Missouri Department of SOCIAL SERVICES

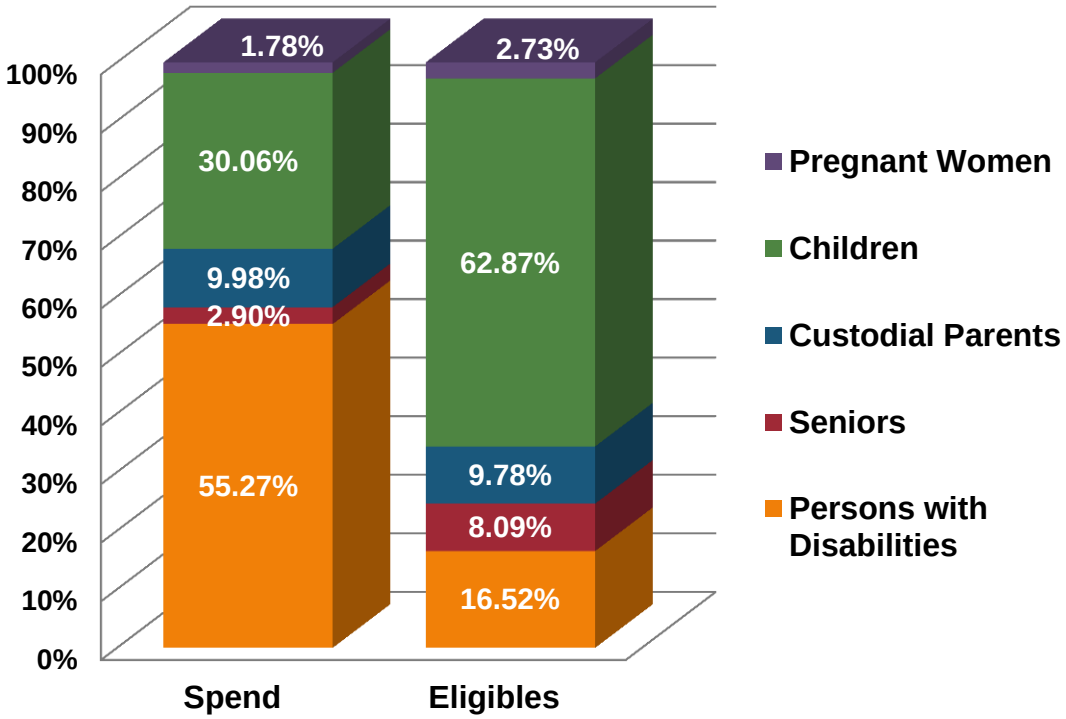
MoHealth Net

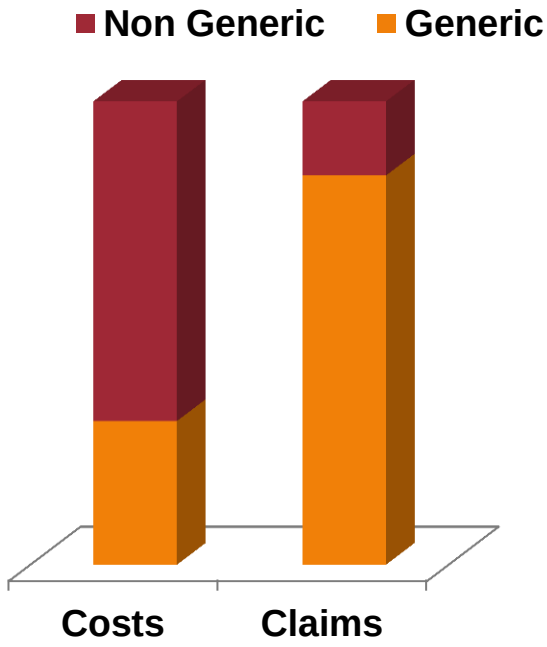
PHARMACY PROGRAM OVERVIEW

FEBRUARY 1, 2017

FAST FACTS BASED ON FY 16 CLAIMS

- $1.2 Billion – Pharmacy claims expenditures
- 12.86 Million – Number of claims/scripts
- 292,111 – Average Pharmacy users per month
- 1,354 Retail Pharmacies
- Spending by eligibility group - graph people to cost





95.7% of time a generic is dispensed when available.

DRUG COVERAGE PROCESS

Does MO HealthNet now have a restrictive formulary?

The MO HealthNet fee for service program has a **preferred drug list (PDL)**. This means the agency solicits supplemental rebates from manufacturers. That economic information will be paired with evidence based clinical information to arrive at preferred drug(s) in each functional therapeutic class. Each drug class on the PDL is reviewed annually. Providers are encouraged to visit the **agency's Web site** for the most current information.

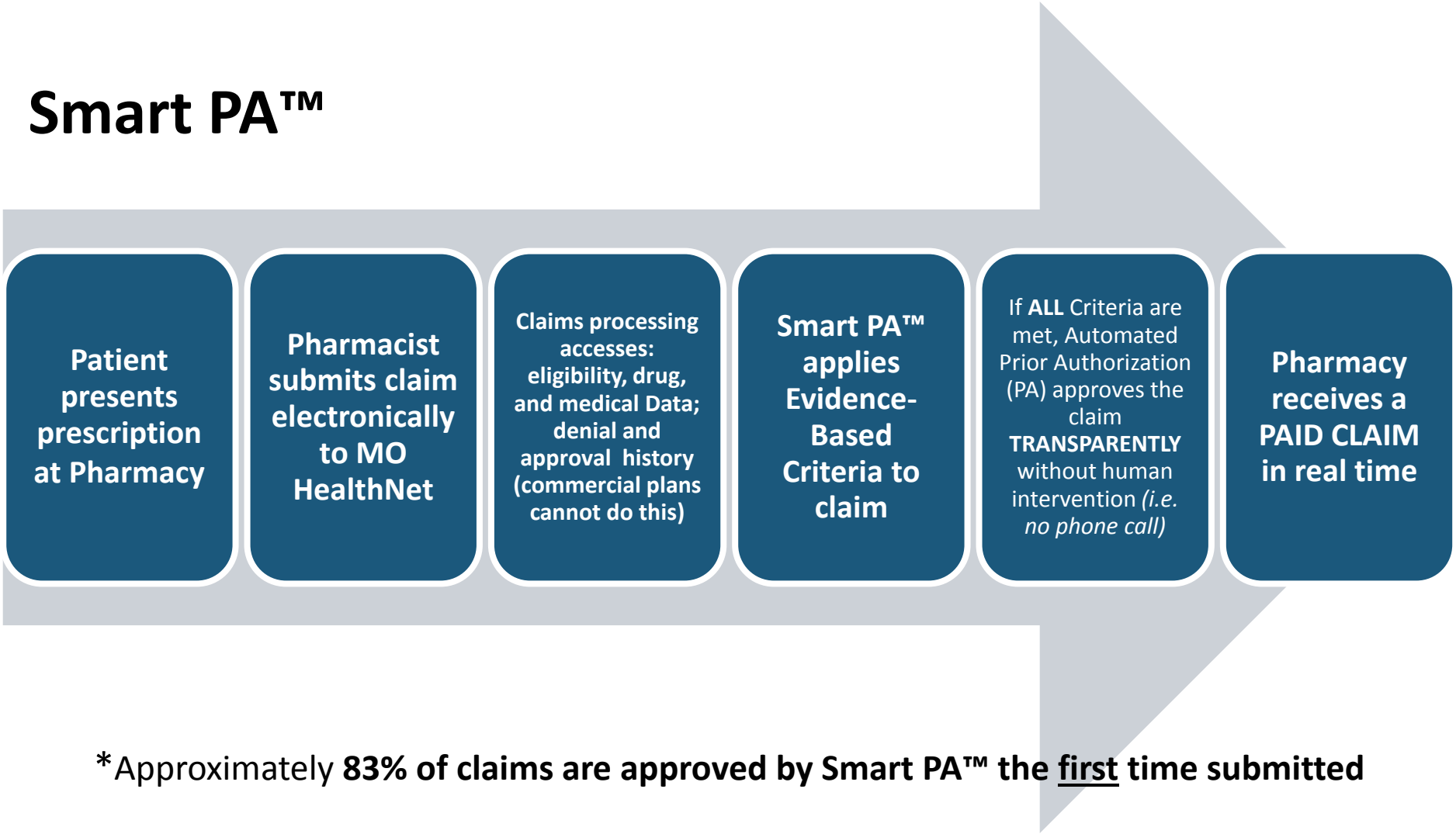
DRUG COVERAGE PROCESS

What does "Preferred Drug" mean?

A preferred drug is the agent in each functional therapeutic class that the agency would like prescribers to use in beginning therapy. MO HealthNet will continue to reimburse for all medications whose manufacturers have entered into the federal rebate program (as required by law). Agents other than the preferred product(s) may be approved on the basis of medical necessity at any time. Non-preferred agents may be transparently approved through the agency's SmartPA™ program after a trial of preferred agents paid for by MO HealthNet. Please see the approval criteria on the Pharmacy Clinical Edit and Preferred Drug List Documents page. MO HealthNet Preferred Drug List FAQ

AUTOMATIC DRUG PRIOR AUTHORIZATION PROCESS

Smart PA™



*Approximately **83% of claims are approved by Smart PA™ the first time submitted**

NEW DRUG COVERAGE PROCESS

- MHD subscribes to First Data Bank for weekly notification of new drugs
- Division identifies reimbursable drugs requiring action by MHD Advisory Groups (i.e. Drug PA Committee and DUR Board)
- ALL new drugs require **Prior Authorization (PA)**; Providers must call the Pharmacy Hotline
- At end of 30-day review, Division recommends status in the Drug Program:
  - Continue Prior Authorization
  - Open Access
  - Clinical Edit
  - Inclusion in the Preferred Drug List (PDL)
- Following evaluation of recommendations by BOTH Advisory Groups, Division finalizes coverage parameters and schedules implementation
  http://www.dss.mo.gov/mhd/cs/pharmacy/pdf/newdrug_process.pdf

HOW DRUGS ARE PRICED

The lower of:

- Wholesale Acquisition Costs (WAC) plus 10%
- Federal Upper Limit (FUL)
- Missouri Maximum Allowable Cost (MAC)
  - Costs avoided in FY 15 = **$120.5M**
- Specialty Missouri Maximum Acquisition Cost (SMAC)
  - Costs avoided in FY 15 = **$29.6M**
- Billed amount

What is a SPECIALTY DRUG?

- Usually a biologic product
- Treats complex conditions (e.g. cancer, arthritis)
- May require special administration
- Must monitor for effectiveness & side effects
- Per member per month cost in excess of $600

TOP 4 DRUG CLASSES PER FY BY $$

HICL Description			FY 2015
ARIPIPRAZOLE	Behavioral Health		$86,374,428
INSULIN GLARGINE,HUMAN RECOMBINANT ANALOG		Diabetes	$25,257,027
ALBUTEROL SULFATE		Asthma/COPD	$22,062,737
METHYLPHENIDATE HCL	Behavioral Health		$21,837,776
HICL Description			**FY 2016**
ARIPIPRAZOLE	Behavioral Health		$83,230,287
LURASIDONE HCL	Behavioral Health		$30,817,059
INSULIN GLARGINE,HUMAN RECOMBINANT ANALOG		Diabetes	$25,943,693
METHYLPHENIDATE HCL	Behavioral Health		$24,797,607
HICL Description			**FYTD 2017**
LURASIDONE HCL	Behavioral Health		$17,315,075.10
PALIPERIDONE PALMITATE	Behavioral Health		$14,228,387.40
INSULIN GLARGINE,HUMAN RECOMBINANT ANALOG		Diabetes	$13,122,612.85
ALBUTEROL SULFATE		Asthma/COPD	$13,109,144.20

DRUG REBATE PROGRAM

Pharmaceutical Manufacturers sign Federal CMS Rebate Agreement	• **Manufacturers must report all drugs to Medicaid Drug Rebate Program** • **If a manufacturer does not sign the agreement, Medicaid cannot cover those drug products.**
MHD manages patient access to approved drugs through:	• **Preferred Drug List (PDL) Process** • **Prior Authorization** • **Clinical and/or Fiscal Edit** • **Open Access**
MHD pays for Rx's at Pharmacies & for Outpatient Physician-Administered Drugs	• **Drug claims information is accumulated by NDC and summarized for each Quarter**

DRUG REBATE PROGRAM

Rebates offset Medicaid costs to the Federal Government and State

- Drugs are rebated at 3 levels based on type of drug:
  - Brand 23.1%
  - Generic 13%
  - Single-Source Generic 17.1%
- MHD negotiates supplemental rebates through a Preferred Drug List

MHD invoices pharmaceutical manufacturers to collect rebates

- Each individual manufacturer receives an invoice Quarterly
- Rebates are paid by specific National Drug Code
- Manufacturers may also be required to pay interest

Rebates are shared between Federal & State based on 60/40 split

PROGRAM MANAGEMENT TOOLS/COST CONTAINMENT INITIATIVES

- Clinical Services Management Program
- Prospective and Retrospective Drug Use Review
- Routine Drug Information Research
- Pharmacy Desk Staffing
  - Prior authorization
  - Claim denials
- Preferred Drug List (PDL) and Supplemental Rebate Program
- Quarterly review/expansion of MAC/SMAC lists
- Prior authorization for all new drugs
- Dose optimization edits
- Maintenance and Updates to Fiscal/Clinical Edits
- Generic dispensing incentives
- CyberAccess Reporting and Authorization Tool
- 340b pricing arrangements

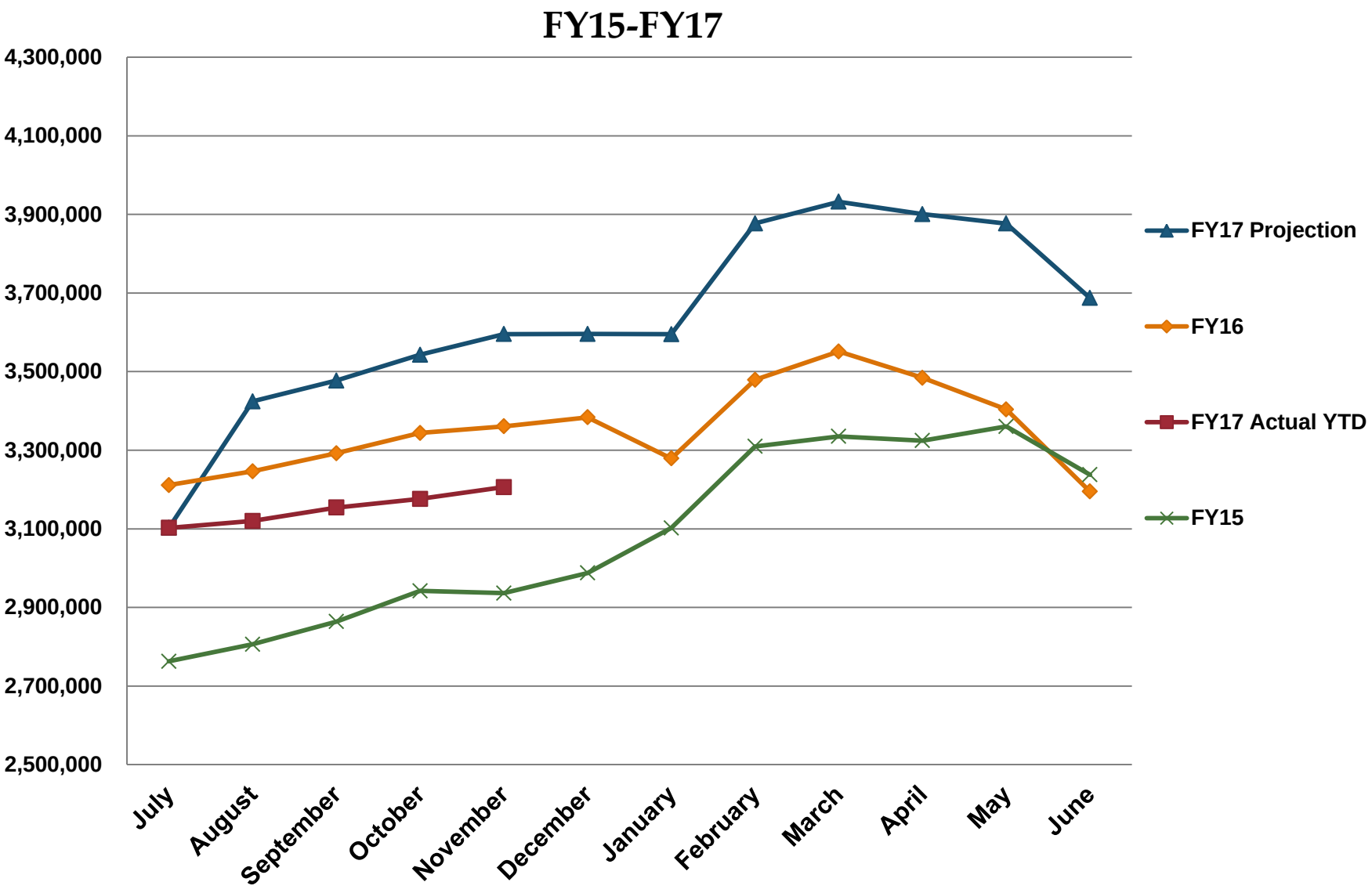
PROGRAM INITIATIVES

- Atypical Anti-psychotics – Metabolic Monitoring
- Opioids Prescribing and Dispensing – CDC Guideline, National Efforts
  - Appropriate Clinical Utilization of Opiates (i.e. Indications, Quantity, Dosing limits)
  - Preventing Neonatal Abstinence Syndrome (Babies exposed to opiates before birth)
  - Supporting Access to Narcan© Nasal (Naloxone) for Opiate Overdose
  - Providing Access to Drugs for Addiction Treatment (Suboxone©)
- Psychotropic for Children in Foster Care – Indications & Monitoring
- Compounding of Topical Preparations
- Poly Pharmacy Risk Reduction Program – MO Pharmacy Association
- 340B Program Optimization

PROJECTING EXPENDITURES

- Begin with historical perspective of expenditures by therapeutic class on a PMPM basis
- Consider drug utilization trends
  - New products
  - Products ending their patent period
  - Likely impact or reaction of marketplace
- Consider the “drug pipeline,” what will be coming to market and its likely reception

PHARMACY COST PER DAY



NEW DRUG PIPELINE CHALLENGES

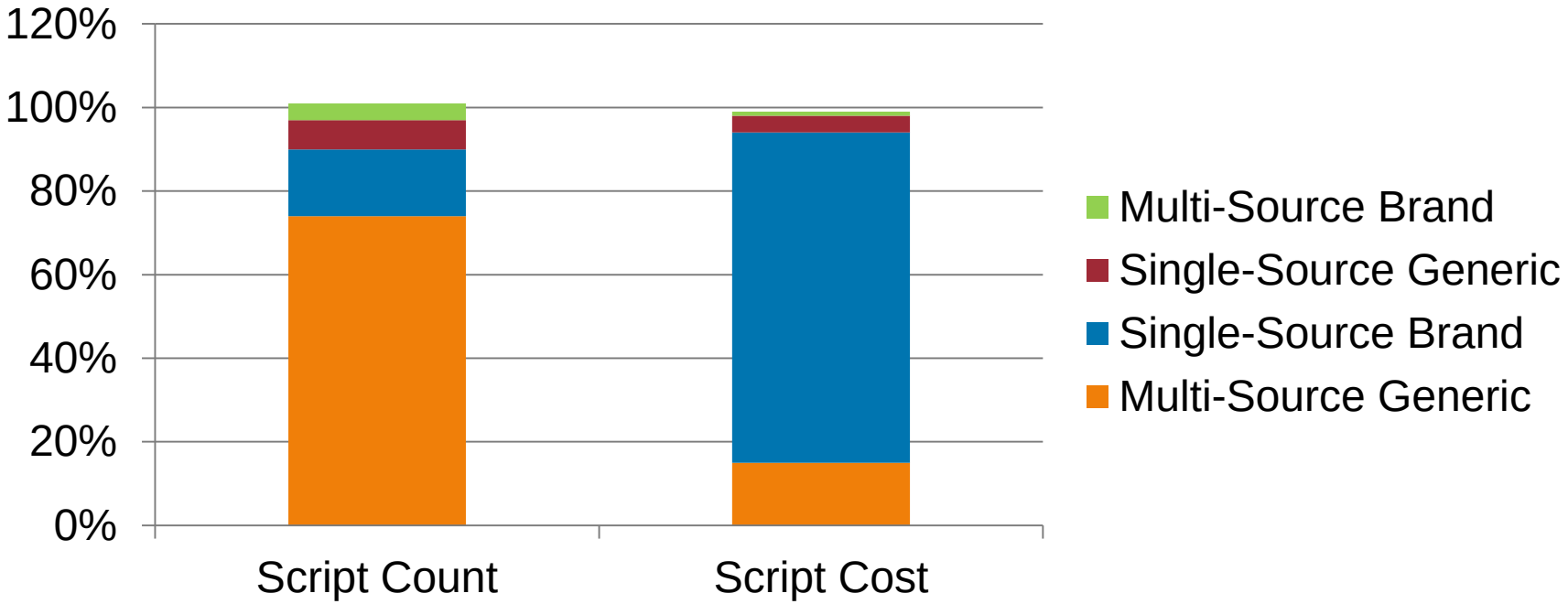
The following four FDA programs are intended to facilitate and expedite development and review of new drugs to address unmet medical need in the treatment of a serious or life-threatening condition:

Fast-Track Designation (1997, 2012)	• Granted on basis of pre-clinical data and the **Potential** to address unmet need
Breakthrough Therapy Designation (2012)	• May have **substantial** improvement on at least one clinically-significant endpoint • **ALL** the Hepatitis C Direct-Acting Antivirals (DAAs) were approved this way
Accelerated Approval Pathway	• Uses "surrogate endpoint" to **Predict** clinical benefit
Priority Review Designation (1992)	• Includes some infections disease products and pediatric indications

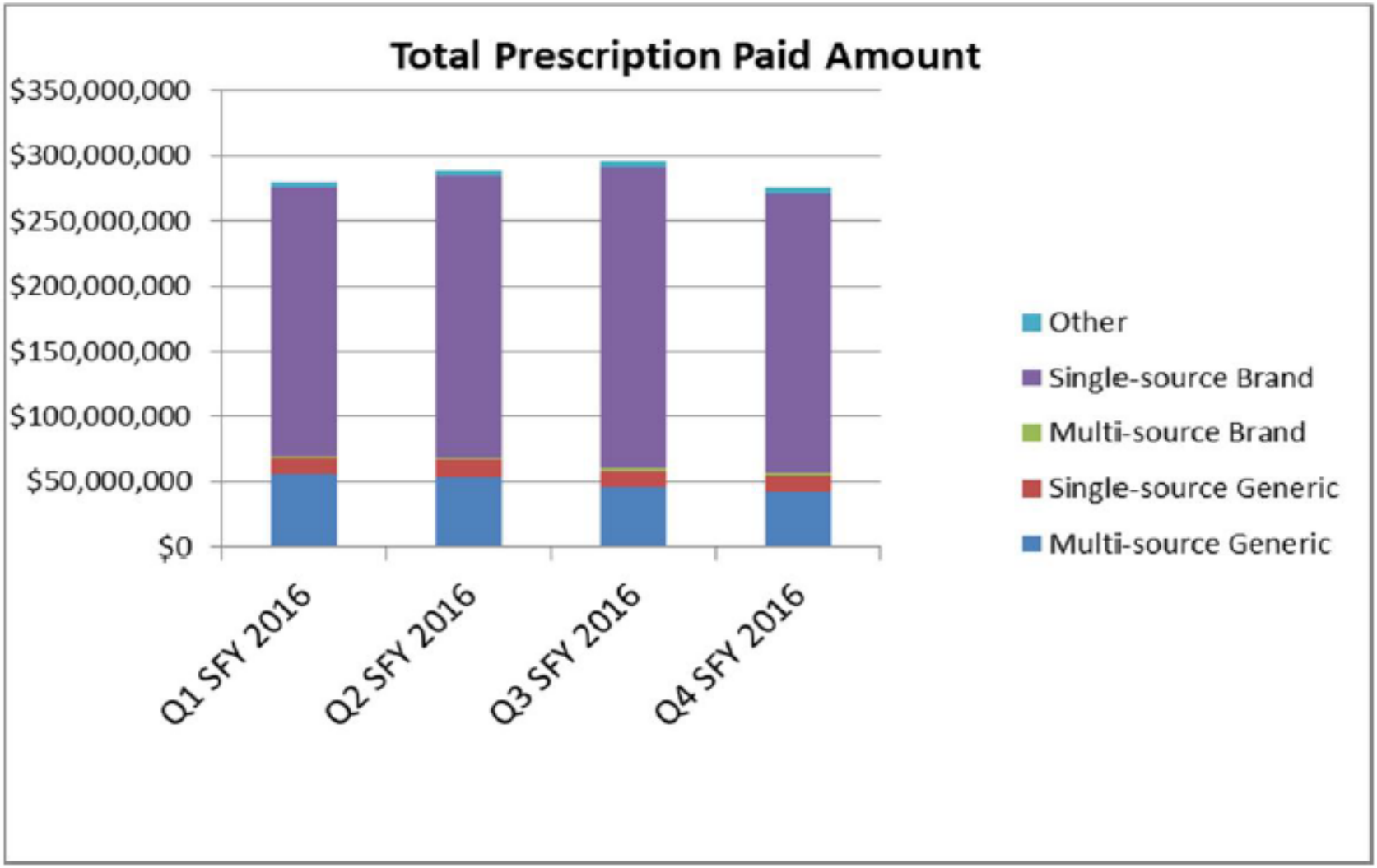
Guidance to Industry issued May 2014

PHARMACY COST TRENDS

- The price of multisource generic prescription decreased from $24.69 in Q2 SFY16 (Oct-Dec 2015) to $20.28 in Q3 SFY16 (Jan-Mar 2016).
  - **This is an 18% drop.**
- The price of a single source brand prescription rose from $435.33 Q2 SFY16 (Oct-Dec 2015) to $464.32 Q3 SFY16 (Jan-Mar 2016).
  - **This is a 7% increase.**



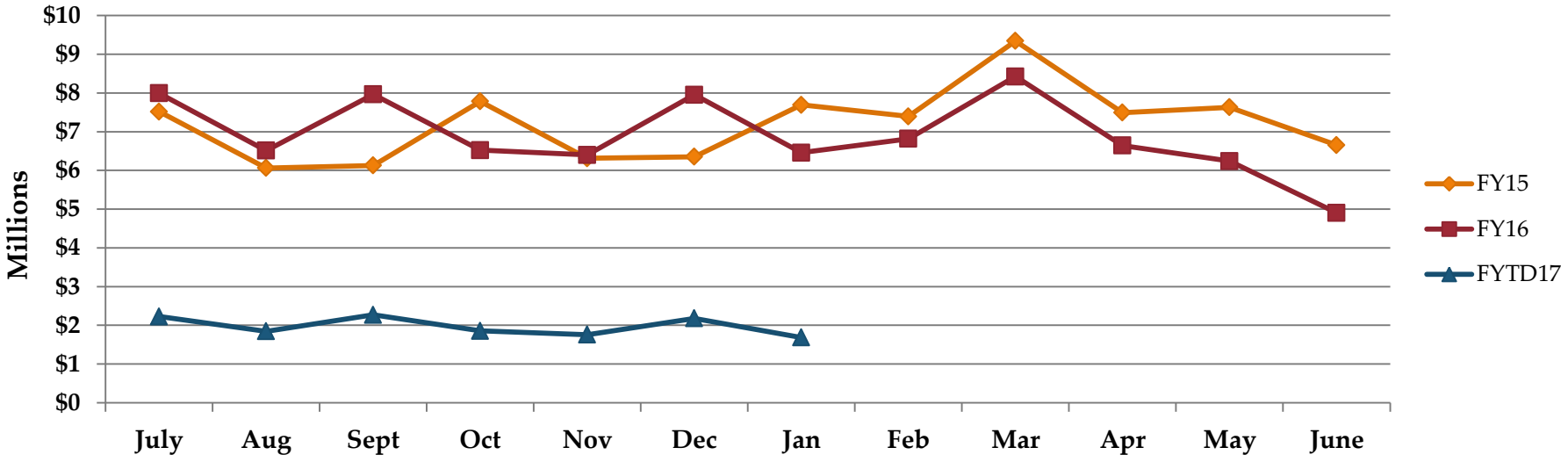
PHARMACY COST TRENDS



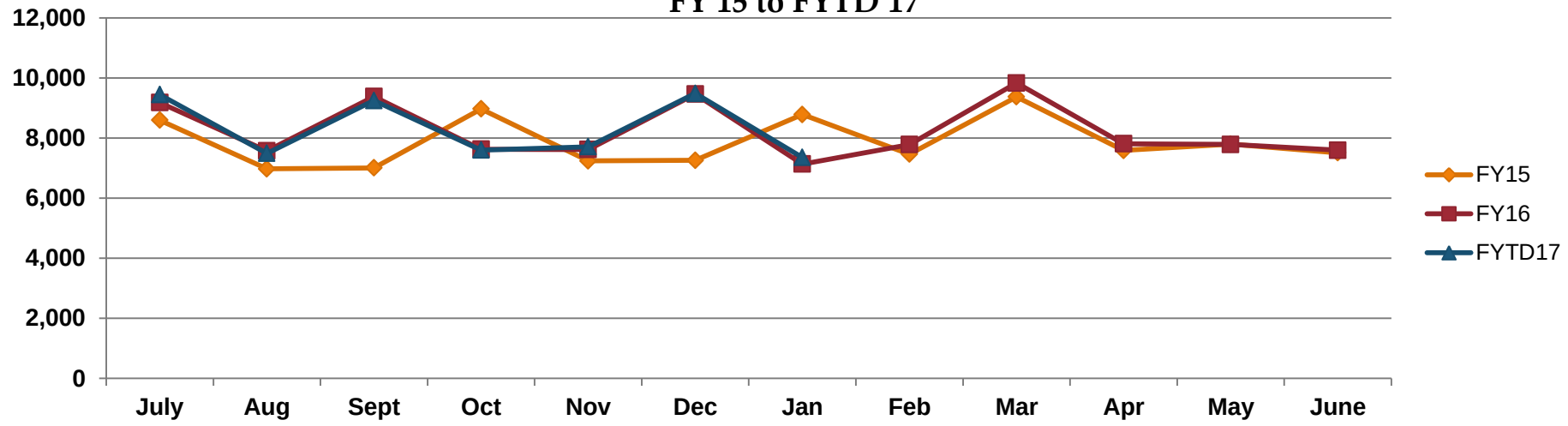
PHARMACY COST TRENDS

- The FDA has approved four biosimilar products, one in 2015 and three in 2016. In Europe, biosimilar product pricing has been approximately 15% below the referenced product.
  - SB 875 (2016) allows Missouri pharmacists to select an interchangeable biological product.
    - Humira © and Enbrel © should have savings once the biosimilar products launch.
      - Humira© had 867 claims (April – June 2016) with an ingredient cost of $4.5M
      - Enbrel© had 563 claims (April – June 2016) with an ingredient cost of $2.4M
- Abilify© provides an example of generic vs. brand drug pricing fluctuations
  - May 2015 generic becomes available – MHD preferred generic over brand drug
  - November 2015 brand rebate lowered the cost of the brand drug to below generic price – MH preferred brand drug over generic
  - June 2016 generic cost was lowered – MHD preferred generic over brand drug

Abilify Expenditures
FY 15 to FYTD 17



Abilify Brand/Generic Claim Count
FY 15 to FYTD 17

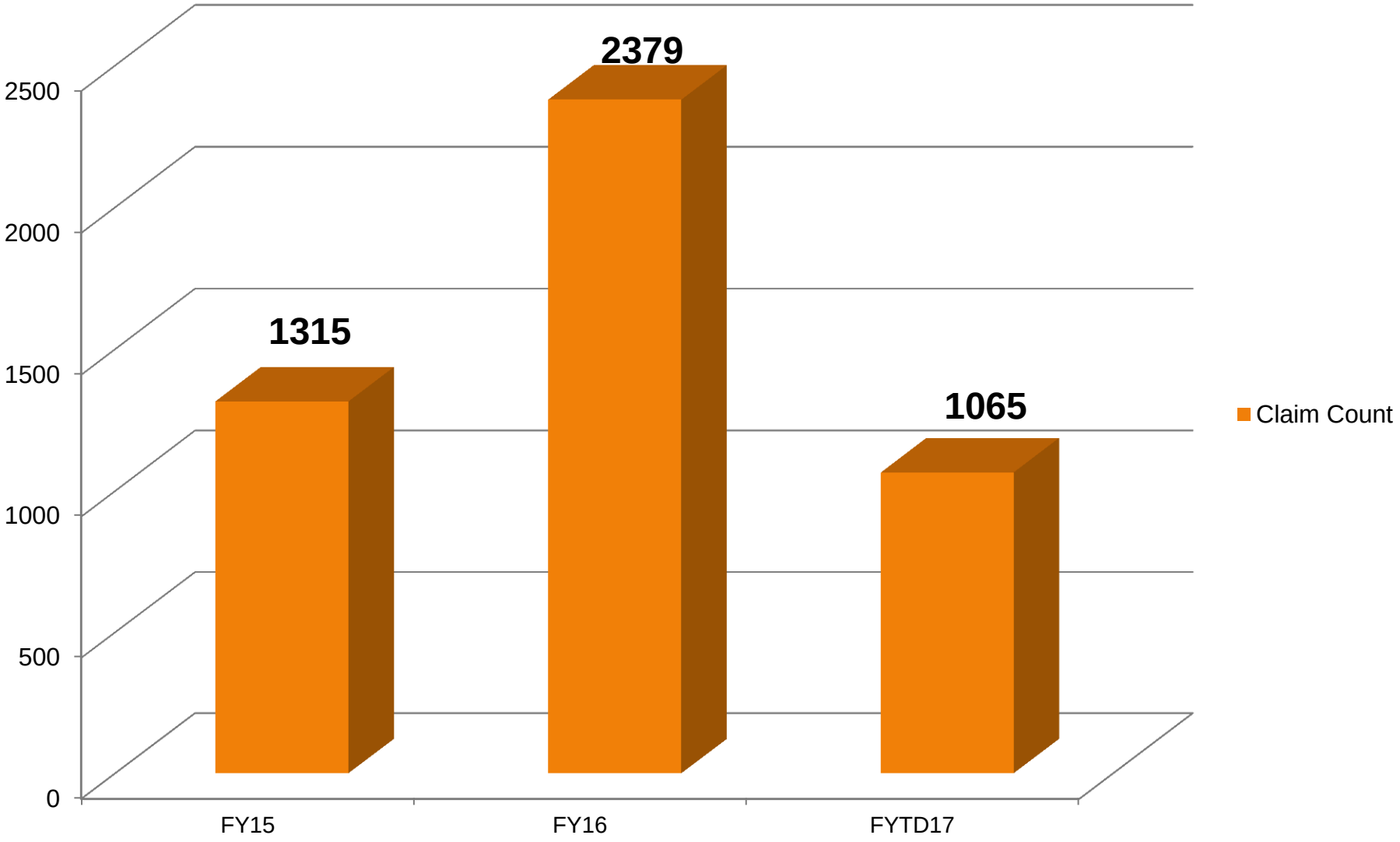


HEPATITIS C DRUG THERAPY

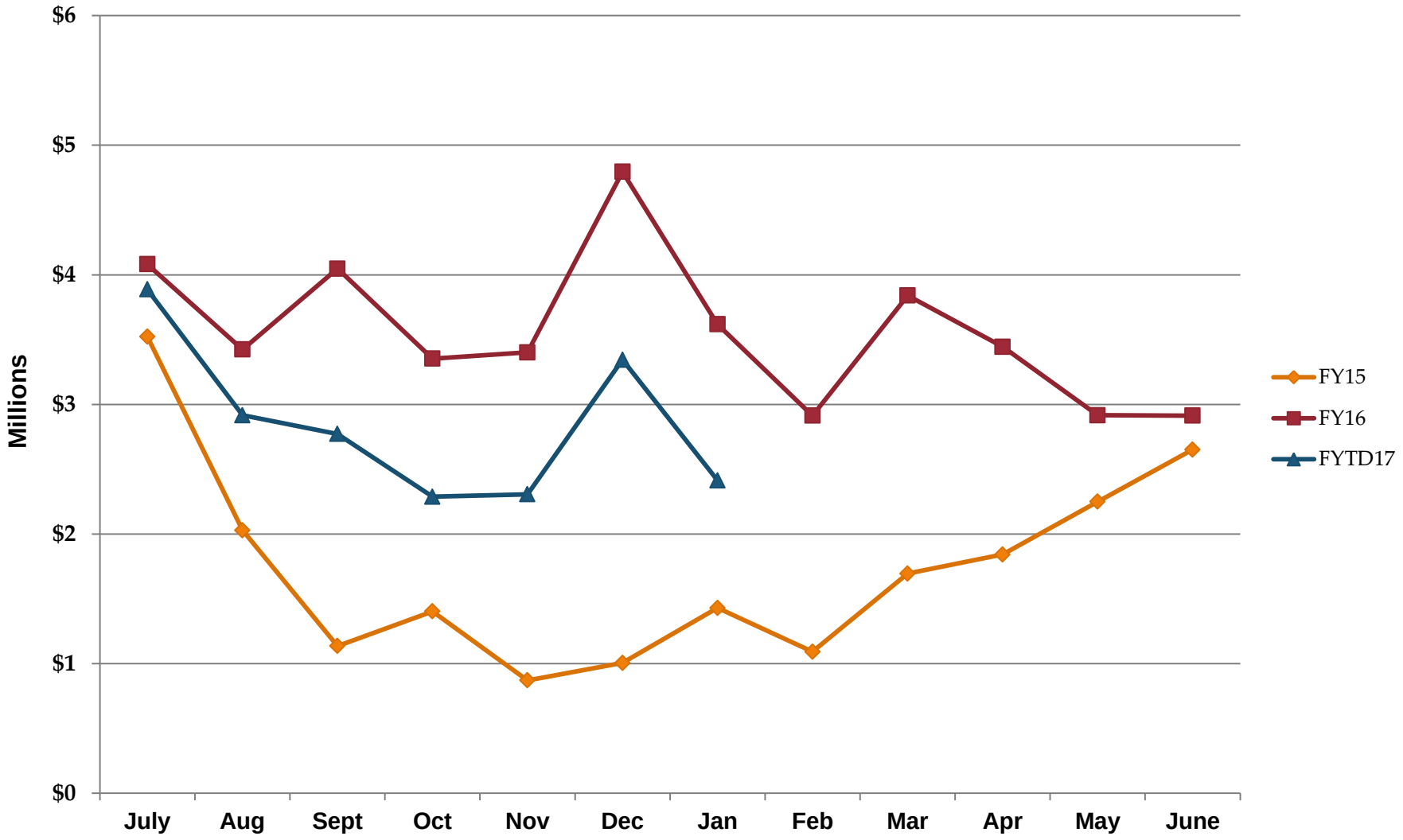
Since NEWER expensive Hepatitis C therapies first became available starting in December 2013, MO HealthNet took active steps to manage this drug class:

- Put Prior Authorization criteria in place to provide appropriate access
- Established and continually revised Preferred Drug List (PDL) to obtain best pricing as additional products came into the marketplace
- Reviewed clinical information and practice guidelines to establish clinical criteria to ensure participants have access to therapy well in advance of significant morbidity
- Continue to review every request for therapy
- Continue to provide fiscally-responsible management of the drug class

Hepatitis C Claim Count FY15-FYTD17



Hepatitis C Expenditures
FY 15 to FYTD 17



PHARMACY PERCENT OF USERS