Utilizing Medication Assistance Programs, Handling Off-Label Requests, Managing High Dollar Medications, and Other Financial Pearls

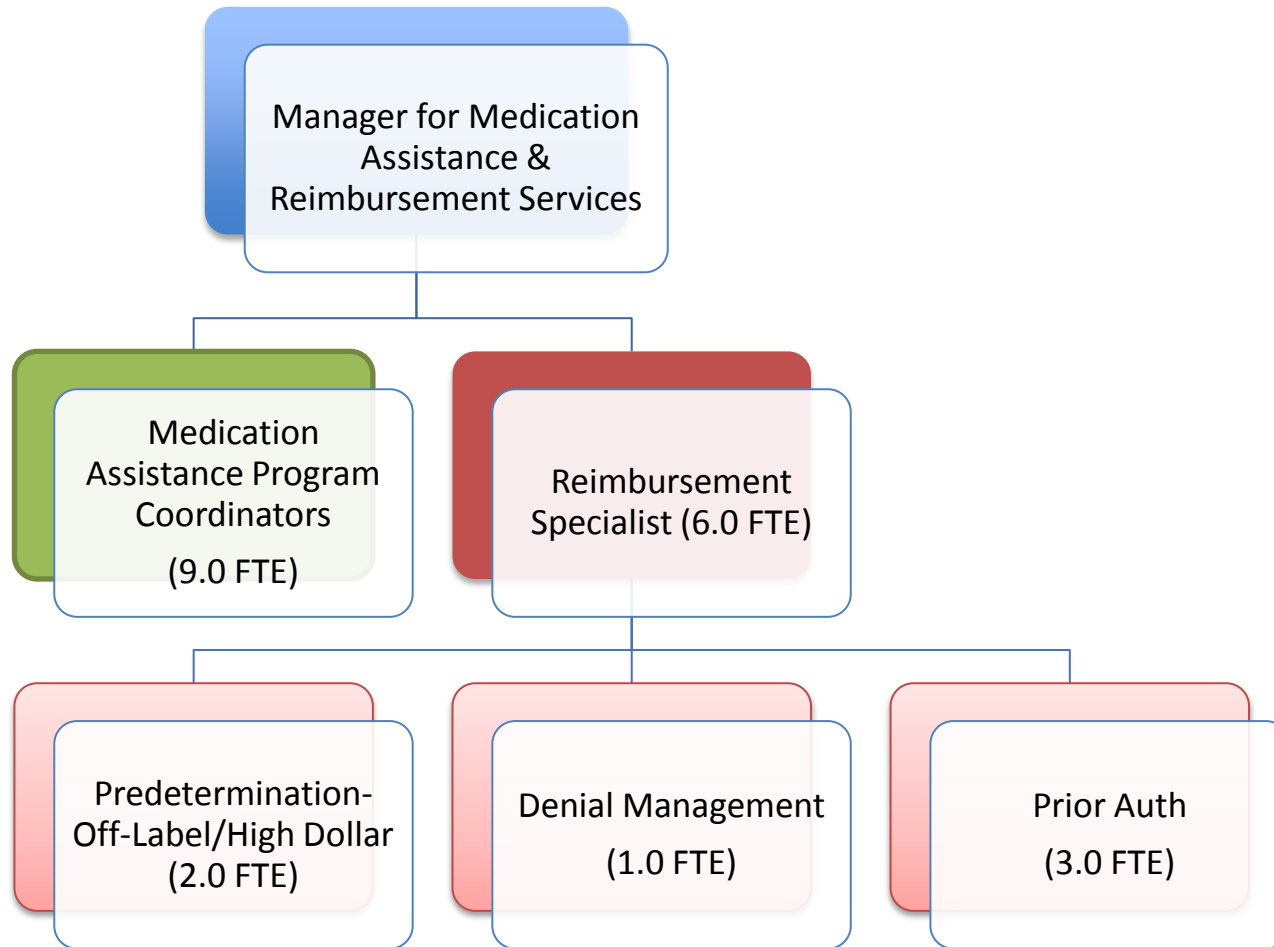Niesha Griffith and Sarah Hudson-DiSalle

Wednesday, March 1, 2017

Workshop Objectives

- Identify the appropriate steps involved in the development and implementation of a Medication Assistance Program (MAP).

- Discuss metrics to assist with justification of a MAP and ongoing metrics to support program continuation.

- Explain the importance of having a policy for off-label uses of medication.

- Describe all resources that are necessary to prepare, submit, and manage an off-label medication claim.

- Describe the process to appeal denied claims for off-label oral and intravenous therapies.
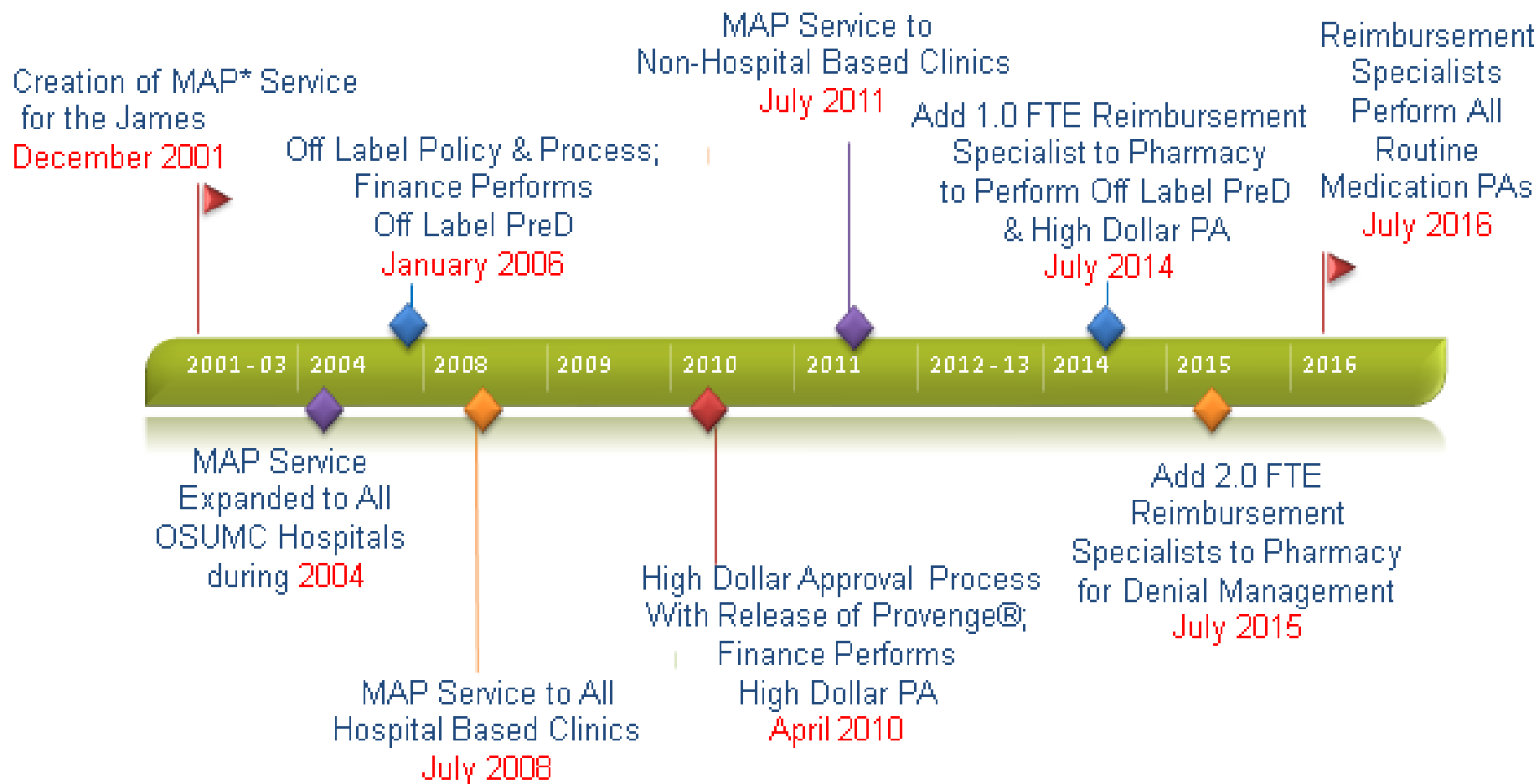
Workshop Outline

- Medication Assistance Program Justification
- Evolution of a Medication Assistance Program
- Precertification of Outpatient Chemotherapy and Supportive Care Medications
- High Dollar Medication Process and Utilization of Copay Programs
- Utilizing Copay Programs for Infused Products
- Development and Implementation of an Off-Label Medication Program
- Managing Denials and Appeals

Medication Reimbursement and Patient Support Services for Oncology

Manager for Medication Assistance & Reimbursement Services

Medication Assistance Program Coordinators
(9.0 FTE)

Reimbursement Specialist (6.0 FTE)

Predetermination-Off-Label/High Dollar
(2.0 FTE)

Denial Management
(1.0 FTE)

Prior Auth
(3.0 FTE)

Growth of Services

Creation of MAP* Service
for the James
December 2001

Off Label Policy & Process;
Finance Performs
Off Label PreD
January 2006

MAP Service to
Non-Hospital Based Clinics
July 2011

Add 1.0 FTE Reimbursement
Specialist to Pharmacy
to Perform Off Label PreD
& High Dollar PA
July 2014

Reimbursement
Specialists
Perform All
Routine
Medication PAs
July 2016

2001-03 | 2004 | 2008 | 2009 | 2010 | 2011 | 2012-13 | 2014 | 2015 | 2016

MAP Service
Expanded to All
OSUMC Hospitals
during 2004

MAP Service to All
Hospital Based Clinics
July 2008

High Dollar Approval Process
With Release of Provenge®;
Finance Performs
High Dollar PA
April 2010

Add 2.0 FTE
Reimbursement
Specialists to Pharmacy
for Denial Management
July 2015

*MAP – Medication Assistance Program for
Un- and Under-Insured Patients

Program Justification for Medication Assistance Services
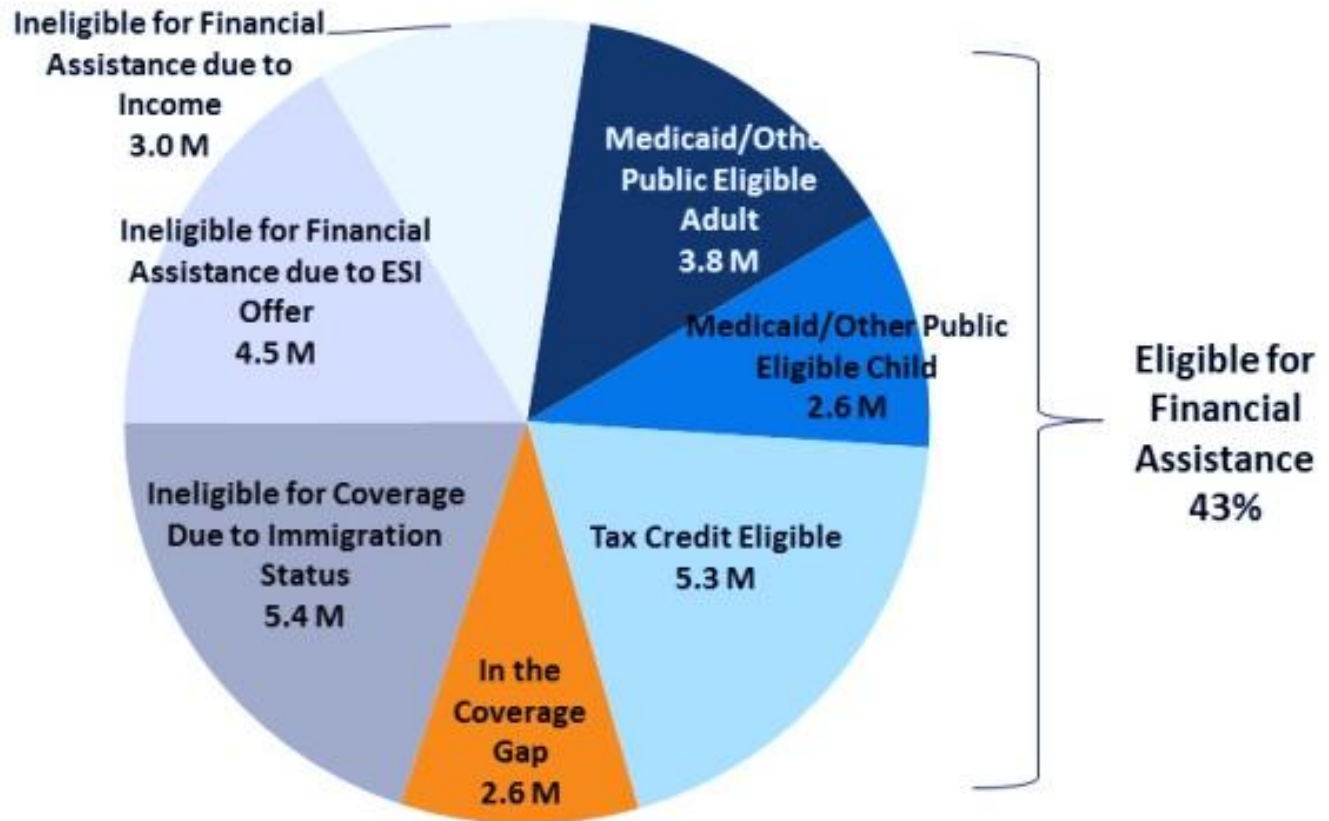
Background

- Large number of uninsured patients in the US
  - Approximately 28.5 million people are uninsured
  - Over two-thirds of uninsured are from working families
  - The uninsured have far less access to care than either the privately or publicly insured
  - Affordable Care Act may reduce numbers by 13 million

- The number of underinsured jumped to 30 million
  - Increased 60% since 2003
  - Middle income families showed the largest increase

Uninsured Definition

- Individuals or groups with no health insurance coverage who lack any medical, dental, prescription, or vision coverage which affects access to care[1]
  - Medically indigent
  - Working uninsured

- Gaps in coverage affect people of all ages, races, ethnicities, and income levels

1. http://www.nlm.nih.gov/nichsr/edu/healthecon/glossary.html

Uninsured Are Eligible for Assistance Under the ACA

Ineligible for Financial Assistance due to Income 3.0 M

Ineligible for Financial Assistance due to ESI Offer 4.5 M

Ineligible for Coverage Due to Immigration Status 5.4 M

In the Coverage Gap 2.6 M

Medicaid/Othe Public Eligible Adult 3.8 M

Medicaid/Other Public Eligible Child 2.6 M

Tax Credit Eligible 5.3 M

Eligible for Financial Assistance 43%

Total = 27.2 Million Nonelderly Uninsured

Definition of Underinsured

A more formal definition of underinsured individuals includes people who are insured all year but have at least one of the following qualifiers:

– Medical expenses greater than 10 percent of annual income

– An annual income less than 200 percent of the federal poverty level and medical expenses greater than 5 percent of annual income

– Health plan deductibles equal to or greater than 5 percent of annual income

Who Are the Underinsured?

- Underinsured patients have some form of health insurance, but lack the financial ability to cover out-of-pocket healthcare expenses:
  - High deductibles and/or co-insurance
  - High copays
    - Specialty drug tiers
    - Formulary restrictions
- Many insurance plans disadvantage oral chemotherapy and other specialty medications by placing them into the highest tier of the plan's prescription program
  - Results in decreased drug costs for payers at the expense of patients

Underinsured - Patient Perspective

- For those with an acute or chronic illness, being underinsured can be more catastrophic than being uninsured

- A patient quote:

 " *Being underinsured is a lot like paying a car payment each month and not being allowed to drive the car.*"

Groups of Underinsured Most at Risk

Medicare Beneficiaries

- Who do not qualify for Medicaid or Low-Income Subsidy for Medicare Part D
- Who have high cost medications covered under Part B and do not have a secondary payer

Medicaid Beneficiaries

- Who have a high spend down

Commercial Coverage

- High deductibles/copays
- Formulary restrictions may require patients to pay partial or full cost for therapies not on formulary

Veterans Affairs

- Formulary restrictions may require patients to pay partial or full cost for therapies not on formulary

Patient Assistance Programs

- Pharmaceutical Manufacturer Assistance Programs (PMAPs) provide medications at no cost or copay assistance to patients who meet specified criteria
- Require completion of forms
  - Proof of income information
  - Clinical information
  - Prescriber signature
  - Requirements vary from one company to another
- Can be accessed for:
  - "Take-home" medications (at no charge)
  - Inpatient/outpatient replacement medications
  - Copay assistance for take-home and outpatient clinic-infused medications

Patient Assistance Programs

- Patient Barriers to Accessing PMAPs
  - Intimidating and overwhelming process, paperwork and websites
  - Require both clinical and financial information
  - Difficult to access healthcare providers for required signatures

- Health Care Organization Barriers
  - Limited personnel resources for accessing financial and clinical information, completing applications, and obtaining signatures

Genesis of The Ohio State University Medication Assistance Program

- Financial losses identified in drug utilization and reimbursement project
- Budget for charity "take-home" medication was increasing at an alarming rate
- Case manager observations that patient discharges were often delayed due to discharge medication access issues
- Identified need for dedicated staff

Program Justification *Then*

- Conduct analysis of self-pay inpatients and outpatients who received one or more high cost agents where manufacturer assistance programs **could have been accessed** during the past year (i.e., these claims were written off)

- Quantify charity dollars spent on assisting patients with take-home medications (oral, self-injectable)

- Take 50% of the sum of the two figures above as a rough, extremely conservative estimate of savings/cost avoidance

Program Justification *Then*

- Justification of first Medication Assistance Coordinator
  - 50% of the sum of inpatient/outpatient replacement and take-home charity = $56,000
  - Goal Return on Investment (ROI) = 1
  - Employee began in 12/2001
  - Medication accessed by 6/30/2002 = $677,676
    - 90 patients
    - 29 referring physicians

Program Justification *Now*

- Justification of *your* first Medication Assistance Coordinator
  - Use 50% of the sum of three things:
    - High dollar outpatient infused medication write-offs (copays and/or full medication write-off costs)
    - Charity dollars provided for take-home medication copays and/or full medication costs
    - Off-label medication write-offs

    Note: This will be a conservative estimate without determining actual patient/indication eligibility for your analysis

  - Goal ROI = 1

Program Justification Pearls

- Consider pilot program rather than full system implementation
- Target areas for greatest opportunity and of greatest need first
- Examples:
  - **Greatest opportunity** – chemotherapy infusion clinic
    - high dollar medication replacement programs
    - take-home supportive care medication programs
    - potential for off-label infusion medications
    - oral chemotherapy copay and PMAPs
  - **Greatest need** – hospital with highest percentage of uninsured or underinsured patients
    - likely to have a high percentage of return ED visits and readmissions

Examples*

- High Dollar
  - Eculizumab
  - Ipilimumab
- Off-Label
  - Bevacizumab for liver carcinoma
  - Rituximab for steroid-refractory graft vs. host disease

*Not an inclusive list

Examples*

- Copay Assistance
  - Oral: pazopanib, pomalidomide, dasatinib
  - Infusion: pegfilgrastim, bevacizumab, denosumab
- Uninsured
  - enoxaparin, ibrutinib, sunitinib
- Underinsured
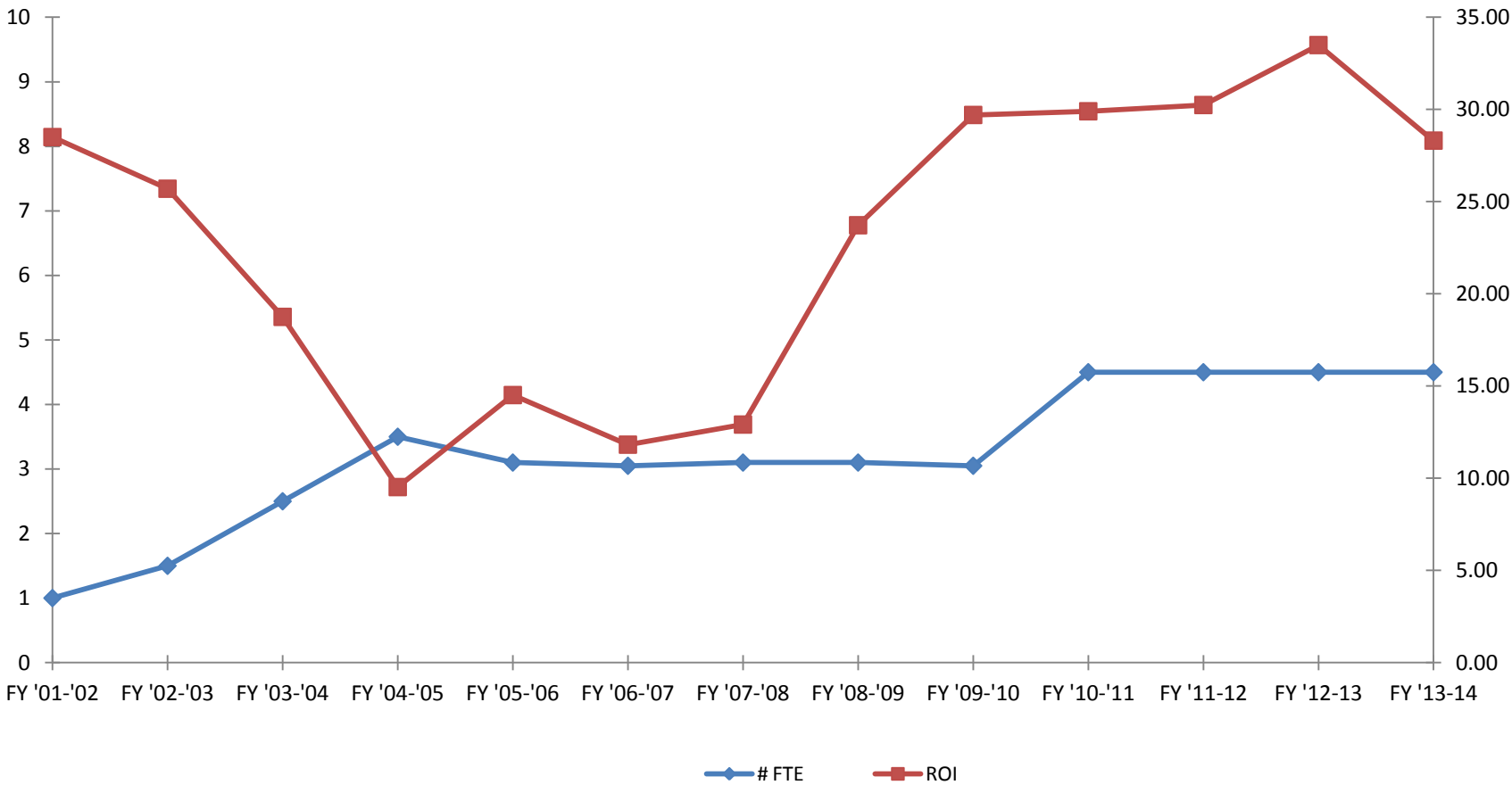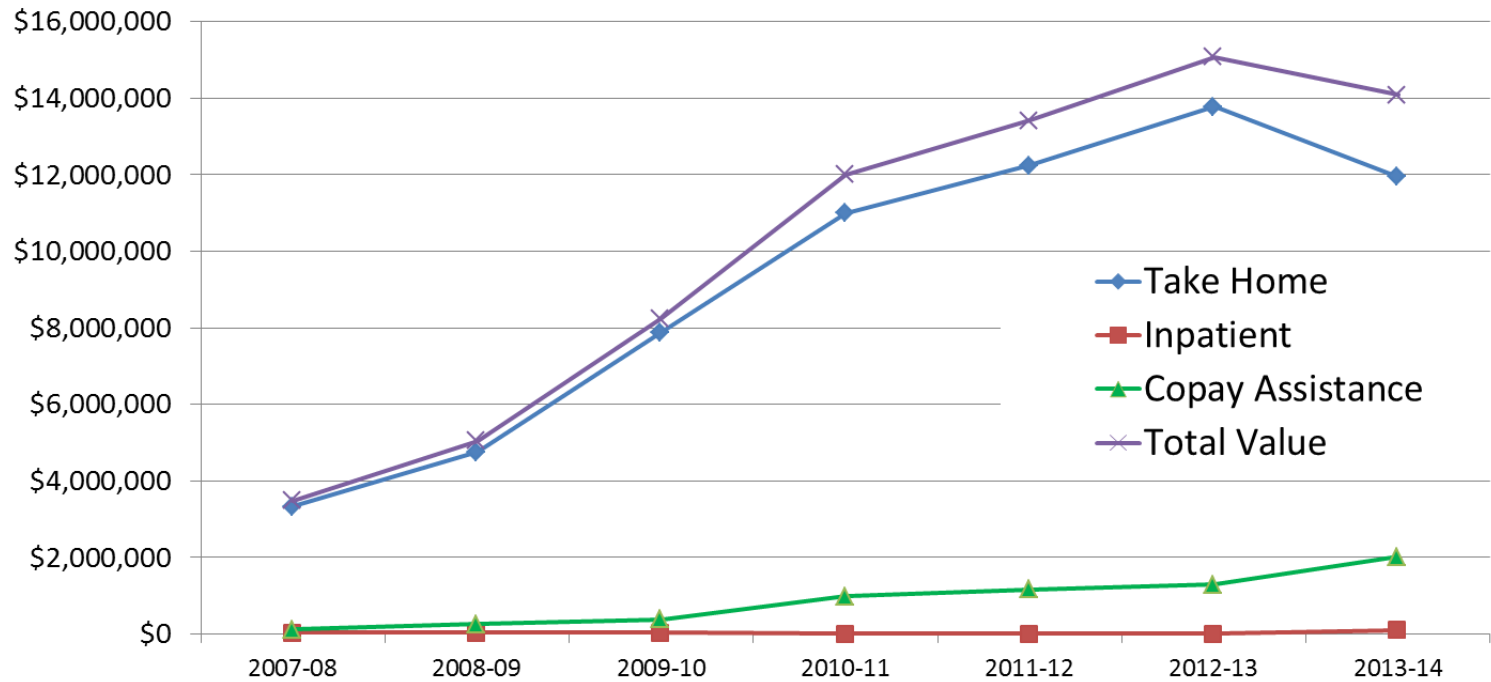 - Most branded oncology products

*Not an inclusive list

Dollars Medications Accessed
The James
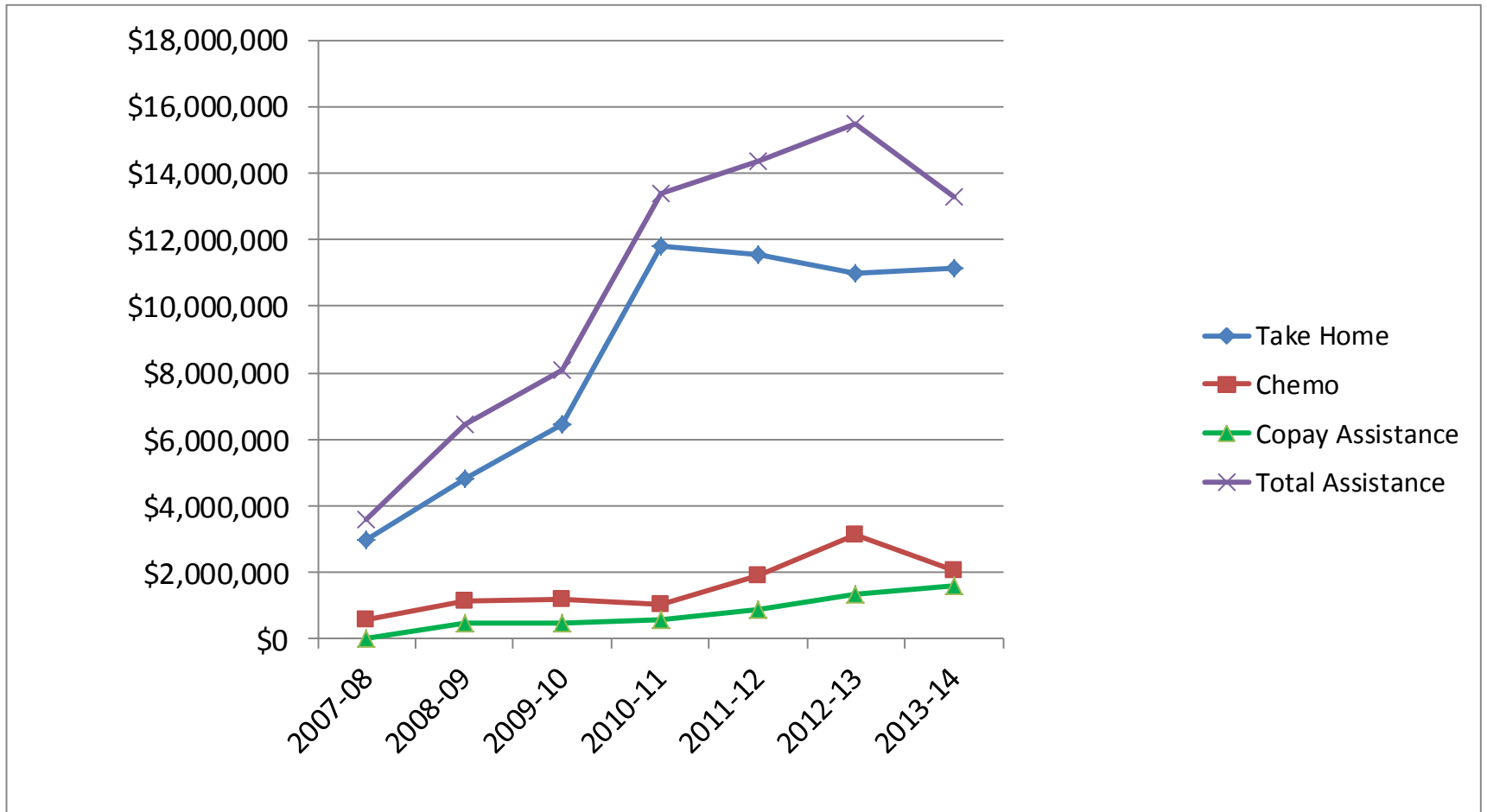
Medication Assistance Program Return On Investment
The James

ROI=Value of Medications Accessed- Cost of Charity, FTE, Supplies, etc

Cost of Charity, FTE, Supplies, etc
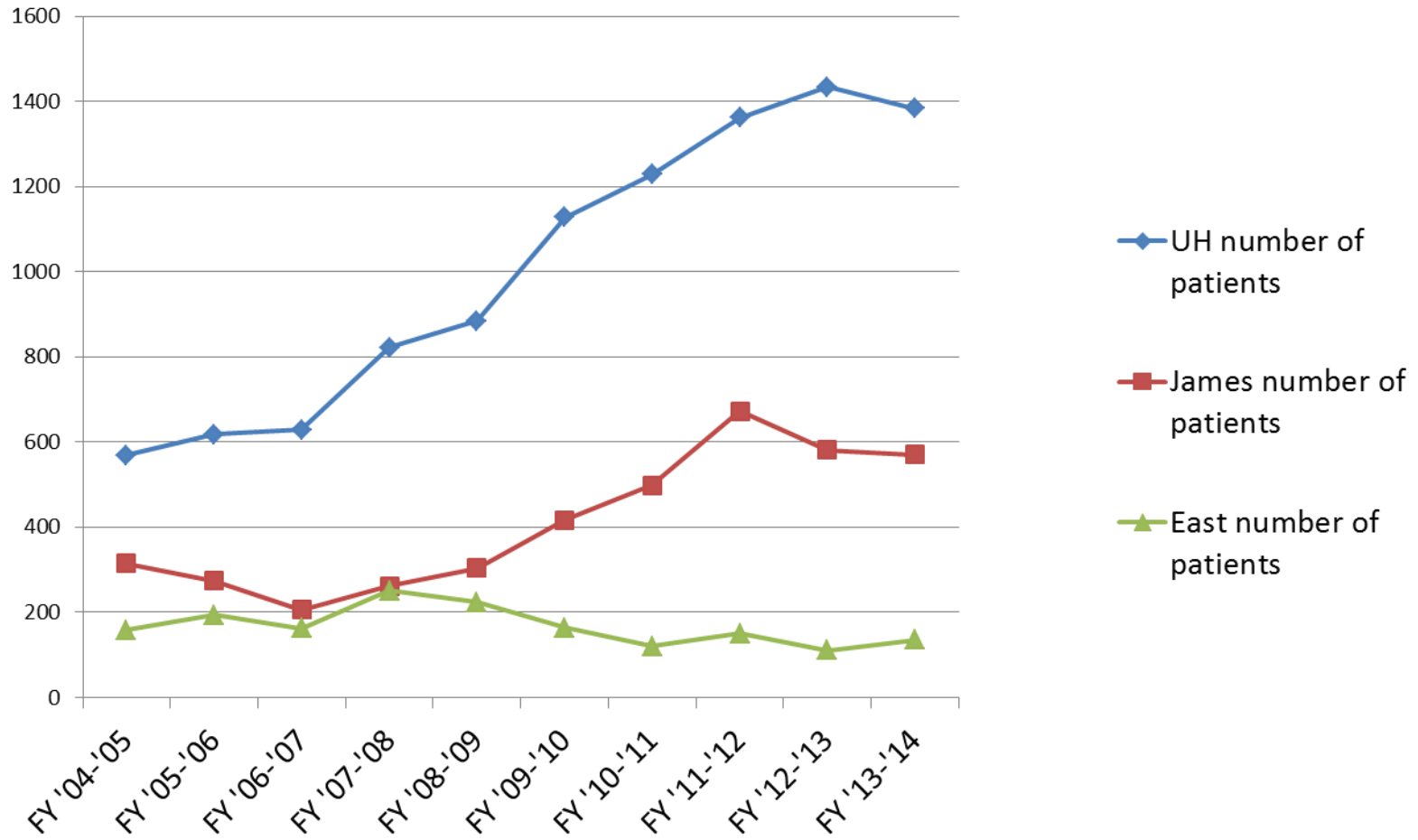
Dollars Medications Accessed University Hospital (UH)

Medication Assistance Program Return On Investment
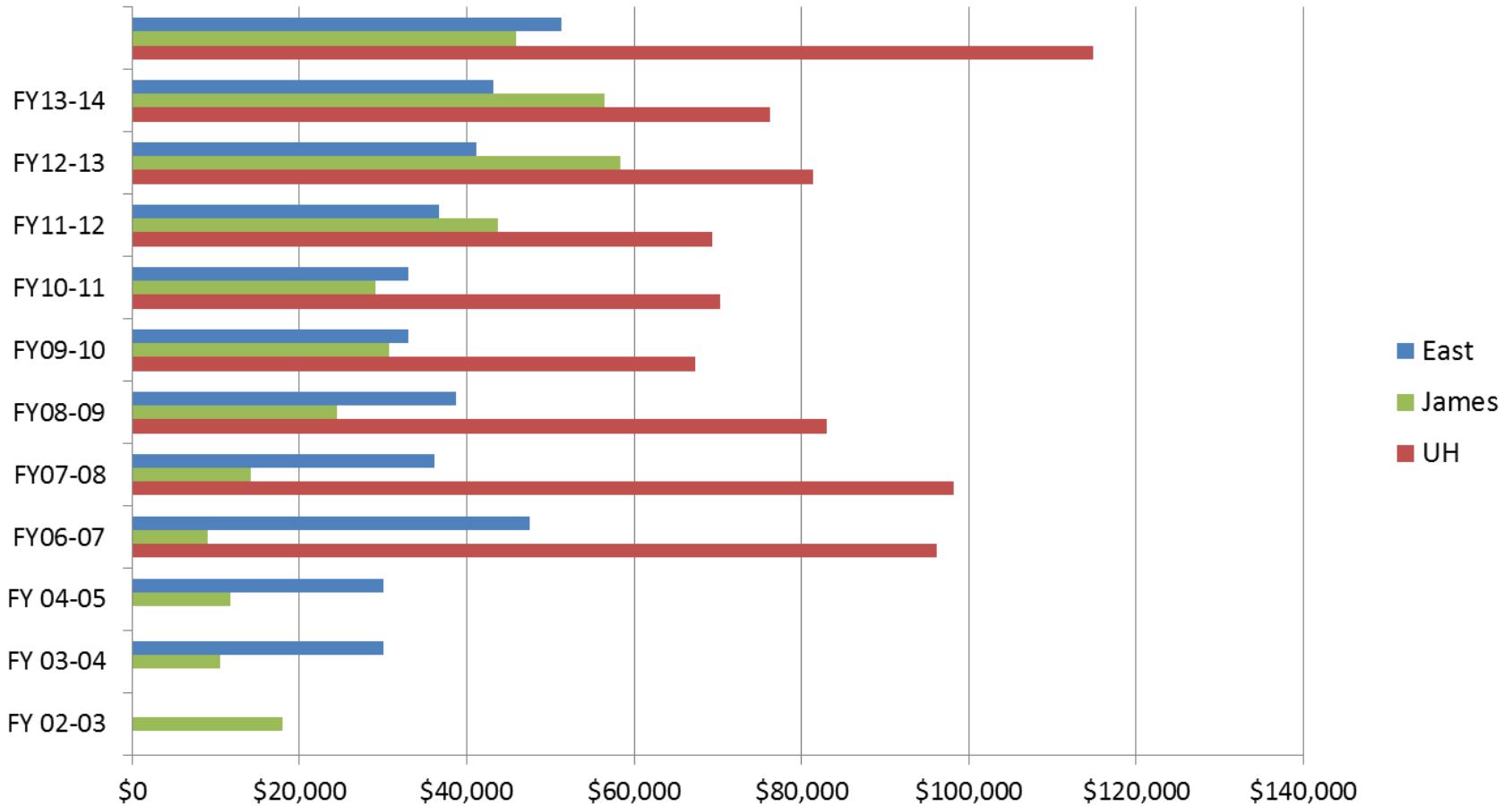## University Hospital (UH)
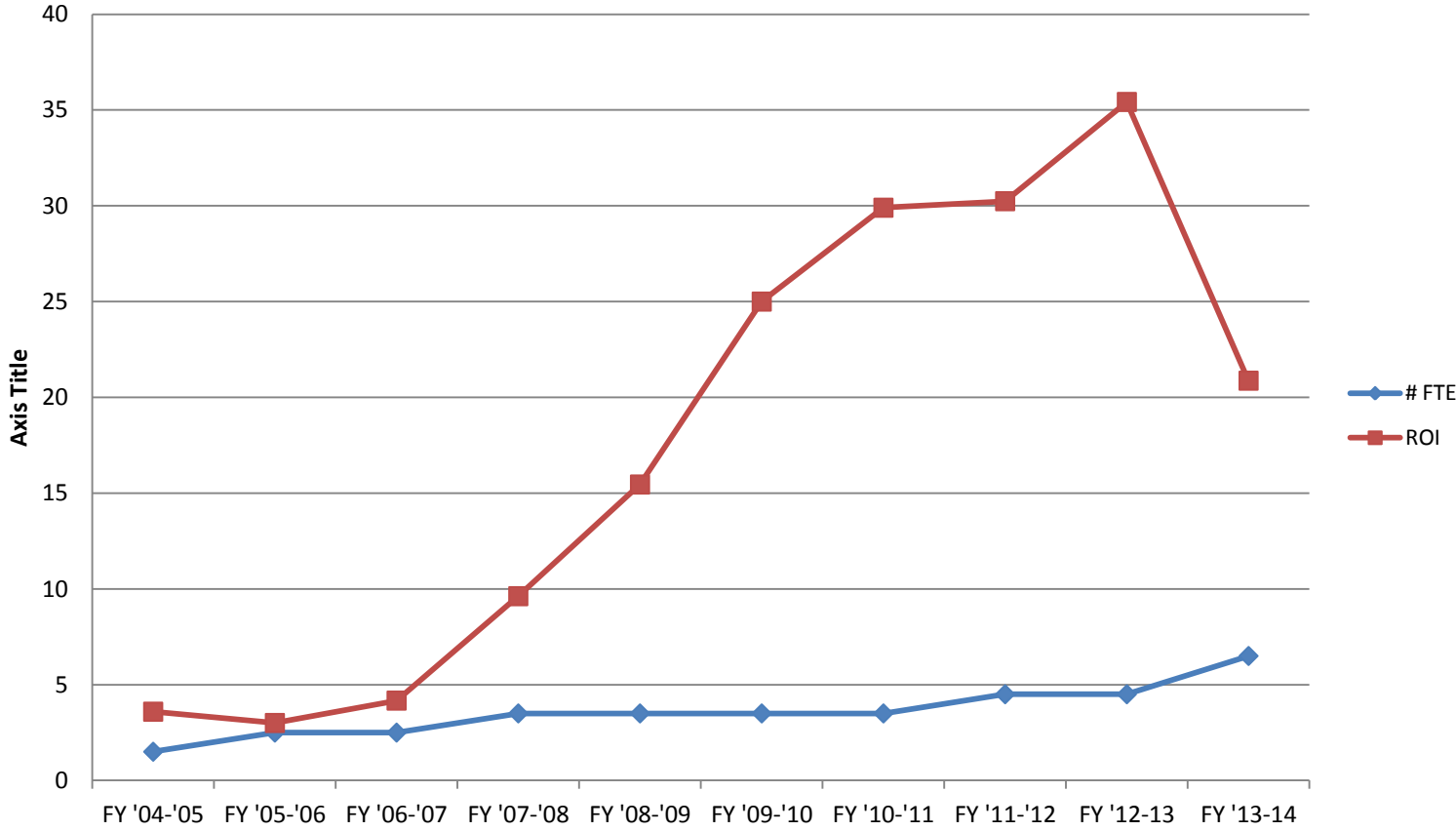
ROI=Value of Medications Accessed- Cost of Charity, FTE, Supplies, etc

Cost of Charity, FTE, Supplies, etc

Patients Assisted

Charity Prescription Costs*

Does not include prescriptions filled through the Medication Assistance Program (MAP) office for purchased 340B medication & non-340B medication

Total OSU Program Impact

- From December 2001 to June 2015
  - $214 million in dollars of medication accessed
  - 44,535 applications submitted
  - 18,762 patients served

Questions?