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The *voice* of the
community
pharmacist.

**Don't Say We Didn't Warn You:
Preparing for the DIR Hangover, DSCSA, and Other
Regulatory Items That Should Be On Your 2023
Pharmacy Checklist**

December 15, 2022

Anti-Trust Statement

- NCPA's policy is to comply fully and strictly with both federal and state antitrust laws
- Direct questions to Emily Jenkins, Owner of Halm Jenkins PLLC
 - emily@halmjenkins.com
 - 571-236-3776



- Founded in 1898, the National Community Pharmacists Association is the voice for the community pharmacist, 19,400 pharmacies that employ approximately 240,000 individuals nationwide.
- Community pharmacies are rooted in the communities where they are located and are among America's most accessible health care providers.

Presenters

- ✓ Steve Postal, JD, NCPA
- ✓ Lisa Schwartz, PharmD, NCPA
- ✓ Scott Pace, PharmD, JD, co-owner, Kavanaugh Pharmacy



Learning Objectives

Upon completion of this presentation, participants should be able to:

- Discuss timelines for implementation in 2023 of:
 - Medicare Part B and D changes;
 - USP compounding chapters revisions; and
 - DSCSA interoperability provisions
- Identify implementation milestones of the Inflation Reduction Act
- Describe changes to Medicare DIR for 2024

Overview

- Changes to Medicare Part B
 - CY 2023 Physician Fee Schedule Final Rule Updates
- Changes to Medicare Part D
 - Electronic Prescribing of Controlled Substances (EPCS)
 - Beneficiary Real-Time Benefit Tool (RTBT)
- Inflation Reduction Act Provisions
- Other Important Changes
 - USP Revisions to Compounding Chapters <795> and <797>
 - The Drug Supply Chain Security Act (DSCSA)
- Medicare DIR Preparation for 2024 in 2023

Changes to Medicare Part B in the CY 2023 Physician Fee Schedule Final Rule

Vaccine Administration: Medicare Part B

Item	2022	2023
Admin. of flu, pneum., and hep B vaccines	\$30.00	\$31.14
Admin. of COVID-19 vaccine	\$40.00	\$41.52
Additional payment for COVID-19 vaccine in the home	\$35.50	\$36.85

COVID-19 mAbs: Pre-Exposure Prophylaxis

Item	2023
Injection: Health Care Setting	\$150.50
Injection: Home	\$250.50

Changes to Medicare Part D

Electronic Prescribing of Controlled Substances (EPCS)

- Mandate for all Medicare Part D controlled substance prescriptions to be e-prescribed starts Jan. 1, 2023
- Prescribers have until Jan. 1, 2024 to be in full compliance
- EPCS mandate for LTC prescriptions in effect Jan. 1, 2025



Beneficiary Real-Time Benefit Tool (RTBT)

- Starting January 1, 2023
- Part D plans must offer real-time comparison tools to enrollees, so enrollees have access to:
 - Real-time formulary and benefit information, including cost-sharing

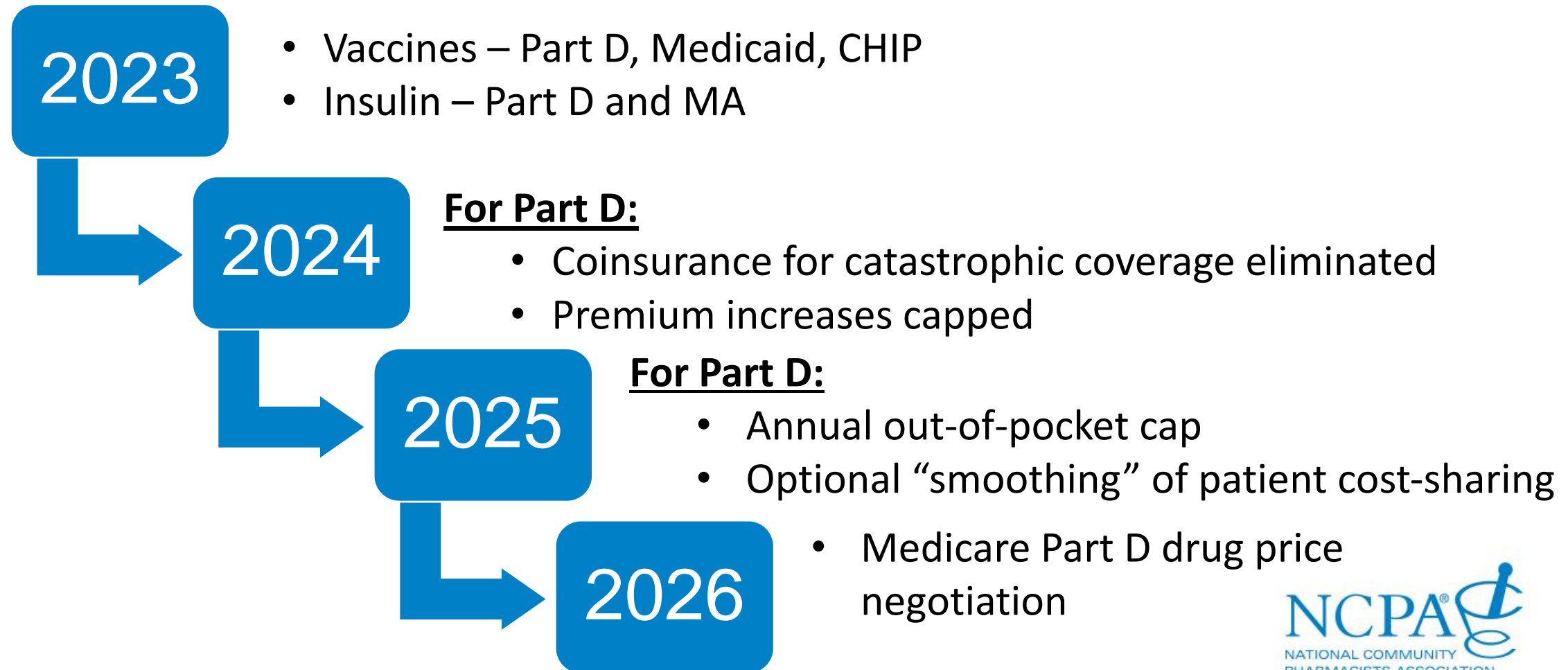


RTBT - 42 CFR 423.128(d)(4)

- Part D sponsors must make available, in an easily understandable manner:
 - Complete, accurate, timely, clinically appropriate, patient-specific formulary and benefit real-time information
 - In their beneficiary specific portal or computer application:
 - Enrollee cost sharing amounts
 - Formulary medication alternatives for a given condition
 - Formulary status, including utilization management requirements applicable to each alternative medication

Inflation Reduction Act Provisions

Key Inflation Reduction Act Provisions



Starting in 2023: Zero Cost-Share for Part D, Medicaid, and CHIP Vaccines

- **Vaccines**
 - No cost-sharing for adult vaccines recommended by ACIP for
 - Part D (starting Jan. 1)
 - Medicaid and CHIP (starting Oct. 1)



Starting in 2023: Insulin Co-Pay Caps

- Monthly copayment spend on insulin is capped at \$35 for PYs 2023, 2024, and 2025 for Part D and MA.
- Medicare Part D plans have 90-day grace period in 2023.
- Insulin furnished through DME under Medicare Part B will also have monthly copayment cap of \$35, with no deductible, beginning July 2023.



Starting in 2024: Part D Coinsurance Eliminated; Cap on Part D Premium Growth

- The 5 percent coinsurance for catastrophic coverage in Medicare Part D is eliminated.
- The growth in Part D premiums is capped at 6 percent per year from 2024 to 2030.



Starting in 2025: Annual OOP Cap; Optional Smoothing of Patient Cost-Sharing

- Out-of-pocket costs for Medicare Part D beneficiaries would be capped at \$2,000 per year in plan year 2025.
 - Will increase at rate of growth in subsequent years
- Part D patients can elect to have cost-sharing smoothed out over the course of the benefit year.

Starting in 2026: Medicare Drug Price Negotiation

- Secretary of HHS will negotiate pricing for:
 - 2026: 10 drugs based on Part D spending
 - 2027: 15 drugs based on Part D spending
 - 2028: 15 drugs based on combined Part D and Part B spending
 - 2029 and beyond: 20 drugs based on combined Part D and Part B spending



USP Revisions to Compounding Chapters <795> and <797>

Overview

- USP published updates to compounding chapters:
 - <795> (Nonsterile Preparations) and
 - <797> (Sterile Preparations)
 - Published: Nov. 1, 2022
 - “Official date”: Nov. 1, 2023
- Updates to beyond-use dates (BUDs) (<795> and (<797>)
- Clarification of definition of compounding (<795>)

Resources

- [2022 Revisions to USP General Chapters to 795 and 797](#)
- Includes FAQs, Fact Sheets and Revisions
- USP [presentation](#) to NCPA Compounding Committee
- [Recordings and Slides](#) of USP's Virtual Open Forum Series

The Drug Supply Chain Security Act (DSCSA)

Recap of Current Requirements

- Authorized trading partners
- Serialized product identifier
- Receive, store, access tracing data
- Identify and investigate suspect product; report illegitimate product
- Exception for specific patient need only for transactions between dispensers

DSCSA Developments

- Interoperability: November 27, 2023
 - Improves product verification workflow – an electronic request better than calling manufacturer
- NCPA Checklist and SOP Guidance Document for 2023 – Coming Soon
- Dispenser resources webpage: DSCSA.pharmacy/
- [FDA Guidances](#)

Policies and Procedures

- Only purchase from authorized trading partners
- Order check in
- Identifying and investigating suspect product
 - Quarantine
 - Verification
 - Document investigation
- Reporting illegitimate product
- Responding to regulator or trading partner request for tracing data



CY 2023 Medicare Part D Final Rule Implementation

DIR Changes Effective 2024



- ✓ Negotiated price redefined
- ✓ Defined pharmacy “price concession”



Rule is A Win, But Need to Remain Vigilant

- Overall, rule is a win
 - Transparency
- Work needs to be done
 - Communicate with PSAO
 - Understand your anticipated cash flow needs
 - Remain vigilant

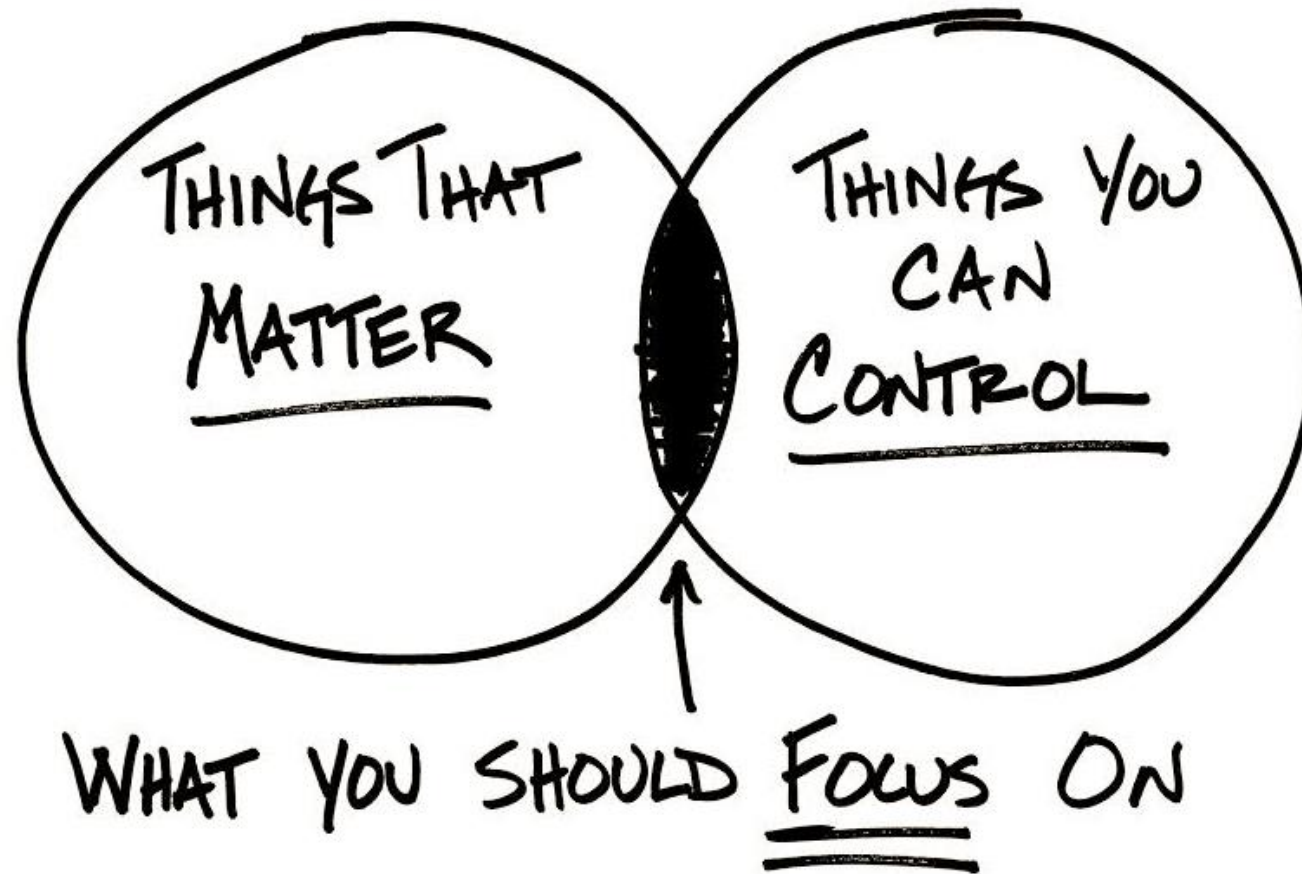


Scott Pace, PharmD, JD



- Scott is an Arkansas-based pharmacist and lawyer passionate about advancing patient care at the governmental level.
- As a partner at Impact Management Group, he works to improve government relations and affairs.
- Scott co-owns Kavanaugh Pharmacy with his wife, Anne.

What You Should Focus On



Feeling the Pain

- Cash flow slowed down. Could hurt worse soon.
- Challenging to pay for COGs, payroll, overhead, growth, etc.
- Inflationary forces on cost to dispense + COGs = not a great profitability outlook for prescription dispensing in the future.



Identifying the Source of the Pain

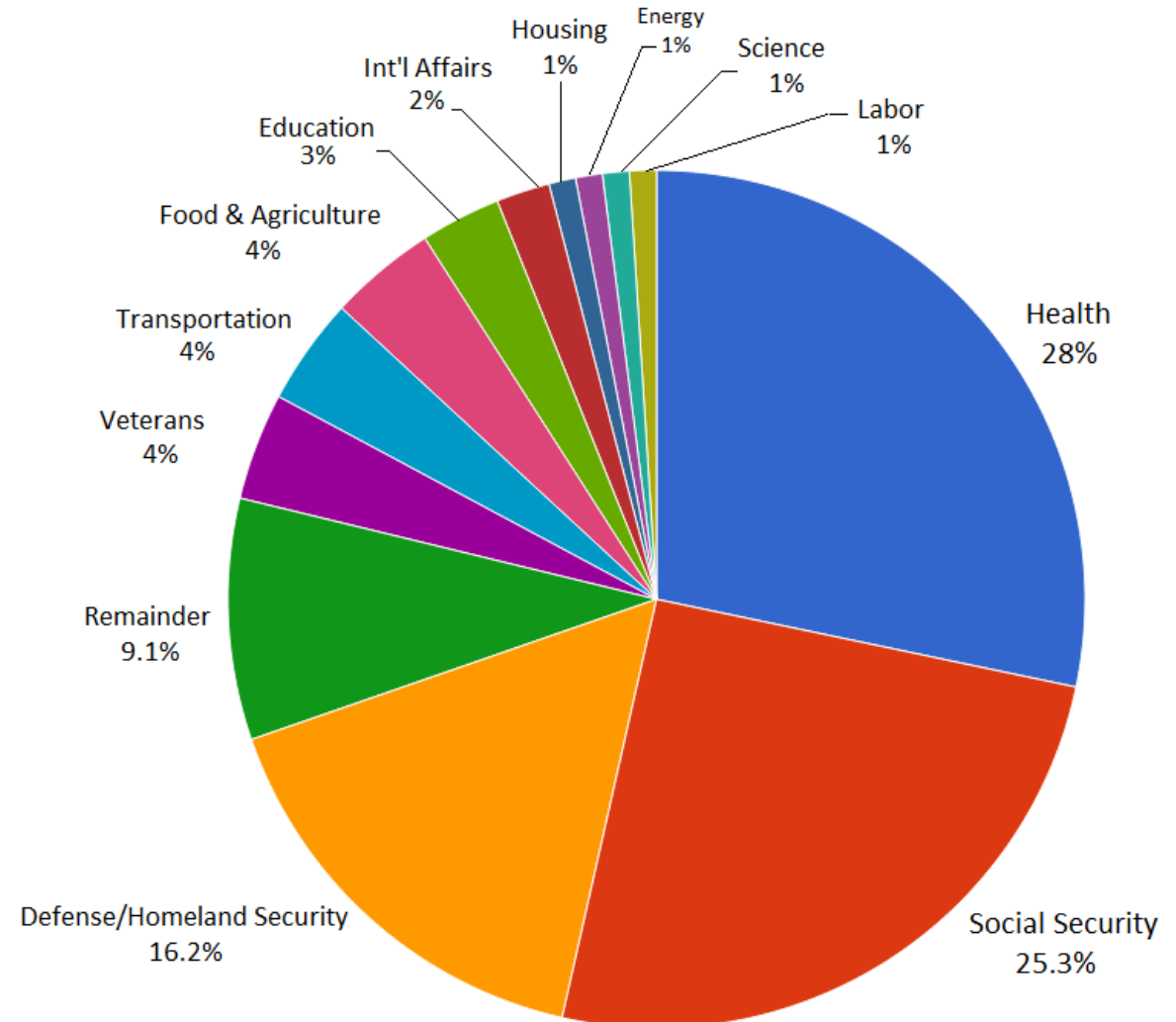
- Reductions in Rx receipts @ POS (DIR @ POS can begin in 2023)
- DIR lag from previous year withholding from current (lower) reimbursements / deposits
- Inflationary impact on cost to dispense and higher drug costs

Images from; <https://www.pngall.com/stomach-ache-png;>
<https://steamcommunity.com/market/listings/603750/Poison>



Avoid Misdiagnosis

- Politicians often say the US spends too much on small budget items like “science” or “international affairs,” yet ignore the largest expenses.
- **Ours are WAGES & COGs**



Treating the Pain

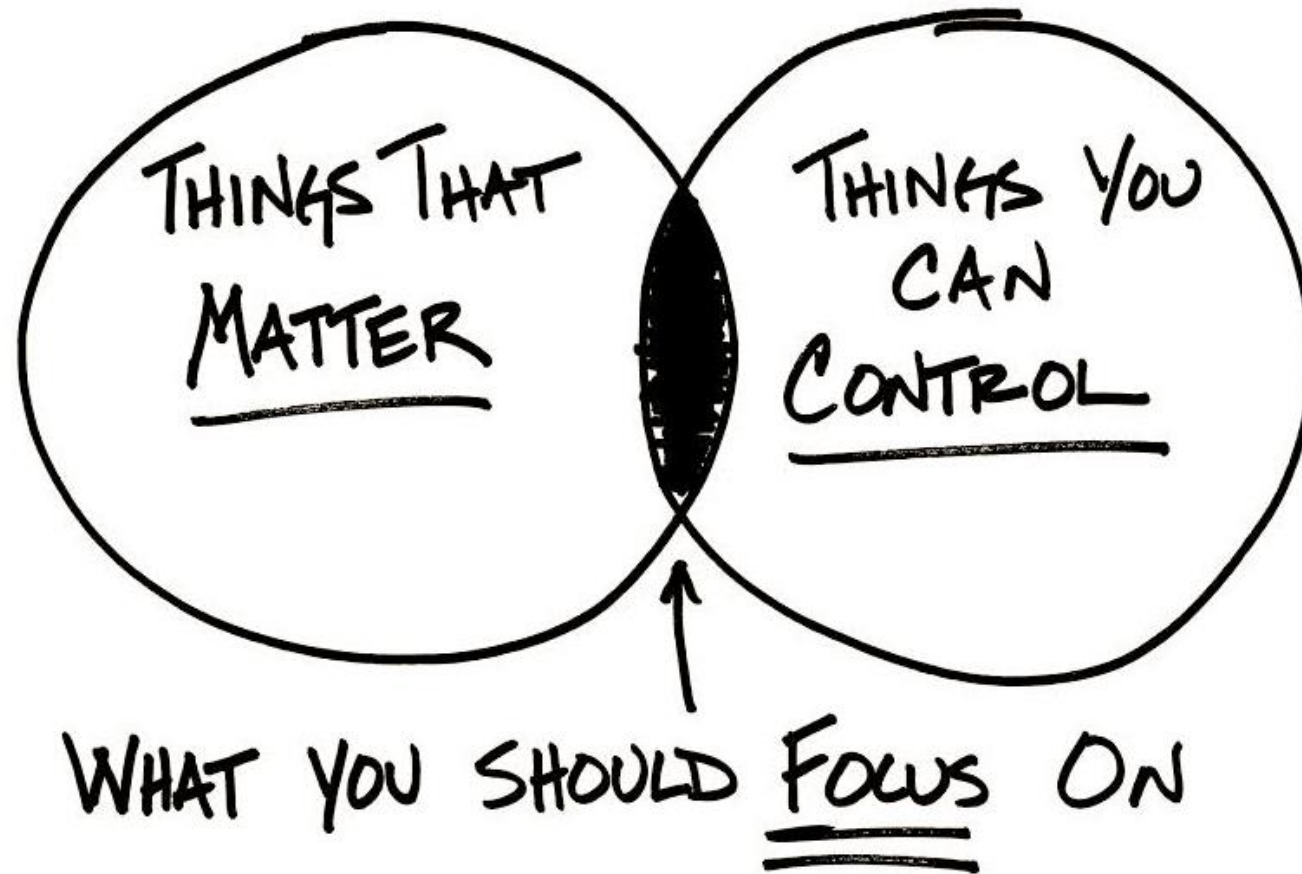
- Implementation of cost saving measures & operational efficiencies like:
 - Scaling MedSync
 - Centralizing ops and inventory
 - Optimizing buy plan
 - Optimizing work schedules / wages
 - Repricing vials, labels, etc.
 - Measuring of billable services + Rxs
 - Scaling current and seeking out new non-dispensing revenue
 - Assessing automation & technology
 - Partnering with colleagues to “share” expenses



Avoiding the Injury Altogether

- Know in advance where (and when) economic stressors will occur
- Med Sync as many Rxs as possible. Not optional
- Determine your current cost to dispense and cut expenses
- Begin setting back reserves to cover potential “injury” period
- Implement efficiencies into service delivery today so you can scale non-dispensing services quickly
- Look for new non-dispensing revenue that can begin paying off over the next 6-12 months

Final Thoughts



Contact Information

Steve Postal, JD, NCPA

Steve.Postal@ncpa.org

Lisa Schwartz, PharmD, NCPA

lschwartz@ncpa.org

Questions?