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Overall Learning Objectives

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- Explain navigating complex healthcare landscapes while driving for success in pharmacy benefit manager (PBM) operations and self-funded plan transformation.
- Discuss strategies to optimize revenue cycle performance to improve financial outcomes for pharmacy services.
- Examine the impact of wholesale acquisition cost (WAC) pricing on the financial sustainability of 340B-covered entities.
- Describe streamlined workflows to implement a preferred product hierarchy to facilitate adoption of biosimilar medications.

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Pharmacy Benefits – Trends in the Market Place

- **Key highlights in 2024**
  - Vertical consolidation continues in the PBM space
  - FTC interim report focuses on potential channel conflict between PBMs and affiliated pharmacies
  - High-cost specialty products continue to dominate formulary management strategies
  - Biosimilars impact how PBMs will deploy cost saving strategies
  - Cell and Gene Therapy at the start of the "S Curve" and gaining traction

- **Impact on Hospitals**
  - Hospital pharmacies challenged to remain "in-network"; need to address pharmacy deserts
  - Hospital pharmacies adversely impacted on reimbursement for drug therapy and dispensing
  - Hospital employee benefit plan administrators challenged with managing costs and gaining transparency
  - Call for Pharmacists and Human Resource Benefits specialists to collaborate on plan design and utilization management

Employee Prescription Payer Model and PBM Excellence: Cost Reduction and Plan Transformation

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Managed Care Manager
University of Toledo Medical Center

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Priyesh Patel PharmD, MBA *(moderator)*
Vice President and General Manager, Alluma

University of Toledo
University of Toledo Medical Center (UTMC)

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Academic

- University

Provider Group

- Provider Clinics

Hospital Enterprise

- Acute care
  - 320 beds
- Ambulatory
  - Clinics
  - Outpatient and Specialty Pharmacies
  - Cancer Center

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Partnerships	Structure	Services
• Human Resources • Onsite Pharmacies • PBM	• Cost-Saving Model • Preferred Onsite Pharmacies	• Mail Order • Population Health

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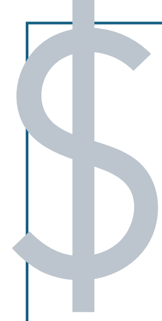
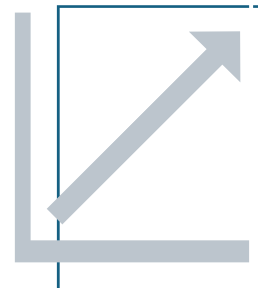
UTledo Self Funded Employee Prescription Benefit 2023



Benefit Spend

- $20M Total Cost

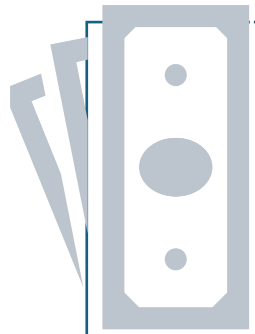


Volume

- Members ~9,500
- Prescriptions 90,000

Capture

- 89% Total Prescriptions



Savings

- $2.25M, Pharmacy Capture
- $3.5M, 340B

Source: Data provided is from UTMC's internal database

Cost Saving Initiatives 2018-2023

Onsite/Preferred Pharmacies

PBM Employee Benefit Contracting

Utilization Management Techniques

$16.8M

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Creating an Integrated Pharmacy Care Model

Inpatient Outpatient Ambulatory

<u>Operational Considerations</u>

- Strategic positioning of service lines
- Defined business model
- Employee capture = savings
- Patient capture = revenue

<u>Service Line Optimization</u>

- Specialty
- Transitions of Care
- Creation of a PGY1 Pharmacy Residency Program
- Utilizing 340B savings to expand services

Volume Growth Over Time

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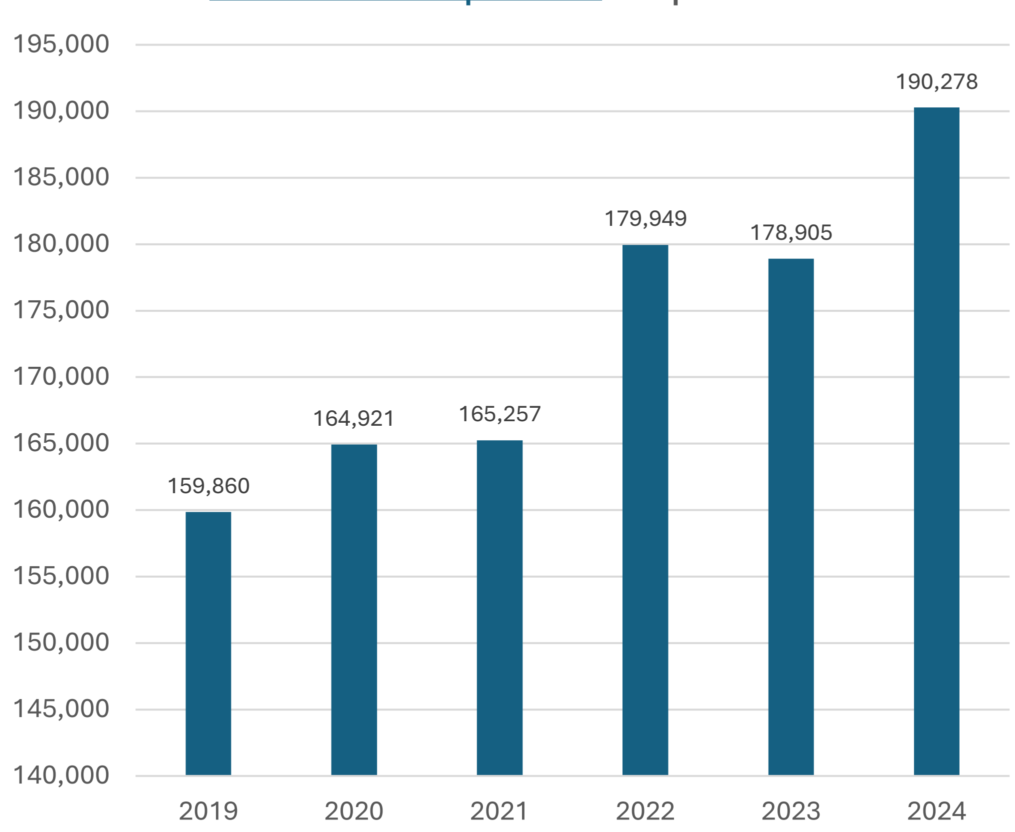

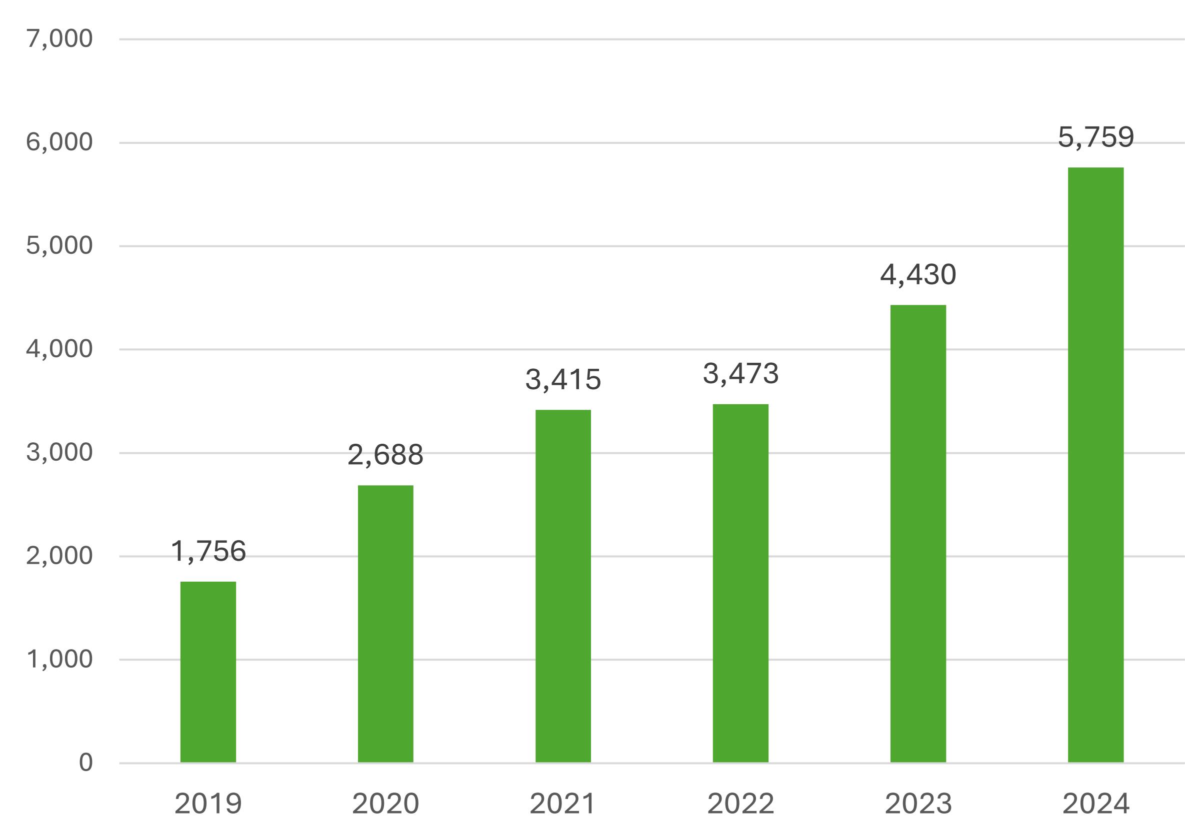

Source: Data provided is from UTMC's internal database

Libby
Eureka
Whitefish
Columbia Falls
Plains
Kalispell
Lakeside
Bigfork
Polson
Ronan
Missoula
Cut Bank
Shelby
Conrad
Great Falls
Helena
Bozeman
Chester

Logan Health Hospitals
Logan Health Outpatient Clinics
Logan Health Long Term Care
Logan Health Visiting Specialists

Images used with permission from Logan Health

Logan Health

- Medical Center 150 beds
- Behavioral Health 40 beds
- Children’s 30 beds
- 5 Critical Access Hospitals
- 68 Outpatient Clinics
- 4 Assisted Living Facilities

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Logan Health Self Funded Pharmacy Benefit

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- Managing $10 million plan benefit
- 6,489 Total Members
- 4,871 Utilizers
- Over 50,000 prescriptions yearly
- 90% of Specialty Filled In-House
- All prescriptions vetted first to In-House
- 96% of Utilization through In-House

Source: Data provided is from Logan Health's internal database

Quantity and Quality

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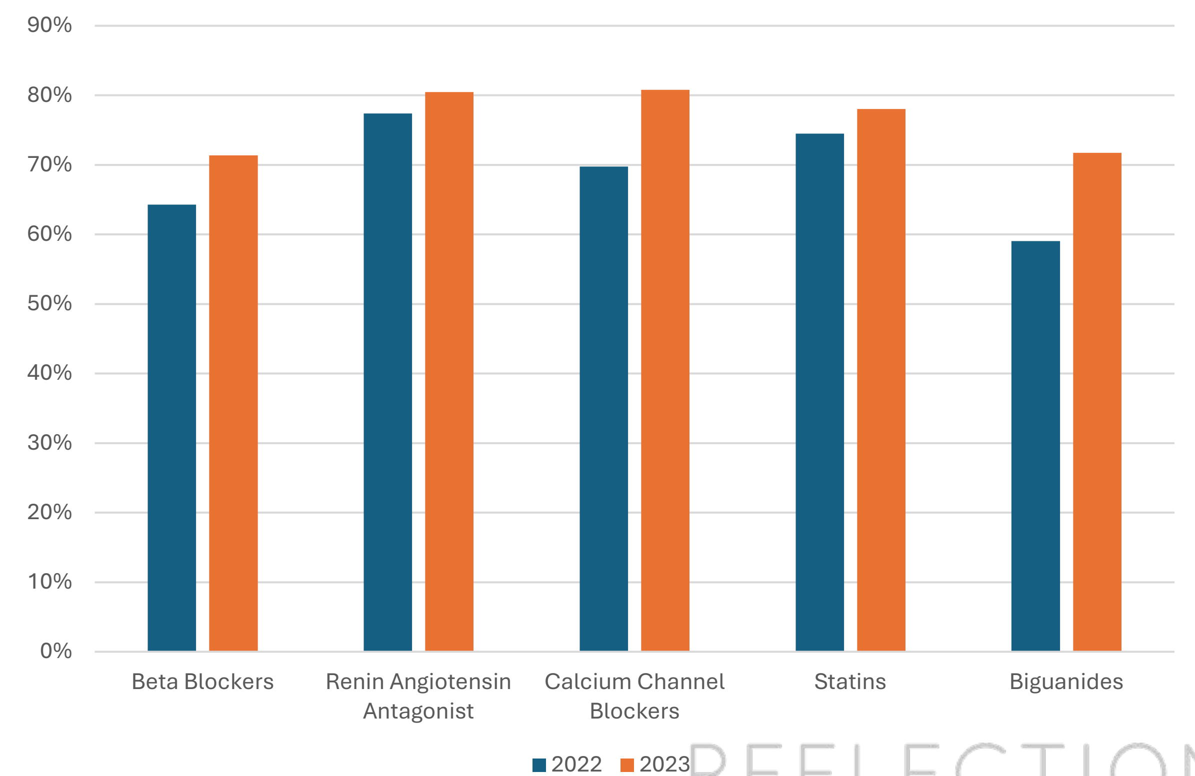
- 25% of generics on the $0 List
- 43% of members filling a generic med on the $0 List
- Achieved $3.36M in Savings for 2023
  - Specialty Management
  - Prior Authorizations
  - Quantity Limits
  - Formulary Management



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Quantity and Quality

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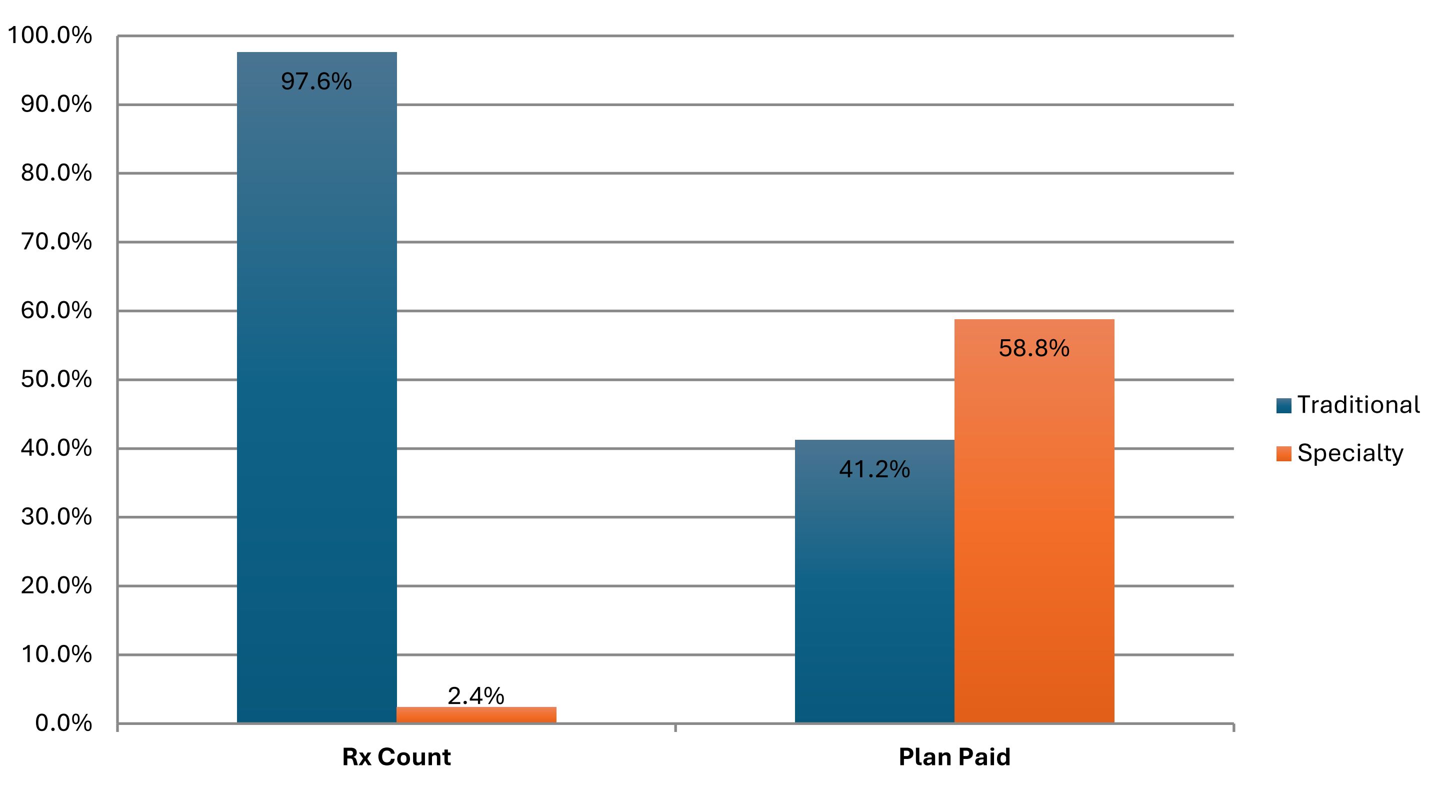

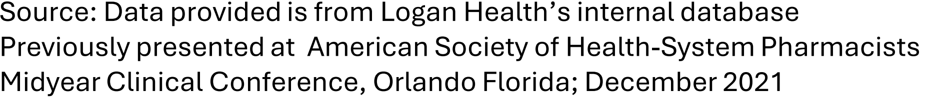
Source: Data provided is from Logan Health's internal database
Previously presented at American Society of Health-System Pharmacists Midyear Clinical Conference, Orlando Florida; December 2021

Panel Discussion

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Panel Discussion: Lessons Learned

- Creating a multidisciplinary team for plan design is critical for success
- Educating the members is important for optimal outcomes (compliance, penetration, savings, etc.)
- Validate the data and regularly review those key performance metrics with your stakeholders
- Working collaboratively with a PBM in the decision-making process can further identify opportunities for improvements
- Strategic alignment and placement of patient-centered services drives growth

Key Takeaways

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- Evaluate both revenue generating and cost saving opportunities on a continuous basis to ensure growth of the program
- Partnering with key stakeholders ensures success across the board
- Transparency is key in removing the complexity and confusion and also allows for individuals to follow the hard dollars
- You own your self-funded plan, properly resourcing it and having strong governance in place is mission critical
- This is a journey and understanding the future landscape and impact to your programs is critical for future success

Questions?

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This educational session is made possible through the collaboration of Vizient Member Networks.

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Mastering Medication Charge Capture and Breaking Barriers in Site of Care Denials

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Chad Hatfield, PharmD, MHA, BCPS, Chief Pharmacy Officer
Brandy Thompson, CPhT, Pharmacy Revenue Cycle Analyst

University of Texas Medical Branch, Galveston, Texas
Michael Eagon, PharmD, DPLA, Senior Pharmacy Manager, Ambulatory Pharmacy
Nathan Vo, RPh, MBA, Senior Pharmacy Manager, Revenue Integrity
Gaurav Goyal, PharmD, BCPS, BCOP, CPHIMS, Senior Pharmacy Manager, Ambulatory Pharmacy
Edward Stemley, PharmD, MS, Administrative Director of Pharmacy

Jim Lichauer *(moderator),* Senior Performance Improvement Program Director, Pharmacy, Vizient

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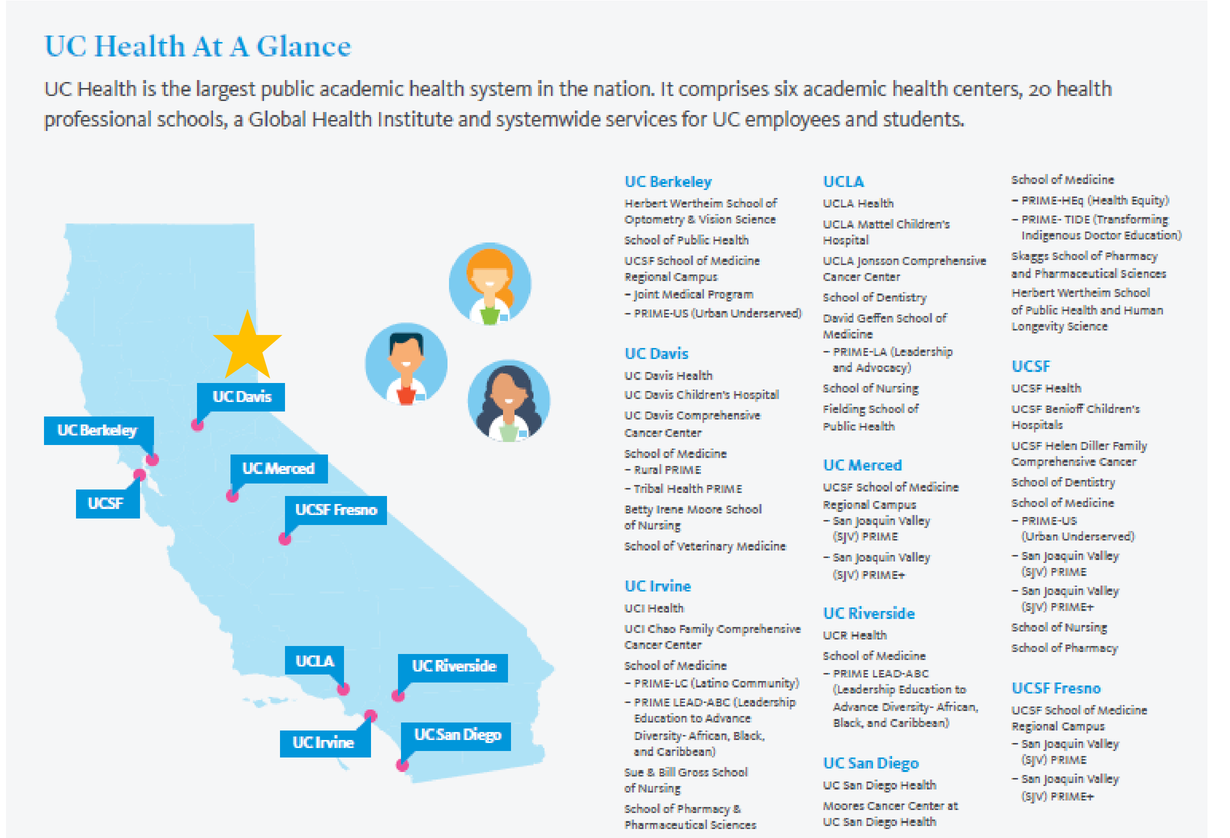
Background

The University of California improves the lives of people in California and around the world. UC Health is the largest public academic health system in the nation.



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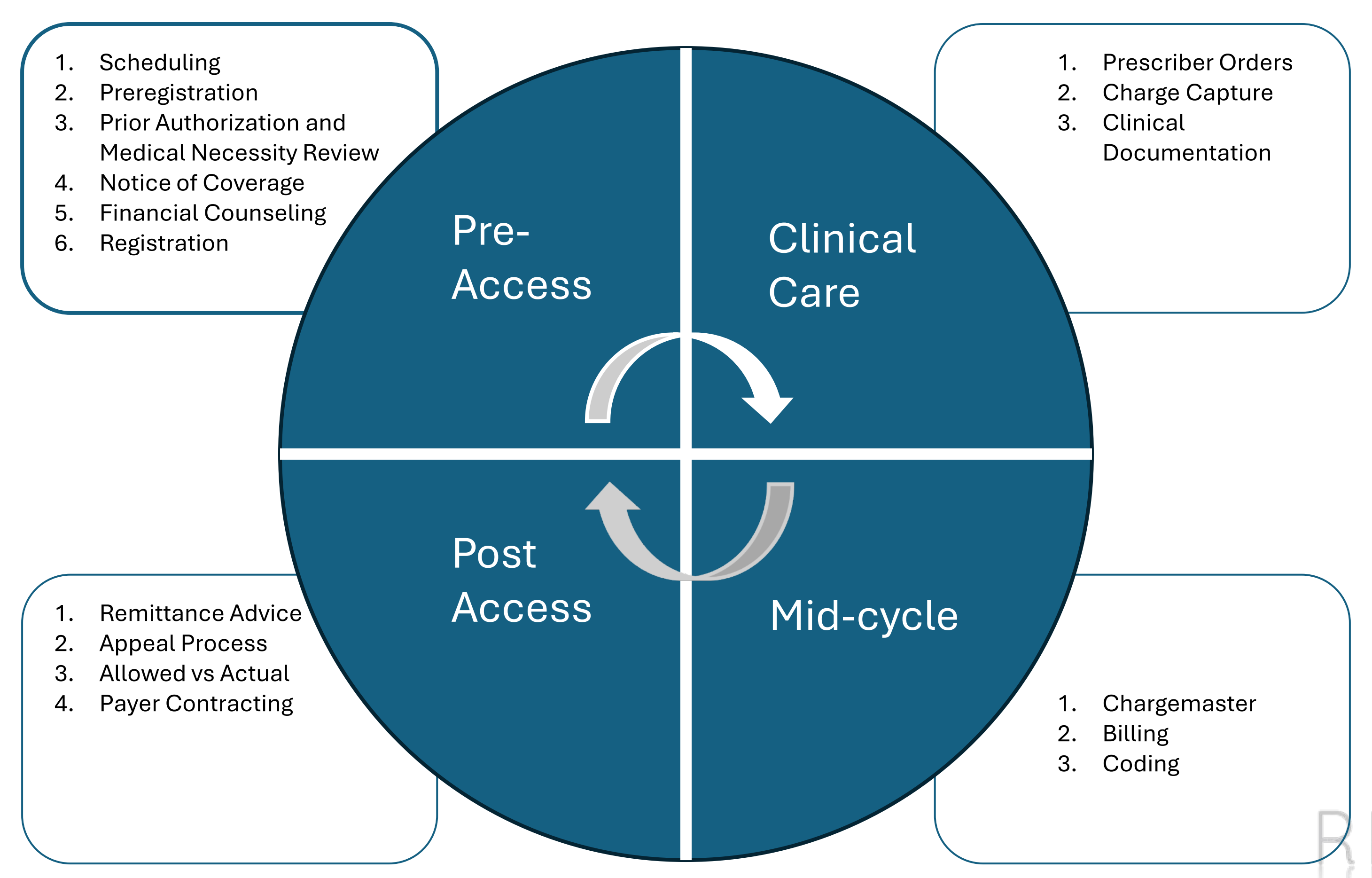
Comprehensive Pharmacy Services to 35 locations

- 3 Inpatient Pharmacies
- 2 Oncology Infusion Pharmacies (6 Infusion Locations)
- 2 Specialty Pharmacies
- 3 Retail Pharmacies
- 1 Home Infusion
- 200 Ambulatory Clinics
- Clinical Pharmacy Services

Background

Pharmacy revenue cycle needs to be inclusive of multiple components. It is beneficial to define specific focus areas and implement targeted strategies with key partners to improve outcomes



Granko, R. P. (2022). *Financial Management for Health-System Pharmacists*. Bethesda MD, USA: ASHP. https://doi.org/10.37573/9781585287130

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Vision and Goals

Vision

- Create a highly collaborative pharmacy revenue cycle team that expands expertise in medication use, fosters key partnerships, and embraces innovation, specialization, and continuous learning to achieve outcomes and demonstrate the value of pharmacy.

Goals

- Comprehensively understand the current state, identify challenges, analyze their root causes, develop countermeasures, and identify quick wins.
- Strengthen our foundation, build key partnerships, establish a team to tackle current and future challenges, and celebrate outcomes.

Framework

Lean A3 Thinking is an ideal framework that enables a structured and systematic approach to problem-solving, leading to more efficient and impactful solutions.

UCDAVIS HEALTH

- Title: Building Pharmacy Revenue Cycle Team – FY23, Year 2 FY24
- Owner: JSL (ACPO), JH (Mgr Pharmacist), Team: BT (Analyst 4), DC (Analyst 3), Consult: Various Teams

Ver: 5	Date: 1/22 Last: 7/12/24	Supervisor: CH

I. Background: What problem are you talking about and why focus on it now?

- UCDH Pharmacy Dept is a billion-dollar business enterprise
- Total Pharmacy expenses grew % increase FY20 to FY24, corresponding revenue grew %
- **Vision:** Develop a new pharmacy revenue cycle team that works in partnership with Pharmacy and Finance to leverage understanding of pharmaceutical billing/revenue cycle and bridge expertise in medication use. Drive financial performance improvement outcomes using data and develop self and teams.
- **Goals FY23/24/25:**
  - Learn - ourselves and our team, improve confidence of knowing drug cycle: purchase to charge to revenue, build standard work, build analytics tools, integrate leadership & lean thinking
  - Collaborate – know who to connect with, improve understanding/teach/learn, common goals
  - Improve – know med charges baseline, opportunities, correct within time allowed for rebilling

II. Current Conditions: What is happening today? (See reference)

- **Pillar 1:** Optimize Revenue Capture – 1) new product onboard – billing codes, AWP, 2) high dollar drugs >+ $50K AWP updates, 3) high impact drugs, 4) NTAP, 5) waste billing
  - Opportunity: 1) new drugs, 2) complex infusions (high, super high dollar), 3) proactive monitor
- **Pillar 2:** Ensure Billing Compliance – 1) CMS new/revise/delete HCPCS, NEW 1/1/24: manufacturer specific
  - Opportunity: 1) proactively keep billing codes current, 2) analytics, 3) automation - how?
- **Pillar 3:** Data - Reimbursement
  - Opportunity: real-time, accessibility, transparency, by drug, by payor – how?
- **Pillar 4:** Minimize Revenue Loss – 1) formulary/prior auth, 2) denials management (preventable)
  - Opportunity: understand infusion authorizations, how billing code aligns with covered benefits

Problem Statement: Opportunities: 1) learn ourselves (requires skills develop/roles), develop standard work , 2) collaborate with relevant teams to improve understanding, and drive towards shared desired outcomes (time for new relationships), 3) performance improvement: baseline, track data to outcomes (requires data).

III. Targets and Goals: What specific measurable outcomes are desired and by when?

Selected Metrics	Baseline	Benchmark	Target by [When]
Medication charge capture improve	$	1% total charges	FY23, FY24

IV. Analysis: Why does the problem exist, in terms of causes, constraints, barriers?

A. People	B. Process	C. Equipment
• Ownership • 1 FTE, desire team approach • Bridge understanding Epic, ops workflows, 340B, purchasing	• HB focused - inpatient, HOPD • Manual processes • "Waste" - reactive vs proactive; miss new drugs, billing codes	• Lack of automation • Epic charge data • Lack of reimbursement data
• CMS, reimbursement codes • AWP: Redbook • IPD Analytics	• Significant growth in med use volume, no change in process • Desire to improve margins	• Organization structure • Leadership structure • Governance
D. Materials/Supplies	E. Environment	F. Management/Structure

V. Countermeasures & Plan:

Countermeasure	Deliverable	Owner	Status
Structure	• 2013 to 2021: Analyst x 1 • FY22: + ACPO Business x 1 (20%) • FY23: + Analyst x 1, ACPO (30%) • FY24 (March): + Mgr x 1 (30%), ACPO (20%)	CH, JSL	FY22 FY23 FY24
Pillar 1 -	• Med charge capture – new drugs, high $ drugs, NTAP • New product onboarding – standard work • High dollar medications - $50K charge per dose • JZ & JW waste billing – oncology teams, expand 7/23	JSL BT, DC	FY22 (NTAP, JW, JZ); FY23 (new product, high $)

Pillar 2	• Ensure Billing Compliance
	• Epic Willow HB WQ (convert emails to WQs)
	  ◦ **High dollar**
	  ◦ High quantity HCPCS
	  ◦ Missing HCPCS
	  ◦ Missing NDC
	  ◦ Invalid NDC
	  ◦ Incorrect date of service
	  ◦ Rx billing error inbox
	  ◦ Other: Incorrect billing → identify white bag
	  ◦ Other: bulk charges → correct missing charges
	• New billing code changes – quarter & ongoing alerts
	• Analytics – Epic, Tableau; Automation explore – new
		BT,
		DC
			FY19 to FY20 (WQ);
			FY23 (billing codes alert, strategic project)
			FY24 analytics;
			FY25 (automation)

Pillar 3	• Reimbursement – accessible data, claim level
	• Partner with Finance teams
	• Proactive track high cost, high value medications
	  ◦ Standard work – identify drugs, data desired
	  ◦ CART-T, Cell/Gene, high value drugs
	  ◦ Analytics – Epic, software solutions (new)
		BT,
		JSL
			FY22 (Finance partnership);
			FY24 (Epic, tool, proactive track)

Pillar 4	• Minimize revenue loss • Collaborate w/ teams: CAR-T, Emerging dates, purchase to administration to charge to review, denials taskforce • Understand infusion, CAM authorizations (FY25)		FY23, FY24 (collabs) FY25 (auth, denials)

VI. Outcomes

- Leader standard work – monthly track outcomes

VII. Follow-Up + Communication Plan

- Executive: CPO
- Pharmacy teams: oncology, infusion, emerging therapies, managed care, analytics/IT, supply chain
- External w/in UCDH: Revenue Integrity, Patient Financial Services, Decision Support, various
- External: Vizient, other organizations

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STRUCTURE

Resource capacity, capability, culture

MEDICTION CHARGE CAPTURE QW

Charge method, inflation, standard work

BILLING COMPLIANCE QW

Automate work queues, proactive HCPCS changes, Committee

DATA ACCESS

Special focus due to lack of comprehensive/consolidate data

PROACTIVE REIMBURSEMENT TRACKING

Lifecycle from drug expense, charge, to payment

QW *Quick Win = Lower/Moderate Effort, High Reward*

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Key Takeaway: Optimizing Revenue Capture

Health Financial Management Association reports that as much as 1% of net charges are lost due to revenue cycle leakage. How robust is our process, and how might we boost revenue?

CHECK LIST

	Approval for Use
	Med Safety
	Wholesaler/Distributor Sourcing
	Package Presentation & storage
	Hazardous Drug
	Estimate Budget Impact
	Medication ID Configurations
	Clinical utilization & inventory set
	New Med Build Request
✓	**Billing/340B**
	Purchase
	Receipt/Barcode Scan

Gaps		Strategy
NEW PRODUCT	⋙	Standard work for new products
HIGH COST	⋙	WQ identifies drugs to monitor
DOCUMENTATION	⋙	Communication channels
NTAP	⋙	Standard work for NTAP updates

NTAP = New Technology Add On Payment

Used with permission: HFMA.org: https://www.hfma.org/revenue-cycle/charge-capture/55358/. Accessed 8 7 2024.

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Key Takeaway: Improving Billing Compliance

Standard work executed to ensure compliance given increasing infusion high dollar volume and complexities, while improving financial integrity.

WORK QUEUES

ACCOUNT
- RX INVALID/MISSING NDC ISSUES
- RX MEDICATION/SERVICE DATE CORRECTION
- RX JW/JZ MODIFIER REVIEW

CHARGE REVIEW
- RX MISSING HCPCS
- RX HIGH DOLLAR OR HIGH QUANTITY CHARGE
- RX HIGH QUANTITY HCPCS

CLAIM EDIT
- RX MISSING NDC
- RX INVALID/MISSING NDC ISSUES

Used with permission from EPIC.

Gaps		Strategy
PROACTIVE REVIEW DRUG CHARGES	⋙	Nine EMR work queues
BILLING CHANGES	⋙	Pharmacy CDM reporting
COMPLEX TOPICS	⋙	Cell and gene, complex infusions, white bagging

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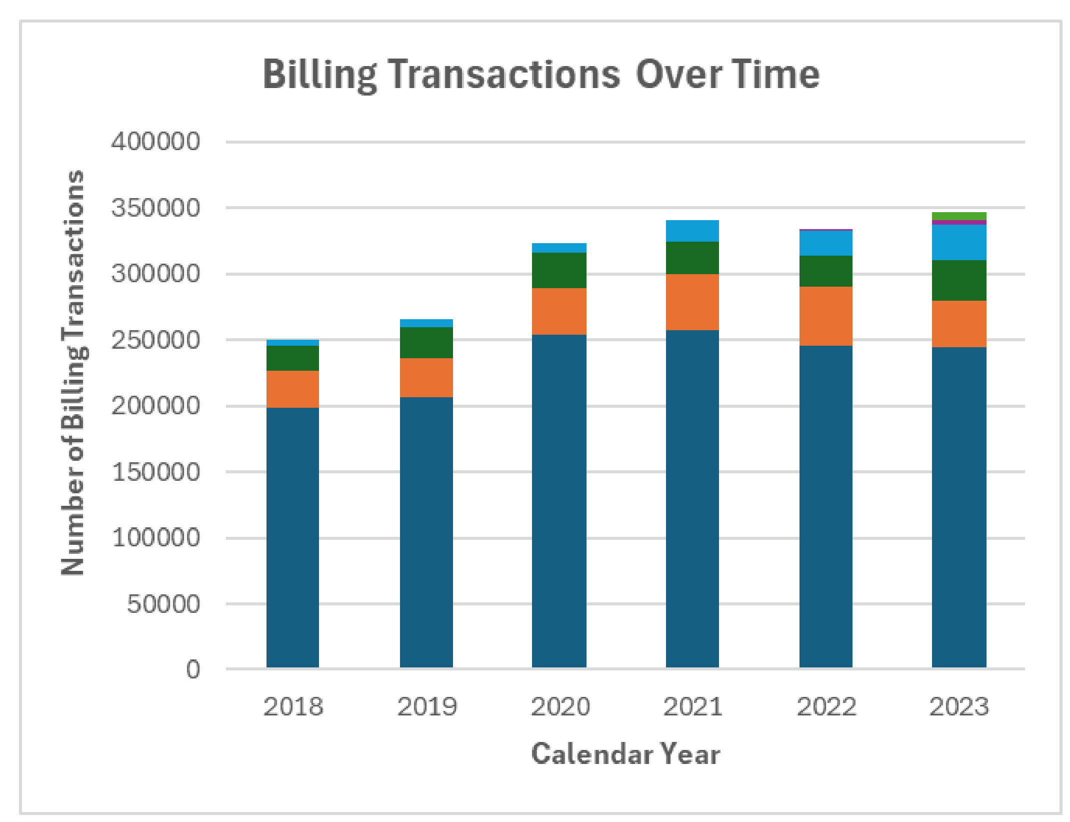
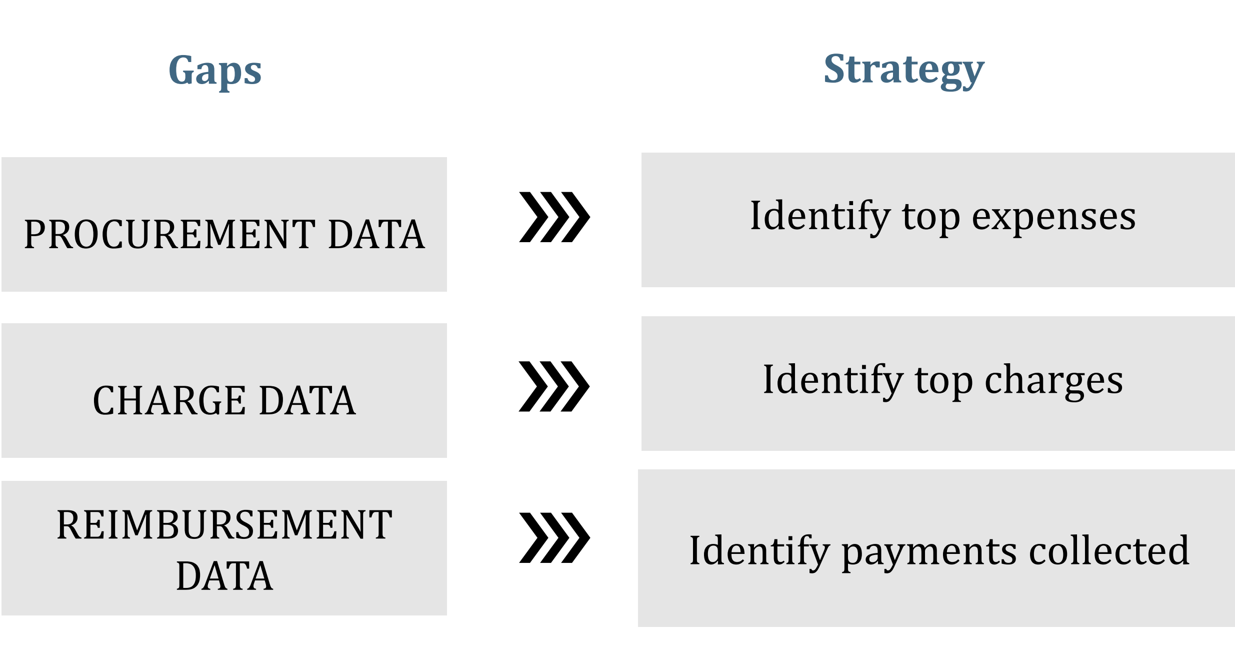
Key Takeaway: Improving Data Access

Comprehensive data availability to the pharmacy were lacking, making data a critical factor for success. As a result, multiple data sources were required and utilized together to gain a holistic view.



Source: UCDavis Health Internal Database.



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Key Takeaway: Proactive Reimbursement Tracking

Standard work executed to proactively monitor reimbursement on complex medications with anticipated barriers. Detect barriers earlier and collaborate with key partners on resolution.

DRUG X CLAIM STATUS

- Claim corrected & Paid, 38%
- Claim corrected & Pending, 24%
- Open, 5%
- Paid, 5%
- Rejected, 28%

Source: UCDavis Health Internal Database.

Gaps		Strategy
REIMBURSEMENT	›››	Payment data to inform barriers or risks
PRIOR AUTH	›››	FY25/26
DENIALS	›››	FY25/26

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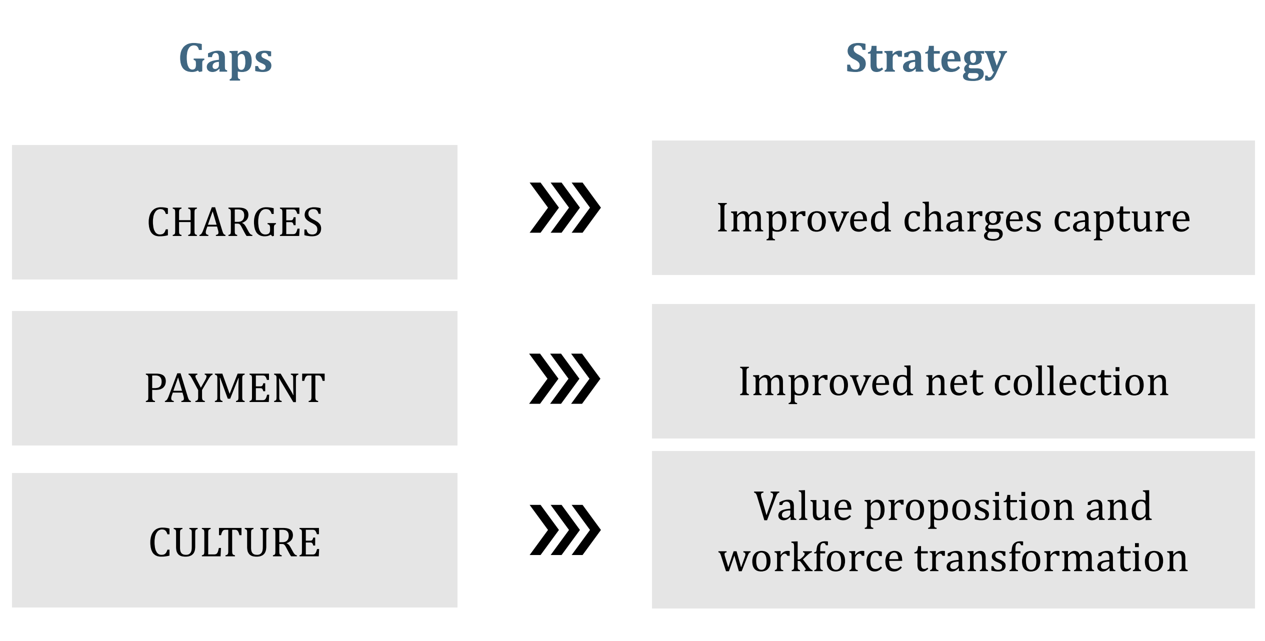
Key Takeaway: Outcomes

Our transformative journey achieved quick wins and sustainable outcomes.

Source: UCDavis Health.
"Transformative Journey" prompt, Adobe Express AI Image Generator, July 24, 2024. https://www.adobe.com/products/firefly/features/text-to-image.html



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Lessons Learned

Empowering success through structured problem-solving, data-driven decisions, and continuous learning

Structured Problem-Solving

- Implement a framework to systematically identify problems and develop effective solutions, leading to improved outcomes, continuous monitor and adjust to explore new opportunities.

Standard Work Execution

- Emphasize the development of standard work around pharmacy revenue cycle processes. This practice not only enhances operational efficiency; it also reinforces financial integrity.

Data Accessibility and Proactive Monitoring

- Recognize the significance of data accessibility gaps. When data is lacking, build new sources or utilize multiple sources to achieve a holistic understanding.
- Establish new monitoring processes for key drugs to facilitate informed decision-making and timely issue resolution.

Vision-Driven and Continuous Learning

- Start projects with a vision to maintain focus and direction and foster a culture of improvement. Dedicate time and pharmacy roles to practice and reflect can lead to expertise over time.

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The University of Texas Medical Branch (UTMB)

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- Pioneer Spirit
  - In 1891, UTMB opened the nation's **<u>first</u>** public medical school *<u>and</u>* hospital under unified leadership
- Health-System with 4 Hospitals
  - Flagship hospital located in Galveston, TX
- Over 100 outpatient clinics serving the Greater Houston and Galveston Area
- UTMB Ambulatory Pharmacy
  - 3 Outpatient Pharmacies
    - 1 designated as Specialty/Mail Order Pharmacy
  - 3 Infusion Pharmacies

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Identifying the Challenge

- UTMB equipped exclusively with hospital billing capabilities for ambulatory infusion services
- Revenue Cycle is managed independent of the Pharmacy Department.
  - Consequently, Pharmacy's involvement in the authorization and denial management aspects of the revenue cycle process is limited.
  - Both the authorization and denial management aspects lacked Pharmacy involvement.
- UTMB observed an increasing volume of site-of-care denials.

Rise of Payer Site of Care Optimization: Background

2021 - Centers for Medicare & Medicaid Services (CMS) finalized its Hospital Price Transparency initiative mandating hospitals to:

- Publicly disclose payer-specific prices for drugs

Outcomes:

- Increased awareness of markup costs associated with hospital-based administration of infusions versus administration via home-infusion, physician office, or non-hospital-based clinic.
- **Average markups compared to Specialty Pharmacy (2019-2021)**:

Clinic-based	23%	↑
Hospital-based	118%	↑

Markups for Drugs Cost Patients Thousand of Dollars. AHIP. Apr 17, 2023. https://www.ahip.org/resources/markups-for-drugs-cost-patients-thousands-of-dollars

Site of Care (SOC): Jcodes Breakdown from Payers

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Specialty Clinics Impacted by SOC – By Jcodes

Endo
Genetics
Gastroenterology
Hematology
Infectious Disease
Internal Medicine, Cardiology
Pulmonology
Rheumatology, Neurology, Nephrology

57%

Site of Care (SOC): Impact on UTMB Infusion Referrals

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UTMB Top 10 Referral Sources:

IM-NEPHROLOGY, RHEUMATOLOGY, NEUROLOGY (COMBINED)

20%

NP-FAMILY
FM-FAMILY MEDICINE
IM-ENDOCRINOLOGY,DIABETES & METABOLISM
IM-INTERNAL MEDICINE
IM-GASTROENTEROLOGY
IM-HEMATOLOGY & ONCOLOGY
IM-HEMATOLOGY & ONCOLOGY
IM-INTERNAL MEDICINE
MISCELLANEOUS SPECIALTY
IM-GERIATRIC MEDICINE

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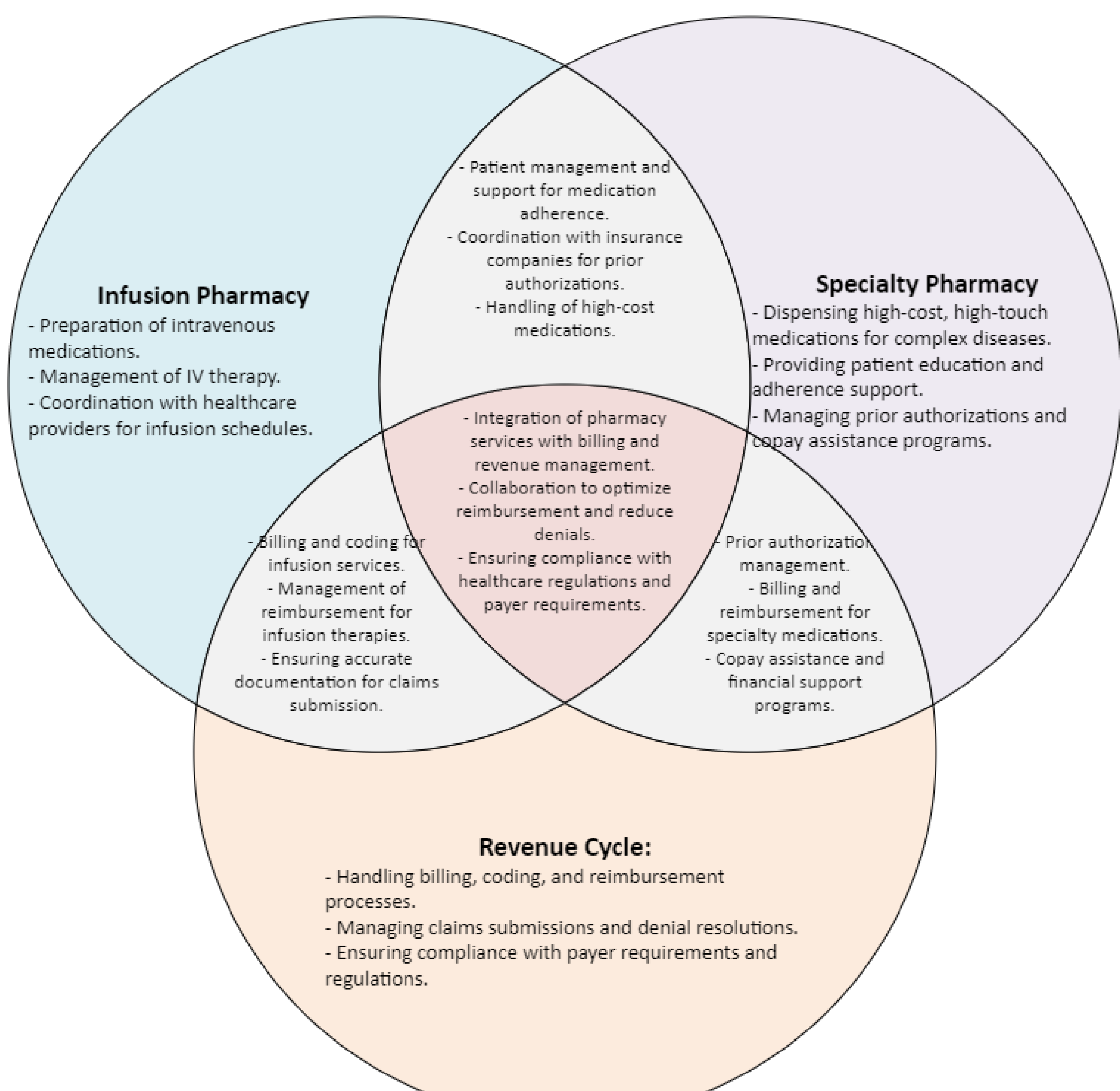
UTMB Collaborative Approach



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UTMB Infusion Clinic Referral Workflow

- Referral > Revenue Cycle > Submit Authorization to Medical Benefits
- Site of Care Denial:
  - Is there a grace period? If Yes, schedule through grace period, Buy and Bill Medication.
  - If no grace period, submit appeal/LOMN while simultaneously assessing opportunity for Clear-Bag via UTMB Specialty Pharmacy.
  - If [grace period] approved via PB, Clear-Bag [through duration of grace period]; if we previously received a grace period via MB, Clear-Bag ***after*** grace period obtained via MB.
  - If not approved via PB, grace period exhausted, appeal/LOMN denied, refer to payor-preferred ISP.
  - For teaching administration of self-injectable meds:
    - Clear-bag 1 dose to Physician office if payor-approved dispense at UTMB
      - Rationale: SOC denials for medication will not cover administration in infusion clinic.
    - Otherwise, white-bag x 1 dose to Physician office.

Site of Care (SOC) Denials: Producing Letter of Medical Necessity (LOMN)Results

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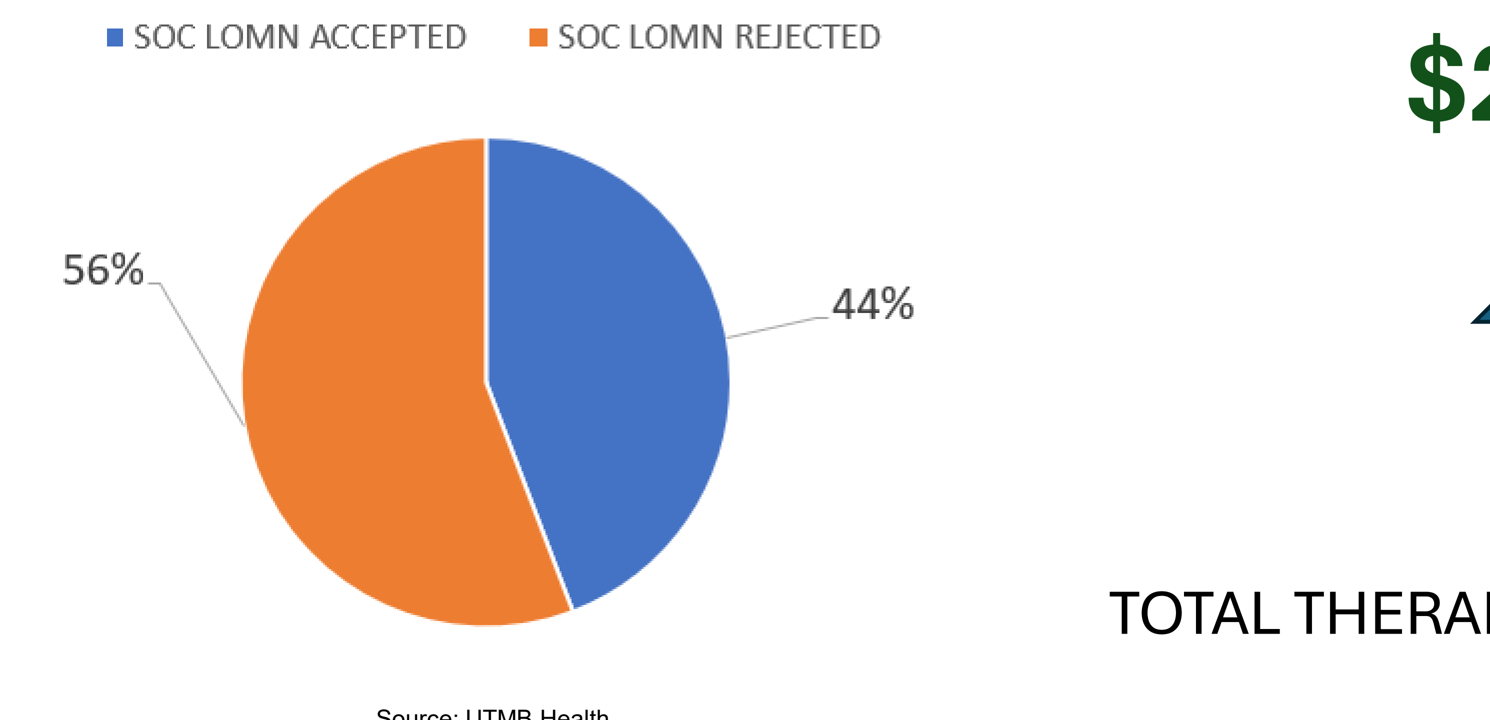
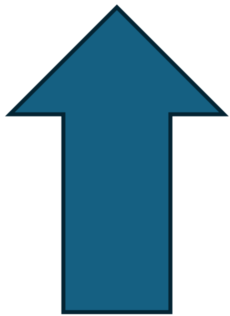


Source: UTMB Health

$2.6M



TOTAL THERAPY CHARGE SALVAGED

SOC Denials: "White-Bag" with Internal Specialty Pharmacy Result

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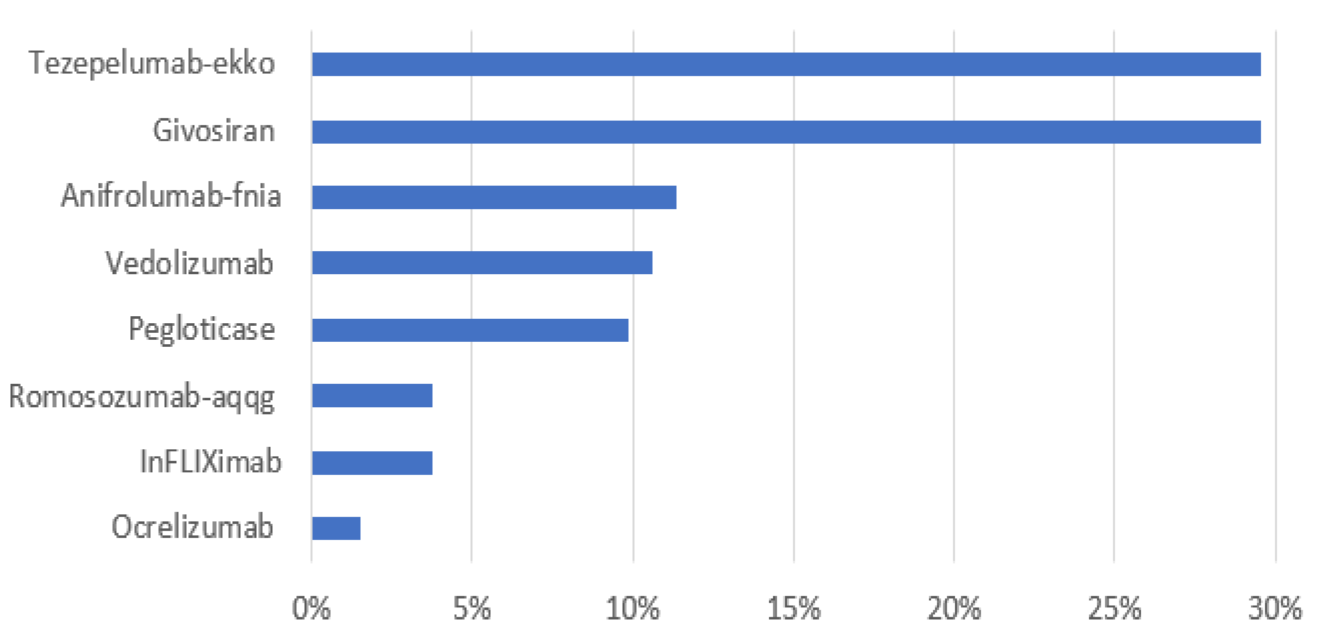

$2.5M

CLEAR-BAG SOC DRUGS SALVAGED

Source: UTMB Health

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Lessons learned

- **Integrated Collaboration**:
  - Foster a strong, continuous collaboration between the revenue cycle, specialty pharmacy, and infusion pharmacy departments to streamline processes and ensure unified efforts in managing and reducing site of care denials.
- **Data-Driven Strategies**:
  - Implement robust data analytics and reporting mechanisms to identify trends, track denial reasons, and develop targeted strategies for timely resolution, thereby enhancing the efficiency of denial management.
- **Education and Training**:
  - Regularly conduct cross-departmental training sessions to ensure all team members are knowledgeable about current billing practices, payor requirements, and effective denial prevention techniques.

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Key takeaways

- **Engage Stakeholders Now**
  - Foster a culture of teamwork and open communication between departments to improve coordination and efficiency.
- **Optimize Charge Capture Processes**
  - Improve the efficiency and accuracy of charge capture processes to minimize errors and denials.
- **Continuously Evaluate Determinations**
  - Track the performance of charge capture and denial management processes through relevant metrics to ensure continuous improvement.

Questions?

UCDAVIS HEALTH

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Thank you to: UCDH Pharmacy Department Finance, Pharmacy Supply Chain, Pharmacy Analytics, UCDH Epic Willow, Oncology, Infusion, Emerging Therapies, Operational Analytics, Revenue Integrity, Decision Support Services, Patient Financial Services, Managed Care and Pharmacy Contracting.

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Yale NewHaven Health

Operationalizing Biosimilar Adoption to Optimize Outcomes

Osama Abdelghany, PharmD, MHA, BCOP
Executive Director, Oncology Pharmacy Services
Man Yee Merl, PharmD, BCOP
Manager, Oncology Pharmacy Services
Taylor Benoit (Harkness), PharmD, CSP, BCPS, BCACP
Coordinator, Pharmacy Business Strategy
Yale New Haven Health System

Goals

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- Describe the principles and structure to support flexible and dynamic use of biosimilars
- Describe the benefits of implementing a hierarchy-based biosimilar adoption strategy

REFLECTION

Yale New Haven Health At-a-Glance

- ❖ Five Hospitals (2,681 licensed beds)
  - Yale New Haven Hospital
  - Bridgeport Hospital
  - Greenwich Hospital
  - Lawrence + Memorial Hospital
  - Westerly Hospital

- ❖ Longstanding commitment to innovation in quality and value
  - Value based models
  - Drug stewardship programs
    - Biosimilars

Used with permission from Yale New Haven Health, Bridgeport Hospital, Greenwich Hospital, Lawrence Memorial Hospital Westerly Hospital.

YNHHS Biosimilar Journey

Formulary Policy
Biosimilar interchangeability

2016 – 2017 – 2018 – 2019 – 2020 – 2021 – 2022 – 2023

- **Formulary Policy** – Biosimilar interchangeability
- **Filgrastim**
- **Bevacizumab**
- **Pegfilgrastim**
- **Trastuzumab**
- **Product Change** – Pegfilgrastim
- **Rituximab**
- **Infliximab**
- **Biosimilar Orderable** – Pegfilgrastim
- **Product Change** – Rituximab
- **Biosimilar Orderable** – Rituximab

Drug	Benchmark	YNHHS	Difference
Filgrastim	93%	**100%**	**+7%**
Bevacizumab	82%	**97%**	**+15%**
Trastuzumab	67%	**98%**	**+31%**
Rituximab	72%	**90%**	**+18%**
Pegfilgrastim PFS	77%	**80%**	**+3%**
Infliximab	44%	**64%**	**+20%**

REFLECTION

2023 Biosimilar Report: Tracking market expansion and sustainability amidst a shifting industry - Cardinal Health

Biosimilar Utilization Strategy

- Payer formulary restrictions
- Therapeutic equivalence for all biosimilar categories
- Implemented using a preferred product hierarchy

Rank	Products	Payer 1	Payer 2	Payer 3	Payer 4	Payer 5
1	Biosimilar A	★	★			
2	Biosimilar B			★	★	
3	Biosimilar C					★
4	Reference					

Ordering Strategies in Medical Record

Default single preferred product in ordering pathway	Specify formulary preference in order nomenclature	Biosimilar orderable contains all products with selection driven by billing code
-- Provider Search: Rituximab --		
Rituximab (Biosimilar A)	Rituximab (Biosimilar A) – First line preferred	Rituximab (Biosimilar/Reference) orderable
	Rituximab (Biosimilar B) – Second line preferred	
	Rituximab (Reference) – Non-preferred	

*Individual ordering records available for all biosimilar products but reserved to pharmacist order entry only

Biosimilar Orderable Workflow

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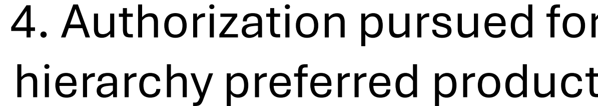
Provider

1. Enters rituximab orderable with clinical details (dose/frequency, etc.)
2. Provider accepts therapeutic substitution

Accept	Do Not Accept - Contact Pharmacist

3. Orderable signed ★

Prior Authorization ★



4. Authorization pursued for hierarchy preferred product
   - If unable to authorize, select most preferred product covered by insurance

5. Document approval in medical record ★
   - HCPCS billing code
   - Authorization Start Date
   - Authorization End Date
   - Authorization confirmation code

Verification

6. Medical record displays and dispenses authorized product

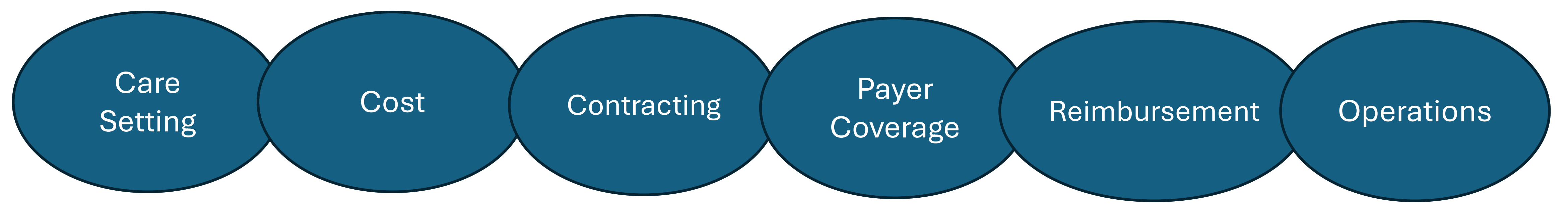
*If no prior auth is required, preferred product is defaulted

*Optimization: Alert informs pharmacist if potential mismatch

Biosimilar Formulary Management Strategy

Preferred Product Hierarchy	Product Match By Payer
Products ranked by preference of utilization	**Product utilization assigned by payer**
Maximizes use of institutional formulary preferred product	Prioritizes product most likely covered by payer
Need for dynamic prior authorization workflow	Reactive prior authorization support
Flexibility in medical record implementation	Sophisticated build to support strategy
No urgent medical record changes with payer formulary changes	Maintenance required with payer formulary changes

Development of Preferred Product Hierarchy



Historical Utilization			Cost		Contract Rates		Charges		Revenue		Margin		Impact
Hospital	Payer	Billed Units	Reference	Biosimilar	Reference	Biosimilar	Reference	Biosimilar	Reference	Biosimilar	Reference	Biosimilar	Reference to Biosimilar
YNHH	One												
YNHH	Two												
YNHH													
L&M													
L&M													
	Total												Net Margin Impact

- Location
- Volume
- Payer mix

- 340b
- GPO

Formulary policies

REFLECTION

Biosimilar Management Program

Strategy
- Coordinated adoption of new agents
- Hierarchy evaluation

Monitoring
- Purchasing/utilization trends
- Utilization by payer

Intervention
- Contracting
- Conversion

Biosimilar Management Program Value

Pegfilgrastim Purchasing Cost and Quantity

$1,800,000
$1,600,000
$1,400,000
$1,200,000
$1,000,000
$800,000
$600,000
$400,000
$200,000
$0

900
800
700
600
500
400
300
200
100
0

Biosimilar Adoption 2018

Adoption of New Biosimilar 2020

Orderable Technology Implemented 2022

10/1/2019, 12/1/2019, 2/1/2020, 4/1/2020, 6/1/2020, 8/1/2020, 10/1/2020, 12/1/2020, 2/1/2021, 4/1/2021, 6/1/2021, 8/1/2021, 10/1/2021, 12/1/2021, 2/1/2022, 4/1/2022, 6/1/2022, 8/1/2022, 10/1/2022, 12/1/2022, 2/1/2023, 4/1/2023, 6/1/2023, 8/1/2023, 10/1/2023, 12/1/2023, 2/1/2024, 4/1/2024

Sum of cost

Sum of quantity

Data provided is from the internal database of the presenting organization.
Date range: October 2019 – April 2024

Lessons Learned

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- Program success is attributed to the collaborative efforts and adaptability of the multidisciplinary team
- Continuous evaluation and monitoring is essential when implementing new technology
- There is no one size fits all approach for biosimilar strategy and workflow (oncology vs. non-oncology)

Key Takeaways

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- Dedicated resources allow for continuous monitoring, periodic hierarchy reassessment, and targeted interventions for biosimilar products
- Preferred product hierarchy can serve as a model for other high-cost therapies in ambulatory formulary and workflows
- Evaluate workflows and available technology to identify ways to optimize biosimilar adoption using innovative approaches

Questions?

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Financially Sustainable Utilization Management of Ultra High-cost Biologic Agents

Sophia Humphreys, PharmD, MHA, BCBBS, CPGx
Director, Formulary Management and Clinical Programs, Sutter Health, **Sacramento, Calif.**

Ryan Stice, PharmD, BCPS
Chief Pharmacy Officer, Sutter Health, **Sacramento, Calif.**

Goals

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- Understand the challenges and methods of financial sustainable utilization management of biologic, cell and gene therapies in the US.

- Be able to explain Principles of Good Practice for Budget Impact Analysis published by the International Society for Healtheconomics and Outcomes Research

REFLECTION

Revolution of Science and Medicine

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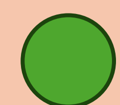
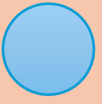
Small Molecule chemical drugs

- $1,000/year



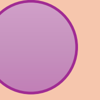
1986: Biologics

- >$10,000/ year



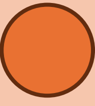
2014: RNA therapies

- $100,000/ year



More recent: Gene therapies

- In **Millions**



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Unmet Needs in Inheritable Diseases and Cancer

Rare diseases burden in US: 997 billion annual costs, affecting 15.5 million patients.

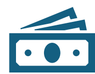
Poor Prognosis in many conditions. Many inherited disorders, cancers and other rare diseases would end in severe disability or premature death if left untreated.

Earlier intervention vs delayed treatment. Gene therapy could help only if the patients received earlier in the course of disease, it has the potential to stop any damage before it occurs.

Targets the cause. Gene and cell therapies make it possible to design treatments that can target any of the thousands of genes in the body which causes cancer and other inheritable diseases.

REFLECTION

Increased Cost of Innovative Therapies



Total drug spend is US exceeded $435 Billion in 2023

In 2023, patient out-of-pocket cost reached $114 Billion ($23 MA)

Specialty medicine spend exceeded 54% in 2023

New therapies in oncology & rare disease > $300,000

RNA, cell and gene therapies are expected to reach $18 Billion by 2028

Sophia Reference: IQVIA Institute for human data and science. The use of Medicines in the U.S. 2024. https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/the-use-of-medicines-in-the-us-2024/the-use-of-medicines-in-the-us-2024-usage-and-spending-trends-and-outlook-to-2028.pdf

Sutter Health Pharmacy Solutions for the Challenge

- Engage system leadership for support
- Formulary Management to align with system pharmacy focus
- Reliable Data to Support Formulary Decisions
- Comprehensive Budget Impact Analysis to Evaluate Impact
- Evidence based formulary decision making
- Specialty and 340B enhancement to maximize financial sustainability

Highest Level System Leadership Support

Chief Pharmacy Officer guidance

C-suite visibility and support

Engage system and market executives

Innovation center and virtual platform

Clinical Improvement Community & service line engagement

Formulary Management Alignment with Pharmacy Goals

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- Provide the most comprehensive, integrated pharmaceutical care
- Develop cost avoidance strategies
- Maximize 340B program
- > $10 Million dollars annual drug savings target
- Expanding specialty and formulary management collaboration
- Explore cell and gene therapy feasibility

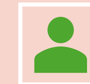
Evidence-Based Formulary Decision Making

GRADE for efficacy and safety evaluation

Focus on high & ultra-high-cost biologic pipeline monitoring

Budget impact analysis for accurate pharmacoeconomic evaluation

Contracting and GPO engagement PRIOR to P&T product selection


Specialty physician leadership engagement and feedback

Reliable data source from specialty service analysts

Example: Gene Therapy agents for Sickle Cell Disease

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- All published data and additional trial data from manufactures
- CLIMB SCD-121 Trail vs HGB-206 Trial
- Gene editing methods
- Risks of non-targeted editing
- Risk of hematological malignancy
- Other side effects
- Trial related mortality
- FDA black box warning (if applicable)

Reliable Data Source to Support Formulary Decisions

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Service line data analysts	Finance and revenue cycle experts	Service line physician leaders	Physician informatics experts
Nursing and Quality experts	Frontline providers	GPO team	Supply chain team

Realistic sizing of the eligible patient population depends on accurate data from service line analysts .

Precise Evaluation of Financial Impact

Budget Impact Analysis (BIA) for high & ultra-high-cost therapies

- Principles of Good Practice for Budget Impact Analysis II *

Multiple reliable data sources

System informatics physician partnership

System population health scientists' involvement

Internationally acclaimed professional society collaboration**

Comprehensive BIA to Estimate Sutter Specific Impact

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Sutter Health specific BIA based upon data availability

- New Preferred Agent
- Existing Therapy
- Population Size
- Supportive Treatment
- Required Labs
- Required Imaging
- Chair time if infused
- Labor
- Monitoring
- Waste
- Any other data as needed

Close Partnership with Financial Experts

Specialty pharmacy leadership engagement
Pharmacy finance department
Supply chain, contracting and buyer team
GPO experts' engagement
Real time post rebate pricing
WAC, GPO and 340B accounts separate evaluation
Payer mapping for high and ultra-high-cost agents
Facility requirement evaluation if needed
All a part of the system formulary decision making

Reimbursement and Payer Considerations

- Prior authorizations
- Financial investigation
- Individual case contract
- Value based contract
- Payment schedule (over time)

REFLECTION

Operationally Efficient Implementation Methods

EHR tools to simplify provider workflow

Regional pharmacy leaders assure P&T decision adherence

Local pharmacy adoption of system P&T formulary

Financial investigation, EHR support for PA

Monthly measure of performance and report out to all levels of Rx leaders to encourage continuous process improvement

IS dashboard upgrade and maintenance

REFLECTION

Expanding Specialty Pharmacy Service

Facility requirement evaluation

New specialty pharmacy system level leader

Expansion of specialty pharmacy service to include high and ultra-high-cost biologics, cell and Gene therapy agents

Maximize HOPD and 340B benefit

Optimize 340B Eligible Purchase

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CAR-T program designs:

– Site of care → Infusion Centers owned by the hospitals

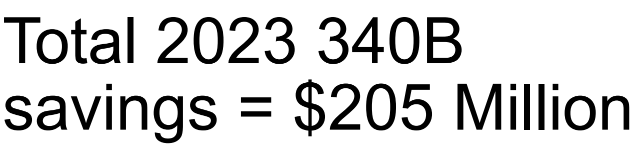
– Purchase record → All 340 B eligible accounts

– Cost variance compared to WAC purchase → > 28%

– 2023 340B savings from one CAR-T program → **$ 889,894.22**

REFLECTION

Significant Contributions to System Financial Health



2023

2023

Total 2023 CAR-T program savings = $ 889,894.22

January to June savings

- Medication Use related savings = **$ 11,736,367**
- Biosimilar utilization related savings = **$4,236,677**
- Alzheimer's disease medications cost avoidance = **$9,836,411**

2024

REFLECTION

Lessons Learned

HIGH AND ULTRA-HIGH-COST AGENTS WILL BE THE FUTURE OF MEDICINE

FINANCIAL SUSTAINABILITY NEEDS ALL TEAMS WITHIN AN IDN TO COLLABORATE

ISPOR PRINCIPLES ARE TRIED AND TRUE AND ARE STILL RELIABLE FOR BIA

LARGE IDNS NEED TO DEVELOP SYSTEM SPECIFIC METHODOLOGIES

SUCCESS CAN BE MEASURED IN MANY WAYS

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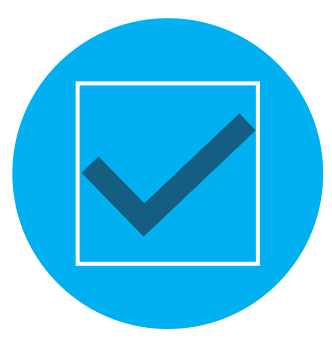
Key Takeaways

ISPOR budget impact analysis model can be useful for system financial impact evaluation



Reliable data source is key for successful and effective BIA

Evidence-based clinical review is the foundation of formulary decision making

Implementation methodologies must be streamlined and user friendly

REFLECTION

Questions?

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Split Billing to Mitigate Site-of-Care Restrictions and Maximize Savings

Steven M. Loborec, PharmD, MS, MPH, BCPS
Associate Director of Pharmacy

Julie A. Cowher, MA, RHIA, CHC
Chief Revenue Officer

The Ohio State University Wexner Medical Center, Columbus, Ohio

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Goals

- List the benefits associated with a split billing arrangement
- Describe the key compliance elements needed to operate a split billing setup

REFLECTION

What is Split Billing?

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- Hospital services generally billed on a UB-04 (CMS-1450) / 837I
- Professional services generally billed on a HCFA-1500 (CMS-1500) / 837P
- Split billing refers to billing using both the UB-04 and HCFA-1500 as permitted by payor rules

REFLECTION

Regulatory Framework

- CMS requires institutional claims to be filed on a UB-04 / CMS-1450 / 837 Institutional
- Other payors determine own rules in payor contracts with providers

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Intervention

- OSUWMC operates an existing limited liability corporation (LLC) known as OSU Physicians, Inc. (OSUP)
  - Has existing contracts with payors
  - Provides patient care using same integrated electronic medical record
- Use charge router to move charges from institutional claims to professional claims for commercial payors
- Payment is returned to the hospital for proper reporting on the Medicare Cost Report
- Hospital reimburses billing company for its services

OSUWMC Policy

- All Medicare and Medicaid patients treated in Provider Based Departments are billed as Hospital outpatients and not as physician's office patients
- Claims for patients receiving services at Departments are bundled into the Hospital claim for patients who are hospitalized within 3 (or 1) day/s of receipt of service in accordance with applicable Hospital policy
- If the Hospital did not submit the claim directly for non-Governmental patients, split billing of the service may be conducted
  - Charges for Department services are submitted on a CMS-1500
  - Payment for services is returned to the Hospital
  - Hospital reimburses the billing company for its services

Rationale

- Site of care restrictions growing in outpatient infusion
  - Commercial payors attempt to control costs
- Offers a lower cost option that appeases payors
- Retain record and ownership of care of the patient
- 340B drug pricing program

Drawbacks

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- Reimbursement based upon separate LLC contract
- Complex revenue cycle process

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Results

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Rheumatology Infusion June 2024 - Key Performance Indicators (KPI)

Charges, Payments - 13 Month rolling

Month	charge	payment
06-2023	44,255,381	7,898,238
07-2023	40,059,442	7,052,907
08-2023	62,279,599	8,824,713
09-2023	37,782,120	7,826,177
10-2023	56,987,458	7,978,246
11-2023	48,703,863	9,032,342
12-2023	47,898,590	10,027,566
01-2024	54,599,204	10,059,096
02-2024	50,454,786	7,019,940
03-2024	54,923,345	8,194,872
04-2024	58,432,179	11,537,872
05-2024	63,486,680	8,642,124
06-2024	57,929,350	10,553,664

Left axis: 0, 10,000,000, 20,000,000, 30,000,000, 40,000,000, 50,000,000, 60,000,000, 70,000,000
Right axis: 0, 2,000,000, 4,000,000, 6,000,000, 8,000,000, 10,000,000, 12,000,000, 14,000,000

Data provided is from Ohio State University Wexner Medical Center internal database, [June 2023-June 2024]
Permission granted to use OSU Physicians Logo

Lessons Learned

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- Watch for secondary / tertiary payors
- Consider modifier differences

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Key Takeaways

- Government payors must continue to be billed through the hospital
- Commercial payors not subject to same regulatory requirements
- Opportunity to leverage 340B program and minimize site of care restrictions

Questions?

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340B Compliance, Optimization, and Reduction in Unintentional Wholesale Acquisition Cost (WAC)

Michelle Schmitt, MBA, 340B ACE

VP Pharmacy Financial Operations

SSM Health

Holly Herring, PharmD, BCPS

Director, 340B Center of Excellence

SSM Health

SSM Health - 340B Journey

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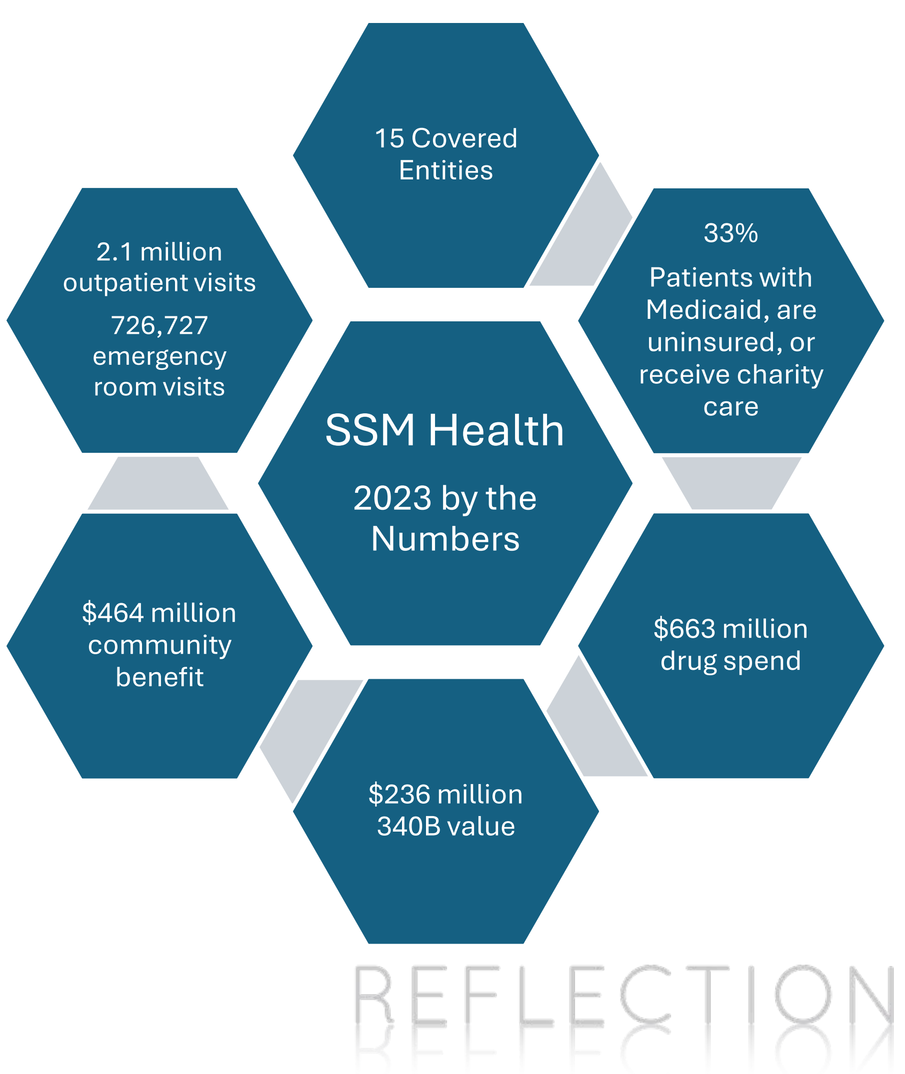
- 340B Center of Excellence established in 2022
  - Prior to 2022:
    - Finance led and managed
    - Passive compliance and optimization management
  - Now:
    - Pharmacy led and managed
      - Program director, manager, and 7 analysts
      - Responsible for active oversight of program integrity and maximization of program savings



Data provided is from SSM Health internal database.
Date range: 2023

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The 340B Program Challenges

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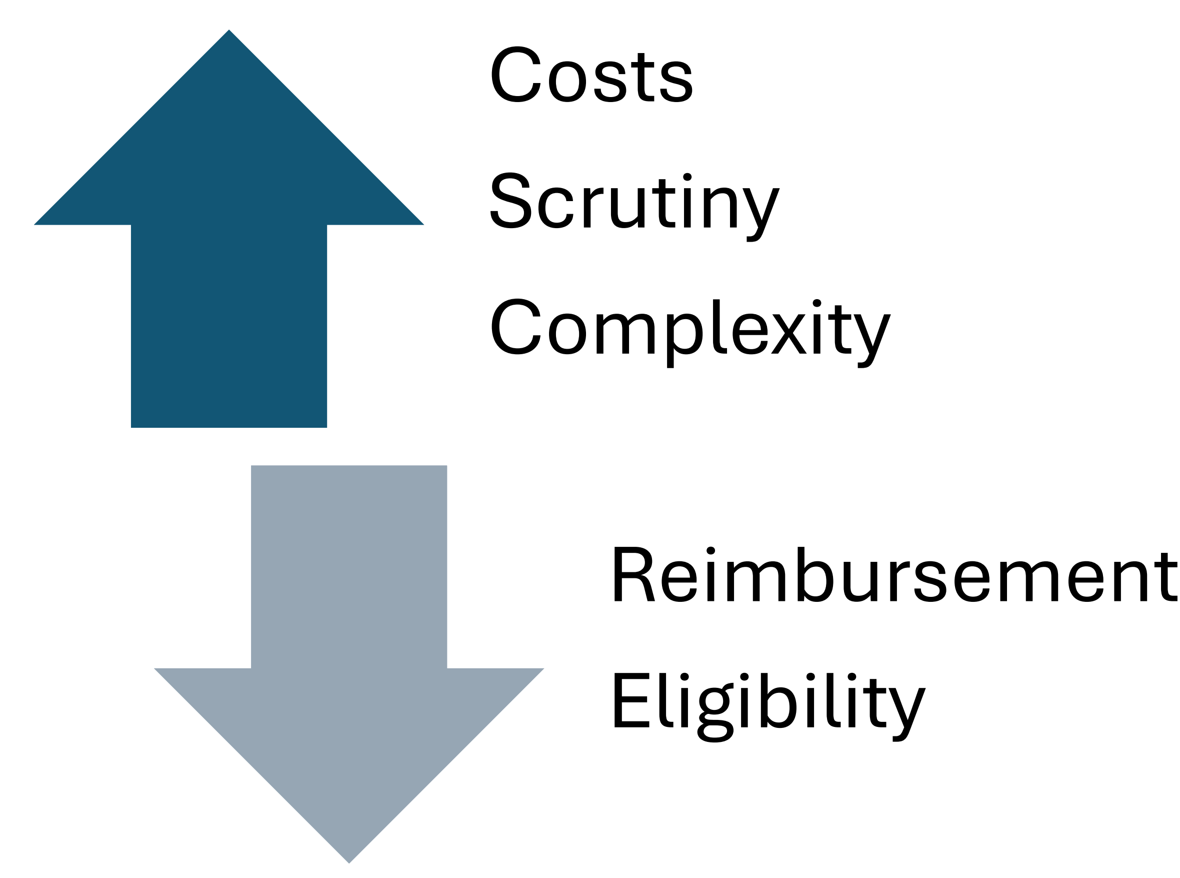
- HRSA audit increases
- Child site eligibility
- Patient eligibility
- Manufacturer restrictions
- Data sharing
- Reimbursement changes



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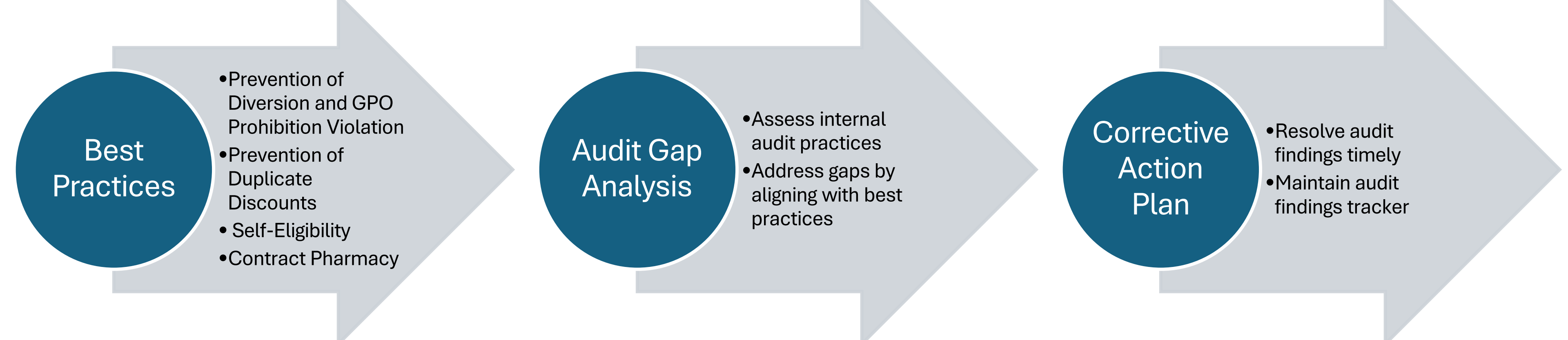
Compliance - Elements to Audit Best Practices



Audit Gap Analysis

Audit	Best Practice	Gap	Action

Prevention of Diversion and GPO prohibition violation	• Eligibility
	  ○ Location
	  ○ Prescriber
	
	• Inventory reconciliation*
	  ○ Dispensation
	  ○ Accumulation
	  ○ Replenishment
	
	• Sample size
		• Prescriber file not routinely updated
		
		• Need to reconcile accumulation and replenishment for each sample
		
		• Opportunity to increase same size
			• Work with credentialing on updating prescriber file
			
			• Develop new audit template to include inventory reconciliation
			
			• Increase sample size

Prevention of Duplicate Discounts	• Medicaid billing is consistent between OPAIS, Medicaid Exclusion File (MEF) and bill
	  ○ Medicaid Billing Number (MPN)
	  ○ National Provider Number
		• Need to verify MPN used to bill is correct on MEF	• Include checkbox to validate MPN is correct MEF
			
			• Implement bi-annual review of MEF for accuracy

Contract Pharmacy	• Contract Pharmacy Network Oversight
	  ○ OPAIS
	  ○ Pharmacy Service Agreements
		• Pharmacies listed in agreement but not in OPAIS	• Reconcile contract pharmacies, agreements and OPAIS

External Mock Audit	• Annual external mock audit of program	• Need process to track and resolve audit findings	• Implement corrective action plan tracker

*Follow 340B claim through the entire inventory reconciliation process including billing

340B Compliance Tools and PVP Resources. https://www.340bpvp.com/resource-center/340b-tools. Accessed 8 7 2024.

Compliance - Audit Findings and Optimization

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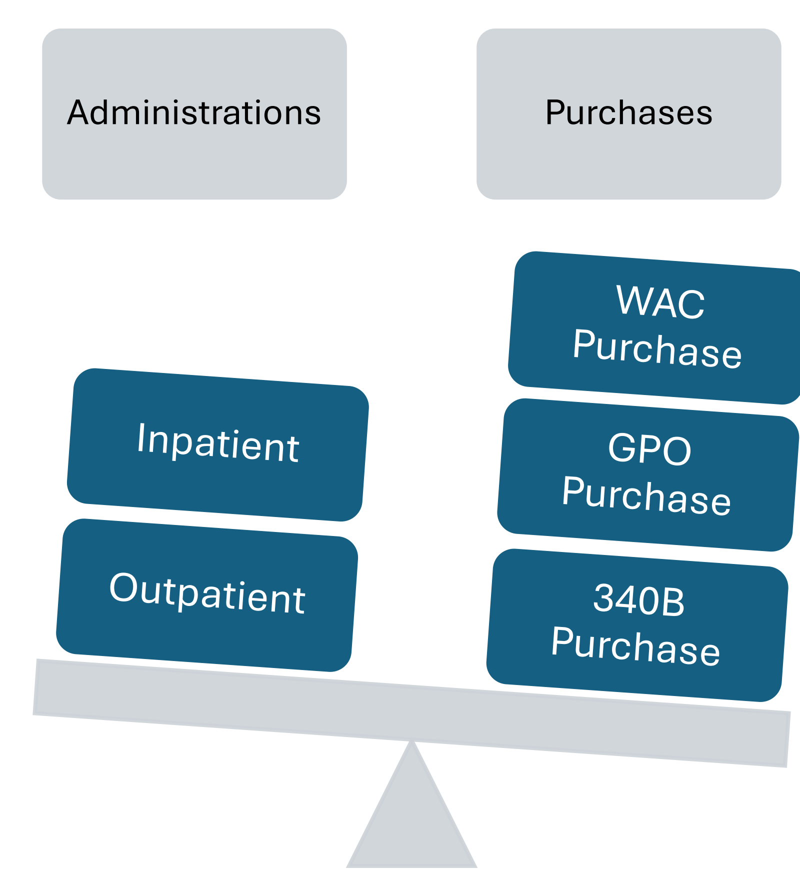
- Maximize accumulations
- Split-billing software maintenance
- EMR updates
- Replenishment optimization
- WAC purchase assessment



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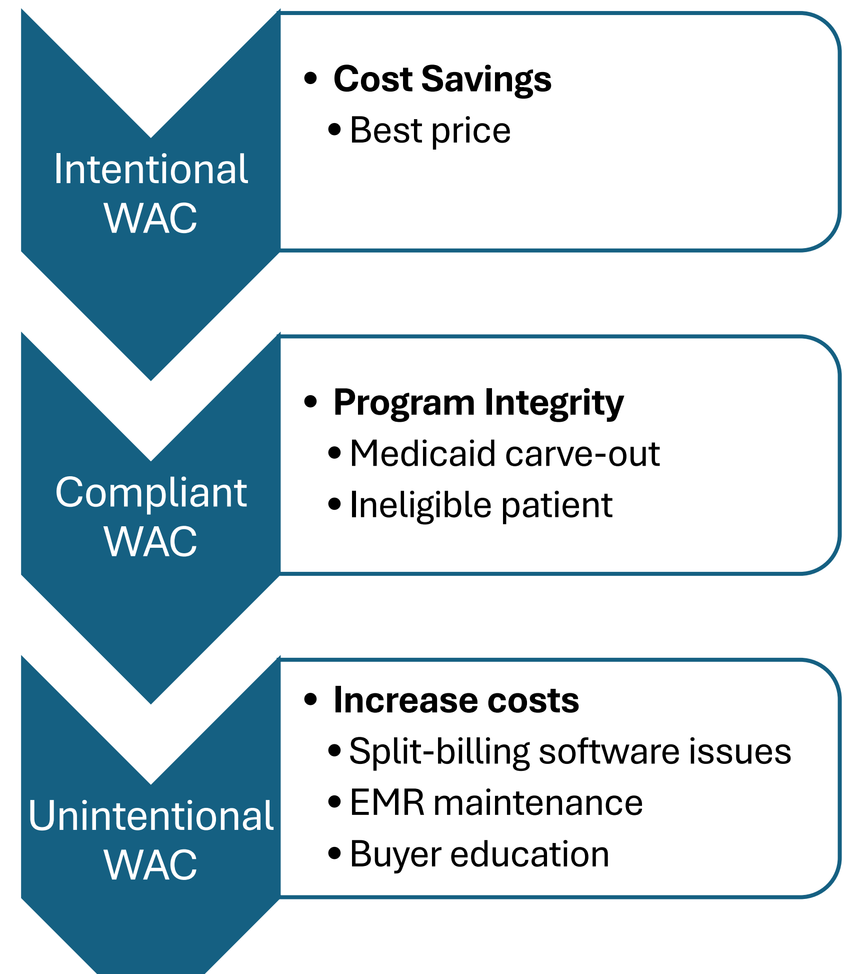
Savings Optimization- Understanding WAC Spend



340B Compliance Tools and PVP Resources. https://www.340bpvp.com/resource-center/340b-tools. Accessed 8 7 2024.

Unintentional WAC Spend Reduction Initiative

Goal:

Reduce unintentional WAC spend to decrease costs and optimize savings

Strategy:

Implement a daily review of previous day WAC purchase to identify and address areas of opportunity

- Developed custom report within TPA in late 2022
- Review collaboratively between 340B team and pharmacy operations
- Work to correct unintentional WAC purchase and prevent future like-purchases
- Track and trend unintentional WAC as % total WAC spend month over month

Outcome:

Overall reduction in expenses from a focused, sustainable, and collaborative process

- Approach provided co-ownership of program optimization and built interdepartmental relationships

Unintentional WAC Spend Reduction Results

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System Average:

2022: 14.28%
2023: 10.83%
YTD 2024: 8.6%

WAC Spend as % of Total Spend

25.00%
20.00%
15.00%
10.00%
5.00%
0.00%

January February March April May June July August September October November December

2022 2023 2024

Data provided is from SSM Health internal database.
Date range: January 2022 – June 2024

WAC Spend Trends and Fixes

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Split Billing Software Opportunity:

-Inner/Outer NDC Mapping Error

-Unit Mapping Discrepancy

-Catalog Price Discrepancy

Purchasing/Inventory Opportunity:

-Expired Drug Replacement

-Purchases for Non-Eligible Office/Clinic

-Buyer Error

Trends

EHR Opportunity:

-Default Med List Incorrect

-Waste Billing Discrepancy

No Opportunity:

-Drug Shortages*

-Wholesaler Allocations*

-Proactive Purchasing

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Lessons Learned

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- Dedicated 340B team
- Strong P&Ps adapted to your program
- Audit best practices
- For multiple CEs: Address findings for all
- Set up right the first time
- Continued education-stay up to date

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Key Takeaways

- Keep up to date with best practices
- Compliance efforts can lead to optimization
- Successful strategies are controllable and collaborative
- Correct the root cause for sustainable program integrity and increased savings

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Questions?

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This educational session is made possible through the collaboration of Vizient Member Networks.

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