

# Sisters of Mercy Health System

## Custom Pack Self-Manufacturing Program

Spring 2010  
April 20, 2010



# Why Change the Game?

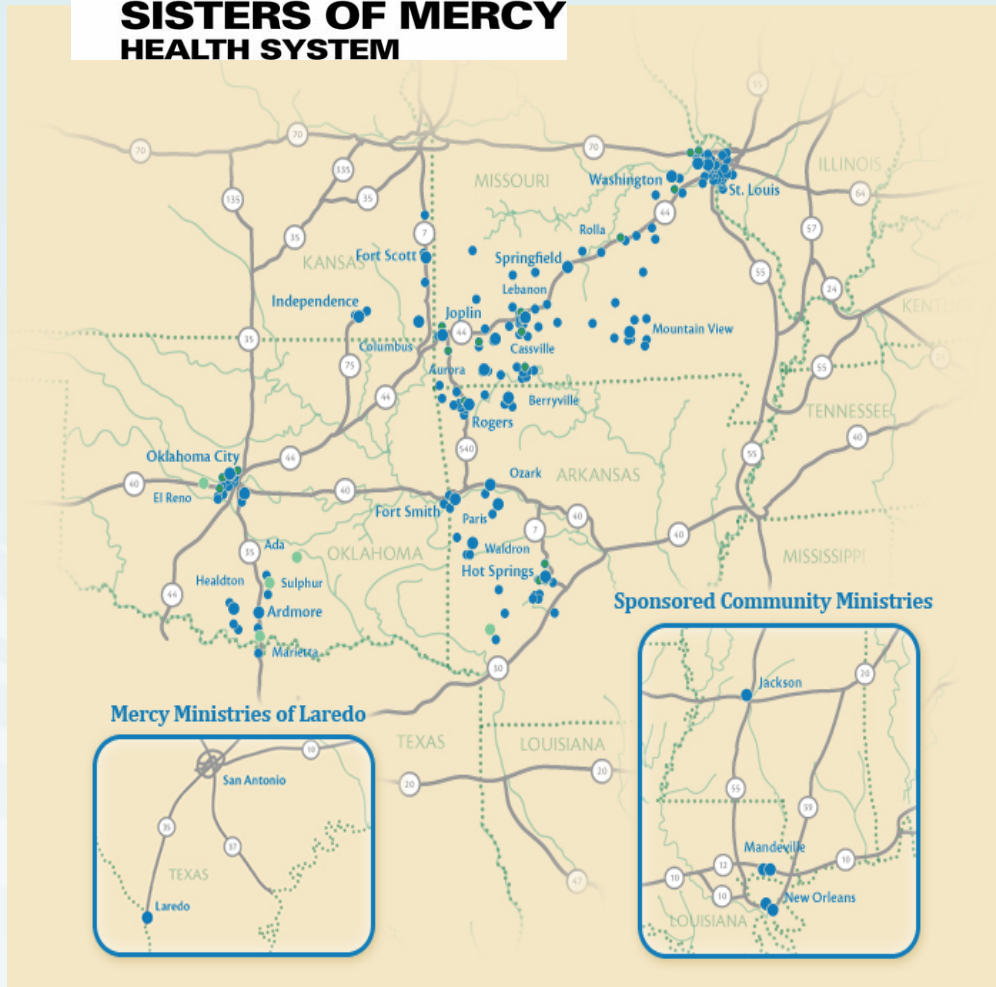
## Feedback received:

- Lack of cost containment
- Poor pack utilization & change management
- End user dissatisfaction
- Unauthorized changes
- Inferior product quality
- Waste

*Who is paying  
for all of this  
extra material  
??*



# Mercy Overview - Profile



**Member Facilities** 26 acute care hospitals  
3 heart hospitals  
1 rehab hospital

**Operating Revenue** \$3.9 Billion

**Co-workers** 36,900

**Medical Staff** 4,650  
(incl. 1,235 integrated physicians)

**Uncompensated Care** \$208.0 million

**Beds** 4,379 licensed beds  
(3,638 acute)

**8<sup>th</sup> Largest Catholic health system in U.S.**

**27<sup>th</sup> Largest health system in U.S.**

Information current for Fiscal Year 2009, ending June 2009



# ROI's Structure

## Supply Chain Management

- ▼ Consolidated Services Center
- ▼ Inventory Management
- ▼ Pharmaceutical Repackaging
- ▼ Purchasing
- ▼ Customer Service
- ▼ Optimization Management
- ▼ Transportation Management

## Group Purchasing

- ▼ Supply and Pharmaceutical Contracting
- ▼ Capital Equipment Contracting
- ▼ Contract Compliance Monitoring
- ▼ Rebate Management
- ▼ Pricing Administration
- ▼ Member Services

## Performance Consulting

- ▼ Patient Care Services
- ▼ Clinical Support Services
- ▼ Operational Support Services



- Facilities**
- Corporate Office – St. Louis
  - Consolidated Services Center – Springfield, MO

**Co-workers** 300 FTEs from varied clinical and business disciplines

*ROI's mission is to improve clinical, operational and financial performance of our customers through a clinically integrated supply chain.*

# ROI's Guiding Principles

- Involvement of All Stakeholders
- Creation of Value
- Keep Our Word

***Simple to Understand...***

***...Highly Effective When Done Well***

# Clinical Input

- Task Force comprised of clinical and materials leadership
- Options reviewed:
  - Re-sign with current vendor w/stringent controls in place
  - Convert to alternative vendor through RFP process
  - Self manufacture: In-depth analysis conducted
- Decision:

	Clinical	Operational	Financial
<b>Self-Manufacture</b>	Internal Clinical Pack Manager	Shorter Production Runs	Component and Operational Cost Control
	Substitution Control	Production Prioritization	Leverage Non-sterile and Sterile Purchases
	Product Quality Control	Platform for Other Kits	Increase Pack Utilization
	Standardization Opportunity	Branding Program	

# CPT Program Objectives

- **Clinical alignment**

- Consistent component choice and contract compliance
- Improved change management & eliminate unauthorized product substitution
- Focused efforts on consolidation, utilization & waste
- Improved turn time for pack modifications
- Clinical expertise to drive evaluations
- Caregiver satisfaction

- **Financial benefits**

- Competitive component pricing
- Control of costs for manufacturing & sterilization
- Transparent pricing model
- Reduced minimum order quantities



# Initial Phase

## Prior to Self Manufacturing

- 93 individual BOMs
- 125 different vendors
- 956 different SKUs

## After Consolidation

- 91 individual BOMs
- 86 different vendors
- 755 different SKUs

- Scrutinized original BOMs and custom packs
- Identify proper manufacture and part number
- Consolidation and standardization of SKUs and vendors
- Product alignment
- Validated vendor cross references and acceptance of components


# Initial Site Visit

- Described program
- Clinical alignment with no sales influence
- Clinician driven program
- Discussed pack shortages and waste
- Utilization and growth
- Increase overall value by decreasing procedure cost



# Transparent Price Model

- Full understanding of pricing
- Allows end users to model pack price
- Activity based
- Determine products that are clinically and financially acceptable



Resource Optimization & Innovation

Pack Name: Minor Pack  
Pack Number:  
Version:

Date: 4/6/2010

Est Usage/Yr: 8400  
Component Price: \$12.54  
Sterilization and Trans: \$1.25  
Assembly and Overhead: \$1.85

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Total Price: \$15.64

Qty	UOM	Description	Vendor	Catalog Number	Price
0.25	EA	CARDBOARD BOX	VENDOR A	456123	\$0.22
1.00	EA	BACK TABLE COVER	VENDOR B	34512	\$0.49
1.00	EA	DRAPE LAPAROTOMY	VENDOR B	1234567	\$4.18
1.00	EA	DRAPE MEDIUM	VENDOR B	612345	\$0.72
1.00	EA	MAYO STAND COVER	VENDOR B	23451	\$0.34
1.00	EA	NDL COUNTER 20CT FOAM	VENDOR C	234561	\$0.29
1.00	EA	TRAY LABEL	VENDOR A	561234	\$0.01
1.00	EA	TUBING SUCTION 3/16X144	VENDOR C	51234	\$0.31
1.00	EA	YANKAUER BULB TIP	VENDOR C	123456	\$0.19
1.00	PK	GAUZE X-RAY 4X4	VENDOR C	45123	\$0.18
2.00	FT	FOAM SHEET	VENDOR A	345612	\$0.06
3.00	EA	SURGICAL GOWN XLG	VENDOR C	12345	\$5.55

Quote is valid for 80 days from date of acceptance.

Clinical acceptance of this sample and component listing by:

_____	_____	_____
Signature	Printed Name	Date
_____	_____	_____
ROI Signature	ROI Printed Name	Date

For Example Only

# Prototypes

- Pack design
- Clinical validation
- Waste
- Shortages



# Program State: Prior & Current

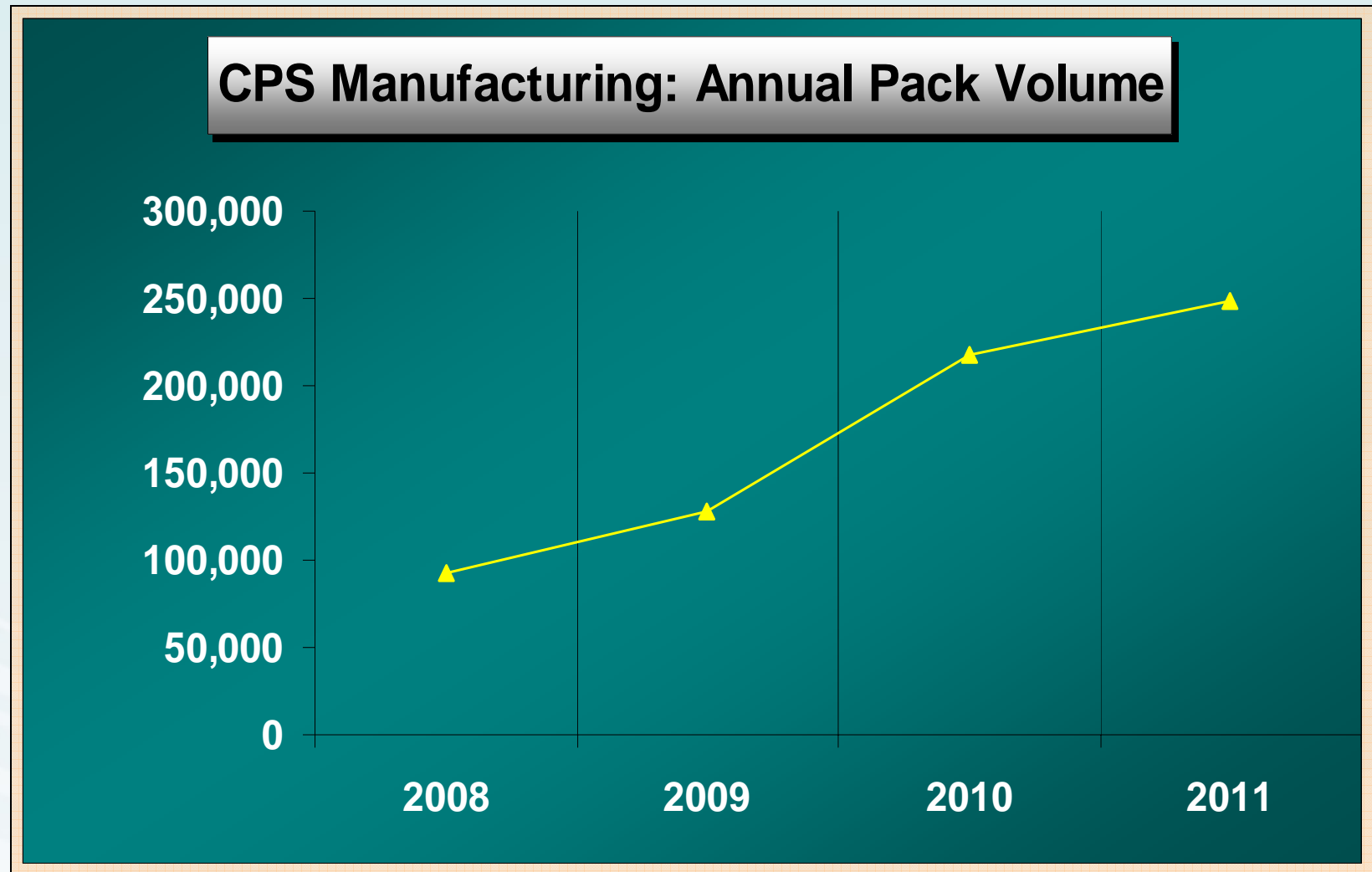
## Prior

- Annual Spend: \$4.5M
- Lack of savings opportunities being driven
- Pack designs: 93
- Annual pack usage: 90k
- Components handled: 4.8m
- Active components: >900
- Material suppliers: >125
- Quality challenges:
  - Unauthorized substitutions
  - Product deletions w/o price adjustments
  - Migration to vendor private label products
  - Lack of collaboration for program management between vendor and clinical user

## Current

- Annual Spend: >\$9.0M
- Saving > 20% of spend
- Pack designs: 187
- Annual pack usage: >200k
- Components handled: 7.8m
- Active components: 755
- Material suppliers: <100
- Quality:
  - No unauthorized substitutions
  - No run with-outs
  - Transparent pricing
  - Quick turn around on device changes
  - 5+ sigma rated
  - Improved trust & confidence
  - Increase pack utilization
  - Quarterly pack reviews

# Manufacturing Plan



# Manufacturing Essentials

- **Controlled access environment**
  - 6000sf for pack assembly operations
  - Annual production capacity: 400k packs
- **Storage capacity**
  - Up to 45,000sf for raw materials & finished goods
- **Sterilization & Lab Services**
  - Lengthy & complex development process

# Manufacturing Essentials

- System Requirements
  - Platform for Bills of Material
  - Design control
  - Raw material qualification
  - Forecast for raw material & finish goods
  - Product labeling

# Manufacturing Fundamentals

- FDA registration is required
  - Medical device manufacturer
  - Re-packager
  - Re-labeler
- Compliance to Federal Regulations:
  - 21 CFR part 820:
    - Medical Device Quality Systems Regulation (QSR)



# Manufacturing Fundamentals

- FDA will audit & enforce QSR on medical device firms
- Regulations governing methods of GMP used in:
  - Pack design
  - Manufacturing processes
  - Training programs
  - Labeling / packaging
  - Storage & handling
  - CAPA and complaint handling



# Our Key Learning Points: Implementable Solutions

- Clinical involvement
- Standardization in a custom program
- Transparency
- Manage your program, don't let your program manage you
- Eliminate unauthorized substitutions