MASSACHUSETTS
HEALTH POLICY COMMISSION

Meeting of the Market Oversight and Transparency Committee

June 5, 2019

MASSACHUSETTS
HEALTH POLICY COMMISSION

AGENDA

- **Call to Order**
- Approval of Minutes
- Registration Of Provider Organizations (RPO) Program: Overview and Updates
- Study Design: The Impact of Prescription Drug Coupons, Discounts, and Other Product Vouchers on Pharmaceutical Spending and Health Care Costs
- DataPoints Issue #12: Cracking Open the Black Box of Pharmacy Benefit Managers
- Key Findings and Recommendations: Review of Third-Party Specialty Pharmacy Use for Clinician-Administered Drugs
- Schedule of Next Meeting (October 2, 2019)

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VOTE: Approving Minutes

MOTION: That the Committee hereby approves the minutes of the MOAT Committee meeting held on February 27, 2019, as presented.

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HEALTH POLICY COMMISSION

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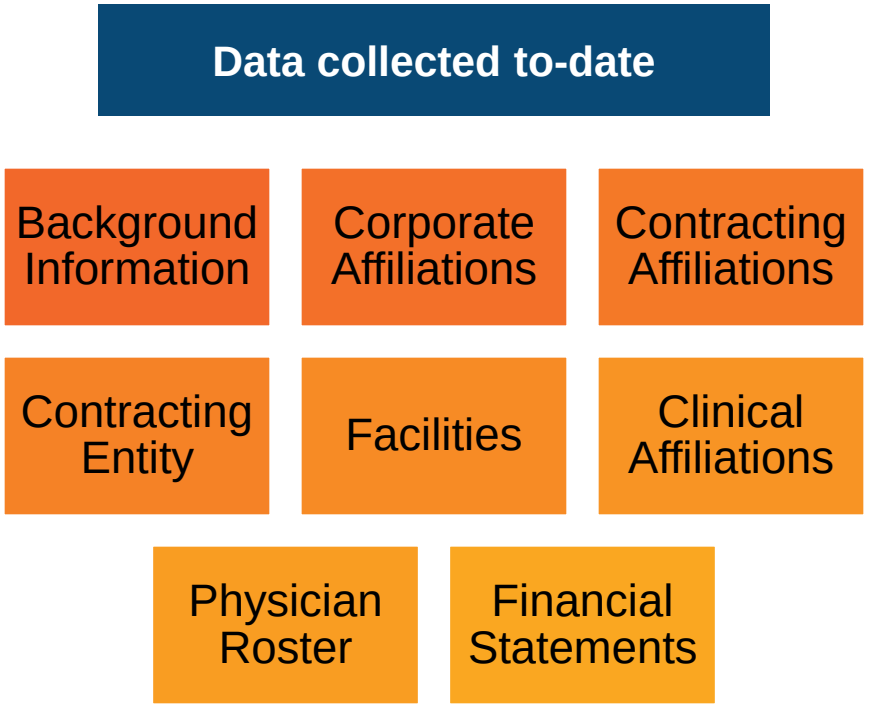
Overview of the MA-RPO Program

- The MA-RPO Program is a **first-in-the-nation** initiative for collecting public, standardized information on Massachusetts' largest health care providers annually
- The data contribute to a foundation of information needed to support **health care system transparency and improvement**
- This regularly reported information on the health care delivery system supports many functions including: care delivery innovation, evaluation of market changes, health resource planning, and tracking and analyzing system-wide and provider-specific trends



HPC

MA-RPO Program Updates

2018 Data Release

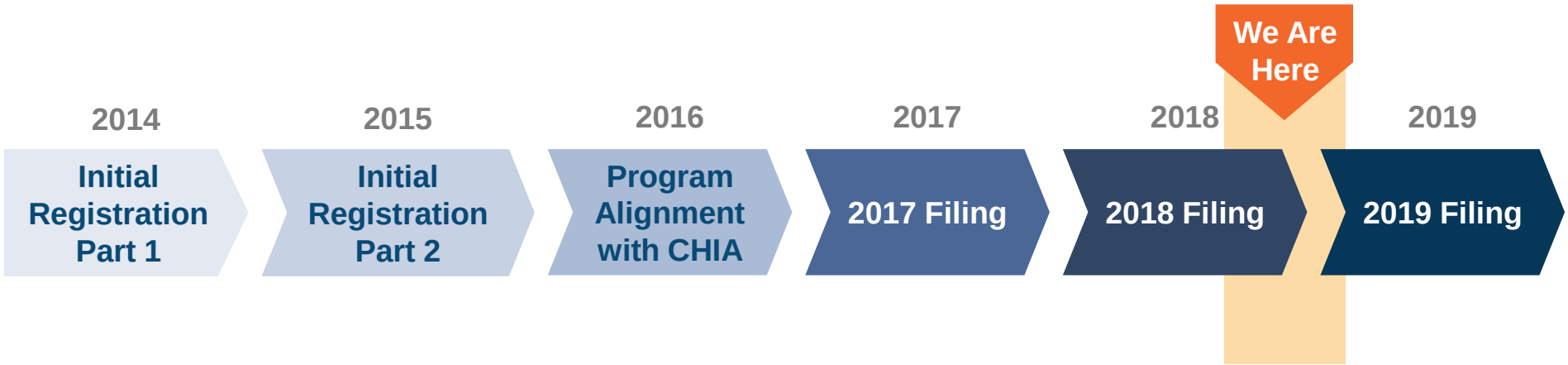
Provider Organizations' 2018 filings are now available on the program website. The 2018 master physician roster is available upon request by emailing program staff at HPC-RPO@mass.gov

Online Submission Platform Open for 2019 Filing

The online submission platform, the web platform used by Provider Organizations to submit their filings, opened on Monday. Filings are due July 31, 2019.

MA-RPO Program Timeline

The 2019 filing will be the fifth data collection cycle since the program's inception



The MA-RPO data provides unique value to market participants, state and federal government agencies, researchers, and the public

Before MA-RPO, basic data about the structure of the Massachusetts market were not available in a standardized, accessible format

Researchers
Ariadne Labs
BU, Harvard, UC Berkeley
NBER
RAND
Market Participants
Providers
Payers
Trade Organizations
Unions
Government
HPC
EOHHS
CHIA
AGO
US Dept. of Labor
Federal Trade Commission

- The HPC uses MA-RPO data as a major input into several ongoing analyses:
  - **Provider Organization Performance Variation**
  - **Cost and Market Impact Reviews**
  - **Performance Improvement Plan assessments**
- Teams across the agency regularly use the data to answer specific questions

Guiding Principles of the MA-RPO Program

From its inception, the MA-RPO Program has used the following principles to guide its work

1. Administrative simplification
2. Phasing in the types of information that Provider Organizations must report over time
3. Avoiding duplicative data requests through ongoing coordination with other state agencies
4. Balancing the importance of collecting data elements with the potential burden to Provider Organizations

Guiding Principles

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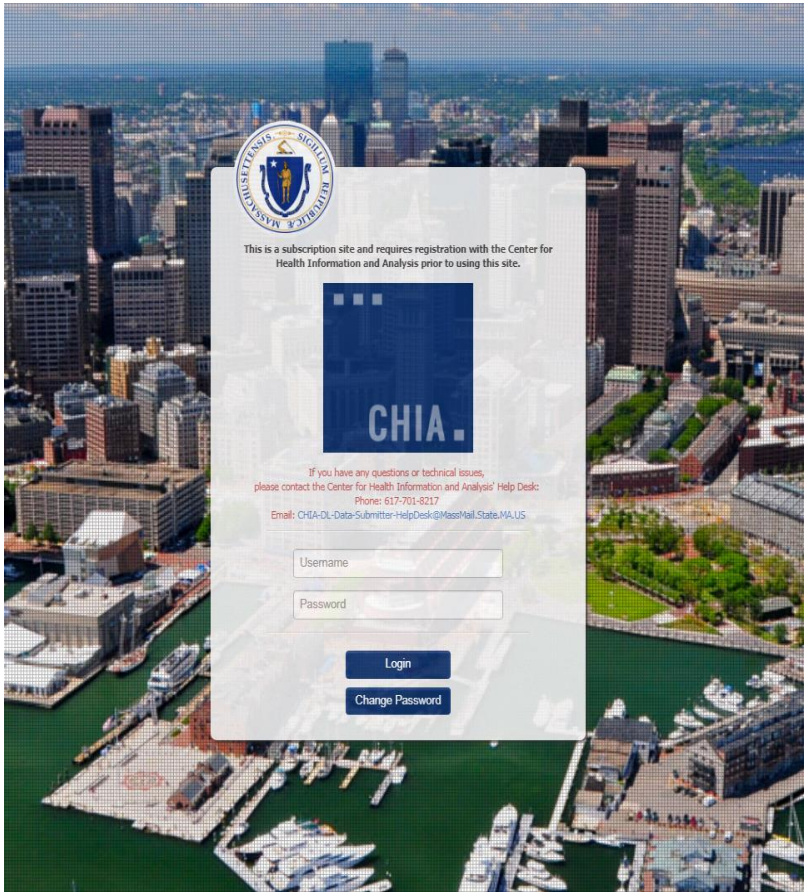
MA-RPO Online Submission Platform

- Provider Organizations use the online submission platform to complete their filings
- Data submitted in the previous year's filing are prepopulated
- Features and tools added based on user feedback



Commitment to Providing Excellent Customer Service

Targeted training sessions

General and customized resources

One-on-one meetings

Online submission platform assistance

MA-RPO Feedback Surveys

The MA-RPO Program regularly seeks anonymous feedback from registrants about their experience and uses the data to improve the program

Registrants expressed interest in a data resource that would map relationships **between existing files** (e.g., contracting relationships and clinical relationships)

Provider Organizations are interested in linking MA-RPO with other datasets, including the **APCD** and other **CHIA** data

Multiple respondents have used, are currently using, or are interested in **using MA-RPO data**

Respondents recommended **increased coordination** with other programs, including ACO Certification and the Risk-Bearing Provider Organization process

Guiding Principles

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Statutory Authority

M.G.L. c. 6D, § 11 and c. 12C, § 9	
(b)(1)	organizational charts showing the ownership, governance and operational structure of the provider organization, including any clinical affiliations and community advisory boards
(b)(2)	the number of affiliated health care professional full-time equivalents by license type, specialty, name and address of principal practice location and whether the professional is employed by the organization
(b)(3)	the name and address of licensed facilities by license number, license type and capacity in each major service area
M.G.L. c. 12C, § 9	
(b)(4)	a comprehensive financial statement, including information on parent entities and corporate affiliates as applicable, and including details regarding annual costs, annual receipts, realized capital gains and losses, accumulated surplus and accumulated reserves
(b)(5)	information on stop-loss insurance and any non-fee-for-service payment arrangements
(b)(6)	information on clinical quality, care coordination and patient referral practices
(b)(7)	information regarding expenditures and funding sources for payroll, teaching, research, advertising, taxes or payments-in-lieu-of-taxes and other non-clinical functions
(b)(8)	information regarding charitable care and community benefit programs
(b)(9)	for any risk-bearing provider organization, certificate from the division of insurance under chapter 176U
(b)(10)	such other information as the center considers appropriate as set forth in the center's regulations
(d)	the commission may require…additional information reasonable and necessary to determine the financial condition, organizational structure, business practices or market share of an RPO.
M.G.L. c. 12C, § 8	
(a)	any agreements through which provider agrees to furnish another provider with a discount, rebate or any other type of refund or remuneration in exchange for, or in any way related to, the provision of health care services.

HPC

Collected or partially collected

Not yet collected or satisfied elsewhere

Overview of MA-RPO Data Collection

1. **Background Information File**
2. **Corporate Affiliations File**
3. **Contracting Affiliations File**

→ **Initial Registration Part 1**

4. Contracting Entity File
5. Facilities File
6. Clinical Affiliations File
7. Physician Roster
8. Financial Statements File

In the first year of the program, registration was divided into two parts to minimize the burden on Provider Organizations

Overview of MA-RPO Data Collection

1. Background Information File
2. Corporate Affiliations File
3. Contracting Affiliations File
4. Contracting Entity File
5. Facilities File
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Initial Registration Part 2

Much of the required information is static year-over-year, allowing Provider Organizations to confirm the existing information or make updates as needed

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1. Background Information File
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2018 Filing

Some categories of information in HPC and CHIA's statutes have not yet been required

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Avoiding Duplicative Data Requests

There are several categories in the statute for which the MA-RPO program does not require organizations to submit information

1. Copies of risk certificates and risk certificate waivers are available through DOI
2. Community benefits information is available through the AGO

The MA-RPO Program allows for attestation when information is available through another state agency

3. Provider Organizations can indicate that financial statements are available through CHIA, DOI, or the AGO
4. Provider Organizations can indicate that information on their community advisory boards is available through the AGO

The MA-RPO Program minimizes duplicative reporting across Provider Organizations

5. Provider Organizations are not required to submit a physician roster if each of their physicians is reported by another Provider Organization
6. Clinical Affiliations are typically only reported by one party to the affiliation due to reporting directionality requirements
7. Corporate systems submit a single filing

HPC

Aligning RPO Reporting Between HPC and CHIA

	HPC RPO	CHIA RPO		MA-RPO Program
Who	▪ Provider Organizations with $25 million in commercial NPSR ▪ Risk Bearing Provider Organizations	All Provider Organizations that register with the HPC	Aligned →	**Same** organizations
What	4 statutory categories of information	10 statutory categories of information, 4 of which are identical to the HPC's categories	Opportunity →	Submit the **same** information
When	Biennially, with off-cycle updates in certain circumstances	Annually	→	**Once** a year
How	Shared online submission platform	Shared online submission platform	Aligned →	Through **one** submission process

Guiding Principles

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Balancing Burden and Value

Routinely reevaluate questions

- Service lines at licensed facilities
- APM & Other Revenue file

Consider competing priorities

- No new data elements during MassHealth ACO launch
- Moved deadline to summer based on feedback

Seek regular feedback

- Biennial survey of Provider Organizations
- Stakeholder engagement sessions
- New data elements based on end user priorities

Five Years Later: A Mix of Successes and Opportunities

- Aligning HPC and CHIA RPO programs
- Routinely reevaluate questions*
- Wide range of organizations and projects using data
- Successful customer service

- Routinely reevaluate questions*
- Increase lead time for new reporting requirements
- Ongoing assessment of areas where information can be sourced from existing datasets
- Wider variety of formats and resources for data release
- Increased alignment across programs

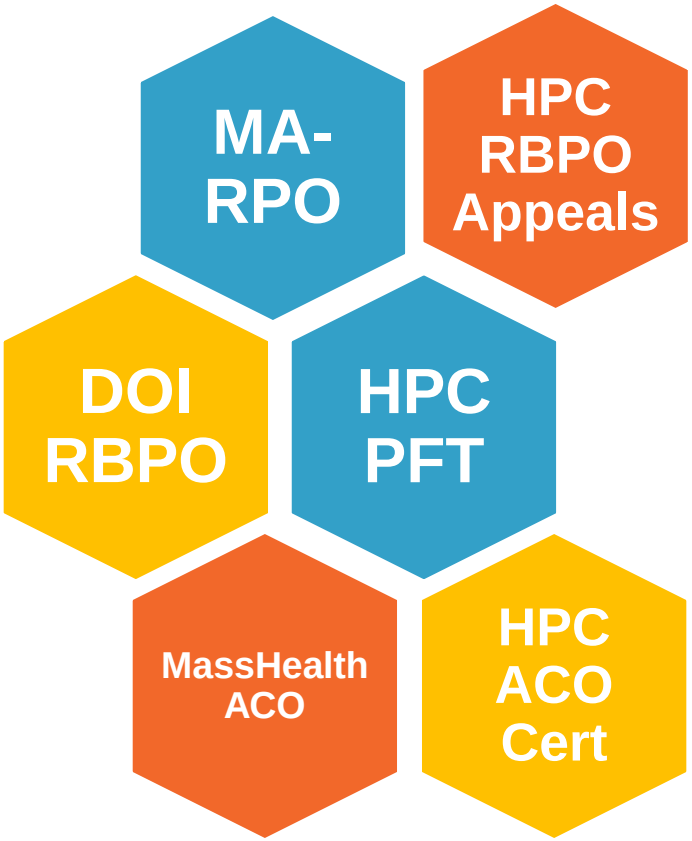
HPC

2019 Filing Updates

A key value of the MA-RPO Program is to balance registrant reporting burden with the utility of the dataset to end users

Financial Statements	CHIA updated their financial reporting requirements to collect annual financial reports from systems and owned physician practices The MA-RPO Program will not require templates to be submitted for systems and physicians practices that have submitted comparable information to CHIA
Facilities	Adding new data elements to capture information on the presence of inpatient beds and EDs at hospitals and clinics Prepopulating using data from DPH
Payer Mix	Collecting payer mix information from each of the Provider Organization's owned physician practices; will complement hospital-level data that's already available

Commitment to Reduce Administrative Complexity



The HPC commits that:

Over the next 12-18 months, HPC will convene staff from related programs to identify opportunities for administrative simplification and enhanced alignment and develop a plan for implementation

2019 Filing Timeline and Next Steps

November 29, 2018 – Released proposed updates for public comment

December 21, 2018 – Comments due to MA-RPO program

March 2019 – Released Final 2019 Data Submission Manual and filing templates

May 2019 – Training sessions and prep work with Provider Organizations

June 3, 2019 – Online Submission Platform opened

June 5, 2019 – 2018 Data Release; MOAT Committee Update

July 31, 2019 – 2019 filing deadline

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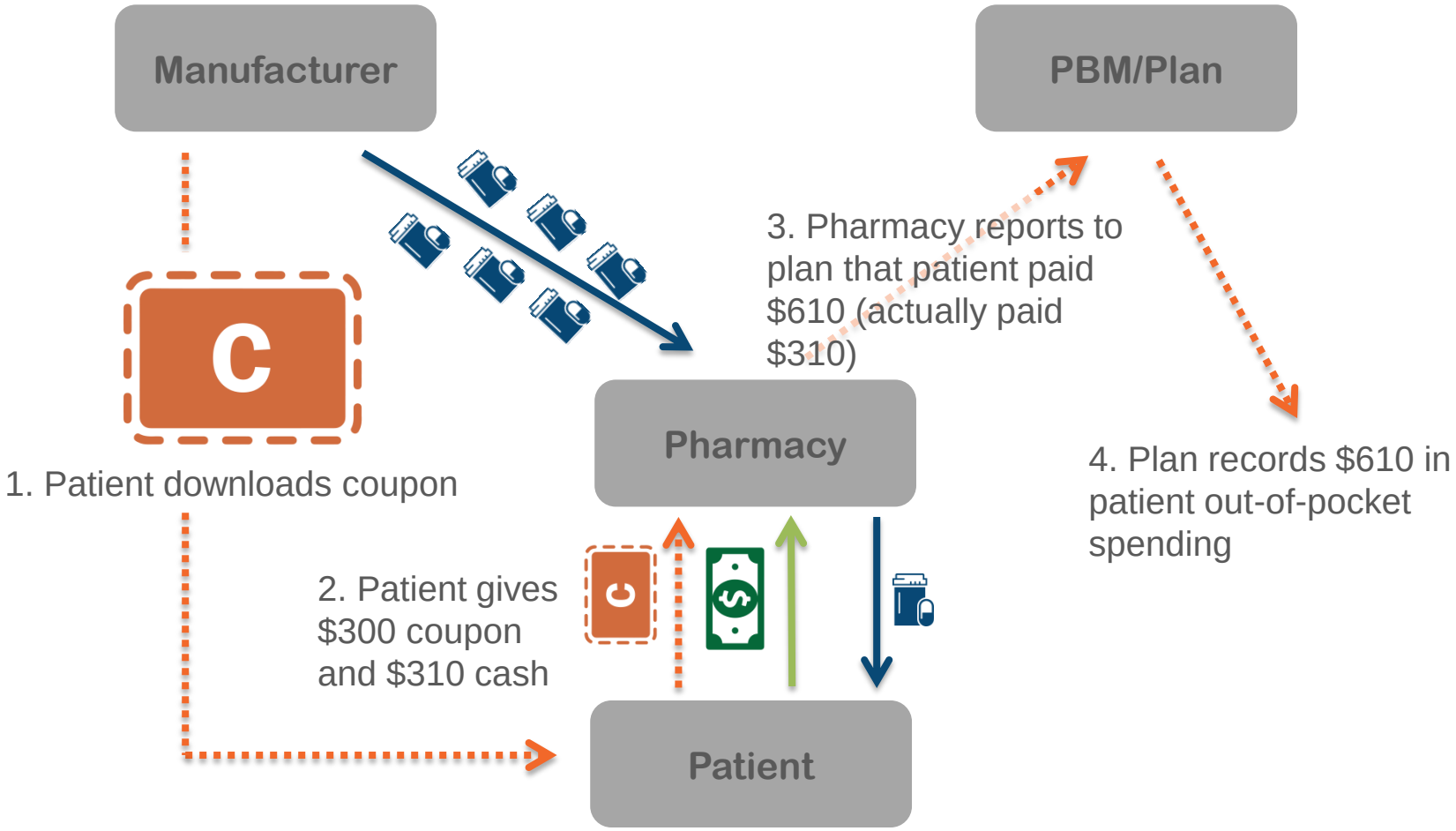
Defining drug coupons for HPC analysis

- Prescription drug coupons offered by manufacturers **reduce the amount of a patient's cost-sharing**, as established by the patient's insurance plan
  - Common terms: coupon, voucher, copay card
  - Distinct from:
    - Patient assistance programs offered by manufacturers, states, or charities for patients who cannot afford their medication
    - Cards or offers that reduce prices for patients without insurance
- Public payers (e.g., Medicare, Medicaid, VA) do not allow the use of coupons

Drug coupons off-set patient out-of-pocket spending at the pharmacy, but may not be transparent to pharmacy benefit managers or health plans

Example: Patient is responsible for cost-sharing of $610, based on insurance plan



Adapted from Memorial Sloan Kettering Cancer Center: Copay Assistance Programs. Available at: https://comm.ncsl.org/productfiles/119423533/DrugPricing-ChenPowerPoint.pdf

Background on authorization of drug coupons in the Commonwealth

Legislative History

- Chapter 139 of the Acts of 2012 authorizes drug manufacturers to provide consumers with drug coupons and vouchers
  - Continues ban on drug coupons for AB rated generic equivalents
  - Sunsets the authorization of drug coupons (January 2015)

- In 2014 and 2016, the Legislature delayed the sunset on drug coupon authorization

- Chapter 363 of the Acts of 2018 delays the sunsets until January 1, 2020, and directs the HPC to conduct a study on the matter by June 1, 2019

Statutory language directing the HPC to complete a study on use of prescription drug coupons in the Commonwealth

Chapter 363 of the 2018 Session Laws, ***An Act Extending the Authorization for the Use of Certain Discount Vouchers for Prescription Drugs***, was signed into law on January 2, 2019. It charges the HPC with conducting an analysis and issuing a report evaluating the effect of drug coupons and product vouchers for prescription drugs on pharmaceutical spending and health care costs in Massachusetts.

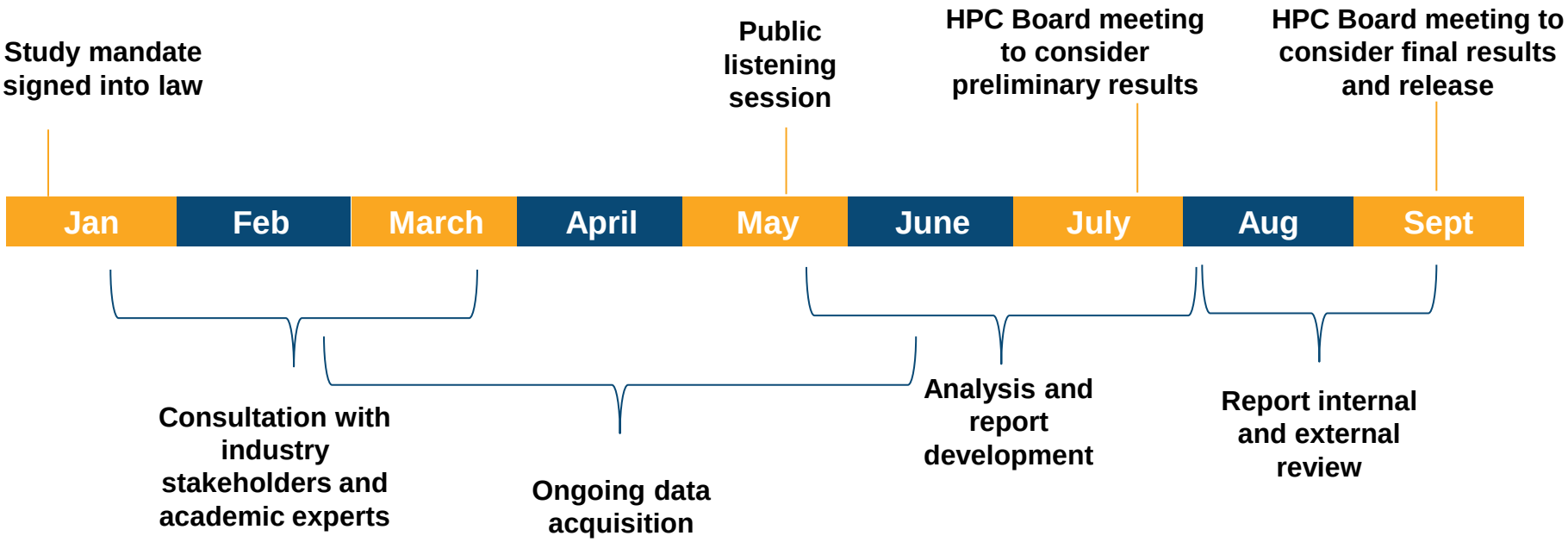
1. Analyze the **total number and value of coupons** redeemed in the Commonwealth, and the **types of drugs** for which coupons were most frequently redeemed.
2. Compare any change in utilization of **generic versus brand name prescription drugs**, and any change in utilization among **therapeutically-equivalent brand name drugs**.
3. Analyze **effects on patient adherence**, and **access to innovative therapies**.
4. Study the **availability of coupons** or discounts upon renewals, and the **cost impact on consumers** upon expiration of coupons.
5. Analyze the **impact of drug coupons on health care cost containment goals** adopted by the Commonwealth, and commercial and GIC health insurance premiums and drug costs.

Framework for analysis of prescription drugs that offer coupons

Study target: Branded drug that offers coupon	1 **Generic equivalent**	2 **Close therapeutic substitute: Generic**	3 **Close therapeutic substitute: Branded**	4 **No close therapeutic substitute**
Example				
Drug with coupon	Lipitor (statin; AB generic available)	Lyrica (nerve pain; no AB generic available)	Repatha (PCSK9; no AB generic available)	Kalydeco (cystic fibrosis; no AB generic available)
Comparator	Atorvastatin (generic Lipitor)	Gabapentin (generic Neurontin)	Praluent	None
Notes	Not eligible in MA		Comparators may also offer coupons	

Source: Van Nuys, Joyce, Ribero and Goldman. University of Southern California Leonard D. Schaeffer Center for Health Policy & Economics. 2018. A Perspective on Prescription Drug Copayment Coupon. Available at: https://healthpolicy.usc.edu/research/prescription-drug-copayment-coupon-landscape/

Prescription drug coupon study timeline



All dates are approximate

Prescription Drug Coupon Public Listening Session: Tuesday, May 21

Testimony

- Blue Cross Blue Shield of Massachusetts
- Massachusetts Association of Health Plans
- New England Hemophilia Association
- Health Care for All
- HPC received additional written testimony from GlaxoSmithKline, Massachusetts Biotechnology Council, the Massachusetts Society of Clinical Oncologists, and a joint letter from 26 organizations, predominately patient advocacy associations
- *A video of the listening session and all written testimony are posted on the HPC's website*

Key Takeaways

- Rising costs of prescription drugs overall and patients facing high financial burdens from deductibles and cost-sharing
- Stakeholders shared diverse perspectives on prescription drug coupons, including impact on use of alternative brand and generic drugs, patient access and adherence to medications, and long term health care system spending and premium challenges
- Other issues raised:
  - General lack of visibility of coupon data to payers and the public
  - Questions on specific coupon program design (e.g., expiration)

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HPC DataPoints, Issue #12: Cracking Open the Black Box of Pharmacy Benefit Managers

Background

- Prescription drug spending continues to drive health care costs in MA:
  - Total prescription drug spending at pharmacies grew **4.1% in Massachusetts in 2017**, net of manufacturer rebates and discounts.
  - MassHealth prescription drug spending **nearly doubled in five years**, from $1.1 billion in 2012 to $1.9 billion in 2017, growing twice as fast as other spending.

- The 12th issue of HPC DataPoints contains new data on pricing practices of pharmacy benefit managers (PBMs) known as “spread pricing” and its impact on prescription drug spending in both the public and commercial markets in MA. The online version features interactive graphics and is available at mass.gov/service-details/hpc-datapoints-series.

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Source: Herkert D, Vijayakumar P, Luo J, et al. Cost-Related Insulin Underuse Among Patients With Diabetes. *JAMA Intern Med.* 2019;179(1):112–114.

As prescription drug spending continues to increase, the HPC has recommended state action to enhance the transparency and accountability of the pharmaceutical market

Addressing drug spending requires focus on all parts of the drug distribution chain, including PBMs

- PBMs manage prescription drug benefits for many health plans and negotiate prices and rebates with manufacturers and payments to pharmacies

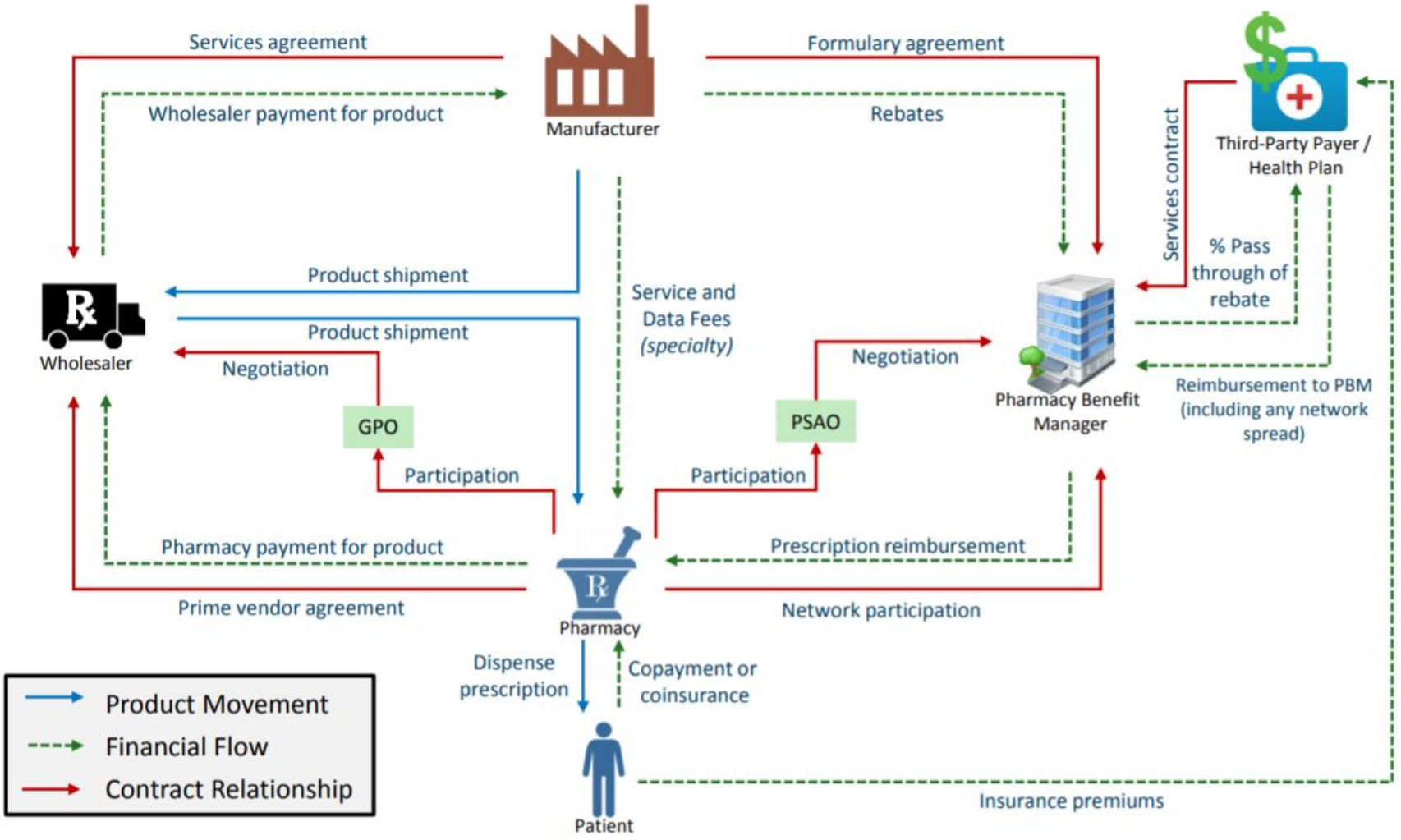
PBMs face increasing scrutiny for using “spread pricing” for generic drugs

- With the practice of spread pricing, PBMs may charge payers substantially more (or less) for drugs than what they reimburse pharmacies
- Due to a lack of transparency, spread pricing has raised concerns about potential impact on value for public and private payers and contributions to high drug costs
- The HPC sought to investigate the potential impact of this practice in the MassHealth MCO and commercial markets in Massachusetts

Commonwealth of Massachusetts. The Governor’s Budget Recommendation. Fiscal Year 2020 House 1. 2019 Jan 23. Available at: https://budget.digital.mass.gov/bb/h1/fy20h1/dnld_20/fy2020h1.pdf

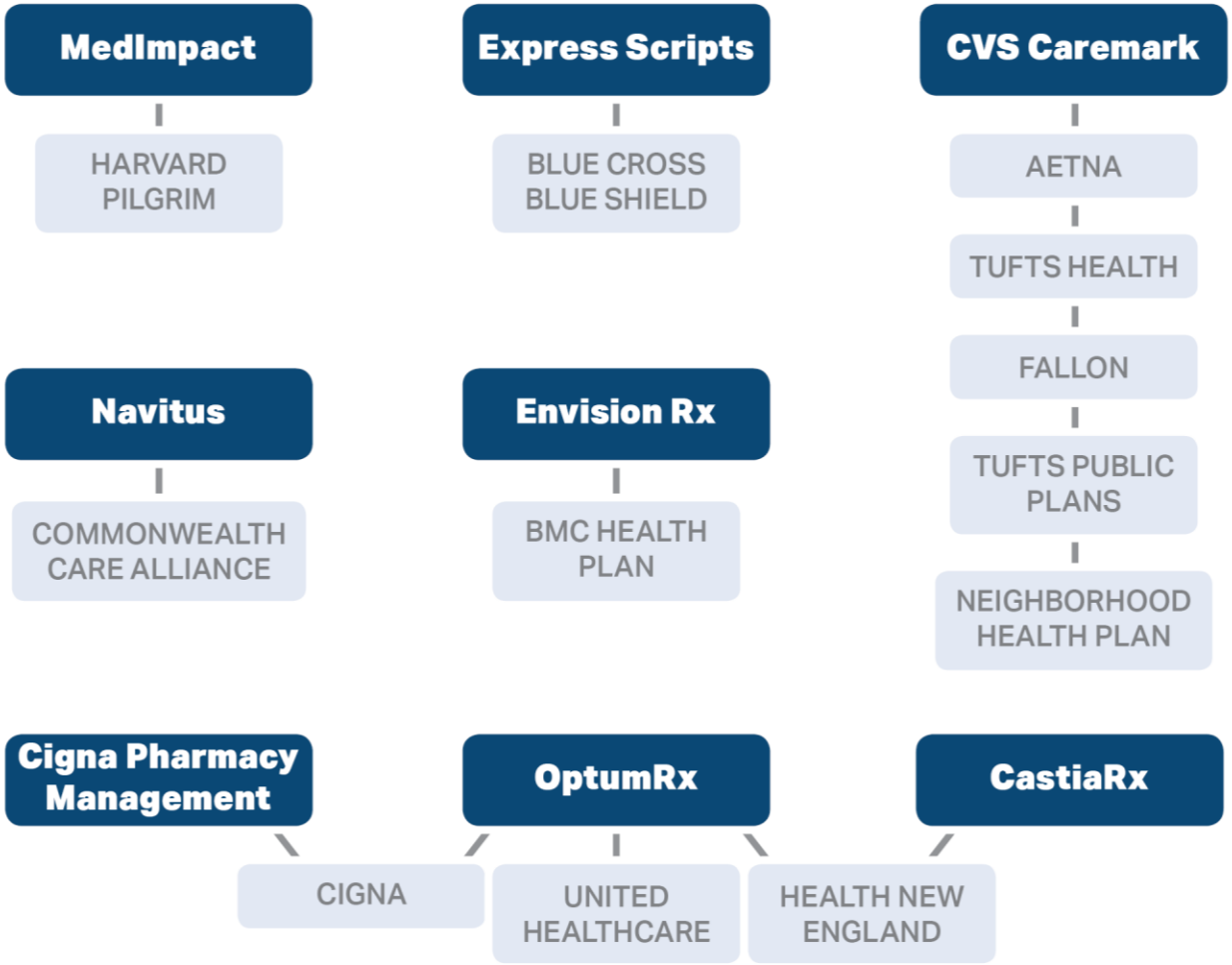
The complexity of the drug distribution and sales chain illustrates the need for transparency and action at many levels

*Flow of drug products, services, and funds for drugs purchased in a retail setting**



* Notes and Source: Fein, Adam J., The 2018 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers, Drug Channels Institute, 2018. Chart illustrates flows for patient-administered, outpatient drugs. GPO = Group Purchasing Organization; PSAO = Pharmacy Services Administrative Organization

In Massachusetts, multiple PBMs contract with different health plans for a variety of functions



PBMS PERFORM A VARIETY OF FUNCTIONS FOR THE 12 PAYERS SURVEYED

12 pharmacy contracting

12 pharmacy claims processing

11 negotiate prices and discounts with drug manufacturers

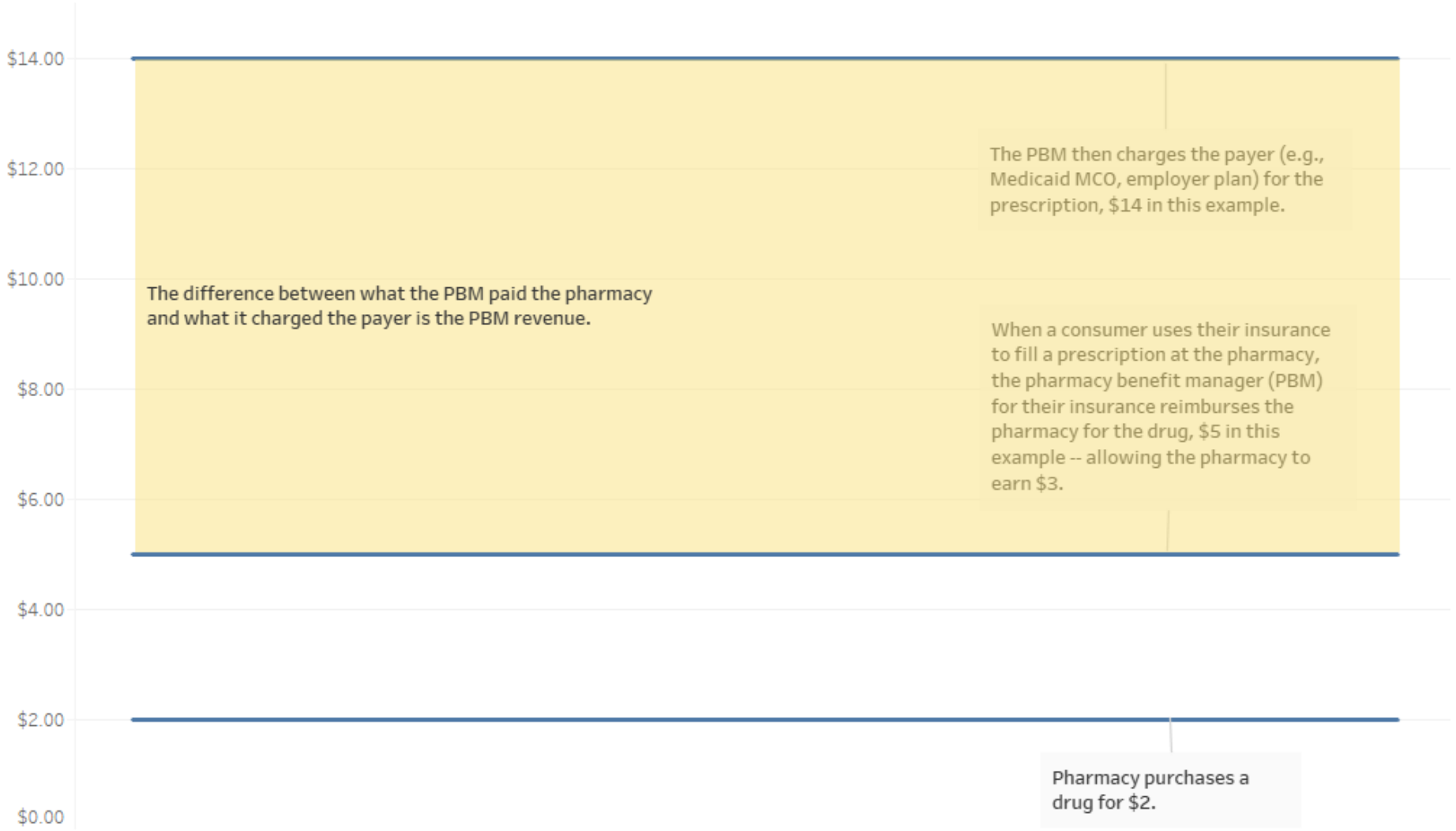
11 negotiate rebates with drug manufacturers

7 provide clinical management care programs to clients

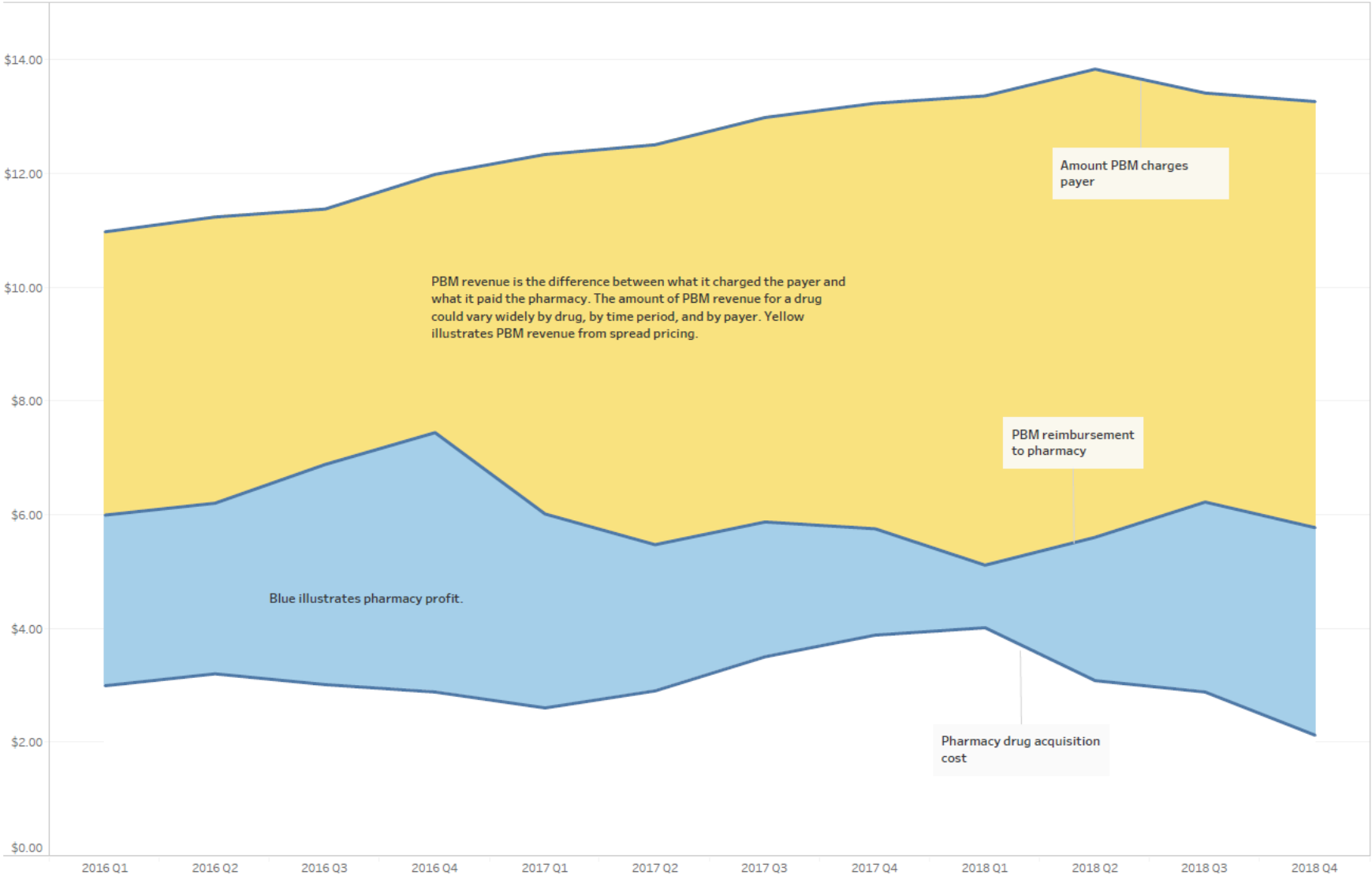
5 develop and maintain the drug formulary

Source: HPC analysis of pre-filed testimony pursuant to the 2018 Annual Cost Trends Hearing

Illustration of spread pricing with Tableau



PBM revenue is opaque to payers, employers, government, and the public



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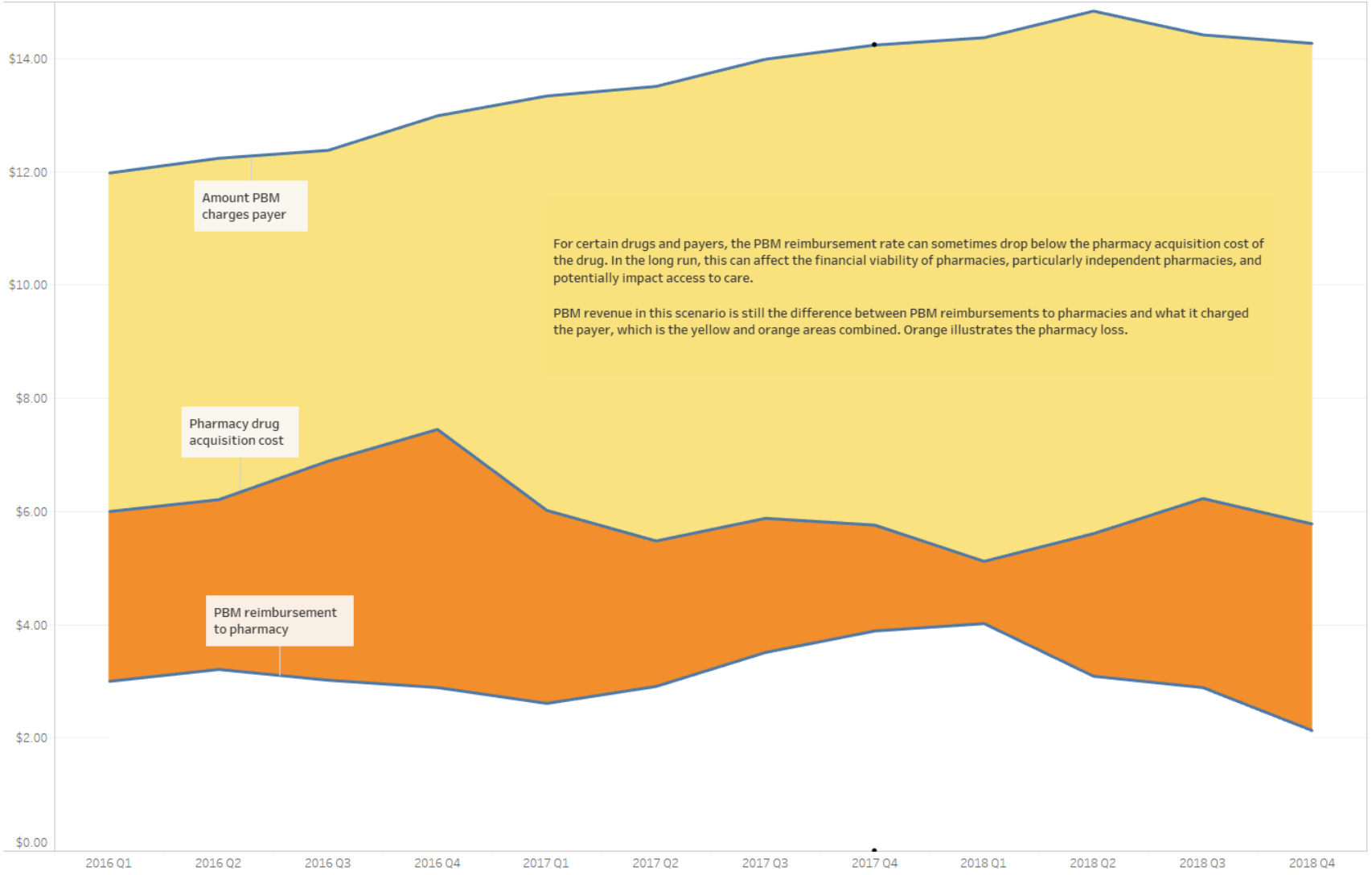
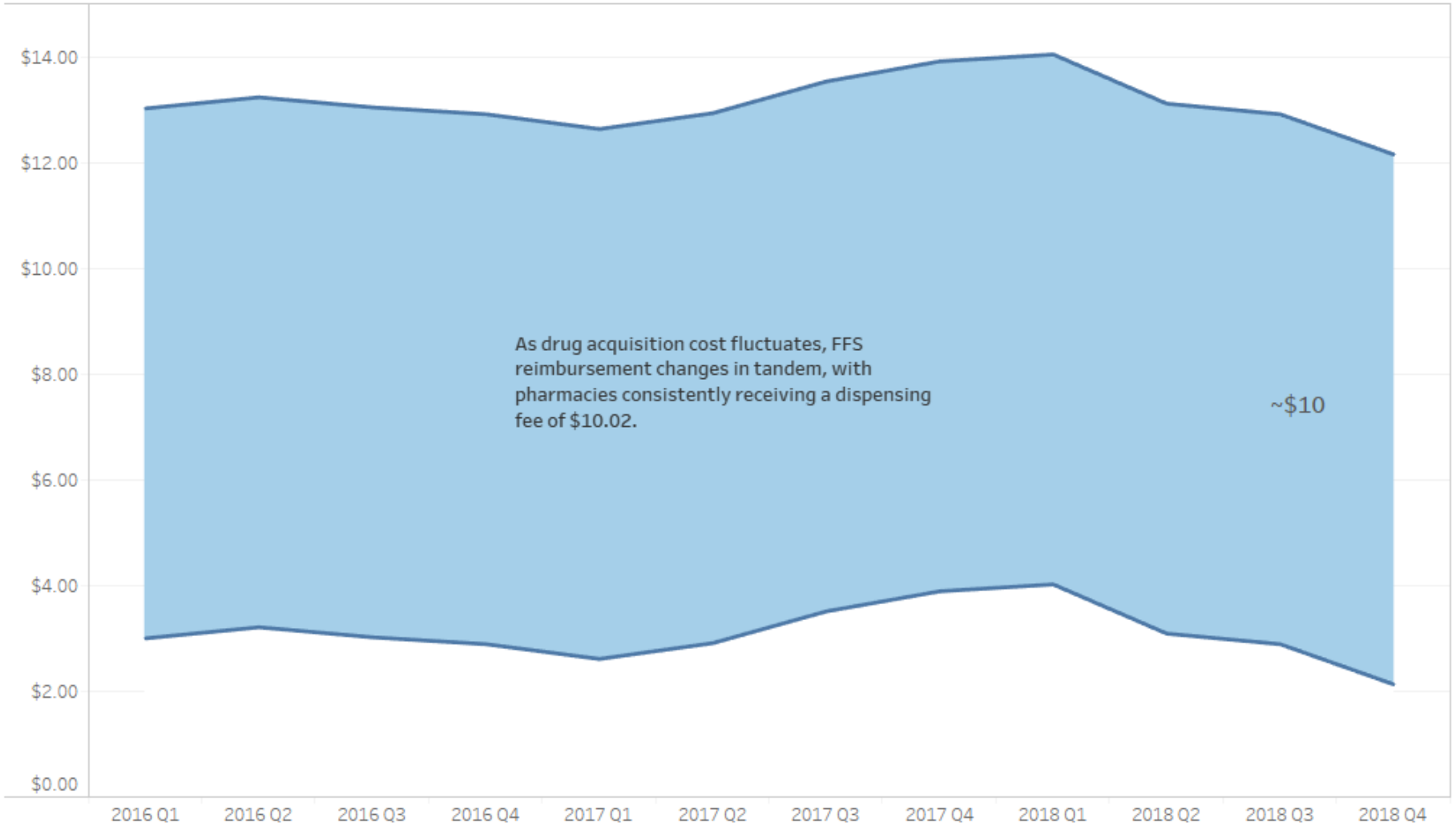
PBM reimbursement can drop below pharmacy acquisition cost



In contrast, the federal government mandates that Medicaid FFS use a "pass through" reimbursement model

FFS reimbursement fluctuates with drug acquisition costs



There is an emerging concern that low pharmacy reimbursements in spread pricing can affect access to care

Low reimbursements can affect the **financial viability of pharmacies**, particularly independent pharmacies and pharmacies with a large share of Medicaid patients.

> *"Middlemen have to make some money, but we didn't expect it to be this extreme," said [Iowa pharmacist] Frahm, who said his pharmacy lost money in the [state's] jail account last year because CVS paid so little. "We figured everyone was playing fair."*
>
> *- Bloomberg*

> *"Everyone says that drug prices are going up, drug prices are going up, drug prices are going up. Historically my average revenue per fill has been going down down down," said a Boston-area pharmacist who wanted to remain anonymous because he fears retaliation from one of the pharmacy benefit managers he does business with.*
>
> *- Boston 25 News*

Langreth R, Ingold D, Gu J. "The Secret Drug Pricing System Middlemen Use to Rake in Millions" Bloomberg. Sept. 11, 2018.
Morelli J. "Prescription Drug Pricing Strategy: Where is the Money Going?" Boston 25 News. Jan. 14, 2019.
Commonwealth of Massachusetts. The Governor's Budget Recommendation. Fiscal Year 2020 House 1. 2019 Jan 23. Available at: https://budget.digital.mass.gov/bb/h1/fy20h1/dnld_20/fy2020h1.pdf

HPC Study Approach: Data Sources and Methodology

MassHealth prices

CMS State Drug Utilization Data (SDUD)

- Reports quarterly drug reimbursements and utilization among Medicaid FFS and MCOs in each state and nationally
- Most recent data available is Q4 2018

Commercial prices

MA APCD v6.0 Pharmacy claims

- Top 3 commercial payers: ~66% of commercially insured members in MA
- Most recent data available is 2016

Pharmacy acquisition costs

CMS National Average Drug Acquisition Cost (NADAC)

- Average prices paid by pharmacies to acquire drugs, based on a national, voluntary survey of 2,000 – 2,500 retail community pharmacies
- Mail orders and specialty pharmacies are excluded

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Notes: SDUD, APCD, and NADAC do not include rebates.

HPC Study Approach: Evaluating Impact of PBM Pricing Practices

MassHealth

- Compares MCO prices to FFS prices for drugs reimbursed by both programs
- Spread pricing vs. pass through policy: FFS prices represent a benchmark to evaluate PBM prices in the MCO program
- Currently no publicly available MCO data on PBM reimbursement rates to pharmacies
- Includes generic oral solids only

Commercial

- Compares average commercial payer price to pharmacy acquisition cost
- Difference includes dispensing fees to pharmacies and revenue kept by PBMs
- Currently no publicly available data on PBM reimbursement rates to pharmacies
- Includes generic oral solids only

Important Note on MassHealth Results:
Higher generic drug prices paid by MCOs come out of the fixed per-member (capitation) payment rate from MassHealth to cover a beneficiary's medical and pharmacy benefits. Therefore, while higher drug prices do not necessarily translate to direct state spending in the short term, these prices can lead to MCOs allocating fewer resources for other medical services and can raise spending in the long term through higher capitated rates.

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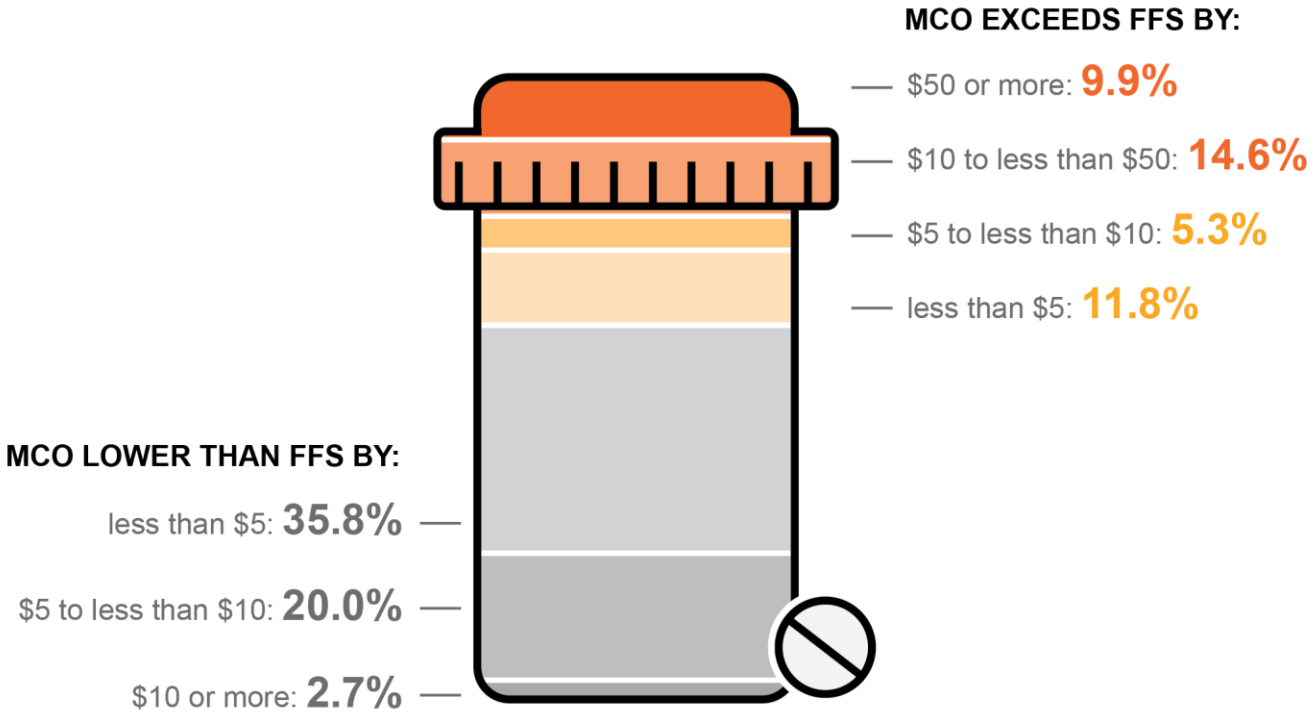
MassHealth Results: For drugs where MCOs paid a higher price than FFS, the difference was often substantial

In 2018 Q4, MCO/PBM prices were higher than acquisition costs for 95% of the unique drugs analyzed and exceeded FFS prices for 42% of unique drugs



Whether the MCO price is higher or lower than the FFS price, it is unclear how much of the payment the PBMs apportion to the pharmacy and how much is retained as revenue

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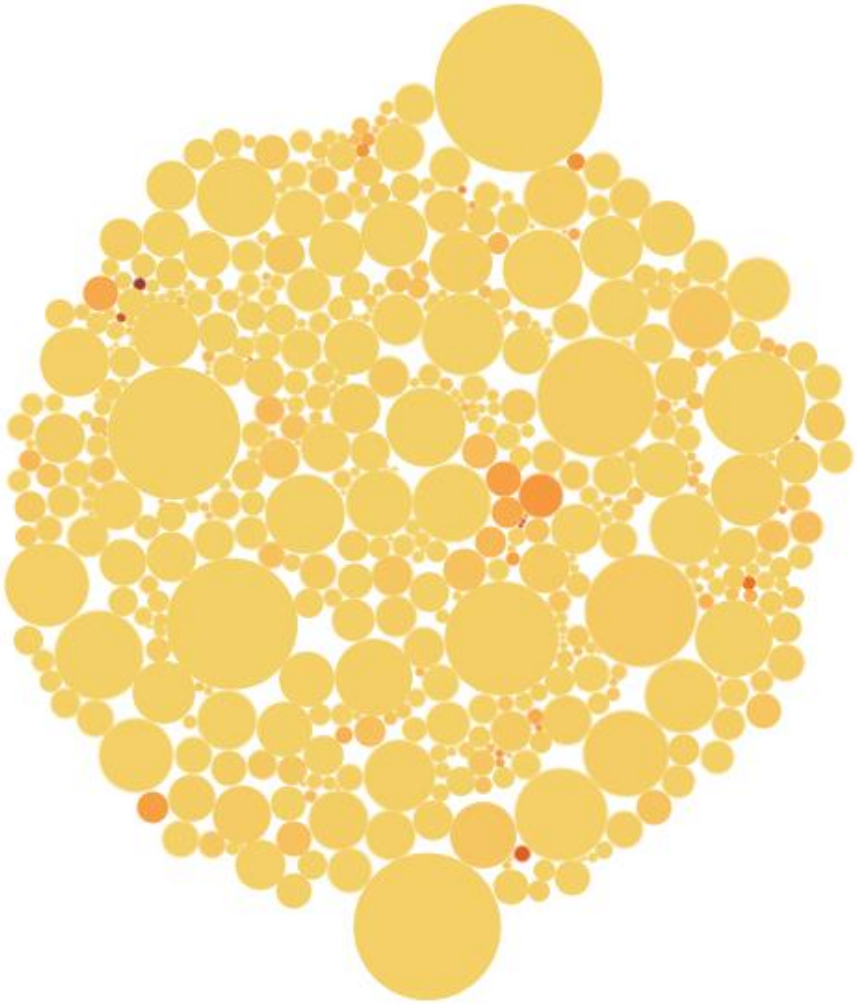
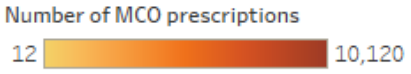
Interactive data visualization of the average difference between MassHealth MCO/PBM and FFS prices per prescription, 2018 Q4

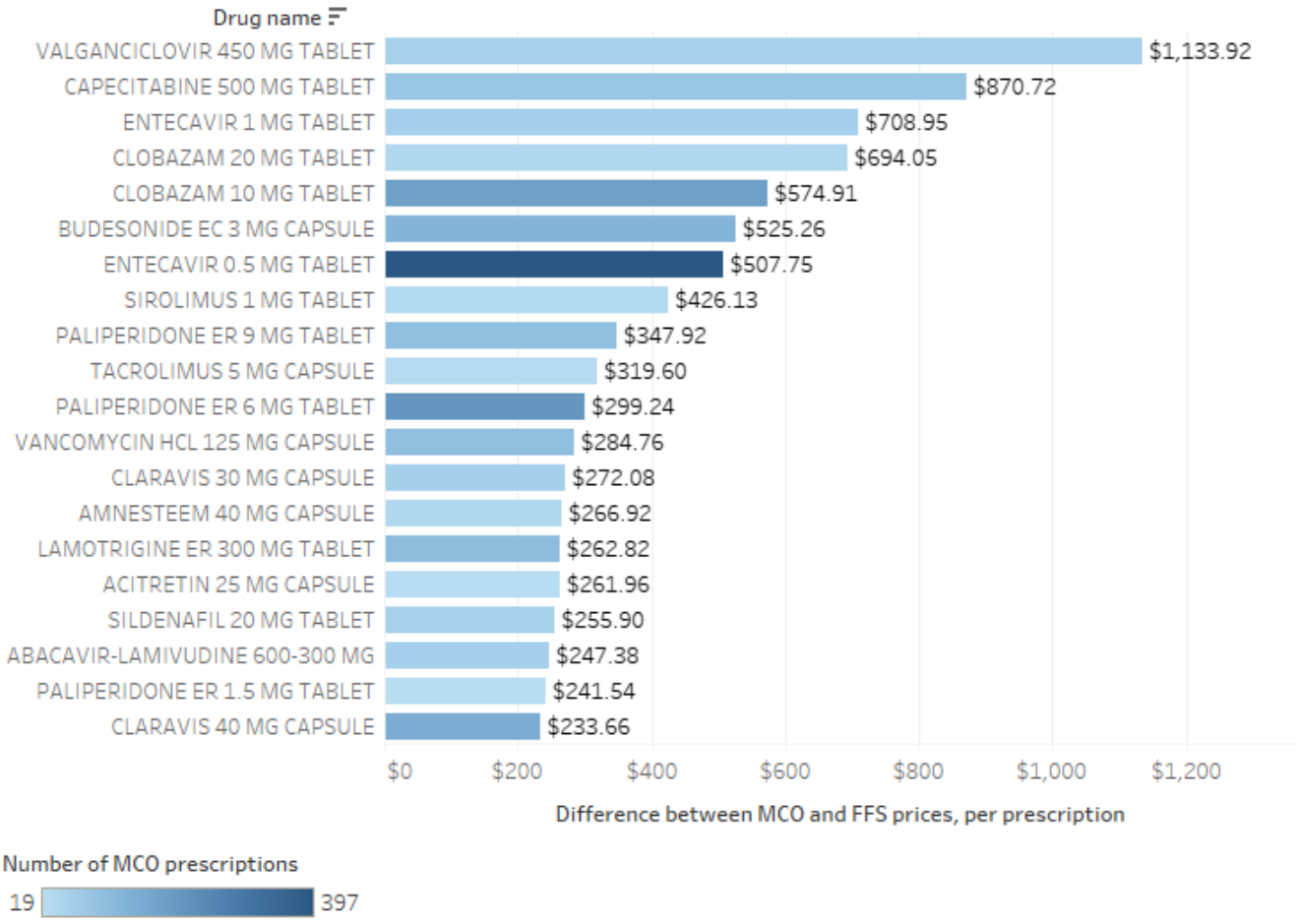




Sources: Centers for Medicare and Medicaid Services, State Drug Utilization Data (SDUD) and National Average Drug Acquisition Cost (NADAC) database.
Notes: Each bubble represents a generic oral solid for which the MassHealth MCO price exceeded the FFS price. Size represents average dollar difference per prescription for each drug. Units refer to a single unit of a dosage form, e.g. tablet, capsule. Each drug represents a single dosage form and dosage strength. Average unit price and average number of units per prescription reflects a weighted average across package sizes. Analysis includes only generic oral solids, identified through linking SDUD to NADAC. Only drugs reimbursed by both MCO and FFS were included. Drugs with 11 or fewer prescriptions dispensed were omitted. HPC methodology is adapted from 46Brooklyn.com.

MassHealth MCO/PBM price per generic drug prescription exceeded FFS prices by hundreds of dollars in many circumstances

Top 20 generic drugs in the MassHealth MCO program by average difference between MCO/PBM and FFS prices per prescription, 2018 Q4

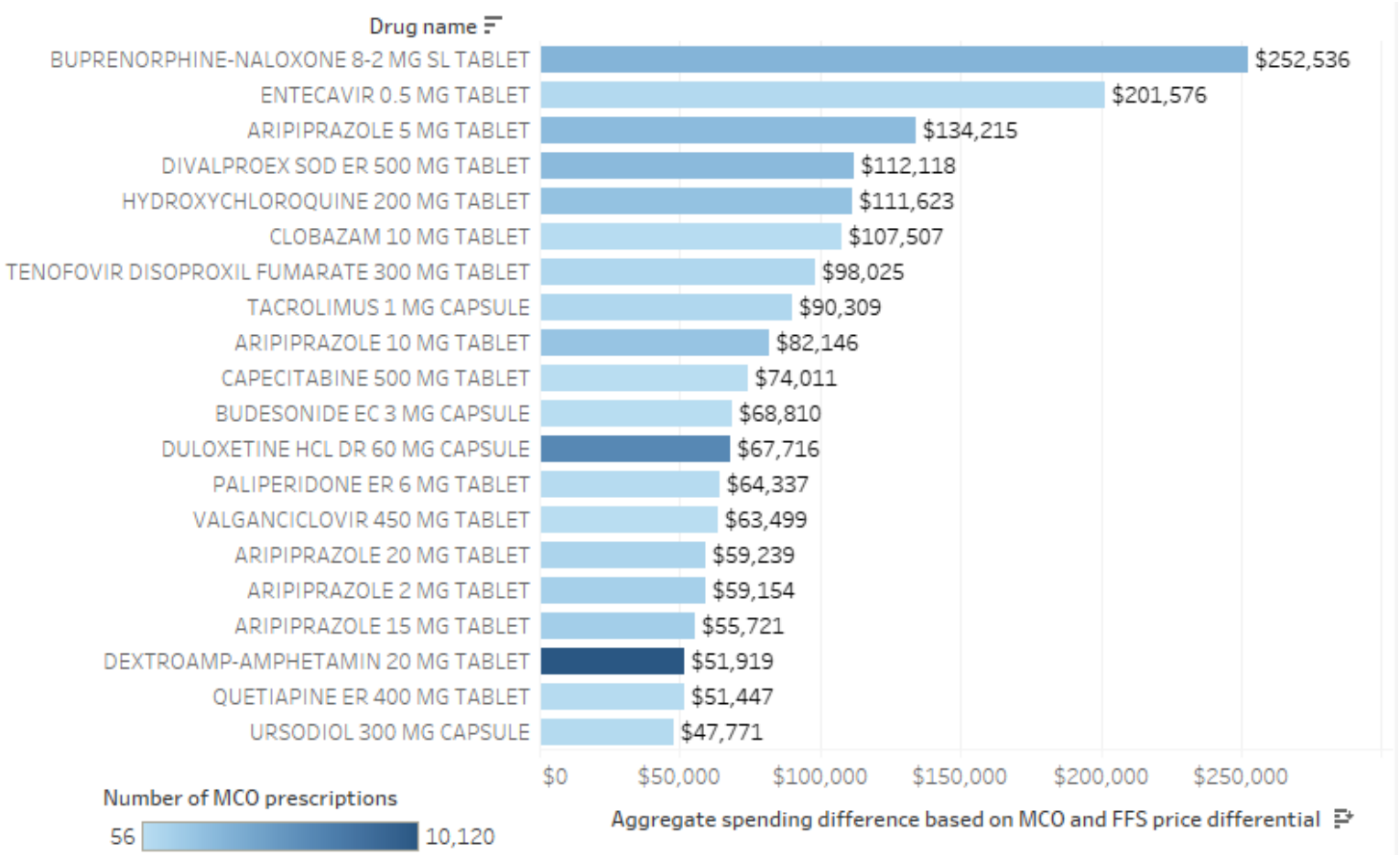


Sources: Centers for Medicare and Medicaid Services, State Drug Utilization Data (SDUD) and National Average Drug Acquisition Cost (NADAC) database. Notes: Units refer to a single unit of a dosage form, e.g. tablet, capsule. Each drug represents a single dosage form and dosage strength. Average unit price and average number of units per prescription reflects a weighted average across package sizes. Analysis includes only generic oral solids, identified through linking SDUD to NADAC. Only drugs reimbursed by both MCO and FFS were included. Drugs with 11 or fewer prescriptions dispensed were omitted. HPC methodology is adapted from 46Brooklyn.com.

HPC

Higher MCO/PBM prices contribute to significantly higher aggregate spending for certain generic drugs compared to FFS

Top 20 generic drugs in the MassHealth MCO program by aggregate spending difference, 2018 Q4



Sources: Centers for Medicare and Medicaid Services, State Drug Utilization Data (SDUD) and National Average Drug Acquisition Cost (NADAC) database. Notes: Units refer to a single unit of a dosage form, e.g. tablet, capsule. Each drug represents a single dosage form and dosage strength. Average unit price and average number of units per prescription reflects a weighted average across package sizes. Analysis includes only generic oral solids, identified through linking SDUD to NADAC. Only drugs reimbursed by both MCO and FFS were included. Drugs with 11 or fewer prescriptions dispensed were omitted. HPC methodology is adapted from 46Brooklyn.com.

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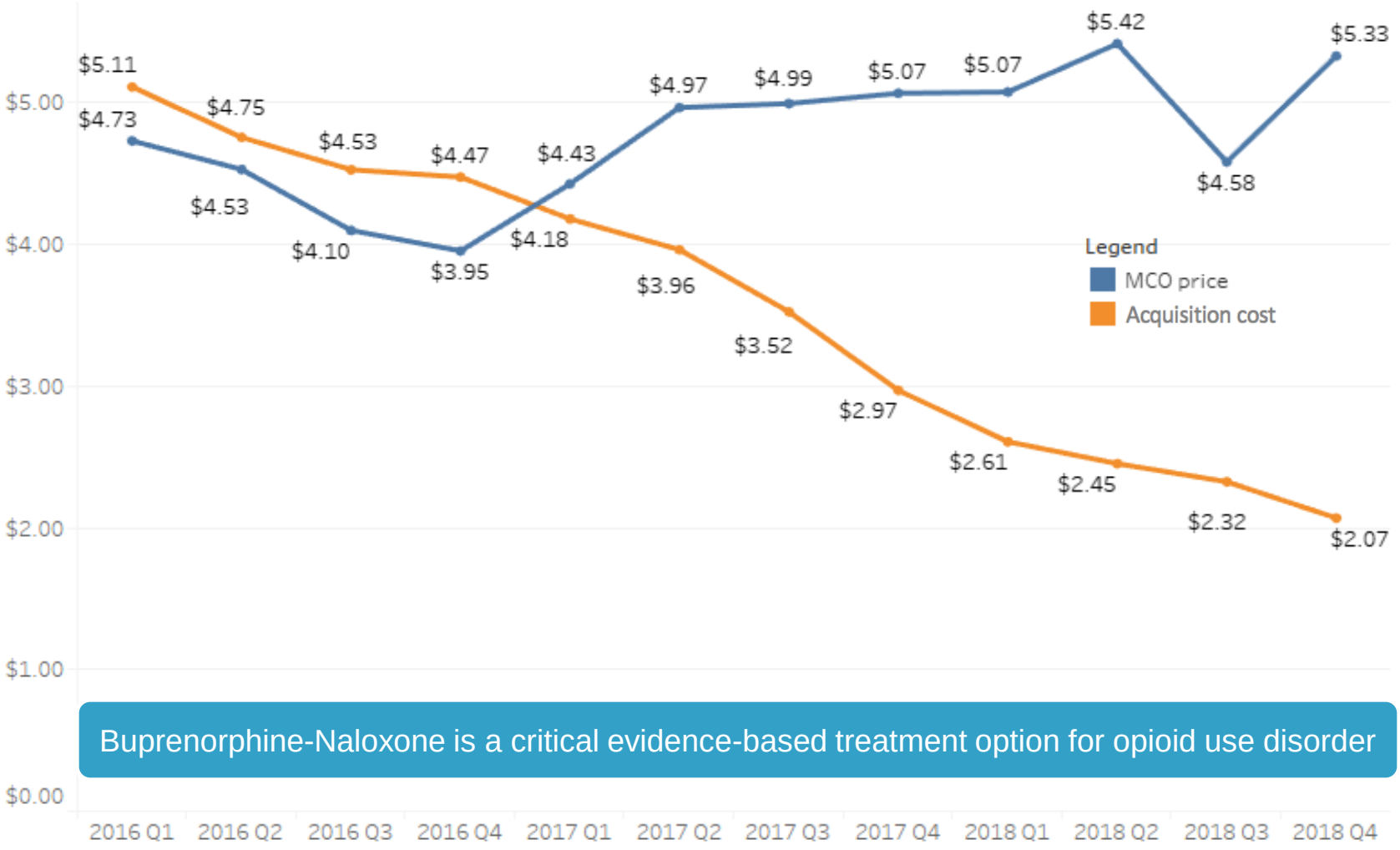
Despite a 60% decrease in the acquisition cost for Buprenorphine-Naloxone (generic Suboxone), MCO/PBM prices increased 13% between 2016 and 2018

Average pharmacy acquisition cost and MCO price for Buprenorphine-Naloxone 8-2mg SL, per tablet

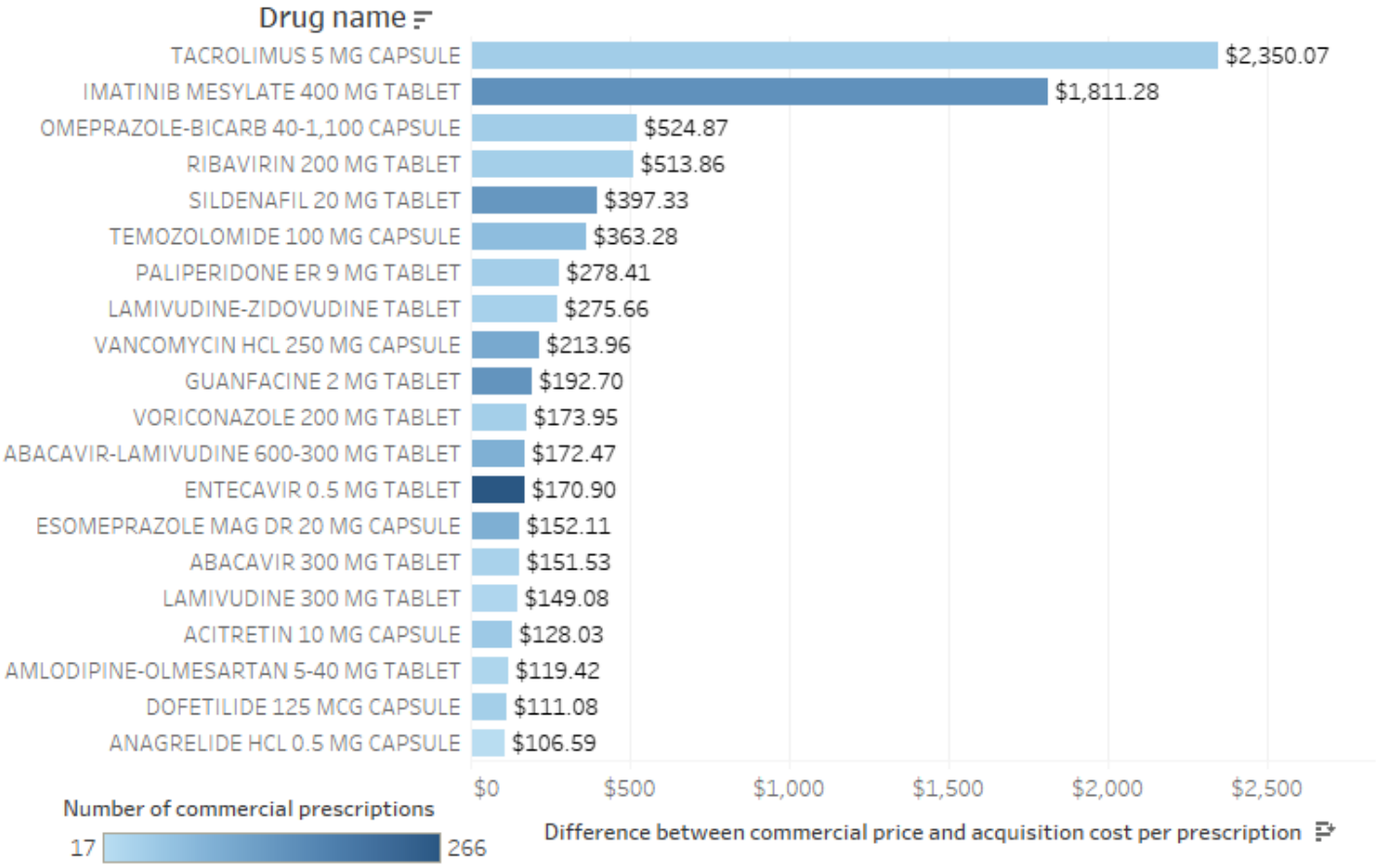


Buprenorphine-Naloxone is a critical evidence-based treatment option for opioid use disorder

Sources: Centers for Medicare and Medicaid Services, State Drug Utilization Data (SDUD) and National Average Drug Acquisition Cost (NADAC) database.
Notes: National Drug Code 00054018913.

PBM price differences per prescription in the commercial market exceeded acquisition costs by hundreds of dollars for many generic drugs

Top 20 generic drugs by average difference between Massachusetts commercial price and acquisition cost per prescription, 2016 Q4

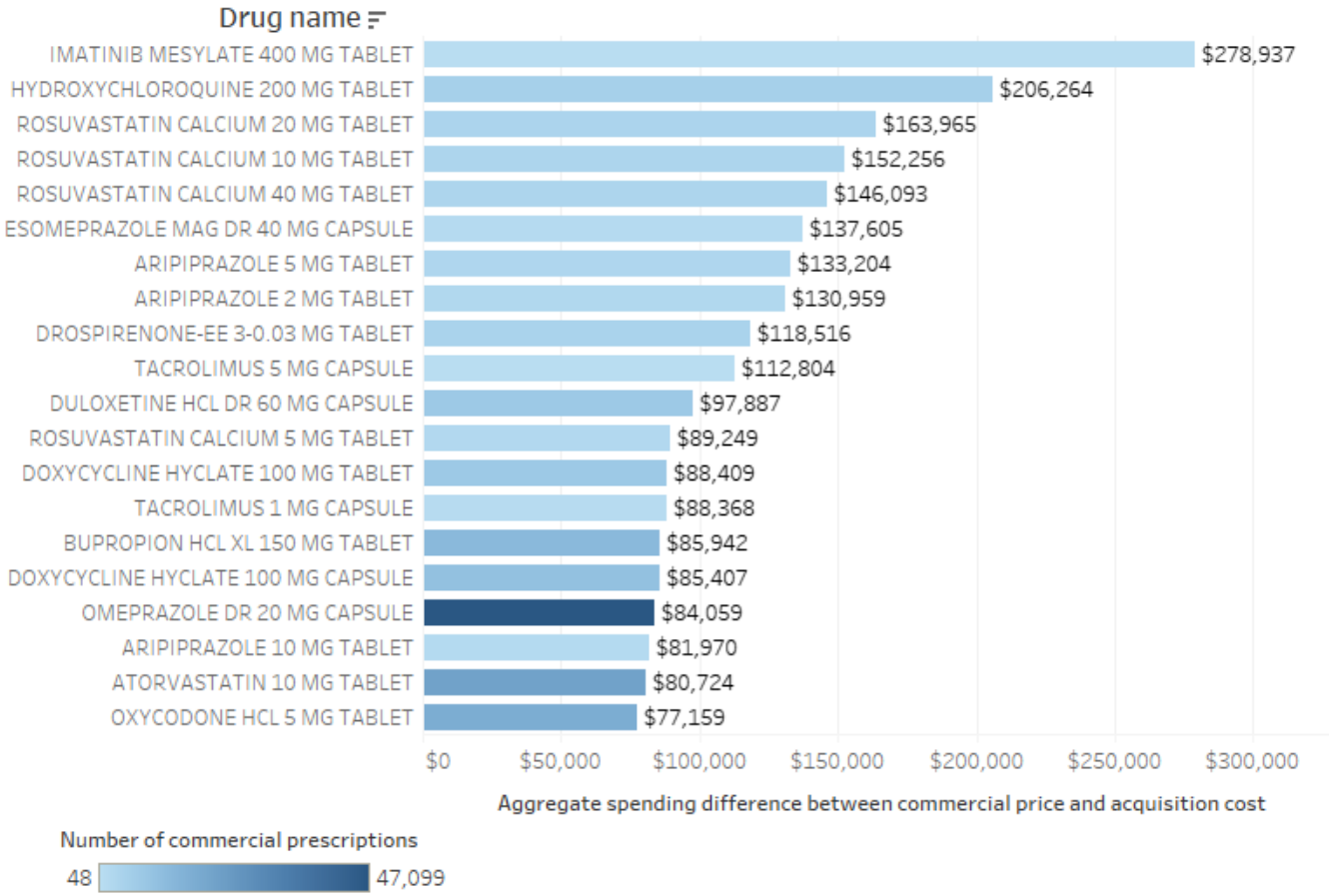


Sources: Centers for Medicare and Medicaid Services, National Average Drug Acquisition Cost (NADAC) database. Center for Health Information and Analysis, Massachusetts All-Payer Claims Database (APCD).

Notes: For drugs with various strengths, only the strength with the highest volume of prescriptions is shown. Analysis includes only generic oral solids. Each drug represents a single dosage form and dosage strength. Average unit price and average number of units per prescription reflects a weighted average across package sizes. Drugs with 11 or fewer prescriptions dispensed were omitted. For each drug, claims in the top and bottom 1 percentile of price were excluded to minimize the influence of outliers. HPC methodology is adapted from 46Brooklyn.com.

Higher commercial PBM prices for generic drugs contributed to significantly higher aggregate spending compared to acquisition costs

Top 20 generic drugs by aggregate spending difference between Massachusetts commercial price and acquisition cost, 2016 Q4



Sources: Centers for Medicare and Medicaid Services, National Average Drug Acquisition Cost (NADAC) database. Center for Health Information and Analysis, Massachusetts All-Payer Claims Database (APCD).

Notes: Analysis includes only generic oral solids. Each drug represents a single dosage form and dosage strength. Average unit price and average number of units per prescription reflects a weighted average across package sizes. Drugs with 11 or fewer prescriptions dispensed were omitted. For each drug, claims in the top and bottom 1 percentile of price were excluded to minimize the influence of outliers. HPC methodology is adapted from 46Brooklyn.com.

States and the federal government are pursuing action to increase transparency and oversight of PBMs

- Many states seek to require PBM licensure and disclosure of pricing and reimbursement to pharmacies and to increase transparency about rebates
- Ohio will end its spread pricing contracts and switch to a pass-through model following a state audit:
  - PBM profit accounted for **31.4%** ($208.4 million) of the $662.7 million paid by Ohio Medicaid MCOs on generic drugs, during the one-year period from April 1, 2017 through March 31, 2018
  - This time period coincided with accelerated closure of pharmacies
- **Activity in Massachusetts**
  - The Baker-Polito Administration proposed a new requirement that PBMs be **transparent about their pricing** and a **limitation on PBM margins** under contracts with MCOs and accountable care organizations (ACOs)
    - $10 million in potential savings for MassHealth
  - MassHealth released a bulletin in April requiring MCOs and ACOs to collect and report data from PBMs, including payments to pharmacies
- The Centers for Medicare & Medicaid Services (CMS) released guidance in May aimed at limiting spread pricing in Medicaid and CHIP contracts

Ohio Auditor of State. Ohio's Medicaid Managed Care Pharmacy Services. 2018 Aug 16. Available at: https://audits.ohioauditor.gov/Reports/AuditReports/2018/Medicaid_Pharmacy_Services_2018_Franklin.pdf
CMS press release May 15, 2019. Available at: https://www.cms.gov/newsroom/press-releases/cms-issues-new-guidance-addressing-spread-pricing-medicaid-ensures-pharmacy-benefit-managers-are-not

Conclusions

- For generic drugs reimbursed by both MCO and FFS programs, the MCO/PBM price was **higher** than FFS in 42% of unique drugs, and the difference was often substantial
  - In 2018 Q4, MCOs paid an average $159 per prescription for generic Suboxone, 111% higher than the average FFS price of $75; this difference and high utilization of the drug led to its #1 rank for highest MCO-FFS spending difference
- High drug spending leaves **fewer resources** for MCOs to allocate to other services and can raise long-term spending through higher capitated rates
- PBMs assert that spread pricing models provide more predictability for payers than pass-through models, in which drug prices for plans fluctuate directly with changes in drug costs
- Greater transparency in spread pricing is needed so payers, employers, and government can make **informed choices** about allocation of state spending or commercial premium dollars, including appropriate compensation for both pharmacies and PBMs

MASSACHUSETTS
HEALTH POLICY COMMISSION

AGENDA

- Call to Order
- Approval of Minutes
- Registration Of Provider Organizations (RPO) Program: Overview and Updates
- Study Design: The Impact of Prescription Drug Coupons, Discounts, and Other Product Vouchers on Pharmaceutical Spending and Health Care Costs
- DataPoints Issue #12: Cracking Open the Black Box of Pharmacy Benefit Managers
- **Key Findings and Recommendations: Review of Third-Party Specialty Pharmacy Use for Clinician-Administered Drugs**
- Schedule of Next Meeting (October 2, 2019)

Legislative Mandate for Review of Third-Party Specialty Pharmacy Use for Clinician-Administered Drugs (White and Brown Bagging Report)

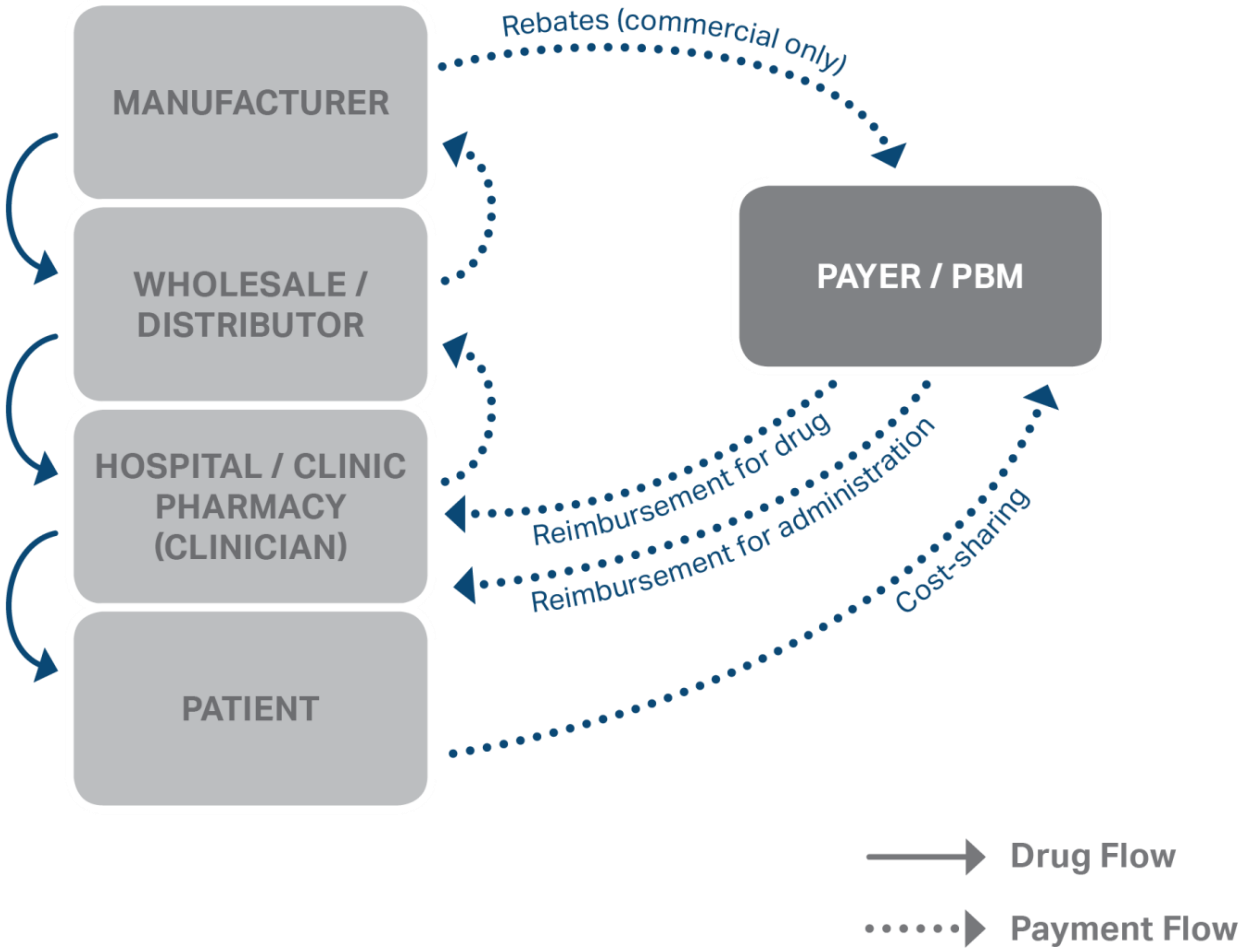
Section 130 of Chapter 47 of the Acts of 2017

The Massachusetts Health Policy Commission (HPC), in consultation with the Department of Public Health (DPH) and the Division of Insurance (DOI), shall:

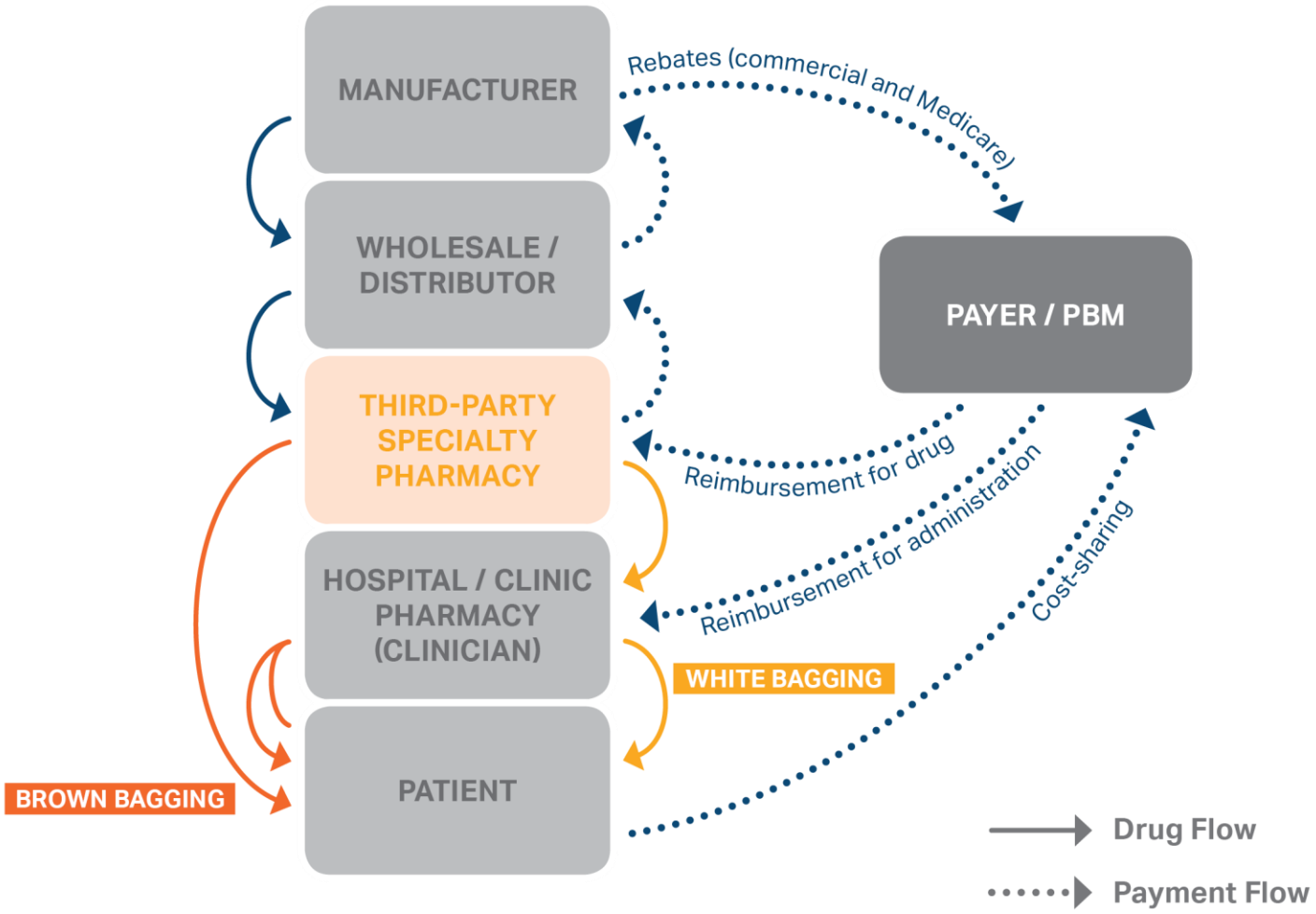
- **Study and analyze health insurance payer practices** that require certain categories of drugs (e.g. those administered by injection or infusion) to be dispensed by a third-party specialty pharmacy directly to a patient or to a health care provider with the designation that such drugs shall be used for a specific patient and not for the general use of the provider

- **Submit a report of its findings and recommendations** to the joint committee on health care financing and the joint committee on public health

Flow of Payments and Drugs with Buy and Bill (Traditional Model)



Flow of Payments and Drugs with White and Brown Bagging (Payers Reimburse Third-Party Specialty Pharmacy for Drugs)



White and Brown Bagging Report: Outline

1. **Prevalence and payer policies**
2. **Financial implications: Impact on health care spending and patient cost-sharing**
   a) Commercial
      i. Results with BCBSMA data (APCD)
      ii. US data
   b) Medicare
3. **Patient safety and access to care**
   a) Brown bagging
   b) Home infusion
   c) White bagging
4. **Other unintended consequences**
   a) Drug waste
   b) Additional provider expenses
5. **Legislative action**
   a) State-level activity
   b) Federal activity
6. **Policy Recommendations**

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White and Brown Bagging Report: Methods and Data Sources

Study Approach

Identified relevant published literature

- Limited information on prevalence of white and brown bagging in US
- Comparison of prices for some drugs in US
- Little information on safety and access; no Massachusetts-specific information

Held Public Listening Session (May 9, 2018)

- Sought written testimony from diverse set of stakeholders, including providers and health plans

Analyzed price data from All-Payer Claims Database (APCD)

Conducted survey of commercial payers

- Six commercial payers, representing 72% of commercial member lives in Massachusetts
- Focused on prevalence, drug selection, and policies related to safety and access
- Supplemented survey by searching publically available plan documents

Key Findings: Prevalence of White and Brown Bagging

Prevalence in the U.S.

- Use of white bagging has become increasingly widespread, while brown bagging remains relatively uncommon
  - White bagging is more common in physician offices than in hospital outpatient departments

Prevalence in Massachusetts (among HPC survey participants)

- Most payers allow the **option** of white bagging, brown bagging, or home infusion
- Two payers **require** white bagging for select drugs
- Two payers **require** home infusion for select drugs
- No payers **require** brown bagging

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Notes: Full presentation from February 27, 2019 MOAT meeting available at:
https://www.mass.gov/files/documents/2019/02/27/20190227_MOAT%20Presentation.pdf

Key Findings: Payer Exception and Payment Policies

- Among payers that ***require*** white bagging or home infusion, some payers only allow exceptions if medical necessity criteria are met or do not allow any exceptions

- Blue Cross Blue Shield of Massachusetts' (BCBSMA) white bagging policy requires certain drugs to be filled by a contracted network specialty pharmacy; however, BCBSMA offers a **site neutral payment policy**
  - Any qualified facility may join the plan's specialty pharmacy network, which allows providers to use a buy and bill system, **with reimbursement set at the third-party specialty rate** for drugs covered by white bagging
  - Providers that do not have pharmacies that meet the plan's criteria may also gain an exception to **buy and bill at the site neutral rate**

Notes: Full presentation from February 27, 2019 MOAT meeting available at:
https://www.mass.gov/files/documents/2019/02/27/20190227_MOAT%20Presentation.pdf
Neighborhood Health Plan, Inc. (NHP) changed its name to AllWays Health Partners, Inc. as of January 9, 2019.

Key Findings: Financial Implications

Commercial market

- Drug prices in Massachusetts were **substantially lower with white bagging**
- Trends in Massachusetts were generally consistent with national estimates
  - US data also indicates price differences by setting of care, highlighting how the impact of white and brown bagging may vary by provider type
- White bagging had higher cost-sharing than buy and bill for most of the four drugs studied, but **differences were relatively minimal** and overall amounts were relatively low
- Some consumers face high cost-sharing under buy and bill, likely reflecting whether patients have already met their medical deductible
- For both buy and bill and white bagging, total patient cost-sharing depends on the price of the drug and on the benefit design

Medicare market

- Prices are generally higher with Part D than Part B, although these prices do not include rebates that a plan may receive under Part D
- While patient cost-sharing trends varied substantially by drug, results suggest that **white bagging has the potential to result in much greater cost-sharing for some Medicare beneficiaries**

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Notes: Full presentation from February 27, 2019 MOAT meeting available at: https://www.mass.gov/files/documents/2019/02/27/20190227_MOAT%20Presentation.pdf

Key Findings: Safety and Access

Brown bagging

*Provider testimony was **virtually unanimous** in detailing safety and access concerns associated with brown bagging. Safety concerns included*:

- Requirements for **drug handling, storage, and temperature control** that may be compromised while the drug is in the custody of the patient
- Difficulty maintaining **accurate documentation** related to the drug

Home infusion

*Findings were mixed: Some providers and patients have raised safety concerns, while other patients **support having the option.***

- Some literature suggests that infusion can be safely performed in the home environment
- Provider safety concerns generally focused on **the lower level of expertise and resources** available in a home setting compared to a clinic setting

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Notes: Full presentation from February 27, 2019 MOAT meeting available at: https://www.mass.gov/files/documents/2019/02/27/20190227_MOAT%20Presentation.pdf

Key Findings: Safety and Access

White bagging

Findings were mixed: Many providers expressed concerns, but some also detailed safeguards that they employ to successfully manage white bagging use

- Providers expressed numerous concerns:
  - Drugs can be **incompatible with in-house infusion** equipment
  - Providers cannot control which **specific formulation of the drug** the patient receives, which can **impact side effects**
- Providers **lack leverage** with specialty pharmacies and distributors to correct safety issues
- Drugs may not be **streamlined with in-house pharmacy systems** that provide safety controls and manage inventory
- **Negative impacts for patients** if the drug is not available at the time of the patient's appointment: wasted time; additional expenses for transportation, child care, and time away from work; and potentially missed doses or lower drug adherence

White bagging can improve access for patients under certain circumstances

- Smaller providers may find advantages in working with a specialty pharmacy with expertise and staff resources to negotiate utilization management requirements with insurers
- Specialty pharmacies may offer specialized medication adherence and education programs

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Notes: Full presentation from February 27, 2019 MOAT meeting available at: https://www.mass.gov/files/documents/2019/02/27/20190227_MOAT%20Presentation.pdf

Key Findings: Safety and Access

Provider and payer testimony detailed varied approaches to maximize safety and access with white bagging

Best practices for payer policies

- Site neutral payment policy allowing providers to use a **buy and bill system** with reimbursement levels set at the specialty pharmacy rate
- Patient and provider **education**
- Expedited exception process based on **provider certification**

Best practices for third-party specialty pharmacies

Considerations for selecting clinician-administered drugs appropriate for white bagging

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Notes: Full presentation from February 27, 2019 MOAT meeting available at:
https://www.mass.gov/files/documents/2019/02/27/20190227_MOAT%20Presentation.pdf

Considerations for Recommendations

Data indicate that prescription drug costs are generally lower with third-party specialty pharmacies, but HPC recommendations should balance considerations for health care costs, safety, and access

Brown bagging

- Recommendations should reflect conclusions of strong clinical consensus that **brown bagging requirements jeopardize patient safety** by requiring patients to properly store and then transport a drug to their clinician for administration

Home infusion

- Recommendations should reflect conclusions of potential for **safety and access concerns** and range of **patient preferences**

White bagging

- Recommendations should reflect conclusions of potential for **safety and access concerns** and evidence that **use of key best practices** can support appropriate white bagging use

Summary of Recommendations

1. Payers should not require brown bagging for any drug
2. Payers should offer home infusion as an optional benefit, not as a requirement
3. Minimum safety standards for third-party specialty pharmacies
4. Payers that require white bagging should offer site neutral payment
5. Lawmakers should take action to increase public transparency and public oversight for the full drug distribution chain
6. All state payers should require all plans with which they contract to adopt best practice provisions

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Recommendations

1 Payers should not require brown bagging for any drug.

Payers should not require direct dispensing to a patient of any specialty drug that must be administered by a clinician. There is strong clinical consensus that brown bagging jeopardizes patient safety, by requiring patients to properly store and then transport a drug to their clinician for administration.

2 Payers should offer home infusion as an optional benefit, not as a requirement.

Use of home infusion should be an individual decision by the provider and patient in cases where a provider and patient determine that drugs can be safely shipped, stored, and administered in the patient's home.

Recommendations

3 **Payers that require white bagging should ensure minimum safety standards and capabilities in the third-party specialty pharmacies with which they contract.**

While providers voiced concerns regarding safety and access, some providers detailed the safeguard practices that they employ to successfully manage use of white bagging in their practices. Provider approaches, strategies, and incentives differ, especially between small and large clinics. Furthermore, needs and preferences may differ by patient. This range of perspectives suggests that white bagging can be used safely, but use of best practices to support patient safety and access are critical.

4 **Payers that require white bagging should offer site neutral payment for buy and bill as an option and allow all in-house hospital or clinic pharmacies to join the payer's specialty pharmacy network for all drugs subject to white bagging.**

Payers should give providers the option for site neutral payment at the contract level through allowing all in-house hospital or clinic pharmacies to join the payer's specialty pharmacy network or otherwise reimbursing drugs under buy and bill at the third-party specialty pharmacy rate. This site-neutral and contracting policy may be limited to ***only those drugs subject to white bagging***. These policies lower drug prices, reduce provider administrative expenses associated with compliance with multiple different policies, and mitigate concerns about safety and access.

Recommendations

5 **Lawmakers should take action to increase public transparency and public oversight for the full drug distribution chain.**

Lawmakers should enable increased public transparency and public oversight for pharmaceutical manufacturers, medical device companies, pharmacy benefit managers, and rebates to payers, consistent with existing Commonwealth requirements on payers and providers.

6 **The Group Insurance Commission, the Massachusetts Health Connector, MassHealth, and all other state payers should require all plans with which they contract to adopt best practice provisions.**

These provisions include not requiring brown bagging or home infusion, implementing safety standards, and providing a site neutral payment option.

The final HPC report on the *Review of Third-Party Specialty Pharmacy Use for Clinician-Administered Drugs* is expected to be released later this month.

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HEALTH POLICY COMMISSION

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- **Schedule of Next Meeting (October 2, 2019)**

Upcoming 2019 Meetings and Contact Information

Board Meetings

Wednesday, July 24
Wednesday, September 11
Monday, December 16

Committee Meetings

Wednesday, October 2
Wednesday, November 20

Contact Us

Mass.Gov/HPC
@Mass_HPC
HPC-Info@mass.gov

Special Events

2019 Cost Trends Hearing
Day 1 – Tuesday, October 22
Day 2 – Wednesday, October 23

HPC