340B Implementation and Audit Preparation

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Assistant Director of Pharmacy
Mercy Hospital Springfield
340B Program Administrator for Mercy Health System

The speaker has no conflict of interest to disclose.

Objectives

- Discuss key components and considerations when implementing a 340b and patient assistance / drug recovery program.
- Recognize key components and considerations when implementing a compliant 340b contract pharmacy network.
- Identify areas of focus when faced with a 340b audit from the Office of Pharmacy Affairs.
- Define a plan to minimize the clinical, financial & operational impacts of caring for the medication needs of patients who are un- or underinsured.

Disclaimer

- The covered entity is ultimately responsible for compliance with the 340B program. Any statements I make should be validated on the part of the covered entity.

Section 340B of the Public Health Services Act of 1992

- Created under Section 602 of the Veterans Health Care Act of 1992
- Law requires pharmaceutical manufacturers participating in the Medicaid program to enter into an agreement with Secretary of State

MFR Agreement with 340B

- Under this agreement, the manufacturer agrees to provide front-end discounts on covered outpatient drugs to covered entities that serve the nation's most vulnerable patient populations.

Covered Entities

- Six categories of hospitals
  - Disproportionate share hospitals (DSHs)
  - Children's hospitals
  - Cancer hospitals
  - Sole community hospitals (SCHs)
  - Rural referral centers (RRCs)
  - Critical access hospitals (CAHs)

Covered Entities

- Hospitals must be:
  - Non-profit
  - Owned or operated by or under contract with state or local government
  - Meet payer-mix criteria related to the Medicare DSH program (excludes CAHs and RRCs)
    - 11.75% for DSH, Children's, Freestanding Cancer Hospitals
    - 8% for SCHs

Covered Entities

- 11 categories of non-hospital covered entities
- Eligible based on federal funding
  - Federally qualified health centers (FQHCs)
  - FQHC "look a likes"
  - State operated AIDS drug assistance programs
  - Ryan White facilities
  - Tuberculosis clinics
  - Hemophilia treatment centers

HRSA/OPA

- Health Resources Services Administration (HRSA) oversees the program through the Office of Pharmacy Affairs
- Check the website for specific qualifications related to each type of covered entity.
- Covered entities have different requirements for participation (i.e. orphan drug exclusion for some facilities like SCHs and CAHs)

Mercy Facilities

Mercy

- 5- DSH Facilities (Missouri, Kansas, Oklahoma)
- 1- SCH (Oklahoma)
- 12 Critical Access Hospitals (participating) (Missouri, Arkansas, Oklahoma)

Initiating 340B

- Consultants
  - the covered entity is ultimately responsible for compliance and integrity of your program
- Websites
  - HRSA's Office of Pharmacy Affairs website
    - www.hrsa.gov/opa
  - Apexus Prime Vendor Program
    - www.340bpvp.com
  - Safety Net Hospitals for Pharmaceutical Access
    - www.snhpa.org

Key Players

- C-Suite – Authorizing Official with HRSA
- Finance
- Compliance Officer
- Internal Audit
- Legal
- Medical Staff Services Office
- Pharmacy

Key Players

- Data Analyst/Report Writer
- Reimbursement Director or Manager
- Advocacy or Government Relations

Pharmacy Oversight

- Dedicated resource(s)
- Support from leadership
- Inventory Specialist
  - Mercy has 3 inventory specialists that help to oversee the program for all of our covered entities.
- Pharmacy Buyer
- Computer systems expert
- Data Analyst/Report Writer

Keys to Compliance

- Policies and Procedures
- Annual Medicare Cost Report checks
- Duplicate discounts
  - make sure your state Medicaid agency knows your status and that you are properly registered on the HRSA website.
- Diversion
  - 340B purchased drugs cannot be resold or transferred to anyone other than the entities patient's.

Keys to Compliance

- Diversion continued
  - HRSA's 2 part patient definition test
    - covered entity maintains records of the individual's health care.
    - The individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g. referral for consultation) such that responsibility for the care provided remains with the covered entity.

Program Integrity Initiative (PII)

- October 5th, 2011 – Mary Wakefield (Administrator of HRSA) sent a letter to all HRSA grantees announcing a department-wide Program Integrity Initiative.
- HRSAs oversight initiatives with 340B were lacking due to funding of the oversight.

Key Points of PII

- Strengthen oversight to ensure program compliance.
- Conduct selective and targeted audits of 340B covered entities.
- Verify all covered entities continue to meet statutory requirements for the 340B program.

Inventory Models

- Separate inventories of drugs for 340B and GPO purchased drugs.
- 340B eligible patients can NOT receive GPO priced drugs if you signed a GPO exclusion (DSH, Children's and Cancer Hospitals): Requires a WAC account for initial purchases.
- Replenishment Model (mixed use settings)
  - NDC to NDC requirement

Audits

- Have an internal audit performed
- Prepare for HRSA audits (it is not a case of if you will be audited, but when it will occur)
- Recertification
- Entity assumes all liability
- Office of Regional Operations and Division of Financial Integrity (DFI) is conducting the audits.

Audits

- Manufacturers can also request an audit.
  - MFR's must submit audit plan to HRSA.
- Risk factors
  - Volume of 340B purchases
  - Complexity of program
  - # of contract pharmacies
  - Reported allegations of abuse
  - Amount of time in the program

Audits

- HRSA will contact "Authorizing Official" by e-mail, letter and phone call regarding audit selection.
- Design of audit is to ensure:
  - The entity is eligible to participate
  - Determine if there is diversion of 340B drugs
  - Ensure your program has proper controls in place to prevent diversion and duplicate discounts.

Preparation for Audit

- Update Policy and Procedures and check for accuracy
- Verify your state Medicaid office has your status correct related to whether or not you are billing Medicaid through the program.
- Ensure your qualification measures related to patient's is accurate (utilization reports)

Audits

- Physician list is up to date
  - Exclusion is taking place for physicians that are not employed or contracted for services with your institution.
- Inclusion criteria for departments in the hospital are on the reimbursable side of the Medicare Cost Report.
- All 340B records are retrievable

Advocacy

- Talk to legislators
  - Importance of the program to your hospital or institution
- Government Relations
- Keep up with the regulatory changes and discussions
- Recent Policy Releases
  - GPO Exclusion
  - Medicaid Exclusion File

Advocacy

- Ask your leadership how you use the 340B savings to help indigent patient's
  - Can you speak to this?
- Is it part of your charity care policy?
- How would your institution cope with the loss of 340B or a significant change where only the uninsured or indigent qualified for what could be purchased?

CE Question

Who is responsible in the event an audit shows your 340B program is not compliant?

A. The consulting group that helped implement your program.
B. The authorizing official representing your hospital.
C. The pharmacist that dispensed 340B drug to a patient that didn't qualify.
D. Your internal audit team because they did not catch this in an internal audit you had conducted.

Questions

340B and Manufacturer Patients Assistance Programs: Contract Pharmacy

Jeremiah McWilliams, PharmD
Cardinal Health
Director of Pharmacy
Ozarks Medical Center

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Disclaimer

- The views expressed do not represent Cardinal Health or Ozarks Medical Center. The information provided is solely my own and all information provided should be confirmed independently.
- I do not have actual or potential conflict of interest in relation to this presentation

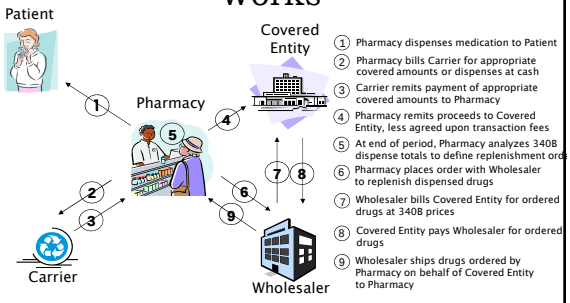
340B Contract Pharmacy Program

- Overview
  - Understand the importance of 340B contract pharmacy programs in relation to both the covered entity and the patients they serve.
- Resources
  - Office of Pharmacy Affairs website
    - www.hrsa.gov/opa
  - Safety Net Hospitals for Pharmaceutical Access
    - www.snhpa.org

Implementation of a 340B Contract Pharmacy Program

- Eligibility
  - Covered entities
- Team
  - Pharmacy, finance, legal, administration, & IT
- Contract pharmacy partners
- Administrator
- Wholesaler bill-to/ship-to account

How 340B Contract Pharmacy Works



1. Pharmacy dispenses medication to Patient
2. Pharmacy bills Carrier for appropriate covered amounts or dispenses at cash
3. Carrier remits payment of appropriate covered amounts to Pharmacy
4. Pharmacy remits proceeds to Covered Entity, less agreed upon transaction fees
5. At end of period, Pharmacy analyzes 340B dispense totals to define replenishment orders
6. Pharmacy places order with Wholesaler to replenish dispensed drugs
7. Wholesaler bills Covered Entity for ordered drugs at 340B prices
8. Covered Entity pays Wholesaler for ordered drugs
9. Wholesaler ships drugs ordered by Pharmacy on behalf of Covered Entity to Pharmacy

340B Contract Pharmacy Barriers

- Challenges
  - Compliance
    - HRSA/OPA guidance
    - Medicare cost report
      - Outpatient facilities, providers
    - Medicaid
      - Missouri & Illinois
    - Audits

340B Contract Pharmacy Barriers

- Challenges
  - Pharmacy
    - Contracting – independent/chain
      - Dispensing fee: flat or percentage
    - Uninsured program
    - Inventory and replenishment
    - True-ups
      - Controlled substances

340B Contract Pharmacy Barriers

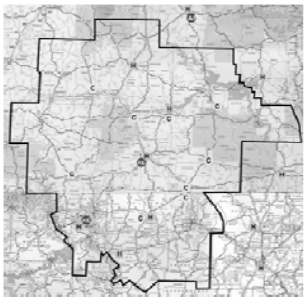
- Challenges
  - Operational issues
    - FTE
    - Invoices
    - Clinic/pharmacy education
  - Administrator
    - Capable
    - Reliable
    - Program integrity

About Ozarks Medical Center

- 114-bed, not-for-profit disproportionate share hospital
- Employees approximately 1,200 people and serves a population base of 160,000.

OMC Clinics & Centers

Heart Care Services
Behavioral Healthcare
Pain Management Clinic
Digestive Health & Liver Disease Specialist
Internal Medicine OMC campus
Neuroscience Center
OMC Rehabilitation Services
Ozark Works/ Urgent Care Clinic
Cancer Treatment Center
Gainesville Medical Clinic Gainesville
Salem 1st Care Salem, Arkansas



Mammoth Spring Medical Clinic

Rheumatology Clinic
Surgical Specialists Clinic
Women's Heath Care
Nephrology Clinic
Orthopaedic Clinic
Mountain Grove Medical Complex, Mountain Grove
McVicker Family Healthcare Mountain View
Shannon County Medical Clinic Winona
Alton Medical Clinic Alton
Thayer Medical Clinic Thayer
Wound Care Services

Payor Mix

- 11th poorest Congressional district in US
- 75 percent Medicare and Medicaid
- Percentage of persons below poverty level

Howell	Oregon	Ozark	Shannon	Wright	Missouri
19.20%	23.40%	21.70%	26.00%	23.20%	13.50%

* 2008 data

Ozarks Medical Center 340B Contract Pharmacy

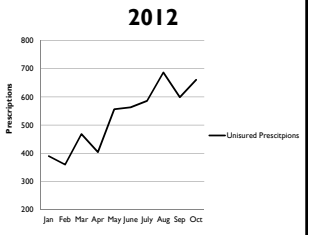
- 2010
  - Multiple contract pharmacy implementation
- 2011
  - Additional pharmacies
- 2012
  - Specialty contract pharmacy
- 2013
  - Discharge scripts

340B Contract Pharmacy

- Current Network
  - 12 contract pharmacies
    - Mixture of independent, chain, and specialty
  - Continued expansion of network

Uninsured Access

- Uninsured Patient
  - 2012
    - 5590 scripts dispensed to patients at 340B price
  - Patient Assistance
    - Covering co-pays for patients that cannot pay
    - Discharge scripts



Patient Assistance Programs

- Specialty Contract Pharmacy
  - Oncology
  - Foundation support
  - Patient Assistance
- Discharge Scripts
  - Processed as a contract pharmacy
  - Patient sent home with medications regardless of ability to pay
  - Core Measurements

Summary

- Implementation of 340B contract pharmacy program has several components
- There are many challenges associated with a 340B contract pharmacy program
- Entities can develop specific patient assistance programs within a 340B contract pharmacy program

Question

- Which of the following departments should provide members to ensure a successful 340B contract pharmacy program?
  A. Pharmacy
  B. Finance
  C. Legal
  D. Administration
  E. Information Technology
  F. All of the above

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Patient Assistance & Drug Recovery Programs in Health System Pharmacy: Complementing or Supplementing 340B

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Vice President, Pharmacy
Mercy Health

The speaker has no conflict of interest in relation to this program.

Objectives

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- Recognize key components and considerations when implementing a compliant 340B contract pharmacy network.
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- **Define a plan to minimize the clinical, financial & operational impacts of caring for the medication needs of patients who are un- or underinsured.**

Patient Assistance vs. Drug Recovery Programs

(Medication) Patient Assistance Program

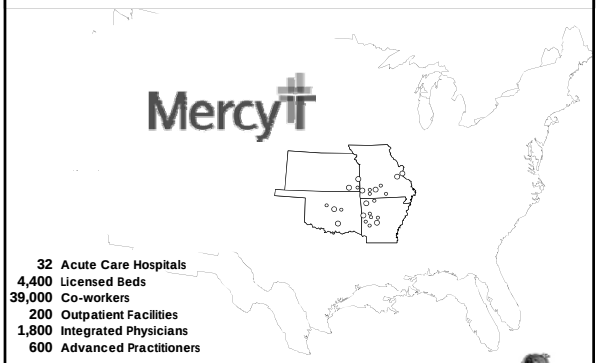
- Usually sponsored by pharmaceutical companies
- Provide free or discounted medicines to low-to-moderate-income, uninsured and under-insured people who meet guidelines.
- The primary benefactor are the patient's themselves
- Usually focused on ambulatory patients

Drug Recovery Program

- Usually sponsored by pharmaceutical companies
- Provide free or discounted ***replacement*** medicines to facilities previously used by patients who meet guidelines.
- Primary focus is to minimize the financial impact of uncompensated care from the **provider standpoint**
- Usually focused on meds administered within the hospital or OP department

Why are these important ? – Mercy numbers

Mercy Ministry Overview



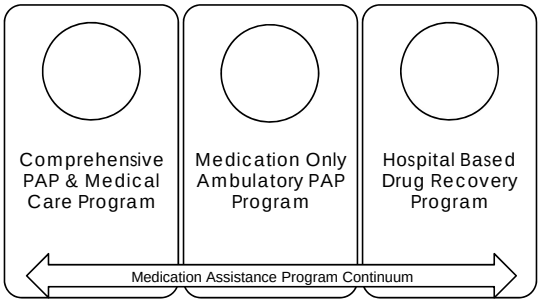
32 Acute Care Hospitals
4,400 Licensed Beds
39,000 Co-workers
200 Outpatient Facilities
1,800 Integrated Physicians
600 Advanced Practitioners

Mercy Pharmacy Overview

Pharmacies
- 21 Retail Pharmacies
- 32 Hospital Pharmacy/Drug Rooms
- 9 Outpatient Infusion Pharmacies
- 2 Home Infusion

FTE's • 620 FTE's
Labor Expense • $53 million
Annual Drug Spend • $270 million
Annual Retail Scripts • 1.1 million

Mercy's Medication Assistance Programs



Project Access

Key Program Strategies

Access to Mercy Providers
- Primary Care and preventive services
- Specialty care

Care Management
- Case Management
- Disease Management
- Nurse On-call

Medication Assistance
- Provide needed medications to decrease non-compliance
- Assistance with applications to pharmaceutical programs
- Formulary management by Pharmacotherapy

Project Access Eligibility Criteria

- 18-64 years of age
- 3 or more Mercy ER visits in a 12 month period
- No insurance and does not qualify for Medicaid
- Has a chronic disease such as diabetes or asthma, etc.
- Household income equal to or <150% of federal poverty level
- Qualifies for Mercy charity care program at both hospital and clinic
- Patients must be willing to sign an accountability contract and agrees to collaborate with the care team

Project Access Results/Outcomes

- 35% reduction in overall cost of IP/OP hospital-based care
- 45% reduction in number of inpatient admissions
- 59% reduction of ER visits
- $3,118 – Average annual cost savings per patient for hospital-based care

Project Access Results/Outcomes

Utilization, preventive and quality data was compiled on 12 Level 2 participants in the Springfield, MO program who were enrolled at least 12 months during the period of 1/1/2010-4/30/2011. The 12 month period prior to program enrollment ("Pre-period") is compared with data from the first 12 months in the program ("Post-period").

Emergency Room & Inpatient Utilization
Level 2 Participants with at least 12 months of Participation

(n=12)	Pre-Period	Post-Period	Difference	% Change	Estimated Savings
Emergency Dept. Visits	24	2	22	92% Decrease (improved)	$73,200
Inpatient Admissions	9	2	7	78% Decrease (improved)	$93,910

Preventive Care

Preventive Screening	Pre-Period	Compliant	Post-Enrollment	Compliant	% Change
Annual Mammogram-Women-Age 40+ (n=8)	0	0%	4	100%	100% improved
Colorectal Screening-Age 50+ (n=8)	1	17%	3	33%	16% improved
Influenza Vaccination (n=12)	1	8%	8	67%	59% improved

Diabetes Outcomes

(n=5)	Pre-Period	Post-Period	Difference	% Change
% w/annual diabetic eye exams	0%	100%	----	100% improved
Avg. HbA1c value	9.98	7.92	2.06	21% improved
Median Hba1c value	9.7	8.1	1.6	16% improved

Medication Only - PAP Program

- Offered in cooperation with other health systems and community organizations
- Referral based service (from Mercy Clinic physicians or Care Management
- ~6 FTE's dedicated to complete pharmaceutical manufacturer program applications/paperwork on behalf of patients in need
- Medications shipped directly to patient
- Program in place since 2010

Medication Only - Results

- Annual value of medications obtained for referred patients
- Additional positive impact on compliance, readmissions, etc.

Drug Recovery Program History

- Pre-2011
  - Outsourced Drug Recovery program in one, large hospital mainly focused on an ambulatory un/underinsured Clinic along with outpatient infusion
  - Outside vendor charged a percentage of any drug recovered
  - Approximately $700,000 in net drug recovery annually
- Challenges
  - Other Mercy facilities didn't have programs
  - High cost of outsourcing program
  - Duplication of work between outside vendor and Mercy's own charity care & Medicaid Eligibility process

Expanded Drug Recovery Process

- Program implemented Jan-11
- Program housed within Patient Financial Services/Medicaid Eligibility to minimize duplication with access to financial information
- Resources
  - 3 FTE Financial Counselors
  - Part time program Manager/Supervisor
  - Software license to access up-to-date pharmaceutical manufacturer information/forms
  - Daily Report of Medications utilized by self pay patients within hospital based services from EHR & compared to programs offered by manufacturers
- Financial Counselor completes PAP/replacement forms on patient's behalf
- Once assistance/replacement drugs is approved by manufacturer, patient charge is credited & benefits tracked

Resource Plan & Proposal

Patient Assistance Program Proposal
September, 2011

S – Situation:
All Mercy hospitals treat patients with high cost medications, where insurance coverage is insufficient to cover the cost of the medication. Pharmaceutical companies have patient assistance programs, designed to assist low income patients without adequate insurance coverage, who receive their medications. A few Mercy hospitals have programs organized to connect with those companies, but most do not. As a result, Mercy experiences bad debt or charity. There are funds left on the table, which Mercy could access, if Mercy organizes a process to access pharmaceutical company programs.

B - Background:
Pharmaceutical companies, which sell high cost medications, frequently have organized programs, which healthcare facilities, purchasing their products, can access. When the pharmaceutical company is provided with case-by-case patient-specific financial information, validating the patient meets their requirements for low income or lack of insurance coverage, the pharmaceutical company will assist in cost avoidance. This is nearly always through supplying the healthcare facility with free drug product to compensate for the product administered to the qualifying patient. Each pharmaceutical company has a different process, different qualifications, and different forms to be completed. There are significant dollars being left on the table, so to speak. This is time consuming work, requiring identification of specific resources to make this program successful. The cost in labor to go after these cost avoidance dollars is also significant. When this is not budgeted, Mercy hospital's programs have not been successful in sustaining maximum impact.

The following table details the four programs Mercy has had in place. Note in the table below, that Springfield has an ambulatory-only program, funded by a Mercy grant, which has an entirely different focus, and it's purpose is NOT cost avoidance. Springfield considered, but did not implement in inpatient program. However, the other inpatient programs, which have either been implemented, or considered and not implemented, are detailed.

Other Mercy facilities, which are without organized programs, may contact pharmaceutical companies on an inconsistent basis, and case management staff is usually involved.

A tool required to make this program successful is a web-based database, which connects to all the pharmaceutical company's online programs. These pharmaceutical company programs are constantly changing in their requirements, their forms, etc. A computerized database will access all disparate programs, and populate the forms, saving much time and effort. The vendor "P.H.S." utilized by St Louis has their own database. The ambulatory program at Springfield utilizes a database provided by "Drug Assistant."

A - Assessment:
We know there are funds being left on the table. Conservatively, there remains approximately $1 million in value that is not being realized today.

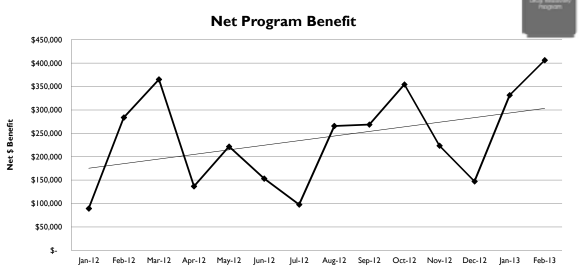
Most Mercy hospitals do not have the capacity to provide the labor intensive service internally without establishing dedicated resources. A few smaller hospitals have initiated internal programs, but these have not been sustained. Staff at Springfield, and St Louis, indicate the workload is too intense to manage this without a labor budget, dedicated to this project. Thus, the need for a Mercy grant to support the ambulatory program at Springfield, and the need to partner with vendor experts at St. Louis.

If a decision is made to partner with a vendor, it would appear the 75/25 split may be typical, as other companies providing a similar service, have similar terms. The Drug Assistant Company, which provides the database to the Springfield ambulatory program, also offers services for the inpatient cost avoidance program. Fees are flexible, determined by the amount of service provided.

R - Recommendations:
Because there are significant cost avoidance funds left on the table, and because the processes to access funds are labor intensive, it is recommended that Mercy partner with a vendor to implement a consistent Mercy drug recovery program followed by Mercy taking ownership of the program. Partnering with a vendor, for implementation, would allow Mercy to analyze the process, realize current savings more quickly and minimize financial risks while minimizing outsourcing costs from day 1.

Expenses	#	Unit Cost	Extended Cost
Reimbursement Analysts	3	$ (42,500)	$ (127,500)
Superviser	1	$ (48,875)	$ (48,875)
Consulting Fees - One time	1	$ (45,500)	$ (45,500)
Coworker Buyout/Recruiting	2	$ (6,120)	$ (12,240)
Travel fees for Consulting	8	$ (1,100)	$ (8,800)
Ongoing Travel Costs	12	$ (450)	$ (5,400)
IndiCare Software - yearly fees	1	$ (8,800)	$ (8,800)
Laptop	1	$ (1,400)	$ (1,400)
Desktop	3	$ (750)	$ (2,250)
Epic Scanners	4	$ (200)	$ (800)
Total Expenses - Year One			$ (261,565)
Consultant Annual Fee Elimination			$ 300,000.00
Estimated New Drug Recovery Savings			$ 750,000.00
Annual Benefit			$ 1,050,000.00
Year 1 Net Benefit			$ 788,435.00

Results/Outcomes



	Jan-12	Feb-12	Mar-12	Apr-12	May-12	Jun-12	Jul-12	Aug-12	Sep-12	Oct-12	Nov-12	Dec-12	Jan-13	Feb-13
Net $ Benefit	$89,472	$283,841	$365,269	$136,864	$221,754	$153,341	$97,764	$265,797	$268,753	$354,528	$223,597	$147,319	$331,666	$406,324

Over $3.3 million in net program benefit since program inception

MSHP/ICHP Spring Meeting 2013: Pathways to Patient Care

Self Evaluation Question

What resources are recommended in order to implement a patient assistance/drug recovery program ?

A. Knowledgeable Financial Counselor/personnel to complete the paperwork
B. Computer systems to identify eligible patients receiving medications with replacement programs
C. Database of medications with PAP and criteria to qualify
D. Access to patient financial information
E. All of the above

MSHP/ICHP Spring Meeting 2013: Pathways to Patient Care