WHITE BAGGING –

IS THIS A STRATEGIC INITIATIVE FOR YOUR HOSPITAL?

JEROME WOHLEB, PHARMD, MBA

HOSPITAL/HEALTH-SYSTEM NETWORK CHAIR FOR NPA (NEBRASKA PHARMACY ASSOCIATION)

HFMA March 2022 Meeting

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UNDERSTANDING THE WHITE BAGGING TOPIC

Objectives

- Overview of White Bagging
- Summarize findings from Survey
- Payer Interest
- Fiscal Impact
- Policy Efforts

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WHITE BAGGING – BASIC DEFINITIONS

Key terms to understand:

1) White Bagging

2) Brown Bagging

3) Clear Bagging

4) Site of Service

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DEFINITIONS FOR TYPE OF "BAGGING"

White	• Distribution of patient-specific medication from a pharmacy, typically a specialty pharmacy, to the physician's office, hospital or clinic for administration.
Brown	• Dispensing of medication from a pharmacy (typically a specialty pharmacy) directly to the patient, who then transports the medication(s) to the physician's office for administration
Clear	• When a practice maintains its own specialty pharmacy that provides prescribe be medication directly to the clinic

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SECONDARY TOPIC -- SITE OF CARE

- This is a specific problem that has been initiated by several insurance carriers to encourage new contracting from existing hospital based services. In particular, the insurance companies are looking for a less expensive option for the administration of specialty medications.
- This presentation is not going to address this topic today, but you also need to be aware this is another tactic by various insures to control or steer patients to non-hospital based clinics.

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SPECIALTY PHARMACEUTICALS

- Patients and payers are burdened with the increasing pressure of costly specialty medication
- Payers implement white bagging and brown bagging as cost reduction strategies
- In both situations, the provider is only able to bill for administration and not capture any costs related to subsequent storage or monitoring services that help ensure quality care

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SURVEY SUMMARY

- Patient access to specialty medications within a hospital-owned provider setting has long been facilitated through a buy-and-bill model. Under a buy-and-bill model, the hospital or provider would buy the medication and bill the payer for the product and its administration. This framework provides the needed safeguards for clinicians to more effectively coordinate care, ensure safety of the product and provide for optimal medication use, among other benefits. However, the growing trend of payer-imposed white/brown bagging complicates delivery and dispensing, creates coverage and access barriers, and most importantly harms patient care.

https://www.vizientinc.com/-/media/documents/sitecorepublishingdocuments/public/noindex/whitebaggingreport.pdf, accessed Sept. 21, 2021.

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SURVEY RESULTS

Responses from GPO Membership Survey – 268

Representation was geographically distributed

- 340-B – 78%
- Community – 50%
- Physician clinics – 45%
- Pediatrics – 41%
- Critical access – 25%

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ISSUES IDENTIFIED: WHITE AND BROWN BAGGING

92% of respondents experience patient care issues due to problems with medications

Response	Percent	Count
Product did not arrive in time for administration to patient	83%	118
Product delivered was no longer correct due to updated patient's treatment course or dose being changed	66%	94
Product delivered was inappropriate/wrong dose	42%	60
Product delivered was damaged	37%	53
Other	27%	38
Product delivered was inappropriate/wrong product	22%	31
Product mixing errors	14%	20
I have not experienced any issues	8%	12

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OPERATIONAL AND SAFETY ISSUES

Response	Percent	Count
Separate inventory management system	65 %	112
Delivery Location/Security disruptions	63 %	107
Lack of space to hold medication (I.e., refrigeration)	60%	102
Product not built-in computer order entry system	43 %	73
Barcode scanning (I.e., administration)	42 %	72
Product was non formulary	42 %	72
Product was not built in IV infusion pump library	35 %	59
Product not built in IV workflow system	31 %	53
Nursing/Staff not trained for administration	23 %	40
Other	22 %	37
Have not encountered any operational or safety issues	5 %	9

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SECONDARY ISSUES IDENTIFIED

- Additional personnel hired to manage white/brown bagging
  - 23% yes (**0.5 to 8 FTEs**)
- Have you quantified the amount of pharmaceutical waste and cost associate with white bagging?
  - No – 95 %
- Have you quantified the loss of revenue association with white bagging?
  - No – 83%
- Do you have any established policy prohibiting white bagging?
  - Yes and follow consistently – 29 %
  - Yes and partially enforced – 19 %
  - Yes and not enforced – 1 %
  - No policy – 52 %

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PATIENT CARE IMPACT TO WHITE BAGGING

1. Day 1: Prior authorization (PA) submitted to patient's insurance for oncology medications and told no PA is required.
2. Day 7: Hospital employee calls insurer to add a prescription and is told of the insurer's white bagging policy and PBM's prior authorization requirement.
3. Days 7-10: Hospital employees spend approx. 6 hours ensuring patient's medications would be covered, including communications with insurer, PBM and specialty pharmacy. Patient consent was also needed multiple times.
4. Day 13: Hospital received some prescriptions, but one was missing. The white bagging policy delayed oncology care by nearly two weeks. In this time, the patient had a complication and never received the treatment.
5. The hospital works to ensure the patient's family was reimbursed for the medication already purchased, but not administered.

"White bagging delays care for patients who need real-time dose adjustments to ensure the best outcome."

ERIN FOX, SENIOR PHARMACY DIRECTOR, UNIVERSITY OF UTAH HEALTH

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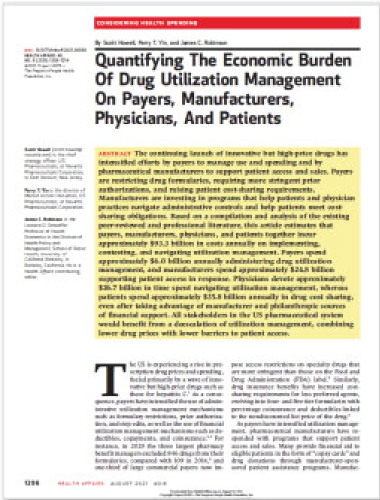
COST OF UTILIZATION MANAGEMENT STRATEGIES


CONSIDERING HEALTH SPENDING

By Scott Howell, Perry T. Yin, and James C. Robinson

Quantifying The Economic Burden Of Drug Utilization Management On Payers, Manufacturers, Physicians, And Patients

ABSTRACT The continuing launch of innovative but high-price drugs has intensified efforts by payers to manage use and spending and by pharmaceutical manufacturers to support patient access and sales. Payers are restricting drug formularies, requiring more stringent prior authorizations, and raising patient cost-sharing requirements. Manufacturers are investing in programs that help patients and physician practices navigate administrative controls and help patients meet cost-sharing obligations. Based on a compilation and analysis of the existing peer-reviewed and professional literature, this article estimates that payers, manufacturers, physicians, and patients together incur approximately $93.3 billion in costs annually on implementing, contesting, and navigating utilization management. Payers spend approximately $6.0 billion annually administering drug utilization management, and manufacturers spend approximately $24.8 billion supporting patient access in response. Physicians devote approximately $26.7 billion in time spent navigating utilization management, whereas patients spend approximately $35.8 billion annually in drug cost sharing, even after taking advantage of manufacturer and philanthropic sources of financial support. All stakeholders in the US pharmaceutical system would benefit from a deescalation of utilization management, combining lower drug prices with lower barriers to patient access.

- Analysis of peer-reviewed literature from Novartis and UC Berkley
- Cost of drug utilization management
  - –Manufacturers = $24.8 billion
  - –Payers = $6 billion
  - –Physicians = $26.7 billion
  - –Patients = $35.8 billion

In total, economic burden is 415.5 B

Health Affairs 2021: 401206-1214

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COST OF UTILIZATION MANAGEMENT STRATEGIES (ABSTRACT)

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Health Affairs 2021: 401206-1214

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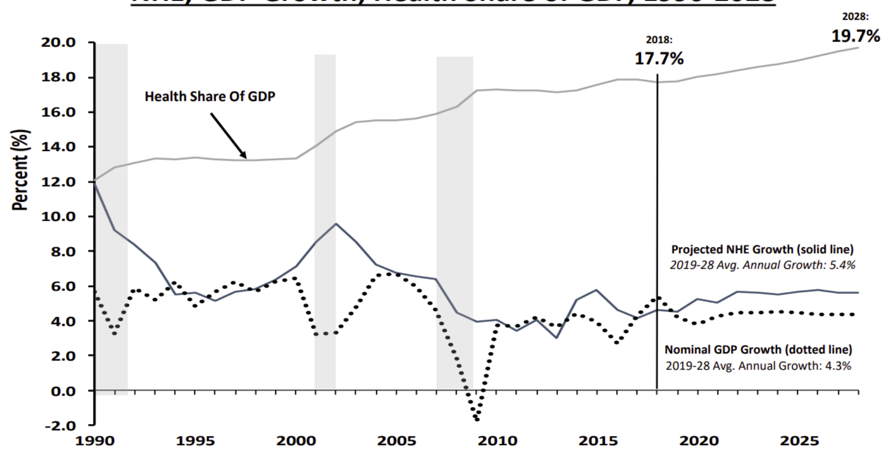
NATIONAL HEALTH EXPENDITURE PROJECTIONS 2019-28

NHE, GDP Growth; Health Share of GDP, 1990-2028



SOURCES: Centers for Medicare and Medicaid Services, Office of the Actuary, National Health Statistics Group; Department of Commerce, Bureau of Economic Analysis; National Bureau of Economic Research.
NOTES: Shaded areas for 1990-91, 2001, and 2007-09 represent recession periods.

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PAYER ISSUES – SPECIALTY DRUG COSTS

TRADITIONAL DRUGS 2020-2021: ------ 1% to 2%
SPECIALTY DRUGS 2020-2021: -----------12% to 16%

- A National Drug Trend Prior to COVID-19, CMS was predicting drug spending to continue to account for approximately 10 percent of overall healthcare spending and to grow at a rate consistent with total healthcare costs. CMS has not issued updated projections since 2019.
- Using the most recent projections, total health spending is projected to grow at an average rate of 5.4% per year between 2019 and 2028, totaling 6.2 trillion by 2028.
- For 2021-2023, Medicaid spending is projected to grow at an average annual rate of 5.7%.

Centers for Medicare and Medicaid Services Office of the Actuary, National Health Expenditure Projections, 2019 – 2028 – Forecast Summary

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DRUG SPEND – WHAT IS AT STAKE

- Medicare covers prescription drugs provided during inpatient hospital and skilled nursing facility stays through Part A, retail prescription drugs through Part D, and drugs provided in physicians' offices and hospital outpatient departments (HOPDs) through Part B.
- In 2017, Medicare financed about 27 percent of the nation's drug spending estimated at $481 billion of which spending by Medicare Part D was $100 billion5 (21 percent) and Medicare FFS Part B was $24 billion (5 percent).

This paper focuses on the drugs provided to Fee-forService (FFS) beneficiaries in the Medicare Part B program

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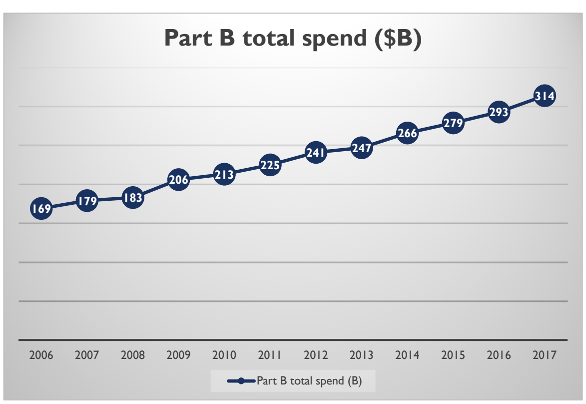
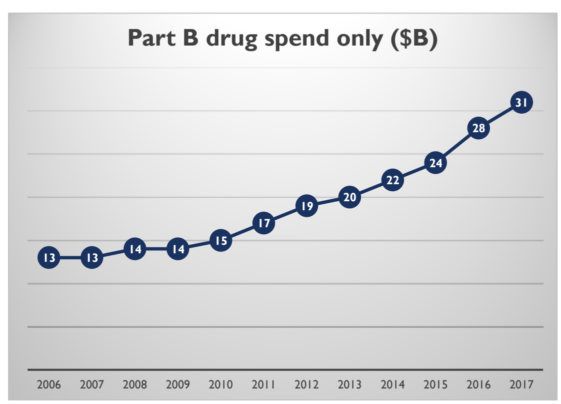
MEDICARE PART B SPEND (EXPECT REIMBURSEMENT DECREASES)

Compare the rate of spend for Part B services (rate of increase is 3x for drugs v/s 2x for total)





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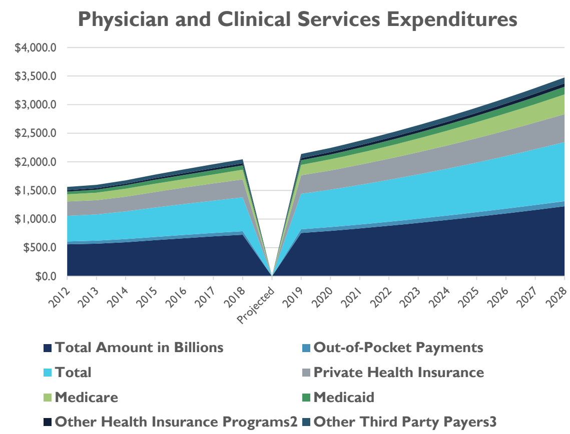
CLINICIAN-ADMINISTERED SERVICES

- An outpatient drug that cannot be reasonably self-administered by the patient to whom the drug is prescribed and is typically administered by a health care provider in a clinical setting
- Alternatively known as "physician-administered drugs" or "provider-administered drugs"



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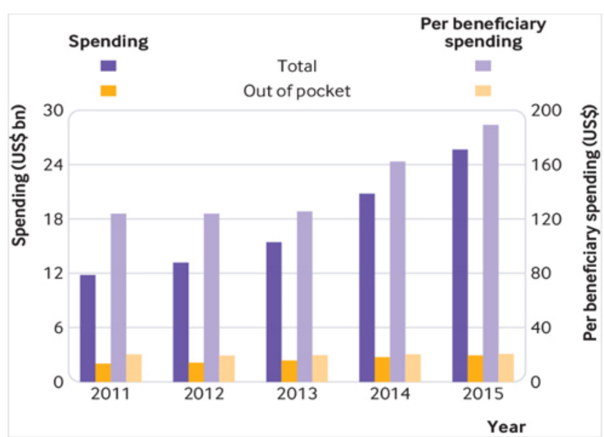
DISPROPORTIONATE DRUG SPEND (FOR SPECIALTY DRUGS)

- Moreover spending is concentrated on a few drugs: the top 10 drugs account for almost half of the total Medicare payment for Part B drugs and grew at about the same rate as all Part B drugs on a per enrollee basis



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TRADITIONAL DRUG PURCHASING PROCESS

- Hospital or clinic buys bulk drug from a wholesaler, then stores and prepares drugs for administration as needed
- Medical plan reimburses the provider for costs associated with both acquisition and administration of the drug
- Process is commonly known as **"buy-and-bill"**

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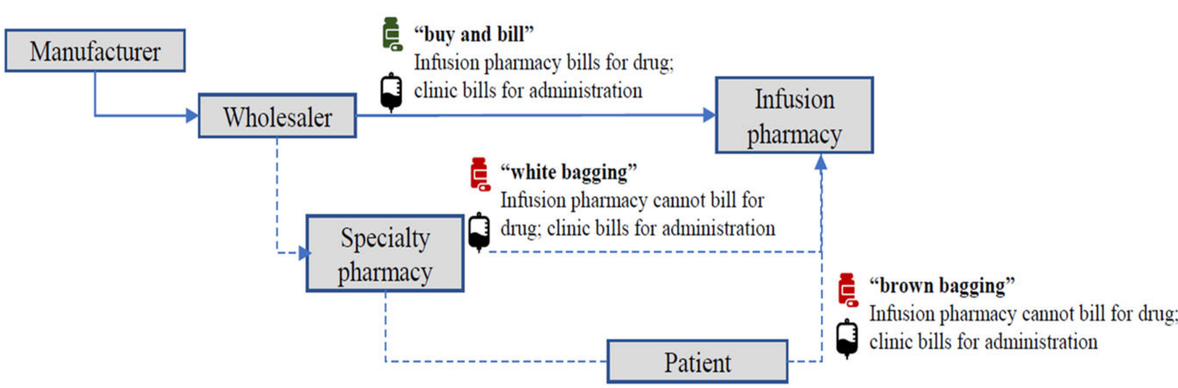
DRUG DISTRIBUTION MODELS



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WHAT IS PAYER-MANDATED WHITE BAGGING

- Plan requires a third-party specialty pharmacy to purchase and dispense patient-specific clinician-administered drugs
- Specialty pharmacy ships drug to directly to the provider prior to administration
- Specialty pharmacy is reimbursed for drug cost and provider is reimbursed for administration

Specialty Pharmacy Requirements for UnitedHealthcare Commercial Plan Members

To support the care provider/patient relationship in managing rare and complex chronic conditions, we require care providers, who participate in UnitedHealthcare's commercial health plans, to follow specialty pharmacy requirements when obtaining certain specialty medications covered under the member's medical benefit.

To meet the requirements, you must order certain medications from the specialty pharmacies listed in the following table. The requirements don't apply to UnitedHealthcare West members.

Therapeutic Class	Brand Name	Specialty Pharmacy
Botulinum Toxin A and B	Botox®, Dysport®, Myobloc®, Xeomin®	Optum Pharmacy (Specialty) Phone: 855-242-2241 Fax: 877-342-4596
Enzyme Replacement Therapy	Brineura™	Orsini Pharmaceutical Services, LLC. Phone: 800-240-9572 Fax: 847-427-7976 US Bioservices Phone: 888-518-7246 Fax: 888-418-7246
Gene Therapy	Luxturna™	Accredo Health Group Phone: 877-222-7336 Fax: 866-579-4655
Immune Modulator	Gamifant™	Biologics, Inc. Phone: 800-850-4306 Fax: 800-823-4506
RSV Prevention	Synagis™	Optum Pharmacy (Specialty) Phone: 855-242-2241 Fax: 877-342-4596
Spinal Muscular Atrophy	Spinraza™	Accredo Health Group Phone: 877-222-7336 Fax: 866-579-4655
Spinal Muscular Atrophy	Zolgensma®	Accredo Health Group Customer Service Phone: 877-787-8704 Clinician Phone: 800-987-5254 Fax: 877-327-8413 Orsini Pharmaceutical Services, LLC. Phone: 800-697-5048 Fax: 877-471-5704

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WHITE BAGGING: PAYER POLICIES

- Payers often implement white bagging policies mid-contract
- Payer position: since drugs are available from plan-designated pharmacy, it is "***not medically necessary***" for hospitals to purchase them directly
- Therefor, buy-and-bill reimbursement for non-acute therapies can be excluded
- Many plans also exclude reimbursement for any "non-preferred" specialty pharmacy

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UHC AND OPTUM

- **2021**

  The company's full-year revenue grew more than $30 billion, or 11.8%, to $287.6 billion year over year (YOY), with growth seen especially in the Optum and UnitedHealthcare businesses. Full-year earnings from operations were $24 billion, with Optum accounting for more than half of that total.

- **2020**

  At the same time, Optum's full-year revenue hit $155.6 billion, up $19.3 billion (14.1%) from the prior year, while full-year operating earnings increased $1.9 billion, to $12 billion for the year.

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ANTHEM

- Fortune 500 Magazine

  The company's 2020 revenue was just shy of $121 billion, a 17% increase over the previous year, assisted by a massive surge in Anthem's Medicare Advantage business. The unit encompassing IngenioRx helped fuel a 9.3% year-over-year spike in first-quarter 2021 sales and is one of the company's main focus areas going forward

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SHOW ME THE MONEY --PBMS

- Between 2017 and 2019, pharmacy benefit managers' gross profit increased by 12 percent despite PBM retention of manufacturer rebates decreasing during this period, according to a report released Dec. 2 by the PBM Accountability Project.
- The report showed that the PBM gross profit increased from $25 billion to $28 billion between 2017 and 2019. It also showed that the sources of these profits changed significantly.
- During this time, gross profit from administrative fees paid by manufacturers for services provided by PBMs increased 51 percent, from $3.8 billion to $5.7 billion. Gross profit from PBM-owned mail-order and specialty pharmacies increased more than 13 percent, from $8.9 billion to $10.1 billion

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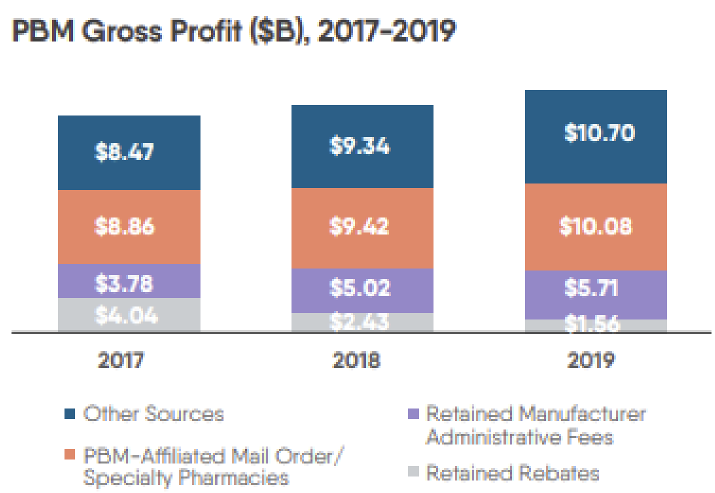
PBMS' PROFITS ARE INCREASING WHILE THEIR REVENUE SOURCES REMAIN UNCLEAR



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PBMS DOMINATE THE SPECIALTY MARKET

The PBM market is highly consolidated, with three main players—

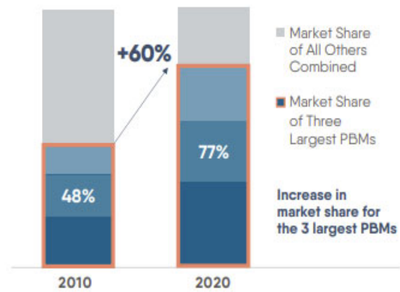
accounting for 77% of the market in 2020.

- CVS Caremark,
- OptumRx, and
- Express Scripts

The insurers are the first (Anthem), third (UnitedHealthcare) and fourth (Cigna) largest by membership in the U.S.

Understanding the Evolving Business Models and Revenue of Pharmacy Benefit Managers

Market Share 2010 - 2020



Note: In 2010, the three largest PBMs were Medco Health Solutions, Argus Health Systems and Express Scripts. In 2020, the three largest PBMs were CVS Caremark, OptumRx, and Express Scripts
Sources: Fein A. "The 2021 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers," Drug Channels Institute, March 2021.

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NATIONAL HEALTH EXPENDITURE DATA (NHE FACT SHEET) 2020 – CMS.GOV

- NHE grew 9.7% to $4.1 trillion in 2020, or $12,530 per person, and accounted for 19.7% of Gross Domestic Product (GDP).
- Medicare spending grew 3.5% to $829.5 billion in 2020, or 20 percent of total NHE.
- Medicaid spending grew 9.2% to $671.2 billion in 2020, or 16 percent of total NHE.
- Private health insurance spending declined 1.2% to $1,151.4 billion in 2020, or 28 percent of total NHE.
- Out of pocket spending declined 3.7% to $388.6 billion in 2020, or 9 percent of total NHE.
- Federal government spending for health care grew 36.0% in 2020, significantly faster than the 5.9% growth in 2019. This faster growth was largely in response to the COVID-19 pandemic.
- Hospital expenditures grew 6.4% to $1,270.1 billion in 2020, slightly faster than the 6.3% growth in 2019.
- Physician and clinical services expenditures grew 5.4% to $809.5 billion in 2020, faster growth than the 4.2% in 2019.
- Prescription drug spending increased 3.0% to $348.4 billion in 2020, slower than the 4.3% growth in 2019.
- The largest shares of total health spending were sponsored by the federal government (36.3 percent) and the households (26.1 percent). The private business share of health spending accounted for 16.7 percent of total health care spending, state and local governments accounted for 14.3 percent, and other private revenues accounted for 6.5 percent.

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SOMETHING TO WORRY ABOUT – VERTICAL INTEGRATION

Vertical Business Relationships Among Insurers, PBMs, Specialty Pharmacies, and Providers, 2021

1. Cigna partners with providers via its Cigna Collaborative Care program. However, Cigna does not directly own healthcare providers.
2. AllianceRx Walgreens Prime is jointly owned by Prime Therapeutics and Walgreens Boots Alliance.
3. Since 2020, Prime sources formulary rebates via Ascent Health Services. In 2021, Humana began sourcing formulary rebates via Ascent Health Services for its commercial plans.
Source: Drug Channels Institute research; Companies are listed alphabetically by insurer name.

This chart appears as Exhibit 210 in *The 2021 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers*. Available at http://drugch.nl/pharmacy

DRUG CHANNELS INSTITUTE

March 2021

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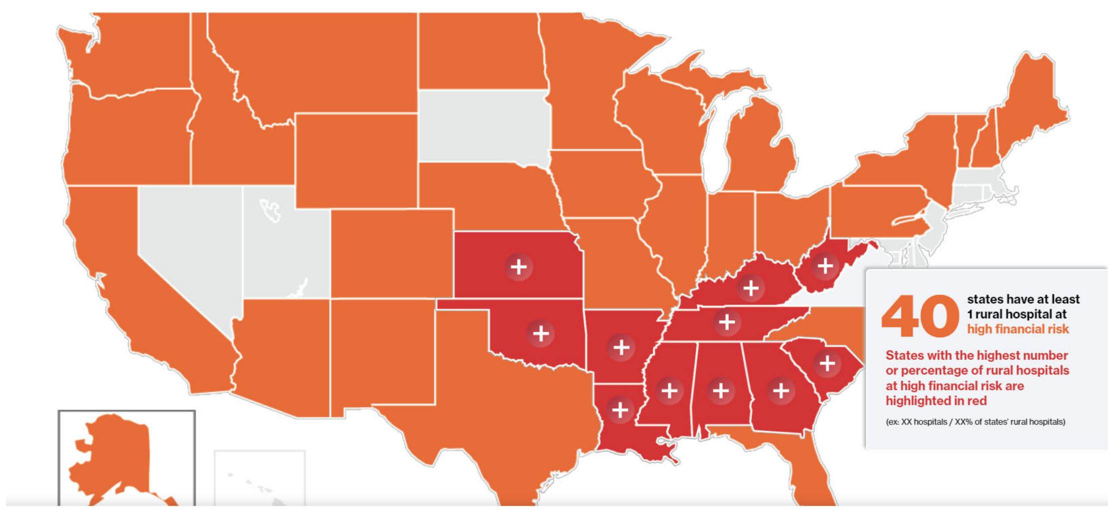
RURAL HOSPITAL FINANCIAL RISK AND COMMUNITY ESSENTIALITY

THE FOLLOWING MAPS DEPICT THE NUMBER & PERCENTAGE OF RURAL HOSPITALS AT HIGH RISK OF CLOSING



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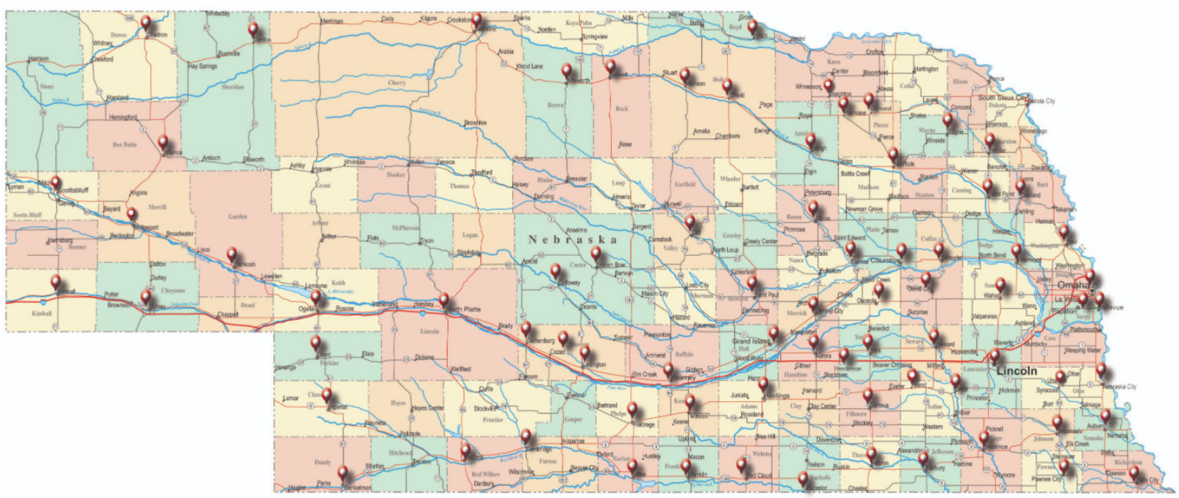
CRITICAL ACCESS HOSPITALS IN NEBRASKA



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FISCAL IMPACTS FOR HOSPITALS

- White bagging removes the benefits from pharmacy revenue (or 340-B realized gains) in the outpatient settings.
- It has been stated that 50% of the critical access hospitals would be negatively impacted without 340-B programs.
- White bagging targets all hospitals in the high-end market of specialty drugs with the goal to eliminate this revenue stream.
- Some non 340-B hospitals will also lose rebates from manufactures when replaced with white bagging options.

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FISCAL IMPACTS FOR HOSPITALS

- Pharmacy leaders from the following organizations have acknowledged the fiscal and safety risks here in Nebraska
  - Memorial Health Care Systems-Seward
  - Phelps Memorial Health Center
  - Pender Community Hospital
  - Valley County Health System ($550K/yr.)
  - Box Butte General Hospital
  - Jennie Melham Memorial Medical Center ($144K/yr)
  - Henderson Health Care (around 40% of annual budget)
  - Fillmore County Hospital (>$100K/yr.)

Additional members from the taskforce:

UNMC
CHI
Nebraska Methodist
Great Plains
Faith Regional
Beatrice Community
Bryan Health
and several others

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KEY ELEMENTS OF EFFECTIVE WHITE BAGGING LEGISLATION

- Targeted specifically to clinician-administered drugs
- Patients and providers choose preferred method of drug distribution (buy-and-bill vs specialty pharmacy)
  - If distributed via pharmacy, may utilize any qualified pharmacy
- Ban payer-mandated brown bagging and payer-mandated home infusion
- Prohibit site-of-service exclusions for in-network providers

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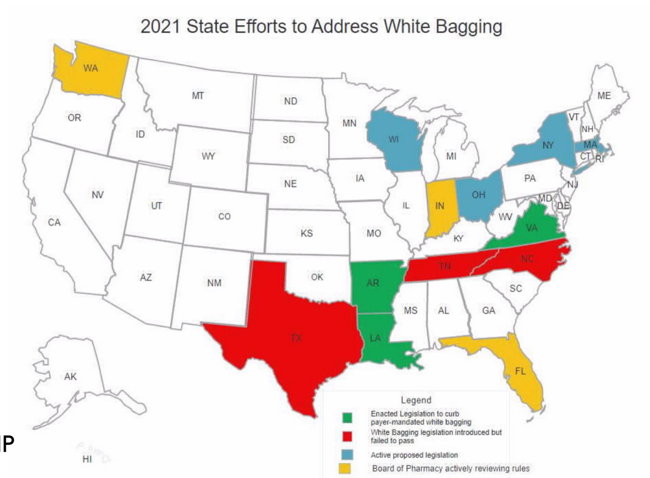
LEGISLATION BY STATE INVOLVEMENT

11 STATES INTRODUCED WHITE BAGGING LEGISLATION
4 STATES HAVE PASSED WHITE BAGGING BILLS TO-DATE

Louisiana & Arkansas: payers required to permit buy-and-bill
Virginia: any willing specialty pharmacy may dispense clinician-administered drugs
Indiana: BOP and stakeholder agencies report to governor on patient impacts of white bagging

ASHP



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2021 LEGISLATION (OTHER STATES)

- LA SB 191 (enacted; effective 06/01/21)
- AR HB 1907 (enacted; effective 01/01/22)
- VA HB 2219 (enacted; effective 07/01/21)
- TX HB 1586 (passed House, died in Senate)
- Additional bills introduced in IN, MA, NC, NY, TN

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PHARMACY TASKFORCE (LB943)

Some of the taskforce members:

- Matt Guzallis (CHI-Lakeside), David Schmidt (CHI-Clinical), Debra Lee (Mary Lanning), Lori Murante (UNMC), Amy Pohlman (Faith Regional), Kris Shubert (Beatrice Community) Paula Danekas (Nebraska Methodist), Jason North (Great Plains), Rachel Forster, Jerome Wohleb (Bryan), Valerie Poppert (Fillmore County Hospital)

LEGISLATURE OF NEBRASKA

ONE HUNDRED SEVENTH LEGISLATURE

SECOND SESSION

LEGISLATIVE BILL 943

Introduced by Bostar, 29.

Read first time January 10, 2022

Committee: Banking, Commerce and Insurance

A BILL FOR AN ACT relating to insurance; to prohibit certain provisions in a health plan in relation to clinician-administered drugs; and to define a term.

Be it enacted by the people of the State of Nebraska,

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NEBRASKA ORGANIZATIONS SUPPORTING THIS LEGISLATION (NATIONALLY: AHA, ASHP)

- Marcia Mueting – NPA
- Jeremy Nordquist – Nebraska Medicine
- Jerome Wohleb –NPA Chair of Hospital/Health System Network
- Andy Hale – NHA
- Bob Hallstrom – NPA
- Carmen Chinchilla-Gutierrez – Executive Director of Specialty Societies NMA
- David Slattery – NHA
- Dexter Schrodt – NHA
- Jenny Minchow – NPA
- Joselyn Luedtke – Zulkoski - Weber (NHA)
- Katie Zulkoski – Zulkoski-Weber (NHA)
- Matt Schaefer – Miller Robak (NMA)
- Michelle Weber – Zulkoski-Weber (NHA)
- Mike Feagler - NHA

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LEGISLATION

- We need to improve the hospital odds against the insurance companies tactics!
- One example would be to **write your senator today** to support LB 943.
  - **A sample** letter is provided as part of this program today.

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THANK YOU – QUESTIONS

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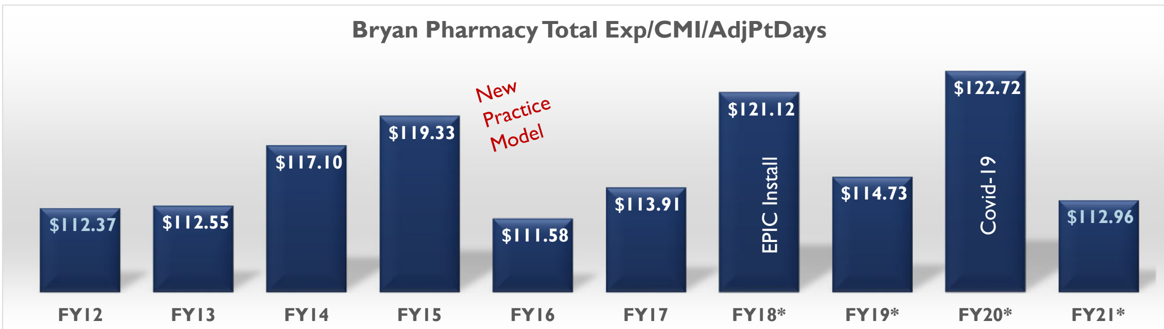
FUTURE TOPIC –
MAXIMIZING THE PHARMACY ENTERPRISE IN YOUR ORGANIZATION

How do you control drug expenses?

How do you maximize revenues (margin)?

The short answer, you have to change the game to win!



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KAUFMAN, HALL FLASH REPORT

NATIONAL HOSPITAL FLASH REPORT FEBRUARY 2022

National Expense Results

EXPENSES % CHANGE	Budget Variance	Month-Over-Month	Year-Over-Year	Year-Over-Year 2020
Total Expense	0.6%	-3.5%	7.4%	9.3%
Total Labor Expense	3.1%	-1.6%	10.1%	11.8%
Total Non-Labor Expense	-2.6%	-5.7%	6.6%	5.7%
Supply Expense	-0.3%	-7.8%	10.4%	9.2%
Drugs Expense	0.1%	-1.7%	5.7%	21.8%
Purchased Service Expense	-3.2%	-5.8%	1.2%	7.2%
Total Expense per Adjusted Discharge	19.4%	11.6%	10.9%	43.5%
Labor Expense per Adjusted Discharge	22.8%	14.6%	14.2%	57.0%
FTEs per AOB	-2.3%	2.4%	-4.9%	3.0%
Non-Labor Expense per Adjusted Discharge	14.7%	7.8%	5.9%	35.5%
Supply Expense per Adjusted Discharge	16.1%	2.7%	8.2%	34.9%
Drug Expense per Adjusted Discharge	27.5%	7.2%	14.5%	65.3%
Purchased Service Expense per Adjusted Discharge	15.1%	8.6%	7.3%	50.2%

Unless noted, figures are actuals and medians are expressed as percentage change

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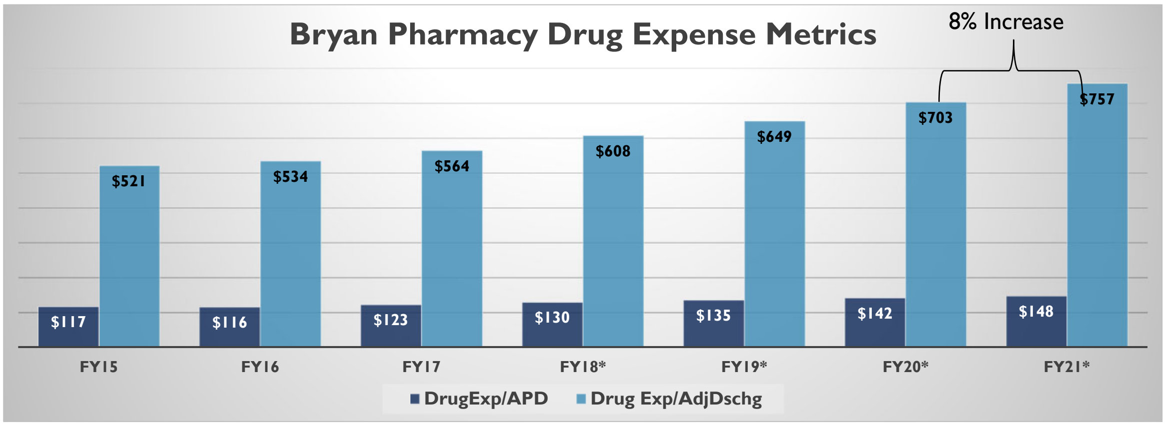
A NEW CARE DELIVERY MODEL IS NEEDED



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