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Interagency Pharmacy Purchasing Council
August 29, 2019
Pharmacy Program Overview

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Today's Topics

- **Pharmacy Primer**
  - Overview of key terms and description of how pharmacy programs work (emphasis on NM Medicaid).
  - Overview of how drug rebates work in NM Medicaid.
- **Pharmacy Trends**
  - Review trends in pharmacy utilization and pricing.
- **Pharmacy Policy Strategies**
  - Discussion of hot topics in pharmacy.
  - Discuss ideas to achieve savings and efficiencies in drug pricing and purchasing.

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Key Pharmacy Terms

- **PBM (Pharmacy Benefits Manager)** – An entity subcontracted by a health plan to process prescription drug claims, negotiate purchase pricing and rebates, determine payments to pharmacies, review drug utilization, and determine formulary design.
- **PDL (Preferred Drug List) or Formulary** – A list of prescription drugs, both generic and name-brand, that have been determined by a health plan (or their PBM) as offering the overall greatest value.
- **340B** – A federal drug discount program that requires drug manufacturers to offer lower pricing of certain products to covered entities.
- **Dispensing Fee** – An amount paid to a retail pharmacy for filling and dispensing prescription drugs. The dispensing fee is paid on a per-prescription basis.

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Key Pharmacy Terms, cont.

- **Brand-Name Drug** – A drug that has a trade name and is protected by a patent, which can be produced and sold only by the manufacturer holding the patent.
- **Generic Drug** – A drug determined to be the same as an existing approved brand-name drug in dosage form, safety, strength, route of administration, quality, and performance characteristics. Generally offered at a significantly lower cost than its brand-name counterpart.
- **Rebate** – An amount paid back to the purchaser under the National Rebate Agreement. States are required to participate in the National Drug Rebate Program through Medicaid.
- **Supplemental Rebate** – An additional price concession made by a drug manufacturer to a health plan or their PBM. Often paid by manufacturers for inclusion on the PDL/formulary. In NM Medicaid, supplemental rebates are negotiated by the MCOs and their PBMs, not by HSD.

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Pharmacy Trends in US

- Americans spend more on prescription drugs per capita than any other country
  - Total US prescription sales in 2017 calendar year were $455.9 billion.
  - Top-three drugs in the US based on expenditures were:

1. Humira® (adalimumab) $5500/month	2. Lantus® (insulin glargine) $488/month	3. Enbrel® (tumor necrosis factor blocker) $2709/month
• Arthritis conditions • Ulcerative Colitis • Plaque Psoriasis	• Type 1 Diabetes • Type 2 Diabetes	• Arthritis conditions • Plaque Psoriasis

  - Four of the top-10 drugs have increased in price by more than 100% since 2011.
  - Longer patent periods – drugs developed for rare diseases gain 7 years of additional exclusivity on drug sales; longer patents may also apply for reformulations, techniques or drug uses.

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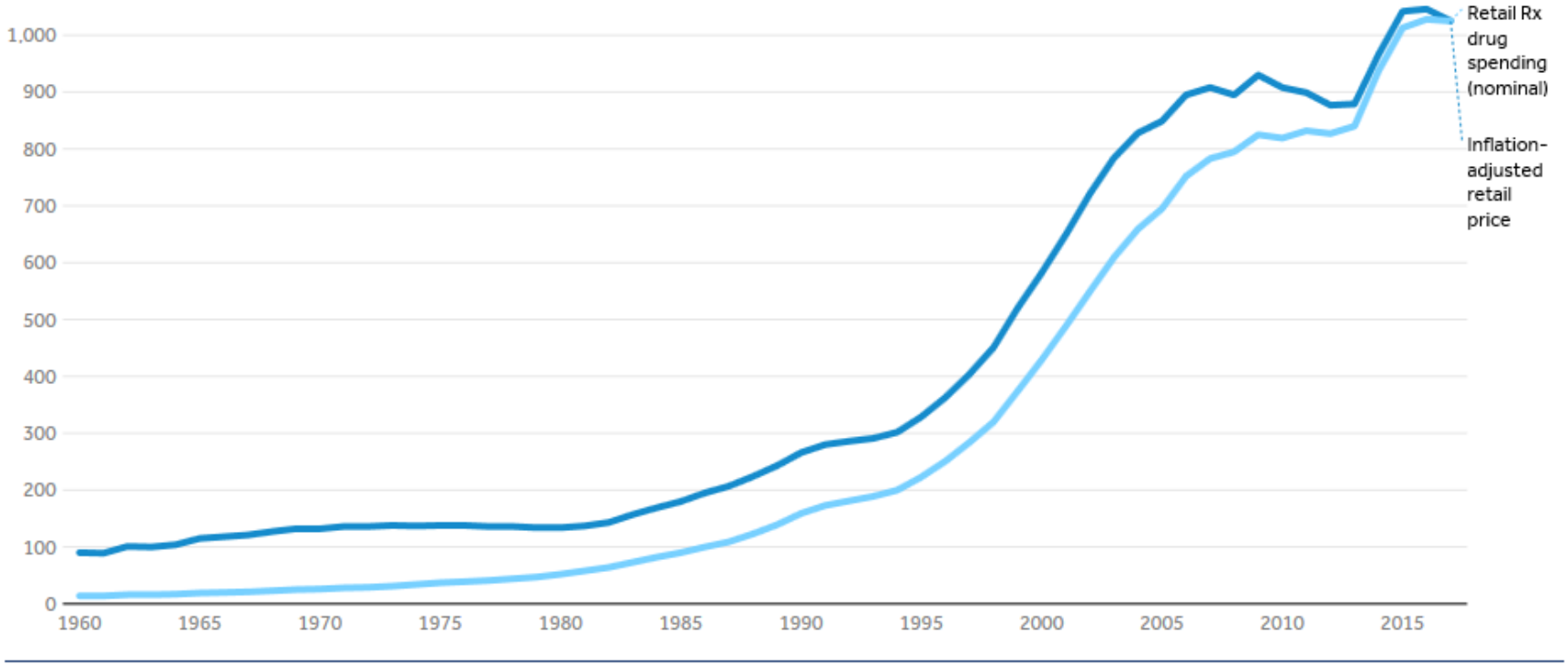
Rapid Rise in Drug Spending Over Past Two Decades

Nominal and inflation-adjusted per capita spending on retail prescription drugs, 1960-2017

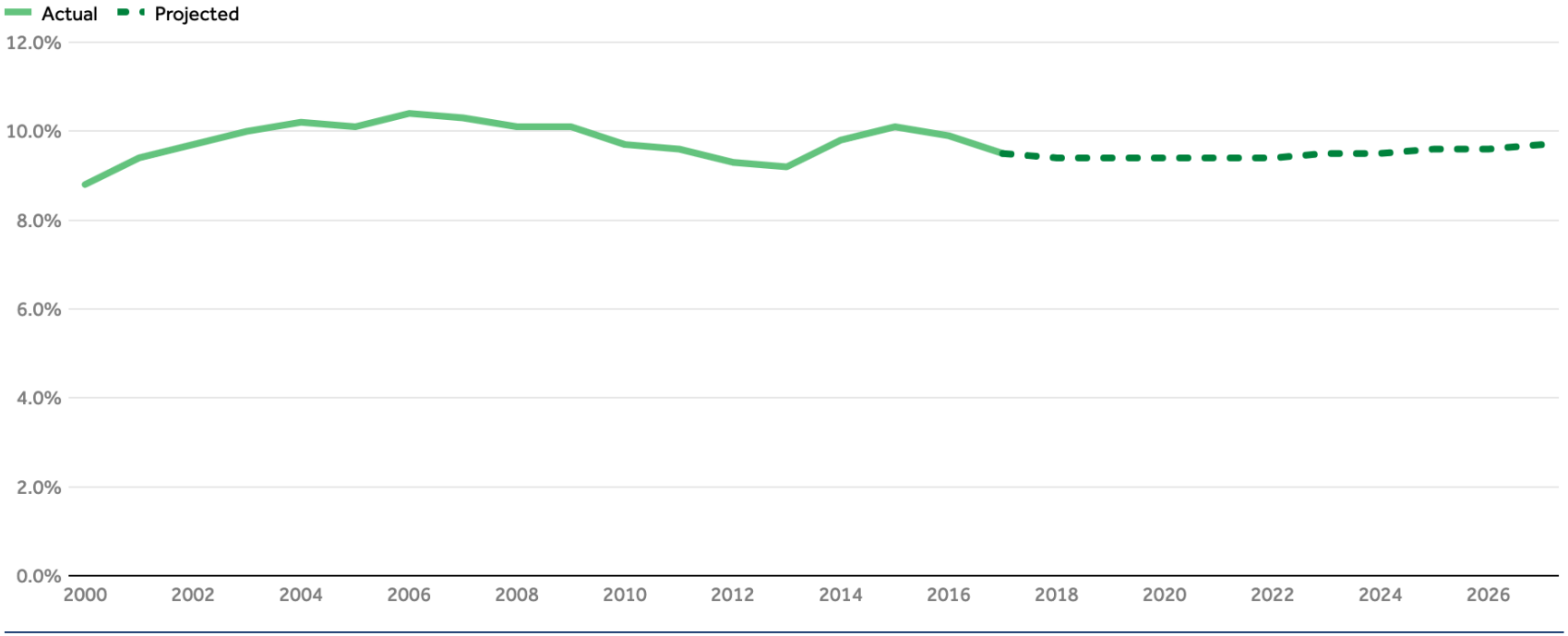


Source: Kaiser Family Foundation Analysis of National Health Expenditures Account • Get the data • PNG

Peterson-Kaiser Health System Tracker

Estimates suggest Rx drugs will represent a similar portion of overall health spending over time

Percent of total health spending that went toward retail prescription drugs, 2000 - 2017; projected 2018 - 2027



Source: KFF analysis of National Health Expenditure Accounts (NHEA) • Get the data • PNG

Peterson-Kaiser Health System Tracker

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What is Typically Considered Part of a Pharmacy Program?

- The NM Medicaid Pharmacy Program includes:

Outpatient prescription drug claims	Legend and Over the Counter (OTC) drugs	Common supplies billed through the pharmacy benefit
Point-of-sale pharmacy claims that are billed and reimbursed instantly. Includes reimbursement for the drug item based on pricing agreements and a dispensing fee.	Legend drugs are drugs that require a prescription. Medicaid also covers certain prescribed OTC drugs, which are billed/reimbursed like pharmacy claims.	Such as diabetic test strips and other common supplies.

- Drugs that are outside of the Medicaid pharmacy spend:

Physician-administered drugs	Drugs that are bundled as part of a service
Drugs that are provided during an office visit and billed on an outpatient or institutional claim. **This represents a growing portion of Medicaid Rx spending in NM.**	Includes most drugs used during an inpatient hospital stay and drugs that are part of bundled payments (i.e., surgeries, FQHC visits).

NM Medicaid Pharmacy Program

- Centennial Care program covers 662,000 New Mexicans; fully integrated model that includes the pharmacy benefit.
  - Centennial Care MCOs subcontract with PBMs
  - Different formularies/PDLs
  - Drug utilization review functions performed by MCOs/PBMs
  - $400 million annual benefit
  - Represents 12% of total projected medical costs
- Full benefit FFS program covers 70,000 New Mexicans; pharmacy claims paid directly by the state through its fiscal agent (Conduent).
  - Not a true PBM model
  - Open formulary; no PDL
  - Most drug utilization review functions are built in through system edits

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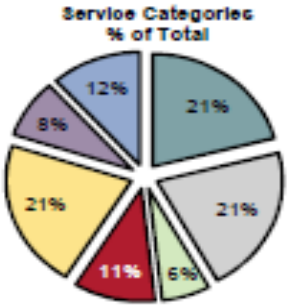
NM Centennial Care Rx Trend (CY17/18)

	Aggregate Costs by Service Categories			Per Capita Medical Costs by Program (PMPM)		
	Previous (12 mon)	Current (12 mon)	% Change	Previous (12 mon)	Current (12 mon)	% Change
Medical	$ 3,078,007,352	$ 3,171,937,149	3%	$ 370.51	$ 396.17	7%
Pharmacy	$ 404,039,902	$ 389,651,035	-4%	$ 48.64	$ 48.67	0%
Total	**$ 3,482,047,254**	**$ 3,561,588,185**	2%	**$ 419.14**	**$ 444.84**	6%

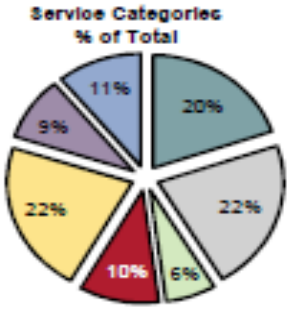
	Aggregate Costs by Service Categories			Per Capita Medical Costs by Program (PMPM)		
Service Categories	Previous (12	Current (12 mon)	% Change	Previous (12 mon)	Current (12 mon)	% Change
Acute Inpatient	$ 726,861,367	$ 702,704,868	-4%	$ 87.73	$ 87.77	0%
Acute Outp/Phy	$ 734,302,474	$ 773,618,725	5%	$ 88.39	$ 96.62	9%
Nursing Facility	$ 216,986,940	$ 230,291,261	6%	$ 26.12	$ 28.76	10%
Community Benefit/PCO	$ 366,608,132	$ 366,685,563	0%	$ 44.13	$ 45.80	4%
Other Services	$ 739,658,756	$ 774,832,106	5%	$ 89.03	$ 96.78	9%
Behavioral Health	$ 291,589,683	$ 323,804,624	11%	$ 35.10	$ 40.44	15%
Pharmacy (All)	$ 404,039,902	$ 389,651,035	-4%	$ 48.64	$ 48.67	0%
Total Costs	**$ 3,482,047,254**	**$ 3,561,588,185**	2%	**$ 419.14**	**$ 444.84**	6%

** Per capita not normalized for case mix changes between periods.*

Previous (12 mon) service distribution



Current (12 mon) service distribution



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Top 10 Drugs by Spend in Centennial Care (CY18)

Rank	Name	Condition(s) Treated	Total Spend	Total Scripts
1	Mavyret ™	Hepatitis C	$34,678,318	2,809
2	Suboxone®	Opioid dependence	$16,687,580	52,089
3	Basaglar Kwikpen U-100®	Diabetes	$13,446,180	36,999
4	Humira Pen®	Arthritis, plaque psoriasis	$11,906,551	2,812
5	Ventolin HFA®	Asthma	$8,454,652	140,334
6	Epclusa®	Hepatitis C	$6,686,114	303
7	Genvoya®	HIV	$4,870,986	1,690
8	Methylphenidate ER	ADHD	$4,709,164	21,842
9	NovoLog®	Diabetes	$4,680,007	8,243
10	NovoLog Flexpen®	Diabetes	$4,633,355	6,985

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Top 10 Drugs by Script in Centennial Care (CY18)

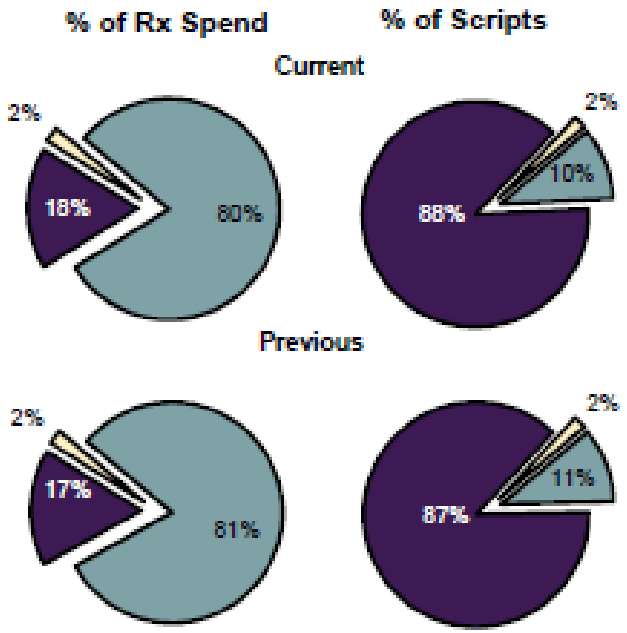
Rank	Name	Condition(s) Treated	Total Spend	Total Scripts
1	Ventolin HFA®	Asthma	$8,454,652	140,334
2	Gabapentin	Anti-seizure/convulsant, pain management	$1,771,122	138,756
3	Lisinopril	Hypertension, congestive heart failure	$430,398	127,719
4	Amoxicillin	Antibiotic	$590,691	127,143
5	Levothyroxine Sodium	Thyroid disorder	$1,519,337	115,319
6	Ibuprofen	Pain management	$474,372	109,868
7	Hydrocodone-Acetaminophen	Pain management	$1,330,561	102,060
8	Fluticasone Propionate	Asthma/COPD	$868,150	90,738
9	Metformin HCL	Diabetes	$483,622	89,773
10	Omeprazole	Heartburn, stomach ulcers, reflux disease	$862,157	88,900

Centennial Care Pharmacy Utilization: Brand-Name vs. Generic (CY18)

- Medicaid Expansion population

Total Generic / Brand Rx

	Previous Costs (12 mon)	Current Costs (12 mon)	% Change
Brand	$ 140,794,316	$ 138,821,121	-1%
Generic	$ 29,533,446	$ 30,640,321	4%
Other Rx	$ 3,799,742	$ 3,970,810	5%
Total	**$ 174,127,505**	**$ 173,432,251**	**0%**



** "Other Rx" represents supplies such as diabetic strips.*

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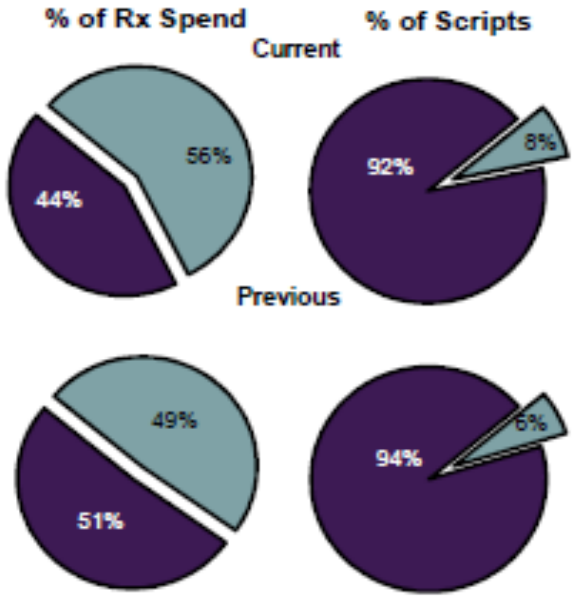
Centennial Care Pharmacy Utilization: Brand-Name vs. Generic (CY18)

- Behavioral Health

Total Generic / Brand Rx

	Previous Costs (12 mon)	Current Costs Current (12 mon)	% Change
Brand	$ 33,285,698	$ 36,208,871	9%
Generic	$ 34,948,616	$ 27,909,843	-20%
Total	**$ 68,234,314**	**$ 64,118,713**	**-6%**



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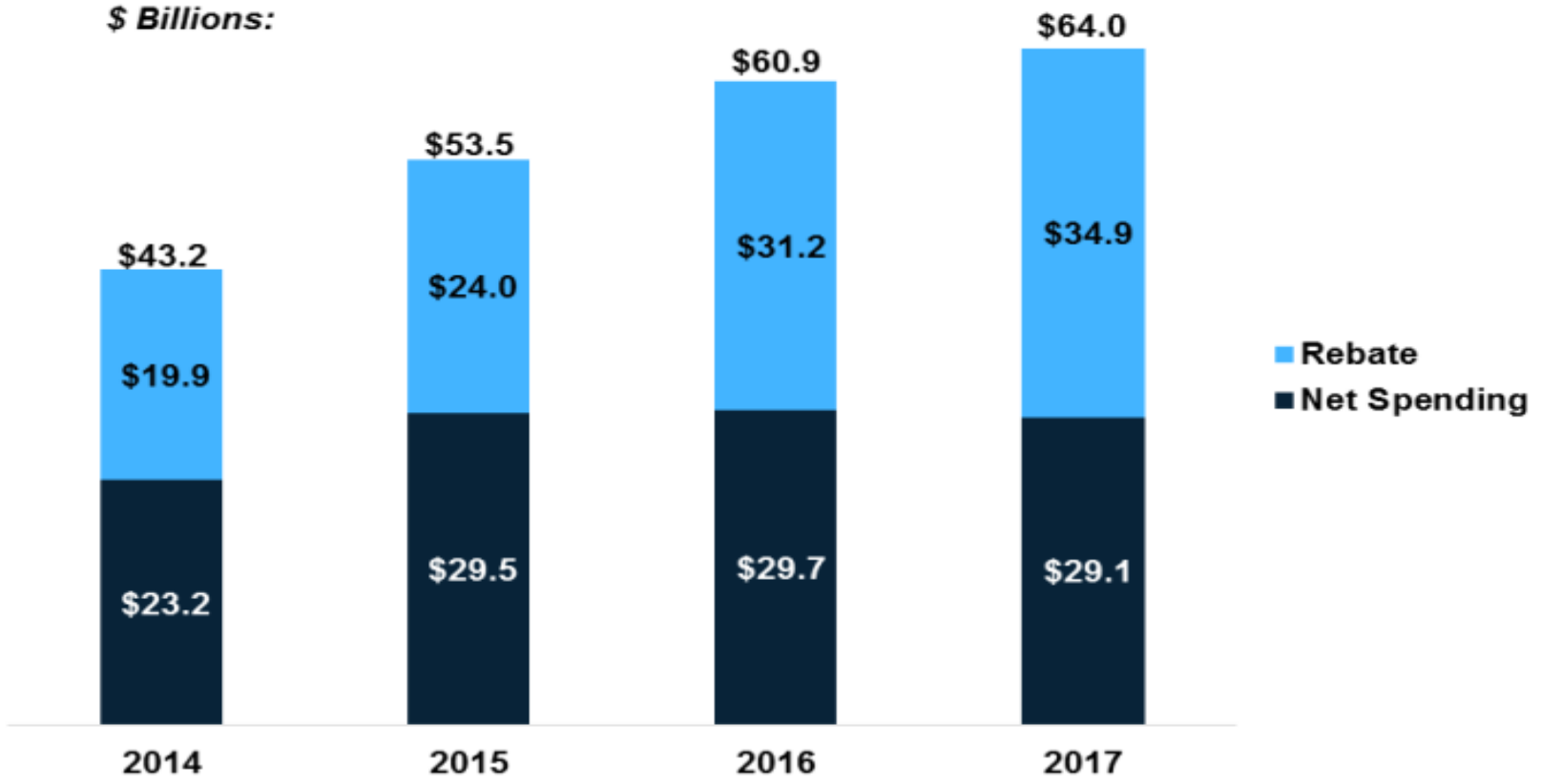
National Medicaid Pharmacy Trend

Medicaid Drug Spending and Rebates, FY2014-17



SOURCE: MACPAC, *Medicaid Drug Spending* Trends, February 2019.

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How Medicaid Pays a Pharmacy Claim

- The total amount paid by Medicaid for a given drug is a factor of several inputs including:
  1. The dispensing fee paid to the pharmacist.
  2. The amount paid to the pharmacy for the ingredients of a drug.
  3. The rebate received from the manufacturer.
- States have some flexibility to establish the dispensing fee amount but the other two inputs are directed by federal requirements.

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Medicaid Drug Rebate Program (MDRP)

- The MDRP requires drug manufacturers to enter into a National Rebate Agreement (NRA) with the federal Medicaid agency in exchange for state Medicaid coverage of FDA-approved drugs.
- Because most manufacturers participate in the MDRP, Medicaid essentially maintains an open formulary in which states are required to provide nearly all prescribed drugs made by manufacturers.
- Manufacturers are responsible for paying rebates on drugs for which payments were made to Medicaid patients.
  - Paid on a quarterly basis to states; states then share savings with the federal government based on their federal match rate (FMAP).

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Medicaid Drug Rebate Program (cont.)

- In addition to signing a National Rebate Agreement, drug manufacturers are required to enter into agreements with two other federal programs in order to have their drugs covered under Medicaid:
  - A pricing agreement for the Section 340B Drug Pricing Program, administered by the Health Resources and Services Administration (HRSA); and
  - A master agreement with the Secretary of Veterans Affairs for the Federal Supply Schedule. (Used by IHS)
- Rebate amounts are established in statute based on a set formula.
- Additional supplemental rebates may be negotiated directly between states/MCOs (or PBMs on working on their behalf) and drug manufacturers.

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NM Medicaid Rebates (CY18)

FFS Rebates	MCO Rebates
$8,502,912	$179,063,943
Total Rebates: $187,566,855	

NM shares savings with the federal government based on the federal match rate (FMAP).

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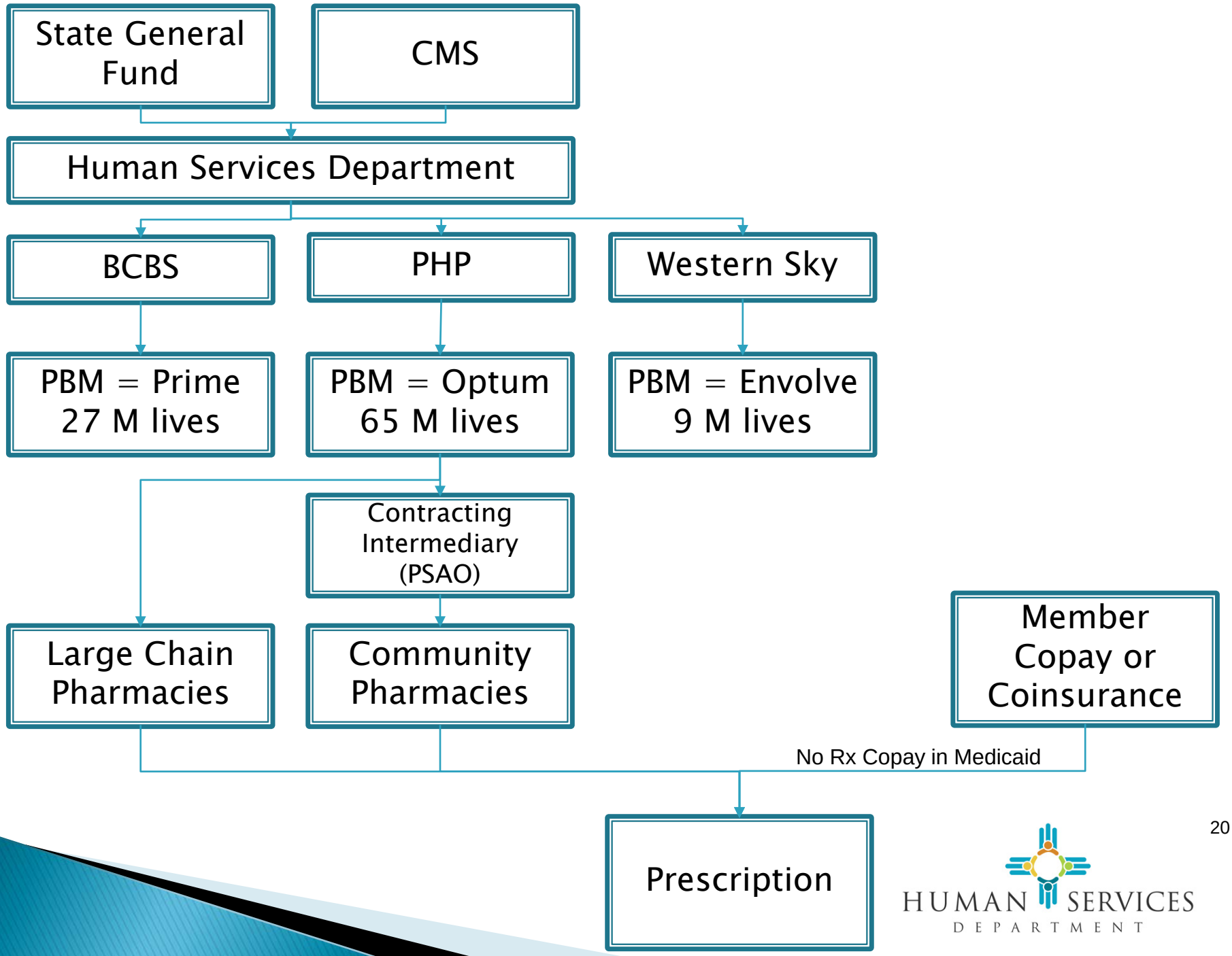

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Role of PBMs

- Five largest PBM companies in US by market share*:
  1. Caremark (CVS Health)/Aetna – 30%
  2. Express Scripts – 23%
  3. OptumRx (UnitedHealth) – 23%
  4. Humana Pharmacy Solutions – 7%
  5. Prime Therapeutics – 6%
  6. MedImpact Healthcare Systems – 6%
- The top-five PBMs within the country manage the drug benefits for approximately 95% of the US population (or 253 million American lives).
- PBMs process prescription drug claims, negotiate purchase pricing and rebates, determine payments to pharmacies, review drug utilization, and determine formulary design.

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

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PBM Pricing: Pass-Through vs. Spread

Pass-Through Pricing	Spread Pricing
More transparent	Less transparent
The PBM pays pharmacies the actual negotiated prices for drug items plus a dispensing fee. The amounts paid to the PBM for drug items/dispensing by the MCO are the same as what is paid to the pharmacy.	The PBM charges the MCO a higher price for a drug/dispensing than what is paid to the pharmacy. The PBM keeps the difference between what the MCO paid and what the PBM paid out to the pharmacy.
Since no spread is collected, PBMs earn their income by charging administrative fees on each drug claim or through per-member-per-month (PMPM) arrangements.	The PBM keeps the spread.
Allows data capture to see exactly what was paid to the pharmacy.	Difficult to determine the amounts paid to pharmacies directly.
Rebates: Under both models, the PBM may also be able to retain all or some of their negotiated rebates, instead of passing them back to the health plan. This depends on the PBM/MCO contract.	

Note: PBM spread pricing to be completely phased out in Centennial Care by CY2020; move to pass-through pricing

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PSAOs: Pharmacy Services Administrative Organizations

- Another "middle person" between the PBM and certain independent/community-based pharmacies.
- Most PSAOs are owned by drug wholesalers and independent pharmacy cooperatives to help them achieve administrative and payment efficiencies.
- PSAOs help independent/community-based pharmacies with PBM contract negotiation, help-desk services, and managing and analyzing data.
- PSAOs enter into contracts with PBMs on behalf of their members and negotiate reimbursement rates.
  - Can be another area lacking in transparency – not always clear to the pharmacy what is driving changes in their reimbursement rates, which can drop suddenly with little notice.

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Key Factors Contributing to Pharmacy Trend

- Market inflation
- Breakthrough therapies
- Pharmacy pipeline
- First-time generics
- Biosimilars, follow-on biologics
- FDA fast-track approvals

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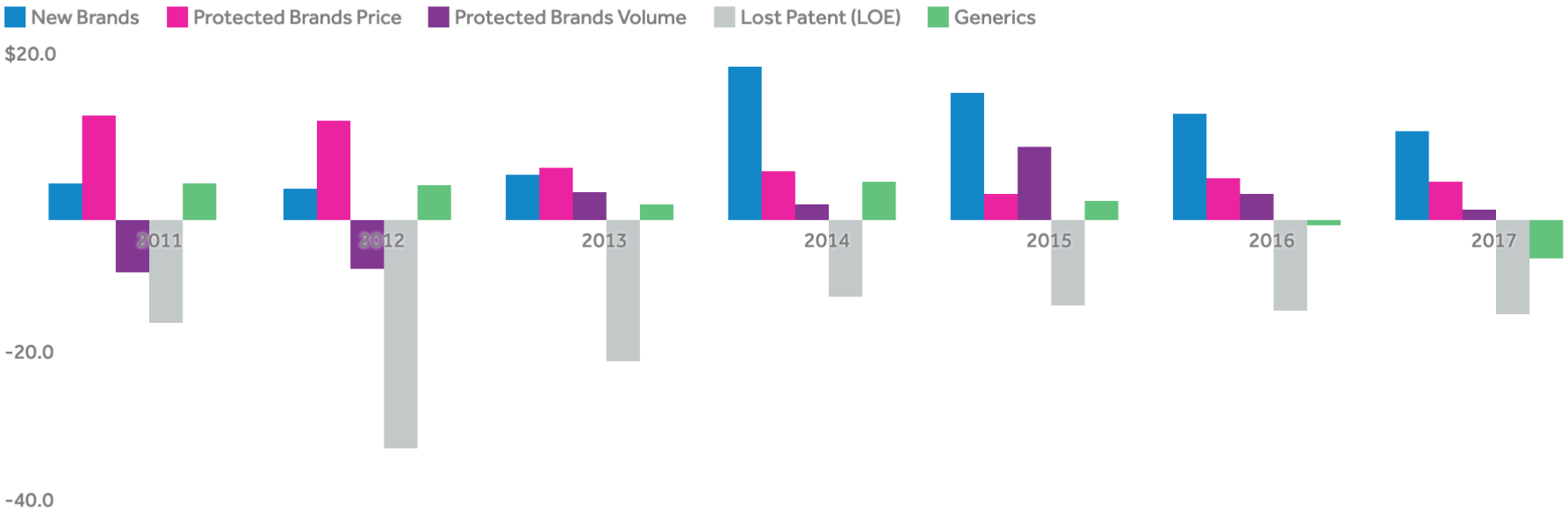
Recent drug spending growth has largely been due to new brands, high prices for existing drugs, and fewer patent expires

Contribution to growth in drug spending, by spending growth drivers, in $US billions, 2011 -2017



New brands are protected branded products on the market less than 24 months during the year reported. Protected brands are products which are no longer "new" and have yet to reach patent expiry. Loss of Exclusivity (LOE) are brands which were once protected and have since lost patent protection. Generics include both unbranded and branded generics. All segments exclude hepatitis C treatments. Hepatitis C spending growth is reported separately from the other segments in the chart as unusually there are declines in spending in both the new and protected segments for these drugs.

Source: IQVIA, Medicine Use and Spending in the U.S., April 2018; IQVIA Institute of Human Data Science • Get the data • PNG

Peterson-Kaiser Health System Tracker

Life-Cycle Cost of Developing a New Drug

- Developing a new prescription medicine that gains market approval is estimated to cost drug manufacturers at least $2.6 billion:
  - Average development costs =$1.4 billion
  - Time costs (the expected returns that investors forego while a drug is in development) = $1.2 billion
  - Clinical trials to gain FDA approval = $19 million
  - Cost of post-approval research and development = $312 million
- Length of patent = 7-20+ years

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High-Cost Specialty Drugs

- More complex than most prescription medications; designed to treat patients with serious and life-threatening conditions.
- Some may be taken orally but these drugs must often be injected or infused and may have special administration, storage, and delivery requirements.
- Often cannot be routinely dispensed at a typical retail pharmacy due to their complexity.
- Expensive – Average monthly cost to payers and patients is $3,000 (10 times the cost of providing non-specialty medication).
  - High launch prices; pricing outpaces CPI
  - Name-brands with little to no competition
  - No longer just for those with rare conditions – increases potential number of patients needing treatment
  - Long period before patent expiration

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Market Inflation

- Upcoming unit cost increases in important categories.
  - New specialty products:
    - HIV (specialty)
    - Hepatitis C (specialty)
    - Inflammatory (specialty)
    - Multiple Sclerosis (specialty)
    - Pulmonary (specialty)
    - Hemophilia (specialty)
- Upcoming utilization and price growth in important categories:
  - Medication for addiction treatment
  - Oncology and oral oncology

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Pharmacy Pipeline

- FDA priority approval process has created faster approvals.
  - Includes fast track pipeline, breakthrough therapy and accelerated approvals.
  - Drugs with FDA priority approval designation may be approved to enter the market within 6 months.

New Single-Source Brand	New and Expected Generics	Biosimilars, Follow-On Biologics
Hemlibra® (hemophilia)	Copaxone® (multiple sclerosis)	Avastin® (cancer)
Kymriah ™ (acute lymphoblastic leukemia)	Effient® (blood thinner)	Epogen® (kidney disease)
Luxterna ™ (retinal disease gene therapy)	Lyrica® (pain management; anti-seizure)	Herceptin® (cancer)
Symtuza ™ (HIV)	Renvela® (kidney disease)	Humalog® (diabetes)
Trogarzo ™ (HIV)	Sensipar® (kidney disease)	Lantus® (diabetes)
Yescarta® (non-Hodgkin lymphoma)	Tamiflu® (flu prevention/treatment)	Neulasta® (cancer)

Hot Topics in Pharmacy Across States

- **Transparency** – PBMs and drug manufacturers; providing more information to the public (spread pricing)
- **US vs. other countries** drug costs and importation
- **Formularies and PDLs** – Pros/cons of requiring uniformity
- **High-cost specialty drugs** – How to treat eligible patients in a sustainable way
- **Pharmacy purchasing** – Exploration of different models (interagency purchasing, subscription model, formulary exclusions, carve-outs, role of PBMs)
- **340B** – How to leverage savings for certain drugs and populations
- **Public health issues** – How to address issues such as the opioid epidemic, Hepatitis C, provision of LARC
- **Other** issues being discussed not mentioned here?

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Questions?

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