drug.

The role of the physician in this pipeline is critical, since they are often making the decision about which drug to prescribe, whether a generic substitution would work equally effectively, or whether a lower-cost drug should be attempted first — all without bearing the actual cost of the prescription itself.

This actual cost is largely paid for by health insurance companies (or their public sector equivalents), and ultimately spread out very thinly among the people buying insurance policies (or paying taxes).

The disconnect between who controls the prescription (the physician), who consumes it (the patient), and who pays for it (the insurance plan) creates some fundamental economic problems:

- The more risk the insurer assumes (e.g. share of drug costs), the more likely it is to incur additional costs or waste through the actions of its insureds. This

phenomenon is known as **moral hazard**.[2] Simply put, people are less likely to care about the costs of medical care generally when someone else is paying the bill.[3] As a result, they consume more services than they would have, had they paid the entire cost themselves.

- Moral hazard is ultimately a tradeoff between risk assumed and cost incurred; the flip side is that the more risk is placed on insureds (i.e., by increasing "skin in the game"), the more likely catastrophic medical bills become — and the less value the insureds will place on the risk-spreading function of insurance.

- Moral hazard is more of a problem at lower levels of care — routine physician visits, elective surgeries, etc. — as opposed to higher levels of care, like life-saving interventions.[4]

- In the pharmaceutical market, insurers act as an intermediary between the patient, the provider, and the pharmacy. In these transactions, there are significant **information asymmetries** (gaps) between the patient, the provider, and the insurer that often lead to inefficient use of healthcare:

  - The patient has more knowledge of his or her own health-related habits than the physician or the insurer, but less information as to the specific diagnosis, the drugs available, and the true costs of those drugs;

  - The provider has more knowledge of the patient's diagnosis and the range of drugs available to the patient, but often less knowledge of the actual costs.

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[2] The name "moral hazard" is archaic -- it has little do with the ethics, morality, or danger. Most experts believe that "moral" originally referred to a psychological state of mind (similar to "morale"), and "hazard" refers to risk or chance. Moral hazard therefore refers to the idea that medical cost outcomes are related more to the insured's state of mind rather than chance. (Kongsvedt. The Essentials of Managed Health Care. 6th Ed. 2012. Pg xiv.)

[3] Cutler and Zeckhauser define moral hazard as "the likely malfeasance of an individual making purchases that are partly or fully paid for by others." "The anatomy of health insurance." Handbook of Health Economics (Volume 1. Chapter 11.) Elsevier Science. 2000. 576. The concept originates with Kenneth Arrow (1963) - https://assets.aeaweb.org/assets/production/journals/aer/top20/53.5.941-973.pdf

[4] Nyman, J.A. "Is 'Moral Hazard' Inefficient? The Policy Implications Of A New Theory." Health Affairs. 2004. (http://content.healthaffairs.org/content/23/5/194.full)

- The insurer has more knowledge of drug cost across the entire insured population and how those costs will be passed on to the patient in terms of future premiums.

- Because of these information asymmetries, both the patient and the insurer are in a **principal-agent relationship** with the provider:

    - The patient, as a principal, expects the provider (agent) to act in her best interests (i.e., restoring health) by providing the *most effective care possible*.

    - The insurer, as a principal, expects the provider to act in its interests by conserving resources and providing only the *most efficient treatment necessary* to restore the patient to health.

In theory, of all the effective pharmacological treatments available, one will be the most cost-effective. The problem is that, in practice, doctors and patients frequently have aligned interests which differ from the insurer. As Cutler and Zeckhauser note, "the result is that patients and physicians want essentially all care that improves health, respectively ignoring and welcoming resource expenditures."[5]

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[5] Cutler Zeckhauser. 589.

Manufacturers

With these basic economic problems on the consumption end noted, let us proceed with the beginning of the value chain: drug manufacture.

The actual cost to the manufacturer of any given prescription does not merely reflect the cost of the ingredients or the value-added in forming the pills, putting them into bottles, labeling, boxing, distributing, and so on. Embodied in this cost are also **massive fixed costs** involved with bringing new drugs to market.

- **Research and development** (R & D) in the pharmaceutical industry makes up a much larger fraction of the cost base than in any other sector.[6] Additionally, returns on any given investment are far from guaranteed; only an estimated 5% of candidate projects in the preclinical stage ever make it to market.[7] These successful drugs need to cross-subsidize for the vast majority of failures.

- **Testing and regulatory compliance** in this R & D pipeline involves a lengthy and costly series of clinical trials, particularly for New Drug Approvals (NDA).

    - Because neither consumers (nor physicians) have any direct, *prima facie* knowledge as to the quality of the product being purchased (often even after it is consumed), prescription drugs are considered "credence" goods.[8]

    - Some credence goods, like auto repairs, are relatively unregulated. In the case of drugs, however, the severe consequences of potentially harmful substances has led us, as a society, to entrust regulatory authorities like the Food and Drug Administration (FDA) to evaluate and certify that drugs are safe and effective.[9]

    - Generally speaking, if preclinical work (including animal trials) is promising, the FDA requires that drugs pass through three increasingly

[6] Scherer. "The Pharmaceutical Industry." Handbook of Health Economics. Vol 1. Elsevier, 2000. 1302.
[7] Morton and Kyle. "Markets for Pharmaceutical Products." Handbook of Health Economics. Vol 2. Elsevier, 2012. 733.
[8] Morton and Kyle. 765.
[9] Beginning with the passage of the Pure Food and Drug Act in 1906.

complex phases in human subjects before considering any New Drug Approval package.

Taken together, the fixed costs of research and regulatory compliance are exceptionally costly. A 2003 study using data from 1983 to 1994, for example, estimated the average investment per successful new molecule at $803 million; a 2007 study updated that number to $1.2 billion; more recent research has estimated an average figure per new drug of $1.3 billion.[10]

In order to create incentives for drug companies to continue making these investments, the United States guarantees significant **intellectual property protections** for new drug development. These protections allow manufacturers time-limited **monopolies** on new brand name drugs they produce.

In this situation — a product with inelastic demand (i.e., consumers aren't sensitive to the total cost), supplied by a monopolist, where the average fixed costs embodied in each prescription dwarf the variable costs of production — **marketing** will be widely used if is effective at generating sales.

And, as anyone who watches any amount of broadcast television can attest, advertising for pharmaceutical products is omnipresent. A recent study estimated that medical marketing has grown from $17.7 billion in 1997 to $29.9 billion in 2016, with the largest share coming from marketing to health care providers (~$20 billion), and most rapid increase ($2.1 to $9.6 billion over the same time period) coming from direct-to-consumer advertising of prescription drugs.[11]

Figure 3, on the next page, illustrates the significant role these large fixed costs play: in 2019, R&D and overhead consumed approximately **two thirds of the total cost** base.

Figure 4, below Figure 3, also shows the generous profit margins (~15-20%) reaped by drug manufacturers over the same time frame.

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[10] Wouters, McKee and Luyten. "Estimated research and development investment needed to bring a new medicine to market, 2009 - 2018." JAMA, 2020.
https://jamanetwork.com/journals/jama/fullarticle/2762311

[11] Schwartz and Woloshin. "Medical marketing in the United States, 1997 -2016." JAMA, 2019.
https://jamanetwork.com/journals/jama/fullarticle/2720029

Figure 3: Trends in cost categories for six major pharmaceutical manufacturers.[12] Dashed lines show reported data; red line and shaded region show expected industry average and 90% credible intervals of this average.

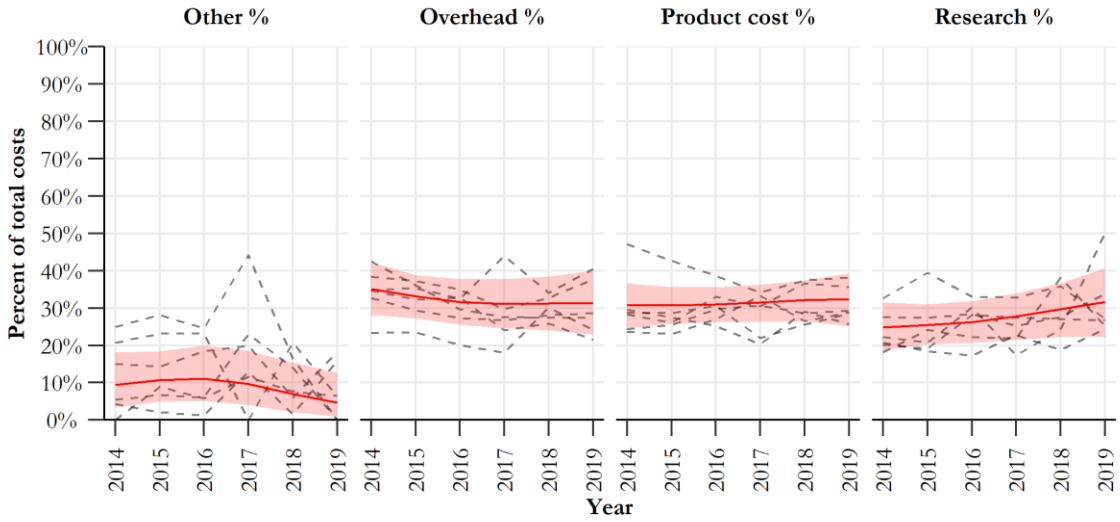
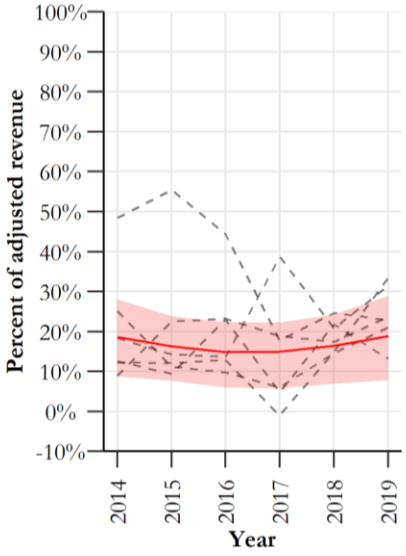


Figure 4: Trends in profit (as percentage of adjusted[13] revenues) for the same companies. Dashed lines show reported data; red line and shaded region show expected industry average and 90% credible intervals of this average.



[12] 10K statements (2014 - 2019) consolidated for AbbVie, Bristol-Meyers Squibb, Eli Lilly, Gilead, Merck and Pfizer.
[13] Negative costs were added to revenues.

The market for drug manufacturer is not particularly concentrated. Table 1, below, shows the US market share for top drug manufacturers in 2015. The time-limited monopoly that each drug maker has over a certain portfolio of branded drugs, however, means that overall market share is a poor reflection of amount of competition that exists in the sector overall.

Table 1: US market share (sales) in 2015[14]

Manufacturer	All	Brand	Generic
Gilead	6.9%	10.9%	-
Johnson and Johnson	5.9%	9.4%	-
Roche	5.7%	9.0%	-
Merck	5.7%	9.0%	-
Amgen	5.3%	8.5%	-
Pfizer	4.7%	7.4%	-
Fresenius Kabi	4.6%	-	3.1%
AbbVie	4.4%	6.9%	-
Sanofi	4.3%	6.8%	-
Novartis	3.3%	5.3%	-
Astrazeneca	3.1%	4.8%	-
Allergan	3.0%	4.7%	-
GlaxoSmith Kline	2.6%	4.2%	-
Pfizer-Hospira	2.3%	-	3.6%
Teva (branded)	2.1%	3.3%	-
Mylan	1.6%	-	8.8%
Teva (generic)	1.5%	-	12.2%
Novartis-Sandoz	1.1%	-	11.5%
Allergan-Actavis	1.1%	-	8.9%
Aspen	0.4%	-	4.1%
Lupin	0.3%	-	2.7%
Total	70%	90%	55%

[14] https://healthpolicy.usc.edu/wp-content/uploads/2017/06/USC_Flow-of-MoneyWhitePaper_Final_Spreads.pdf

Wholesalers and retailers

Wholesalers serve as the connective tissue between ~1,300 drug manufacturers and ~180,000 drug dispensing locations, including pharmacies, hospitals, and physician offices. [15]

In addition to the logistics of transportation and warehousing, wholesalers manage significant amounts of risk for manufacturers, by:

- Verifying the credit and licenses of pharmacy customers, as well as performing on-site inspections, thus ensuring regulatory compliance in the chain of custody;

- Taking legal ownership of product upon purchase, thus assuming risk of managing and warehousing inventory, as well as the burden of obtaining payment.[16]

Unlike manufacturing and retail, this particular link in the chain is exceptionally concentrated: approximately 95% of all drug volume is handled through "the Big Three" pharmacy distributors[17], shown in Table 2, below, with approximate market share:

Table 2: the "Big Three" wholesalers (2019)

Wholesaler	Est. market share	Est. revenue (billions)
McKesson	35%	$164.15
AmerisourceBergen	34%	$125.53
Cardinal Health	26%	$168.98
Others	5%	$24.14

Interestingly, while the industry is concentrated, profit margins among wholesalers are among the smallest in the entire chain (~0.5% for brand name drugs, for example).[18]

The main customers of wholesalers are the retail pharmacies, which serve as the primary dispensing point for most customers. Unlike wholesalers, the retail

[15] Deloitte and HAD. "The role of distributors in the US health care industry." 2019.
[16] Ibid.
[17] https://www.drugchannels.net/2019/10/the-big-three-wholesalers-revenues-and.html
[18] https://healthpolicy.usc.edu/wp-content/uploads/2017/06/USC_Flow-of-MoneyWhitePaper_Final_Spreads.pdf

pharmacy industry is very diverse; while big chain stores make up almost half the market, the other half are smaller chains and independent pharmacies, as shown in Table 3, below.

Table 3: Retail pharmacy market share (2015)[19]

Retail pharmacy	Est. market share (2015)
Walgreens	14.9%
CVS Retail	13.8%
Express Scripts - Mail Order Pharmacy	11.0%
CVS Mail Order	9.0%
Walmart	5.5%
Others	45.8%

In addition to dispensing valid prescriptions, pharmacies end up collecting payment for their product by both billing private insurance and collecting any applicable cost-sharing from customers.

This payment side is where the simple diagram in Figure 2 (page 8) becomes far more complex.

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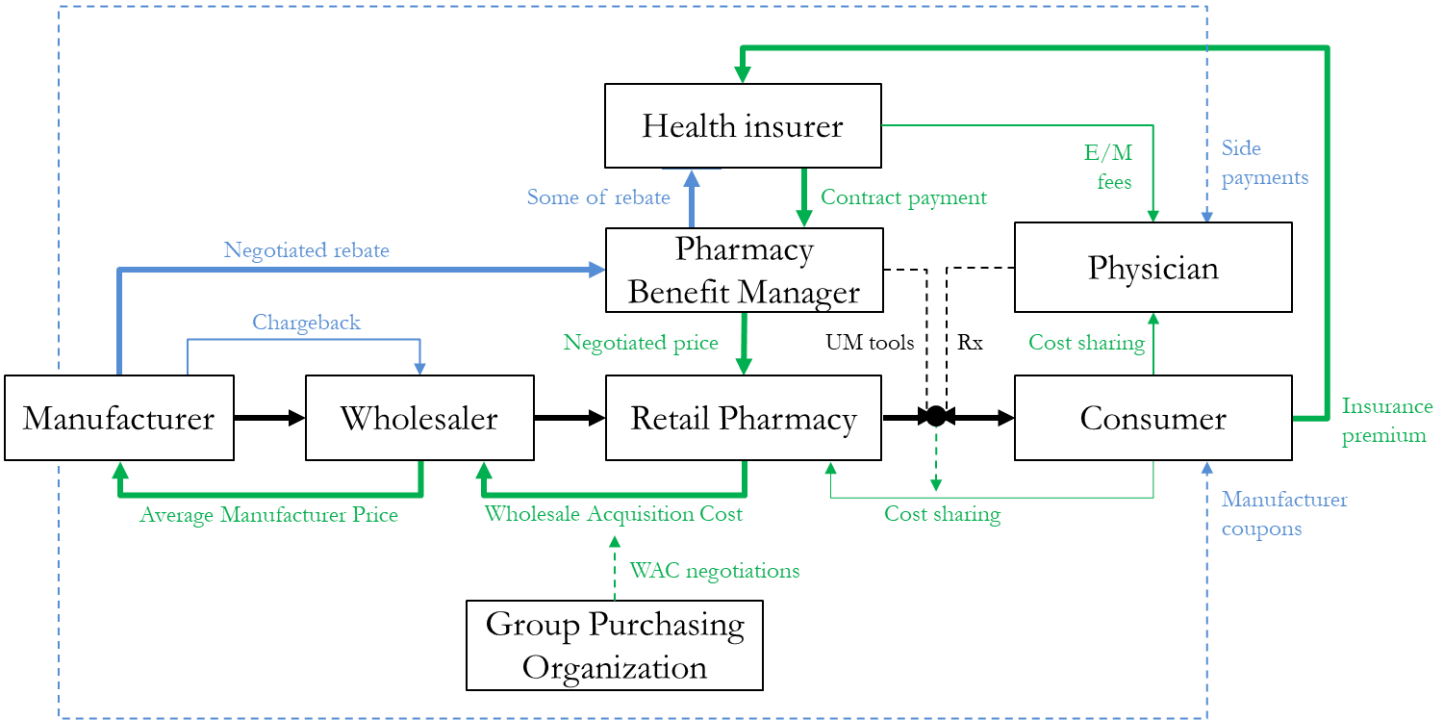
[19] Ibid.

Payment systems: privately-insured

Figure 5, below, shows how payments (in green) and "reverse payments" (in blue) flow between all the entities involved in the general case of a privately-insured patient.

Figure 5: Product and payment flow - privately insured



First, we introduce some new actors:

- The **health insurer** pools general medical cost risk across an entire population by collecting monthly premiums from members and making payments to all medical providers (including, in this case, payments to physicians for, at the very least, an evaluation and management (E/M) visit before prescribing.)

- In many cases, insurers will contract with a **pharmacy benefit manager** (PBM) to handle pharmacy claims, since these firms often offer specialized expertise in managing drug claims and can aggregate their purchasing power in negotiations with manufacturers. The PBM market is moderately concentrated, with

approximately 75% of total prescription volume being handled by three big firms, shown in Table 4, below.

Table 4: PBM market share (2018)[20]

Pharmacy benefit manger	Est. market share (2018)
CVS Health (Caremark) / Aetna	30%
Express Scripts	23%
OptumRx (UnitedHealth Care)	23%
Humana Pharmacy Solutions	7%
Medimpact Healthcare Systems	6%
Prime Therapeutics	6%
All others	4%

- As this name suggests, the role of the PBM is to manage pharmacy-related claims, with "management" ostensibly focusing on reducing or containing costs to the health insurer. These activities include:
    - Negotiating rates with individual retail pharmacies;
    - Defining what drugs will be covered by the health plan on its **formulary**;
    - Setting up **cost-sharing tiers** for drugs within the formulary (e.g., encouraging members, through lower cost sharing, to opt for generics or "preferred" brand-name drugs instead of non-preferred brand name drugs that are still covered);
    - Defining and enforcing other **utilization management (UM) tools**, to include:
        - **Prior authorization**, where consumers and physicians have to have a prescription reviewed by PBM medical staff for appropriateness before the prescription will be paid for; and,

[20] https://www.drugchannels.net/2019/05/cvs-express-scripts-and-evolution-of.html

        - **Step therapy**, where the PBM will require the physician to attempt treating certain diseases with a lower-tier or generic drug before authorizing the use of a more expensive drug.

    - Once established, using these collective UM tools as **leverage** for negotiating with pharmacy manufacturers for additional "rebates" (reverse payments); and,

    - Passing some fraction of the rebates received back to their health insurer clients.

- On the bottom of the figure, you'll note the addition of **Group Purchasing Organizations**, who represent retail pharmacies in negotiations with wholesalers and manufacturers.

The solid green and blue flows on Figure 5 show just how complex calculating the effective 'price' for any given drug can be.

- The 'price' for wholesalers is known as the **Average Manufacturer Price (AMP)**, but the wholesalers receive a form of rebate known as a **chargeback** by manufacturers for their services in warehousing, distributing and managing risk.

- The 'price' that retailers face from wholesalers is termed the **Wholesale Acquisition Cost (WAC)**. Since wholesaler profit margins are fairly small, this price is usually similar to the AMP, but it is often influenced by negotiations by retail pharmacies and their group purchasing agents.

- The 'price' that consumers face depends on their benefit plan, the tier of the drug in the formulary and the status of their cost-sharing obligations. In most cases, cost sharing is a relatively small fraction of the overall cost of any prescription.

- The 'price' faced by the PBM is a function of the negotiated payments they make to retail pharmacies, less "Direct and Indirect Remuneration" (DIR) fees[21] and copay "clawbacks" paid from pharmacies to PBMs, and less whatever rebate they

[21] DIR fees are paid from pharmacies to participate in PBM networks as well as any reimbursements or penalties for meeting or failing PBM quality measures.

are able to negotiate from manufacturers. On the commercial side, PBMs make most of their money from the 'spread' between how much rebate they receive and how much of the rebate they remit back to the health insurer (i.e., the effective price to the health insurer).

Since the effective prices paid by the PBM and the amounts of rebate they receive are considered proprietary trade secrets, the exact amount of 'spread' is usually shrouded in mystery — and thus is often a source of finger-pointing in the health care debate.

Finally, note the dashed payments on the figure, from manufacturers to physicians (side payments) and to consumers (coupons). These don't always happen, but when they do, they are designed to subvert attempts by the PBM and health insurer to manage utilization.

- "Side payments" to physicians include fees for consulting and speaking, and payments for travel and meals, with the intent of influencing prescribing behavior. Approximately half of US physicians have reported receiving some kind of side-payment from a pharmaceutical or biomedical industry.[22]

- "Coupons" are designed to reimburse consumers for cost-sharing, usually for high-cost brand-name drugs, and thus subvert the incentives created by PBMs and insurers for people to select preferred drugs on the formulary.

  Usually these "patient assistance programs" are pitched at the end of direct-to-consumer advertisements, with something like: "if you are unable to afford Nozulla, Gene Enterprises may be able to help."

  While operating these programs does cost manufacturers real money, since most of their revenue ultimately comes from insurers, not patient cost sharing, they are clearly worth their while.

[22] "Types and distribution of payments from industry to physicians in 2015." Tringale, Marshall, et. al. JAMA. 5/2/2017. https://jamanetwork.com/journals/jama/fullarticle/2623606?resultClick=1. A database of these reported side-payments is available here: https://openpaymentsdata.cms.gov/

Industry-wide costs and profits

When all of these payment flows are reconciled, how does the overall value chain look in terms of costs and profits?

We do not reinvent the wheel here. The University of Southern California analyzed how a hypothetical average $100 payment for a drug broke down across this supply chain in 2017, and Table 5, below, is reproduced from their report.[23]

The table is meant to be read line-by-line. For example, the manufacturer on the first line spends $17.00 to produce the drug, has $26.00 of additional fixed costs (e.g., R & D), makes $15.00 profits, and sells the drug to the wholesaler for $58.00.

The wholesaler purchases the drug for $58.00, incurs $1.70 in costs and takes $0.30 in profit, and sells the drug to the retailer for $60.00.

And so forth.

Table 5: Estimated costs and profits by actor

Entity	Drug cost	Other cost	Profit	Total revenue
Manufacturers	$17.00	$26.00	$15.00	$58.00
Wholesalers	$58.00	$1.70	$0.30	$60.00
Retail pharmacies	$60.00	$13.00	$3.00	$76.00
Pharmacy benefit manager	$76.00	$3.00	$2.00	$81.00
Health insurer	$81.00	$16.00	$3.00	$100.00

Note on the table that the largest sources of drug costs are, in order:

- Manufacturer fixed costs (e.g. R & D, marketing);
- Variable costs to produce drugs;
- Health insurer overhead; and,
- Retail pharmacy overhead.

Note as well that the largest profits in the system are clearly reaped by drug manufacturers.

[23] Sood, Shih, et al. "The flow of money through the pharmaceutical distribution system." USC Schaeffer Center for Health Policy and Economics. June 2017. https://healthpolicy.usc.edu/wp-content/uploads/2017/06/USC_Flow-of-MoneyWhitePaper_Final_Spreads.pdf

Payment flows vary significantly for public programs

While many of the concepts from this general case are apply to public payers like Medicare, Medicaid and the VA, each is different enough to warrant a brief description of the system and how it diverges.

Payment systems: Medicare Part D

Standard Medicare Part D plans (e.g., a standalone drug benefit plan combined with regular Medicare fee-for-service, not a Part C Medicare Advantage plan) are most similar to the privately-insured system. This similarity was intentional; Part D was specifically designed to be administered by private companies within a regulatory framework when it was created as part of the 2003 Medicare Modernization Act.

Because this is a background section, please indulge the following brief digression of how Medicare Part D works — we promise it will be relevant for the drug importation discussion later.

Part D plans are designed to offer a standard benefit with four phases of drug coverage that kick in at various levels of total spending for each member.[24] These phases include:

- The **deductible phase**, where the Medicare member begins by paying 100% of negotiated drug prices, up to $435 (in 2020).

- The **initial coverage phase**, where members pay approximately 25% of the negotiated price in copayments or coinsurance, and Part D plans pay the remaining 75%. For most plans, this phase goes from the $435 deductible up to $4,020 in total payments.

- The **coverage gap phase** — formerly known as the notorious "donut hole" — which goes from the end of initial coverage up to a catastrophic limit of $6,350 in member out-of-pocket expenditures. Where consumers were previously exposed to significant out-of-pocket costs in the "donut hole," the Affordable Care Act modified this phase so that, effective 2020, consumers only pay an

[24] Kaiser Family Foundation. An Overview of the Medicare Part D Prescription Drug Benefit. https://www.kff.org/medicare/fact-sheet/an-overview-of-the-medicare-part-d-prescription-drug-benefit/

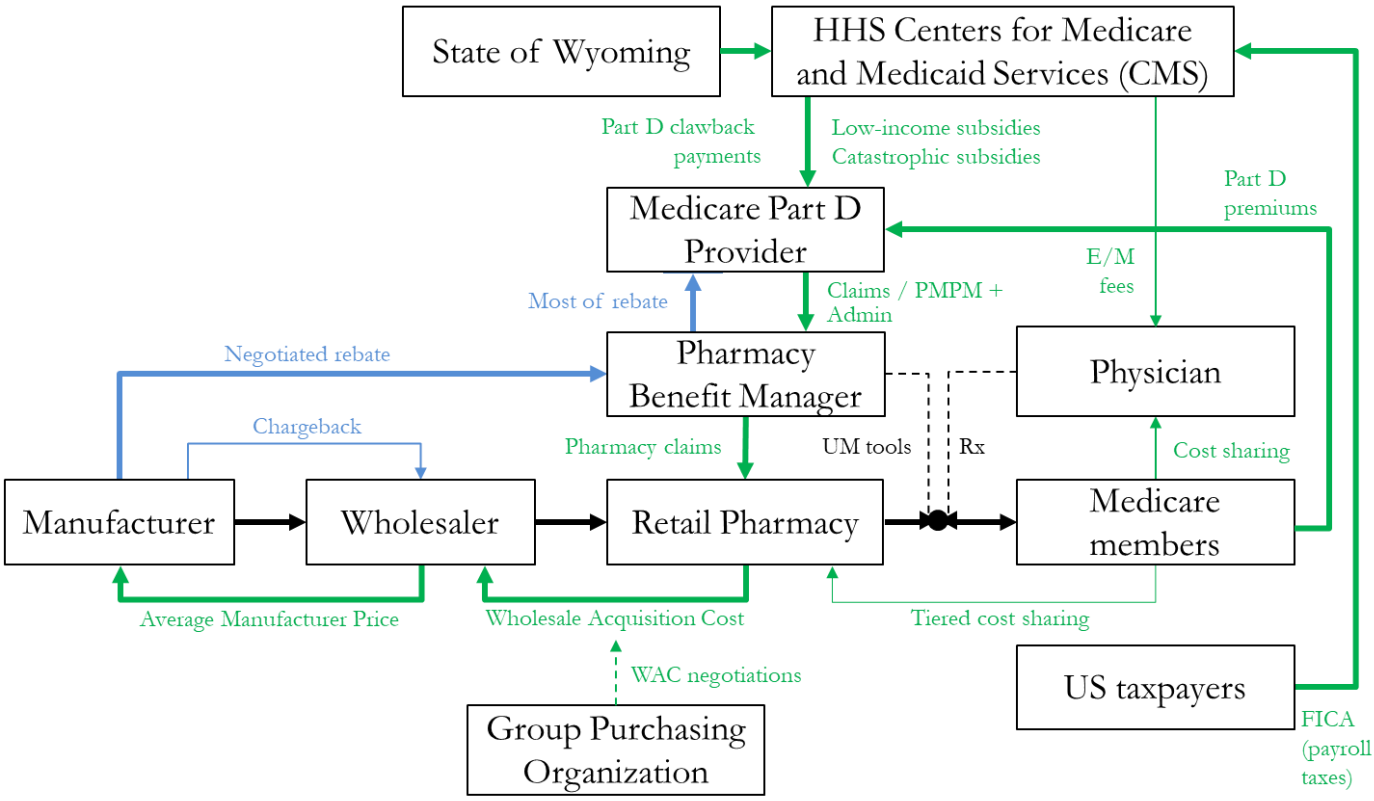
estimated 25% of costs for both branded and generic drugs during this phase, drug manufacturers absorb 70% of the drug payments in rebates, and plans pay the remaining 5%.

- In the **"catastrophic" phase**, above the $6,350 in member out-of-pocket spending (or an estimated average of $9,719 in total drug spending), members pay 5% coinsurance on all payments, plans pay 15% of negotiated payments, and Medicare itself covers the remaining 80% of drug spending.

Part D plans are allowed to offer alternative benefits that are equal in actuarial value, however, so the actual cost sharing parameters that members face can vary.

Figure 6, below, sketches out how the payment flows work in this system.

Figure 6: Product and payment flow - Medicare FFS + Part D



Note on the figure that:

- **Medicare Part D providers** are generally private insurers, with Medicare plans making up a separate book of business in their overall portfolio. These insurers collect Part D premiums from their membership, but also receive subsidies from the Medicare program itself. These subsidies include:
    - Payments to reduce premiums and cost-sharing for low-income Medicare members;
    - Payments to cover the cost of the catastrophic portion of the benefit design.
- These subsidies, as well as other payments made by Medicare to physicians, etc., are paid for out of payroll taxes, as well as State-level "clawback" payments (of which the members of Wyoming's Joint Appropriations Committee are acquainted).
- Most Part D providers will contract with a **Pharmacy Benefit Manager** to actually handle the claims, formularies, and rebate negotiations. Unlike the private-pay case, however, where PBMs generate most of their profit through "spread," most (> 99%) of the rebate is actually passed back to the Part D provider; the PBMs make most of their Medicare revenue from volume-based or per-member-per-month fees.[25]

The most important thing to note on Figure 6 is that there is effectively little difference regarding price regulation/negotiation between Medicare Part D and the privately-insured sector. Because Part D providers and their PBMs negotiate prices and rebates individually, the prices any given plan sees are likely based on two factors:

- The market share of the plan provider (e.g., how much weight they can swing around), and;
- The degree of utilization management that the plan has imposed, and how much leverage this translates into when negotiating rebate.

[25] https://www.gao.gov/assets/710/700259.pdf

The Medicare program itself is, in fact, is *statutorily prohibited*[26] from interfering in any price negotiations (i.e., by using the collective mass of all Medicare members as market power).

Moreover, while Part D providers do have some freedom to structure their benefit plans and formularies as part of these price negotiations, the regulatory framework imposed to protect beneficiaries can actually limit what leverage these plans might otherwise have. Medicare restrictions, for example, require that plans:

- Include drug classes covering all disease states;
- Cover at least two chemically-distinct drugs in each drug class;
- Cover all (or "substantially all") available drugs in six "protected" therapeutic classes:
    - Immunosuppressants for transplant rejection treatment;
    - Anti-depressants;
    - Anti-psychotics;
    - Anti-convulsants;
    - Anti-retrovirals;
    - Anti-neoplastics (e.g. oral chemotherapy);

There are also a few other minor differences:

- The law prohibits manufacturer coupons for being used by Medicare members in conjunction with their Part D benefits. Medicare members are free to use them, however, if they are bearing 100% of the cost of the drugs being purchased, presumably in the deductible phase of their coverage, or if they choose to go outside the Part D system.

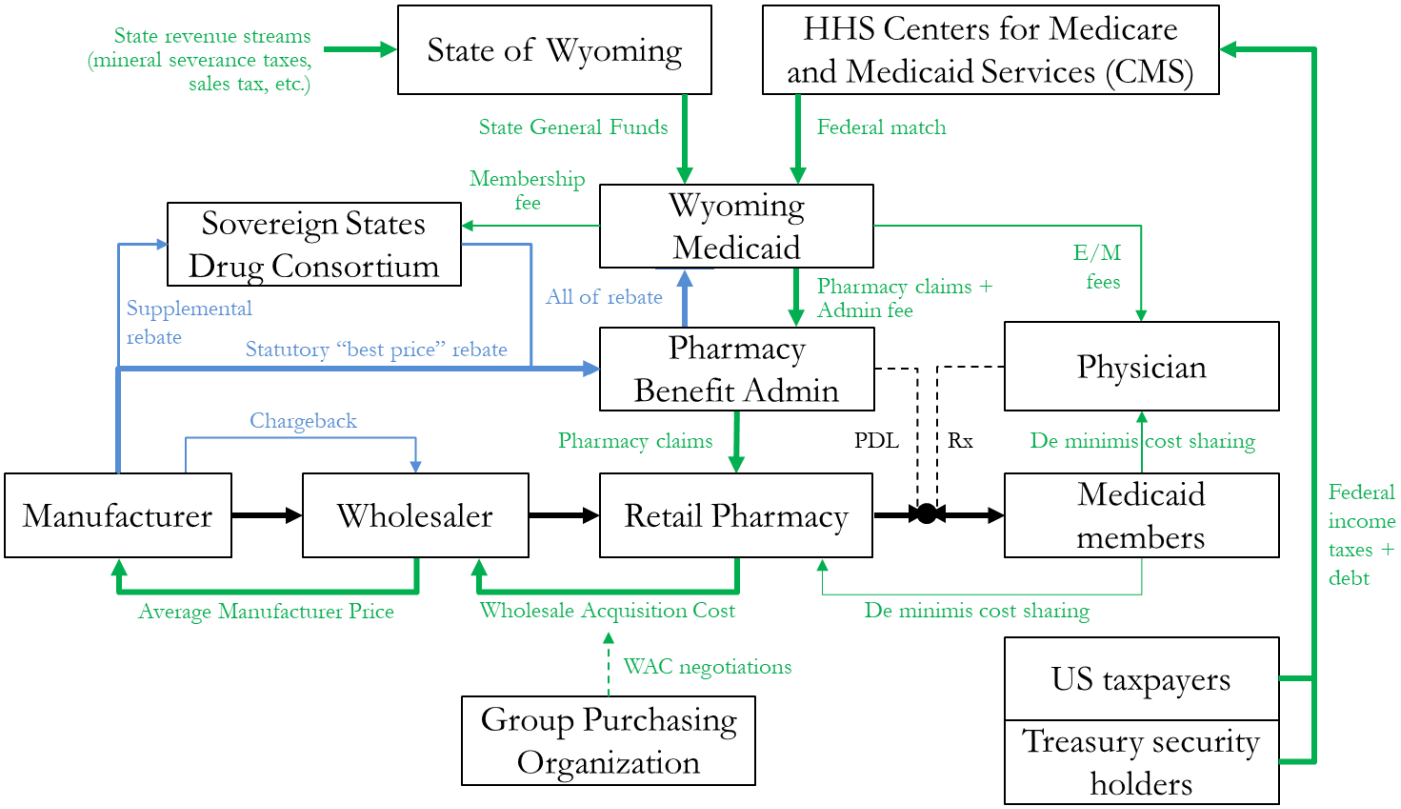
- As noted in the digression, both the cost sharing and drug tiering that members face is more structured and limited than in the privately-insured market.

[26] SSA 1860D-11(i)

Payment systems: Medicaid

Wyoming Medicaid's pharmacy payment system is shown in Figure 7, below.

Figure 7: Product and payment flow - Wyoming Medicaid



You will note that this system retains many of the same actors and flows as the previous two diagrams. There are, however, significant differences.

The most important is the role of rebate and utilization management in Medicaid.

In 1990, the Omnibus Budget Reconciliation Act (OBRA) began to require that drug manufacturers offer State Medicaid programs the "best price" they offer to any other payer (with a few exceptions), or be shut out of all federal drug purchasing programs (including Medicare).

In exchange for this maximal rebate, Medicaid programs **must cover essentially all manufacturers' drugs on their formulary**. States do have the ability, however, to

impose some limited utilization management tools like prior authorization. Drugs exempt from these tools are placed on what is called the Preferred Drug List (PDL).

Medicaid programs can use placement on the PDL to negotiate additional rebate beyond the OBRA "best price" rebate. To improve purchasing power in maximizing this supplemental rebate, many states band together in purchasing organizations. Wyoming Medicaid, for example, is a member of the Sovereign States' Drug Consortium (SSDC), which negotiates rebate on behalf of 13 states and 10 million covered Medicaid lives. The total impact of rebate is significant. Table 6, below, shows, for two fiscal years, what total pharmacy expenditures are before (top line) and after (bottom line) OBRA and supplemental rebates.

Table 6: Wyoming Medicaid pharmacy expenditures and rebate

	State Fiscal Year	
	2019	2020
Medicaid pharmacy expenditures	$61,612,808	$60,535,188
IHS-related expenditures (100% FMAP)	$14,276,757	$14,304,217
Non-IHS expenditures eligible for rebate	$47,336,051	$46,230,971
OBRA "best price" rebate	$26,868,678	$24,763,484
Supplemental rebate	$2,412,419	$2,415,980
Total rebate collected	$29,281,097	$27,179,464
Net non-IHS pharmacy expenditures	$18,054,954	$19,051,507

Additional differences:

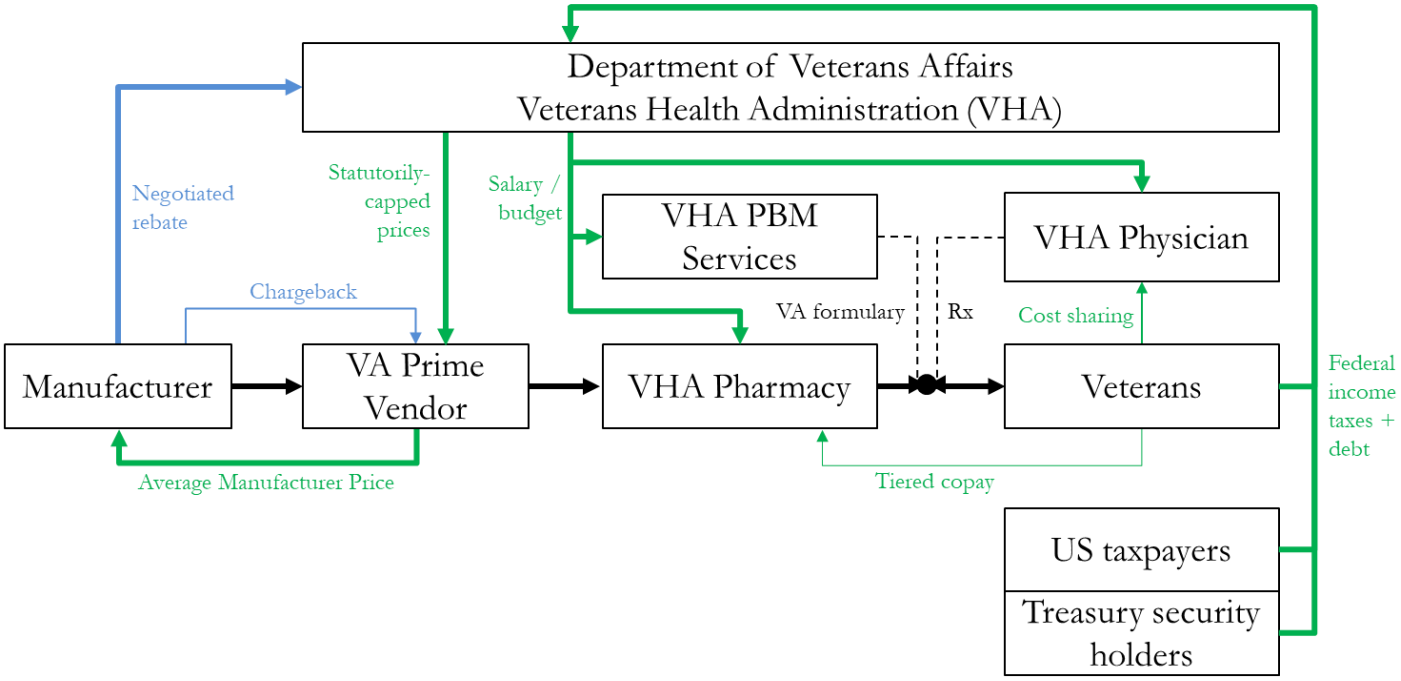
- Wyoming Medicaid utilizes a Pharmacy Benefit Administrator (PBA) instead of a PBM. The PBA collects rebate, administers pharmacy claims and prior authorizations for the State for a contracted fee. All rebate dollars are passed through to Wyoming Medicaid, and Medicaid pays all pharmacy claims processed by the PBA directly.

- Wyoming Medicaid members pay little, if any, cost sharing. The system is financed entirely by the taxpaying public. State dollars are provided through the General Fund, which is derived from the revenue streams Wyoming relies on. For every State dollar, Medicaid receives a matching federal dollar from general federal revenues, which come from a combination of taxes and debt instruments.

Payment systems: Veterans' Administration

The VA's payment system is radically different from all other payers in that it "owns" all of its physicians and pharmacies, as shown in Figure 8, below. In this sense, the VA is the closest analogue to a 'socialized' medical system like the National Health Service in the United Kingdom.

Figure 8: Product and payment flow - Veterans Health Administration



Several factors, both on and off this diagram, make drug costs for the VA among the lowest among payers in the United States.[27]

- First, per the 1992 Veterans Health Care Act, the VA is eligible for maximal rebate, similar to Medicaid. The VA is also excepted from Medicaid "best price" calculations. This means that drug manufacturers are willing to negotiate even lower discounts with the VA since any lower price does not trigger automatic discounts for every State Medicaid program.

[27] HealthAffairs. "Prescription Drug Pricing: Veterans Health Administration." August 2017.

- Since 1997, the VA has maintained a single national formulary that is relatively restrictive. The VA Pharmacy Benefit Management (PBM) Services makes the call on which drugs to include or exclude. VA pharmacists are also empowered to make therapeutic substitutions and provide direct input to assist in controlling costs.

- Physicians are employed by the VA, and thus have no incentives to contravene the formulary. In addition, they undergo training on cost-effective prescribing by "academic detailing" from VA pharmacies. This makes generic substitution very common, and is one of the main factors why the VA costs are so low.[28]

Payment principles

This background section illustrates that payment methods, while complex, genuinely matter: **how** you buy drugs ultimately affects the overall cost. Specifically:

- **Volume matters**. The more covered lives a payer has to negotiate with, the more market share and the more leverage they have on payment terms.

- **Coordinated volume matters more**. Payers will be more effective in negotiating prices when they can use their purchasing power as a single mass. The epitome of this strategy (for consumer goods generally) is WalMart, which constantly uses its purchasing power to press on its suppliers for lower costs (and thus provide "everyday low prices" to its customers).

- **"Just say no" to drugs**. In any negotiation, you have to be willing to walk away. Payers do this most effectively through restrictive formularies like the VA. By contrast, tiering and cost-sharing arrangements are less-effective, particularly when manufacturers can subvert these incentives through coupon or charity programs. Restricting access to certain drugs, of course, comes with its own set of tradeoffs regarding patient access and choice.

- **Physician involvement is key.** The importance of prescribing behavior cannot be understated; where clinically appropriate, generic drug choices and step therapy can significantly reduce costs. Payers should seek to create incentives for physicians to care about the total cost of the drugs they prescribe.

[28] Ibid, citing a 2013 GAO report.

DRUG IMPORTATION

This section considers the policy lever of importing drugs from Canada as a way to lower prescription drug prices for Wyoming consumers.

The Department of Health does not recommend pursuing this option.

While there are genuine price differences that might be able to be exploited, the complexities of payment systems across both private insurance and Medicare make it difficult to pass on those savings to consumers.

Worse, if price differences are exploited on any kind of scale, economic fundamentals imply they will likely disappear. Because states like Florida, Vermont and Colorado are well ahead of Wyoming in setting up drug importation programs, it is unlikely that we could exploit this kind of arbitrage for very long.

Drug importation will require meeting several federal hurdles

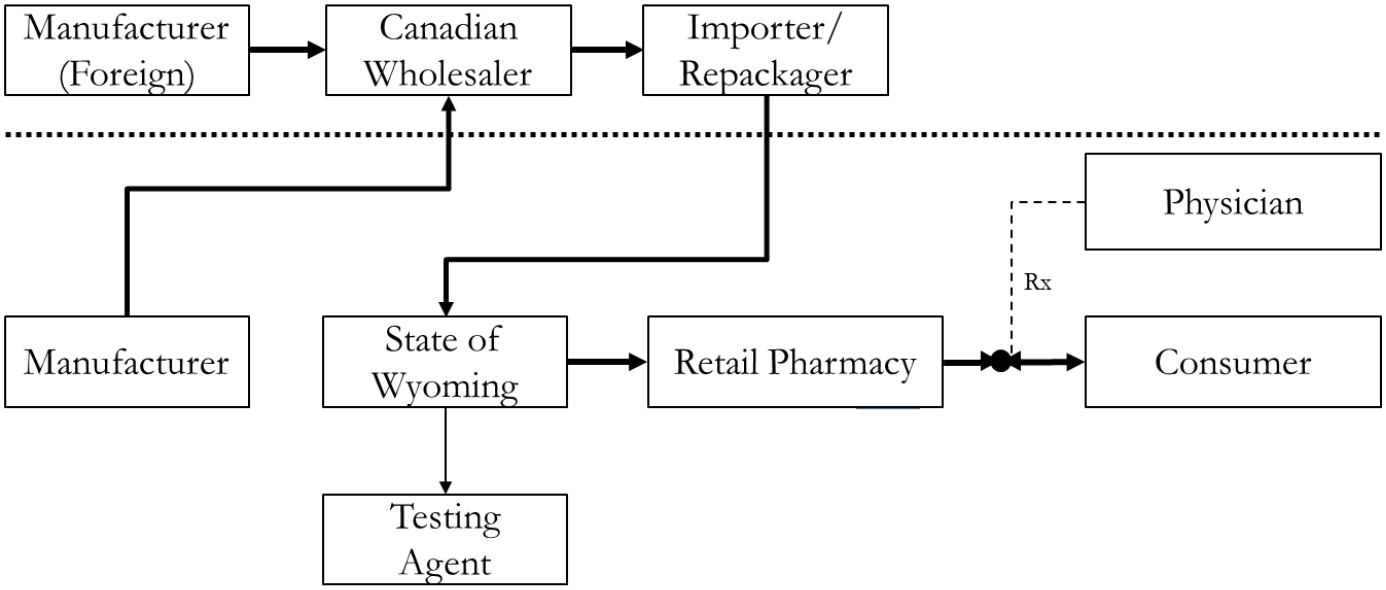
Canadian drug importation is (potentially) authorized through Section 804 of the Federal Food, Drug, and Cosmetic Act (21 USC § 384). This section allows states to construct a State Importation Program (SIP) if the Department of Health and Human Services certifies the program will (a) pose no additional risk to public health and safety and (b) will result in a "significant reduction in the cost of covered products to the American consumer."

Certain types of drugs are specifically excluded:

- Controlled substances;
- Biologics (including insulin);
- Infused drugs;
- Intravenously-injected drugs;
- Drugs inhaled during surgery;
- Drugs that might pose a threat to public health.

Generally speaking, the pipeline for Canadian importation for drugs not on this list would resemble Figure 9, on the next page.

Figure 9: Notional Canadian drug SIP pipeline (dotted line is Canadian border)



In this notional plan, the State of Wyoming would contract with a Canadian seller, likely a wholesaler. The State would need to verify the wholesaler's compliance, as part of this contract, with Canadian laws and FDA requirements, as well as ensure that contractually-agreed upon prices actually provide cost savings. All drugs under contract would additionally need to be able to be traced to an FDA-approved manufacturer and are FDA-approved for the US market. The only substantial difference in the drug product itself should be the packaging.

Because Section 804 requires that (a) imported drugs are labeled according to US requirements and (b) drug identification and documentation complies with the Drug Supply Chain Security Act (DCSA), the State will also have to contract with an entity that can meet several requirements:

- Repackage and relabel drugs with an approved National Drug Code (NDC) and serialized identifier that meets DCSA standards;
- Is an "Authorized Trading Partner" as registered with the FDA;
- Is a licensed pharmacist or wholesale distributor;

At various stages in this process, drugs will also need to be tested at a qualified laboratory in the United States for authenticity and degradation.

As previously noted, the states of Colorado, Florida and Vermont have already drafted white papers describing these processes.[29] If so directed by the Legislature, Wyoming's plan would draw on these existing sources and incorporate any lessons learned during implementation.

Theoretical savings come from genuine price differences

When standardized lists of drugs and the total dollars paid are compared with price lists published by Canadian provinces,[30] large price differences are often apparent.

After excluding biologics, insulin, and controlled substances from consideration, we looked at the potential total savings from two perspectives:

- Wyoming Medicare members, with **cost sharing by members** as the primary consideration; and,

- The Wyoming Employee's and Officials Group Insurance Plan ("EGI"), where **total dollars paid by the State** was the primary consideration.

We considered these two payers because actual price data was readily available, either publicly (Medicare) or, in the case of EGI, through the Multi-Payer Claims Database (MPCD). Tables 7 and 8, on the next two pages, list the drugs with the highest "bang-for-the-buck" for each program, respectively.

Note, however, that because HHS must certify that any State Importation Program must lower drugs to the American consumer, the focus on SGF savings to EGI needs to be tempered with a view on reducing out-of-pocket costs to State employees as well.

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[29] Vermont's paper is here:
https://www.nashp.org/wp-content/uploads/2019/12/vt-submittal-to-omb-12-3-2019.pdf
Florida's paper is here:
https://ahca.myflorida.com/executive/communications/requested_documents/Florida_Canadian_Prescription_Drug_Importation_Concept_Paper.pdf
Colorado's paper is here:
https://www.colorado.gov/pacific/hcpf/drug-importation

[30] We averaged prices from two provinces, where drug information was available: Quebec and its guaranteed selling price from the "List of Medications" (Dec 18, 2019), and British Columbia, with an online PharmaCare Formulary Search tool (https://pharmacareformularysearch.gov.bc.ca/)

Table 7: Top 16 drugs with potential cost saving to Medicare members

Drug	Members	Est. savings per fill	30-day fills	Total potential savings (cost sharing)
Eliquis	1,406	$47.52	9,190	$436,684
Combivent Respimat	538	$42.21	2,669	$112,699
Flovent HFA	546	$41.81	2,459	$102,827
Janumet	361	$37.90	3026	$114,706
Namenda XR	307	$37.67	3,246	$122,296
Xarelto	1,257	$37.03	8,447	$312,826
Premarin	746	$36.48	3,976	$145,073
Januvia	1,042	$33.41	8,435	$281,806
Spiriva	1,084	$33.36	6,685	$223,022
Lumigan	584	$32.91	4,015	$132,171
Dexilant	685	$32.76	5,573	$182,585
Advair Diskus	1,912	$30.74	10,405	$319,841
Symbicort	1,445	$28.31	7,652	$216,652
Celecoxib	1,419	$17.37	8,640	$150,099
Ventolin HFA	4,640	$17.21	12,381	$213,108
Synthroid	1,308	$15.52	12,359	$191,808
Total			**109,165**	**$3,258,206**

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Table 8: Top 24 drugs with potential saving to the State employee group insurance plan (State dollars)

Drug	Members	Est. savings per fill	30-day fills	Total potential savings (SGF)
Advair	410	$176.61	2,078	$366,974
Aubagio	11	$5,181.53	86	$445,956
Breo	176	$164.07	925	$151,820
Dexilant	186	$213.62	1,504	$321,245
Eliquis	268	$270.97	2,078	$563,035
Forteo	8	$2,728.63	75	$205,374
Gilenya	17	$5,688.62	143	$813,851
Janumet	146	$288.27	1,400	$403,530
Januvia	205	$321.95	1,935	$622,903
Jardiance	84	$333.27	681	$226,792
Latuda	39	$1,060.53	222	$235,437
Myrbetriq	117	$276.61	857	$236,938
Opsumit	3	$5,103.49	32	$163,311
Premarin	387	$115.78	2,347	$271,730
Revlimid	8	$1,905.41	70	$132,934
Sabril	3	$13,413.17	23	$308,502
Spiriva	133	$238.30	886	$211,152
Symbicort	219	$165.22	897	$148,173
Tecfidera	22	$5,217.95	151	$787,562
Trulicity	114	$528.97	832	$439,975
Victoza	162	$557.92	1,268	$707,428
Xarelto	224	$290.94	1,623	$472,232
Xeljanz	17	$2,435.75	117	$284,982
Xtandi	5	$6,567.43	39	$256,129
Total			**20,269**	**$8,777,965**

While there are also theoretical savings to privately-insured and self-pay consumers, we cannot estimate them here as we do not have data on drug costs or drug spending. The State would need to proceed with employer plans or insurance companies on a case-by-case basis, with plans opting-in.

There may also be additional unquantifiable savings to self-pay or uninsured consumers, if imported drugs are made available to retail pharmacies with the intent of serving Medicare members, and these individuals opt for the Canadian imported alternatives.

There are two good options for in-State distribution logistics

Once drugs pass the required federal hurdles and begin arriving in wholesale quantities in Wyoming, the Department recommends implementing one or both of the following options for distribution, depending on the audience chosen.

(1) If distributing to retail pharmacies across the State is a requirement, we recommend using existing warehousing and distribution infrastructure of the Liquor Division in the Wyoming Department of Revenue.

Because most of the drugs in question do not require any special handling (some require refrigeration), the distribution process would look similar to the existing distribution of liquor throughout the State of Wyoming. Specifically:

- The Liquor Division would receive bulk shipments for selected high-value drugs from the Canadian importer at its warehouse, and — just as with any wholesale liquor shipments — staff would break down pallets and stock a set of gravity flow-racked carton shelves in a separate designated section of the warehouse.

- Retail pharmacies would place orders with the Liquor Division for Canadian imported drugs. Warehouse pickers would stock pharmacy totes with the requested orders and prepare them for distribution.

- Totes would be loaded on the same trucks distributing to liquor retailers, per plans and direction from the Department of Revenue's third party distribution contractor. Since there are over 10 times as many liquor retailers (1,268) as there are retail pharmacies (118) in the State, it is unlikely that distribution routes would need to be altered significantly.

Assuming, conservatively, that this program has 100% take-up of the 16 drugs listed for Medicare members, and that the Liquor Division would need to maintain a two-month inventory in the warehouse, this would require handling ~485 ft^3 worth of drug cartons. It is unclear if the warehouse could be reconfigured to allow some fraction of this additional space (i.e., on the margin) or at what point entirely new facilities would be required.

(2) On the other hand, if drugs could be distributed to members directly (e.g., State employees), it may be more efficient to augment the mail-order pharmacy capabilities of the Medication Donation Program in the Wyoming Department of Health.

We present this option despite the Legislative requirement that the Department to study "the feasibility of establishing a prescription drug importation program for distributing prescription drugs to voluntarily participating, state-licensed pharmacies in Wyoming for retail sale to persons in Wyoming with valid prescriptions," because of the significantly higher likelihood of cost-savings in the short-term.

- Under this concept, the Medication Donation program (which operates a licensed pharmacy) would receive wholesale shipments and stock ~ 24 drugs, listed in Table 8, in a separate designated section of their workspace in the basement of the Hathaway building.

- Prescriptions would be filled and mailed directly to enrolled members by additional Medication Donation staff. Total additional prescription volume is estimated at around five (5) times existing volume.

- EGI would cause its Pharmacy Benefit Manager (PBM) to accept Canadian drugs on its formulary, and further solicit enrollment in the new mail-order program by State employees who receive those specific drugs.

- Cooperation from State employees could either be required (e.g., through a restrictive formulary) or incentivized (through altered cost-sharing arrangements that significantly favors the mail-order Canadian drug option).

- Pharmacy claims would be submitted to EGI's PBM by the Medication Donation Program, which would use the revenue in an enterprise fund structure

to purchase wholesale drugs and fund its own operations. Note, however, that a new pharmacy claims system would need to be implemented for this billing to work.

Costs of in-State distribution

Depending on the course of action, we estimate (very roughly) the costs of standing up this program at between $1.1 million (for just the Medication Donation option) to $2.8 million (both options) in the first year. The expected one-time and annual costs are shown in Table 9, below.

Both cases would require additional staff, modifications to buildings and computer systems, and additional regulatory costs.

Table 9: Operational expenses

Category		Costs (thousands)	
		Liquor Div.	Med. Donation
One-time	Building modifications	$500	$50
	Computer system modifications	$250	$100
	Initial legal and regulatory consulting	$250	$250
	Subtotal - one-time expenses	$1,000	$400
Annual	Additional staff (~ 4 positions)	$300	$350
	Contractual testing services	$100	$100
	Repackaging and importing services	$200	$200
	Legal and regulatory consulting	$50	$50
	Subtotal - annual expenses	$650	$700

The Department of Health (or Department of Revenue) will also need an initial amount of funding to purchase drugs in bulk quantities. Approximately $12 million would cover one year of costs for all the drugs in Table 8 and Table 9, at estimated Canadian prices.

Savings are more likely for the State Employees' and Officials' Group Insurance Program

Unlike the case with Medicare, savings (to the State General Fund) are more likely for the State employee insurance plan for three major reasons:

- Since the State shoulders the lion's share of drug costs, most of the reduction in the overall cost of the drugs will accrue to the State.

- The State has control (i.e., depending on how policy changes would affect its existing Pharmacy Benefit Manager contract) over its formulary and cost-sharing structures.

- State employees could be strongly incentivized, through reduced cost sharing and the convenience of a mail-order pharmacy, to use the Canadian drug imports, thus ensuring maximal take-up.

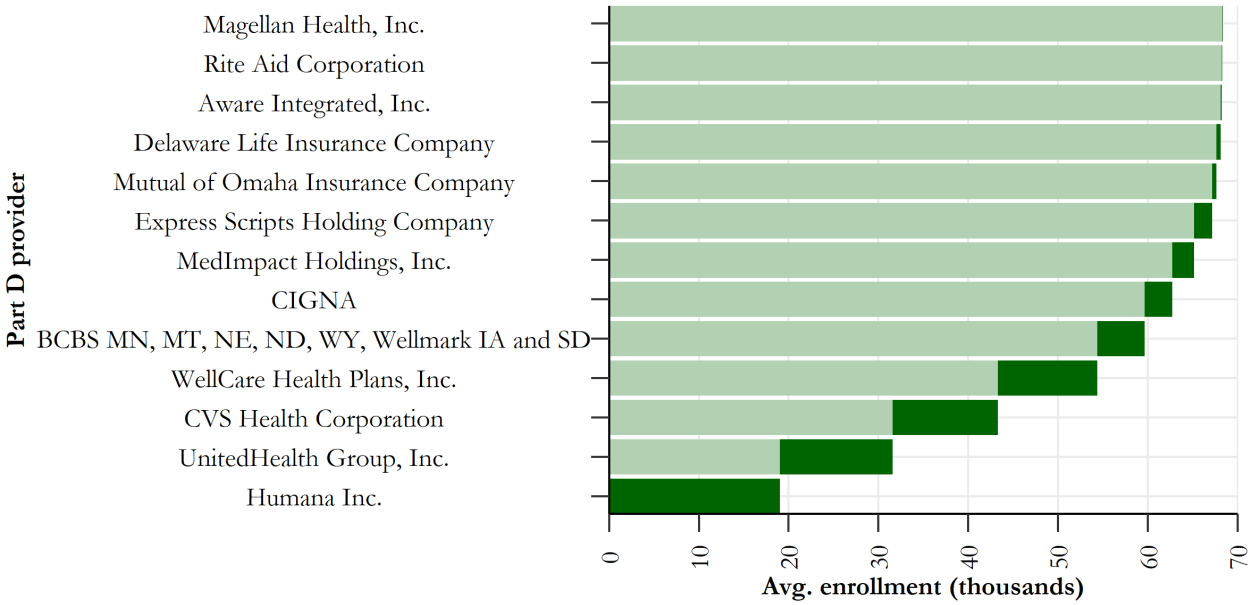
Actual savings for Medicare members are less clear

While the State may be able to import Medicare drugs at lower wholesale prices, as noted in the background section, the cost sharing actually experienced by the consumer is largely set by Medicare Part D plans. This means that the State would need to negotiate with these plans to place imported Canadian drugs on each respective Part D formulary.

This is no easy task. Figure 10, on the next page, shows the Part D market share in Wyoming, on a cumulative basis. In order to reach 85% of the Medicare market in the State, for example, the State would need to negotiate and successfully place Canadian drugs on the formularies of five large insurers (Humana, UnitedHealth Group, CVS, WellCare and BCBS).

The outcome of these negotiations is uncertain, particularly regarding what fraction of the potential cost savings available on a wholesale level would go to Wyoming Medicare members, and what share would be retained by the insurer.

Figure 10: Wyoming Medicare Part D cumulative average enrollment, by plan insurer (CY 2019)



Any savings under this program are probably unsustainable

This is because of a fundamental economic problem behind the entire concept of importing Canadian drugs: it relies on a form of **arbitrage**.

We typically see this in currency and commodity markets, where traders exploit differences in prices for the same good across different markets to make a profit. These profits are fleeting, however, because the activity itself typically drives prices to converge. In theory, this activity benefits society by correcting market inefficiencies.

In the context of Canadian drugs, however, any **potential savings to consumers** or the State from exploiting the price differential **are likely unsustainable**. Particularly if exploited at scale, either the Canadian government or American manufacturers will likely respond by imposing export restrictions.

In direct discussions with the State as part of this study, the Canadian government has already expressed deep concerns with the idea, particularly if quantities being exported harm access to drugs there, and noted that "Canada would be forced to

respond to any actions that could endanger the health and safety of Canadians by threatening the supply of prescription drugs or causing the costs of prescription drugs for Canadians to increase." A letter from the Canadian Consulate General further articulating these concerns is attached to this study.

You may be asking yourself at this point: why does the price difference exist in the first place? Why do manufacturers sell to Canada at such lower prices anyway?

The simple answer is that — when the market is segmented by national borders — it is profitable for the manufacturers to do so.

As noted in the background section, the cost of any given prescription embodies the significant fixed costs of research, development and overhead.

Once drugs have come to market, however, the **marginal cost** of producing another pill or inhaler is far lower than this average cost. Once the US market is covered (and direct to consumer advertising makes sure of this), it makes economic sense for drug manufacturers to look abroad for other markets, as long as those consumers are willing to pay a price above the marginal costs of production.

This idea of **price discrimination** — pricing a product so it maximizes revenue for a given market segment — is well established in other areas.

Consider going to the movies. Theaters often price tickets for senior citizens and students at a lower rate than adults. This maximizes revenue in two market segments where demand is more sensitive to price: seniors have more free time to go to the matinee showings, and students have less income. What allows the price discrimination to work is the *ability for the theater to tell the difference* between senior citizens, students, and full-freight-paying adults, ultimately through visual inspection of an official ID.

So, what do you think would happen if these full-freight adults started posing as senior citizens? The idea of importing drugs from Canada due to the price difference will likely fail for pretty much the same reasons.

ALTERNATIVE PURCHASING ARRANGEMENTS

This brief section considers two separate policy levers — group purchasing and subscription model — for both the Department of Health and Department of Corrections, when it comes to the objective of lowering prescription drug costs.

We do not believe either strategy will materially affect these costs.

Group purchasing

Medicaid is the Department of Health's single largest purchaser of prescription drugs. As noted in the background, however, Medicaid enjoys a unique statutory position when it comes to rebate and effective drug prices. Additionally, it is already involved in the Sovereign States Drug Consortium in negotiations for supplementary rebate.

Thus, it would not make financial sense for Medicaid to embark in alternate group purchasing schemes, nor would it even be legal for Medicaid to co-mingle its purchasing power with any other non-Medicaid program.

When it comes to non-Medicaid programs within the Department of Health and the Department of Corrections, the fundamental problem is that these programs, even combined, would likely be too small to make any difference on the market.

The Department of Corrections, for example, spends less than $1.7 million on prescription drugs annually. Its largest single drug expenditure is less than $200,000. By comparison, Medicaid spends approximately $60 million each year on drugs — and it is the smallest Medicaid program in the entire United States. As small as it is, DOC purchasing power is likely far larger than non-Medicaid WDH programs (e.g., at the State Hospital, since clients at other facilities can use their Medicare and Medicaid pharmacy benefits). It is therefore unlikely that DOC would have any more leverage on the marketplace than any other large employer.

In addition to size, contractual nuance matters. DOC's pharmacy spending, for example, is bound up in an overall health services contract, which was just recently renewed. For DOC to see any savings on drugs, it would need to restructure and re-procure this contract.

Finally, even if DOC and other non-Medicaid entities could band together and negotiate prices as a single entity, any actual savings would be the end product of negotiations, and thus are completely speculative for this study.

Subscription models

Louisiana and Washington are two states have attempted to move away from fee-for-service purchasing of some drugs to what is known as a "subscription" or "Netflix" model. Under this arrangement, the states have solicited bids from drug manufacturers to be the sole provider of a given drug class. So far, these bids have centered on Hepatitis C drugs, but other states are considering bids for things like HIV prophylaxis and opioid antagonists like Naloxone.

The deal is similar to an "all you can eat" buffet. The states typically offer a guaranteed fixed amount under the contract, but expect that all drugs provided after this fixed minimum be provided by the manufacturer at *de minimis* cost.

The most significant point here is that the purpose of these arrangements is **not to save money**, at least in the short-term. The negotiated minimum fixed amounts seem to start at historic budget amounts.[31] The goal is really twofold:

- Generate budget stability for the State; and,
- Eradicate the targeted disease entirely by providing as many drugs as it takes to do so.

In theory, there are long-term cost savings from eradicating Hepatitis C. It's unclear, however, the degree to which any long-term savings would accrue to the State, compared to other payer like Medicare. It's also unclear how well an eradication policy would work on a State-wide level, when migration to Washington or Louisiana from other states would provide ample chances to reintroduce the disease.

These programs are also new. And because many of the contractual details are still proprietary, it's yet unclear if Washington or Louisiana are actually saving money on a per-dose basis.[32]

For these reasons, we do not recommend pursuing this kind of model either.

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[31] https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2019/02/25/a-netflix-model-for-hepatitis-c-one-price-unlimited-meds

[32] https://khn.org/news/pharma-sells-states-on-netflix-model-to-wipe-out-hep-c-but-at-what-price/

CONCLUSION

While the cost of prescription drugs can no doubt painful for both consumers and payers, the Department of Health recommends against pursuing any of the three policy options that are the focus of this study.

The primary option — importing drugs from Canada — will require significant administrative effort and cost, without any guarantee of savings to consumers. Economic fundamentals also suggest it is not sustainable in the long-term.

The other two options are largely intended to save State General Funds for the Department of Health and Department of Corrections. For both legal and practical reasons, they are unlikely to be more effective than the status quo.

Unfortunately, in a general sense, Wyoming's small population likely precludes it from implementing any effective State-level solutions to lower overall drug costs for payers. These drug costs are mostly the product of price negotiations between payers (or their agents) and manufacturers, and the result of those negotiations hinges on how much market leverage payers have, and how willing they are to use it.

Because of these realities, policies designed to lower drug costs for payers may be more effective if they focus on creating incentives for physicians and pharmacies to prescribe the most cost-effective drugs possible. These might include bundled or episode-based payments that include some degree of risk by the provider on which drug is prescribed, or some kind of side payments for meeting effective prescribing or dispensing targets.

The story is different, however, if this issue is about out-of-pocket costs for consumers. Part of this issue may resolve itself without State action. Due to recently-implemented provisions from the Affordable Care Act, for example, Medicare members may see significant reductions in "donut hole" costs.

In most cases, however, crushing out-of-pocket drug costs may simply be the result of being uninsured or indigent. There are several options the State could pursue in this regard to expand insurance or prescription drug coverage (e.g. Medicaid expansion), but this is, of course, a separate policy discussion.

Consulate General of Canada | Consulat général du Canada

August 18, 2020

Ms. Kathryn Burkell
Consulate General of Canada
1625 Broadway Suite 2600
Denver, Colorado 80202

Director Michael Ceballos
Wyoming Department of Health
Director's Unit for Policy, Research and Evaluation
401 Hathaway Building
Cheyenne, WY 82002

Dear Mr. Ceballos,

We are writing today to offer comments from the Government of Canada on the feasibility study on importing prescription drugs as a way to lower drug prices in Wyoming, as mandated by the Wyoming House of Representative's Enrolled Act No. 45, *An Act relating to food and drugs; requiring the department of health to study the feasibility of a prescription drug importation program for possible implementation in Wyoming; specifying study parameters; requiring a report; and providing for an effective date.*

The problem of the high cost of prescription drugs is one that Canada understands and shares. However, we are very concerned about any proposal for a program to allow bulk importation of prescription drugs from Canada, as we are concerned about any action that would negatively impact access to affordable medicine for Canadians.

As Wyoming and other states consider policy options to reduce the price of prescription drugs, including options to allow drug imports from Canada, it is important to recognize that Canada's drug prices are now the third highest among Organization for Economic Co-operation and Development (OECD) countries - that is about 25% above the OECD median. And in recent years, drug spending has accounted for an increasingly large proportion of expenditures in the Canadian health care system, with these expenditures growing faster than any other component of health care. Expenditures on drugs have now surpassed spending on physician remuneration to become the second largest cost in the Canadian health care system, after hospitals.

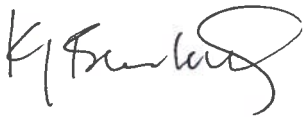
Furthermore, the Canadian market is too small to make a real impact on U.S. drug prices. To put this in perspective, the U.S. consumes 44% of the global prescription drug supply, compared to Canada's 2%. Canadian stakeholders, including health care practitioners, patients, pharmacists and industry, have accordingly expressed their concerns with the potential negative impact on Canada's supply of prescription drugs, and on Canadians themselves.

In addressing high prescription drug costs, we urge you to consider some of Canada's practices as detailed in the comments provided to the U.S. Food and Drug Administration on its Proposed Rule on the Importation of Prescription Drugs. These are available here: https://www.regulations.gov/document?D=FDA-2019-N-5711-1208.

The Government of Canada's priority is to ensure that Canadians have reliable and steady access to a safe, effective and affordable drug supply. As such, the Government of Canada would be forced to respond to any actions that could endanger the health and safety of Canadians by threatening the supply of prescription drugs or causing the costs of prescription drugs for Canadians to increase.

The Government of Canada remains dedicated to working with our U.S. friends, partners, and allies, including in the state of Wyoming, to improve our citizens' health and well-being. Instead of looking to importation of prescription drugs from Canada, we urge Wyoming to focus on domestic solutions to address this crisis of pharmaceutical costs in the United States and in the Equality State.

Very Respectfully,



Kathryn Burkell
Acting Head of Mission